10 Views of veterinary manufacturers and wholesalers

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Introduction

10.1. In this chapter we set out the views of the veterinary manufacturers, in alphabetical order. We then set out the views of the five veterinary wholesalers, also in alphabetical order.

Views of veterinary manufacturers

Animalcare Ltd

Provisional complex monopoly situation—supply of POMs to animal owners

10.2. Animalcare had no comments on our provisional conclusion that a complex monopoly situation existed in relation to the supply of POMs to animal owners. Nor did it comment on our view that it was appropriate to regard certain conducts of manufacturers, wholesalers and veterinary surgeons as a single complex monopoly situation affecting all parts of the supply chain.

10.3. With regard to the conduct identified in paragraph 9(d) of the statement of 17 September (refusal/failure to negotiate discounts and rebates with buying groups), Animalcare said that it was prepared to deal with buying groups, but there would have to be a benefit to itself. It had talked to various groups and was dealing with the largest of them, but its experience had been that no buying group was able sufficiently to influence the individual purchasing decisions of the veterinary practices within the group to deliver any additional sales volumes. In general, it had also found that buying groups were unwilling to accept a sliding scale of discount related to volume. They expected discounts at the level that a manufacturer would offer to the largest veterinary practices; consequently, manufacturers could find themselves giving away discount for no additional volume. Animalcare commented that individual practices within buying groups made purchasing decisions on other factors as well as price, so the groups were unable to achieve full economies of scale on their purchases.

10.4. Animalcare believed that it was not a party to the conduct described in paragraph 9(e) of the statement (operation by manufacturers of rebate schemes that make it difficult for veterinary surgeons to ascertain with certainty at the time of purchase the cost to themselves of POMs). It said that its discount levels were individually negotiated with veterinary practices, were confirmed in writing and were applied until the agreed review date. It considered its scheme to be completely transparent. Net prices could be ascertained through a simple calculation and Animalcare was prepared to supply a net price list on request. It added that it did not offer the scheme to more than a handful of individual practices that it thought would do the most for it in terms of sales of its products.

10.5. Animalcare said that there were problems with lack of transparency in rebate schemes operated by some other manufacturers. This could make it difficult for Animalcare to make sales to veterinary practices at a satisfactory price, because veterinary surgeons were sometimes unclear as to how much they were paying for a rival product. There was also a problem with bundling within rebate schemes, which acted as a definite barrier to Animalcare’s gaining new customers.

10.6. Animalcare also commented that rebate schemes could prevent veterinary surgeons from calculating their margins accurately. It was likely that if they were not certain about the prices they were paying for POMs then discounts would not be passed on to the end-users.

10.7. Commenting on the conduct described in paragraph 9(f) of the statement (failure of manufacturers to supply pharmacies with POMs and/or enable pharmacies to obtain supplies of POMs on terms that enable them to compete with veterinary surgeons), Animalcare said that it did not directly supply any pharmacy with POMs. It did not know whether any wholesaler supplied any of its POM products to pharmacies, as it did not buy sales data from wholesalers. It did not have a policy on the payment of rebates to pharmacies. No pharmacy had sought inclusion in any rebate arrangement from Animalcare and no pharmacy was receiving rebates from it. Animalcare stated that it would provide pharmacies with the same commercial terms as veterinary surgeons for similar volumes of business using the same distribution channel.
Provisional complex monopoly—supply of cat and dog vaccines to veterinary surgeries

10.8. Animalcare accepted the analysis in paragraph 21 of the statement. It said that there was no doubt that the largest manufacturers used their leverage in their product portfolios in order to gain sales volume. It believed that bundling was anti-competitive and a barrier to entry. Although cat and dog vaccines were leading examples, other very significant products were also affected. One of them was anaesthetics, where Animalcare had launched two new products in the preceding year. It told us that veterinary practices were able to buy leading products at reduced prices, provided they bought other products from the manufacturer’s range, and this made practices reluctant to switch to new products from different manufacturers. It also told us that it had received reports that one company, Bayer, had offered its microchips and microchip reader (for animal identification) to some veterinary practices at a greatly reduced price, subject to a commitment from the practice regarding its purchase of veterinary medicines from Bayer. This had created an effective barrier to sales of Animalcare’s rival microchip and reader.

Possible remedies

Prohibition on manufacturers operating rebate schemes in which the level of rebates given on purchases of cat and dog vaccines is based on, or substantially influenced by, the combined value of purchases of these vaccines (paragraph 25 of the statement)

10.9. Animalcare supported this possible remedy. It urged us to go further and recommend prohibition of all bundling rebate schemes, which it considered to be anti-competitive and a barrier to entry by companies without a wide product portfolio. It believed that prohibition would lead to greater transparency and competition.

Regulatory issues

10.10. Animalcare said that although it had on occasions been frustrated by the length of time it took to obtain an MA, or a variation to an MA, it had confidence in the regulatory framework and the quality of veterinary medicines used in the UK. It would not support any major relaxation of regulatory requirements. On the question of classification, it was content for the decision to be taken by the regulatory body. It would have no objection to a review of classification being undertaken as part of the five-yearly review, or at the instigation of a third party, provided that the VMD considered all aspects of the product concerned, including route of administration.

Possible recommendations for regulatory changes

10.11. Animalcare’s comments on some of the possible recommendations set out in the statement of 17 September are recorded below.

The Secretary of State to consider negotiating changes to the draft Directive (also proposed in COM (2001) 404 final) so as to legitimise cross-border trading, without need for a further marketing authorisation, of any veterinary medicine authorised through the decentralised procedure, between member states in which it is authorised, and to remove barriers to labelling in the appropriate language (Recommendation (2))

10.12. Animalcare said that it supported this recommendation, but only on the assumption that the integrity of the licensing process in all EC member states would be maintained. Implementation of the recommendation would ensure that products could be brought to the UK market much more quickly than was presently the case and would enable the export of UK licensed products.

The Secretary of State to oppose the European Commission’s proposal that all veterinary medicines for food animal species must be classified POM (Recommendation (6))

10.13. Animalcare was opposed to this possible recommendation. It believed that the European Commission’s proposal was a tangible step to protect European food animals and, more importantly, the perception of food safety by consumers.
The Secretary of State to consider negotiating changes to the draft Directive to make it clear that the procedure through which an MA is given has no bearing on the scope of member states’ freedom to control channels of distribution and supply of veterinary medicine (Recommendation (7))

10.14. Animalcare commented that this proposal was at odds with possible Recommendation 2. It appeared that it would have the effect of impairing free movement between member states, since a member state could control the channel of distribution and, if it so wished, obstruct the objective of Recommendation 2.

The Secretary of State to consider negotiating changes to the proposed Directive to allow provisional marketing authorisation to be given to any product for which an efficacy claim is made and which has successfully completed safety and quality assessments so that commercialisation may begin before completion of efficacy assessment (Recommendation (16))

10.15. Animalcare thought that a recommendation on these lines would be unworkable. It said that a manufacturer could make claims about the efficacy of a product that might subsequently be found to be spurious. Meanwhile, an existing product could have been displaced from the market as a result of the claims.

The Secretary of State to consider negotiating changes to the proposed Directive to remove the ranking of cascade options in respect of non food-producing animals so that, where circumstances allow recourse to cascade, a veterinary surgeon may use whichever option he considers best (Recommendation (18))

The Secretary of State to consider negotiating changes to the proposed Directive to allow recourse to the cascade in the case of non food-producing animals where, notwithstanding the existence of an authorised medicine for the species and condition in question, the veterinary surgeon having the animal under his care considers this justified on grounds of animal welfare including cases where the cost of treatment would otherwise cause the animal to go untreated (Recommendation (19))

10.16. Animalcare said that the veterinary market already used branded generic products and that these were driving down prices. For example, in June 2002, Animalcare had launched an anaesthetic at £50 for 250 ml as against a proprietary product sold by a competitor at £90 for 250 ml. It said that the current human generic price for this product was £32 and it was aware of it being sold to a veterinary practice by a competitor for £24. It was clear, therefore, that the launch of generic products by Animalcare had increased competition and led to price reductions. In its opinion, therefore, the relative speed and efficiency of the licensing process for generics should be the focus of our report, and not the cascade.

Animal Reproductive Technologies Ltd

10.17. In response to the statement of 16 April, Animal Reproductive Technologies Ltd (ART) said that Issue II(i) (whether veterinary manufacturers tie in the sales of some or all products in their ranges with anti-competitive effect) was a matter that certainly affected small companies such as itself. The larger companies offered retrospective discounts to veterinary surgeons, based on annual turnover. Typically, the discount would apply to all of the manufacturer’s product range and the percentage would increase as targets were met. Consequently, it was difficult for small companies with a limited product range to enter the market.

10.18. By way of example, ART said that it had recently launched a new product with a list price that was 40 per cent less than that of the market leader. Both products exhibited similar efficacy. Although it was able to match the discounted price of the competitive product, veterinary surgeons were unwilling to switch to the ART product, because to do so would result in a reduction in the discount on all other purchases from the manufacturer of the other product. ART believed that tying was an anti-competitive practice that resulted in farmers paying too much for some of their veterinary medicines.

10.19. ART also responded to the statement of 17 September. [Details omitted. See note on page iv.]
10.20. ART pointed out that a similar problem existed with the supply of prostaglandins to farmers. These products could be fatal if self-injected and were therefore normally administered only by veterinary surgeons. Supply on prescription through pharmacies did not, therefore, seem to be an option. ART told us that list prices of prostaglandins varied from £1.80 to £2.70 a dose and that the market leader was discounted by as much as 35 per cent, the discount being linked to all of the products that the manufacturer supplied. Companies with a small product range could not compete, even though their list prices might be among the lowest.

10.21. In ART’s opinion, an appropriate remedy would be to ban retrospective discount schemes that required the veterinary surgeon to buy a range of products from the same manufacturer. Price transparency would thereby be increased and farmers would be given the option of having cheaper medicines administered to their stock: decisions about which POM to use could be taken on the grounds of therapeutic efficacy and price instead of price alone.

Arnolds Veterinary Products Ltd

Provisional complex monopoly situations—supply of POMs to animal owners and supply of cat and dog vaccines to veterinary surgeries

10.22. Arnolds did not comment on our provisional conclusions regarding the existence of complex monopoly situations, but endorsed the views expressed by its sister company, NVS (see paragraphs 10.906 to 10.917).

10.23. With regard to the conduct identified in paragraph 9(d) of the statement of 17 September (refusal/failure of manufacturers to negotiate discounts and rebates with buying groups), Arnolds said that it did not have any formal arrangements with buying groups. It met some of them regularly and did occasionally deal with them, but not on a basis where it was giving them discounts.

10.24. Commenting on the conduct identified in paragraph 9(e) of the statement (operation by manufacturers of rebate schemes that make it difficult for veterinary surgeons to ascertain at the time of purchase the cost to themselves of POMs), Arnolds said that it did not operate a general rebate scheme. It had contracts with ten large veterinary practices (many of them specialist equine practices) based on annual turnover whereby if they met an agreed threshold they would be eligible for either a cash rebate or free products of their choice (these could be instruments, equipment or pharmaceuticals). Qualifying thresholds were negotiated individually and rebates paid either annually or quarterly. Arnolds was unable to comment on the rebate schemes operated by other manufacturers, but said that its arrangements with its largest customers reflected the fact that rebates were available from the major manufacturers.

Other issues

10.25. Arnolds said that most of the issues identified in the statement of 16 April had little bearing on its position, given that it had only a small share of supply of POMs. Its comments on some of the issues are recorded below.

Whether veterinary manufacturers tie in the sales of some or all products in their ranges with anti-competitive effect (Issue II(i))

10.26. Arnolds said that issues of tying and bundling did not arise in its case because it did not have a wide range of products, nor did it make widespread use of retrospective rebates. Furthermore, given its product strategy, Arnolds was unlikely to be affected significantly by tying or bundling practices adopted by other manufacturers.
Whether veterinary manufacturers design their rebate schemes in such a way as to reduce price
transparency (Issue II(ii)a)

Whether veterinary manufacturers’ rebate schemes are structured in such a way as to cause veterinary surgeons to charge higher prices than they would otherwise do (Issue II(ii)b)

10.27. Arnolds thought that these were issues essentially for veterinary practices. It thought that veterinary surgeons would be likely to take account of the fact that they would be receiving rebates and would factor this into the margin they required on the sale of medicines. If, therefore, rebates were terminated, then veterinary practices might compensate by increasing the percentage margin they charged on the then lower list price. However, the real issue was the relationship between profit on medicine sales and charges for professional services.

Whether veterinary manufacturers who operate rebate schemes gain an informational advantage over those who do not, and whether this enables them to strengthen their position in the market in an anti-competitive way (Issue II(ii)c)

10.28. Arnolds said that sales information about their own products was commercially available to all manufacturers, whether or not they operated a rebate scheme.

Whether veterinary manufacturers with a large market share in particular veterinary medicine sub-markets carry out anti-competitive practices to maintain their position, and in particular: whether veterinary manufacturers engage in predatory pricing (Issue II(ii)d)

10.29. Arnolds stated that it was not in a position to engage in predatory pricing, although it had to respond to intense competition from other suppliers, either on price or through a superior product offering in its specialist areas. It was unaware of instances of predatory pricing by others, or attempts to engage in any anti-competitive market sharing.

Whether the manufacturers of veterinary medicines are protected by the provisions of the cascade from competition from substitutable human medicines, and whether they exploit this protection by charging higher prices than would otherwise be the case (Issue II(iii))

10.30. Arnolds said that although medicines used for treating humans could be effective in animals, there were many issues such as dosage levels and the means of delivery that were particular to different species. In its view, it was therefore essential that the veterinary pharmaceutical industry should continue to specialize in animal treatments. This would not be possible if veterinary surgeons used human medicines, since it would deprive manufacturers of the income needed to support R&D specific to animal species. Arnolds commented that the veterinary medicines market was far smaller than the market for human medicines, with only 68 animal products with annual sales in excess of £1 million. It said that the cascade served the useful purpose of protecting animal welfare, both immediately and in the longer term. It added that licensed products carried with them clear product liability for the manufacturer, which could never be the case for unlicensed human products.

Whether veterinary manufacturers set the price or influence the retail mark-up on veterinary medicines, and in particular whether veterinary manufacturers, through published list prices, effectively set minimum resale prices (Issue II(iv))

Whether veterinary manufacturers otherwise set, or influence, the price at which their products are resold (Issue II(v))

10.31. Arnolds had little information on how veterinary surgeons set their retail prices, but thought it likely that it was by application of a margin to the list price. It was of course open to them to set retail prices below list prices, relying on the retrospective rebates from manufacturers, but Arnolds thought this was unlikely to happen in practice as it would assume a very limited margin. It did not believe that manufacturers could have any influence over resale prices, given that there were some 3,500 veterinary practices in the UK.
Whether veterinary manufacturers request, or fail to initiate review of, classification of a medicine as prescription-only in cases where this is not necessary on grounds of safety (Issue II(vi))

10.32. In Arnold’s view, products should be classified according to objective criteria related to the risks involved in their use. There appeared to be no reason why the VMD should not be able to reclassify when appropriate on its own initiative. It would prefer this approach to the alternative of allowing a third party to apply for review of classification, since the party concerned might be commercially motivated. It was not Arnold’s policy to attempt to protect its market share by failing to apply for reclassification.

Whether veterinary manufacturers charge differential prices to veterinary surgeons in such a way as to restrict competition (Issue II(viii))

10.33. Arnolds said that as it did not, in the main, operate rebate schemes it did not have any sales relationship with veterinary surgeons and was therefore unable to charge differential prices. It only used rebates on a limited scale as a response to the bargaining power of individual veterinary practices, and it had little option but to respond to those realities.

Regulatory issues

10.34. Arnolds had not found the VMD to be over-zealous in its application of EC regulations, but it thought that there should be more of a level playing field in the EC as a whole. The mutual recognition process was often protracted and costly because individual member states seemed to put up unnecessary hurdles to recognition instead of being ready to accept another state’s licensing decision.

10.35. Arnolds believed that efficacy testing was an essential part of the regulatory process and there should be no relaxation of the requirements. From a commercial point of view, any situation where efficacy was jeopardized could create significant animal welfare problems, loss of customer base and loss of credibility for the manufacturer concerned.

Bayer plc (Animal Health Business Group)

Provisional complex monopoly situation—supply of POMs to animal owners

10.36. Bayer did not comment on the provisional conclusion that a single complex monopoly situation existed in relation to the supply within the UK of POMs to animal owners. It did, however, disagree that such a complex monopoly situation would operate in favour of manufacturers supplying POMs in the UK. It noted that we had thought it likely that manufacturers would benefit because lower competition and higher prices at the retail level would reduce competitive pressures on prices further up the supply chain. Bayer, however, believed that it would benefit from lower retail prices as these would increase the overall use of veterinary medicines and boost the sale of its products.

10.37. Bayer said that it did not engage in the conduct identified in paragraph 9(d) of the statement of 17 September (refusal/failure to negotiate discounts and rebates with buying groups). It told us that it currently supplied around ten buying groups, including all the large ones. By virtue of the fact that they were very big customers, these groups were on Bayer’s top discount band and would get the highest level of discount on the same terms as any veterinary practice that bought similar amounts.

10.38. Commenting on the conduct described in paragraph 9(e) of the statement (operation by manufacturers of rebate schemes that make it difficult for veterinary surgeons to ascertain with certainty at the time of purchase the cost to themselves of POMs), Bayer said that it published net price lists for veterinary surgeons to determine their net purchase price in view of their discount level. It acknowledged that there was an element of uncertainty because its scheme had two components: the discount, where there was no uncertainty, and the rebate, which was an end-of-year payment. However, purchases by veterinary practices tended to be consistent from month to month and year to year, so it should be possible, by comparing one year’s turnover with that of the previous year, for a practice to work out the rebate it could expect. Bayer provided each practice with a monthly statement setting out purchases in that month, the amount of discount and the year’s purchases in comparison with those in the previous year. If a practice believed it was going to reach a higher rebate level than in the previous year, it would
have sufficient information to estimate the total rebate it would receive and hence know within about 1 per cent accuracy the price it paid for any Bayer product.

10.39. With regard to the conduct described in paragraph 9(f) of the statement (failure to supply pharmacies with POMs and/or enable pharmacies to obtain supplies of POMs on terms that enable them to compete with veterinary surgeons), Bayer said that it supplied a number of pharmacy wholesalers/retailers on terms that enabled them to compete with veterinary wholesalers. It did not currently supply veterinary medicines direct to any purely retail pharmacies, but they should be able to purchase its products from veterinary wholesalers on terms that would enable them to compete with veterinary practices. Bayer did not impose any restrictions on veterinary wholesalers supplying pharmacies with its products. It confirmed that it would supply its POMs to any holder of an appropriate wholesale licence.

10.40. Bayer said that it had one veterinary practice customer that historically always used to buy direct and still had a direct account, although that had virtually lapsed as the practice found it more convenient to order from a wholesaler. Apart from that case, and a few poultry accounts, all Bayer’s POMs were supplied via wholesalers.

10.41. Bayer told us that in 2001, [X] per cent of the veterinary practices that it supplied did not participate in its discount/rebate scheme because their turnover was less than the minimum required to participate (E[X]). Bayer explained that this turnover threshold was based on customer mix. It related to sales of all Bayer’s products, not just sales of POMs. Bayer’s view was that pharmacies should be able to compete on price with those [X] per cent of veterinary practices that did not take part in the scheme. It said that any pharmacies buying directly from Bayer would be paying less for its products than those veterinary practices because the pharmacies, unlike the veterinary practices, would not have to pay a mark-up on the price paid by the wholesaler.

10.42. [Details omitted. See note on page iv.]

10.43. Responding to comments from bodies representing pharmacists and from individual pharmacists about difficulties that pharmacies experienced in obtaining supplies of POMs, and in some cases other veterinary medicines, Bayer said that it had had meetings with the NPA on the subject. It had explained to the NPA that it received very few requests from individual pharmacies and that any pharmacy that did ask about supply would be directed to the veterinary wholesalers, because in most cases pharmacies would want to order only small quantities of veterinary medicines. [Details omitted. See note on page iv.]

] It supplied Drontal to many of the major pharmacy wholesalers, including Jobsons, and would be prepared to supply it direct to any pharmacy that met Bayer’s turnover and order size criteria. Bayer had not come under any direct pressure from veterinary surgeons not to supply pharmacies. [Details omitted. See note on page iv.]

Provisional complex monopoly situation—supply of cat and dog vaccines to veterinary surgeries

10.44. Commenting on the provisional finding of a complex monopoly in relation to supply to veterinary surgeries of vaccines for cats and dogs (paragraphs 20 to 23 of the statement of 17 September), Bayer said that it would go further than this conclusion. It thought that manufacturers of vaccines for cats and dogs tied in pharmacological products with their vaccine range through their annual rebate schemes, making it difficult for a company (like itself) that was not in the vaccine business to compete. Bayer said that in some very competitive markets, for example, the market for flea treatments, it felt at a disadvantage as a small company without a full range of products. This was because its rebate levels could not match those offered by companies with a full range of veterinary medicines. Customers of those companies could achieve a higher total turnover, and a higher level of rebate than would otherwise be available, by buying products from across the range. Where a rebate scheme applied across all
products, there was an incentive for the customer to buy all medicines from one manufacturer instead of buying a particular product from a smaller manufacturer, even though it might be a superior product.

10.45. Bayer said that vaccines were a very important part of veterinary surgeons’ product portfolio, so if a manufacturer was negotiating an annual agreement with a veterinary practice then vaccines were going to account for a large part of it. A manufacturer that could offer a vaccine was in a stronger negotiating position than one that could not.

Other issues

10.46. Bayer’s comments on some of the matters raised in our statement of 16 April 2002 are recorded below.

Whether veterinary manufacturers tie in the sales of some or all products in their ranges with anti-competitive effect (Issue II(i))

10.47. Bayer told us that under its discount and rebate scheme a veterinary practice was not penalized for buying a competitor’s product, although it would mean that the level of purchases from Bayer in any year would be less and therefore the practice might receive a lower discount. However, this would tend to be offset by higher discounts from the supplier to which business was transferred. Bayer said that to the extent that such discounts might affect competition, this would benefit those manufacturers that were able to supply a complete product range. Bayer had no products in over half of the UK companion animal market.

10.48. We asked Bayer to comment on an allegation that it provided microchips or microchip readers linked to discounts on POMs (see paragraph 10.8). Bayer said that microchips were part of its rebate scheme, along with the rest of its range of products. It did not give free microchips as an inducement to buy any other of its products, although it might sometimes give free microchips on an order for microchips.

Whether veterinary manufacturers, via linked price promotions, use the existing market power of some products as a lever to gain share of other markets (Issue II(iia))

10.49. Bayer said that it had offered linked price promotions in order to meet competition from integrated products, but a veterinary practice had always had the option to buy its products separately. A better price was available if both products were bought and in Bayer’s view this should be for the benefit of the animal owner.

Whether veterinary manufacturers operate rebate schemes which are a barrier to successful market entry, in that they encourage veterinary surgeons to buy more from larger veterinary manufacturers (Issue II(iib))

10.50. With regard to rebate schemes as a possible barrier to entry, Bayer said that its operation of discount and rebate schemes allowed it to compete against larger manufacturers. It commented that prohibition of such schemes might not have the desired effect of encouraging veterinary practices to buy competing products. If rebates and discounts were replaced by straightforward price cuts, the larger manufacturers might not reduce the price of their strong products but instead reduce the price of their slower-moving products by a greater amount than veterinary practices would receive under a rebate scheme. Bayer also feared that a prohibition on discount schemes could lead to increased use by some manufacturers of such practices as ‘car boot stock’ in order to compete.

Whether veterinary manufacturers design their rebate schemes in such a way as to reduce price transparency (Issue II(iia))

10.51. Bayer said that its rebate scheme was simple and easy to understand. To assist transparency, it supplied each veterinary practice with a net price list for the discount band that applied to it. Practices should not, therefore, have any difficulty in estimating the price of a Bayer product net of discount and rebate if they wished to make a comparison with a competing product. Bayer told us that it did not negotiate rebates individually with veterinary practices. All were offered the published discount and rebate levels, subject to achieving the qualifying levels of purchases.
Whether veterinary manufacturers’ rebate schemes are structured in such a way as to cause veterinary surgeons to charge higher prices than they would otherwise do (Issue II(ii)b)

10.52. Commenting on the practice of veterinary surgeons setting retail prices of veterinary medicines by reference to manufacturers’ list prices rather than the discounted price, Bayer said that its discount was paid monthly and, therefore, veterinary practices should be able to take it into account when setting prices to animal owners. Although a practice would not know until the end of the year into which rebate band it fell, it should be able to make a reasonably accurate estimate and take it into account in the retail prices charged.

Whether veterinary manufacturers who operate rebate schemes gain an informational advantage over those who do not, and whether this enables them to strengthen their position in the market in an anti-competitive way (Issue II(ii)c)

10.53. With regard to manufacturers’ access through their rebate schemes to information obtained from wholesalers about the purchases of individual products by individual veterinary practices, Bayer said that it paid for the information (which related solely to its own products) by giving an additional discount to veterinary wholesalers. It used the information to calculate discounts and rebates. It also made limited use of it in order to target sales representatives more efficiently, although greater use was made of information bought from GfK for that purpose.

Whether veterinary manufacturers with a large market share in particular veterinary medicine sub-markets carry out anti-competitive practices to maintain their position, and in particular: whether veterinary manufacturers engage in predatory pricing (Issue II(ii)d)

10.54. Bayer said that it did not engage in predatory pricing, nor had it done so in the past.

Whether veterinary manufacturers promote brand loyalty to such an extent as to limit price competition and restrict market entry (Issue II(ii)e)

10.55. With regard to non-price competition in the supply of veterinary medicines through means such as manufacturers’ funding of CPD for veterinary surgeons, free gifts and other inducements, Bayer said that its CPD scheme was popular with veterinary surgeons. It was in reality a discount scheme, as the veterinary surgeon received a monetary discount that could either be spent on CPD training or passed on to animal owners in the form of lower prices. It was unlikely that the value of a free gift could be passed on to animal owners. Bayer believed that the existence of non-price competition showed that there was variety within the market and hence competition, which ought to benefit animal owners.

10.56. With regard to the development of a patent-protected medicine as a brand in order to maintain some market share after the patent had expired, Bayer said that the instances of this happening in veterinary medicines were extremely few in comparison with human medicines. Bayer had withdrawn five products in the last three years because of generic competition, which illustrated the difficulty of creating and maintaining post-patent brand awareness. Experience had shown in the pharmaceutical industry that after a product went off patent, sales and profitability would fall significantly because of generic competition.

Whether veterinary manufacturers engage in anti-competitive market sharing, by jointly choosing not to launch or promote products that directly compete with those of other suppliers (Issue II(ii)f)

10.57. Bayer said that it did not engage in any form of anti-competitive market sharing. It commented that high market shares in individual product markets were typical of the markets for human and animal medicines, where there were patent-protected products with technical/therapeutic advantages. Without high market shares in some sectors, the research-based companies would continue to decline, which would not be in the interests of animal owners.

Whether the manufacturers of veterinary medicines are protected by the provisions of the cascade from competition from substitutable human medicines, and whether they exploit this protection by charging higher prices than would otherwise be the case (Issue II(iii))

10.58. Bayer said that the provisions of the cascade were intended to protect both animal and human health. It thought that veterinary surgeons might be reluctant to prescribe a human medicine that had not
undergone the same trials as a veterinary medicine specifically licensed for the animal concerned, because of legal liability issues. Bayer commented that permitting the use of substitutable human generics would not benefit R&D, and that innovative products would not be delivered in the future.

**Whether veterinary manufacturers set the price or influence the retail mark-up on veterinary medicines, and in particular whether veterinary manufacturers, through published list prices, effectively set minimum resale prices (Issue II(iv))**

**Whether veterinary manufacturers otherwise set, or influence, the price at which their products are resold (Issue I(v))**

10.59. Bayer said that it did not know what prices veterinary surgeons charged their customers, nor did it seek to influence the retail mark-up. This was entirely a matter for individual veterinary surgeons. Bayer commented that it had no interest in high retail prices. Its interest was in persuading veterinary surgeons to buy as much of its products as possible.

10.60. Bayer told us that its representatives did not discuss resale prices on their visits to veterinary practices. Nor did it offer higher or lower discounts in relation to list price in order to influence the resale price, or attempt to influence or set retail prices by advertising prices to animal owners.

**Whether veterinary manufacturers request, or fail to initiate review of, classification of a medicine as prescription-only in cases where this is not necessary on grounds of safety (Issue II(vi))**

10.61. Bayer commented that classification of veterinary medicines within the UK was controlled by the VMD, which could also initiate the review of a classification if it wished.

10.62. Bayer said that if a veterinary medicine were to be recategorized so that it would be available through pharmacies and agricultural merchants, then the following points would need to be kept in mind:

- Manufacturers would incur additional costs in employing representatives to call on pharmacists as well as veterinary surgeons.

- There was currently no procedure for pharmacovigilance in respect of veterinary medicines sold through pharmacies and merchants. This was an additional cost that those groups might have to incur if they were to make substantial sales of veterinary medicines.

- Reclassification would result in additional costs, for example on packaging and literature.

- Based on previous experience, there must be doubt as to whether many pharmacies would be interested in stocking the entire range of veterinary medicines and providing a 24-hour, 7-day-a-week service.

- The European Commission had proposed that all new veterinary medicines should be classified as POM.

**Whether veterinary manufacturers encourage veterinary surgeons to buy certain prescription-only medicines by asserting that they will not be subject to reclassification (Issue II(vii))**

10.63. Bayer said that this issue highlighted the anomalies between POMs authorized via the centralized procedure and those authorized via the mutual recognition or national route, and the possibility of attempted exploitation because there was not a level playing field. Bayer added that it also highlighted the dangers of reclassification as a result of an application by a third party where that third party could be acting on behalf of a competitor. In its view, if a POM were to be recategorized, then the classification of all similar competing medicines should be reviewed at the same time.

**Whether veterinary manufacturers charge differential prices to veterinary surgeons in such a way as to restrict competition (Issue I(viii))**

10.64. Bayer told us that it did not allow its sales representatives to negotiate prices individually with veterinary surgeons (with the exception of poultry customers). Different veterinary surgeons paid
different prices only to the extent that their volume of purchases varied according to Bayer’s discount/rebate schemes.

**Whether the provision of detailed sales information by veterinary wholesalers to veterinary manufacturers is detrimental to veterinary surgeries or consumers (Issue III(iii))**

10.65. On the question of whether the supply of sales information by wholesalers was detrimental to veterinary practices or animal owners because it gave manufacturers an informational advantage, Bayer said that it did not use the information in price negotiations with veterinary practices. It added that without the involvement of the veterinary wholesalers, it could not offer to veterinary practices an effective and transparent discount and rebate scheme.

**Whether veterinary surgeons influence veterinary manufacturers not to reclassify prescription-only medicines to a lower classification (Issue IV(vi))**

10.66. Bayer said that it was open to argument whether some veterinary surgeons attempted to influence manufacturers in this way. However, the fact that the issue had been raised illustrated the importance of ensuring that any changes in the rules relating to reclassification of POMs should be fair and be applied consistently among manufacturers of competing products.

**Possible remedies**

10.67. Bayer’s views on certain of the possible remedies listed in the statement of 17 September are recorded below.

**Possible remedies to reduce barriers to obtaining prescriptions (paragraph 24(a) of the statement)**

10.68. Bayer said that it would not be directly affected by the possible remedies proposed under this subparagraph, nor would it want to object to them if they were in the public interest. In its view, however, it would be uneconomical for pharmacies to hold stocks of most of the veterinary medicines (except for a few blockbusters) because the market was so small. Bayer suggested that animal owners with prescriptions would be told to come back to the pharmacy a few hours later, allowing express delivery from a wholesaler. The cost of this delivery as well as fuel (veterinary surgeon to pharmacy + pharmacy to home + home to pharmacy + pharmacy to home) and time/cost for the animal owner made this a dubious remedy.

**A requirement for veterinary surgeons when quoting the price at which they will dispense any POM also to state the cost of that POM to themselves (paragraph 24(b)(iv))**

10.69. This proposal did not directly concern Bayer. However, it thought that it would be wrong for a seller to be obliged to state the cost at which it purchased a product. Bayer could not think of any other business involving sales to the public where this was required. It said that in the case of veterinary practices, the disclosure of the cost of a product to the practice might be misleading because there were many unavoidable costs that would reduce its gross profit margin. Bayer also asked whether, if pharmacists wanted to be treated on the same footing as veterinary surgeons, they should be required to state the cost of a POM to themselves when quoting their price for dispensing it.

**A requirement for manufacturers of POMs giving rebates to veterinary surgeons to provide sufficient information, either directly or through wholesalers, so as to enable the veterinary surgeon to ascertain with certainty the cost net of rebates of POMs supplied to them (paragraph 24(b)(v))**

10.70. Bayer said that by its very nature a rebate was a repayment of a sum at a later date than the date of purchase. Therefore, neither the veterinary surgeon nor the manufacturer would be absolutely certain at the time of purchase how much rebate would be paid. It was also unclear whether manufacturers would be expected to be aware of the price invoiced for their POM products by the wholesaler to the veterinary surgeon. Bayer asked whether it would be sufficient if the veterinary surgeon were to be advised of the total amount of discounts and rebates to be received from the manufacturer and then deducted this amount from the net invoice amount from the wholesaler for the product.
10.71. Bayer would be worried if rebate schemes were abolished in the interests of transparency only to be replaced by something even less transparent, such as a bonus stock system whereby instead of discount or rebate a purchaser was provided with additional stock—in effect, a ‘buy-one-get-one-free’ arrangement. Bayer thought that discount schemes offered the greatest transparency.

A requirement for manufacturers and wholesalers that supply POMs in the UK to supply pharmacies on terms that enable them to compete with veterinary surgeons (paragraph 24(c)(ii))

10.72. Bayer said that it had no problem with this proposal. It already supplied pharmacies with POMs. Supply to pharmacies could be either via wholesalers or direct (subject to minimum order and annual purchase requirements that Bayer required for its wholesalers). If supply was via wholesalers, Bayer would offer the same discount/rebate scheme as it offered to veterinary surgeons, subject to qualifying volumes. However, it should be noted that like small veterinary practices, small pharmacies would not receive any discount or rebate from Bayer unless they achieved the minimum annual turnover required.

10.73. Bayer doubted whether many pharmacies would want to dispense veterinary medicines given that they would need to carry extra stock and that the turnover was likely to be small in comparison with their other business. Bayer was concerned that implementation of the possible remedies might possibly give pharmacies an advantage over veterinary practices. It believed that there should be a level playing field for the two groups.

A requirement for veterinary surgeons when they write prescriptions for POMs to do so on an ‘or equivalent’ basis to enable those dispensing such prescriptions to supply alternative authorised veterinary medicines to the brand specified (paragraph 24(c)(iv) of the statement)

10.74. Bayer queried whether ‘on an equivalent basis’ meant the same molecule (generic substitute) or any product for the treatment of the same indication. It said that if pharmacies were allowed to substitute a competitive product, some manufacturers might offer pharmacies substantial discounts across a range of products to encourage such substitution. This would distort competition and would be unacceptable to Bayer. There were also safety concerns about pharmacists being given discretion to decide which medicine to dispense out of a possible range: for example, as far as medicines for food animals were concerned, different brands of the same drug might have different withdrawal periods and substitution could increase the risk of residue violation. Even with medicines for companion animals, bio-equivalents of different formulations were not necessarily exactly the same and substitution could pose some risks to animal safety.

Regulatory issues

10.75. Bayer commented that the European Commission’s regulatory function in respect of veterinary medicines had expanded into an enormous framework of directives, regulations and guidelines, which had increased the manufacturer’s workload dramatically in bringing a new product to the market and indeed in maintaining existing products on the market. Bayer’s R&D money had been increasingly diverted to the defence of existing products rather than to development of new products. The difficulty had been compounded by the UK’s practice of interpreting the regulations relatively severely and enforcing them before the deadline laid down. This meant that in the UK manufacturers were sometimes asked to provide data that was not yet required in other EC member states. There were also problems arising from lack of harmony between countries on such matters as the name of the product and packaging and labelling requirements. These all added to manufacturers’ costs.

10.76. In Bayer’s view, the net effect of the regulations had been to reduce the number of products available to treat animals and to limit R&D activity to the major indications in the major species, so that products were no longer being developed for animals such as sheep, or even pigs. The cost of producing the data required for the authorization process exceeded any likely return multiplied by the risk.

10.77. We invited Bayer to estimate the extra cost of regulation to it by considering the effects of three different hypotheses: no external regulation of veterinary medicines anywhere in the world; mutual recognition by the EC of US Food and Drug Administration (FDA) authorization; UK acceptance of EC central or national authorization without further regulatory requirements.
10.78. Bayer said that under the first hypothesis safety testing would remain essentially unchanged, although no ecotox data would need to be generated for most products. Other parts of the approval process would be replaced by simplified internal procedures and a reduced amount of clinical efficacy testing. It was hard to quantify the cost savings, but at a rough estimate they might amount to between €10 million and €20 million. There was also likely to be a time saving of three to five years in development.

10.79. Commenting on the second hypothesis, Bayer said that the USA drove the market as a whole. Data needs for each system were similar, but style and presentation were different. Although some time would be saved there would be little change in the cost of data generation.

10.80. With regard to the third hypothesis, Bayer said that progress with authorization in the UK was blocked by the rigid and strict interpretation of the need for environmental risk assessments for all products. This did not appear to be an issue elsewhere in the EC, in most countries of which environmental risk assessments were not needed for companion-animal products and were often less stringent for food-animal products. Furthermore, the UK imposed state-of-the-art human quality guidelines to veterinary applications although they were not required by the veterinary guidelines. This had caused many years of delay in the authorization process. There were other UK requirements that would be removed under the hypothesis, in the areas of operator exposure assessments, expensive state-of-the-art packaging and interventions in the process by other agencies such as the Environment Agency and the Food Standards Agency. Bayer estimated that removal of all these additional requirements would save 10 per cent of development costs and a time saving of many years. It was not possible to be more specific because savings would depend on the product concerned.

10.81. Bayer also commented that mutual recognition under the EC regime was not recognition as such, but rather mutual reassessment of the data. Other countries tended not to accept the first country’s assessment of the data and results but instead went through the whole dossier again and typically put another hundred or so questions to the manufacturer.

10.82. Bayer’s comments on regulatory matters contained in the statement of 16 April are recorded below.

Whether the inclusion of an efficacy test in the marketing authorisation procedure unnecessarily increases the barriers to introducing a veterinary medicine to the market (Issue I(ii))

10.83. In Bayer’s view, an efficacy test did not significantly delay the process of obtaining an MA although in the UK, unlike in France and Germany, efficacy testing could not be carried out at the same time as safety testing. In Bayer’s view, efficacy testing should ensure that a product was competitive when launched, assuming that other factors did not present a barrier. It commented that any change in the requirement for an efficacy test would involve a change in EC Regulations.

Whether the absence of provision for a third party to request reclassification of a veterinary medicine, or for regular review of classification, leads to an over-classification of veterinary medicines (Issue I(iii))

10.84. Bayer said that the VMD already had the power to consider the reclassification of a veterinary medicine without an application from the MA holder. Bayer was concerned that giving third parties the right to request reclassification could be open to abuse and lead to unfair competition: for example, a competitor might be behind the third party application, wishing to disadvantage a rival. Bayer said that if there were concerns that the VMD (an independent body) was not exercising its power to review regularly the classification of veterinary medicines, the correct remedy would be to require it to do so.

10.85. Bayer said that if the concern was that some veterinary medicines had been given a higher classification in the UK than in some other EC member states, there should be pressure for harmonization of a three-tier classification throughout the EC. It pointed out that this might not necessarily result in a lower classification in the UK, since the European Commission had proposed that all new veterinary medicines should be classified as POM.
Whether the lack of a prescription-only sub-classification for medicines that could be prescribed by a veterinary surgeon (for animals under his/her care) without prior clinical examination restricts competition (Issue I(iv))

10.86. Bayer agreed that the introduction of such a sub-classification might reduce the effective price for the pet/livestock owner. However, it could not see that this would itself increase the extent of competition between veterinary surgeons and other legal distribution channels. Bayer commented that such a change would also involve an amendment to the RCVS Guide to Professional Conduct.

Whether the length of time allowed to regulators to reach a decision on marketing authorisations is a barrier to introducing a new medicine (Issue I(v))

10.87. Bayer said that it supported any proposal to minimize any delay in receiving MAs.

Whether the conditions under which the European centralised procedure is available could restrict competition, either: by being too narrow, and therefore compelling companies to use the decentralised procedure even if this is a greater barrier to introducing the product to market, or by being too narrow, and so allowing companies to gain a POM classification for their products which cannot subsequently be revised to PML (Issue I(viii))

10.88. Bayer did not think that the conditions under which the European centralized procedure was available had reduced the range of its veterinary medicines available in the UK.

Whether the potential for competition from extra-EU markets is prevented by the lack of mutual arrangements between the EU and other regulatory regimes (Issue I(ix))

10.89. Although Bayer supported any measures that would reduce global regulatory costs, it commented that it was not realistic to expect this to happen quickly and to work in practice.

Possible recommendations for regulatory changes

10.90. Bayer said that it supported recommendations 1, 6, 7, 8, 13, 14 and 15 in the statement of 17 September. Its comments on others of the recommendations are recorded below.

The Secretary of State to consider negotiating changes to the draft Directive (also proposed in COM (2001) 404 final) so as to legitimise cross-border trading, without need for a further marketing authorisation, of any veterinary medicine authorised through the decentralised procedure, between member states in which it is authorised, and to remove barriers to labelling in the appropriate language (Recommendation (2))

10.91. In Bayer’s view, there was a need for a minimum regulatory procedure to check at least that a product was properly labelled and that the people who handled it were properly trained to do so. Currently, any relabelling was subject to good manufacturing practice and should remain so. Bayer also commented that any changes to the draft Directive so as to legitimize cross-border trading must respect a manufacturer’s copyright and trademark rights as interpreted by current EC jurisprudence.

The Secretary of State to consider amending the remits of the Veterinary Products Committee and the Veterinary Medicines Directorate to preclude them from taking into consideration manufacturers’ views on the classification of a product for which they are seeking marketing authorisation (Recommendation (3))

10.92. Bayer believed that the manufacturer that had developed a product would be in the best position to advise on its merits and its risks. Therefore, the VMD should not be prevented from taking into account the manufacturer’s views on the classification of the product. Bayer pointed out that this recommendation appeared to conflict with the subsequent one, under which the information on which it was proposed to base a review of classification would, after all, largely emanate from the manufacturer.
The Secretary of State and the Veterinary Medicines Directorate to consider instituting automatic review of classification whenever a product’s marketing authorisation is renewed (or at similar intervals if the European Commission’s proposal to make marketing authorisations permanent is adopted) and to base such reviews exclusively on the product’s existing dossier and accumulated field experience unless there is good scientific reason to require fresh testing to be carried out (Recommendation (4))

10.93. Bayer supported this recommendation but reiterated its earlier comment that before the VMD reached any decision to reclassify a product, it should consider the competition aspect of reclassification in relation to other products within the same product group. Bayer also confirmed its view that third parties with an economic interest, or that marketed a competitive product, should not be allowed to initiate a review.

The Secretary of State to consider widening the remits of the Veterinary Products Committee and Veterinary Medicines Directorate to take into account the welfare of animals overall (Recommendation (5))

10.94. Bayer stated that economic considerations should not be taken into account in what should be a scientific appraisal of the total product presentation.

The Secretary of State to consider establishing one or more new classifications of veterinary medicines to allow specific categories of persons (such as agricultural merchants and saddlers as well as veterinary surgeons and pharmacists) to dispense veterinary prescriptions for medicines so classified and to make corresponding changes to the law governing the dispensing of prescriptions (Recommendation (9))

10.95. Bayer said it was concerned that if the UK widened dispensing rights for POMs, a lack of uniformity within the EC would create confusion and distort competition.

The Secretary of State to consider negotiating changes to the proposed Directive to allow provisional marketing authorisation to be given to any product for which an efficacy claim is made and which has successfully completed safety and quality assessments so that commercialisation may begin before completion of efficacy assessment (Recommendation (16))

10.96. Bayer opposed this recommendation and suggested that the alternative solution of bringing the UK into line with France and Germany (where efficacy testing could be carried out at the same time as safety testing) might be considered. If our recommendation were to succeed, Bayer’s view was that it would be for a manufacturer to decide whether it wanted to begin commercialization of a product before completion of an efficacy assessment. Bayer believed that there might be product liability considerations to be taken into account. It assumed that the time limit on first marketing a product after an MA had been granted would not apply in the case of a provisional MA.

The Secretary of State to consider negotiating changes to the proposed Directive to remove the ranking of cascade options in respect of non food-producing animals so that, where circumstances allow recourse to cascade, a veterinary surgeon may use whichever option he considers best (Recommendation (18))

The Secretary of State to consider negotiating changes to the proposed Directive to allow recourse to the cascade in the case of non-food-producing animals where, notwithstanding the existence of an authorised medicine for the species and condition in question, the veterinary surgeon having the animal under his care considers this justified on grounds of animal welfare including cases where the cost of treatment would otherwise cause the animal to go untreated (Recommendation (19))

10.97. Bayer opposed these recommendations, for the reasons set out in paragraph 10.59.

Boehringer Ingelheim Ltd

Provisional complex monopoly situation—supply of POMs to animal owners

10.98. Commenting on the question of whether we should be considering one or potentially several complex monopoly situations, Boehringer accepted that the possible remedies we had suggested did not
depend upon which of these conclusions we reached. Boehringer said that the previous MMC reports to which we had referred in support of our provisional conclusion that a single complex monopoly existed dealt only with two levels (suppliers and retailers in Domestic Electrical Goods 1997 and distributors and exhibitors in Films 1994) as opposed to three levels in this inquiry. Boehringer said that it would prefer us to approach the matter on the basis of the three different levels in the supply chain, rather than closely linking the conducts we had identified in the statement of 17 September and regarding them as a single complex monopoly situation.

10.99. Boehringer said that it did not engage in the conduct described in paragraph 9(d) of the statement (refusal/failure to negotiate discounts and rebates with buying groups). It stated that it had a dedicated person whose task it was to negotiate discounts and rebates directly with veterinary buying groups where the volumes of purchases merited such discounts.

10.100. Commenting on the conduct described in paragraph 9(e) of the statement (operation by manufacturers of rebate schemes that make it difficult for veterinary surgeons to ascertain at the time of purchase the cost to themselves of POMs), Boehringer said it did not agree that it was necessarily difficult for veterinary surgeons to calculate the average input prices for products bought under discount or rebate schemes. It considered, however, that discounts and rebates would not necessarily be used by veterinary surgeons to modify retail prices directly. They might be treated as a revenue stream affecting the profitability of the business that, by contributing to overall margin, might allow lower prices to be charged to end-users. It noted that the selling price of a product sold by veterinary surgeons was a composite price reflecting a number of different input costs.

10.101. Boehringer said that to date, discount and rebate schemes had not been significant for its business and it did not get involved in complex discount schemes. Its discounts were primarily based either on a given volume of purchases or a given growth in purchases, over a defined period. It agreed that the veterinary surgeon would not know the average price of veterinary medicines covered by the discount scheme until the end of the period, but that information would not in any case directly relate to the prices actually charged by the veterinary surgeon for a given product on a given day.

10.102. With regard to the conduct described in paragraph 9(f) of the statement (failure of manufacturers to supply pharmacies with POMs and/or enable pharmacies to obtain supplies of POMs on terms that enable them to compete with veterinary surgeons), Boehringer said that it had no intention of behaving in an anti-competitive way towards pharmacies. Efficient supply to the market was achieved by using the wholesaler network to distribute products to veterinary practices. Direct supply would entail higher distribution and administration costs. In the same way, Boehringer would not find it commercially viable to supply pharmacies direct. It had six UK wholesaler accounts to which it delivered on average at fortnightly intervals. If it opened accounts with all pharmacies this number could rise to around 11,000 pharmacy accounts, mostly small, none of which would be likely to take the whole product range. It believed that it would then have to allow veterinary surgeons to compete with pharmacies by offering them the same service, increasing its potential number of accounts to around 14,000. That would have a severe impact on its business and apply upward pressure on prices.

10.103. In purely commercial terms, the volume of sales currently required by pharmacies did not justify setting up trading accounts with them. The relevant products were available from the wholesalers and Boehringer did not put pressure on wholesalers to refuse supply. Boehringer stated that if pharmacies purchased similar volumes of POMs as the veterinary surgeons, it would treat both groups in a similar manner in terms of discounts and rebates.

10.104. Boehringer said that issues relating to discounts and rebates were relevant in terms of its ability to compete with larger manufacturers but were minor factors in driving consumer prices, when compared with the significant mark-up by veterinary surgeons.

Other issues

10.105. Boehringer said that the industry was competitive, with generic competition, innovation and in general a number of products being available for most indications. It was appropriately regulated and regulatory costs, while significant, were compatible with market entry.
10.106. Boehringer’s views on other issues identified in the statement of 16 April are recorded below.

**Whether veterinary manufacturers tie in the sales of some or all products in their ranges with anti-competitive effect (Issue II(i))**

10.107. Boehringer said that it had evidence, primarily obtained from its field force, that the use of its product [X] had been affected by tie-ins from a competitor’s product and its vaccine range. [Details omitted. See note on page iv.]

10.108. Boehringer told us that its ability to compete was constrained by the fact that it did not have a large enough product range to offer. It was absent from important segments of the market—vaccines, antiparasiticides and antibiotics—and therefore could not meet the overall requirements of veterinary practices should they wish to move to its niche products. Veterinary practices that did so would lose out to rebates from Boehringer’s competitors.

10.109. Boehringer emphasized that it was not clear that these practices and schemes necessarily had a significantly adverse effect on the prices paid by the consumer for veterinary treatment.

**Whether veterinary manufacturers who operate rebate schemes gain an informational advantage over those who do not, and whether this enables them to strengthen their position in the market in an anti-competitive way (Issue II(ii))**

10.110. Boehringer considered it unlikely that rebate schemes conferred an informational advantage on those manufacturers that operated them, since all manufacturers could purchase veterinary wholesaler information at relatively low cost. Boehringer had itself bought this data in 2002 in order to identify its major customers so that field-force activity could be targeted and field-force staff rewarded.

10.111. Although other companies might use this information to administer a rebate or discount scheme, Boehringer did not consider this activity detrimental to the interest of veterinary practices or consumers. The effective and efficient administration of reasonable discounts should tend to reduce input prices.

**Whether veterinary manufacturers set the price or influence the retail mark-up on veterinary medicines, and in particular whether veterinary manufacturers, through published list prices, effectively set minimum resale prices (Issue II(iv))**

**Whether veterinary manufacturers otherwise set, or influence, the price at which their products are resold (Issue II(v))**

10.112. Boehringer said that it did not endeavour to influence the price charged by veterinary surgeons for its products, and actively avoided any discussion about this. Its list prices for veterinary surgeons were not intended to be the price to the end-user. It was theoretically possible for veterinary surgeons to sell products below list price if they passed on the discount they received from wholesalers.

**Whether veterinary surgeons set medicine charges in such a way that consultation fees are subsidised (Issue IV(x))**

10.113. Boehringer said that the standard mark-up appeared to be [X%] per cent in companion-animal practices, especially in south-east England. VAT was added and often a dispensing fee was charged. In mixed practices, especially in the more rural parts of the country, mark-ups appeared to be lower, perhaps [X%] per cent, which might reflect the lower overhead costs borne by practices in those areas. Boehringer said that its information came from consumers’ enquiries about the prices charged by
veterinary practices for its products (from which mark-ups could be calculated) and from information gained by its representatives in the field.

10.114. Boehringer believed that the income generated from the margin on the sale of medicines in companion-animal practices offset other costs associated with running these practices, and that should this revenue stream be curtailed, other costs would increase and owners of companion animals in general would not be better off. Should there be a widespread move to pharmacy dispensing, the cost of animal treatment might increase overall, because the supply chain would need to generate the additional profit retained by the pharmacist.

*Price sensitivity of owners of companion animals as regards repeat prescriptions (Appendix D, paragraph 9)*

10.115. Boehringer said it was clear that some owners of companion animals shopped around for repeat or long-term treatments. Nevertheless, especially with long-term treatment, it was essential for veterinary surgeons to check the patient. In the case of congestive heart disease, for example, animals deteriorated quickly and needed regular professional re-evaluation.

10.116. Boehringer observed that if veterinary practice revenue were reduced by loss of margin on the sale of medicines, the consultation fee would presumably have to increase to compensate. Given that any other provider, for example pharmacies, would also require a margin, the likely overall effect would be increased prices to the end-user. One means of maintaining revenue for veterinary practice might be to charge for prescriptions. Boehringer referred to the costs levied for such simple administrative tasks in human medicine, and quoted examples of patients being charged between £20 and £25 for the signature on a private health insurance claim form.

*Possible remedies*

10.117. Boehringer commented that, because the retail price was not usually considered when manufacturers set their prices, any changes in such prices might have little direct effect on manufacturers’ prices, which usually reflected the ex-factory prices of competing products. Retail prices were more likely to be affected by competition between veterinary practices and pharmacies.

10.118. Boehringer’s views on certain of the possible remedies listed in the statement of 17 September are recorded below.

*A requirement for veterinary surgeons when quoting the price at which they will dispense any POM also to state the cost of that POM to themselves (paragraph 24(b)(iv) of the statement)*

10.119. Boehringer said that this would be an extraordinary deviation from normal retail practice. The proposal was impractical and potentially misleading. In any case, it did not believe that the consumer would be able to judge or compare the price of products, given the different presentations, strengths and concentrations available. Boehringer observed that the same requirement would presumably apply to pharmacies.

*A requirement for manufacturers and wholesalers that supply POMs in the UK to supply pharmacies (paragraph 24(c)(i))*

10.120. Boehringer supported the idea that manufacturers should be required to supply pharmacies if that were done through wholesalers, which would allow competition. If, however, manufacturers supplied pharmacies direct, then veterinary surgeons would be put at a competitive disadvantage, because they had to buy through wholesalers.

*A requirement for veterinary surgeons when they write prescriptions for POMs to do so on an ‘or equivalent’ basis to enable those dispensing such prescriptions to supply alternative authorised veterinary medicines to the brand specified (paragraph 24c(iv))*

10.121. Boehringer strongly objected to this proposal. It said that the use of POMs required a diagnosis by a qualified veterinary surgeon. If a pharmacist, who was not qualified to evaluate the needs of the animal, was entitled to provide an ‘equivalent’ medication, the animal’s welfare could be put at risk.
10.122. Boehringer said that the ability to dispense an ‘equivalent’ could in itself prove to be anti-competitive if pharmacies were persuaded by one manufacturer to stock only their brand of a particular medicine, perhaps through a dominant market position and large discounts. A pharmacy permitted to dispense on an equivalent basis would always dispense the brand it stocked even if there were good medical reasons for another brand being specifically prescribed. This would inhibit free competition and have serious implications for animal welfare. Boehringer commented that the proposed remedy would remove veterinary surgeons’ right to ensure that their patients received the intended medicine. It went much further than current practice in relation to human medicines.

10.123. Boehringer added that if pharmacies were effectively handed the prescribing decision in this way, manufacturers would have to promote their products to pharmacies as well as to veterinary practices. That would increase sales and marketing costs and put upward pressure on prices. Also, smaller companies, or those without related human medicine businesses supplying pharmacies, might find themselves in a strongly uncompetitive position, facing increased promotional costs while being unable to leverage their related businesses’ presence to gain access to the pharmacy segment.

**Regulatory issues**

10.124. Commenting on the regulatory regime for veterinary medicines, Boehringer said that the VMD’s approach tended in some respects to be more stringent than that of some of the other regulatory authorities in the EC. However, under the decentralized procedure, it would in many cases choose the UK as a rapporteur, since if a product was granted an MA here it would probably be granted one in all the other EC member states because the quality threshold in the UK was high. Boehringer did not, however, believe that the threshold was too high. It had itself managed to overcome the barriers of regulation and achieve a successful business in the UK, so it was clearly possible.

10.125. We invited Boehringer to estimate the extra cost to a manufacturer of regulation by considering the effects of three different hypotheses: no external regulation of veterinary medicines anywhere in the world; mutual recognition by the EC of US FDA authorization; and UK acceptance of EC central or national authorization without further regulatory requirements.

10.126. Boehringer commented that our hypotheses were far removed from reality. In its case, the flow of regulation tended to be from the EC to the USA. The testing regime in the USA was so different, and in some cases so stringent, that a number of Boehringer’s products sold in the EC were not for sale in the USA. Boehringer pointed out that market forces would influence whether a pharmaceutical company went through the testing process and launched a product.

10.127. Boehringer said that even if there were no specific regulation of veterinary medicines anywhere in the world, pharmaceutical companies would still need to test a product for safety etc because of the risks of claims by users and the requirements of companies’ product liability insurers.

10.128. With regard to reliance on a US authorization as a basis for sales anywhere else in the world, Boehringer said that a number of the tests required for authorization were common to the USA and the EC, so there was no need to repeat them when applying for authorization in both areas. However, testing costs would be incurred in any event and it was impossible to quantify them in a hypothetical situation. If a company could rely completely on the US authorization, no additional test costs would be incurred for regulatory purposes, but testing costs for safety/risk control reasons would still arise.

10.129. In the case of acceptance of EC authorizations without further testing, Boehringer said that there was no additional testing required specifically for the UK market for medicines authorized through the centralized or decentralized procedure. As regards accepting any EC national authorization, Boehringer said that there was not a completely level playing field of testing throughout the EC and so there could be concerns in the UK about the national standards used and whether they would be sufficient for the UK market. If, however, an EC national authorization were to be accepted at face value, no further testing would be needed for regulatory reasons but would still have to be undertaken, at a cost to the company concerned, for product liability/risk control reasons.
Possible recommendations for regulatory changes

10.130. Boehringer’s comments on our possible recommendations for regulatory change are recorded below.

The Secretary of State to consider negotiating changes to the draft Directive (also proposed in COM (2001) 404 final) so as to legitimise cross-border trading, without need for a further marketing authorisation, of any veterinary medicine authorised through the decentralised procedure, between member states in which it is authorised, and to remove barriers to labelling in the appropriate language (Recommendation (2))

10.131. Boehringer would expect any repackaging and/or relabelling to be in accordance with the guidelines in the ECJ case of Boehringer Ingelheim AG (and others) v Swingward Limited (and others).\(^1\) It would expect a simple regulatory procedure along the lines of the parallel import licences issued for centrally-registered products to ensure the quality of the repackaging/relabelling and to ensure that traceability was maintained in the event of a product recall.

The Secretary of State to consider amending the remits of the Veterinary Products Committee and the Veterinary Medicines Directorate to preclude them from taking into consideration manufacturers’ views on the classification of a product for which they are seeking marketing authorisation (Recommendation (3))

10.132. It was Boehringer’s strongly-held view that manufacturers had a right for their views to be considered when product classification was reviewed and should have the opportunity to present evidence in support of any proposed change. Also, it seemed only prudent that new molecules should usually be classified as POM until sufficient data was accumulated to warrant reclassification.

The Secretary of State and the Veterinary Medicines Directorate to consider instituting automatic review of classification whenever a product’s marketing authorisation is renewed (or at similar intervals if the European Commission’s proposal to make marketing authorisations permanent is adopted) and to base such reviews exclusively on the product’s existing dossier and accumulated field experience unless there is good scientific reason to require fresh testing to be carried out (Recommendation (4))

10.133. Boehringer agreed that regular reviews should take place to ensure that all products attained similar quality standards. There should be a level playing field across the industry. It was not reasonable for new products to have to satisfy current quality standards while older competitors remained on the market with specifications that would be unacceptable by today’s standards. Such regular reviews could also accommodate a review of classification based on pharmacovigilance data.

10.134. Boehringer pointed out, however, that having to support different classifications in different countries might increase regulatory costs to companies. Should divergence between labelling occur due to different classifications, this too would increase cost and might even cause the loss of certain products where, as in Boehringer’s case, companies had striven to maintain joint labelling for different countries. Increased costs might also accrue from the potentially differing levels of regulatory support for each category and the need for regulators to judge amendments. This might increase the cost of medicines to the end-user.

10.135. Boehringer noted that there was an evolving harmonization of the regulatory requirements within the EC. Any local changes to regulation in the UK that were inconsistent with EC regulations would ultimately increase the cost of medicines.

The Secretary of State to consider widening the remits of the Veterinary Products Committee and Veterinary Medicines Directorate to take into account the welfare of animals overall (Recommendation (5))

10.136. Boehringer stated that it opposed this recommendation if the suggestion was that the levels of safety testing and regulation relating to POMs should be relaxed.

\(^1\)Case C-143/00 ECJ 23.4.02.
The Secretary of State to consider negotiating changes to the draft Directive to make it clear that the procedure through which an MA is given has no bearing on the scope of member states’ freedom to control channels of distribution and supply of veterinary medicine (Recommendation (7))

10.137. Boehringer did not agree, as it believed that this approach would lead to further inequalities in the marketplace.

The Secretary of State to consider negotiating changes to the draft Regulation to give effect to Marsh Report’s Recommendation 11 in favour of a classification review mechanism for centrally-authorised products (Recommendation (8))

10.138. Boehringer agreed with this, but said that harmonization of the categories would be required before such a change could be successful.

The Secretary of State to consider establishing one or more new classifications of veterinary medicines to allow specific categories of persons (such as agricultural merchants and saddlers as well as veterinary surgeons and pharmacists) to dispense veterinary prescriptions for medicines so classified and to make corresponding changes to the law governing the dispensing of prescriptions (Recommendation (9))

10.139. Boehringer said that it was difficult to comment on this proposal without knowing what the categories would be. It might be acceptable for agricultural merchants or saddlers to dispense original packs, but Boehringer was less comfortable with the idea of these persons breaking packs to dispense smaller quantities. There was essential information in the form of pack inserts and original carton labelling. Boehringer was also concerned about the storage of partly-used packs and about traceability should a product have to be recalled.

The Secretary of State to support the European Commission’s proposal to make marketing authorisations permanent (in the absence of adverse field experience or other comparable grounds for review) (Recommendation (13))

10.140. Boehringer referred to its objections to Recommendation 4 (see paragraphs 10.134 and 10.135). It would still wish to see a five-year classification review system, to ensure that each product carried a licence that reflected current standards, particularly those that could not be covered directly by pharmacovigilance.

The Veterinary Medicines Directorate to consider offering applicants for marketing authorisation the option of submitting their dossier in stages (Recommendation (15))

10.141. In Boehringer’s view, regulatory processes would become harder, longer and more expensive. A phased-review procedure currently practised in the USA by the FDA/Center for Veterinary Medicine demonstrated that there were no benefits to the applicant or to the consumer in terms of speedier market availability.

The Secretary of State to consider negotiating changes to the proposed Directive to allow provisional marketing authorisation to be given to any product for which an efficacy claim is made and which has successfully completed safety and quality assessments so that commercialisation may begin before completion of efficacy assessment (Recommendation (16))

The Secretary of State to consider negotiating changes to the draft Directive so as to allow Maximum Residue Limits for minor food-animal species to be set by extrapolation from major-species data where this is scientifically justifiable (Recommendation(17))

10.142. Boehringer did not agree with these proposed recommendations. In order to evaluate whether or not a particular product had a positive risk/benefit ratio, information on both safety and efficacy of the product was required. Even with the phased review approach, as practised in the USA, generation of efficacy data according to an approved protocol was required for final registration and in order to agree on the final product labelling. To release a product on to the market without appropriate efficacy data could be considered irresponsible and give rise to product liability issues for the manufacturers and a loss of confidence in animal medicines.
10.143. Procedures for emergency licensing (for example, to react to a sudden outbreak of an uncommon disease where no suitable nationally authorized product was authorized) already existed. There was also a provisional MA route available in the UK.

The Secretary of State to consider negotiating changes to the proposed Directive to remove the ranking of cascade options in respect of non food-producing animals so that, where circumstances allow recourse to cascade, a veterinary surgeon may use whichever option he considers best (Recommendation (18))

The Secretary of State to consider negotiating changes to the proposed Directive to allow recourse to the cascade in the case of non food-producing animals where, notwithstanding the existence of an authorised medicine for the species and condition in question, the veterinary surgeon having the animal under his care considers this justified on grounds of animal welfare including cases where the cost of treatment would otherwise cause the animal to go untreated (Recommendation (19))

10.144. Boehringer did not agree with either of these proposals. It noted that veterinary medicines were designed to be palatable to the target species, in a form whose bioavailability had been tested in the target species, in the appropriate dose size and presentation. To encourage the use of products that did not address these points would potentially increase side effects and decrease the likely therapeutic value of the medicine that was untested in animals. It would, moreover, reduce the incentive to develop animal medicines with similar active ingredients to those used in humans, to the long-term detriment of animal health. This might be particularly relevant for companies such as Boehringer, where many products were derived from substances used in human medicine.

10.145. Boehringer said that it did not agree with some of NOAH’s responses on these issues. It said that its different views might be related to its R&D base, its European and global perspective or its current position as a supplier of, in the main, companion-animal products in the UK, which meant that it had less knowledge of the PML and large-animal segments of the market.

Eli Lilly & Company Ltd (Elanco Animal Health)

10.146. Elanco did not comment on our provisional conclusions and hypothetical remedies.

10.147. With regard to market definition, Elanco considered the whole of Great Britain as a single market and Northern Ireland as separate. Elanco said that it competed on both price and the technical features of its medicines. Considering the industry generally, it said that there was much price competition with standard products such as bulk penicillin, but where the uniqueness of the product was more pronounced then technical features were more important.

Rebate schemes

10.148. Elanco told us that it operated rebate schemes because that was normal in the industry. Hypothetically, it would prefer a system where rebates and discounts did not exist and there was simple net pricing. However, in its view that was not acceptable to veterinary surgeons.

10.149. As to whether Elanco linked sales of different products into a single discount scheme, it said that maximum discount could be achieved by purchasing any combination, or just one product, from its range. Within this scheme, the two leading products could be linked to achieve a discount, but this was not a requirement in order to achieve the maximum discount available.

10.150. Elanco said that veterinary surgeons made their own pricing decisions and it was up to them whether or not they passed on discounts and rebates. Retrospective rebates were advantageous to them because they involved no capital outlay and lowered the risk of being left with out-of-date stock. Elanco did not accept that veterinary surgeons in general were confused about the rebate system. In large-animal practices, 70 per cent of income was from drug sales and rebates were a large part of that.

10.151. Elanco said that in a few cases it would negotiate with individual veterinary surgeons who approached them about rebates. For example, during the FMD crisis it had allowed rebates to certain practices that had been unable to reach their target sales because of the special circumstances.
10.152. Elanco told us that the only prices it disclosed were its own selling prices. It did not issue a recommended retail price or enquire about the final retail prices of its products.

**Pharmacies**

10.153. Elanco said that its products were not sold to pharmacies. If it were to sell to pharmacies, it would expect to offer them the same rebate schemes as veterinary surgeons. It was not aware of any institutional barriers that would prevent pharmacies from entering the market and no pressure had ever been put on it to refuse to sell to them. It noted that pharmacies used to be much more involved in retailing its POMs, but had taken a business decision to pull back.

10.154. Elanco would be in favour of more retail outlets to increase competition at the retail level. It also said that it would like to be able to communicate direct with end-users, both farmers and owners of companion animals.

**Predatory pricing**

10.155. Elanco said that it had not been aware of any instances of predatory pricing by competitors.

**Cascade**

10.156. Elanco was against any relaxation in the prescribing cascade to allow access to treatment with human generic products. In the longer term, this would lead to research in animal medicine drying up. Elanco stressed that generics were not necessarily equivalent to a branded product.

**Regulatory issues**

10.157. In Elanco’s opinion, the regulatory system was a barrier to entry and also reduced competition. It was concerned about the huge amount spent on maintaining products in the market. Industry surveys had shown that 60 per cent of R&D expenditure was on maintenance compared with 40 per cent on innovation. Some products were 40 or 50 years old, but the wealth of market experience accumulated by the company was not taken into account. The amount of data required for renewal was a huge burden on the industry and the weight of regulatory demands led to products disappearing from the market. Elanco believed there should be more reliance on pharmacovigilance.

10.158. The regulatory system also affected innovation, not only because it was a financial burden but also because of inconsistencies between different European systems and a lack of predictability. Changes to laboratory standards meant that earlier work became out of date. In the case of antibiotics, because of the implications for human health, new questions were being considered that were not enshrined in the regulatory system. This had led to requests by the regulatory authority for further substantial data after the company had made its original presentation.

10.159. Elanco considered that time delays in the regulatory system were more important than cash considerations, but it would not wish to see any relaxation in standards of safety and efficacy, concepts which it said could not be separated.

10.160. Elanco agreed with the view that the UK regulatory system was ‘gold plated’ compared with some other EC countries on matters of mutual recognition.

10.161. Elanco said that it was not concerned about issues relating to the distribution classification of veterinary medicines, because most of its business was antibiotics, and therefore POMs. Asked how classification would impact on its possible entry into the companion-animal market, Elanco replied that this initiative was driven by research rather than by considering markets or methods of distribution.

10.162. In discussion about prices of POMs across Europe, Elanco said that regulatory conditions had a great influence. The highest prices in the world were in Scandinavia, because of its regulatory system. Recently, however, exchange rates also had played a large role in price variations.
10.163. Elanco wished us to note that, although in building its plant at Speke it had received significant financial support from the Department of Trade and Industry, as sponsor of manufacturing industries, the animal health industry as such was not sponsored by any government department.

**Fort Dodge Animal Health Ltd**

_Provisional complex monopoly situation—supply of POMs to animal owners_

10.164. Fort Dodge accepted that the conduct described in paragraph 9(d) of the statement of 17 September (refusal/failure to negotiate discounts and rebates with buying groups) could have the effect of preventing, restricting or distorting competition. It stated that it did not engage in that conduct, since it supplied significant volumes of product to buying groups and offered them discounts, although they would not necessarily be the same for each buying group as they were negotiated individually and an appropriate level offered in order to win the business. The discounts to buying groups reflected the fact that they usually offered a larger volume of business than a veterinary practice, but would be at a comparable level for comparable volumes of purchases.

10.165. [Details omitted. See note on page iv.]

10.166. Fort Dodge said that it was difficult to envisage a way of making its rebate scheme more transparent. The scheme’s main features were common to all veterinary practices, although discount rates might vary as they were negotiated individually with practices, and a veterinary surgeon would have no difficulty in working out the cost price of any product. Fort Dodge added that its discount rates were not incremental: they did not increase by reference to volumes purchased, and so did not have fidelity or loyalty consequences or retroactive effects.

10.167. Fort Dodge asked us to take its position on both conducts (9(d) and (e)) into account when considering the jurisdictional basis of any remedies that might be recommended.

10.168. With regard to supply to the conduct identified in paragraph 9(f) of the statement (failure to supply pharmacies with POMS and/or enable pharmacies to obtain supplies of POMs on terms that enable them to compete with veterinary surgeons), Fort Dodge said that it expected retailers selling veterinary medicines (whether veterinary practices or pharmacies) to obtain its products from wholesalers. It was not equipped to supply small amounts of product to retailers and to require it to do so would significantly and substantially change the basic nature and economics of its business. Terms of supply would be a matter of negotiation between the wholesalers and the pharmacies.

10.169. Fort Dodge did not directly supply any pharmacy with POMs and directly supplied only a very small, and decreasing, number of veterinary practices, for historical reasons. Its preference was never to supply direct to a veterinary practice. It had never been asked to supply POMs to a wholesaler other than a veterinary wholesaler. If a request were made, it would be considered in the light of the volume of business that might be expected, given that Fort Dodge’s aim was to have its products delivered to customers in the most efficient way. If the request came from a pharmacy group that held a wholesaler licence, it would also be considered in the light of the size of the business. In Fort Dodge’s view, a few pharmacies or veterinary practices getting together to act as a wholesaler for their own group was an entirely different situation from a wholesaler that intended to supply any customer.
With regard to a specific complaint from a pharmacy about its failure to supply them with POMs (see paragraph 12.221), Fort Dodge said that, in accordance with its policy, it had advised the pharmacy to buy the POMs from a veterinary wholesaler. Although the complainant held a wholesaler licence, Fort Dodge had regarded the request as from an agricultural pharmacy, which was the main business of the individual concerned, and had sent a copy of its price list and details of the nearest veterinary wholesaler.

Under present circumstances, Fort Dodge would not expect to give rebates or discounts to pharmacies that were comparable with those available to veterinary practices, because pharmacists did not prescribe veterinary medicines, nor did they play any part in the choice of POM. One of the most important roles of the veterinary surgeon, as far as Fort Dodge was concerned, was to generate demand for its products. It did not see that pharmacists would generate any demand. As pharmacies and veterinary surgeons did not provide the same kind of service to manufacturers, it would therefore not be reasonable for them to be treated in the same way.

Fort Dodge would not agree with a general proposition that every company must supply everybody with everything. It thought it was reasonable to say that discounts and rebates were usually given in return for some marketing or other service provided by the intermediary, and therefore it was reasonable not to give a discount to a pharmacist who did not play such a role. Discounts and rebates, generally speaking, would follow commercial reality and go to the veterinary surgeon who prescribed the product and was effectively the customer. Fort Dodge did not regard a pharmacist as being equivalent to the veterinary surgeon customer, and so would not regard a failure to offer equivalent discounts and rebates as discriminatory.

Commenting on the argument that the practical effect of its policy would be a lower level of competition than would exist if pharmacists were eligible for discounts and rebates on the same terms as veterinary surgeons, Fort Dodge said that the assumption seemed to be that the manufacturer should compensate someone who effectively was a third party, with whom the manufacturer was not in a contractual relationship and who did not choose the product. Fort Dodge thought it was something of an exaggeration to say that without access to manufacturers’ rebates pharmacists would be unable to compete effectively against veterinary surgeons in the sale of medicines. It commented that the margins veterinary surgeons were realizing on POMs were quite high, so there was scope for pharmacists to compete on price. The veterinary price would have to fall substantially to make it uneconomic for a pharmacist to compete. [Details omitted. See note on page iv.]

The fact that those veterinary practices that did not receive rebates were able to survive in competition went to the point, in Fort Dodge’s view, of whether pharmacists could compete in a market in which they did not have identical terms with those of the average veterinary practice.

Fort Dodge commented that it was also unclear how the market would evolve if veterinary surgeons regularly wrote prescriptions. It was economically efficient to pay for services rendered, in this case demand creation by veterinary surgeons, so if a system was set up which made it difficult to tailor the payments to the service, the overall functioning of the market could be impaired.

Provisional complex monopoly situation—supply of cat and dog vaccines to veterinary surgeries

Fort Dodge took issue with a number of the statements contained in paragraph 21 of the statement of 17 September, regarding the supply to veterinary surgeries of vaccines for cats and dogs. It believed that it was misleading to single out those vaccines as highly concentrated markets. There were six companies supplying both dog and cat vaccines in the UK, which in Fort Dodge’s view was sufficient to give customers a wide choice. In addition, the structure of the alleged markets for dog and cat vaccines was in fact less concentrated than many other animal health product groups, such as small animal wormers and cattle and sheep vaccines. The statement referred to rebate schemes that, in effect, gave customers an incentive to buy both cat and dog vaccines from the same supplier. Fort Dodge told us that it did not offer a rebate based upon combined value of purchases of SAVs. It also said that it did not understand the significance in the statement of the words ‘…or substantially influenced by’. However, even if these words of wide and uncertain application were included, Fort Dodge did not consider that its rebate schemes, which under no circumstances aggregated purchases of dog and cat vaccines and which were not retrospective or cumulative, would be caught. It was therefore unclear about the jurisdictional basis of our provisional conclusion. In Fort Dodge’s view, the statement that a manufacturer seeking to
enter the dog or cat vaccine market (but not both) would face particular barriers to entry was not substantiated. It added that the market structure as we had reviewed it was currently inaccurate as Fort Dodge was, in the second half of 2001, not active in the markets for cat and dog vaccines for regulatory reasons in the Republic of Ireland, and was unsure when it would be able to re-enter those sectors.

10.176. At our request, Fort Dodge provided further information on the effect of rebates on sales of cat and dog vaccines. Fort Dodge commented that we appeared to be exploring whether it used its rebate system to encourage customers to buy both their cat and dog vaccines from the company and to discourage customers from switching to other suppliers, but analysis of the data it had provided demonstrated that this was not the case. [Details omitted. See note on page iv.]

Either there was no change in cat vaccine rebates (the usual result) or, when Fort Dodge feared that it might also lose a customer's cat vaccine business, it responded competitively by increasing future rebates on cat vaccines. Fort Dodge said that the data also provided no support for a theory that it used its rebate scheme to discourage customers from switching to other suppliers. New customers accounted for a significant percentage of its customer base, and in any year it also lost a significant percentage of existing customers. Fort Dodge said that this was evidence of lively competition among manufacturers. The data did not support the hypothesis that veterinary practices tended to buy all their SAVs from a single supplier: instead, the evidence was that some frequently bought cat and dog vaccines from multiple suppliers.

Other issues

10.177. Fort Dodge’s comments on other issues, including those set out in the statement of 16 April, are recorded below.

10.178. Fort Dodge said that the separation of the prescribing, dispensing and administration of veterinary medicines would not always be in the public interest. In the case of vaccines, animal welfare might be seriously prejudiced if, at least for small animals, injections were administered by a person other than a veterinary surgeon. Fort Dodge did not consider it practicable for pharmacists to inject small animals in pharmacies, nor for owners to do it safely at home. It was true that a number of farmers might be able, with appropriate training, to inject their own livestock safely and Fort Dodge agreed that there was a case for farmers being able to obtain certain vaccines from sources other than the prescribing veterinary surgeon and if necessary administer them. In particular, Fort Dodge agreed that customer choice would be widened if a veterinary surgeon was allowed to dispense veterinary medicines prescribed by another veterinary surgeon.

Whether veterinary manufacturers tie in the sales of some or all products in their ranges with anti-competitive effect (Issue II(i))

10.179. Fort Dodge said that the rebate systems operated in the UK veterinary medicine industry varied from manufacturer to manufacturer. [Details omitted. See note on page iv.]

10.180. [Details omitted. See note on page iv.]

10.181. [Details omitted. See note on page iv.]

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10.182. Fort Dodge commented that some veterinary practices might choose to buy particular types of product from a single source, but in its view this decision was driven primarily by the clinical effectiveness of the products and the competitiveness of the manufacturer’s prices and rebates. Fort Dodge told us that veterinary practices usually bought from at least three different manufacturers, and larger ones might buy from six or seven. It believed that many practices changed supplier for a major part of their requirements on average once every four years.

10.183. With regard to rebate schemes as a possible barrier to entry, Fort Dodge said that by the time a manufacturer had obtained an MA it would have incurred considerable cost and would therefore launch the product without regard to the rebate levels offered by other suppliers. It knew of no example of competitors’ rebates deterring a manufacturer from launching a product, and did not believe there was any evidence for such a proposition.

10.184. Fort Dodge drew attention to recent entry into the UK market by manufacturers with single products or a small range. These included Abbott Animal Health, Alstoe, Lohman Animal Health and Alpharma. It suggested that these examples argued against any proposition that it was difficult to enter the market without a large range of products.

**Whether veterinary manufacturers design their rebate schemes in such a way as to reduce price transparency (Issue II(ii)a)**

10.185. Fort Dodge did not believe that rebate schemes resulted in reduced price transparency. It said that veterinary practices were not short of information about the products and terms (including rebates) available from different manufacturers. Individual negotiations gave veterinary surgeons a strong incentive to shop around and compare prices. Fort Dodge told us that each veterinary practice in the UK was visited regularly by all suppliers. Its own representatives, for instance, visited all veterinary practices at least once a year and, in most cases, usually every three months. All veterinary surgeons were thus aware of the discount levels offered by all suppliers.

**Whether veterinary manufacturers’ rebate schemes are structured in such a way as to cause veterinary surgeons to charge higher prices than they would otherwise do (Issue II(ii)b)**

10.186. In Fort Dodge’s view, there was no reason to believe that if manufacturers quoted lower list prices (instead of offering rebates off a higher original list price), then the prices charged by veterinary surgeons would fall. It was far more realistic to suppose that, if manufacturers quoted lower list prices, veterinary surgeons would simply apply a higher mark-up to this lower base. Fort Dodge believed that the current pricing practice of veterinary surgeons contradicted the proposition that the manufacturer’s list price influenced the veterinary surgeon’s retail price. Some suppliers had lower list prices than others yet, in Fort Dodge’s experience, such lower prices did not have any downward influence on the retail price. Furthermore, veterinary practices would be likely to differ from each other not only in their overall price for any treatment but also in the allocation between service fee and medicine charge.

**Whether veterinary manufacturers who operate rebate schemes gain an informational advantage over those who do not, and whether this enables them to strengthen their position in the market in an anti-competitive way (Issue II(ii)c)**

10.187. Fort Dodge said that the only purpose of its purchase of data from wholesalers was to allow it to track sales of its products to veterinary practices and monitor the performance of its sales force. It had no other way of doing this, since it sold almost no products direct to practices. If it did sell direct, it would have this information as a matter of course. It did not see how this monitoring could have any anti-competitive effect, since the information purchased related only to sales of the relevant supplier’s own products.

**Whether veterinary manufacturers with a large market share in particular veterinary medicine sub-markets carry out anti-competitive practices to maintain their position, and in particular: whether veterinary manufacturers engage in predatory pricing (Issue II(ii)d)**

10.188. Fort Dodge said that it had no evidence of manufacturers engaging in predatory pricing or other similar anti-competitive practices.
Whether veterinary manufacturers promote brand loyalty to such an extent as to limit price competition and restrict market entry (Issue II(ii)e)

10.189. Fort Dodge said that price and marketing were the main instruments used by manufacturers to compete with one another and maximize the value of their innovation in veterinary medicines. Both were important components of the competitive process in the industry. Fort Dodge observed that some degree of non-price competition was the norm in nearly all industries. It said that, furthermore, a significant reason for the promotion of its products was to inform veterinary surgeons. Fort Dodge believed there was no evidence for the proposition that non-price competition had an adverse effect on competition in this sector.

Whether veterinary manufacturers engage in anti-competitive market sharing, by jointly choosing not to launch or promote products that directly compete with those of other suppliers (Issue II(ii)f)

10.190. Fort Dodge said that it did not engage in anti-competitive market sharing and had no reason to believe that other manufacturers did so. It commented that it was natural, in an industry where first-mover advantage was important, that different manufacturers should have high shares of the supply of products in defined market segments. There was vigorous competition for the rewards of the innovation race, but once a product had been successfully launched it tended to remain the leader until the launch of a new product that constituted a major improvement.

Whether the manufacturers of veterinary medicines are protected by the provisions of the cascade from competition from substitutable human medicines, and whether they exploit this protection by charging higher prices than would otherwise be the case (Issue II(iii))

10.191. Fort Dodge was opposed to any suggestion that human medicines should be prescribed for animals. It thought that such a procedure would be informal and imprecise and would allow the administration to animals of products that had not undergone the costly and thorough procedures necessary to ensure their licensing for veterinary use. This could lead to the use of products which were not efficacious or were even detrimental to health. Fort Dodge believed it was artificial to suggest that the cascade protected manufacturers from competition where the competition in question would be with a less efficacious and potentially more dangerous category of product.

Whether veterinary manufacturers set the price or influence the retail mark-up on veterinary medicines, and in particular whether veterinary manufacturers, through published list prices, effectively set minimum resale prices (Issue II(iv))

Whether veterinary manufacturers otherwise set, or influence, the price at which their products are resold (Issue II(v))

10.192. Fort Dodge told us that it had no influence or control over any of the prices at which its products were sold by wholesalers or by veterinary practices.

Whether veterinary manufacturers request, or fail to initiate review of, classification of a medicine as prescription-only in cases where this is not necessary on grounds of safety (Issue II(vi))

10.193. Fort Dodge said it believed that its products were correctly classified and that the classification of its POM products was necessary on grounds of safety in all cases. Fort Dodge also believed that the vast majority of its competitors’ products were correctly classified.

Whether veterinary manufacturers encourage veterinary surgeons to buy certain prescription-only medicines by asserting that they will not be subject to reclassification (Issue II(vii))

10.194. Fort Dodge said that it did not tell veterinary surgeons that its products would not be subject to reclassification. It pointed out that its non-vaccine products Cydectin cattle injection and Cydectin sheep injection had been reclassified as PML in 1999. Prior to that date they were POM products whereas all competitor products were PMLs. As the veterinary channel accounted for only 20 per cent of cattle and sheep wormers, the POM licence had put Fort Dodge at a considerable disadvantage, since it was unable to access the other 80 per cent of the market.
Whether veterinary manufacturers charge differential prices to veterinary surgeons in such a way as to restrict competition (Issue II(viii))

10.195. Fort Dodge said that its rebates to veterinary practices varied from practice to practice because they were individually negotiated. It submitted that Office of Fair Trading (OFT) guidelines on individual agreements and conduct recognized that differential pricing of this type (price discrimination) was a normal feature of industries such as veterinary medicines with very high fixed costs (principally R&D) and low marginal costs. Fort Dodge said that it was aware of no evidence that manufacturers’ pricing practices had restricted competition in the UK veterinary medicines industry.

Whether veterinary manufacturers refuse to supply to certain intermediaries (wholesalers or retailers) or certain classes of intermediaries; supply certain intermediaries on less favourable terms than others; or fail to respond to requests for supply by certain intermediaries (Issue II(ix))

10.196. Fort Dodge stated that it had not declined a request for supply, supplied to any of its customers on less favourable terms than others or failed to respond to requests for supply. It told us that it had recently received a handful of requests for its price list. In each case, it had responded by sending the price list and explaining that its products were available through veterinary wholesalers.

Whether veterinary wholesalers refuse to supply certain customers other than veterinary practices, universities and research establishments, and in particular refuse to supply pharmacies (Issue III(i))

10.197. Fort Dodge said that it had no involvement in or knowledge of veterinary wholesalers’ decisions about which customers they would supply or on what terms. It believed that there was not currently a great demand from pharmacies but that if demand grew the products would become available to them. It thought that veterinary wholesalers in general did not have any rigid policy concerning the identity of their customers.

Whether discounts granted by veterinary wholesalers are cost-related (Issue III(ii))

10.198. Fort Dodge said that it had no evidence on this but believed that veterinary wholesalers operated efficient businesses on low margins. Discounts to veterinary practices could be expected to operate within a tight range across all veterinary wholesalers, since that was how they competed.

Whether the provision of detailed sales information by veterinary wholesalers to veterinary manufacturers is detrimental to veterinary surgeries or consumers (Issue III(iii))

10.199. Fort Dodge did not understand how the provision of this information could be detrimental, for the reasons set out in paragraph 10.187.

Whether veterinary surgeons fail to inform animal owners of the option to have written prescriptions for veterinary medicines dispensed by a pharmacist (Issue IV(i))

Whether veterinary surgeons refuse to write prescriptions, or by some action or omission, discourage requests from animal owners for prescriptions (Issue IV(iv))

10.200. In Fort Dodge’s opinion, the obligations imposed by the RCVS on veterinary surgeons in the Guide to Professional Conduct had lessened the concern about these issues. Fort Dodge believed that veterinary surgeons were increasingly aware of their obligations, as were their large customers in the farming industry. It told us that it had no knowledge of how many veterinary surgeons in the UK might be failing to inform animal owners of the option to have written prescriptions.

Whether veterinary surgeons set their charges for dispensing medicines in such a way that they subsidise their consultation fees (Issue IV(v))

10.201. Fort Dodge said that veterinary surgeons were free to set their levels of charges as they liked and it did not see why they should be forced to set higher charges for their services. It believed that, for animal welfare reasons, it was preferable for veterinary surgeons to have the option of charging low call-out rates in the current climate of decline in the farming industry. Farmers would be deterred from paying higher call-out rates and the health of animals would consequently suffer.
10.202. In Fort Dodge’s opinion, veterinary surgeons chose to make a certain profit on drugs as part of an overall treatment package. It did not see how this was different from any other business operating to make a profit, nor was it aware of any evidence of anti-competitive excessive pricing.

Possible remedies

10.203. Fort Dodge’s views on certain of the possible remedies listed in the statement of 17 September are recorded below.

Possible remedies to reduce barriers to obtaining prescriptions (paragraph 24(a) of the statement)

10.204. Fort Dodge said that it considered the general proposition that veterinary surgeons should make prescriptions available to customers to be reasonable. It did not wish to comment on each of the possible means to achieving this end but believed that a remedy under which veterinary surgeries would be required to display signs advising clients of the availability of prescriptions might be the most practical approach. It commented that any remedy must be considered carefully for its effects on animal welfare. As noted in paragraph 10.178, it considered that there would be potentially a serious threat to animal welfare if vaccines were administered to small animals by persons unskilled in their administration or in unsuitable locations. Fort Dodge suggested that we bear in mind the later possible recommendation that a veterinary surgeon should be allowed to supply items in accordance with a veterinary prescription, whether or not the animal concerned was under his or her care.

A requirement for veterinary surgeons when quoting the price at which they will dispense any POM also to state the cost of that POM to themselves (paragraph 24(b)(iv) of the statement)

10.205. Fort Dodge did not think it would be reasonable to require veterinary surgeons to inform customers of their cost price. So far as it was aware, this remedy would put veterinary surgeons in a uniquely unfavourable commercial position. It was their selling prices rather than their buying prices that were relevant to their customers.

A requirement for manufacturers of POMs giving rebates to veterinary surgeons to provide sufficient information, either directly or through wholesalers, so as to enable the veterinary surgeon to ascertain with certainty the cost net of rebates of POMs supplied to them (paragraph 24(b)(v) of the statement)

10.206. Fort Dodge insisted that its rebate scheme was such that veterinary surgeons could ascertain with certainty the net costs to them of its products.

A requirement for veterinary surgeons when they write prescriptions for POMs to do so on an ‘or equivalent’ basis to enable those dispensing such prescriptions to supply alternative authorised veterinary medicines to the brand specified (paragraph 24(c)(iv) of the statement)

10.207. In Fort Dodge’s opinion, this proposal was both impracticable and likely to have adverse effects on animal health and welfare. It said that the key function of the veterinary surgeon was to determine the appropriate treatment for the animal under his or her care. In many cases the treatment would comprise or include the administration of a medicine. The choice of the right medicine was a critical professional judgement and it would be wholly wrong to allow the dispenser of the medicine (if a person other than the veterinary surgeon) to make a judgement as to what might be an equivalent product. Indeed, in some cases it might be perfectly clear that there was no equivalent to the product prescribed by the veterinary surgeon, while in others there might be room for argument. Fort Dodge said that in the human medicines field only doctors were allowed to prescribe by generic, ie non-proprietary, name. The pharmacist was required to dispense the product stipulated by the prescription and could not substitute a generic product for a proprietary product. Fort Dodge also said that under both the human and veterinary medicines regulations, generic medicines were only given an MA where they were ‘essentially similar’ to the original product. The criteria to satisfy this requirement were extremely exacting and in effect meant that the generic drug would have to comprise the same chemical entity as the original drug. The ‘essentially similar’ requirement was clearly much more specific than our suggested ‘equivalent product’ wording. In Fort Dodge’s view, it would be quite wrong (and contrary to the
objectives of the regulatory regime) to replace the veterinary surgeon’s professional judgement as expressed in the prescription with the dispenser’s opinion as to what might or might not be an ‘equivalent’ product.

**Regulatory issues**

10.208. We asked Fort Dodge to outline the differences between the regulatory systems of the USA and the UK. In response, it said that the efficacy requirements for vaccine and pesticide products in the USA were far less onerous than they are in the UK/EC, but the differences for pharmaceuticals were less significant.

10.209. For veterinary pharmaceuticals many of the efficacy and safety requirements were broadly similar in both countries, but there were some differences: for example, pre-clinical data requirements were less onerous in the USA; there were no specific injection site residue guidelines that must be complied with in the USA whereas this was a major issue in Europe; in the USA safety and efficacy data generated in a major species could be extrapolated to minor species without new studies, which was not currently the case in Europe; and there was a more interactive dialogue between the company and the FDA in the USA than was possible between the company and the VMD in the UK. The US process was more efficient because the company could agree in advance a programme of work with the FDA and the FDA readily reviewed and approved protocols. The VMD was not permitted to do this and a company had to operate to fixed guidelines which could not be discussed in advance and which allowed no flexibility in interpretation. The lack of dialogue and flexibility was a major disadvantage in Europe.

10.210. With regard to biological products (vaccines), Fort Dodge told us that there were a number of differences between the USA and the UK in the study and testing requirements. In the UK (and EC) efficacy had to be tested for each antigen in a vaccine to show the onset and duration of immunity. These time-consuming and expensive studies lasted for at least a year and might be longer. In the USA there was a general understanding that the duration of immunity would be one year, but no data was required for most vaccines. Another difference related to testing in animals with maternally derived antibodies: these tests were not required in the USA but had to be carried out in the UK if there was any possibility that animals would still have such antibodies. Fort Dodge said that most efficacy studies were carried out in the field in the USA whereas both laboratory studies and field studies were required in the UK (and EC), to more onerous standards than applied in the USA. The requirement to validate the potency test was also more stringent in the EC than the USA, and the test had to be linked directly with efficacy. Finally, the EC requirement that all vaccines had to be produced in good manufacturing practice (GMP) facilities did not exist in the USA. Fort Dodge said that GMP facilities were very expensive and were inspected frequently to ensure compliance.

10.211. In summary, Fort Dodge said that the difference between the US and UK licensing regimes added considerably to the cost of developing veterinary medicines in the UK. The additional cost had to be borne by the consumer. We invited Fort Dodge to estimate the extra cost of regulation by considering the effects of three different hypotheses: no external regulation of veterinary medicines anywhere in the world; mutual recognition by the EC of US FDA authorization; UK acceptance of EC central or national authorization without further regulatory requirements.

10.212. Fort Dodge said that the first hypothesis ran counter to the environment in which the industry operated. On balance, it believed that a complete absence of regulation would be undesirable. Certain costs of regulatory compliance would be avoided and certain medicines might come to the market sooner if there were no regulation, but these benefits were likely to be outweighed by the costs of an increase in low-quality, ineffective and/or unsafe products on the market.

10.213. Under the second hypothesis, Fort Dodge estimated that in relation to its products across the EC some five years would be saved in the registration process. For each vaccine product, this would amount to an R&D saving of between $0.5 million and $1 million. The saving for pharmaceutical products used on food animals would be between $3 million and $3.5 million. For the centralized and mutual recognition procedures in the EC, the five-year renewal and annual licence maintenance fee was currently an estimated £0.25 million across its product portfolio. There could be further savings if manufacturers were able to supply customers in the UK from the factories that supply the USA, thus avoiding the need to meet GMP guidelines. Manufacturers would also benefit from generating revenue
streams significantly earlier than at present. In Fort Dodge’s case the value of this could be as much as $8 million, which equated to 20 per cent of current turnover.

10.214. Fort Dodge said that it was difficult to assess the impact on cost of the removal of additional regulatory requirements in the UK (the third hypothesis). It estimated the typical fee for one application to the VMD for registration of one product as £12,000 to £20,000. This was the only out-of-pocket expense that would be avoided. However, the indirect benefits in terms of extra revenue created by earlier marketing would be considerably higher. Fort Dodge estimated that applications to the VMD under the mutual recognition procedure involved a delay, on average, of approximately one year and that avoiding this would lead to about £600,000 of increased revenue for each new product. Under the current regime, applications for mutual recognition were not always successful, so automatic recognition would result in the creation of new revenue streams in the UK and a greater variety of products on the market.

10.215. Fort Dodge commented as follows on regulatory questions contained in our statement of issues.

Whether the current MRL requirements restrict competition in, and availability of, veterinary medicines, particularly for minor species (Issue(I)(i))

10.216. Fort Dodge said that the cost of providing supporting data to develop an MRL had deterred manufacturers from developing medicines for minor food species, since the expected market return did not justify the cost of the data. Extrapolation of MRLs for minor species (as recommended in the Marsh report) would be a major step forward and reduce the need for additional studies and costs. It could also be argued that the cost of MRL data was too high for a major species, namely the horse, in countries where it was not used as food. Horse owners and veterinary surgeons in the UK were disadvantaged because full MRLs need to be completed on equine medicines, resulting in extra expense and delay, even though the animals that would be treated with them would not enter the food chain. For these reasons, Fort Dodge agreed that the current MRL requirements limited the availability of medicines for minor species and for certain major species.

Whether the inclusion of an efficacy test in the marketing authorisation procedure unnecessarily increases the barriers to introducing a veterinary medicine to the market (Issue II(ii))

10.217. Fort Dodge agreed that full efficacy testing was an unnecessary barrier to the introduction of a veterinary medicine to the market. Tests had to be carried out on a large number of animals, which was inevitably time-consuming, but whatever the number used, it could often be difficult to demonstrate full efficacy in any laboratory or field trial. In Fort Dodge’s view, where a product had been tested satisfactorily for safety, its use in the market was normally the best indication of efficacy. Fort Dodge believed that it was especially difficult to justify the expense of full efficacy trials for products for minor species. It pointed out that the absence of a requirement for full efficacy testing in the USA made it easier to bring a product to market once its safety had been demonstrated. In its view, this was one of the reasons for the greater variety of more advanced veterinary medicine products available in the USA than in the UK.

Whether the absence of provision for a third party to request reclassification of a veterinary medicine, or for regular review of classification, leads to an over-classification of veterinary medicines (Issue I(iii))

10.218. In Fort Dodge’s opinion, there was no general problem of over-classification of veterinary medicines in the UK. It considered that its own products were correctly classified. It did not therefore believe that the absence of a provision for third parties to request reclassification or review of classification had had any effect on the classification of veterinary medicines.

10.219. Fort Dodge said that it had no objection in principle to regular reviews of classification, but it believed that giving third parties an automatic right to instigate review could make efficient marketing of veterinary medicines more difficult. It suggested that a fair review process could be achieved through interested parties making representations to the VMD which, if it saw fit, should then review the classification with the manufacturer. Fort Dodge commented that while in some circumstances a third party might have a genuine reason for requesting a review, there might equally be occasions where a review was initiated by a competitor merely as a commercial tactic.
Whether the lack of a prescription-only sub-classification for medicines that could be prescribed by a veterinary surgeon (for animals under his/her care) without prior clinical examination restricts competition (Issue I(iv))

10.220. In Fort Dodge’s view, its own products and almost all its competitors’ products were correctly classified in the UK. In general it believed that POM classification ensured that a wide range of specialized products was properly used. It said that for the vast majority of POMs, the requirement for prior clinical examination was an integral part of ensuring proper use. It thought that the potential danger to health of removing this requirement would be likely to exceed any benefits. It had seen no evidence that the absence of the proposed sub-classification operated as a restriction on competition.

Whether the length of time allowed to regulators to reach a decision on marketing authorisations is a barrier to introducing a new medicine (Issue I(v))

10.221. Fort Dodge said that under EC regulation decisions on MAs were excessively delayed. These delays were a barrier to the introduction of new medicines.

Whether the requirement that PMLs may only be dispensed by veterinary surgeons, pharmacists, and suitably qualified persons (SQPs) employed by agricultural merchants or saddlers restricts competition in the supply of PMLs (and hence of any POMs which may be reclassified as PMLs) (Issue I(vi))

10.222. In Fort Dodge’s opinion, its own products and (in almost all cases) the products of other suppliers were correctly classified in the UK. It said that, in any event, none of its PML products was suitable for sale in pet shops, supermarkets or other retail outlets, because they all required some degree of qualified advice. Even if there were veterinary medicines on the market that could be sold in general retail outlets, this would have no relevance to the sale of POMs in the UK. Fort Dodge said that it would only be in exceptional cases, if at all, that there could be a good argument for reclassification of a POM.

Whether the current arrangements which preclude SQPs from breaking bulk in supplying veterinary medicines places them at a competitive disadvantage to veterinary surgeons (Issue I(vii))

10.223. Fort Dodge said that arbitrary requirements on suppliers to provide veterinary medicines in certain pack sizes could be a disincentive to the supply of certain products. In its view pack size should remain at the manufacturer’s sole discretion. If there was demand for a particular pack size, market forces should ensure that manufacturers met the demand.

Whether the conditions under which the European centralised procedure is available could restrict competition, either: by being too narrow, and therefore compelling companies to use the decentralised procedure even if this is a greater barrier to introducing the product to market, or by being too narrow, and so allowing companies to gain a POM classification for their products which cannot subsequently be revised to PML (Issue I(viii))

10.224. Fort Dodge said that the centralized procedure was available for too narrow a range of products and that in consequence an already lengthy procedure was further delayed. At present, the centralized procedure was the best system for EC-wide registration of a new product, because of the strict timetable applied and collective decision-making process. The procedure avoided the possibility of one or more member states refusing to grant an authorization because of some strongly-held view on an insignificant point, as had been known to happen during the mutual recognition procedure, when a concerned member state could raise trivial queries which nevertheless had to be addressed in full. Fort Dodge believed that the centralized procedure, currently limited to novel active ingredients and high-technology products, should be expanded to cover a broader range of products. It supported the recommendation in the Marsh report for increased flexibility at the initial authorization stage.

10.225. As the centralized procedure was at present limited to high-technology products, Fort Dodge believed it was irrelevant to discuss the question of reclassification to PML status. If the centralized procedure were extended to cover other products, Fort Dodge saw no reason why classification through that procedure would involve the classification as POMs of products that should arguably be PMLs.
Whether the potential for competition from extra-EU markets is prevented by the lack of mutual arrangements between the EU and other regulatory regimes (Issue I(ix))

10.226. Fort Dodge agreed that a thorough licensing procedure was needed to ensure the marketing of safe veterinary products. It believed, however, that certain aspects of the licensing regime in the EC [Details omitted. See note on page iv.] were unnecessarily onerous. In its opinion, a far greater choice of veterinary medicines would be achieved by a mutual authorization arrangement between EC and non-EC regimes, and in particular with the USA, where a large number of veterinary medicines were marketed without the delays typical in the EC.

Possible recommendations for regulatory change

10.227. Fort Dodge said that it supported, or had no objections to, Recommendations 1, 7 and 20 in our statement of provisional conclusions and hypothetical remedies. Its comments on others of the possible recommendations are recorded below.

The Secretary of State to consider negotiating changes to the draft Directive (also proposed in COM (2001) 404 final) so as to legitimise cross-border trading, without the need for a further marketing authorisation, of any veterinary medicine authorised through the decentralised procedure, between member states in which it is authorised and to remove barriers to labelling in the appropriate language (Recommendation (2))

10.228. Fort Dodge commented that this recommendation was very similar to the recommendation in the Marsh report, that the VMD should permit the import of medicines authorized in other member states provided that they were properly labelled in English and sold via the approved distribution system in the UK. Fort Dodge said that it had considerable sympathy with the proposition that a product authorized in one EC member state should be allowed free circulation provided that the health, safety or wellbeing of animals and humans would not be prejudiced thereby. It believed that any regulatory changes must avoid any risk to health and take into account the pharmacovigilance and other obligations placed on manufacturers. It therefore considered that the optimum solution would ensure that the appropriate national authority was notified in advance of any importation of a medicine from another EC country so that it could verify that there would be no risk of importation of counterfeit products or products incorrectly labelled (or labelled in the wrong language). Fort Dodge believed that the current regulations covering this whole area were very simple and ensured that basic requirements were met.

The Secretary of State to consider amending the remits of the Veterinary Products Committee and the Veterinary Medicines Directorate to preclude them from taking into consideration manufacturers’ views on the classifications of a product for which they are seeking marketing authorisation (Recommendation (3))

10.229. Fort Dodge disagreed with this recommendation. It said that the VPC and VMD needed to take the manufacturer’s view into consideration with respect to classification, as it would be the most informed view that it was possible to have on a product. The views of other interested parties would, however, no doubt also be sought so that any commercial bias in the manufacturer’s stated views could be appropriately discounted. Fort Dodge added that in the field of human medicines it was normal procedure to take the manufacturer’s views into account, and it was difficult to see why the right of a party affected by a decision to state its case should not apply in the case of veterinary medicines. Fort Dodge was not aware of any case where a classification had been unduly influenced by a manufacturer’s preference.

The Secretary of State to consider widening the remits of the Veterinary Products Committee and Veterinary Medicines Directorate to take into account the welfare of animals overall (Recommendation (5))

10.230. Fort Dodge said that it was unclear about the intended effects of this recommendation. It was concerned at the apparent suggestion that there could be a trade-off between cost on the one hand and safety and efficacy on the other. It said that so far as the regulation of medicinal products was concerned, the meaning of efficacy was well established and did not include commercial and economic factors. It did not believe, therefore, that considerations of price or availability should determine the classification of a veterinary medicine as this would inevitably entail the risk that a different classification might be adopted than if the decision were made solely on safety and efficacy grounds.
The Secretary of State to oppose the European Commission’s proposal that all veterinary medicines for food animal species must be classified POM (Recommendation (6))

10.231. In Fort Dodge’s view, this recommendation was reasonable. It believed that the European Commission’s proposal was too inflexible.

The Secretary of State to consider negotiating changes to the proposed Directive to remove the ranking of cascade options in respect of non food-producing animals so that, where circumstances allow recourse to cascade, a veterinary surgeon may use whatever option he considers best (Recommendation (18))

The Secretary of State to consider negotiating changes to the proposed Directive to allow recourse to the cascade in the case of non food-producing animals where notwithstanding the existence of an authorised medicine for the species and condition in question, the veterinary surgeon having the animal under his care considered as justified on grounds of animal welfare including cases where the cost of treatment or otherwise allow the animal to go untreated (Recommendation (19))

10.232. Fort Dodge said that it did not support any changes to the cascade provisions that went beyond those referred to in recital 14 of the proposed Directive. The purpose of the cascade was to avoid risks to health. In particular, Fort Dodge believed that Recommendation 19 was misconceived. It would allow recourse to an unauthorized medicine even where a medicine existed that was authorized for the species and condition in question. This inevitably involved a risk to animal health and welfare, as seemed clear from the limitation of the proposed change to medicines for non-food animals, ie we did not recommend any change where there might be a risk to human health. Fort Dodge was also concerned that a relaxation of the cascade would detract from the use of appropriately licensed products and so would reduce the incentive for manufacturers to undertake R&D, with adverse effects on the introduction of new products to the market.

Intervet UK Ltd

Provisional complex monopoly situation—supply of POMs to animal owners

10.233. Intervet believed that it would be wrong in law to conclude that veterinary surgeons, manufacturers and wholesalers were engaged in a single complex monopoly situation. It submitted that the conducts we had identified in the statement of 17 September fell properly to be treated as three discrete complex monopoly situations. Consequently, a remedy directed at manufacturers with the aim of addressing perceived problems at the retail level would, in Intervet’s view, be ultra vires the CC under sections 49 and 54 of the FTA.

10.234. Furthermore, Intervet believed that, on the facts of the case under investigation, any remedy aimed at constraining the commercial conduct of undertakings operating at the competitive manufacturing level of the market would be a disproportionate and unjustifiable measure, regardless of whether separate complex monopoly situations were identified at the manufacturer and retail levels. Intervet also commented that such a remedy was unlikely to lead to lower retail prices to end-consumers and might even make matters worse by reducing competition elsewhere in the supply chain.

10.235. Intervet submitted that we were able to consider recommending remedies only after we had completed in turn each of the steps set out at (a) to (e) in our terms of reference (see Appendix 1.1). Consequently there was a direct link between the finding that a complex monopoly situation existed and the legal ability to direct remedies at the complex monopoly group. A remedy could therefore be aptly applied to manufacturers only when all of the tests (a) to (e) had been met.

10.236. Intervet was aware of no evidence to suggest that any complex monopoly situation was acting in favour of manufacturers. It noted that we had accepted, in the statement of 17 September, that the market was competitive at the manufacturing level. Intervet had itself provided ample evidence of vigorous competition between manufacturers, and it had seen no evidence of excessive ex-manufacturer pricing or manufacturer profitability, or other conduct that could support a finding of lack of competition at manufacturer level. Intervet believed that in these conditions it would be unreasonable to conclude anything other than that the discount schemes operated by manufacturers were a manifestation of competition.
10.237. Intervet noted that the statement cited two precedents (*Films* and *Domestic Electrical Goods I*) in support of a conclusion that conducts at different levels of the supply chain could nevertheless be viewed as a single complex monopoly situation. It did not agree, however, that competition in the veterinary medicines market was comparable with the situations that existed in those other markets. In the *Films* inquiry most of the major players in the market were vertically integrated and the market structure was conducive to practices whereby distributors would supply films to their aligned circuits but not to others. Intervet maintained that there was no vertical integration of undertakings active at the various levels of the veterinary medicines supply chain: manufacturers, wholesalers and veterinary surgeons were independent of each other. It said that all manufacturers supplied their full product range to each and every veterinary wholesaler and the national veterinary wholesalers were able to supply any veterinary surgeon anywhere in Great Britain. In the *Domestic Electrical Goods I* case, although there were no structural links between suppliers and retailers, the market was characterized by a recommended retail price (RRP) system in which there was a direct behavioural link between the two groups in which both parties gained from observance of the RRP. Intervet maintained that it was difficult to see any similarities with the veterinary medicines market, where manufacturers had no influence over retail prices. It commented that while the upstream electrical goods manufacturers were imposing the RRP on the downstream market and therefore remedies focused on RRP were an attempt to address the upstream problem, the same situation did not arise in the veterinary medicines market.

10.238. Intervet noted our provisional conclusion that the pricing of POMs by veterinary surgeons failed to reflect the cost of supply to them, in so far as a mark-up on the manufacturer’s list price did not take account of any discounts and rebates received from manufacturers and wholesalers. Intervet submitted that this method of setting retail prices was not evidence of any behavioural link between the different levels of the supply chain. Intervet believed that veterinary surgeons were certainly aware of their net buying prices for POMs and used this information in their negotiations with manufacturers.

10.239. In Intervet’s opinion, there was no evidence that higher retail prices were of any benefit to manufacturers. It told us that on a few occasions it had tried to keep retail prices to a minimum so as to increase uptake of particular products. It said that any evidence of perceived problems with the level of retail prices clearly remained at the retail level.

10.240. With regard to the conducts identified in paragraph 9 of the statement, Intervet told us that it did not refuse or fail to negotiate discounts and rebates with buying groups formed by, or acting on behalf of, veterinary surgeons (see paragraph 9(d)). A significant proportion of its business was with buying groups. It did not discriminate against such groups: they were eligible for the same levels of rebate as veterinary practices and in some cases achieved higher levels than single veterinary practices because of the scale of their purchases. Intervet said that there was no particular reason to think that the lower prices at which veterinary practices were able to obtain POMs through buying groups would automatically translate to lower prices at the retail level.

10.241. In Intervet’s view, its arrangements with the four buying groups had led to higher volumes of sales of its product than would otherwise have been the case. It provided sales data for the year to 30 September 2002 compared with the year to 30 September 2001 that revealed that [Details omitted. See note on page iv.]. Intervet believed that buying group members’ access to increased levels of discount was beneficial to all parties concerned, offering lower prices to veterinary practices and bringing about increased purchases of its products.

10.242. We asked Intervet whether the buying groups with which it dealt had generally achieved the volumes on which the deals were based. Intervet said that its discount arrangements with the groups were not based on the achievement of specific sales targets. It was true that the groups with the highest sales attracted more generous discount terms, and these were reviewed annually, but they were not subject to a minimum level of purchases in any period. This was in line with Intervet’s arrangements for all its veterinary customers.

10.243. Intervet said it believed that it was not a party to the conduct described in paragraph 9(e) of the statement (operation by manufacturers of rebate schemes that make it difficult for veterinary

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surgeons to ascertain with certainty at the time of purchase the cost to themselves of POMs). It was confident that any veterinary surgeon could say what he or she paid for Intervet products in the UK.

Details omitted. See note on page iv.

Intervet said that its scheme was comparatively simple and transparent and that it would provide its veterinary customers, on request, with all the information they needed on a monthly basis to calculate their net purchasing costs.

10.244. In Intervet’s view, the majority of its veterinary surgeon customers were aware of their net buying costs for its products. Although Intervet did not know the details of its competitors’ rebate schemes, it seemed clear from negotiations with customers that they were able to calculate the net prices of competing products. Intervet’s scheme did not tie customers in for any period of time. They were free to switch or negotiate better terms if other manufacturers offered keener prices. Intervet provided evidence of switching between manufacturers, which it said would not be possible if veterinary surgeons were ignorant about purchasing costs.

10.245. With regard to the conduct identified in paragraph 9(f) of the statement (failure to supply pharmacies with POMs and/or enable pharmacies to obtain supplies of POMs on terms that enable them to compete with veterinary surgeons), Intervet said that, with the exception of some direct supply to specialist poultry practices, veterinary practices and pharmacies would be supplied with POMs through four veterinary wholesalers and with PML products through three trade wholesalers. One of the trade wholesalers had recently obtained a full wholesaler’s licence so it could, if it wished, distribute POMs and, if approached, Intervet would supply it on the same terms as it supplied POMs to the veterinary wholesalers. Intervet said that it had not been approached by any pharmacy group wanting to act as a wholesaler for its products. It did not, however, automatically supply to anyone who held the appropriate licence: it selected its wholesalers against certain criteria and the appointment of additional wholesalers, whether pharmacies or otherwise, would be subject to those criteria.

10.246. Intervet said that any pharmacy that obtained POMs through a wholesaler would not be eligible for its rebate scheme, because pharmacies did not have any decision-making power about which POM to dispense. If pharmacies dispensed veterinary POMs, they would be doing so only as part of the logistics of delivering the product to the customer and Intervet would have no need to enter into the same kind of relationship with them as it had with the veterinary surgeons who were making purchasing decisions. Intervet said that its rebate scheme existed to help it sell its products in a competitive market. Such schemes were a standard form of pricing competition. Veterinary surgeons, who occupied the gatekeeper role, were critical to sales of POMs and that is why the rebate schemes were targeted at them. Extending the schemes to pharmacies would not enhance sales of POMs because pharmacies did not perform the same role as veterinary surgeons.

10.247. Commenting on specific complaints from pharmacies (see paragraphs 12.108 and 12.117), Intervet said that they seemed to be based on the misconception that it supplied veterinary practices directly with POMs, whereas in fact its sales were through veterinary wholesalers. It believed that its reply to R M Jones had clearly stated its position, that there was no problem with pharmacies being supplied with POMs through the wholesalers. It had even offered direct supply for an interim period should R M Jones have any difficulty in obtaining POMs.

Provisional complex monopoly situation—supply of cat and dog vaccines to veterinary surgeries

10.248. Intervet said that it did not accept our conclusion that cat vaccines or dog vaccines could correctly be categorized as a market. The grouping of cat vaccines or dog vaccines covered a range of product classes, each of which had entirely separate therapeutic indications. This meant that the purchase of products from one class did not influence whether products from a different class were required. For example: rabies vaccines were supplied by Intervet, Merial and Schering-Plough (Pfizer, Fort Dodge and Virbac did not have a product in this class); leptospirosis vaccines were available from all manufacturers; and bordetella vaccines were supplied only by Intervet and Schering-Plough. Only Intervet and Schering-
Plough were able to supply all three classes of product. Intervet said that veterinary practices buying its leptospirosis or bordetella vaccines could and did choose to purchase the other vaccine from Schering-Plough. Equally, veterinary practices buying a leptospirosis vaccine from Virbac, Merial or Fort Dodge would have to choose a different manufacturer for their rabies and bordetella vaccines. Intervet told us that these separate buying patterns were due to the different indications for the products. They demonstrated that cat vaccines and dog vaccines did not form separate, single markets.

10.249. Leaving aside the question of market definition, Intervet believed that the existence of six manufacturers within the SAVs market was indicative of the competitive nature of the industry at the manufacturing level. It said that it was difficult to think of an industry characterized by similarly high sunk costs and regulatory barriers to entry in which there were as many as six direct competitors.

10.250. Intervet also challenged our provisional conclusion that discounts substantially influenced by the combined value of purchases of SAVs constituted a barrier to entry or to expansion by smaller manufacturers. It said that, first, small manufacturers were not a feature of the biologicals industry, largely because of the large capital commitments required. In reality, discounts and rebates had no foreclosure effect. Second, the current system had not prevented manufacturers from expanding sales. Intervet told us that the SAVs market segment had experienced some substantial changes following one manufacturer’s recent difficulties with out-of-stock products. Whilst the other manufacturers had acquired some incremental business as a result of this situation, one had gained disproportionately even though it had had little or no SAVs business in the UK until very recently. Furthermore, a recent entrant to this market sector had been able rapidly to expand its SAV business after the launch of [Details omitted. See note on page iv.].

10.251. In addition, Intervet said that [Details omitted. See note on page iv.]. Whilst a practice purchasing all of its SAVs from Intervet would be in a position to negotiate a higher discount, it was not tied to Intervet in any way.

Other issues

10.252. In this section we record Intervet’s views on other matters raised in the statement 16 April 2002.

Whether veterinary manufacturers, via linked price promotions, use the existing market power of some products as a lever to gain share of other markets (Issue II(i)a)

10.253. Intervet told us that linked price promotions were not a significant feature of its marketing approach. [Details omitted. See note on page iv.]

] Intervet had offered linked discounts infrequently (usually in relation to seasonal products) and generally for a limited period. It had run only three such promotions in the previous three years. They had not been repeated, as they were deemed far too complex to administer in practice.

10.254. Intervet said that it would run a linked promotion only if there was a therapeutic relationship between the products concerned. Decisions were not based on the relative market power of different products. In its view it would in any event be a considerable leap to conclude from the mere fact of linked discounting of Products A and B in a case where Product A had market power that rivals making substitutes to Product B might not be able to compete. The producer of the substitute for Product B might not produce a substitute Product A but might produce other products which could be equally effectively link-discounted with the Product B substitute. Moreover, even if the rival producing the Product B substitute had no other products suitable for linked discounting, it did not follow that its production costs would preclude it from matching the net price for Product B achievable under the linked discount. Intervet said that linked discounting offered customers lower prices; before concluding that this was objectionable on the ground that it might preclude rivals from competing, we first needed to demonstrate that there was an expectation that it would operate against the public interest.
Whether veterinary manufacturers operate rebate schemes which are a barrier to successful market entry, in that they encourage veterinary surgeons to buy more from larger veterinary manufacturers (Issue II(i)b)

10.255. Intervet commented that in any market the supplier who offered what the customer judged to be the best deal would secure the trade and thereby preclude other suppliers from securing it: that was competition in operation, not a foreclosure of competition. When suppliers of veterinary medicines offered rebates to veterinary surgeons they were simply engaging in price competition. Naturally the rebate schemes were designed to encourage veterinary surgeons to buy more from the manufacturer offering the rebate. Intervet believed, however, that in so far as the rebates were calculated in respect of specific products or groups of products (for example, a named dog vaccine or all Intervet SAVs) a small manufacturer was as well able to offer such discounts as a larger manufacturer. Rebate schemes could only potentially act as barriers to entry to the extent that they had an across-the-board element. [Details omitted. See note on page iv.]

Other anti-competitive effects of rebate schemes

Whether veterinary manufacturers design their rebate schemes in such a way as to reduce price transparency (Issue II(ii)a)

Whether veterinary manufacturers’ rebate schemes are structured in such a way as to cause veterinary surgeons to charge higher prices than they would otherwise do (Issue II(ii)b)

10.257. Intervet said that its rebate scheme was one of the simplest and fairest in the industry. The majority of its basic rebates were paid out monthly to each veterinary practice, although individual practices could elect to receive their rebates at less frequent intervals. Upon request, Intervet would provide each veterinary practice with a breakdown of how the rebate was calculated, showing precisely how much discount was earned, down to the individual product level. Intervet did not consider that its current discount and rebate structure prevented veterinary practices from knowing their net buying prices. Furthermore, a significant proportion of its business was with veterinary buying groups, where practices had joined together to increase their buying power and gain the maximum discount available. Intervet’s rebate scheme therefore offered even smaller purchasers the opportunity to receive maximum discounts, thus contributing to lower net prices into veterinary practices.

Whether veterinary manufacturers who operate rebate schemes gain an informational advantage over those who do not, and whether this enables them to strengthen their position in the market in an anti-competitive way (Issue II(ii)c)

10.258. Intervet said that rebate schemes provided the manufacturers with a direct link to the veterinary surgeons which, given the wholesaler distribution system, would otherwise be lacking. In industries where wholesalers controlled the distribution of products it was not unusual for manufacturers to seek to market directly to the retailer, who interfaced with the end-user and in that sense enjoyed a gatekeeper role. This was particularly so in relation to POMs. Given that all manufacturers were free to offer a rebate scheme and that anyone could buy the GfK data, any informational advantage was not exclusive to certain manufacturers. Intervet said that, in addition to the GfK data, information down to individual practice level was purchased direct from the wholesalers by the manufacturers who operated rebate schemes. All manufacturers were free to negotiate the purchase of sales data from the wholesalers.
Whether veterinary manufacturers with a large market share in particular veterinary medicine sub-markets carry out anti-competitive practices to maintain their position, and in particular: whether veterinary manufacturers engage in predatory pricing (Issue II(ii)d)

10.259. Intervet did not believe that predatory pricing had occurred in the veterinary medicines market. It told us that it had never engaged in predatory pricing in an attempt to remove a competing product from the market and it was not aware of any attempts to do so by a competitor.

Whether veterinary manufacturers promote brand loyalty to such an extent as to limit price competition and restrict market entry (Issue II(ii)e)

10.260. Intervet said that non-price competition was not an inferior or undesirable form of competition. It was indeed beneficial when found in conjunction with strong price competition. Product promotion and other activity aimed at raising brand awareness was a form of non-price competition. Intervet told us that it attempted to stimulate growth in its markets by providing assistance to veterinary surgeons through such means as training programmes in practice management. If veterinary surgeons were able to grow their businesses, there would be an opportunity for Intervet to participate in this growth. Intervet said that this was normal and desirable commercial behaviour in a competitive market.

Whether veterinary manufacturers engage in anti-competitive market sharing, by jointly choosing not to launch or promote products that directly compete with those of other suppliers (Issue II(ii)f)

10.261. Intervet said that it did not engage in anti-competitive market sharing, nor was it aware of any attempts by its competitors to engage it in such activities.

Whether the manufacturers of veterinary medicines are protected by the provisions of the cascade from competition from substitutable human medicines, and whether they exploit this protection by charging higher prices than would otherwise be the case (Issue II(iii))

10.262. Intervet said that the prescribing cascade regulations existed for the protection of animal and human health. They were not designed to protect the manufacturers. The cascade recognized that animal medicine was a more complicated discipline than human medicine, with a greater number of variables. Medicines that were safe to use in one species were not necessarily safe for another and the cascade ensured that the first port of call was always a medicine that had been tested and authorized for the particular species of animal being treated.

Whether veterinary manufacturers set the price or influence the retail mark-up on veterinary medicines, and in particular whether veterinary manufacturers, through published list prices, effectively set minimum resale prices (Issue II(iv))

10.263. Intervet said that it did not attempt to influence, still less determine, the price at which its medicines would be resold. It said that veterinary surgeons’ selling prices would be set by reference to the conditions prevailing in the local market, ie the level of competition faced and the veterinary surgeon’s marginal cost of supply. Intervet told us of just three specific instances where it had sought directly to influence veterinary surgeons’ pricing. These all concerned medicines for food animals. Intervet had advertised the list prices of those products to ensure that the retail prices were kept to a reasonable level. Intervet commented that with food animals in particular, if veterinary prices were too high, animals would not be treated.

Whether veterinary manufacturers otherwise set, or influence, the price at which their products are resold (Issue II(v))

10.264. Intervet said that it would always seek to ensure a POM classification for products that it believed merited such a classification and would defend the POM classification of any of its medicines where it believed this was necessary on safety grounds. The nature of its business meant that the vast majority of its products would be POMs, but it had obtained recategorization as PML for one product and was applying for PML status for another. It would apply for recategorization of other products in due course if this were justified on technical and safety grounds.
Whether veterinary manufacturers encourage veterinary surgeons to buy certain prescription-only veterinary medicines by asserting that they will not be subject to reclassification (Issue II(vii))

10.265. Intervet said that it did not do this. Under the current regulatory regime, farmers were able to inject their herds with PML and certain POM products after a veterinary consultation. Intervet was opposed to the European Commission’s proposal that all medicines for food animals be classified as POM. Consequently, it was not its policy to seek to ensure that its products were classified only as POM: it wanted its products to be available through the appropriate channels according to the regulations in force. Veterinary surgeons’ preference for a certain classification was not a significant factor in Intervet’s assessment of the appropriate classification, but it would take into account, on a product by product basis, the potential benefits of the degree of veterinary involvement in product selection and use.

Whether veterinary manufacturers charge differential prices to veterinary surgeons in such a way as to restrict competition (Issue II(viii))

10.266. Intervet said that the supply of veterinary medicines was characterized by manufacturers engaging in differential pricing, which were a response to two key features of the market: the significant sunk R&D costs associated with bringing new products to market; and the gatekeeper role played by veterinary surgeons in determining the success of products. Intervet said that differential pricing in these circumstances was not discriminatory, predatory or otherwise objectionable.

10.267. Expanding on its comments, Intervet said that the commercialization of veterinary medicines involved significant investment in R&D. Its own expenditure on R&D amounted to [Details omitted. See note on page iv.]. In consequence, the unit cost of producing a veterinary medicine represented only a small proportion of the total costs incurred. Such cost characteristics implied that competitive prices must exceed short-run production costs in order to maintain incentives to invest in R&D.

10.268. Intervet said that experience of other industries with similar cost structures, for example the airline industry, illustrated that where there were significant sunk or fixed costs firms were unlikely to engage in uniform pricing. Since any incremental sale that yielded revenues in excess of the unit cost of production would contribute to the recovery of the fixed costs associated with the product, each firm had incentives to seek incremental sales. If, however, a general price reduction was necessary to secure the incremental sales then the result might be a fall in overall profitability. In contrast, if the incremental sale could be made without affecting the general price level, then total profitability would be increased. For this reason, different prices would be charged to different consumers.

10.269. Intervet commented that consumers as well as suppliers benefited from differential pricing since the level of output was higher where prices varied between customers than where a uniform price was charged. Such pricing behaviour could therefore be seen to be pro-competitive in the sense of expanding the total level of output.

10.270. Intervet maintained that differences in the level of discount given to veterinary surgeons were cost justified in the sense that they continued to be supplied at prices exceeding the marginal cost of production. Any sale in these circumstances would contribute to the recovery of the fixed costs. The key point was that, for firms with low marginal costs relative to fixed costs, even large discounts or rebates were warranted from the perspective of economic efficiency provided that marginal revenue exceeded marginal cost of supply. Intervet said that although differences in the level of discount or rebate were not related to cost savings (for example, where the costs of supply did not vary across customers), such sales were still beneficial to suppliers since they helped to secure a sale that would not otherwise have been made. Intervet concluded from this analysis that differential pricing could not be regarded as anti-competitive in itself.

10.271. Intervet further commented that in many industries, suppliers provided retailers with incentives to sell their products. In veterinary medicines, veterinary surgeons accounted for the large majority of sales and enjoyed a gatekeeper role as the prescribers of the medicines. In this market, the final consumer (the farmer or companion-animal owner) generally lacked all the necessary information on which medicines were appropriate to treat the animal’s ailment and/or the relative merits of competing suppliers’ products. The lack of information was particularly true of owners of companion animals, who (unlike farmers) were less likely to be repeat purchasers of the services of a veterinary surgeon. In such
situations, the scope for suppliers to stimulate demand for their products by appealing directly to the end-consumer was limited and the success of a veterinary medicine depended significantly on the efforts of veterinary surgeons. That was why suppliers offered incentives to veterinary surgeons to promote their products rather than a competitor’s. Intervet said that this was a standard form of competition.

Possible remedies

10.272. Intervet noted our provisional conclusion that the conducts we had identified in paragraph 9 of the statement had the effect of preventing, restricting or distorting competition in the supply of POMs at the retail level. It commented that any remedies we recommended should be aimed, therefore, at unlocking the benefits of competition for retail customers. They must address the public interest detriment identified and must also be practicable and proportionate. Intervet said that the duty of proportionality was particularly present where the public interest detriment was identified as arising at one particular level of the market (high retail prices) and measures being considered to address that issue potentially involved regulatory interference in the working of markets higher up the supply chain, in this case at the manufacturer and wholesaler levels.

10.273. In Intervet’s view, the appropriate regulatory approach would be first to assess whether the objective of increasing price competition at the retail level consistent with the need to safeguard animal welfare could be achieved by remedies directed specifically at the retail level. It suggested that the key lay in equipping retail customers and veterinary practices to exert pressure on those veterinary practices that were not at present subject to sufficient competitive pressure. Intervet said that this was most importantly a matter of increased transparency. [Details omitted. See note on page iv.] Intervet said that these remedies would encourage price competition at retail level and ultimately would be likely to result in lower prices. In this way, the remedies would work with market forces in a proportionate way.

10.274. It was Intervet’s opinion that there was unlikely to be significant entry by pharmacists into veterinary medicines dispensing, regardless of what was done to encourage it. Intervet considered, therefore, that it would be disproportionate to require manufacturers to supply pharmacies directly (bearing in mind that all other outlets were supplied via wholesalers) or to extend to pharmacies the same discount and rebate benefits as were available to veterinary practices, notwithstanding the crucial gatekeeper role of the veterinary surgeon, which had no parallel in the dispensing function. If there were not significant entry by pharmacies it might be said that no harm would be done since the impact on manufacturers would be similarly insignificant. In Intervet’s view, however, the remedy would have amounted to an ineffective regulatory intervention that had distorted the normal workings of a competitive market (ie the veterinary medicines manufacturing/supply market). If, contrary to Intervet’s expectations, pharmacies entered the market on a significant scale, then it believed that the market should be trusted to deal with that development, and a series of pricing responses by the manufacturers, recognizing the growing importance of pharmacies to the business, could be expected to emerge. Intervet thought that any prescription of how manufacturers must trade with pharmacies would be unjustified in the absence of evidence that the veterinary medicines market was not competitive at the manufacturing level.

10.275. Intervet’s views on the possible remedies set out in the statement of 17 September are recorded below.

A requirement for manufacturers of POMs giving rebates to veterinary surgeons to provide sufficient information, either directly or through wholesalers, so as to enable the veterinary surgeon to ascertain with certainty the cost net of rebates of POMs supplied to them (paragraph 24(b)(v) of the statement)

10.276. As reported in paragraph 10.243, Intervet maintained that it did not engage in the conduct identified in paragraph 9(e) of the statement. [Details omitted. See note on page iv.]
Intervet considered that the possible remedy we had suggested would not only be disproportionate to the perceived failure of competition but would also fail to achieve the goal of lowering retail prices.

A requirement for manufacturers and wholesalers that supply POMs in the UK to supply pharmacies (paragraph 24(c)(i))

10.277. Intervet did not accept that there could be any justification for requiring manufacturers to deal direct with pharmacies when veterinary and trade customers were supplied through wholesalers, particularly given the likely scale of any business with pharmacies. Any such requirement on Intervet would potentially introduce inefficiencies into the existing supply chain, which would ultimately result in higher prices to consumers. Intervet told us that it had already restructured its supply to trade customers resulting in a far more efficient system. Intervet confirmed that it would consider supplying any pharmacy that held a wholesaler licence, provided that it met the same criteria as the other wholesalers it supplied.

A requirement for manufacturers and wholesalers that supply POMs in the UK to supply pharmacies on terms that enable them to compete with veterinary surgeons (paragraph 24(c)(ii))

10.278. Intervet was opposed to this possible remedy. It said that pharmacies that were in the market or might choose to enter performed a very different role to that played by its veterinary customers, who were in a unique gatekeeper position. Manufacturers’ discounts and rebates were a legitimate attempt to incentivize veterinary surgeons to prescribe certain products in preference to others: they were in fact a manifestation of inter-manufacturer competition. A pharmacy, however, would merely supply the drug prescribed by a veterinary surgeon without influencing the product choice, so there was no incentive for manufacturers to offer pharmacies the same terms as they offered to veterinary surgeons. Intervet suggested that to do so would in fact discriminate against veterinary surgeons (ie by treating unlike trades in a like manner) and distort the trade patterns to be expected in a competitive market. Intervet commented that if pharmacies started to play a more important part in the supply and distribution of veterinary medicines, the market could be expected to adapt with a new strategy of incentives.

A requirement for veterinary surgeons when they write prescriptions for POMs to do so on an ‘or equivalent’ basis to enable those dispensing such prescriptions to supply alternative authorised veterinary medicines to the brand specified (paragraph 24(c)(iv))

10.279. Intervet said that there were very few veterinary generics on the market. A generic medicine could be granted a licence only after the branded product had been licensed in accordance with EC Directive 2001/82 for ten years. Veterinary medicine licences were reviewed in the late 1980s and early 1990s and consequently it was only recently that the first products became available for exploitation by generic manufacturers. Intervet added that the small scale of the veterinary medicines market would continue to be a constraining factor on the production of generic medicines.

10.280. In Intervet’s view, this possible remedy would be a potential threat to animal welfare. First, there were few true veterinary generics (as opposed to drugs which were merely similar). Second, there might be differences between apparently ‘equivalent’ drugs, such that broadening the ‘or equivalent’ definition from generic copies to products with identical active constituents would raise significant legal and animal welfare issues. Products that had identical active constituents might have very different licensed uses and even products with identical licensed uses might have significantly different physical characteristics, such as the incidence of pain or irritation on application. Intervet said that a dispensing pharmacist would not know why a veterinary surgeon had prescribed a specific product. Any substitution of another product was therefore likely to result in illegal or inappropriate use.

10.281. By way of example, Intervet said that its oxytetracycline injection product Engemycin 5% had a cattle and pig meat withholding period of 8 days, while Animalcare’s Oxyxare 5% had a cattle and pig meat withholding period of 15 days. If a prescription was written for Engemycin 5% but the pharmacist dispensed Oxyxare 5%, there was a possibility of residues violation and human safety risk. In addition, Oxyxare was indicated only for cattle, pigs and dogs, while Engemycin 5% was additionally indicated for horses, sheep and cats. Intervet said that Oxyxare had either not been tested for safety in these other species or might have been tested to find it unsuitable for use. Intervet thought that pharmacists would lack specialist knowledge of veterinary medicines and would continually need to refer back to the prescribing veterinary surgeon before dispensing a medicine.
10.282. Intervet said that the possible remedy would be feasible only if the same checks and balances were introduced for veterinary medicines as were in place for human medicines, i.e. a list, controlled centrally by the VMD, documenting which products were substitutable for which other products in all circumstances. Intervet suggested that the small scale of the animal medicines market in comparison with the human market made it unlikely that the remedy would ever have practical relevance.

Prohibition on manufacturers operating rebate schemes in which the level of rebates given on purchases of cat and dog vaccines is based on, or substantially influenced by, the combined value of purchases of those vaccines (paragraph 25)

10.283. Intervet did not believe that any remedy was necessary, for the reasons set out in paragraphs 10.248 to 10.251. It said that the presence of a significant number of vaccine suppliers was indicative of the competitive nature of the industry at the manufacturing level. It was highly implausible that the six manufacturers would engage in any form of tacit collusion, and hence veterinary surgeons were able to shop around for the best net price available irrespective of any linking of discounts between SAV purchases. In addition, any remedy focusing on this aspect but ignoring other linked discount schemes would have a disproportionate effect on certain manufacturers.

Regulatory issues

10.284. We asked Intervet about the costs of regulation and invited it to consider the effects on its development costs of three different hypotheses: no external regulation of veterinary medicines anywhere in the world; mutual recognition by the EC of US FDA authorization; and UK acceptance of EC central or national authorization without further regulatory requirements.

10.285. Intervet said that there would be strong commercial (and ethical) reasons for it to carry out studies to satisfy itself in relation to quality, safety and efficacy of all products that it intended to market. Consequently it would still incur considerable costs even if there were no regulatory requirements. It did appear, however, that the development of the regulatory system in the EC had led to a general rounding up of requirements, with the result that some pilot studies had to be repeated at a later date, and it was not normally possible to argue that a particular study might not be relevant in some cases. If there were no regulatory requirements, Intervet would make its own judgement as to which new or repeated studies were needed. It was impossible to quantify the savings that might be made: they could range from very little for a pharmaceutical product with a new active ingredient to a very significant amount (perhaps 75 per cent) for an uncomplicated vaccine similar to a product already marketed. In addition, Intervet would be able to market products as soon as the data was complete rather than waiting some six months for dossier compilation and 18 months for authorization, thus gaining at least two years of sales. The cost of licensing fees would also be saved (over £3 million a year in Intervet’s case) as would the cost of a regulatory department.

10.286. As for the second hypothesis, Intervet said that for pharmaceuticals the authorization system was under the aegis of the FDA and was not essentially dissimilar to the EC system. Biologicals were regulated by the US Department of Agriculture, which was more closely involved during the development of the product, and the efficacy testing required was somewhat different from EC requirements. Assuming that the US system did not involve demonstration of efficacy at all, the same issues as discussed in response to the first hypothesis would be relevant. Some savings might be possible, although it was impossible to quantify them. There would be some relatively insignificant time savings as well, although for biologicals this could be as much as one to two years.

10.287. Commenting on the third hypothesis, Intervet said that it was aware of no studies required in the UK that would not be required by other EC member states. However, the UK regulatory authority was more stringent than other member states in certain respects. For instance, it interpreted guidelines more strictly than other authorities and this could result in additional studies being required. It also used the five-yearly renewals procedure to request additional data to update the dossier, which was not always required by other member states. There could therefore be potential savings under this hypothesis, but in the post-authorization period rather than in relation to new product development and authorization. It was very difficult to quantify any such savings.

10.288. Intervet’s comments on regulatory issues raised in the statement of 16 April are recorded below.
Whether the current MRL requirements restrict competition in, and availability of, veterinary medicines, particularly for minor species (Issue I(i))

10.289. Intervet said that it supported the European Commission’s proposals to allow the extrapolation of MRLs for major species to be used to calculate MRLs for minor food species. It said that an extrapolated MRL would establish the safe maximum quantity of the drug in animal tissue for human consumption purposes, but the purpose of residue studies was to determine how long a withdrawal period was required between treatment and slaughter. The proposed changes would therefore obviate the need for Intervet to produce new species-specific toxicity studies to defend old products. Intervet did not, however, believe that existing MRL requirements restricted competition in veterinary medicines to any appreciable extent, as residue studies would still be required for new products in order to ensure consumer safety.

Whether the inclusion of an efficacy test in the marketing authorisation procedure unnecessarily increases the barriers to introducing a veterinary medicine to the market (Issue I(ii))

10.290. Intervet said that it did not believe that efficacy requirements added an unnecessary barrier to the introduction of new veterinary medicines. It told us that the quality, safety and efficacy assessments required by regulation were assessed concurrently by different VMD teams, so that the authorization process would be no shorter were the efficacy requirements to be relaxed or removed. Intervet did not believe that relaxation or removal would have public interest benefits. It said that efficacy would not necessarily be revealed by market use and at least not as rapidly. In the case of a product that individual veterinary practices dispensed only rarely, it would take considerable time for data to be gathered to form a collective professional view on non-efficacy. The public interest would be best served by retention of the efficacy test in those circumstances. Intervet said that, as a responsible manufacturer, it would in any event carry out efficacy tests as part of its own product development programme and therefore any savings to it in terms of cost and/or time arising from the removal of a requirement to test would not be significant.

Whether the absence of a provision for a third party to request reclassification of a veterinary medicine, or for regular review of classification, leads to an over-classification of veterinary medicines (Issue I(iii))

10.291. Intervet said that it had serious concerns about the involvement of third parties in any review of a medicine’s classification. First, it believed that the MA holder must be very closely involved in any review as the party in possession of an array of additional data from its own field and development trials prior to authorization of the product and from subsequent experience during marketing. This data was likely to be invaluable in assessing any application for reclassification. Intervet believed, therefore, that the MA holder should have the right to contest any decision to review the authorization given to one of its products, by making appropriate written and oral submissions. Second, Intervet was concerned about who would bear the considerable expense of either a VMD review or a review requested by a third party. It suggested that the direct costs to the MA holder of engaging in a review requested by a third party should be met by that party in the event either that the VMD rejected the application or that the VMD’s decision to accept reclassification was overturned on judicial review. However, even if direct costs were paid by the third party, the MA holder would bear some, possibly substantial, cost (even where a review proved reclassification not to be merited) which would feed through into higher medicine prices.

Whether the lack of a prescription-only sub-classification for medicines that could be prescribed by a veterinary surgeon (for animals under his/her care) without prior clinical examination restricts competition (Issue I(iv))

10.292. Intervet said that Recommendation 14 in the Marsh report effectively advocated the merging of the POM, PML and P classification categories, creating one new POM category, which would then be divided into three sub-categories, one of which, POM(B), would allow for dispensing by veterinary surgeons to animals not under their care and to pharmacists upon provision of a written prescription. In the absence of any formal proposals, it was difficult for Intervet to comment on how this recommendation could be implemented within the scope of the centralized procedure. It believed, however, that the recommendation might allow a product to be classified centrally as POM while at the same time the UK would have the flexibility to control the route of distribution.
Whether the length of time allowed to regulators to reach a decision on marketing authorisations is a barrier to introducing a new medicine (Issue I(v))

10.293. Intervet said that the 210-day ‘clock’ required to obtain an MA in the UK was not unduly long. It thought that there were incentives for the VMD to complete assessments promptly since its performance in dealing with national applications would be reflected in the number of applications made to the UK as reference member state under the decentralized procedure. This would have reputational importance for the VMD. Intervet told us that it had informally discussed with the VMD the possibility of introducing a fast-track system, whereby manufacturers could pay an additional sum in return for decisions guaranteed within a shorter time. The additional fee would be related to the extra costs incurred by the VMD to achieve this aim.

Whether the requirement that PMLs may only be dispensed by veterinary surgeons, pharmacists, and Suitably Qualified Persons (SQPs) employed by agricultural merchants or saddlers restricts competition in the supply of PMLs (and hence of any POMs which may be reclassified as PMLs) (Issue I(vi))

10.294. Intervet said that this issue would be addressed by the implementation of Recommendation 9 in the Marsh report, which it understood the Government was working towards. Intervet considered that the existing situation was anomalous. It supported the proposed changes.

Whether the current arrangements which preclude SQPs from breaking bulk in supplying veterinary medicines places them at a competitive disadvantage to veterinary surgeons (Issue I(vii))

10.295. Intervet said that pack-splitting could be dangerous, and, unless carried out in a controlled way, could lead to contamination of the medicine. This was not, however, a major issue with its own products, which were invariably registered in a variety of pack sizes including smaller ‘farm appropriate’ packs. The range of pack sizes was such that no disadvantage existed for non-veterinary distribution channels.

Whether the conditions under which the European centralized procedure is available could restrict competition, either: by being too narrow, and therefore compelling companies to use the decentralised procedure even if this is a greater barrier to introducing the product to market; or by being too narrow, and so allowing companies to gain a POM classification for their products which cannot subsequently be revised to PML (Issue I(viii))

10.296. Intervet said that a review mechanism for the classification of medicines authorized under the centralized procedure would not address the inherent problem, namely the need for one pan-European classification. Intervet told us that it was a strong advocate of the centralized procedure and would always choose that route where possible. It had concerns regarding the application in practice of the decentralized procedure, mainly because national authorities tended to fully review the dossier upon receipt from the RMS, often seeking further information and/or tests. In Intervet’s view, the centralized procedure should be available for all products. The current conditions for its use were too narrow. It believed that implementation of Recommendation 14 in the Marsh report would alleviate any concerns that opening the centralized procedure to all products would result in inappropriate classifications.

Whether the potential for competition from extra-EU markets is prevented by the lack of mutual arrangements between the EU and other regulatory regimes (Issue I(ix))

10.297. Intervet agreed in principle with the extension of the system of mutual recognition to extra-EC markets. However, in view of the considerable difficulties that were a feature of the European decentralized procedure, it believed that such a proposal could not be implemented until agreement on standards had been reached between the countries concerned. Such an agreement, once implemented, should ensure automatic mutual recognition of each other’s authorizations, without requiring further detailed evidence and testing results. Without such an agreement, mutual arrangements would have no practical relevance.
Possible recommendations for regulatory change

10.298. Intervet’s comments on the possible recommendations listed in the statement of 17 September are recorded below. Intervet also told us that it agreed with Recommendation 1 in the statement.

The Secretary of State to consider negotiating changes to the draft Directive (also proposed in COM (2001) 404 final) so as to legitimise cross-border trading, without need for a further marketing authorisation, of any veterinary medicine authorised through the decentralised procedure, between member states in which it is authorised, and to remove barriers to labelling in the appropriate language (Recommendation (2))

10.299. Intervet said that there was an existing requirement for all product labels for veterinary medicines marketed in the UK to be checked by the VMD. Intervet believed that this safety feature should be retained. Although products authorized for use through the decentralized procedure would necessarily be the same, this could not be said of two similar products authorized under the national route. An importer would not know whether a marketing authorization was national or decentralized and it was therefore important for there to be some reference to the licensing authority (as there was under the existing system). Intervet commented that it had never asserted copyright over packaging text.

The Secretary of State to consider amending the remits of the Veterinary Products Committee and the Veterinary Medicines Directorate to preclude them from taking into consideration manufacturers’ views on the classification of a product for which they are seeking marketing authorisation (Recommendation (3))

The Secretary of State and the Veterinary Medicines Directorate to consider instituting automatic review of classification whenever a product’s marketing authorisation is renewed (or at similar intervals if the European Commission’s proposal to make marketing authorisations permanent is adopted) and to base such reviews exclusively on the product’s existing dossier and accumulated field experience unless there is good scientific reason to require fresh testing to be carried out (Recommendation (4))

10.300. In Intervet’s opinion, the VMD should not be precluded from considering the views of the manufacturer on classification, both initially and at review. It believed not only that the manufacturer had a right to be heard by the VMD, but also that it would bring to the process the benefit of its in-depth knowledge of the product in question. Intervet pointed out that it had recently had two applications for PML status turned down by the VPC, which had not accepted its argument that the products in question did not require veterinary diagnosis. Consequently, they continued as POMs.

The Secretary of State to consider widening the remits of the Veterinary Products Committee and Veterinary Medicines Directorate to take into account the welfare of animals overall (Recommendation (5))

10.301. Intervet commented that the VMD and the VPC did in practice take into account the welfare of animals overall in making their assessments, even though it was not a specific requirement.

The Secretary of State to consider changes to the Veterinary Medicines Directorate’s remit to encourage it to seek out ways to structure authorisation procedures to minimise delays to product commercialisation (Recommendation (14))

10.302. Intervet said that it continued to believe that the introduction of an alternative fast-track procedure for an increased fee would be a beneficial change (see paragraph 10.293) and suggested that this recommendation could be widened to include such a change.

The Veterinary Medicines Directorate to consider offering applicants for marketing authorisation the option of submitting their dossier in stages (Recommendation (15))

10.303. Intervet said that this recommendation was of trivial significance as it would be relevant only to the declining number of national authorization applications. It would have no effect on the majority of applications through the centralized and decentralized procedures as these would still be required to meet the overall EC standards.
The Secretary of State to consider negotiating changes to the proposed Directive to allow provisional marketing authorisation to be given to any product for which an efficacy claim is made and which has successfully completed safety and quality assessments so that commercialisation may begin before completion of efficacy assessment (Recommendation (16))

10.304. Intervet said that the current system allowed a company to market a new and innovative product through a provisional marketing authorization (PMA), which could be issued without the provision of full efficacy data. The PMA would be issued for a period of two years and would then be subject to annual renewal by the VPC, with a requirement on the company to update to a full MA as soon as possible. Subsequent products being introduced for the same indication were, however, unable to benefit from a PMA and full efficacy data was needed for them before a full MA could be granted.

10.305. Intervet’s view, there were important animal welfare reasons why our suggested recommendation was inappropriate and why the current system should be retained. While there were benefits in accelerating the route to market for new and innovative medicines, there could be no justifiable reason for a veterinary surgeon to prescribe a product for which there was no efficacy data when an alternative product with full efficacy data was already available. Furthermore, Intervet believed that it was often extremely difficult for veterinary surgeons to determine the efficacy of certain products, so that if a product was authorized without efficacy data many animals might be treated with an ineffective medicine before this became apparent. Some products (such as rabies vaccines) protected public health and in such cases the use of products with non-proven efficacy could not be accepted.

The Secretary of State to consider negotiating changes to the proposed Directive to remove the ranking of cascade options in respect of non food-producing animals so that, where circumstances allow recourse to cascade, a veterinary surgeon may use whichever option he considers best (Recommendation (18))

The Secretary of State to consider negotiating changes to the proposed Directive to allow recourse to the cascade in the case of non food-producing animals where, notwithstanding the existence of an authorised medicine for the species and condition in question, the veterinary surgeon having the animal under his care considers this justified on grounds of animal welfare including cases where the cost of treatment would otherwise cause the animal to go untreated (Recommendation (19))

10.306. Intervet believed that the existing cascade system should be retained. It said that the cascade ranking ensured that veterinary surgeons turned first to medicines that had been specifically developed and marketed for a particular indication in the particular species being treated. Products for human use might contain the same or similar active ingredients as licensed veterinary products, but they would not have been tested in the target species. Intervet said that some excipients could cause problems for one species and not for others—for example, benzyl alcohol was toxic to cats and so would not feature in a veterinary product licensed for cats, while it might appear in an equivalent human generic form.

10.307. Intervet’s understanding of the RCVS guidelines was that the cost should be a factor for a veterinary surgeon to consider when treating animals. Intervet believed, therefore, that provided the guidelines were being followed and any cost savings passed on to the animal owner concerned, Recommendation 19 was a reiteration of current practice.

The Secretary of State to consider changing the law to allow a veterinary surgeon to dispense a veterinary prescription, whether or not the animal concerned is under his care. (This retains the requirement that the prescribing veterinary surgeon must have the animal under his care.) (Recommendation (20))

10.308. In Intervet’s view, the implementation of alternative measures would sufficiently meet our competition concerns in the supply of veterinary medicines. Intervet considered that were this recommendation to be implemented, the dispensing veterinary surgeon should no more have the right of substitution than should a pharmacist, for the reasons set out in paragraph 10.280.
Janssen-Cilag Ltd

Provisional complex monopoly situations

10.309. Janssen did not comment on our provisional conclusion that a complex monopoly situation existed in relation to the supply within the UK of POMs to animal owners, nor on our provisional conclusion that a complex monopoly situation existed in relation to the supply to veterinary surgeries of vaccines for cats and dogs.

Issues

Whether veterinary manufacturers tie in the sales of some or all products in their ranges with anti-competitive effect (Issue II(i))

10.310. Janssen said that as a small company it considered that some of its products would certainly look less attractive to a customer who already bought large quantities of product from another manufacturer and received a substantial discount as a consequence. However, it thought that linking products through price promotions could be justifiable with closely-related products, where it could lead to increased efficiency for the manufacturer or distributor and thence benefits which could be shared with the customer.

10.311. Janssen said that rebate schemes could act as a barrier to entry to smaller companies without the range of products. Commenting on whether manufacturers designed their rebate schemes in a way that reduced price transparency, Janssen thought that veterinary surgeons would have no difficulty comparing the net prices of drugs from each manufacturer where the terms of a discount scheme were clearly written down.

Whether veterinary manufacturers’ rebate schemes are structured in such a way as to cause veterinary surgeons to charge higher prices than they would otherwise do (Issue II(ii)b)

10.312. Janssen did not think that the structure of rebate schemes caused veterinary surgeons to charge higher prices than they would otherwise do. They were free to charge whatever price they felt was appropriate for the product. Veterinary surgeons were also able to offer retrospective discounts to their own customers.

Whether veterinary manufacturers who operate rebate schemes gain an informational advantage over those who do not, and whether this enables them to strengthen their position in the market in an anti-competitive way (Issue II(ii)c)

10.313. Janssen said that it understood that veterinary-practice-specific information from wholesalers was only available for a manufacturer’s own products, and not those of its competitors.

Whether veterinary manufacturers with a large market share in particular veterinary medicine sub-markets carry out anti-competitive practices to maintain their position, and in particular: whether veterinary manufacturers engage in predatory pricing (Issue II(ii)d)

10.314. Janssen believed that a policy of predatory pricing would be more likely to be adopted by a company with a cost leadership position in the industry, not necessarily by a large manufacturer offering a rebate scheme, but it was not aware of any company that was using predatory pricing.

Whether veterinary manufacturers promote brand loyalty to such an extent as to limit price competition and restrict market entry (Issue II(ii)e)

10.315. Janssen believed that establishing a brand was a reasonable business objective. The use of end-user promotions, qualified sales representatives and other promotional activities within the terms of the NOAH code of practice was appropriate and served to increase competition. Use of inducements which were not appropriate to the product concerned was prohibited by the NOAH code, by its business conduct policy and, it believed, by the business conduct policies of at least some other manufacturers.
Whether veterinary manufacturers engage in anti-competitive market sharing, by jointly choosing not to launch or promote products that directly compete with those of other suppliers (Issue II(ii)j)

10.316. Janssen was not aware of any cases of manufacturers engaging in anti-competitive market sharing.

Whether the manufacturers of veterinary medicines are protected by the provisions of the cascade from competition from substitutable human medicines, and whether they exploit this protection by charging higher prices than would otherwise be the case (Issue II(iii))

10.317. Janssen stated that the use of products that had not been tested for use in animals, in substitution for licensed medicines, was likely to result in reduced safety for animals. This would happen both directly, and indirectly through loss of pharmacovigilance monitoring.

Whether veterinary manufacturers set the price or influence the retail mark-up on veterinary medicines, and in particular whether veterinary manufacturers, through published list prices, effectively set minimum resale prices (Issue II(iv))

Whether veterinary manufacturers otherwise set, or influence, the price at which their products are resold (Issue II(v))

10.318. Janssen said that professional prices published in veterinary price lists were simply benchmark figures provided to make it easier for veterinary surgeons to calculate net prices. Veterinary surgeons were free to compete and charge what they wished. It queried why any manufacturer would wish to persuade a veterinary surgeon to increase the selling price of a particular drug unnecessarily, which would make it less attractive to the end-user.

Whether veterinary manufacturers request, or fail to initiate review of, classification of a medicine as prescription-only in cases where this is not necessary on grounds of safety (Issue II(vi))

10.319. Janssen observed that initiating review of classification of a POM to PML directly increased cost and frequently led to demands for new data from the competent authority, which indirectly increased both cost and risk to the product’s MA. It would be unreasonable to expect such a review to happen automatically without a prior commitment from the regulatory authorities that there would be no further demands for additional data and that the costs of the review would be borne by the individual or individuals requesting the review.

Whether veterinary manufacturers encourage veterinary surgeons to buy certain prescription-only medicines by asserting that they will not be subject to reclassification (Issue II(vii))

10.320. Janssen was not aware of any cases where a manufacturer had encouraged veterinary surgeons to buy certain POMs by asserting that they would not be subject to reclassification.

Whether veterinary manufacturers charge differential prices to veterinary surgeons in such a way as to restrict competition (Issue II(viii))

10.321. Janssen said that differential pricing might be defended for different veterinary practices if it was linked to special promotional activities that could only be organized locally but provided benefit to the manufacturer. Certain customers would be prepared to put more effort into promoting a particular brand, for example by organizing meetings for clients, overcoming local geographical distribution problems or using non-clinical staff in the practice to organize promotions, and the pricing would reflect this shared activity.

Whether veterinary manufacturers refuse to supply to certain intermediaries (wholesalers or retailers) or certain classes of intermediaries; supply certain intermediaries on less favourable terms than others; or fail to respond to requests for supply by certain intermediaries (Issue II(ix))

10.322. Janssen said that it was unaware of any such cases.
Whether veterinary wholesalers refuse to supply certain customers other than veterinary practices, universities and research establishments, and in particular refuse to supply pharmacies (Issue III(i))

10.323. Janssen was unaware of instances of veterinary wholesalers refusing to supply pharmacies. Given the large number of community pharmacies, it suspected that the smaller veterinary wholesalers would not have the service capability to deliver to them. To insist that all veterinary wholesalers should supply all pharmacies would result in only those with the greatest market share being able to trade, thereby reducing competition.

Whether discounts granted by veterinary wholesalers are cost-related (Issue III(ii))

10.324. Janssen believed that wholesalers’ discounts were for prompt payment of invoices, but it had no information on this issue.

Whether the provision of detailed sales information by veterinary wholesalers to veterinary manufacturers is detrimental to veterinary surgeons or consumers (Issue III(iii))

10.325. In Janssen’s view, provision of detailed sales information on customers to manufacturers should ultimately benefit the customer by enabling better sales call planning and therefore greater efficiency.

Whether veterinary surgeons fail to inform animal owners of the option to have written prescriptions for veterinary medicines dispensed by a pharmacist (Issue IV(i))

10.326. Janssen said that it naturally supported the rights of individuals to make their purchases through pharmacies if they wished. However, it suspected that the main issue for most modern consumers was convenience: being able to buy the medicine at the premises where the animal was examined.

Whether veterinary surgeons fail to provide itemised invoices showing a breakdown between the cost of professional fees and the cost of medicines dispensed (Issue IV(ii))

10.327. Janssen believed that an itemized invoice would be easy to generate in a computerized practice for those medicines that were dispensed, but difficult for other products such as anaesthetics or analgesics used as part of a medical procedure.

Whether veterinary surgeons charge unreasonable sums for writing a prescription to be dispensed by a pharmacist (Issue IV(iii))

10.328. Janssen observed that if the animal owner was made aware of the cost of the prescription, he or she could go elsewhere if the cost was too high.

Whether veterinary surgeons by some action or omission may have indicated to veterinary manufacturers and/or veterinary wholesalers that they should refuse to supply pharmacists, or supply them on less-favourable terms (Issue IV(v))

10.329. Janssen reported that it already supplied pharmacists.

Whether the regulatory regime causes veterinary surgeons not to dispense prescriptions written in other veterinary practices, thereby restricting competition between veterinary surgeons (Issue IV(vii))

10.330. Janssen told us that those practices wishing to dispense large quantities of POMs for animals not under their care on behalf of other veterinary surgeons could and should apply for a pharmacy licence.

Whether veterinary surgeons take steps that make it difficult for animal owners to switch from one veterinary surgery to another (Issue IV(ix))

10.331. Janssen doubted that this was within a veterinary surgeon’s power. It believed that animal owners had the right to request and receive copies of their own animal’s records under data protection legislation.
Whether veterinary surgeons set their charges for dispensing medicines in such a way as to subsidise their consultation fees (Issue IV(x))

10.332. Janssen understood that this was the case but doubted that it mattered, provided that veterinary surgeons’ clients understood what they were paying for.

Whether veterinary surgeons charge higher than necessary prices on prescription-only medicines (Issue IV(xi))

10.333. Janssen said that if veterinary surgeons used POMs rather than PMLs or other products to subsidize the cost of their services then logically it would probably be necessary to charge higher prices for them.

Whether veterinary surgeons allow purchasing and dispensing decisions to be influenced by rebates or discounts from veterinary manufacturers, in such a way as to restrict consumer choice or to increase prices to animal owners (Issue IV(xii))

10.334. Janssen did not believe that the majority of veterinary professionals would do this.

Whether veterinary surgeons charge relatively higher prices in areas where there is less competition from other similar practices (Issue IV(xiv))

10.335. Janssen observed that in the 1990s it had often been said that upwards of 70 per cent of large-animal veterinary practice income came from sales of medicines. The demise in farming and loss of profitability of the farm-animal veterinary sector would inevitably lead to lower numbers of farm-animal veterinary surgeons. Provided that the PML classification, or an equivalent non-prescription class of farm-animal medicines, was retained and widely used, there would still be competition in the market for medicines. However, those farmers who wished to retain the services of farm-animal veterinary surgeons would have to pay for them one way or another. Reducing the money made in sales of drugs would simply mean that farmers had to pay increased fees.

Response to complaints

10.336. [Details omitted. See note on page iv.]

10.337. [Details omitted. See note on page iv.]

10.338. [Details omitted. See note on page iv.]

10.339. [Details omitted. See note on page iv.]

10.340. [Details omitted. See note on page iv.]
Regulatory issues

10.343. In Janssen’s view, the requirement for an MRL, together with residues depletion data, was the principal barrier to new entrants and therefore to competition in the market when comparing the EC to other regions of the world such as the USA. The barrier to new market entrants in the animal vaccines sector was higher for other reasons. The EC treated these products as medicines; the US authorities treated them as animal products, with correspondingly less stringent requirements.

10.344. Janssen said that efficacy tests for many products were less stringent than those, for example, in the USA. It believed that quality and safety were more important issues than efficacy, provided that the claims made for a product were consistent with the supporting data.

10.345. Janssen had no objection in principle to a third party requesting reclassification of a veterinary medicine, for example from POM to PML, provided that it would not have to pay for the review, justification of retention of the current classification, or costs of the licence variation. It said that the cost of the review, including the costs to the company marketing the medicine, should be borne by the individual or individuals requesting reclassification.

10.346. Janssen believed that it would be unreasonable, and probably morally wrong, to require any veterinary surgeon to prescribe a POM without first examining the animal. There was also the question of who would indemnify the veterinary surgeon in the event of problems caused by inappropriate administration.

10.347. The length of time allowed to regulators to reach a decision on MAs was a barrier to the introduction of new medicines. That reduced the time available before patents expired to recover development costs and make a reasonable return on investment. Both direct and indirect costs were increased, as was uncertainty and therefore perceived risk for investors.

10.348. Janssen noted that the requirement that PML medicines could be dispensed only by veterinary surgeons, pharmacists and SQPs employed by agricultural merchants and saddlers reflected the fact that expertise was required in handling these products. Where products were suitable for general retailing with little advice other than that given on the packaging, the GSL category was available.

10.349. Janssen agreed that the conditions under which the centralized procedure was available restricted competition. It said that potential for competition from extra-EC markets was prevented as in many areas, such as vaccines from the USA, standards were very different.

Possible recommendations for regulatory changes

10.350. Janssen said that the majority of its farm-animal products were PML. The few which remained POM had not been reclassified either because Janssen had been obliged to accept a POM classification for regulatory or contractual reasons; because the product was physically administered by the veterinary surgeon; or because the revenue generated by the product did not justify the costs of review.

10.351. Janssen strongly supported Recommendations 6 and 7 in the statement of 17 September. Its comments on others of the recommendations are recorded below.
The Secretary of State to consider amending the remits of the Veterinary Products Committee and the Veterinary Medicines Directorate to preclude them from taking into consideration manufacturers’ views on the classification of a product for which they are seeking marketing authorization (Recommendation (3))

The Secretary of State and the Veterinary Medicines Directorate to consider instituting automatic review of classification whenever a product’s Marketing Authorisation is renewed (Recommendation (4))

10.352. Janssen said that it was opposed to Recommendation 3. It inferred from our statement that we believed manufacturers might wish deliberately to restrict distribution to certain channels in order to limit competition. That was not Janssen’s position, but there were other reasons why it might be against automatic review of particular products. There was inevitably a commercial consideration to anything it did, even if the reasons were scientific or technical.

10.353. For some products the costs of placing and keeping a product on the market might well be higher for the PML route of classification than for the POM route. These costs included logistics and customer services, sales and marketing, technical servicing, pharmacovigilance and regulatory compliance costs. If there was not sufficient reason to believe that sales would also be significantly higher, the product might not be viable via this route.

10.354. Automatic review of an older POM product would probably result in demands for more data from the VMD and other authorities to meet requirements that had not applied when the product was initially placed on the market. Or the authorities might consider that PML classification would result in more widespread use and therefore greater potential environmental contamination, leading to further questions and possibly demands for new data.

10.355. Janssen noted that the most significant costs of reviewing a product were in generating new data and costs of staff or consultants handling the review. There would be a significant opportunity cost if staff were regularly diverted from more urgent priorities in order to respond to reviews of products that Janssen had not initiated.

10.356. Janssen also commented that a manufacturer might know that for minor products with an uncertain future the chances of supporting a product through one regulatory classification would be greater than for another.

10.357. Any of the above points could, in Janssen’s view, have a bearing on whether a product remained on the market. It was far better both for competition and for animal welfare to have a product on the market as a POM than not to have it on the market at all.

10.358. Janssen said that the VPC and VMD should definitely take manufacturers’ views into consideration. If a manufacturer expressed a preference for a particular classification without scientific, welfare or other good reasons, Janssen believed that the VMD or VPC would ignore it.

10.359. Janssen would not be opposed to Recommendation 4 if it were not obliged to pay for any additional costs of reviewing a product as a PML rather than a POM and if it were not obliged to accept any additional costs of supporting a product through review and reclassification.

The Secretary of State to consider widening the remits of the Veterinary Products Committee and Veterinary Medicines Directorate to take into account the welfare of animals overall (Recommendation (5))

10.360. Janssen doubted that this recommendation would make any difference since in its experience the VMD would already occasionally consider retaining minor products on welfare grounds with additional restrictions where the costs of supporting the product were not justified.

The Secretary of State to consider re-defining the categories of business permitted to sell PMLs so that any business may do so subject to registration of its premises (as now) and the authorisation of each sale by a Suitably Qualified Person (SQP)(Recommendation (10))

10.361. Janssen said that any business should be permitted to sell PMLs subject to registration of its premises and the authorization of each sale by an SQP. It said that, in order for a level playing field to exist, the veterinary surgeon, or another trained SQP such as a veterinary nurse, should be able to sell PMLs to clients other than those specifically registered with the veterinary practice.
A further regulatory issue

10.362. Janssen said that because the horse was regarded as a food animal in most of Europe, the consequence if currently proposed European legislation were implemented would be that many equine products would be lost, with adverse effects on both competition and animal welfare. Since our proposed recommendations were already wide-ranging, Janssen wondered whether we could consider recommending to the Secretary of State that, in addition to each country choosing the appropriate distribution channel for products given an MA, each country should also be allowed to choose which species were regarded as food species.

Leo Laboratories Ltd (Leo Animal Health)

10.363. Leo had no comment on our provisional conclusion that a complex monopoly situation existed in relation to the supply within the UK of POMs to animal owners, nor did it comment on our provisional conclusion that a complex monopoly situation existed in relation to the supply to veterinary surgeries of vaccines for cats and dogs.

Prices

10.364. Leo said that its prices were not primarily cost-related. It set prices with a view to maximizing revenues but it could not just charge what it liked. In the food-animal business, and particularly in intramammary injectors for treating mastitis, there was healthy competition and its products were vulnerable. This was equally true of most products for small animals.

10.365. Leo did not concern itself with how veterinary surgeons determined the final price of its products, but it had occasionally received letters from owners of companion animals complaining about price rises, when its own prices to veterinary surgeons had not changed. It thought that transparency in pricing by veterinary surgeons would make it more difficult for them to blame suppliers for unrelated price increases. Leo believed that the average mark-up by veterinary surgeons was about 50 per cent on small-animal products and about 35 per cent on large-animal products, although it deducted that for some it was as much as 150 per cent.

Rebate schemes

10.366. Leo told us that it had had a unique policy of ‘no deals, no discounts’ for the past ten years. It said that it was an ethical pharmaceutical company that sold on quality and that priced products reasonably and sensibly, compatible with the competition. When it first stopped giving discounts it had lost sales but eventually the business had grown, partly because of customers’ respect for the policy. It was not aware that other Leo companies in Europe had the same policy.

10.367. It was not unknown for veterinary groups buying large volumes to ask Leo for discounts, which had been refused. One or two groups had stopped buying from Leo as a result.

10.368. Asked about the effect of rebate schemes offered by competitors, Leo said that its market share had suffered. For example, its drug Canaural had been hit by the entry of a competitor drug with heavy discounting, although it had since climbed back. Although Leo was irritated and disappointed by the competitor’s action, it did not consider it improper. Competitors’ rebates had not caused problems in Leo’s introduction of new products, because it concentrated on niche markets.

10.369. Leo said that the animal health business was shrinking and it regretted massive discounts which drove down prices, taking money that could otherwise be spent on R&D. In its view, it was not a sensible way to run a business.

Advertising

10.370. Leo said that its market share was affected by competitors’ advertising to end-users. Leo itself did not advertise in this way because it considered it irresponsible to advertise antibiotics, given the concerns about the development of resistance to these drugs.
Pharmacies

10.371. Leo said that it would not know, without asking its wholesalers, whether its products were supplied to pharmacies. Wholesalers made a charge for supplying information about the location of buyers, which Leo could not afford.

10.372. If a pharmacy were to ask Leo to sell medicines to it, the request would be treated like that from any other prospective account customer. If the volume were sufficient to justify a direct account, the usual credit references would be taken. If not, the customer would be referred to the nearest veterinary wholesaler. Where appropriate, goods could be shipped to the pharmacy for the account of the veterinary wholesaler. Leo would expect most pharmacy enquiries to be below the volume criterion for a direct account. Although it would have no problem about supplying to pharmacies, it was concerned that they would be selective in what they stocked, with an emphasis on fast-moving flea preparations. This would reduce the service to customers.

The cascade

10.373. Leo said that any relaxation of the cascade would be the death knell of the industry. If it were made easier for veterinary surgeons to use human medicines, even though they might not be as appropriate as the veterinary product, the incentive to develop better formulations specifically for animals would diminish. Cheap generics were sold by people who did no R&D.

Regulation

10.374. Leo said that it would welcome a proposal to drop periodic reviews of medicines. It believed that monitoring and the logging of adverse reactions would be sufficient. Applying for renewal of a licence for a drug today was almost like introducing a new drug because of the need to meet current data requirements. The future of the only two drugs Leo still had in the large-animal sector, intramammary injectors for mastitis, which had been sold for 25 or 30 years, was in doubt because of the cost of the necessary evaluation. It commented that renewals for human medicines seemed to be less burdensome.

10.375. Leo emphasized that it wanted good regulation but also wanted a level playing field with other countries. It thought that the VMD was now more stringent than authorities in other countries, although this had not always been the case. It would favour a single market in animal medicines, whereby authorization in one EC country would apply in all the others.

10.376. Considering classification of medicines, Leo said that it would have no objection to accepting a PML rather than a POM classification if the VMD recommended that. It would not want a third party to be able to initiate a classification review; it believed that, as the company investing in the product, it should decide in which sector it should be sold.

10.377. Leo said that it would not be opposed to the suggestion that the sale of PMLs should be allowed in retail outlets other than agricultural merchants and saddlers, provided that this were done by appropriately qualified people.

Merial Animal Health Ltd

Market definition

10.378. Commenting on the view of the market set out in the statement of 17 September, Merial said that although the distinction between curative and preventive was useful medically, it was not useful in the economic analysis of the markets in which Merial operated. It considered that a correct approach to market definition was essential for us properly to address the matters in our terms of reference.

10.379. Merial also told us it did not accept that the narrow definition we had put forward for a market in the POM small-animal flea treatments reflected the reality of the market in which it competed. The market was, in Merial’s view, a broad one that included POMs together with a wide range of other products sold in veterinary practices and a broad range of other retail outlets for treating fleas and ticks.
Merial said that paragraph 6 of the statement seemed to suggest that the regulatory system limited competition. But it could equally be argued that without any regulation there might be few or no sales of veterinary medicines in the UK as the use of many of these products had direct consequences for human health and might be prohibited from circulation or sale. It could be said that regulation permitted these products to circulate in the economy, creating the possibility of markets for them, and was therefore an essential precondition for competition.

**Jurisdiction**

Merial noted that in the statement of 17 September we had not identified any evidence to suggest that there was anything other than intense competition at manufacturer level. Our provisional complex monopoly finding and hypothetical remedies seemed to be directed primarily at remedying perceived problems with competition at the level of veterinary practices. It seemed to Merial odd that we should propose remedies that would apply to manufacturers, given the intensity of competition at that level.

Merial commented that we appeared to be focusing on concerns about the impact on competition at retail level of certain practices of veterinary surgeons, and that the possible remedies we had proposed had the aim of ensuring that veterinary surgeons would write ‘portable prescriptions’, to allow for the development of a distinct medicine dispensing function. Merial said that it understood our reasoning. It believed, however, that we were going further than seeking to eliminate perceived obstacles to competition and recommend remedies, and we should then leave it to market forces to create a pharmacy channel for retail sales of POMs.

Merial suggested that we were attracted to novel and artificial complex monopoly analyses in order either to create an obligation for manufacturers to supply direct to some future new pharmacy channel or to seek to exercise control over the terms on which manufacturers granted rebates to those future market players. It believed that attempting in this way to regulate matters necessary to the creation of a future, new pharmacy channel was neither within the scope of the FTA nor necessary.

**Provisional complex monopoly situation—supply of POMs to animal owners**

- **Conducts**

Merial said that it did not engage in the conduct identified in paragraph 9(d) of the statement of 17 September (refusal/failure to negotiate discounts and rebates with buying groups). It supplied all the buying groups and in most cases had done so since the group was set up. It negotiated levels of discount with each group individually, depending on a number of factors including number of members and volumes of purchases.

Merial questioned whether unilateral failure to negotiate could amount to conduct supporting a complex monopoly finding, as this behaviour was merely unilateral abstention from action and did not restrict the freedom of others in the marketplace. Furthermore, there was no evidence that it appreciably or materially prevented, restricted or distorted competition.

Merial also maintained that it did not engage in the conduct identified in paragraph 9(e) of the statement (operation of rebate schemes that make it difficult for veterinary surgeons to ascertain with certainty at the time of purchase the cost to themselves of POMs). It said that its rebate scheme was transparent to veterinary surgeons, who were able to calculate with a high degree of accuracy the price they paid for any POM bought from Merial. It also told us that it conducted market research annually to confirm that its scheme was achieving an optimum degree of transparency. Whilst any scheme that included retrospective rebates (in Merial’s case calculated over a three-month period) meant that prices could vary depending on the precise level of purchase, the effect of this should not be exaggerated. Merial said that veterinary practices tended to buy relatively stable volumes and ranges of products from quarter to quarter and could easily calculate the effect of changes in purchasing patterns on prices in the previous quarter. Merial understood that veterinary practices could readily obtain from the major
veterinary wholesalers information about the volume of their purchases and this made calculation of rebates, and hence of net prices, a straightforward matter. In order to demonstrate the transparency of rebates under its own scheme, Merial provided a number of examples of statements that it had sent to customers with their rebate payments. The other element of the veterinary surgeon’s purchase price was the discount received from the veterinary wholesalers, which Merial understood to be transparent and consistent across all products.

10.387. In Merial’s view, even a less transparent scheme than its own would not distort competition. It put forward a number of points in support of this view.

10.388. First, Merial argued that our provisional finding was based on an error in the BMRB Social Research report upon which we had relied. The report stated that the published list price was the basis for mark-up for POMs of three-quarters of veterinary surgeons. However, Merial maintained that analysis of the telephone questionnaire, attached to the report, showed that this conclusion was incorrect because BMRB had misinterpreted the relevant question. Veterinary surgeons had been asked a connected list of questions, prefaced by the following explanation: ‘I would now like to ask you about average mark-up percentages on different types of medicines. For example, if you buy medicine at a list price of £10 and sell it to the client for £15, your mark up would be 50 per cent.’ Merial commented that the question gave the veterinary surgeon no discretion as to the basis of calculation. The only compliant answer had had to be based on the list price at which the medicine was purchased. There followed three questions about the average mark-up for different categories of medicine. The final question of the series asked ‘Can I check—is your mark-up for POMs based on…’ followed by a choice of responses, of which the published list price was the first option. Merial commented that BMRB appeared to have concluded that this question provided information on the surgery’s normal practice on marking up of POMs. Merial argued that it did not: the question was a check on the answer just given in relation to the surgery’s mark-up. The only correct basis upon which the question could be answered was for the respondent to use the list price as the basis for calculation. Accordingly, Merial’s view was that the answers to the question simply indicated that 75 per cent of respondents had calculated the mark-up for POMs on the basis on which they had been required to do so.

10.389. Merial argued that no conclusion could be drawn from the survey responses as to what the respondent would have said if asked a self-standing question about the surgery’s policy on marking up. It maintained that the survey could provide no support for our inference that many veterinary surgeons based mark-ups on published list prices because lack of transparency of some rebate or discount schemes made it difficult for them to calculate net prices.

10.390. Second, Merial said that if 92 per cent of veterinary surgeries had computers (as found by BMRB) and 75 per cent of these had practice management software (with more than 60 per cent of the surgeries having received either the software or the hardware from a veterinary wholesaler) then it was reasonable to assume that many practices were equipped to ascertain net cost. Indeed, in Merial’s experience most of its customers were able to do this.

10.391. Third, Merial argued that if veterinary surgeons used a different basis for setting prices, the end result would be the same. It noted the BMRB findings that veterinary surgeons applied a substantial mark-up to all veterinary medicines, including POMs. Merial concluded from this that they priced to the market they had created in their resale activities rather than on a cost-plus basis. Merial maintained that there was no evidence to suggest that the retail prices would change if surgeries had more information about their net prices for each product.

10.392. In Merial’s view, rebate schemes constituted an element of competition between manufacturers that benefited customers. They did not prevent, restrict or distort competition.

10.393. With regard to the conduct identified in paragraph 9(f) of the statement (failure to supply pharmacies with POMs and/or enable pharmacies to obtain supplies of POMs on terms that enable them to compete with veterinary surgeons), Merial said that it had highly efficient distribution arrangements through the veterinary wholesalers, who undertook the logistics, pricing, invoicing, cash collection etc. Merial did not itself have the infrastructure to undertake physical distribution or selling to a large number of customers. It supplied no veterinary practices direct with POMs, except for a small number of poultry specialists, and no pharmacies. It had not been asked to do so before the start of our inquiry. It did not understand why we should consider that failure to supply a category of retailer in circumstances where Merial had received no request for supply from that category of retailer could constitute a conduct which
could be the basis for a complex monopoly finding. It suggested that enforced supply to retail customers (specifically to pharmacies) was likely to lessen efficiency in the distribution chain.

10.394. Merial said it was clear that the wholesale level of the market was competitive and efficient. Veterinary wholesalers seemed to operate their businesses on a small incremental price addition to the price charged by the manufacturers, which was indicative of strong competition between the wholesalers.

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\text{Details omitted. See note on page iv.}
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10.395. Merial told us that it applied no constraints on the resale of its products by veterinary wholesalers, with regard either to the terms of sale or the customers to whom its products were sold. It said that it had received no enquiries from pharmacies about supply of POMs until after our inquiry had started. As far as it was aware, its POM products were not currently supplied to any pharmacy by veterinary wholesalers, but it emphasized that it was not involved in decisions about whether or not to supply particular channels at retail level. It had structured its business so as to supply POMs only to veterinary wholesalers (with the exception of some direct supply to the avian sector) and the individual wholesalers decided whether or not to supply pharmacies.

10.396. In Merial’s view, the fact that it did not directly supply to pharmacies did not amount to, or contribute to, a complex monopoly situation. It maintained that a unilateral decision to supply to the wholesale level of the market, and not to supply to retail level, could not be described as a conduct or practice, nor could it be described as preventing, restricting or distorting competition. There was no restriction of the freedom of other market participants, but merely adoption of a unilateral decision as to the definition of the business the supplier was in.

10.397. With regard to terms of supply offered to pharmacies, Merial said that veterinary surgeons and pharmacies performed different functions in the supply of POMs. It believed that competition in the market should be allowed to determine the levels of discounts and rebates available, and it may be that they would be different for different functions. Merial did not, however, exclude the possibility that the different functions would attract the same rewards, ie that if pharmacies came into the market it would offer them discounts and rebates on the same terms as veterinary practices. However, Merial’s position was that veterinary surgeons offered it additional value: they chose to prescribe or sell its products, gave advice on their use and handled any complaints. Merial would need to consider carefully what value a pharmacy could add.

10.398. Merial told us that prior to the start of our inquiry it had not been asked by pharmacies to provide rebates. It did not consider that a failure to offer rebates when they had not been requested could be said to constitute ‘conduct’, let alone conduct on which a complex monopoly finding could be based.

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\text{Details omitted. See note on page iv.}
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- **Single complex monopoly**

10.400. Merial did not consider that we could permissibly identify a single complex monopoly situation including manufacturers, wholesalers and veterinary surgeons on the basis we had suggested. Our position seemed to be that so long as veterinary surgeons supplying one-quarter of the reference products to animal owners were undertaking conducts identified as falling within the complex monopoly situation definition, other members of the supply chain (manufacturers and wholesalers) formed part of that single complex monopoly situation, whatever the conduct at, say, the manufacturer level and whatever the proportion of the reference products supplied at, say, the manufacturer level. Merial
considered that this went beyond the permissible boundaries prescribed by the FTA and that the circumstances in this case differed considerably from the previous cases we had cited.

10.401. As regards a suggestion that we made to Merial at a hearing, to the effect that the purchase by manufacturers from wholesalers of information about sales to veterinary surgeons constituted a sufficient nexus between manufacturer, wholesale and retail level on which a complex monopoly finding could be based, Merial said it did not believe that this was correct. It pointed out that this basis was not set out in the statement of 17 September. Merial told us, first, that the only information it obtained from wholesalers related to onward sales of products that it had supplied to the wholesaler. It did not extend to the sales of individual veterinary practices to their customers. Second, Merial was not arguing that there were no links between players at different levels of the supply chain. Its position was, rather, that both precedent and a correct interpretation of the FTA supported the view that only links having a particular character could supply the nexus placing the relevant companies in a single group for the purposes of a multi-level complex monopoly situation. Merial noted that in Domestic Electrical Goods I and II, for example, manufacturers recommended retail prices which the MMC had found were taken into account by retailers to whom they supplied directly, and who sought to influence the suppliers’ RRPs. There was therefore a very close (including contractual) nexus. Merial said that nothing of the sort applied as regards its relationship to the retail level in connection with the supply of POMs, where it should be viewed as simply a supplier on to the market, in the context of a highly competitive manufacturing level.

10.402. In Merial’s opinion, a complex monopoly situation could only be identified here, so far it was concerned, at the manufacturer level, and would require a clear-cut finding that manufacturers supplying at least 25 per cent of all reference products in the UK conducted their affairs in a manner which was capable of constituting a complex monopoly situation in relation to the supply of veterinary medicines in the UK—namely, that the conduct prevented, restricted or distorted competition in that supply.

10.403. Merial noted our provisional view that such a manufacturer-level complex monopoly situation existed (paragraph 1 of the statement of 17 September). It asked us to re-evaluate this conclusion on the basis of its comments. In particular, Merial said that it did not undertake conducts 9(d) or (e), and suggested that we checked the share of supply test in relation to any manufacturers that did undertake them. In relation to 9(e), Merial said that even on the approach set out in our statement, any other company whose rebate scheme permitted a workable level of transparency of net prices would fall outside the complex monopoly situation identified. In relation to 9(f), Merial did not consider that, properly viewed, it undertook the conduct. It also considered that a failure to supply did not in the circumstances amount to conduct capable of giving rise to a complex monopoly situation.

• Persons in whose favour

10.404. Merial did not agree with our provisional view, as set out in the statement of 17 September, that the complex monopoly situation we had identified operated in favour of all manufacturers supplying POMs in the UK, on the basis that a complex monopoly situation or situations led to less competition and higher prices at retail level, reducing competitive pressures on prices further up the supply chain. It did not consider that the fact of less competition at the retailer level than might otherwise exist necessarily reduced competition at the manufacturer level, where individual manufacturers were constrained by the need to compete intensely for the business of veterinary surgeons. Competition between manufacturers was quite independent of the degree of competition between veterinary surgeons to attract customers. Merial said that the existence of discounts and rebates offered by manufacturers to veterinary wholesalers and retailers was consistent with competition between manufacturers being a key dynamic of the market. Merial also commented that manufacturers could in no way benefit if veterinary surgeons marked up the price of POMs beyond what might be expected in a competitive market, since manufacturers in all markets benefited from having a competitive downstream sector.

10.405. In Merial’s view we had failed to demonstrate the close and precise linkage (for example, a corporate link) that the FTA required. To the extent that our position was that manufacturers, because they participated in the market two levels upstream of the retail level, could be said to be persons in whose favour the complex monopoly situation existed, Merial did not believe that this was a sufficient condition to satisfy the test.
Provisional complex monopoly situation—supply of cat and dog vaccines to veterinary surgeries

10.406. Merial said that its comments were informed by the fact that it had historically had a relatively low market share in the cat and dog vaccine market segments and until recently did not offer a full range of cat and dog vaccines. Despite this, it had been able to compete actively in both segments. It also remarked that the existence of six manufacturers within the market would not generally be a sign of absence of competition.

10.407. In respect of the conduct that we had identified, Merial said that it did not offer a specific rebate targeted solely at combined purchases of cat and dog vaccines.

10.408. Merial did not believe we were right to conclude that there was a complex monopoly situation in the supply to veterinary surgeries of vaccines for cats and dogs. Whether such discounts linking purchases of these categories of vaccine had an exclusionary effect was a matter of fact. Merial believed that we had failed to provide evidence in support of our view. It reiterated that for a long time it had not itself offered a full range of cat and dog vaccines but had still been able to compete in the market. It did not believe that combined discounting practices had had, or were having, a substantial adverse effect on its position in the market or competition in general in these market segments. In Merial’s view, combined discounting merely reflected the way in which participants in the vaccine market segments had historically competed.

10.409. Merial said that it would expect us, in making this provisional finding of a complex monopoly situation, to be able to identify products or manufacturers that had been excluded from the market as a result of discounting practices, or products of a similar efficacy which were marketed elsewhere in Europe but not in the UK. It was concerned that we had apparently reached our finding without such evidence.

10.410. Furthermore, Merial considered that the structure of the market provided evidence of active and effective competition between manufacturers in that:

— the six manufacturers identified had different strengths in their vaccines portfolios; and

— there were a number of suppliers with relatively low market shares and/or limited ranges (for example, Merial, Virbac and Schering-Plough) that were still able to compete.

Merial said that success in the veterinary medicines markets depended upon a product’s value proposition (incorporating efficacy, price, ease of use, safety and other factors). It believed that the markets for cat and dog vaccines were no exception. Smaller participants in the market (including Merial) and new entrants were not prevented from developing and marketing products that offered better value. Veterinary surgeons bought products from any manufacturer they chose, as was evidenced by companies that did not supply a full line but were nevertheless able to make sales.

10.411. Merial did not believe that the operation of rebate schemes in the cat and dog vaccine market segments operated to restrict competition, and on that basis it maintained that grounds for finding a complex monopoly situation had not been established.

Other issues

10.412. Merial’s comments on other matters contained in the statement of 16 April are recorded below.

Whether veterinary manufacturers tie in the sales of some or all products in their ranges with an anti-competitive effect (Issue II(i))

10.413. Merial said that it was important to distinguish between tied sales—where a product was made available only when another was purchased as a condition of sale—and cross-sales, where an economic incentive might be provided to purchase a range of products. The latter were a common feature of many markets and might be entirely consistent with intense competition.
10.414. Merial told us that its rebate scheme operated as an incentive to a veterinary practice to increase its overall purchases from Merial, but did not have the object or effect of tying practices to the purchase of particular products. The range of discounts available under Merial’s scheme was moderate and not, so far as Merial was aware, atypical of other industries. It did not believe that such discounts could be described as tie-ins.

**Whether veterinary manufacturers, via linked price promotions, use the existing market power of some products as a lever to gain share of other markets (Issue II(i)a)**

10.415. Merial said that all its products were subject to intense competition in the marketplace. It did not operate limited period linked price promotions of the type suggested.

**Whether veterinary manufacturers operate rebate schemes which are a barrier to successful market entry, in that they encourage veterinary surgeons to buy more from larger veterinary manufacturers (Issue II(i)b)**

10.416. Merial told us that its rebate scheme was a response to competition. Although its sales representatives discussed with veterinary surgeons the extent to which higher discounts could be achieved through the purchase of additional products, volume and range rebates were set at absolute levels of purchases and were not individually negotiated.

10.417. In Merial’s view, the rebate was an element of the price available. Veterinary surgeons looked at all aspects of the product when deciding whose product to buy, including price. Merial offered discounts in response to competition on price between manufacturers.

10.418. Merial said that a new entrant to a competitive market must offer a product with advantages over existing products in terms of performance or, in some cases, cost benefit. There was evidence that companies with good products had been able to enter the UK market successfully. There were examples of smaller manufacturers, with a single or limited product range, successfully penetrating the market in recent years. Merial did not, therefore, consider that the rebate schemes operated by manufacturers created a barrier to successful market entry.

**Whether veterinary manufacturers’ rebate schemes are structured in such a way as to cause veterinary surgeons to charge higher prices than they would otherwise do (Issue II(ii)b)**

10.419. Merial said that it did not control prices charged by veterinary surgeons to their customers. It was forced, in order to meet competition, to give discounts to wholesalers and rebates to veterinary surgeons. However, whether and to what extent these discounts and rebates were passed on to animal owners was a matter for each veterinary surgeon independently to decide.

**Whether veterinary manufacturers who operate rebate schemes gain an informational advantage over those who do not, and whether this enables them to strengthen their position in the market in an anti-competitive way (Issue II(ii)c)**

10.420. Merial said that veterinary manufacturers who operated rebate schemes were not at an informational advantage over those who did not. This was because the manufacturers paid wholesalers to provide information about sales of particular products, and provision of the information by wholesalers did not depend on a manufacturer running a rebate scheme. Manufacturers who did not run such schemes could also obtain information on veterinary surgeons’ purchases.

**Whether veterinary manufacturers with a large market share in particular veterinary medicine sub-markets carry out anti-competitive practices to maintain their position, and in particular: whether veterinary manufacturers engage in predatory pricing (Issue II(ii)d)**

10.421. Merial said that it did not engage in predatory pricing.

**Whether veterinary manufacturers promote brand loyalty to such an extent as to limit price competition and restrict market entry (Issue IIe)**

10.422. Merial said that advertising was necessary to provide information to its customers and to the end-consumer. It advertised to veterinary surgeons and nurses to draw attention to the technical benefits
of its products, and to consumers to increase awareness of the medical conditions suffered by animals, and the possibility of treatment. Merial did not consider that such advertising created brand loyalty to such an extent that price competition or market entry were restricted.

Whether veterinary manufacturers engage in anti-competitive market sharing, by jointly choosing not to launch or promote products that directly compete with those of other suppliers (Issue II(ii))

10.423. Merial said that it did not engage in this practice.

Whether the manufacturers of veterinary medicines are protected by the provisions of the cascade from competition from substitutable human medicines, and whether they exploit this protection by charging higher prices than would otherwise be the case (Issue II(iii))

10.424. In Merial’s opinion, the provisions of the cascade system did not unnecessarily protect veterinary medicine manufacturers from generic competition (in particular, from human medicines). Merial believed that abolition of the cascade system would threaten the future development and availability of many products for companion animals (as human generics made no contribution to the cost of veterinary R&D), while placing too great a burden on the expertise of the individual veterinary surgeon in extrapolating from one species to another.

Whether veterinary manufacturers set the price or influence the retail mark-up on veterinary medicines, and in particular whether veterinary manufacturers, through published list prices, effectively set minimum resale prices (Issue II(iv))

Whether veterinary manufacturers otherwise set, or influence, the price at which their products are resold (Issue II(v))

10.425. Merial drew attention to its comments in paragraph 10.419.

Whether veterinary manufacturers request, or fail to initiate review of, classification of a medicine as prescription-only in cases where this is not necessary on grounds of safety (Issue II(vi))

10.426. On the issue of classification of medicines, Merial said that it agreed with the view of NOAH, as expressed in its response to recommendations in the Marsh report, that the possibility of third-party initiation of review merited further consideration, provided that those making the case were confined to scientific and clinical arguments and that the MA holder had the opportunity to respond. Merial also shared NOAH’s concerns that MA holders might be required to pay for a variation which was instigated by an outside body or another company, and pointed out that the cost to the manufacturer of a change of classification could be significant (setting up new sales channels, new labelling etc).

Whether veterinary manufacturers encourage veterinary surgeons to buy certain prescription-only veterinary medicines by asserting that they will not be subject to reclassification (Issue II(vii))

10.427. Merial said that it did not engage in this practice.

Whether veterinary manufacturers charge differential prices to veterinary surgeons in such a way as to restrict competition (Issue II(viii))

10.428. Merial said that this issue was based on a misunderstanding of the typical chain of supply. It did not sell direct to veterinary surgeons other than those in the avian segment. For all other business it sold its products to veterinary wholesalers, who then sold them on to the veterinary surgeons. Merial did not seek to influence the price, net of discount, charged by veterinary wholesalers.

Whether veterinary surgeons fail to inform animal owners of the option to have written prescriptions for veterinary medicines dispensed by a pharmacist (Issue IV(i))

10.429. Merial believed that veterinary surgeons should be required, by strengthened professional guidance, to offer a written prescription, so that animal owners had a choice as to where to buy the medicine.
Whether veterinary surgeons by some action or omission may have indicated to veterinary manufacturers and/or veterinary wholesalers that they should refuse to supply pharmacists, or supply them on less-favourable terms (Issue IV(v))

10.430. Merial said that, to its knowledge, no veterinary surgeons had behaved in that way. It had been contacted by a small number of veterinary surgeons reporting that on-line pharmacies were promoting the sale of POMs, and asking about the legality of this practice. Merial had advised them that it was legal provided that the POM was supplied against a prescription from a registered veterinary surgeon with care of the animal. This had generally been accepted by the enquirers.

Whether veterinary surgeons influence veterinary manufacturers not to reclassify prescription-only medicines to a lower classification (Issue IV(vi))

10.431. Merial said that comments were occasionally made to it on issues of potential reclassification, but there had been no formal attempts by veterinary surgeons to influence Merial not to reclassify POMs to a lower classification.

Whether veterinary surgeons allow their purchasing and dispensing decisions to be influenced by rebates or discounts from veterinary manufacturers, in such a way as to restrict consumer choice or to increase prices to animal owners (Issue IV(xii))

10.432. Merial drew attention to its comments in paragraph 10.417.

Possible Remedies

10.433. Merial’s views on certain of the possible remedies listed in the statement of 17 September are recorded below.

A requirement for manufacturers of POMs giving rebates to veterinary surgeons to provide sufficient information, either directly or through wholesalers, so as to enable the veterinary surgeon to ascertain with certainty the cost net of rebates of POMs supplied to them (paragraph 24(b)(v) of the statement)

10.434. Merial reiterated that its rebate scheme was transparent so that veterinary surgeons were able to do this at present. It did not believe that there was additional information that it could reasonably provide to ensure greater transparency. It said that it would have concerns, on grounds of commercial confidentiality and allocation of costs, if we sought to require either the manufacturers or the wholesalers to provide information about both manufacturers’ and veterinary wholesalers’ schemes. As a matter of principle, each should be responsible for its own discounts and rebates.

A requirement for manufacturers and wholesalers that supply POMs in the UK to supply pharmacies (paragraph 24(c)(i))

10.435. Merial did not consider that any remedy in relation to manufacturers was necessary. It said that any such remedy would be disproportionate in its application to Merial. Its business was configured to make highly efficient supplies to veterinary wholesalers in the UK, and it did not restrict those wholesalers in terms of their on-sales. It told us that it would supply to a new wholesaler with comparable purchase levels. It believed that it should not be forced to identify and deal with a potentially substantial number of new customers, many of whom would have small volumes of orders, and so change the entire nature of its operations and supply logistics in the UK.

A requirement for manufacturers and wholesalers that enable POMs in the UK to supply pharmacies on terms that enable them to compete with veterinary surgeons (paragraph 24(c)(ii))

10.436. Merial said that it saw no basis or justification for this remedy as it did not accept that there was a complex monopoly situation in respect of supply by manufacturers to pharmacies.

10.437. Merial believed we were going beyond what was necessary to remedy any distortions of competition that we may have identified (see also paragraphs 10.385 and 10.386). It also appeared to Merial that we were considering a remedy that would amount to imposition of a form of price control so that manufacturers would be required to deal with pharmacies on identical terms to those offered to
veterinary practices. Merial believed that a recommendation of exact parity would tend to rigidify markets and distort and restrict competition. It considered that if we were concerned about competition at the retail level we should address those concerns and allow the operation of the free market to ensure the creation of a viable pharmacy channel to the extent that there was a real demand for one. We should not at this stage recommend interventionist measures such as price control mechanisms at a different level of the supply chain to remedy problems that we thought might arise at a later stage, when written prescriptions for veterinary medicines became more common. We should be confident that in those circumstances pharmacies seeking supply would be able, through competition between manufacturers, to negotiate favourable rebate terms. It was competition between manufacturers that would set those terms and it was guesswork to predict how they might relate to rebates to veterinary surgeons.

10.438. A representative of Merial said at a hearing that he did not in principle see a problem with offering pharmacies similar terms to those offered to veterinary surgeons. However, Merial did not see the justification for any remedy and anticipated that competition between manufacturers would ensure that discounts were offered to pharmacies. It was important to note that pharmacies performed different functions from veterinary surgeons and would continue to do so even if all our proposed regulatory changes were implemented. In Merial’s view, if a manufacturer were to supply to a pharmacy this should follow arm’s length negotiations which would take account of such differences—the terms of supply offered to the two types of customers might well, therefore, be different for good reasons dictated by efficiency and economic rationality.

A requirement for veterinary surgeons when they write prescriptions for POMs to do so on an ‘or equivalent’ basis to enable those dispensing such prescriptions to supply alternative authorised veterinary medicines to the brands specified (paragraph 24(c)(iv))

10.439. Merial said that it saw no justification for this possible remedy. First, nothing in the statements of 16 April or 17 September provided any reasoning to suggest that such a remedy might be justified to deal with any possible public interest finding. Second, the remedy would cut across the role of the veterinary surgeon, and the need to promote animal welfare, in a fundamental manner. Merial told us that in relation to human medicines, section 58(2)(a) of the Medicines Act 1968 stated that subject to the provisions of that section: ‘No person shall sell by retail, or supply in circumstances corresponding to a retail sale, a [prescription-only medicine] except in accordance with a prescription given by an appropriate practitioner.’ This meant that a prescription written for a medicine under a brand name would be dispensed only using the appropriate branded product. The position was different where a prescription was written for a medicine under a generic name: in that case, any appropriate branded or generic product could be supplied.

10.440. Merial said we needed to be aware that even products with the same active ingredient might differ in their action on the animal being treated, depending not only on the amount of active ingredient and mode of administration, but also on many other factors including, for example, precise formulation, particle size and coating. When a veterinary surgeon examined an animal, he or she would assess which particular product among the options available was the most suitable to prescribe, taking account of such factors as the age, breed, sex and prior medical history of the animal, medicines previously prescribed and price/cost to the customer of the various products. The veterinary surgeon would balance all these factors in reaching a decision. If the conclusion was that the price/cost of a product was not justified by the benefits it offered to the animal, then the veterinary surgeon would not prescribe it.

10.441. In Merial’s view, if a veterinary surgeon specified a brand, he or she should not be compelled to add the words ‘or equivalent’, which would allow a judgement to be made by a pharmacist. If, and only if, the veterinary surgeon prescribed by a generic name should it be permissible for the pharmacist to have this latitude. Merial said that it was important in animal welfare terms that a veterinary surgeon could be sure that the brand prescribed would be supplied and administered. To the extent that ‘equivalent’ was to be interpreted as meaning a product with an equivalent indication, the product could contain a different active ingredient, and could have different characteristics (route of administration, efficacy, safety profile). Implementation of the remedy would interfere with veterinary surgeons’ clinical judgement, whether the substitution was made by a pharmacist or another veterinary surgeon, and would thereby compromise animal welfare.

10.442. Merial believed that implementation of this remedy was likely to make animal record-keeping, product traceability and pharmacovigilance more difficult. Veterinary surgeons would not know which veterinary medicines had actually been dispensed against their prescriptions. Animal record-
keeping had been the subject of significant legislative change in recent years and the suggested remedy was likely to impede the monitoring process. Merial was concerned, therefore, that the remedy might act against the public interest.

10.443. Merial said that it would not be in its commercial interest (or indeed that of any manufacturer) to have one of its products dispensed by a pharmacist in circumstances where, in the informed opinion of a veterinary surgeon, an alternative competitor product would be more suitable and offer better value for money. This could undermine customer perception of Merial’s products and potentially lead to loss of sales in circumstances where its products did indeed represent the best value for money.

10.444. Merial concluded that there were potential risks to the public interest associated with the possible remedy. In addition, it said that there was considerable uncertainty as to whether it would have any significant impact on reducing barriers to pharmacies competing with veterinary surgeons. In its view, therefore, the remedy was both unnecessary and potentially detrimental to animal health. The same considerations would apply to an alternative hypothetical remedy that we discussed with Merial, which would require veterinary surgeons to specify one or more similar medicines when writing a prescription. Merial pointed out that this hypothetical remedy was not mentioned in the statement of 17 September.

Prohibition on manufacturers operating rebate schemes in which the level of rebates given on purchases for cat and dog vaccines is based on, or substantially influenced by, the combined value of purchases of these vaccines (paragraph 25)

10.445. Merial confirmed that it did not consider any complex monopoly situation existed, nor that any remedy was warranted.

Regulatory issues

10.446. Merial said that there were no particular regulatory barriers in the UK to the availability of veterinary medicines beyond those encountered in all EC member states. There were some similarities between the EC/UK and US regulatory requirements, and trends towards harmonization would be likely to bring them closer in future. Some fundamental differences did exist, but Merial commented that they had no specific implications for the UK business.

10.447. We invited Merial to consider the effect on its development costs of three different hypotheses: no external regulation of veterinary medicines anywhere in the world; mutual recognition by the EC of any US authorization; UK acceptance of EC central or national authorization without further regulatory requirements.

10.448. Merial said that it was not possible to estimate cost savings with any degree of accuracy. Even under the first hypothesis, significant R&D would still be necessary to ensure that products were of sufficient quality, safety and efficacy for Merial to meet its legal and other obligations to customers, animal welfare, the environment and the general public. It is possible that the amount of testing could be reduced and there would be some savings in management time and regulatory cost. Consequently, products might be brought to the market more rapidly than under a regulated regime, although Merial pointed out that early marketing would not necessarily lead to an increase in overall income, since the life cycle of the product would be brought forward rather than extended. Under the second hypothesis, full testing would be required for the USA. Any savings would relate only to additional testing required in the EC plus additional management time and regulatory costs. Under the third hypothesis, there would be some minor direct regulatory costs savings (less than £60,000 on the basis of 2001 costs), together with the cost of Merial’s annual fee to the VMD (£220,000). There would be little or no savings on R&D or time to market.

10.449. Merial’s comments on the regulatory issues set out in the statement of 16 April are recorded below.

Whether the current MRL requirements restrict competition in, and availability of, veterinary medicines, particularly for minor species (Issue II(i))

10.450. Merial said that the health and safety of consumers was of paramount importance, and this was best achieved through the MRL process. It welcomed the European Commission’s proposals to
extend the MRLs for 12 substances to all food species, and the proposal for two further MRLs with an all-food-species indication. It said that MRLs for all food species would both improve the availability of medicines for minor species and increase the number of products available in these areas of the market. The positive effect of these initiatives would be further enhanced if the requirements for obtaining MAs for minor species products were changed. For instance, despite the MRL extrapolation to minor species being possible under certain circumstances, the additional residue data package to be generated to obtain MA was still considerable. Merial thought that this situation was likely to continue to prevent companies from developing medicines for minor species.

Whether the inclusion of an efficacy test in the marketing authorisation procedure unnecessarily increases the barriers to introducing a veterinary medicine to the market (Issue I(ii))

10.451. In Merial’s view, testing for efficacy was essential, regardless of whether it made it more difficult for a manufacturer to introduce a veterinary medicine to the market. These medicines were powerful tools that had a benefit for the animal, but this had to be balanced by the regulatory process against the risks that might be associated with use. There was a case, however, for prudent relaxation of the efficacy requirements for minor species and minor indications where this would increase the availability of medicines.

Whether the lack of a prescription-only sub-classification for medicines that could be prescribed by a veterinary surgeon (for animals under his/her care) without prior clinical examination restricts competition (Issue I(iv))

10.452. Merial considered that the existing classification and distribution system in the UK worked well, and that there was no evidence to suggest that the lack of a sub-classification for medicines to be prescribed by a veterinary surgeon without prior clinical examination restricted competition.

Whether the length of time allowed to regulators to reach a decision on marketing authorisations is a barrier to introducing a new medicine (Issue I(v))

10.453. Merial agreed that delay to the commercialization of a product could be considered to operate as a barrier to entry. It would, therefore, favour a reduction in timetable consistent with a single, efficient, in-depth and thorough review of the product. It said that in a true mutual recognition system, it should not be necessary for CMSs to reassess the dossier and the RMS’s assessment report: it should be sufficient for the CMS to recognize the RMS’s evaluation of the quality, safety and efficacy of the product.

Whether the requirement that medicines on the Pharmacy and Merchants List (PMLs) may only be dispensed by veterinary surgeons, pharmacists, and Suitably Qualified Persons (SQPs) employed by agricultural merchants or saddlers restricts competition in the supply of PMLs (and hence of any POMs which may be reclassified as PMLs) (Issue I(vi))

10.454. Merial noted that PML veterinary medicines fell outside our terms of reference. It believed that this type of product should be provided only with advice from a suitably trained individual. Provided that such a suitable level of training (at least to SQP level) was required for sales persons in pet shops and other retail outlets, and that effective monitoring was put in place, Merial would have no objection to pet shops and other retail outlets selling companion-animal PMLs.

Whether the current arrangements which preclude SQPs from breaking bulk in supplying veterinary medicines places them at a competitive disadvantage to veterinary surgeons (Issue I(vii))

10.455. Merial said that SQPs should not be permitted to break bulk and repackage veterinary medicines. This was essentially a pharmaceutical act that required specialist knowledge, and care had to be taken over the storage, repackaging and labelling of the split medicines to avoid degradation and ensure the provision of product information and advice to the end-user. In Merial’s view, any potential change would need to maintain strict quality control of the dispensed product and appropriate provision of suitable product information and advice. This would require substantial training of persons who were going to undertake the task.
Whether the conditions under which the European centralised procedure is available could restrict competition, either by being too narrow, and therefore compelling companies to use the decentralised procedure even if this is a greater barrier to introducing the product to market, or by being too narrow, and so allowing companies to gain a POM classification for their products which cannot subsequently be revised to PML (Issue I(viii))

10.456. Merial said that it had successfully used both centralized and decentralized procedures in recent years, and supported the principle of free choice between the procedures. With regard to the reclassification of products authorized through the centralized procedure, Merial agreed that the practical implementation of the centralized procedure had resulted in less flexibility regarding the classification of veterinary medicines than was the case with either the mutual recognition procedure or the national procedure.

Possible recommendations for regulatory changes

10.457. Merial’s comments on the possible recommendations contained in our statement of provisional conclusions and hypothetical remedies are recorded below.

The Secretary of State to consider negotiating changes to the draft Directive (also proposed in COM (2001) 404 final) so as to legitimise cross-border trading, without a need for a further marketing authorization, of any veterinary medicine authorized through the decentralised procedure, between member states in which it is authorised, and to remove barriers to labelling in the appropriate language (Recommendation (2))

10.458. In Merial’s view the existing rules on parallel importing, which allowed for the importation of products licensed in both the UK and other member states, provided that English-language labelling was present, were straightforward and inexpensive and did not constitute a barrier to trade. Merial said that misuse of veterinary medicines could have serious consequences for the safety of the animal, the operator or the environment. In addition, the reputation of a brand and a manufacturer could be damaged if an adverse reaction followed non-compliant administration. Merial said that there was considerable emphasis on correct labelling in the risk/benefit analysis carried out by the regulatory authorities. The removal of a need for comprehensible labelling would not be consistent with the protection granted by the licensing process.

The Secretary of State to consider amending the remits of the Veterinary Products Committee and the Veterinary Medicines Directorate to preclude them from taking into consideration manufacturers’ views on the classification of a product for which they are seeking marketing authorization (Recommendation (3))

10.459. Merial said that the process for obtaining an MA depended on cooperation and dialogue between the regulatory authorities and the MA holder concerned. In Merial’s opinion it was not therefore reasonable for the manufacturer’s views to be excluded from consideration. The manufacturer had the most complete knowledge of the product, including all safety and efficacy aspects, and an appreciation as to how it was or might be used in different scenarios, and could therefore contribute to the regulatory authority’s understanding and assessment. An effective prohibition on taking manufacturers’ views into consideration would risk making the MA process less effective.

10.460. Merial commented that we had not provided evidence to show that any manufacturers had been able to influence the classification of a product to their commercial advantage. Merial also drew attention to comments by NOAH that changes in the legal classification of medicines would result in additional costs to companies which could potentially lead to the loss of products with small turnover.

10.461. Given these consequences, Merial said that the views of the manufacturers must be taken into account by the regulatory authority when classification, or a change of classification, was being considered. Merial had no objection to the views of other parties being taken into account as well, provided that classification was based on scientific and clinical evidence and not on commercial or political grounds.
The Secretary of State to consider negotiating changes to the proposed Directive to remove the ranking of cascade options in respect of non-food-producing animals so that, where circumstances allow recourse to cascade, a veterinary surgeon may use whichever option he considers best (Recommendation (18))

The Secretary of State to consider negotiating changes to the proposed Directive to allow recourse to the cascade in the case of non-food-producing animals, where, notwithstanding the existence of an authorized medicine for the species and condition in question, the veterinary surgeon having the animal under his care considers this justified on grounds of animal welfare including cases where the cost of treatment would otherwise cause the animal to go untreated (Recommendation (19))

10.462. Merial said that it supported the principle of the cascade in European legislation, but it was concerned that implementation of our proposal would allow veterinary surgeons, irrespective of the availability of appropriate licensed products, to prescribe medicines that had not been licensed for use on the particular species for the particular condition. This would be likely to undermine the licensing system for veterinary products. Merial believed that if these recommendations were adopted, the incentives for manufacturers to seek MA for any particular species and a particular condition would be reduced or eliminated. It also believed that giving the right to prescribe any option under the cascade would place an undue burden on the expertise of the individual veterinary surgeon in extrapolating from one species to another.

10.463. Merial noted that our reason for proposing relaxation of the cascade was the lack of availability of generic treatments in the veterinary medicines market. In Merial’s view, however, the proposed remedies would not result in the introduction of generic medicines to the market as there would be no incentive for manufacturers to produce them. Furthermore, relaxation in the application of the cascade might discourage manufacturers from investing in R&D to develop new products. This would lead to the use of increasing numbers of molecules that had not been tested fully on the particular species, so the proposal would not benefit animal health and welfare in the long term. For these reasons Merial considered that the recommendations would be detrimental to both the welfare of animals and the availability of veterinary medicines.

Norbrook Laboratories Ltd

10.464. Norbrook did not comment on the statement 17 September. Its views on issues raised in the statement of 16 April are recorded below.

Issues relating to manufacturers

Whether veterinary manufacturers tie in the sales of some or all products in their ranges with an anti-competitive effect (Issue II(i))

10.465. Norbrook understood from some of its veterinary customers that certain manufacturers ‘bundled’ products and applied additional discounts based upon total sales. This was particularly apparent where manufacturers had a unique or ‘must-have’ product in their portfolio and used those products to tie in sales of other products normally open to competition. However, it was often done in ways other than directly linking two products. For example, a manufacturer would offer a discount for a total purchase of £50,000, knowing that the veterinary practice concerned would need to buy, say, £40,000 of its main product. The practice would then have to buy £10,000 of the manufacturer’s other products in order to reach the target, even though it could buy similar products cheaper elsewhere. Some manufacturers’ discount schemes were based on preset overall targets; if these were missed, so was the retrospective discount. This was a disincentive to veterinary practices to source certain products from other manufacturers.

10.466. Norbrook said that it offered retrospective discounts to particular customers, with no cross-linkage of products. If competition was increasing or it otherwise wanted to offer a better price, it tended to increase the rebate rather than reduce the list price. Certain veterinary surgeons had a preference for this approach because they generated income by marking up against list price. Consequently, if list prices were to fall, so would their margin. Norbrook said that high list prices and large discounts, rather than net prices, also presented some advantages for the company in terms of cash flow, but that was offset by the
administrative costs incurred. Norbrook told us that the practice of high list prices and low net prices was primarily historic and new products that it had launched in recent years had been on the basis of lower competitive list prices with limited, or no, retrospective discounts.

**Whether veterinary manufacturers, via linked price promotions, use the existing market power of some products as a lever to gain share of other markets (Issue II(i)a)**

10.467. Norbrook said that some manufacturers offered linked price promotions that resulted in an overall reduction in competition. It had not itself undertaken linked price promotions.

**Whether veterinary manufacturers operate rebate schemes, which are a barrier to successful market entry, in that they encourage veterinary surgeons to buy more from larger veterinary manufacturers (Issue II(i)b)**

10.468. Norbrook said that its rebate schemes did not work by increasing discount in line with volume of purchases: the discount took effect at a constant level from the first unit purchased onwards. If a veterinary practice chose to buy a certain product from a competitor, this would not affect the discounts quoted on other Norbrook products. Under its scheme, rebates were calculated monthly and quarterly depending on throughput, they were not incremental by practice and the highest increment applied from unit 1 of purchase and did not change. Consequently, there was no need for retrospective application of rebates triggered by hitting incremental targets. Norbrook said that although target levels of purchases were agreed at the beginning of the period concerned, these were not contractual or enforced, ie there was no financial penalty if they were not met. Norbrook commented that veterinary surgeons’ purchasing decisions were driven first and foremost by considerations about clinical presentation and potential efficacy. Once the clinical position was established the veterinary surgeon would decide which product to buy on the basis of lowest cost or potential product mark-up.

10.469. We asked Norbrook whether its entry into markets had been influenced by the pricing mechanisms adopted by others. Norbrook said that it was hard to tell. It observed that most veterinary practices liked to deal with two or three different manufacturers. Norbrook had been successful with its recently-launched second-generation or generic products because they were priced competitively and offered quality and value. It said that the fact that certain pioneer companies did not always reduce price in order to compete made the Norbrook offering even stronger.

**Whether rebates have any other anti-competitive effect, apart from as a barrier to entry or expansion (Issue II(ii))**

**Whether veterinary manufacturers design their rebate schemes in such a way as to reduce price transparency (Issue II(ii)a)**

10.470. Norbrook told us that it would welcome and benefit from a system of greater transparency. Veterinary surgeons at present were often unclear about what they were paying for the products of other manufacturers and found it difficult to compare prices. Price transparency was not reduced by the Norbrook scheme, which was relatively simple and should enable the veterinary practice to calculate its ultimate buying price on each product line.

**Whether veterinary manufacturers’ rebate schemes are structured in such a way as to cause veterinary surgeons to charge higher prices than they would otherwise do (Issue II(ii)b)**

10.471. Norbrook said that undoubtedly in the past there had been an attraction for veterinary surgeons to purchase from companies with the highest list but lowest net selling prices. In the last two years Norbrook had launched a number of reasonably significant POM products into the Great Britain market. For each of these it had pursued a net-price-focused strategy, offering veterinary surgeons a clear transparent deal to make comparison as easy as possible. This consisted of:

— a list price at significant discounts to list prices of the market leading competitor(s);

— limited retrospective discounts to go from list price to ultimate buying price;

— opportunity for veterinary surgeons to maintain margin while passing on cost savings to consumers; and
— price unrelated to any other Norbrook business or discount.

Whether veterinary manufacturers who operate rebate schemes gain an informational advantage over those who do not, and whether this enables them to strengthen their position in the market in an anti-competitive way (Issue II(ii)c)

10.472. Norbrook said that any information accessed from either wholesalers or GfK came at a significant cost. This information was available to any manufacturer who paid the fee and was generally directly proportional to sales value and therefore comparatively cheaper for smaller manufacturers. Ex-wholesaler sales data was available to each manufacturer only about its own products and not those of competitors. It was difficult to see how access to this information could be used in an anti-competitive way. It was essential not only for operating discount schemes but to enable managers to make individual assessment of performance by territory.

Whether veterinary manufacturers with a large market share in particular veterinary medicine sub-markets carry out anti-competitive practices to maintain their position, and in particular: whether veterinary manufacturers engage in predatory pricing (Issue II(ii)d)

10.473. Norbrook was not aware of any examples of this happening in the UK. It said that large companies in particular were reluctant to let their prices drop too much, and that generally when prices were reduced it was difficult to increase them again.

Whether veterinary manufacturers promote brand loyalty to such an extent as to limit price competition and restrict market entry (Issue II(ii)e)

10.474. Norbrook said that it was normal commercial practice to use marketing activity to increase brand awareness. Most of its marketing budget was spent on branded advertising of POM and PML products in national magazines. It also used direct mail, conferences, exhibitions, product brochures and point-of-sale material to boost awareness and increase pull through. Norbrook undertook some limited direct client development through activities such as golf days and social evenings but this was an insignificant element of its overall sales and marketing focus and spend.

10.475. Veterinary manufacturers, like any patent holder, would use the period of patent protection to build brand loyalty. Norbrook said that, because of its focus on producing the first generic or first second generation products to enter the market it often had to try to overcome such brand loyalty. The patent protection had frequently run for so long that it could take new market entrants a considerable time to erode loyalty and get customers to switch. This was despite offering an equally effective product and the possibility of significantly lower buying prices.

10.476. Norbrook said that in growing its sales it had the advantage of good, modern facilities that reassured potential customers about the security of future supply of the product. The company was well known in Northern Ireland and the Republic of Ireland and benefited from customer loyalty, but it was more difficult to gain similar levels of market share elsewhere.

Whether veterinary manufacturers engage in anti-competitive market sharing, by jointly choosing not to launch or promote products that directly compete with those of other suppliers (Issue II(ii)f)

10.477. Norbrook stated that it had never engaged in any anti-competitive market sharing. It said that other reasons were more likely to explain limited competition in certain markets: patent issues, small markets for certain products or species and significant entry barriers.

Whether the manufacturers of veterinary medicines are protected by the provisions of the cascade from competition from substitutable human medicines, and whether they exploit this protection by charging higher prices than would otherwise be the case (Issue II(iii))

10.478. Norbrook pointed out that the cascade system was driven by clinical and ethical considerations rather than commercial objectives. It said that the reduction in the number of manufacturers in the animal health industry, particularly large-animal-based manufacturers, indicated that conditions were extremely competitive, the market was high risk and profits were not easily earned. Assuming that the ethical and safety considerations were resolved, opening the animal health market to human medicines not separately tested on animals might reduce the price of certain products. However, it could
also cause some manufacturers to decide that the return in the market was not worthwhile, which would ultimately reduce competition. It would also act as a further disincentive for manufacturers to invest in expensive research into new products, presentations, delivery methods and so on, as the commercial return was too low, too risky or non-existent.

**Whether veterinary manufacturers set the price or influence the retail mark-up on veterinary medicines, and in particular whether veterinary manufacturers, through published list prices, effectively set minimum resale prices (Issue II(iv))**

10.479. Norbrook emphasized that the seller of veterinary medicines set the ultimate selling price, not the manufacturer. The convention had been for veterinary surgeons to apply a mark-up to the published list price, the difference between this and the net buying price being a profit for the veterinary surgeon. Mark-ups could vary significantly between practices and, within practices, between different product categories. Norbrook described its own approach:

— Almost every one of its products had entered the market in competition with an established branded version that had often enjoyed significant patent protection. In order to win business it had to market products on the basis of existing list prices and net net prices and had had to be competitive in order to gain business.

— The POM products it had launched in the previous two years had lower list prices than the established competition, limited retrospective discounts and a lower net price to the veterinary surgeon. If, therefore, a veterinary surgeon applied a standard mark-up to the Norbrook list price, the consumer would pay less than for the competitor product.

— The difference between the list price and the ultimate buying price was only small. Consequently, the relevance of whether a veterinary surgeon’s selling price was driven by list or net price was significantly reduced. This also demonstrated that the percentage mark-up was not as important as the size of the mark-up in money terms. Norbrook added that certain veterinary practices did mark up off the net price and not the list price, so that merely comparing percentage mark-ups would be irrelevant.

**Whether veterinary manufacturers otherwise set, or influence, the price at which their products are resold (Issue II(v))**

10.480. Norbrook said that manufacturers did not directly determine veterinary surgeons’ retail prices. Unless manufacturers invested in a field-based sales force, veterinary surgeons were extremely unlikely to use their POM products, but resale prices were not a key element in the discussions that Norbrook’s territory managers had with the veterinary surgeons. Most recently-launched Norbrook POM products had lower retail prices and lower discounts, which it presumed should lead to lower prices to the consumer. Norbrook did not include prices in its advertising to consumers.

**Whether veterinary manufacturers request, or fail to initiate review of, classification of a medicine as prescription-only in cases where this is not necessary on grounds of safety (Issue II(vi))**

10.481. Norbrook generally launched products to compete with existing pioneer or first generation products. Its products generally had the same classification as the original. In terms of all the variables manufacturers might consider when marketing or attempting to commercialize a product, many issues were more important than product classification.

**Whether veterinary manufacturers encourage veterinary surgeons to buy certain prescription-only veterinary medicines by asserting that they will not be subject to reclassification (Issue II(vii))**

10.482. Norbrook said that this might be more relevant to manufacturers of medicines for companion animals where veterinary surgeons might be concerned that they would find themselves competing with high-street retailers on certain products if the classification were changed.

**Whether veterinary manufacturers charge differential prices to veterinary surgeons in such a way as to restrict competition (Issue II(viii))**

10.483. Norbrook told us that there was a significant level of price competition in the markets where its business was concentrated: products for food animals that were also available from alternative
suppliers. It had, therefore, to offer value. Although price was important, it was not the sole determinant of value, and other factors such as in-field support, product availability, packaging and delivery mechanisms, efficacy and ease of use could be just as important.

10.484. Norbrook said that although the ultimate buying price for certain products might vary from practice to practice, by and large there was a limited price range. There was bargaining power on both sides but in many of Norbrook’s product areas it had no exclusivity: there were plenty of other manufacturers with the same or similar offerings. The bargaining power might, therefore, actually be weighted towards the buyer.

**Whether veterinary manufacturers refuse to supply to certain intermediaries (wholesalers or retailers) or classes of intermediaries; supply certain intermediaries on less favourable terms than others; or fail to respond to requests for supply by certain intermediaries (Issue II(ix))**

10.485. To its knowledge, Norbrook had not refused to supply certain wholesalers or retailers. It might refer certain retailers to wholesalers (as opposed to offering direct terms) for logistical reasons.

10.486. Norbrook told us that it supplied pharmacies that were also animal health merchants, mainly with PML products. Other pharmacies had rarely requested supplies. When they did so, they might be offered the same terms as wholesalers, list price minus 15 per cent. Norbrook commented that it had a number of existing trading relationships across the country with long-standing customers for its POM products and it need to be mindful of these so that it treated all its customers equitably and appropriately. Norbrook did not think that pharmacies would be greatly interested in selling medicines for food animals, partly because of the size of some of the bulk packs they would have to stock.

**Issues relating to wholesalers**

**Whether veterinary wholesalers refuse to supply customers other than veterinary practices, universities and research establishments, and in particular refuse to supply pharmacies (Issue III(i))**

10.487. Norbrook was not aware of any circumstances where it had refused to supply or quote for business, except for credit control, logistical or product delivery reasons.

**Whether the provision of detailed sales information by veterinary wholesalers to veterinary manufacturers is detrimental to veterinary surgeries or consumers (Issue III(iii))**

10.488. Norbrook said that the only information it obtained from wholesalers related to its own products. It did not see how possessing that information could be anti-competitive.

**Issues relating to veterinary surgeons**

**Whether veterinary surgeons fail to inform animal owners of the option to have written prescriptions for veterinary medicines dispensed by a pharmacist (Issue IV(i))**

10.489. Norbrook said that most farmers were now aware that it was possible to obtain a prescription from their veterinary surgeon that could be dispensed elsewhere. This awareness had arisen because of the frequency of contact and the relationship between farmer and veterinary surgeon, and also because of the growth of Internet sales of veterinary medicines. Norbrook thought that owners of companion animals were less likely to know that they could request a prescription.

**Whether veterinary surgeons fail to provide itemised invoices showing a breakdown between the cost of professional fees and the cost of medicines dispensed (Issue IV(ii))**

10.490. Norbrook understood that it would now be very much the exception for farmers to be given an account that was not itemized.
Whether veterinary surgeons charge unreasonable sums for writing a prescription to be dispensed by a pharmacist (Issue IV(iii))

10.491. Norbrook thought that the process of writing a prescription represented more than a marginal administrative cost, given the clinical judgement and other elements it involved. Writing a prescription also placed a legal and professional responsibility on the clinician to ensure that the prescribed treatment was safe and appropriate.

Whether veterinary surgeons refuse to write prescriptions, or by some action or omission, discourage requests from animal owners for prescriptions (Issue IV(iv))

10.492. Norbrook said that the RCVS Guide to Professional Conduct made the responsibilities of veterinary surgeons clear. If, for instance, a veterinary surgeon required an additional consultation before issuing a repeat prescription that would not be required if the practice had dispensed the repeat medicine, he or she was potentially exposed to the College’s guidelines. This practice was unlikely to be commonplace. Farmers could be expected to look in the round at the overall service and product received from their veterinary practice. In Norbrook’s experience, most veterinary surgeons in large-animal or mixed practices were not motivated purely by financial gain: the vocational and job satisfaction aspects were also important. Nevertheless, given their position, experience and qualifications they should be reasonably rewarded. There was little evidence of them enjoying anything like monopoly profits. They worked long hours in difficult environments and often had to provide night cover.

Whether veterinary surgeons by some action or omission may have indicated to veterinary manufacturers and/or veterinary wholesalers that they should refuse to supply pharmacists, or supply them on less-favourable terms (Issue IV(v))

10.493. Norbrook stated that any request from pharmacists for prices of or access to its products had been facilitated.

Whether veterinary surgeons influence veterinary manufacturers not to reclassify prescription-only medicines to a lower classification (Issue IV(vi))

10.494. Norbrook was not aware of any approach by veterinary surgeons about product classification.

Whether veterinary surgeons set their charges for dispensing medicines in such a way that they subsidise their consultation fees (Issue IV(x))

10.495. Norbrook had found with a general acceptance among veterinary surgeons that, in many instances and over time, veterinary medicines were overpriced to offset the undercharge in fees. If this practice were changed in line with changes in other professions, for example accountants and solicitors, the price of drugs to clients might be reduced but the professional fees might increase. This would benefit clients who required limited clinical time but were heavy purchasers of product but it might increase charges for clients who required significant consultation time but few drugs.

10.496. There had already been a change in some large-animal practices, with veterinary surgeons now charging higher professional fees but applying a smaller mark-up on medicines.

Whether veterinary surgeons charge higher than necessary prices on prescription-only medicines (Issue IV(xi))

10.497. Referring to large-animal practices, Norbrook said that veterinary surgeons did not generally apply a flat rate mark-up across all products and services. Norbrook had pursued a net price pricing strategy for products launched in the previous two years. It hoped that as a result there would be an increase in margin for the veterinary practice and a saving for the consumer, although veterinary surgeons had the choice of whether to retain the margin.

10.498. Norbrook said that veterinary surgeons appeared to struggle to compete on non-POM products with trade outlets, which indicated that pricing was not working to their advantage. For PML products, Norbrook attempted to leave veterinary surgeons in a position to compete with the trade should they wish to do so.
10.499. Most veterinary practices that Norbrook worked with (large-animal or mixed) appeared to be commercially efficient despite limited training having been given to veterinary surgeons in the commercial aspects of running a practice. It commented that the farming sector was so tight and competitive that veterinary practices that were not well run were likely to go out of business.

10.500. Norbrook did not think that large-animal practices were making excessive profits at the expense of their customers. It commented that they were selling to an extremely depressed market that had suffered bovine spongiform encephalopathy (BSE), FMD, falling prices etc and could not deliver excess profits at this time.

Whether veterinary surgeons allow their purchasing and dispensing decisions to be influenced by rebates or discounts from veterinary manufacturers, in such a way as to restrict consumer choice or to increase prices to animal owners (Issue IV(xii))

10.501. Norbrook said that as a second-generation or generic manufacturer it entered markets with established players. The only way it could win business was by offering value, generating pull-through and meeting the needs of its customers.

Whether veterinary surgeons charge relatively higher prices in areas where there is less competition with other similar practices (Issue IV(xiv))

10.502. Norbrook said that there was certainly little competition between large-animal practices in certain geographical areas. This was because many veterinary surgeons had chosen to leave the profession or switch to small-animal practice because farm work was not considered attractive and the returns were low or non-existent.

Regulatory issues

Whether the current MRL requirements restrict competition in, and availability of, veterinary medicines, particularly for minor species (Issue I(i))

10.503. Norbrook said that a number of its products had been withdrawn simply as a result of MRL enforcement. Generally these were well-established products, which were comparatively inexpensive as there was significant competition. Customers were now buying more expensive alternative products instead.

Whether the inclusion of an efficacy test in the marketing authorisation procedure unnecessarily increases the barriers to introducing a veterinary medicine to the market (Issue I(ii))

10.504. Norbrook said that the retention of an efficacy test was clearly important if the product provider wished to make and support claims regarding efficacy, and was particularly important for POMs.

Whether the absence of provision for a third party to request reclassification of a veterinary medicine, or for regular review of classification, leads to an over-classification of veterinary medicines (Issue I(iii))

10.505. In Norbrook’s view, in order to create an open market, classification should be driven by the regulatory authority and the product, not by the applicant.

Whether the lack of a prescription-only sub-classification for medicines that could be prescribed by a veterinary surgeon (for animals under his/her care) without prior clinical examination restricts competition (Issue I(iv))

10.506. Norbrook said that with regard to large-animal practices it was debatable whether there was an excess cost that would be eliminated as a result of reclassification. It understood that if a veterinary surgeon was supplying a farmer with PML products such as anti-parasitic treatments, a separate visit, resulting in a separate fee, would not be necessary.
Whether the length of time allowed to regulators to reach a decision on marketing authorisations is a barrier to introducing a new medicine (Issue I(v))

10.507. In Norbrook’s opinion, the sooner competitive products were available, the better the prospect for increased competition and reduced prices. However, safety rather than speed was the primary driver for regulatory authorities, particularly in the UK.

Whether the requirement that PMLs may only be dispensed by veterinary surgeons, pharmacists, and SQPs employed by agricultural merchants or saddlers restricts competition in the supply of PMLs (and hence of any POMs which may be reclassified as PMLs) (Issue I(vi))

10.508. Assuming no change in product classification and provided those involved were suitably qualified and trained, Norbrook thought it would be only reasonable to extend the supply of PML products to those outlets. However, Norbrook referred to the debates in Europe, as a result of which the classification of products might be amended. Distribution might actually be narrowed if prescriptions were required for all items.

Whether the current arrangements which preclude SQPs from breaking bulk in supplying veterinary medicines places them at a competitive disadvantage to veterinary surgeons (Issue I(vii))

10.509. Norbrook said that it produced a number of sizes and presentations for its products, which were normally sufficient to meet customer and consumer needs. Pack splitting could be dangerous, particularly where individual items were not fully labelled.

Whether the potential for competition from extra-EU markets is prevented by the lack of mutual arrangements between the EU and other regulatory regimes (Issue I(ix))

10.510. Norbrook said that the UK and European standards were among the highest and most stringent. Mutual recognition should be encouraged provided it was on the basis of standards and requirements at least equivalent to those of the UK and EC.

Novartis Animal Health UK Ltd

Provisional complex monopoly situation—supply of POMs to animal owners

10.511. Novartis did not comment on our provisional finding of a single complex monopoly situation involving all parts of the supply chain (manufacturers, wholesalers and veterinary surgeons), the effect of which was felt at the retail level. It disputed, however, that it had pursued the conducts that we had identified in paragraph 9 of the statement of 17 September and it was not convinced that the conducts of manufacturers identified in paragraph 9 were present in quite the way that we had described. Novartis was, therefore, unable to say whether or not the complex monopoly situation operated in favour of manufacturers.

10.512. With regard to the conduct identified in paragraph 9(d) of the statement (refusal/failure of manufacturers to negotiate discounts and rebates with buying groups), Novartis said that it had no recollection of any buying group wanting to buy direct from it. Some buying groups had in the past asked Novartis to quote prices or to quote rebate levels that it was prepared to give them, but they had not wanted to change the business model: they had intended that the veterinary practices concerned would continue to buy from the veterinary wholesalers as usual. It did not appear that Vetcel or any other group had intended to buy direct or to enter into any commitment on volumes, but they wanted to take any discount available. Novartis said that in those circumstances it had declined to quote because it could not see any advantage to itself. It saw no obligation to give a better price to a buying group than to a veterinary wholesaler. If, however, a buying group were to open a direct account and trade with Novartis, then it could have the same price as the veterinary wholesalers had, subject to the minimum order requirement of £25,000 a year.

10.513. In response to specific complaints from buying groups, Novartis said that correspondence from Ciba-Geigy Agrochemicals, withdrawing terms from St Francis, dated from October 1991. The current business of Novartis was the result of a merger between Ciba-Geigy AG and Sandoz AG in 1997 and a merger with VHL in 2000. Novartis was therefore unable to comment on changes in business terms.
that had taken place in 1991. To its knowledge, St Francis had not subsequently approached Novartis. In its view it would be quite wrong to use the correspondence in question as evidence of any ongoing conduct in the market.

10.514. With regard to the complaint from Vetcel (see paragraph 11.428), Novartis said that Vetcel acted as an intermediary for a number of veterinary practices. It did not take delivery of products, which were delivered directly to the practices. It was Novartis’s understanding that Vetcel would have taken a commission from volume rebates paid by Novartis to the veterinary practices represented by the buying group. Novartis stated that it did not refuse to negotiate discounts and rebates with Vetcel. It had refused to quote for inclusion on the Vetcel price list. At no time did Vetcel wish to be supplied with the product itself. If it had wished to take delivery of the product then Novartis would have considered the request according to its normal terms and considered any discounts and rebates, but Vetcel did not request supplies. Vetcel had threatened to organize a boycott of Novartis products by the veterinary practices it represented. In fact, as far as Novartis was aware, those practices continued to take its products from wholesalers. It did not believe that the relevant practices received a worse price from wholesalers than they would have received from Vetcel.

10.515. Regarding the eligibility of buying groups to join its Premier Partner Group (PPG), Novartis said that in practice buying groups did not play a major role in the market and had not sought to join the PPG. They would not be suitable for inclusion because the benefit of the PPG to Novartis was the enhanced access it offered to decision-makers within larger veterinary practices, whom sales representatives might not otherwise be able to meet.

10.516. With regard to the conduct identified in paragraph 9(e) of the statement (operation by manufacturers of rebate schemes that make it difficult for veterinary surgeons to ascertain with certainty at the time of purchase the cost to themselves of POMs supplied to them), Novartis said that its PPG scheme, which gave a guaranteed 5 per cent rebate to its top 200 customers, was straightforward and transparent. While it was true that some of the schemes of other manufacturers were more complex, Novartis thought that most veterinary surgeons would nevertheless be clear about the purchase cost to themselves of POMs. It accepted, however, that in many cases it would be easier for them to set their retail prices by referring to the list price rather than to reprice their medicines each month according to the rebate they believed they were going to get. Novartis suggested that the end-price to the consumer was driven by the veterinary practice’s decision as to the mark-up it was going to apply rather than by the transparency or lack of transparency in the price paid by the practice itself.

10.517. As for the conduct identified in paragraph 9(f) of the statement (failure of manufacturers to supply pharmacies with POMs and/or enable pharmacies to obtain supplies of POMs on terms that enable them to compete with veterinary surgeons), Novartis said that it had never refused to supply a pharmacy with its products where that pharmacy could meet the requirements for a direct account, ie a minimum order of £25,000 a year. Where a pharmacy or any other customer could not meet those requirements, Novartis would advise it to buy products through wholesalers, in the same way that veterinary surgeons acquired their supplies. In general, Novartis had found that pharmacies were unlikely to have the facilities or desire to stock veterinary POMs. They would instead request delivery of small quantities of specific POMs when presented with a prescription. It would be extremely inefficient for Novartis to supply pharmacies or any other customer with such small quantities and it would therefore advise them all to buy from wholesalers. Novartis commented that pharmacies could, presumably, also ask the wholesalers of human medicines to supply them with veterinary POMs, although it was not aware that any had used that route. It had never instructed wholesalers not to supply its products to pharmacies. In its view, it was not reasonable to conclude that the conduct in question could be said to prevent, restrict or distort competition, given that there was no genuine demand by pharmacies for supply of veterinary POMs.

10.518. Commenting on a complaint we had received from R M Jones, a pharmacy, that Novartis had not replied to a letter dated 1 November 2001 enquiring about supply of POMs, Novartis said that although it did not reply in writing, the enquiry was dealt with by telephone. It was Novartis’s recollection that R M Jones did not specifically request supply of a POM, but only discussed the matter in principle. Novartis confirmed that it would not refuse to supply this pharmacy with veterinary POMs, subject to minimum order requirements.

10.519. Novartis said that it had in the past agreed to supply Laycock’s, a second pharmacy that complained to us about difficulties with obtaining POMs, with an order of POMs after the pharmacist
had received a prescription for the product, but the order was withdrawn by the pharmacy. Since then Novartis had received no further orders for POM products from this pharmacy. Novartis stated that it had never refused to supply a pharmacy with POMs where requirements were met for a direct account.

10.520. Novartis told us that it would be willing to supply POMs to wholesalers other than the five veterinary wholesalers provided that they met the minimal order requirement, but so far none had ever requested supply or asked about terms.

10.521. Novartis confirmed that it was a common practice for manufacturers and wholesalers to offer introductory deals to new veterinary practices. Such deals were an insignificant part of its business and were left to the discretion of the sales representatives, who might, for example, offer free product to the value of about £[

10.522. Commenting on the availability of discounts and rebates to pharmacy customers, Novartis said that pharmacies would not meet the criteria for its PPG scheme, the purpose of which was to provide access to, and means of influencing, veterinary practices. Giving the same benefits to pharmacies would not help Novartis to sell more of its products, since, even if they became more involved in the supply of POMs, the prescribing veterinary surgeons would still be the decision-takers.

Other issues

10.523. Novartis’s comments on other matters contained in the statement of 16 April are recorded below.

Whether veterinary manufacturers tie in the sales of some or all products in their ranges with an anti-competitive effect (Issue II(i))

10.524. For the purposes of commenting on this issue, Novartis assumed that we meant by ‘tie-in sales’ the situation where a supplier of a product stipulated that a customer must also buy from that supplier part or all of his requirements for a second product (pure bundling). In other words the tied products would not be offered on a stand-alone basis. Novartis said that it did not tie in sales of its POMs in this way and was not aware of any other manufacturer doing so.

10.525. The issues statement also referred to ‘mixed bundling’, where the products remained available on a stand-alone basis but were also offered as a package on discounted terms, for example in the form of linked promotions or cross-product rebates. Novartis said that it did not carry out mixed bundling of its POMs. The rebate schemes involved no element of tying between specific products or groups of products and the amount of discount was small. Other manufacturers did, however, operate mixed bundling schemes.

Whether veterinary manufacturers, via linked price promotions, use the existing market power of some products as a lever to gain share of other markets (Issue II(ii)a)

10.526. Novartis told us that it did not offer linked price promotions.

Whether veterinary manufacturers operate rebate schemes which are a barrier to successful market entry, in that they encourage veterinary surgeons to buy more from larger veterinary manufacturers (Issue II(ii)b)

10.527. Novartis said that most or all of the veterinary manufacturers operated rebate schemes across some or all of their product ranges in response to competitive pressures. Novartis said it did not consider that its rebate scheme was a barrier to successful market entry, because the level of rebates offered was low, particularly in comparison with rebates offered by some manufacturers, and the scheme did not include any dominant products. Its purpose was to try to keep business with larger veterinary practices in the face of competition from other manufacturers.
Whether veterinary manufacturers design their rebate schemes in such a way as to reduce price transparency (Issue II(ii)a)

10.528. Novartis said that it did not believe that veterinary manufacturers designed their rebate schemes for POMs in such a way as to reduce price transparency. In fact, sales representatives of manufacturers typically told veterinary surgeons the prices available to them under the rebate scheme and competed to offer them the cheapest price.

Whether veterinary manufacturers’ rebate schemes are structured in such a way as to cause veterinary surgeons to charge higher prices than they would otherwise do (Issue II(ii)b)

10.529. Novartis said that it did not believe that veterinary manufacturers designed their rebate schemes for POMs in such a way as to cause veterinary surgeons to charge higher prices than they would otherwise do. In fact, sales representatives of manufacturers typically told veterinary surgeons the prices available to them under the rebate scheme and competed to offer them the cheapest price.

Whether veterinary manufacturers who operate rebate schemes gain an informational advantage over those who do not, and whether this enables them to strengthen their position in the market in an anti-competitive way (Issue II(ii)c)

10.530. Novartis said that it exercised no control over veterinary surgeons, the prices they charged to end-users, nor the extent to which they passed rebates on to their customers. It believed that veterinary surgeons typically calculated the price to the consumer on the basis of the suggested professional price and so did not pass on any rebate, even where it was guaranteed.

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Whether veterinary manufacturers with a large market share in particular veterinary medicine sub-markets carry out anti-competitive practices to maintain their position, and in particular: whether veterinary manufacturers engage in predatory pricing (Issue II(ii)d)

10.531. Novartis stated that it did not operate any anti-competitive practices to maintain its position and did not engage in predatory pricing.

Whether veterinary manufacturers promote brand loyalty to such an extent as to limit price competition and restrict market entry (Issue II(ii)e)

10.532. Novartis commented that branding was important to veterinary surgeons and consumers, because they needed to be able to rely on a product. This was particularly so for farmers and veterinary surgeons, who used veterinary medicines to maintain their livelihood. Novartis did not believe that manufacturers promoted brand loyalty to such an extent as to limit price competition and restrict market entry.

Whether veterinary manufacturers engage in anti-competitive market sharing, by jointly choosing not to launch or promote products that directly compete with those of other suppliers (Issue II(ii)f)

10.533. Novartis said that it did not engage in anti-competitive market sharing and was not aware of such activity being carried on by other manufacturers.

Whether the manufacturers of veterinary medicines are protected by the provisions of the cascade from competition from substitutable human medicines, and whether they exploit this protection by charging higher prices than would otherwise be the case (Issue II(iii))

10.534. In Novartis’s view, while the cascade might to some extent protect some products from competition, overall it worked in the public interest because it encouraged innovation in the form of development of treatments and appropriate dose rates for minor species. This would be unlikely to happen in the absence of the cascade. Novartis did not believe that veterinary manufacturers exploited the cascade. It pointed out that the Government’s interim response to the Marsh recommendations supported the maintenance of the cascade because of the importance of having products authorized for the species in which they were used.
Whether veterinary manufacturers set the price or influence the retail mark-up on veterinary medicines, and in particular whether veterinary manufacturers, through published list prices, effectively set minimum resale prices (Issue II(iv))

Whether veterinary manufacturers otherwise set, or influence, the price at which their products are resold (Issue II(v))

10.535. Novartis said that it did not set the price or influence the mark-up on its veterinary medicines or otherwise set minimum resale prices. It sold to veterinary wholesalers at a wholesaler price and published a suggested professional price. A veterinary wholesaler selling at the suggested price would make a 15 per cent margin, but wholesalers almost invariably discounted from the suggested price. Veterinary practices were free to set their own resale prices. Typically, they chose to sell at a mark-up from the suggested professional price. Novartis believed that the level of this mark-up was usually about 50 per cent. It understood that a practice typically bought from the veterinary wholesaler at a discount of 12 per cent from the suggested professional price and also received rebates direct from the veterinary manufacturer. It did not believe that these rebates were normally reflected in prices to consumers.

10.536. In Novartis’s opinion, the publication of the suggested professional price was beneficial in so far as it acted as a reference point against which its sales representatives could offer discounts and rebates to veterinary practices. (It did not know the actual prices charged to individual practices by veterinary wholesalers and so could not offer rebates based on actual prices.) In addition the suggested professional price acted as an upper limit: without it, veterinary wholesalers would possibly charge more, particularly for small products where practices would be unlikely to carry out price comparisons.

Whether veterinary manufacturers request, or fail to initiate review of, classification of a medicine as prescription-only in cases where this is not necessary on grounds of safety (Issue II(vi))

10.537. Novartis told us that its policy on classification was based on an assessment of each medicine on an individual basis, including consideration of the most effective routes to market given the positioning of the Novartis sales force. It would prefer companion-animal products to be classified as POMs for the following reasons:

— its companion-animal sales force was focused on veterinary surgeons and it would need to sell PML companion animal products through someone else, resulting in increased costs; and

— its companion-animal products were more likely to be used safely and properly if distributed through veterinary surgeons.

10.538. Novartis did not believe that its approach to classification had any adverse effect on competition or the public interest. It stated that its approach with regard to particular products was not materially influenced by classification of competing products.

Whether veterinary manufacturers encourage veterinary surgeons to buy certain prescription-only veterinary medicines by asserting that they will not be subject to reclassification (Issue II(vii))

10.539. In Novartis’s experience, veterinary surgeons were reluctant to sell products that they thought might be reclassified PML. They frequently asked, when a product was launched, whether there was an intention to reclassify. Novartis told us that it had often stated, on launch of companion-animal products, that it did not intend to reclassify. In the case of one product, Clik (a farm-animal product), it had stated that the POM classification would be reviewed after a year. Sales through veterinary surgeons were disappointing. The product had since been reclassified PML and was selling well.

Whether veterinary manufacturers charge differential prices to veterinary surgeons in such a way as to restrict competition (Issue II(viii))

10.540. Novartis did not consider that its pricing policy restricted competition, in particular because rebates or discounts were offered in response to pressure from the customer and/or threats to take business elsewhere.
Whether veterinary manufacturers refuse to supply to certain intermediaries (wholesalers or retailers) or classes of intermediaries: supply certain intermediaries on less favourable terms than others: or fail to respond to requests for supply by certain intermediaries (Issue II(ix))

10.541. Novartis said that its entire range was available to all veterinary wholesalers and any retailers who purchased through the wholesalers.

Whether veterinary wholesalers refuse to supply customers other than veterinary practices, universities and research establishments, and in particular refuse to supply pharmacies (Issue III(i))

10.542. Novartis said that it did not prevent or discourage veterinary wholesalers from supplying any customer.

Whether the provision of detailed sales information by veterinary wholesalers to veterinary manufacturers is detrimental to veterinary surgeries or consumers (Issue III(iii))

10.543. Novartis stated that it adhered to the provisions of the Data Protection Act 1998, which protected veterinary surgeries against the misuse of information relating to them. Detailed sales information was used to calculate rebates due and was therefore not detrimental to veterinary practices. The sales information also assisted Novartis in targeting its sales effort and so contributed to an efficient sales and marketing effort.

Whether veterinary surgeons allow their purchasing and dispensing decisions to be influenced by rebates or discounts from veterinary manufacturers, in such a way as to restrict consumer choice or to increase prices to animal owners (Issue iv(xiii))

10.544. Novartis said that it came under pressure to offer rebates to some veterinary practices that threatened to cease or reduce prescriptions of Novartis products. In addition, some pig and poultry veterinary practices demanded ‘scrip fees’ in return for prescribing particular generic products. The scrip fees could be up to 10 per cent of sales.

Possible remedies

10.545. Novartis’s views on certain of the possible remedies listed in the statement of 17 September are recorded below.

A requirement for veterinary surgeons to provide on request prescriptions for POMs whose use they have recommended (paragraph 34(a)(iv) of the statement)

10.546. Novartis believed that this remedy was already included in the RCVS Guide to Professional Conduct and was therefore unnecessary.

A requirement for veterinary surgeons when quoting the price at which they will dispense any POM also to state the cost of that POM to themselves (paragraph 24(b)(iv))

10.547. In Novartis’s view, this was not an appropriate remedy. It commented that no other retail business was required to state the prices at which it bought goods, and it would be unfair to place this requirement on veterinary surgeons. Furthermore, it would be likely to mislead the consumer, who might assume that the difference between the two figures represented pure profit. It was also not clear how such a proposal would take account of rebates or other benefits received from the supplier.

A requirement for manufacturers of POMs giving rebates to veterinary surgeons to provide sufficient information, either directly or through wholesalers, so as to enable the veterinary surgeon to ascertain with certainty the cost net of rebates of POMs supplied to them (paragraph 23(b)(v))

10.548. Novartis believed that veterinary surgeons could ascertain the net prices of its products. It said that if we intended to recommend a remedy to increase transparency of rebate schemes then it should be proportionate to the perceived problem. It considered that the veterinary surgeon was already the person best placed to calculate the cost of POMs, since only he or she would know what deal had been struck with the manufacturer and wholesaler. To impose obligations on all manufacturers or
wholesalers to make information public or set out rebate schemes in a prescribed way would be disproportionate and could be positively harmful in that it might result in an alignment of pricing policies between manufacturers. Novartis noted that we had alluded to perceived problems with particular types of rebate scheme: a proportionate remedy would be to address the problems of those schemes rather than impose a remedy that would affect transparent schemes as well. A ‘light touch’ remedy might require manufacturers to respond to reasonable requests from individual veterinary surgeons for more transparent information on individual rebates. Novartis thought that this would be the least intrusive remedy and would also be relatively easy to enforce as the OFT would have to respond to specific complaints rather than monitoring the entire market.

**A requirement for manufacturers and wholesalers that supply POMs in the UK to supply pharmacies (paragraph 24(c)(i))**

10.549. Novartis stated that it was willing to supply pharmacists on the same terms as it supplied veterinary surgeons. Its opinion was that any remedy should not require a manufacturer to supply any prospective customer who did not meet the manufacturers’ reasonable terms for a direct account. Novartis had, in 2000, implemented a policy decision to reduce the number of direct accounts in favour of supply through veterinary wholesalers. The reasons for this were the enhanced service levels that wholesalers were able to offer and the lack of sufficient resources after Novartis acquired VHL to service a large number of direct accounts. Only one veterinary practice was still supplied direct by Novartis as it was a large purchaser that met the volume requirements for a direct account.

10.550. Novartis said that it would be inefficient for it to supply small quantities of products to numerous customers when such products were available from veterinary wholesalers at better service levels and on better terms. It had not asked any veterinary wholesaler not to supply pharmacies. Direct supply would entail an additional delivery charge to cover invoicing and delivery costs, and additional staff costs for Novartis.

**A requirement for manufacturers and wholesalers that supply POMs in the UK to supply pharmacies on terms that enable them to compete with veterinary surgeons (paragraph 24(c)(ii))**

10.551. Novartis would strongly oppose any remedy that might require it to supply pharmacies on more favourable terms than veterinary surgeons, since this would distort competition and weaken the competitive position of veterinary surgeons through whom Novartis sold the majority of its POMs.

10.552. Novartis said that the criteria for membership of its PPG would probably preclude membership by pharmacies, which would be unlikely to achieve sufficient purchasing volumes to be eligible and so would be offered the same prices as the vast majority of veterinary surgeons, who were not PPG members. Moreover, pharmacies would not fit easily into the PPG model, whose purpose was to give Novartis access to decision-makers in large veterinary practices.

10.553. Novartis suggested that if pharmacies genuinely wanted to sell veterinary POMs, they could obtain supply and negotiate advantageous terms outside the PPG. For example, pharmacies that were major customers for PML medicines could leverage their buying power in that market into the purchase of POMs. Veterinary surgeons would not generally have that advantage. Other pharmacies that bought human pharmaceuticals from Novartis could similarly leverage their position in that area into the purchasing of veterinary POMs. The fact that pharmacies had failed to do this could not be attributed to a failure by Novartis to supply a non-existent demand.

**A requirement for veterinary surgeons to display the name, postal address, telephone number and website address of any pharmacy supplying veterinary medicines that so requests (paragraph 24(c)(iii))**

10.554. Novartis did not consider that this remedy was necessary or appropriate. It said that it was for pharmacies to publicize their own services and there were no restrictions to prevent them from advertising. If veterinary surgeons were required to display such information, pharmacies should be required to do the same for veterinary surgeons and other pharmacies.

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A requirement for veterinary surgeons when they write prescriptions for POMs to do so on an ‘or equivalent’ basis to enable those dispensing such prescriptions to supply alternative authorised veterinary medicines to the brand specified (paragraph 24(c)(iv))

10.555. Novartis was strongly opposed to this remedy, believing it to be inappropriate for medicinal products. It said that there were very few true approved veterinary generics, so the opportunities for supplying alternatives were limited. It believed that the veterinary surgeon was best placed to decide what was best suited to the animal under treatment, and that allowing switching could lead to misuse of drugs since products that appeared identical might have important differences, for example in terms of withdrawal times. For example, Novartis marketed Aurogran, the active ingredient of which was chlorotetracycline 100g/kg, which was also the basis for competing products. If a prescription for chlorotetracycline were written on an ‘or equivalent’ basis, the customer could be prescribed and advised on Aurogran 100g, but given either Aurogran 100g (which had a withdrawal time of three days for chickens and seven days for pigs) or a competing brand, Aurofac 100g (also containing chlorotetracycline 100g/kg), which had a withdrawal time of one day for chickens and ten days for pigs.

10.556. Novartis said it appeared that we had in mind ‘or substitute’ prescribing, i.e. that a veterinary surgeon would be able to write on a prescription not only the product he or she wished to prescribe but also substitute products whether or not they contained the same active ingredient or worked in the same way. Novartis believed that a remedy on those lines would be against the public interest. It said that the veterinary surgeon’s prescribing decision was based on a professional opinion as to the most effective and suitable treatment for the animal concerned, and discussion with its owner. If the veterinary surgeon were required to specify alternatives, then his or her role would be largely redundant, because the actual choice of medicine would be determined by what the pharmacy had in stock and at what price. In Novartis’s view, a purchasing decision taken by reference to price would negate the whole purpose of the POM classification. In addition, such a remedy would be impractical and impossible to police because the OFT could not be expected to monitor the prescriptions written by several thousand veterinary surgeons.

Prohibition on manufacturers operating rebate schemes in which the level of rebates given on purchases of cat and dog vaccines is based on, or substantially influenced by, the combined value of purchases of those vaccines (paragraph 25)

10.557. Novartis said that this remedy would not adequately tackle the problem of manufacturers’ bundling. In particular, it did not address rebate schemes that awarded rebates on the basis of the combined value of dog or cat vaccines with other products in the manufacturer’s range; a practice that distorted competition and placed those manufacturers without a vaccine product at an unfair disadvantage.

Regulatory issues

10.558. Commenting on the regulatory regime in the UK, Novartis said that there had been examples of ‘gold plating’ by the VMD. The clearest example was in the mutual recognition procedure, with the UK acting as CMS. Figures compiled by FEDESA and the Veterinary Mutual Recognition Facilitation (VMRF) Group showed that the UK (jointly with the Republic of Ireland) asked the second highest number of questions on the dossier submitted by the applicant, with an average of 18 questions per procedure in 2001. The FEDESA/VMRF survey also showed that the UK had a high percentage of withdrawals when used as a CMS, the most likely reason being differences in interpretations of guidelines.

10.559. Novartis suggested that the widely-held belief in the industry that the VMD ‘gold-plated’ the regulations might be why the UK was so often chosen as the rapporteur under the decentralized procedure. The perception in the industry was that once approval was granted in the UK the mutual recognition procedure would be easier because there were few questions left that could be asked by other member states.

10.560. Novartis had a specific concern relating to the data requirements and time taken to obtain an Animal Test Certificate in the UK. The system in the UK was one of the most rigorous in the EC, particularly in comparison with major competitors in research such as France and Germany. Novartis believed that the burdensome requirements in the UK were driving away research.
10.561. At our request, Novartis estimated the extra costs of regulation (including the time factor) that would be avoided if: there were no specific regulation of veterinary medicines anywhere in the world; there was no regulation in the EC and, instead, member states accepted every authorization granted in the USA; and there was no regulation in the UK and any EC central or national authorization was accepted. Novartis said that its estimates were highly speculative. Under the first hypothesis, it estimated that it would save four to five years of development and £10 million to £15 million for a farm-animal product and three to four years of development and £5 million to £10 million for a companion-animal product. Under the second hypothesis there would be likely to be shortages of medicines in key areas, for example medicines for sheep, where there were few authorized products in the USA. Cost savings would be likely to be less than £1 million, and timing would be likely to be unaffected. Under the third hypothesis, shortages of medicines could also arise in key areas. There might be savings of around £100,000 in the provision of data and time savings of approximately one year in bringing a product to market.

10.562. Novartis’s views on regulatory matters set out in the statement of 16 April are recorded below.

**Whether the current MRL requirements restrict competition in, and availability of, veterinary medicines, particularly for minor species (Issue I(i))**

10.563. Novartis considered that the current MRL requirements restricted availability of veterinary medicines for minor species.

**Whether the inclusion of an efficacy test in the marketing authorisation procedure unnecessarily increases the barriers to introducing a veterinary medicine to the market (Issue I(ii))**

10.564. Novartis did not consider that the inclusion of an efficacy test was a barrier to entry.

**Whether the absence of provision for a third party to request reclassification of a veterinary medicine, or for regular review of classification, leads to an over-classification of veterinary medicines (Issue I(iii))**

10.565. Novartis believed that the absence of provision for third party requests for reclassification or for regular review of classification did not lead to over-classification. In its view, it was not appropriate to make such generalizations. Instead, products should be assessed on a case-by-case basis taking account of all relevant factors, including animal health, safety, quality and efficacy.

10.566. Novartis said that if we were minded to recommend more regular review, the best approach would be to allow the regulatory authorities to review the classification of the product simultaneously with the five-yearly review of the MA. In the event that a medicine was likely to be reclassified, it would be appropriate for the classification of all medicines in that category to be reviewed at the same time to avoid any distortion of competition arising from one product being available OTC whilst competing products in the same category remained POM. This solution would achieve a regular review of products without adding unnecessarily to the regulatory costs of MA holders.

10.567. Novartis suggested that third party requests could be heard in the context of the five-yearly review. It believed that it would be inappropriate and disproportionate to carry out ad-hoc reviews in response to third party requests since this would add to the regulatory costs of MA holders with no real benefit. Wider third party intervention would be inappropriate because:

- Third parties did not have the relevant data on safety in use, toxicology etc and so might make requests which could never be granted, for example in relation to medicines containing antibiotics.
- Third party requests would give rise to significant and unnecessary regulatory review potentially overloading the system and increasing regulatory costs.
- It would be impossible to reclassify in this way products that had been centrally approved.
- Third parties might be tempted to abuse the system by making frivolous or vexatious requests.
Whether the lack of a prescription-only sub-classification for medicines that could be prescribed by a veterinary surgeon (for animals under his/her care) without prior clinical examination restricts competition (Issue I(iv))

10.568. Novartis said that the lack of such a sub-classification might in theory restrict competition, although it was hard to imagine that a veterinary surgeon would be able to prescribe medicines for an animal properly under his or her care without having conducted a reasonably recent clinical examination.

Whether the length of time allowed to regulators to reach a decision on marketing authorisation is a barrier to introducing a new medicine (Issue I(v))

10.569. Novartis did not consider that the time allowed to regulators was an absolute barrier to introduction of a new medicine. However, the regulatory process did delay new medicines reaching the market and Novartis would welcome a remedy that speeded up the regulatory process for both old and new products.

Whether the requirement that medicines on the Pharmacy and Merchants List (PMLs) may only be dispensed by veterinary surgeons, pharmacists, and Suitably Qualified Persons (SQPs) employed by agricultural merchants or saddlers restricts competition in the supply of PMLs (and hence of any POMs which may be reclassified as PMLs) (Issue I(vi))

10.570. Novartis said that this issue was outside our terms of reference. In any event, it did not consider that the requirement restricted competition to any material extent since many supermarkets had in-store pharmacies and already employed SQPs. In most cases there were appropriate medicines classified as GSL that could be sold without SQPs.

Whether the current arrangements which preclude SQPs from breaking bulk in supplying veterinary medicines places them at a competitive disadvantage to veterinary surgeons (Issue I(vii))

10.571. Novartis said that this too fell outside our terms of reference. It did not believe that current arrangements placed SQPs at any material competitive disadvantage because POM veterinary products were increasingly supplied in single-animal packs. Very few veterinary surgeons had any need to break bulk except on a small range of POM products that were mostly antibiotics, and that were therefore unlikely to be classified as PML.

Whether the conditions under which the European centralised procedure is available could restrict competition, either: by being too narrow, and therefore compelling companies to use the decentralised procedure even if this is a greater barrier to introducing the product to market, or by being too narrow, and so allowing companies to gain a POM classification for their products which cannot subsequently be revised to PML (Issue I(viii))

10.572. Novartis believed that competition could be restricted for the reasons given.

Whether the potential for competition from extra-EU markets is prevented by the lack of mutual arrangements between the EU and other regulatory regimes (Issue I(ix))

10.573. Novartis said that the lack of mutual recognition of approvals from certain extra-EC markets (for example, the USA) restricted the potential for competition.

Possible recommendations for regulatory changes

10.574. Novartis said that it supported recommendations 6, 7, 8, 13, 14, 17 and 20 in the statement of 17 September. Its comments on other of the possible recommendations are recorded below.

The Secretary of State to consider amending the remits of the Veterinary Products Committee and the Veterinary Medicines Directorate to preclude them from taking into consideration manufacturers’ views on the classification of a product for which they are seeking marketing authorisation (Recommendation (3))

10.575. Novartis did not believe that this recommendation was appropriate. If manufacturers’ views on classification were not taken into account they would have less incentive to launch products in the...
UK. For example, Novartis had in the past successfully sought a PML classification for products that would normally have been automatically classified as POM. Implementation of this recommendation would preclude the valid and relevant input of the manufacturer.

The Secretary of State and the Veterinary Medicines Directorate to consider instituting automatic review of classification whenever a product’s marketing authorisation is renewed (or at similar intervals if the European Commission’s proposal to make marketing authorisations permanent is adopted) and to base such reviews exclusively on the product’s existing dossier and accumulated field experience unless there is good scientific reason to require fresh testing to be carried out (Recommendation (4))

10.576. If such a recommendation were adopted, Novartis considered that manufacturers should have the right to appeal against any change in classification following a review by the VMD. That would help to ensure that the VMD had considered all aspects. Novartis also considered that manufacturers should be allowed to request a review at any time.

The Secretary of State to consider widening the remits of the Veterinary Products Committee and Veterinary Medicines Directorate to take into account the welfare of animals overall (Recommendation (5))

10.577. Novartis believed that the VPC and the VMD already took account of the welfare of animals overall.

The Secretary of State to consider establishing one or more new classifications of veterinary medicines to allow specific categories of persons (such as agricultural merchants and saddlers as well as veterinary surgeons and pharmacists) to dispense veterinary prescriptions for medicines so classified and to make corresponding changes to the law governing the dispensing of prescriptions (Recommendation (9))

10.578. In Novartis’s view, the current classification system for veterinary medicines worked well. It would, however, support reclassification to preserve existing distribution channels if the European Commission’s proposal to classify all farm-animal medicines as POM were to be adopted.

The Veterinary Medicines Directorate to consider offering applicants for marketing authorisation the option of submitting their dossier in stages (Recommendation (15))

10.579. Novartis said that it would support such a recommendation if the VMD were prevented from ‘clock-stopping’ whereby they refused to assess any part of the submission until a specific question was answered.

The Secretary of State to consider negotiating changes to the proposed Directive to remove the ranking of cascade options in respect of non food-producing animals so that, where circumstances allow recourse to cascade, a veterinary surgeon may use whichever option he considers best (Recommendation (18))

10.580. Novartis opposed this recommendation. It said that it believed the European Commission was committed to the cascade system in its current form. Novartis was also of the view that changes to the cascade would reduce manufacturers’ incentives to invest in products for minor species and so would reduce availability of species-specific products. It doubted whether veterinary surgeons had enough detailed information to make decisions on the most appropriate product using the cascade, and said it would not necessarily follow that they would select cheaper generic products and pass on the savings.

The Secretary of State to consider negotiating changes to the proposed Directive to allow recourse to the cascade in the case of non food-producing animals where, notwithstanding the existence of an authorised medicine for the species and condition in question, the veterinary surgeon having the animal under his care considers this justified on grounds of animal welfare including cases where the cost of treatment would otherwise cause the animal to go untreated (Recommendation (19))

10.581. Novartis said that this option had already been considered and rejected by the European Commission.
Pfizer Ltd

Provisional complex monopoly situation—supply of POMs to animal owners

10.582. Commenting on our provisional conclusion that a number of conduct engaged in separately by manufacturers, wholesalers or veterinary surgeons could appropriately be considered as part of a single complex monopoly situation, Pfizer suggested that a distinction should be drawn between the facts established in the Films (1994) and Domestic Electrical Goods I and II (1997) reports (see footnote to paragraph 10.237) and the provisional findings in the present case. In relation to both Films and Domestic Electrical Goods, the conduct on the part of the supplier and retailer were closely and intimately connected, to the extent that the anti-competitive consequence of the behaviour identified could have occurred only by the participation of both supplier and retailer (or distributor and exhibitor, in the case of Films). It was in consequence of the agreed terms of trade between the supplier and retailer that the anti-competitive consequences followed. Pfizer argued that the situation was completely different in the supply of veterinary POMs. There was no identifiable nexus between the conduct of the veterinary surgeons, manufacturers and wholesalers identified in paragraph 9 of the statement of 17 September. In particular, the connection between the conduct of veterinary surgeons identified in paragraph 9(a), (b) and (c) and the conduct of manufacturers and wholesalers identified in paragraph 9(d) to (g) was, in Pfizer’s view, unclear. Pfizer pointed out that we had not suggested that any of these conduct on the part of veterinary surgeons was the result of any agreement or understanding with a manufacturer, or a term of trade used by a manufacturer or wholesaler. Nor had we suggested that the conduct in paragraph 9(g) on the part of wholesalers in relation to supplying pharmacies was in any way the result of any agreement or understanding with, or a term of trade used by, a manufacturer. In Pfizer’s view, it was only in an exceptional case that the CC should conclude that a single complex monopoly situation covered supply of reference goods at different levels of trade. There was nothing in our findings to suggest that the supply of POMs should be such an exceptional case.

10.583. Pfizer noted that paragraph 18 of the statement of 17 September had concluded that the share of supply test was satisfied whether the manufacturers, wholesalers and veterinary surgeons were viewed as a group involved in a single complex monopoly situation or as three separate groups involved in three separate complex monopoly situations. In relation to veterinary surgeons, we had based this finding on the data from a survey conducted by BMRB (BMRB1). Pfizer commented that it was, however, unclear why we had concluded that the share of supply test was satisfied in relation to manufacturers and wholesalers, because we referred only to data on sales and purchases supplied by manufacturers and wholesalers. There was therefore a lack of transparency in relation to this aspect of our provisional complex monopoly finding and further explanation was needed of the basis on which the share of supply test had been satisfied.

10.584. In Pfizer’s opinion, there was an artificiality in our analysis of a single complex monopoly arising at three different levels of trade. The analysis in paragraph 18 of the statement implied that, in such a case, it would be sufficient for the share of supply test to be satisfied at only one such level of supply and the complex monopoly would therefore include persons at other levels who together supplied less than 25 per cent of the reference goods. This appeared to represent a substantial potential widening of the concept of a complex monopoly to include situations in which no complex monopoly could have been found if each level of supply had been viewed separately (as, Pfizer suggested, should more appropriately have been the case in the present inquiry).

10.585. Pfizer submitted that it should not be regarded as a member of the group of persons in whose favour the provisional POM complex monopoly existed. In support of this view, it made the following statements in relation to the conduct identified in paragraph 9(d) to (f) of the statement:

— In relation to paragraph 9(d), Pfizer did, from time to time, enter into negotiations with structured buying groups such as [ ... ]. Moreover, there was no evidence that Pfizer’s general (but not inflexible) policy of preferring to deal with individual veterinary surgeons rather than buying groups had restricted the ability of smaller veterinary practices to benefit from participation in a buying group, having regard to the terms on which Pfizer had been willing to supply individual members of buying groups.

— In relation to paragraph 9(e), Pfizer’s rebate scheme allowed veterinary surgeons to ascertain with certainty at the time of purchase, for all practical purposes, the cost to them of POMs. It
was in any event unclear from paragraph 10 of the statement what anti-competitive effect the conduct we had identified was thought to have.

— In relation to paragraph 9(f), Pfizer’s policy in respect of the supply of pharmacies with POMs was to make POMs freely available to all full-line veterinary wholesalers, who were free to supply any pharmacy that placed orders with them. Pfizer had not received orders for POMs from pharmacies. These facts together demonstrated that, to the extent that Pfizer had failed to supply POMs to pharmacies, this conduct reflected existing demand conditions in the industry. As it did not lead to demand from pharmacies being unsatisfied, it could not be regarded as a conduct that prevented, restricted or distorted competition.

10.586. Finally, Pfizer noted that our statement provided only the briefest and most general analysis of the relevant economic markets. Pfizer commented that the CC’s analysis would normally proceed on the basis that, in order to assess the competitive effects of a particular practice, it was necessary first to identify the relevant economic market or markets in which those effects were felt. As our statement did not clearly identify the markets, Pfizer questioned the basis for our conclusion that the conduct identified in paragraph 9 of the statement of 17 September prevented, restricted or distorted competition. Similarly, without the identification of the markets, Pfizer questioned the basis on which we had identified adverse effects on competition giving rise to public interest detriments that were a consequence of the complex monopoly. In addition, Pfizer considered that the public interest detriments that would be remedied by the possible remedies listed in the statement of 17 September were also called into question by the lack of clear identification of relevant economic markets.

10.587. Pfizer’s detailed comments on each of the conduct we identified in paragraph 9 of the statement are summarized below.

10.588. With regard to refusal/failure of manufacturers to negotiate discounts and rebates with buying groups (paragraph 9(d)) Pfizer said that although it had from time to time offered terms for certain products to [] members, buying groups had offered few of the benefits, in terms of efficient account servicing and cost savings, of dealing with large veterinary practices. In general, therefore, Pfizer had had no commercial incentive to deal with these buying groups, on the basis that they were in a similar position to a single veterinary practice. Moreover, it had found that buying groups were unable to enter into firm purchasing commitments. It had continued to deal with the individual veterinary practices that had joined the buying groups and had been under very little pressure from such practices to deal with the buying groups instead of, or in addition to, the practices.

10.589. Expanding on these comments, Pfizer said that in recent years it had relaxed its policy in supplying buying groups to the point of giving its sales teams discretion as to whether they would deal with them. This had resulted in some discussions and promotions with buying groups, and seasonal products had been supplied to [ ]. Whether such promotions would be repeated would depend on analysis of whether they had led to any additional sales, but Pfizer believed that it had not gained much from such exercises. Since it continued to supply the individual members of the buying group, and provide support to them, Pfizer was not benefiting from the usual advantages offered by buying groups such as a single point to deal with and a clear commitment on volumes of purchases, but it nevertheless had to incur additional administrative costs in dealing with them.

10.590. With regard to the conduct identified in paragraph 9(e) of the statement (operation of rebate schemes that make it difficult for veterinary surgeons to ascertain at the time of purchase the cost of POMs to themselves), Pfizer said that it had no detailed knowledge of the rebate schemes operated by other manufacturers. It did not consider that its own Vetsave scheme fell within the scope of the conduct we had identified, nor that the scheme would to any appreciable extent have the detrimental consequences we had suggested.

10.591. Pfizer said that its Vetsave scheme was highly transparent for all practical purposes and the discounts it offered to veterinary surgeons were predictable with a high degree of certainty. All veterinary surgeons buying POMs from Pfizer were informed of the basis on which Vetsave discounts were granted (they were provided with written details of the scheme, including the curve linking purchase levels and rebate levels), and received clear monthly statements detailing their purchases and the consequent level of rebate. Whilst it might be true that veterinary surgeons did not have absolute certainty at the time of purchase (because rebates were calculated retrospectively each month, based on purchases in the previous 12 months), this did not mean that the Vetsave scheme was not transparent and predictable. The magnitude of any such uncertainty was likely to be negligible.
10.592. Pfizer provided an illustrative example showing that a typical veterinary practice, with an MAT of £[£] in purchases of products covered by the Vetsave scheme, would need to increase its purchases (in MAT terms) by almost [£] per cent in order to qualify for an additional [£] per cent rebate. This increase in MAT would also result in an increase in rebate on SAVs of around [£] per cent of list price. Hence the overall impact on the price paid by the practice would lie between [£] and [£] per cent of list price, depending on the mix of SAVs and other products in the practice’s total purchases. Pfizer said that whilst the illustration was based on an ‘average’ practice, at an MAT of £[£], the conclusions would be very similar for either smaller or larger practices.

10.593. Since discounts were based on MAT rather than purely on a single month’s purchases, it would take 12 months for the entire [£] per cent increase in rebate to come into effect if each month’s purchases consistently increased by nearly 20 per cent. The change would therefore be very gradual (an increment of less than [£] per cent of list price each month) and predictable. Alternatively, in order for the full [£] per cent increase in rebate to be achieved from one monthly statement to the next, the practice’s monthly purchases would have to increase by well over 200 per cent of the average monthly purchase for the previous 12 months, which would be unlikely to happen. Pfizer concluded that for all practical intents and purposes, veterinary surgeons would be able to predict the net cost of its products with a high degree of accuracy.

10.594. Pfizer noted that our concerns related to the potential impact on retail prices of any lack of transparency of rebate schemes. It said that the Vetsave scheme could not be regarded as contributing to retail prices that were excessive or not cost-reflective, for two reasons. First, a veterinary practice would alter its retail prices only periodically. As explained in paragraph 10.593, any changes in Vetsave rebate levels would be clearly identifiable and predictable over the time periods in question. The BMRB survey carried out on our behalf (BMRB1) suggested that the majority of veterinary practices had computerized information and management systems, allowing precise information on previous levels of rebate to be available as a basis for future retail pricing decisions. Practices would therefore be able to set their retail prices for each time period with a clear expectation as to the net cost to them of Pfizer POMs over the course of that period.

10.595. Second, and even more importantly, the scale of any potential uncertainty over the precise level of future Vetsave rebate was negligible relative to the retail price of the products. The BMRB survey concluded that the average mark-up applied by veterinary surgeons to POMs was of the order of 70 per cent. The majority of respondents had said that these mark-ups were applied to list prices. The potential impact of uncertainty over net prices under the Vetsave scheme (of the order of [£] per cent of list prices) was therefore dwarfed by the mark-up applied by veterinary surgeons. Pfizer said that any inability by veterinary surgeons to calculate net prices with certainty under the Vetsave scheme could have no more than a negligible impact on retail prices.

10.596. Commenting on the conduct identified in paragraph 9(f) of the statement (failure of manufacturers to supply pharmacies with POMs and/or enable them to obtain supplies of POMs on terms that enable them to compete with veterinary surgeons), Pfizer told us that it did not supply veterinary practices direct; in order to reduce overall logistical costs, it supplied only through full-line veterinary wholesalers. For the same reason it did not supply pharmacies direct with POMs and in fact had received only a few general enquiries from pharmacies about product availability. Pfizer had tended to refer these pharmacies to the veterinary wholesalers and it understood that the wholesalers had indicated their willingness to supply.

10.597. Pfizer told us that it directly supplied a number of PML retailers. If some of these were to decide to employ a pharmacist so that they could sell POMs as well, then Pfizer saw no reason why it should not supply POMs to them direct. It was certainly a possibility to be considered if the shape of the market changed. Similarly, Pfizer saw no reason not to supply the wholesalers of human medicines with veterinary POMs if they chose to enter the market.

10.598. Pfizer said that it had no formal scheme for offering introductory deals to new veterinary practices, although it believed that its sales representatives might informally help. It believed that if a new pharmacy had a real intention of selling veterinary POMs then the sales representatives might well offer similar assistance.

10.599. In Pfizer’s view, any difference in terms of supply between veterinary practices and pharmacies did not amount to discrimination but simply reflected the different functions of the prescriber
and dispenser of POMs. In particular, the differences recognized the importance of the veterinary surgeon’s gatekeeper role. We asked Pfizer whether pharmacies buying its products through veterinary wholesalers would be eligible to benefit from its rebate arrangements on the same terms as veterinary practices. Pfizer said it was unlikely, under existing conditions, that any pharmacy would buy enough POMs to qualify for a rebate, but that if in future the prescribing and dispensing functions were separated then it would have to look again at the varying costs and benefits of the different channels. Any comments it made on this would be entirely hypothetical because demand from a dispensing channel was not yet apparent. However, it could say that the existing incentives reflected the part that veterinary surgeons played in the distribution chain, and if pharmacies became more active than they currently were in dispensing veterinary POMs, then appropriate incentives would have to be designed to reflect their contribution. The incentives might differ from those available to veterinary surgeons, but might well be non-discriminatory in the sense that the rewards would reflect the investment made respectively by the veterinary surgeons and the pharmacies and the value that they added to Pfizer. This did not mean that there would necessarily be the same discount for the same level of purchase. Pfizer would still wish to recognize the fact that demand was effectively primed by the prescribing function of the veterinary surgeon, which must remain with the veterinary surgeon to fall within regulatory requirements.

**Provisional complex monopoly situation—supply of cat and dog vaccines to veterinary surgeries**

10.600. Pfizer maintained that we had provided insufficient evidence or reasoning to support our provisional conclusion that the level of concentration in the manufacture and supply of cat and dog vaccines in the UK was caused or appreciably exacerbated by the existence of rebate schemes linking both types of vaccine. It considered that the available evidence contradicted our conclusion.

10.601. Pfizer told us that the process of developing a new SAV and bringing it to market involved substantial costs and risks even by comparison with other animal health POM products. Examples of additional costs associated with vaccines, as compared with pharmaceuticals, were:

   — Because vaccines could contain potential pathogens, their production required dedicated manufacturing sites, designed to prevent release of potentially infective agents into the environment by use of filtration of air and sterilization of waste material, with the additional expense involved. These dedicated sites and machinery were not suitable for production of other animal medicines.

   — Manufacturers were required to produce additional pre-production batches of vaccines (compared with the number for pharmaceuticals). That is, in addition to normal batches produced for stability studies, vaccine manufacturers had also to make separate high- and low-titre batches of the proposed vaccine specification in order to demonstrate efficacy at the lowest titre and safety at the highest titre.

   — Genetically modified organisms might be used in vaccine production but were generally not used in pharmaceutical manufacture. Manufacture of such vaccines had to comply with EC guidelines covering deliberate release of genetically modified organisms.

10.602. Pfizer commented that because a manufacturer needed to recover these additional fixed costs and compensate for the risk of failing to obtain regulatory approvals, relatively concentrated markets for these products could be expected even in the absence of any ‘artificial’ barriers to entry and growth. But in Pfizer’s view, the markets for SAVs in the UK were intensely competitive. In order to conclude that the level of concentration in these markets was due to linked rebate schemes, we would need additional evidence showing the causal connection between rebate schemes and market structure.

10.603. We had argued in paragraph 21 of the statement of 17 September that the prevalence of linked rebate schemes for cat and dog vaccines gave buyers an incentive to purchase both types of vaccine from one and the same manufacturer, thus raising barriers to entry or growth for manufacturers who were unable to offer competitive products in both market segments. In Pfizer’s view, this argument did not appear to be supported by the facts. It drew our attention to the following:

   — Almost [حَ]% per cent of Pfizer’s customers for either cat or dog vaccines bought from it one type of product but not the other, even though Pfizer offered both types of product and had
similar overall market positions in both (around 10 per cent of the total UK market in both cases). Around [3%] of its SAV customers were therefore sourcing cat and dog vaccines from more than one manufacturer.

— The two largest manufacturers in both cat vaccines and dog vaccines in the UK were Fort Dodge and Intervet. However, the respective positions of these two suppliers in the two markets were far from symmetrical (both had similar shares in cat vaccines, while Intervet had a substantially higher share than Fort Dodge in dog vaccines). Nor was the position static: in cat vaccines, Fort Dodge had recently gained share and Intervet had weakened, while in the dog vaccine market the reverse pattern had been displayed in recent years. These facts appeared inconsistent with our hypothesis that the major manufacturers successfully tied the sales of cat vaccines and dog vaccines together on any significant scale.

— The patterns described above could more readily be explained by the introduction of new and innovative products than by the supposed impact of linked rebate schemes.

— In dog vaccines, Intervet had maintained its market-leading position by its innovations in recent years. In 1998, it had achieved a licence change allowing its primary puppy vaccination course to finish at 10 weeks of age (rather than 12 weeks, which was still the norm for rival products). It also generated data that had recently allowed a licence change relating to the frequency of its vaccine boosters. Immunity for some antigen components now lasted for two years, enabling customers to have full boosters every two years (rather than annually), with ‘mini boosters’ in between.

— In cat vaccines, innovations introduced by Fort Dodge (the market leader) included the introduction in 1999 and 2001 of products in pre-filled syringes that did not require reconstitution, and hence were easier to administer than vaccines that came as freeze-dried pellets. Fort Dodge also introduced a polyvalent vaccine (Fevaxyn Pentofel) in 1999 that contained the complete range of antigens (excluding rabies) against which cats were normally immunized, thus removing the need for multiple vaccinations. Merial’s recent increase in share of this market had coincided with its launch of Eurifel FeLV, the first FeLV vaccine that did not contain an adjuvant. (Adjuvants could be associated with undesirable reactions at the injection site.)

10.604. Pfizer said that these developments indicated that the crucial determinant of competitive success was the ability to offer attractive and innovative products. Marketing initiatives, such as particular rebate schemes, were at most of secondary importance.

Other issues

10.605. Pfizer’s views on other matters raised in our statement of issues, published on 17 April 2002, are recorded below.

Whether veterinary manufacturers tie in the sales of some or all products in their ranges with an anti-competitive effect (Issue II(i))

10.606. Pfizer said that it did not tie in or oblige customers to buy some or all of the products in its range. It rewarded customers that purchased higher volumes with higher discounts through its Vetsave rebate scheme. The scheme was a response by Pfizer to the competitive nature of the market. It was not designed to have anti-competitive effects, and nor did Pfizer believe that its actual impact on the market was anti-competitive. With one exception Pfizer did not operate any additional discount schemes that related to the purchase of more than one POM product. Pfizer said that it faced strong competition in the sale of all its products and that it supplied only around 13 per cent by value of all POMs in the UK. Consequently its rebate policies could not have any material impact on the market overall.

10.607. We asked Pfizer whether tying was a particular feature of sales of vaccines, particularly in small-animal veterinary practices where vaccines would form a relatively large proportion of the drugs bill. It had been suggested to us that practices tended to buy all their vaccines from the same supplier and that they then had a strong economic incentive to buy other medicines from the same supplier, in order to benefit fully from its rebate scheme. Pfizer said that there was considerable competition in the supply of
vaccines, which had led to manufacturers offering higher discounts on them than on other medicines. The fact that vaccines constituted a substantial proportion of some practices’ expenditure on medicines gave them considerable buying power and made manufacturers vulnerable to switching. It would not therefore make sense for a manufacturer to rely on vaccines as a starting point for any tying or bundling of products.

**Whether veterinary manufacturers, via linked price promotions, use the existing market power of some products as a lever to gain share of other markets (Issue II(i)a)**

10.608. Pfizer said that every one of its products faced direct competition from one or more rival products. In view of this, any attempt to force sales of its products by tying them to other products via linked price promotions would not generally make commercial sense, but would merely jeopardize sales of both of the products in question. Other than the general Vetsave discount scheme there was only one specific instance where Pfizer operated a linked discount scheme in respect of POM products and this related to two products in the same market. [Details omitted. See note on page iv.]

] It did not represent any attempt to lever strong demand for one product to the benefit of another product: Pfizer did not enjoy a particularly strong position in the market in question.

**Whether veterinary manufacturers operate rebate schemes which are a barrier to successful market entry, in that they encourage veterinary surgeons to buy more from larger veterinary manufacturers (Issue II(i)b)**

10.609. Pfizer said that under its Vetsave scheme rebate payments were made to veterinary surgeons on a monthly basis on their purchases of POMs in that month (subject to a small number of exceptions). The size of the rebate was determined by the value of the customer’s purchases over the past 12 months, ie based on the MAT of purchases. The rationale for the scheme, from Pfizer’s perspective, was to be able to offer larger customers more favourable terms, which these customers would routinely expect. Pfizer saw the Vetsave scheme as a systematic and transparent way of achieving this objective.

10.610. Pfizer did not consider that the Vetsave scheme could have any material effect on competition and could not be regarded as anti-competitive. In particular, it did not prevent veterinary surgeons from purchasing non-Pfizer products. In Pfizer’s view, the following factors support this view:

— Veterinary surgeons were well-informed professional purchasers, who based their prescribing (and hence purchasing) decisions on efficacy and technical benefits as well as price. They bought from manufacturers who offered effective products at reasonable prices, and switched to effective new products when they entered the market. Consequently, Pfizer faced strong competition in each product area in which it operated, and competed with both larger and smaller manufacturers.

— A significant proportion of Pfizer’s sales of POM products were outside the Vetsave scheme: Pfizer had agreed fixed rebate levels (ie not dependent on the level of purchase) with a number of large veterinary practices, which accounted for a material proportion of its POM sales. There could be no incentive for these practices to buy further Pfizer products in order to increase rebate levels. In reality, large practices were the customers that manufacturers targeted first when introducing new products to the market. Particularly for smaller manufacturers, such a strategy was an effective way of reaching a significant market without having to incur substantial marketing costs.

— The incentive provided by the Vetsave scheme to buy additional Pfizer products was weakened by the linkage of the monthly rebate to the MAT of the past 12 months’ purchases. The decision between a Pfizer product and a competing product for any given application would typically have only a small effect on the MAT and hence on the rebate level applicable in the month in question.
Pfizer was not dominant in the overall market, and it did not consider that any of its products was a ‘must-have’ product: in each case, one or more viable alternatives existed. Pfizer had no ability, therefore, to influence the market through its rebate scheme.

For all these reasons, Pfizer considered that it was not plausible that the Vetsave scheme could act as a barrier to market entry.

10.611. Pfizer said that veterinary surgeons participating in its scheme received monthly statements that informed them of the prices they paid for its products and which should assist them with making price comparisons with competitor products. Moreover, where Pfizer individually negotiated fixed rebates with veterinary surgeons, pricing was necessarily transparent. Pfizer maintained that its rebate scheme did not inhibit price transparency from the customer’s point of view. Its rebates did have the effect of reducing price transparency in respect of other veterinary manufacturers, who would not be aware of the net prices paid by veterinary surgeons under the Vetsave scheme. In Pfizer’s view this effect was pro-competitive rather than anti-competitive.

Whether veterinary manufacturers’ rebate schemes are structured in such a way as to cause veterinary surgeons to charge higher prices than they would otherwise do (Issue II(ii)b)

10.612. Pfizer said that it was not involved in veterinary surgeons’ pricing decisions. It was unclear how lower net prices to veterinary surgeons, when administered in a predictable and transparent way, could cause them to charge higher prices to animal owners.

Whether veterinary manufacturers who operate rebate schemes gain an informational advantage over those who do not, and whether this enables them to strengthen their position in the market in an anti-competitive way (Issue II(ii)c)

10.613. Pfizer said that it bought information from veterinary wholesalers on sales volumes of its products to each veterinary practice in order to operate the Vetsave rebate scheme. It understood that this data would be made available to all manufacturers, regardless of whether they operated similar rebate schemes. It also understood that the veterinary wholesalers had agreements with each of their practice customers that allowed them to pass details of purchases to any relevant manufacturer. Even if procurement of this information was dependent upon agreement by veterinary surgeons, there was nothing to stop other suppliers from operating such schemes or paying veterinary surgeons to consent to the disclosure of the information, if they believed that the benefits would outweigh the associated costs.

10.614. Pfizer told us that information from veterinary wholesalers was useful but not essential. Lack of access to the information would not prevent market entry, provided that a manufacturer had a good product to offer. The data could not be used in anti-competitive ways, as it related only to Pfizer’s own sales. Moreover, there were other ways of obtaining data of this kind, for example through sales representatives as had happened in the past.

Whether veterinary manufacturers with a large market share in particular veterinary medicine sub-markets carry out anti-competitive practices to maintain their position, and in particular: whether veterinary manufacturers engage in predatory pricing (Issue II(ii)d)

10.615. Pfizer said that the pricing policies it had observed in the market were consistent with active competition. Pfizer responded to changes in competitors’ pricing when necessary to remain competitive. However, it did not set prices with a view to driving competitors out of the market.

Whether veterinary manufacturers promote brand loyalty to such an extent as to limit price competition and restrict market entry (Issue II(ii)e)

10.616. In Pfizer’s view, veterinary surgeons were well-informed purchasers, who made decisions based on both product characteristics (notably efficacy) and cost. They did not display any perceptible brand loyalty per se, as was evidenced by the fact that patented branded products typically lost share to generic products once their patents had expired. Most veterinary surgeons, and some farmers, were familiar with the active ingredients contained in these products and switched to effective alternatives where these were cheaper. [Details omitted. See note on page iv.]
10.617. Pfizer commented that in many markets competition occurred not only on the basis of price, but also on technical features and benefits, service level and non-price promotions. It said that competition on non-price attributes did not limit competition, nor did it restrict market entry if customers were informed and able to compare prices as well as the non-price aspects of the goods and services offered. Moreover, all manufacturers, irrespective of size, were able to compete on equal terms in this regard.

10.618. Pfizer told us that it offered a limited range of non-price benefits that, however, had a clear pecuniary value to customers, such as contributions to the purchase of practice equipment. One example of this was the Rimadyl promotion that had been drawn to our attention, in which a range of items of equipment was offered in return for purchases. Pfizer said that offers of that kind were an alternative form of discounting and, in its view, should be regarded as a variant on price competition. It said that all manufacturers were able to engage in competitive discounting.

Whether veterinary manufacturers engage in anti-competitive market sharing, by jointly choosing not to launch or promote products that directly compete with those of other suppliers (Issue II(ii)f)

10.619. Pfizer told us that its history of product launches and its experience of product launches by competitors was inconsistent with the suggestion of market sharing. The market was characterized by a succession of products launched in direct competition with established products. Pfizer provided examples of products it had launched itself and products launched by other manufacturers that competed directly with its products. It said that if a manufacturer developed a potentially marketable product, there was a very strong economic incentive to bring the product to market, provided the expected revenues outweighed the costs of production and product introduction (notably regulatory approvals in each jurisdiction). However, given the small size of many animal health markets, relative to entry costs, it was unsurprising that there were relatively few players in some market segments.

Whether the manufacturers of veterinary medicines are protected by the provisions of the cascade from competition from substitutable human medicines, and whether they exploit this protection by charging higher prices than would otherwise be the case (Issue II(iii))

10.620. Pfizer said that the current licensing system for veterinary medicines was based on quality, safety and efficacy and had been constructed to protect animals and the general public. The prices of veterinary medicines reflected the costs incurred by manufacturers and others in complying with the regulatory requirements laid down in order to meet these essential objectives. Modifications of the prescribing cascade as we had suggested would remove the pillars of safety and efficacy and would dissuade manufacturers from investing in product development. Pfizer said that the cascade was not a barrier to the use of generic medicines in animal health. Properly licensed veterinary generic medicines could already be used. There was no guarantee that a human generic would be equivalent to the parent/original veterinary medicine. For instance, it might not contain the same quantities or proportions of ingredients or be the same or similar formulation. Veterinary surgeons would find it difficult to predict the precise effect of a particular human generic in different species of animals.

Whether veterinary manufacturers set the price or influence the retail mark-up on veterinary medicines, and in particular whether veterinary manufacturers, through published list prices, effectively set minimum resale prices (Issue II(iv))

Whether veterinary manufacturers otherwise set, or influence, the price at which their products are resold (Issue II(v))

10.621. In Pfizer’s view the retail pricing of POMs was a matter for veterinary surgeons or others dispensing the products. Its professional price list contained the base prices from which discounts to veterinary wholesalers and to veterinary surgeons were negotiated and calculated. It was unavoidable that there should be some form of published price list to inform customers, but Pfizer’s list prices were not recommended or minimum resale prices and veterinary surgeons were entirely free to price its products to their customers at any level they saw fit. Pfizer did not advertise POM prices to animal owners in the UK as it had no control over retail prices.
Whether veterinary manufacturers encourage veterinary surgeons to buy certain prescription-only veterinary medicines by asserting that they will not be subject to reclassification (Issue II(vii))

10.622. Pfizer commented that it was practically very difficult for POM medicines authorized by the centralized procedure to be subsequently reclassified even though there was no legal impediment (subject to the legal requirement for certain classes of medicine to be prescription-only). Pfizer had campaigned to have the legislation/process changed to make it easier for centrally authorized products, where and when appropriate, to be reclassified as PML in countries such as the UK where such alternative classification and distribution systems existed.

Whether veterinary manufacturers charge differential prices to veterinary surgeons in such a way as to restrict competition (Issue II(viii))

10.623. Pfizer said that under its Vetsave scheme larger purchasers generally paid less than smaller purchasers. However, any differences in net prices between different purchasers arose as a result of the functioning of the scheme (which was national in scope and covered most Pfizer POM products). Vetsave could not therefore have the effect of restricting competition. In addition to the Vetsave scheme, Pfizer's product promotions were generally UK-wide. Its sales representatives were able to negotiate some customer-specific discounts within guidelines agreed by management. In Pfizer’s view, all these policies were characteristic of normal, vigorous competition and not in any way anti-competitive.

Whether veterinary surgeons by some action or omission may have indicated to veterinary manufacturers and/or veterinary wholesalers that they should refuse to supply pharmacists, or supply them on less-favourable terms (Issue IV(v))

10.624. Pfizer told us that its decision regarding distribution channels for POMs would not be influenced by any such indication from veterinary surgeons.

Whether veterinary surgeons influence veterinary manufacturers not to reclassify prescription-only medicines to a lower classification (Issue IV(vi))

10.625. Pfizer said that veterinary surgeons might occasionally ask whether a product was likely to be reclassified. This would not, however, affect any commercial decision Pfizer might make about reclassification, which would be based on its independent view. A particular example was Dectomax, which had been reclassified from POM to PML within a 12-month period. Pfizer had made it clear to the veterinary profession from an early stage that this was what it intended.

Whether veterinary surgeons allow their purchasing and dispensing decisions to be influenced by rebates or discounts from veterinary manufacturers, in such a way as to restrict consumer choice or to increase prices to animal owners (Issue IV(xii))

10.626. Pfizer said that veterinary surgeons were free to pass on to their customers the benefit of the rebates and discounts they had negotiated with manufacturers. It could not understand how lower net prices, particularly when provided through a predictable and transparent scheme such as Vetsave, could cause veterinary surgeons to charge higher prices to animal owners.

Possible remedies

10.627. Pfizer’s comments on certain of the possible remedies set out in the statement of 17 September are recorded below.

A requirement for veterinary surgeons when quoting the price at which they will dispense any POM also to state the cost of that POM to themselves (paragraph 24(b)(iv) of the statement)

10.628. In Pfizer’s view this remedy was unreasonable and disproportionate from veterinary surgeons’ point of view, as well as being unnecessary. It said that competition between retailers did not require product cost to be made known to customers. Conversely, if we thought that competition was lacking for other structural reasons, for instance bundling of POMs and services, then cost transparency would make no difference to this. Pfizer knew of no other market in which retailers were required to state their product cost. Such a requirement in the present case would be likely to damage the veterinary
surgeon-client relationship as veterinary surgeons needed to mark up the cost of the product in order to cover their overheads, resulting in what might appear to a client to be a high margin. Pfizer did not see how the remedy would enhance competition between veterinary surgeons since customers were already able to compare the prices charged by different practices if they so wished. If, conversely, we were concerned that customers did not have any real choice between veterinary surgeons, then the provision of information on margins would have no effect.

10.629. Pfizer did not believe that the implementation of the suggested remedy would assist competition; it could instead have anti-competitive effects. A requirement for veterinary surgeons to state product costs was likely to lead to increased transparency between manufacturers, who would be able to gain information on their rivals’ discounting which was not currently available in the market in any systematic fashion. Similarly, it would give directly competing veterinary surgeons (such as neighbouring practices) greater knowledge of the cost base underlying their rivals’ pricing. Pfizer did not believe that it would be helpful to competition if precise information of that kind were available.

10.630. Given the variety of rebating and discounting arrangements that Pfizer understood to exist, it thought that there would be considerable practical difficulties in implementing and policing any such remedy.

10.631. Finally, Pfizer noted that the possible remedy did not specifically relate to the conducts on which our complex monopoly finding was based.

A requirement for manufacturers of POMs giving rebates to veterinary surgeons to provide sufficient information, either directly or through wholesalers, so as to enable the veterinary surgeon to ascertain with certainty the cost net of rebates of POMs supplied to them (paragraph 24(b)(v))

10.632. Pfizer said it did not consider that its operation of the Vetsave scheme fell within the scope of the conduct identified in paragraph 9(e) of the statement or could have, to any appreciable extent, the detrimental consequences that we had suggested. Nor did it consider that any remedy to alter the Vetsave scheme was necessary. It did not believe that it would be affected by the implementation of a remedy on the lines we had suggested, although this would depend on the precise terms.

A requirement for manufacturers and wholesalers that supply POMs in the UK to supply pharmacies (paragraph 24(c)(i))

A requirement for manufacturers and wholesalers that supply POMs in the UK to supply pharmacies on terms that enable them to compete with veterinary surgeons (paragraph 24(c)(ii))

10.633. In Pfizer’s view its policy as regards the supply of pharmacies could not properly be categorized as a refusal to supply or as a conduct that prevented, restricted or distorted competition in the supply of POMs. Pfizer said that there was no rationale for manufacturers to provide identical terms and incentives to pharmacies and veterinary surgeons, given their fundamentally different functions. If such a requirement were imposed, Pfizer believed that, considering the essentially passive role of pharmacies in the supply chain, manufacturers would be unlikely to provide them with the same level of incentive as was currently provided to veterinary surgeons. They would therefore support and incentivize veterinary surgeons in non-price ways, and the current levels of rebate would no longer be available to be passed on to end-consumers. Pfizer suggested that the final outcome would be a reduction in price competition between manufacturers, which would be unlikely to benefit consumers.

10.634. In general, given our implicit acceptance of the effectiveness of competition at the manufacturer and wholesaler level of supply, Pfizer considered that the response to any demand from pharmacies for POMs, in terms of distribution channels and terms of supply, should be left to market forces. If we concluded that there were competition issues arising from the bundling of services by veterinary surgeons, Pfizer considered that these should be addressed by an appropriate unbundling remedy. This would allow all parties in the market to respond appropriately. If price transparency at the retail level and demand for POMs from pharmacies increased, this channel had the potential to become an effective alternative. Existing competitive pressure at the manufacturer level would then ensure that terms were agreed with pharmacies that reflected their value in the supply chain. Pfizer said that our suggestion of imposing a particular outcome might not be in the best interests of end-users. It considered that these possible remedies went beyond what was necessary to overcome the harm to competition that we had provisionally identified.
A requirement for veterinary surgeons when they write prescriptions for POMs to do so on an 'or equivalent' basis to enable those dispensing such prescriptions to supply alternative authorised veterinary medicines to the brand specified (paragraph 24(c)(iv))

10.635. In light of the discretion that veterinary surgeons currently had in prescribing, Pfizer considered that such a requirement was unnecessary and would also be a potentially harmful and unsafe restriction on veterinary surgeons’ ability to ensure that animals under their care received the most appropriate treatment, correctly administered. It believed that it would be inappropriate, and in some circumstances dangerous, for veterinary surgeons’ prescribing role, which was based on compelling health and safety and animal welfare reasons, to be interfered with. Only a prescribing veterinary surgeon would examine the animal and be aware of all the circumstances of the particular case, such as local disease conditions and the animal’s housing conditions. A non-prescribing veterinary surgeon or pharmacist would not have access to this information. Pfizer also suggested that veterinary surgeons were the professionals most likely to understand the full benefits of a new innovative product. Pharmacists focused on human medicines and were likely to deal infrequently with veterinary medicines, and training in veterinary medicines was optional for them. Pharmacists might not, therefore, have the experience or expertise required to dispense an alternative to the veterinary medicine specified on a prescription.

10.636. In Pfizer’s view, such a remedy, which in effect allowed dispensers to change a prescription, ran counter to the principles upon which POMs were so classified, and could encourage pharmacists, either deliberately or accidentally, to break the cascade or go against the conditions of farm assurance schemes.

10.637. In view of the fact that a prescription did not identify the indication or animal species for which the product was prescribed, Pfizer was also concerned as to how widely the words ‘or equivalent’ would be interpreted by pharmacists, especially as species suitability, specific indications, withdrawal periods, dosing schedules and routes of administration could vary between different manufacturers’ brands. [Details omitted. See note on page iv.]

Pfizer said that similarly, in relation to livestock and thus of relevance to food safety, there were several amoxicillin injections which all had the same level of active but greatly varying durations of activity and therefore milk and meat withholding periods. Giving an inappropriate medicine to an animal could be detrimental to its welfare and give rise to food safety concerns. Pfizer found it difficult to see how the term ‘or equivalent’ could be defined precisely enough to remedy these concerns. It was concerned about who would be legally liable if an animal was given an inappropriate POM. A further problem was that if manufacturers experienced particular problems with their veterinary medicines it could be difficult for them to track the users if a medicine could be dispensed without record of user, on an ‘or equivalent’ basis.

10.638. We put to Pfizer an alternative hypothetical remedy to that contained in the statement of 17 September. Pfizer said it would be equally concerned by any remedy that required veterinary surgeons to list two or more products on a prescription, any one of which could be chosen by the dispenser. In addition to its concerns about animal welfare, health and safety issues, it said that any such proposal had the potential to distort or impair competition on the merits between POMs, including overall value for money, for the following reasons:

— The veterinary surgeon would examine the animal and consult the owner and would thus be in the best position to take account of the owner’s financial situation and make a cost-benefit trade-off between alternative POMs.

— Pharmacists might not dispense the best product in terms of value for money; their decisions could be influenced by their margins on the products listed on the prescription and they might not have as much information as the veterinary surgeon about the relative merits of the products in the context of the animal’s specific condition. Pfizer suggested that the only basis they would have for selecting a product would be the financial implications for themselves.

— Customers’ ability to make a cost-benefit assessment was likely to be even more limited.

Pfizer said that if the suggested remedy were to have any systemic effect, it would be to skew dispensing towards lower-priced products with fewer benefits. This would be to the detriment of manufacturers of

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innovative products and would potentially remove incentives to the development of further new products, hence reducing choice and adversely affecting animal welfare. Such an outcome would not be in consumers’ interests.

10.639. In Pfizer’s view, any remedy that required veterinary surgeons to list two or more products on a prescription, any of which could be chosen by a dispenser, would be materially different from the ‘or equivalent’ prescribing remedy contained in the statement of 17 September. Pfizer did not consider that there had been adequate consultation on the ‘multiple choice’ remedy. It said that we should not, therefore, consider recommending it in our report. It also commented that such a remedy would be extremely difficult to monitor and police.

10.640. Pfizer considered that under both the hypothetical prescribing remedies animal welfare issues could arise from the fact that a prescription might not be presented by the animal’s owner and that veterinary surgeons might be ignorant of products previously dispensed in the context of their ongoing treatment of an animal.

10.641. Pfizer commented that these possible remedies did not specifically relate to the conducts on which our POM complex monopoly finding was based. It also pointed out that to the extent that any prescribing remedy was inconsistent with existing regulations (in particular Article 67 of Directive 2001/82/EC, which linked the responsibility of the veterinary surgeon and the choice of POM) and therefore would require a change in the law at EC or UK level, it fell outside the scope of the Secretary of State’s powers under the FTA.

Prohibition on manufacturers operating rebate schemes in which the level of rebates given on purchases of cat and dog vaccines is based on, or substantially influenced by, the combined value of purchases of those vaccines (paragraph 25 of the statement)

10.642. Pfizer did not believe that any remedy was necessary or appropriate, for the reasons set out in paragraphs 10.600 to 10.604. It said that in any event, any remedy seeking to address our concerns in this area should not apply to Pfizer, which was a minor player in the markets concerned and did not operate rebate schemes specifically targeted at linking cat and dog vaccines.

Regulatory issues

10.643. Pfizer said that there were a number of regulatory barriers to the availability of a wider range of veterinary medicines in the UK. Many of them were European rather than UK-specific issues, but it did seem that the regulatory authorities in the UK tended to be over-zealous in their application of guidelines. One example was the approach to the withdrawal period guidelines, which were applicable to new products (ie those being authorized through the centralized and mutual recognition procedures). Pfizer told us that in the UK these guidelines were being applied on renewal to older products with a national licence in the absence of any concerns being raised through national residue surveillance and pharmacovigilance schemes. [Details omitted. See note on page iv.]

As there was no consistency of approach across the EC, the UK suffered considerable disadvantage as a result.

10.644. Commenting on the regulatory processes in the USA and the EC/UK, Pfizer said that there were a number of differences between them that were reflected in significant differences in the costs associated with obtaining and maintaining MAs.

10.645. The US system for pharmaceutical products allowed for a single opinion to be given by the FDA on scientific queries; this was binding and allowed the applicant to proceed confidently with a development programme. In the EC, although scientific advice could be obtained through the centralized procedure (albeit non-binding), this option was not available in the decentralized procedure and national authorities often provided conflicting advice. This could also arise in the centralized MRL procedure if the rapporteur and co-rapporteur gave conflicting advice that could not be resolved between the two authorities. As a consequence, development programmes to support registration in the EC could be delayed and additional studies required at a late stage in the process.
10.646. For vaccines there were significant differences in favour of the USA: first, the system did not require efficacy trials in veterinary patients, and second, it was not necessary to validate a potency assay linked to protection in the target species. These two differences potentially trimmed some 30 to 50 per cent off the development time and cost in the USA compared with the UK and other EC member states.

10.647. For all products the EC ecotoxicity requirements were more burdensome than those in the USA. The Veterinary International Council on Harmonization had gone some way to harmonise EC and US requirements for products requiring Phase I assessment, but this was not the case for products requiring Phase II assessments, where EC requirements generally necessitated more extensive studies at greater expense.

10.648. In the area of consumer safety in relation to residues in food animals, the EC increasingly took a more conservative approach to residues at the injection site and setting of appropriate withdrawal times for injectable products. Very long withdrawal times could make it impracticable to use a product in certain farm-animal production systems and could seriously impair its final commercial value in EC markets.

10.649. The EC system for maintaining authorizations required a statutory five-yearly renewal plus continuous updating of the MA in the light of new scientific knowledge and changing pharmacopial standards. This was not a feature of the US system. Furthermore, regulatory authorities in EC member states and the UK in particular insisted that when authorization of an old product was renewed, data had to be generated to show that it met the latest guidelines for new products. This necessitated significant expenditure and in extreme cases reformulation, or even the loss of the authorization. Similarly, data on ecotoxicity and new data using latest assays to re-establish withdrawal times were demanded on five-yearly renewal. Thus the EC renewal system required constant investment and reinvention of otherwise safe and effective products with uncertainty as to what in future would be demanded and whether or not the particular product would be able to meet requirements and thus remain authorized.

10.650. Pfizer said that these differences had clear implications for UK business. Inevitably, if regulatory costs, attributable to more complex regulatory structures and requirements, were unnecessarily high in the UK, the return on investment there was likely to be depressed. A possible consequence was that production of medicines for minor indications or species was less likely to be commercially justifiable. A further possible consequence was that the EC, including the UK, would be less attractive to animal health businesses.

10.651. We invited Pfizer to estimate the extra cost of regulation by considering the effects of three different hypotheses: no external regulation of veterinary medicines anywhere in the world; mutual recognition by the EC of US authorization; UK acceptance of EC central or national authorization without further regulatory requirements.

10.652. In responding to our request, Pfizer said that the consequences of these different regulatory hypotheses would be far reaching. They would, for example, affect the flow of products to, and competition in, the market. The figures it provided were based on very general assumptions and gave only a broad indication of possible cost savings.

10.653. With regard to the first hypothesis, Pfizer stated that it was an ethical company with a reputation to maintain. It would, therefore, always have to meet its own minimum standards of quality, safety and efficiency. However, without compromising those standards, it envisaged development cost savings and some savings on efficiency and safety testing required by some regulatory agencies. It estimated that these savings would be in the region of £18 million per new chemical entity (NCE). Regulatory costs under this hypothesis would amount to about £22 million per NCE, disregarding any attrition costs for unsuccessful product developments.

10.654. Pfizer said it was possible that removal of the costs it had identified would ensure that some products that might otherwise be regarded as of marginal profitability would come to market. In addition, the total time for a product to reach the market would be cut because there would be a small fall in development time and the regulatory preparation and review time for the EC would be saved. Pfizer estimated that this could add two to three years to the commercial life of an NCE.
10.655. Pfizer said that it found it difficult to estimate savings under the second hypothesis as it developed products for a global market. Its best estimate on a global development would be a saving of 15 to 20 per cent on the £40 million cost of developing an NCE. It added that there was no five-yearly renewal of authorizations under the US system, so under the second hypothesis all the incremental costs associated with renewal in the UK would be saved. These costs were variable, depending on the number and type of studies required by the VMD for renewal of existing products. Pfizer said that other aspects of the US regulatory system did not save money but added a degree of certainty to the time lines of development projects. These included the ability to file a phased submission of the dossier and the fact that scientific advice was binding.

10.656. With regard to the third hypothesis, Pfizer said that new products were subject to EC harmonized standards and procedures, but some national authorities were less stringent than the UK in their application of EC requirements and were more flexible in accepting alternative approaches. Pfizer would welcome greater flexibility in the UK. It was not, however, able to estimate possible cost savings associated with this suggestion.

10.657. Pfizer’s comments on regulatory issues discussed in the statement of 16 April are recorded below.

**Whether the current MRL requirements restrict competition in, and availability of, veterinary medicines, particularly for minor species (Issue I(i))**

10.658. Pfizer agreed that the current MRL requirements limited the availability of licensed veterinary medicines, particularly for minor species, and were a significant burden on companies trying to maintain or develop indications for minor species. Pfizer said that the return on investment in generating the required MRL data was often insufficient to justify developing such medicines, even where they had real potential therapeutic value in the species.

**Whether the inclusion of an efficacy test in the marketing authorisation procedure unnecessarily increases the barriers to introducing a veterinary medicine to the market (Issue I(ii))**

10.659. Pfizer said that if just the safety and pharmaceutical quality of a veterinary medicinal product needed to be addressed in the authorization process, it was not clear how therapeutic claims would be addressed. These claims were at the core of existing regulation, labelling, promotion and use of veterinary medicinal products and were fundamental to the definition of what was a veterinary medicinal product. Properly evaluated and approved efficacy claims enabled the user to choose the most appropriate veterinary medicine for a particular indication. These claims, and the data from which they were derived, formed the basis for further product developments and improvements. Evaluation and regulation of such claims set the level playing field for competition between different products.

10.660. Although Pfizer considered that there was scope to reduce the efficacy data requirements for minor species indications in respect of products with established efficacy in major species, it would not support a general proposal to remove efficacy testing from the approval process as a means of reducing testing costs and speeding review. In its view, there were other aspects of testing requirements for veterinary medicinal products which were of questionable value, in particular the pharmaceutical quality testing and standards which required veterinary medicinal products to meet the same criteria as human medicinal products. The generation of the data for this part of a new MA application was extremely costly, as was the additional cost of having to generate yet more data (and even in some cases develop a new formulation) on five-yearly renewal in order to meet the latest standards and stay in line with human medicinal requirements.

**Whether the absence of provision for a third party to request reclassification of a veterinary medicine, or for regular review of classification, leads to an over-classification of veterinary medicines (Issue I(iii))**

10.661. Pfizer said that it was a strong supporter of multi-tiered categories and PML agricultural merchant sales. It was campaigning against the current European Commission proposal to categorize as POM all medicines for food animals. It supported a change to EC regulations to facilitate the conversion of centrally authorized products to PML at an appropriate time. It believed that each medicine should be classified on its individual merits and was unaware of any of its own products that were inappropriately classified.
10.662. Pfizer would not support the suggestion that the regulatory authority should be able to review the classification of a veterinary medicine on application from a person other than the MA holder, for the following principal reasons:

- Regulatory compliance costs were already very substantial. Review of classification on the initiative of a third party would impose significant additional costs on the manufacturer, which would ultimately have to be recovered through higher prices, with no guarantee that any customer benefits would result from the review.

- Diversion of resources to deal with classification reviews initiated by third parties would slow down progress with the regulatory compliance work needed for new, improved and modified products. This was likely to inhibit effective competition and reduce customer benefits.

- Third-party-motivated reclassification procedures would also occupy the resources of the VMD and might adversely affect its ability to deal with applications from manufacturers in respect of new, improved and modified products.

- The manufacturer was responsible for the safe and appropriate use of its veterinary medicines. Under existing procedures, a veterinary medicine would not be given a classification lower than considered appropriate (to meet safety and appropriate use considerations) by the manufacturer. If review of classification on the initiative of a third party resulted in a lower classification than that which the manufacturer considered capable of ensuring safety and appropriate use, the manufacturer would either withdraw the product from the market or otherwise limit its distribution.

- A manufacturer had to make a significant investment in the distribution infrastructure appropriate to its product portfolio. Product reclassification might force the manufacturer to invest in alternative distribution arrangements for the product that might not be economically efficient. If there was no adequate business case for such investment, the product might be withdrawn.

Whether the lack of a prescription-only sub-classification for medicines that could be prescribed by a veterinary surgeon (for animals under his/her care) without prior clinical examination restricts competition (Issue I(iv))

10.663. Pfizer said that it would support the proposal to enable veterinary surgeons to prescribe certain medicines without the need for prior clinical examination, subject to such medicines, and the circumstances in which they were used, being evaluated on their individual merits.

Whether the length of time allowed to regulators to reach a decision on marketing authorisations is a barrier to introducing a new medicine (Issue I(v))

10.664. Pfizer told us that it had experienced both the centralized and decentralized (mutual recognition) procedures. The mutual recognition procedure followed a tight timetable that ensured that regulators and the applicant reviewed and responded to queries with minimal delay. The first step of approval by the reference member state, however, could take a long time because of its concern to have every possible issue answered before defending its authorization in the subsequent mutual recognition process. In the centralized procedure, the scientific review by the CVMP could progress at a satisfactory pace until the CVMP opinion was delivered to the European Commission, but there was no clock running thereafter. Pfizer agreed that there was no incentive for regulators to complete assessments ahead of timetable. It told us that it had had no experience of published timetables being exceeded.

Whether the requirement that medicines on the Pharmacy and Merchants List (PMLs) may only be dispensed by veterinary surgeons, pharmacists, and Suitably Qualified Persons (SQPs) employed by agricultural merchants or saddlers restricts competition in the supply of PMLs (and hence of any POMs which may be reclassified as PMLs) (Issue I(vi))

10.665. Pfizer recognized the need for expertise being available at the point of purchase.
Whether the current arrangements which preclude SQPs from breaking bulk in supplying veterinary medicines places them at a competitive disadvantage to veterinary surgeons (Issue I(vii))

10.666. Pfizer commented that this was not an issue for POMs, which could be dispensed only by veterinary surgeons and pharmacists. Where packs of POMs had to be broken for administration to companion animals by their owners, Pfizer invariably issued free dispensing packs containing preprinted instructions and other necessary information. Furthermore, Pfizer presumed that this was not currently an issue with PMLs as agricultural merchants were already the prime retailers of these products, which were packed in sizes suitable for single end-user purchases. If some POMs were to be reclassified as PMLs, it was reasonable to suppose that the packaging would reflect the needs of the new distribution channel.

Whether the conditions under which the European centralised procedure is available could restrict competition, either: by being too narrow, and therefore compelling companies to use the decentralised procedure even if this is a greater barrier to introducing the product to market, or by being too narrow, and so allowing companies to gain a POM classification for their products which cannot subsequently be revised to PML (Issue I(viii))

10.667. Pfizer agreed that, although there might be no legal impediment to the downward reclassification of medicines authorized under the centralized procedure, practical difficulties currently made this unlikely. It would therefore support amendments to facilitate reclassification and allow different routes of distribution in different EC member states. Pfizer would also support the opening up of the centralized procedure to give manufacturers greater choice of which procedure to follow.

Whether the potential for competition from extra-EU markets is prevented by the lack of mutual arrangements between the EU and other regulatory regimes (Issue I(ix))

10.668. In Pfizer’s view, lack of international harmonization acted as a barrier to the availability of a wide range of veterinary medicines. It supported efforts to harmonize requirements and reduce duplicate testing and associated costs.

Possible recommendations for regulatory changes

10.669. Pfizer said that it supported Recommendations 1, 6, 7, 8, 10, 11, 13, 14, 15 and 17 in the statement of 17 September. Its comments on others of the recommendations are recorded below.

The Secretary of State to consider negotiating changes to the draft Directive (also proposed in COM (2001) 404 final) so as to legitimise cross-border trading, without need for a further marketing authorisation, of any veterinary medicine authorised through the decentralised procedure, between member states in which it is authorised, and to remove barriers to labelling in the appropriate language (Recommendation (2))

10.670. Pfizer did not consider this recommendation necessary as there was already a perfectly acceptable, rapid and inexpensive system whereby an MA could be provided for a product to be parallel imported into the UK (a MAPI). This was was essential to ensure consumer and user safety, in that the regulatory agency ensured that suitable warnings were prominently displayed on the packaging of the product. Under current legislation this system could be applied to all forms of authorizations: centralized, decentralized and national. In Pfizer’s opinion, the MAPI system should remain in place to ensure that similarly-named products that did not have identical formulation or authorized indications between member states were not imported erroneously. Pfizer also believed that regulatory agencies should continue to control this situation so that, if necessary, products could be promptly recalled under the EC Rapid Alert System.

The Secretary of State to consider amending the remits of the Veterinary Products Committee and the Veterinary Medicines Directorate to preclude them from taking into consideration manufacturers’ views on the classification of a product for which they are seeking marketing authorisation (Recommendation (3))

10.671. Pfizer believed that every individual product should be classified on its own merits according to its nature and its usage, and that the MA holder, with its intimate knowledge of the molecule, should be able to express a view on the classification. Pfizer commented that the decision
regarding classification was taken by the VMD and VPC. The MA holder merely made recommendations at the time of application.

The Secretary of State and the Veterinary Medicines Directorate to consider instituting automatic review of classification whenever a product's marketing authorisation is renewed (or at similar intervals if the European Commission's proposal to make marketing authorisations permanent is adopted) and to base such reviews exclusively on the product’s existing dossier and accumulated field experience unless there is good scientific reason to require fresh testing to be carried out (Recommendation (4))

10.672. Pfizer was opposed to this proposal because it would be unnecessarily bureaucratic and would impose additional cost. As the VMD operated on a full cost recovery basis, the costs for such re-classification exercises would have to be found from the licence fees paid by MA holders. In addition, an arbitrary amendment to classification without reference to the MA holder could result in significant cost in terms of write-off of packaging, whereas if an MA holder wished to seek an amended classification it might be able to minimize its costs in packaging changes by appropriate timing of production runs. Moreover, Pfizer said that, where a classification review was instigated by the VMD in circumstances where fresh testing was required, the additional costs involved could be onerous for MA holders and might lead to a decision, for economic reasons, to withdraw the product from the market instead.

The Secretary of State to consider widening the remits of the Veterinary Products Committee and Veterinary Medicines Directorate to take into account the welfare of animals overall (Recommendation (5))

10.673. Pfizer was unclear about the meaning of this recommendation, but thought it would be outside the scope of the present inquiry.

The Secretary of State to consider establishing one or more new classifications of veterinary medicines to allow specific categories of persons (such as agricultural merchants and saddlers as well as veterinary surgeons and pharmacists) to dispense veterinary prescriptions for medicines so classified and to make corresponding changes to the law governing the dispensing of prescriptions (Recommendation (9))

10.674. Pfizer said that the existing classification system in use in the UK functioned well and did not seem to need additional categories. It was not obvious which medicines could be included in additional categories. The classification awarded to a medicine was dependent upon its properties, so it was difficult to understand why compounds that required professional advice and control in their supply could be reclassified to an intermediate category. If POMs had a history of safe use and were deemed suitable for a lower category, they would pass to PML (or lower) and be suitable for sale by retailers such as agricultural merchants or saddlers.

The Secretary of State and the Veterinary Medicines Directorate to consider safe and practical extensions of the PML concept to new combinations of species and indications (Recommendation (12))

10.675. Pfizer said that it was unclear about the purpose of this recommendation as the VMD could already consider safe and practical extensions of the PML concept. Pfizer would support extension of the PML concept to new combinations of species and indications where this could be achieved safely. It considered that nothing should prevent the addition of new claims if proper evidence of safety and efficacy were provided.

The Secretary of State to consider negotiating changes to the proposed Directive to allow provisional marketing authorisation to be given to any product for which an efficacy claim is made and which has successfully completed safety and quality assessments so that commercialisation may begin before completion of efficacy assessment (Recommendation (16))

10.676. Pfizer did not fully support this recommendation. It said that a product could already be made available before an efficacy assessment was completed, by means of a PMA or a special treatment authorization if there was an urgent or specific therapeutic need. Pfizer believed that, in the absence of such need, products should not be marketed before all safety, quality and efficacy assessments had been completed and all claims made for the product substantiated. Pfizer believed that relaxation of the system
to the extent we had suggested might lead some companies not to complete the efficacy assessments in a timely fashion or at all. This would be against the interests of animal welfare and consumer safety.

The Secretary of State to consider negotiating changes to the proposed Directive to remove the ranking of cascade options in respect of non food-producing animals so that, where circumstances allow recourse to cascade, a veterinary surgeon may use whichever option he considers best (Recommendation (18))

10.677. Pfizer was strongly opposed to this recommendation. Its implementation would remove any incentives for the companies (including Pfizer) that continued to invest considerable time and effort on R&D for veterinary medicines. If any medicine, whether licensed for animal use or not, could be administered, there would be no incentive for manufacturers to develop novel treatments since the costs were significant and the proposed recommendation would remove the opportunity for the investment to be recouped. Pfizer commented that such a recommendation would indicate a failure of the regulatory system for authorizing veterinary medicines.

10.678. Pfizer believed that there was also an animal welfare issue with such a proposal, since non-licensed products could be used in the absence of any safety or efficacy data in the animal species and disease condition being treated. In particular, there was no guarantee that a human generic would be equivalent to the parent/original veterinary medicine, and there were significant differences in the way in which animals and humans responded to medicines. Pfizer commented that we appeared to support the EC proposal to remove the five-year renewal (which was to be replaced with enhanced pharmacovigilance systems), but, in its view, our proposals to open up the cascade ran contrary to this. It was concerned that there would be no pharmacovigilance system for human generic products used in animals and no involvement of either the MCA or the manufacturers in the pharmacovigilance system.

The Secretary of State to consider negotiating changes to the proposed Directive to allow recourse to the cascade in the case of non food-producing animals where, notwithstanding the existence of an authorised medicine for the species and condition in question, the veterinary surgeon having the animal under his care considers this justified on grounds of animal welfare including cases where the cost of treatment would otherwise cause the animal to go untreated (Recommendation (19))

10.679. Pfizer opposed this recommendation. It considered that there were cost-effective licensed animal medicines available to treat most diseases even if they did not use the most up-to-date technology or products. In addition, to the extent that the recommendation would lead to substitution of licensed products with non-licensed products, it would reduce manufacturers’ incentive to invest in and develop veterinary medicines for particular species and indications (including minor species and less common diseases) and would inevitably lead to animal welfare issues. Pfizer also believed that there would be considerable practical difficulties with implementing and regulating this recommendation, since it was unclear how the circumstances in which veterinary surgeons could ignore the cascade for economic reasons could be controlled.

The RCVS to modify its Guide to Professional Conduct to remove restrictions on advertising of medicines by veterinary surgeons (except of advertising that clearly brings the veterinary profession into disrepute) (Recommendation (21))

10.680. Pfizer said that it supported this recommendation to the extent that it was implemented within the existing legal restrictions on advertising.

Pharmacia Ltd (Pharmacia Animal Health)

10.681. Pharmacia did not comment specifically on our provisional conclusions that a complex monopoly situation existed in relation to the supply within the UK of POMs to animal owners and that a complex monopoly existed relating to the supply to veterinary surgeries of vaccines for cats and dogs.

Issues

10.682. Pharmacia’s comments on matters raised in the statement of 16 April are recorded below.
Whether veterinary manufacturers tie in the sales of some or all products in their ranges with an anti-competitive effect (Issue II(i))

Whether veterinary manufacturers, via linked price promotions, use the existing market power of some products as a lever to gain share of other markets (Issue II(i)a)

10.683. Pharmacia said that it had received only anecdotal reports of competitor companies tying in purchases of one product with rebates on others. Pharmacia did not itself use that type of promotion. Its sales representatives were not allowed to negotiate price terms individually with customers. [Details omitted. See note on page iv.]

Whether veterinary manufacturers operate rebate schemes which are a barrier to successful market entry, in that they encourage veterinary surgeons to buy more from larger veterinary manufacturers (Issue II(i)b)

10.684. Pharmacia explained that its rebate scheme had been designed to offer a fair reward to those buying its veterinary medicines regularly, while at the same time ensuring that a reasonable rate of return was maintained. [Details omitted. See note on page iv.]

10.685. Rebates were commonplace in the industry [Details omitted. See note on page iv.]

10.686. Pharmacia said that the existence of a rebate scheme did not prevent customers from buying competing products. It thought it was extremely unlikely that any one manufacturer would have a sufficiently wide range to be able to enter into exclusive dealing with veterinary practices. Furthermore, the fact that generic veterinary medicines were so readily available meant that there were few brands or ‘must have’ products that could not be substituted by less expensive, generic veterinary medicines.

10.687. In Pharmacia’s opinion, therefore, rebate schemes in general were not anti-competitive. It speculated that at least one of its major competitors did not operate a rebate scheme.

Whether rebates have any other anti-competitive effect, apart from as a barrier to entry or expansion (Issue II(ii))

Whether veterinary manufacturers design their rebate schemes in such a way as to reduce price transparency (Issue II(ii)a))

10.688. [Details omitted. See note on page iv.]
Whether veterinary manufacturers’ rebate schemes are structured in such a way as to cause veterinary surgeons to charge higher prices than they would otherwise do (Issue II(ii)b)

10.689. Pharmacia said that it had no influence or control over the price charged for its medicines by veterinary surgeons and intermediaries. It made its veterinary price list available, but the veterinary surgeon determined his or her eventual charge to the customer. [Details omitted. See note on page iv.]

Whether veterinary manufacturers who operate rebate schemes gain an informational advantage over those who do not, and whether this enables them to strengthen their position in the market in an anti-competitive way (Issue II(ii)c)

10.690. Pharmacia was not aware of any manufacturer obtaining information from veterinary wholesalers solely as a result of the existence of a rebate scheme. Whilst manufacturers needed sales data in order to operate their schemes, wholesalers were not obliged to provide information to manufacturers. Pharmacia understood that any manufacturer, whether or not it operated a rebate scheme, could negotiate with any full-line veterinary wholesaler to obtain sales data relating to its veterinary medicines. Pharmacia had not found the information available from wholesalers particularly useful [Details omitted. See note on page iv.].

Whether veterinary manufacturers with a large market share in particular veterinary medicine sub-markets carry out anti-competitive practices to maintain their position, and in particular: whether veterinary manufacturers engage in predatory pricing (Issue II(ii)d)

10.691. Pharmacia said that it did not engage in predatory pricing and was not aware that any other manufacturer did so.

Whether veterinary manufacturers promote brand loyalty to such an extent as to limit price competition and restrict market entry (Issue II(ii)e)

10.692. Pharmacia said that branding was essential to its business, in creating and maintaining awareness of its veterinary medicines and developing confidence in them and in Pharmacia’s technical expertise and back-up. It regarded such means as sponsorship and gifts as an extension of branding, and normal commercial practice. The brand loyalty created did not replace price competition: if price was the sole or major consideration for the final customer then he or she would buy the cheapest medicine available. Pharmacia said that demand for a particular branded product would act as an incentive to other manufacturers to enter the market with generic, or similar, competitor medicines. In its view, the presence and success of generics illustrated that brand loyalty was not an absolute barrier to entry, not least because branded products were nearly always more expensive than generics. The success of a generic inevitably led to a fall in market shares of branded competitor products. Pharmacia did not believe that the cost of brand promotion was passed on to the consumer in higher prices.

Whether veterinary manufacturers engage in anti-competitive market sharing, by jointly choosing not to launch or promote products that directly compete with those of other suppliers (Issue II(ii)f)

10.693. Pharmacia said that it did not engage in market sharing and had no agreements of that kind with any company, nor had it ever been approached by a competitor about entering into such an agreement.

Whether the manufacturers of veterinary medicines are protected by the provisions of the cascade from competition from substitutable human medicines, and whether they exploit this protection by charging higher prices than would otherwise be the case (Issue II(iii))

10.694. Pharmacia said that safety and tolerability were the primary concerns when using any kind of medicine in an animal. There was no guarantee that medicines designed for humans would be appropriate for animals, or indeed that veterinary medicines designed for one animal species could be safely used in a different species. Although the cascade prevented the manufacturers of human generics from directly competing with veterinary manufacturers, there was nothing to stop them carrying out the
necessary tests and applying for veterinary MAs for their products. Pharmacia would be concerned at any suggestion that human medicines that had not been reviewed for use in animals could be substituted for properly tested animal medicines. There would be risks to animal welfare, and possibly to human health if unapproved medicines were used in food animals.

**Whether veterinary manufacturers set the price or influence the retail mark-up on veterinary medicines, and in particular whether veterinary manufacturers, through published list prices, effectively set minimum resale prices (Issue II(iv))**

**Whether veterinary manufacturers otherwise set, or influence, the price at which their products are resold (Issue II(v))**

10.695. Pharmacia said that it had no influence over the resale prices charged by veterinary surgeons. It had no control or influence over the wholesale price, [Details omitted. See note on page iv.]

not discuss resale prices with veterinary surgeons; nor did it structure its list price, price promotions [Details omitted. See note on page iv.] in order to influence the resale price. Pharmacia suggested that the wide range of veterinary surgeons’ prices was evidence of manufacturers’ inability to control or influence them, and was a function of the competitive process.

**Whether veterinary manufacturers request, or fail to initiate review of, classification of a medicine as prescription-only in cases where this is not necessary on grounds of safety (Issue II(vi))**

10.696. Pharmacia did not believe that any of its veterinary medicines were incorrectly classified in the UK. They were almost all antibiotics and so had to be POMs. It did not consider that any MA holder benefited from, or would have commercial reasons for encouraging, the classification of medicines as POM when a lesser classification would be possible. It said that the levels of promotional spend for POM and PML products for food animals were roughly the same and a PML classification increased the potential for sales, because of the wider distribution channel and lower end-user prices—PML distributors tended to apply a lower mark-up than veterinary surgeons. Although non-POM products for companion animals might require large-scale consumer advertising, the cost could be offset by an increase in sales, arising from a combination of easier access to the products by end-users and lower retail prices.

**Whether veterinary manufacturers encourage veterinary surgeons to buy certain prescription-only veterinary medicines by asserting that they will not be subject to reclassification (Issue II(vii))**

10.697. As Pharmacia’s portfolio consisted largely of antibiotics, there was an inherent assumption that they could not be reclassified. Nevertheless, Pharmacia had never asserted that any of its products would not be subject to reclassification. Indeed, given the existence of the five-yearly review mechanism, it thought it would be difficult for any manufacturer to make such an assertion about any product.

**Whether veterinary manufacturers charge differential prices to veterinary surgeons in such a way as to restrict competition (Issue II(viii))**

10.698. Pharmacia said that in general its rebates were calculated on a volume basis and without geographical influence. Within the pig and poultry business there was some limited scope for individual discounts to be negotiated with direct customers. These were veterinary surgeons with considerable bargaining power, and Pharmacia regarded its deals with them as a legitimate response to competition.

**Whether veterinary manufacturers refuse to supply to certain intermediaries (wholesalers or retailers) or classes of intermediaries; supply certain intermediaries on less favourable terms than others; or fail to respond to requests for supply by certain intermediaries (Issue II(ix))**

10.699. Pharmacia said that it would supply any intermediary that was legally entitled to purchase veterinary medicines, subject to a minimum order threshold. As regards terms, Pharmacia had given the pharmacists that it currently supplied the option to be treated as either a veterinary wholesaler (and receive the wholesaler discount) or a veterinary surgeon equivalent (and participate in the veterinary
practice rebate scheme), but terms to be offered to any new pharmacists would be considered on a case by case basis.

**Whether veterinary wholesalers refuse to supply customers other than veterinary practices, universities and research establishments, and in particular refuse to supply pharmacies (Issue III(i))**

10.700. Pharmacia said that it had no knowledge of any such refusal by a veterinary wholesaler. In its experience, very few pharmacists had expressed an interest in selling veterinary medicines.

**Whether veterinary surgeons influence veterinary manufacturers not to reclassify prescription-only medicines to a lower classification (Issue IV(vii))**

10.701. Pharmacia told us that it had received no representations from veterinary surgeons about the classification of its products. It recognized that there were differences in the classification and distribution of veterinary medicines across Europe, but commented that this was because of the vagaries of the system rather than any wish of manufacturers to restrict routes of supply in the UK.

**Whether veterinary surgeons charge higher than necessary prices on prescription-only medicines (Issue IV(xii))**

10.702. Pharmacia said that it was aware of variations in the prices charged by veterinary surgeons for POMs. It believed that prices were influenced by the type of animal involved, local competition between veterinary surgeons and variations in price between wholesalers. Pharmacia had little information about final resale prices, [Details omitted. See note on page iv.].

**Possible remedies**

10.703. Pharmacia’s comments on the possible remedies set out in the statement of 17 September are recorded below.

*A requirement for manufacturers of POMs giving rebates to veterinary surgeons to provide sufficient information, either directly or through wholesalers, so as to enable the veterinary surgeon to ascertain with certainty the cost net of rebates of POMs supplied to them (paragraph 24(b)(v) of the statement)*

10.704. Pharmacia said that in principle it supported the aim of the remedy, but it thought that what constituted ‘sufficient information’ needed to be clarified to ensure that it did not become an administrative burden on manufacturers. [Details omitted. See note on page iv.]

10.705. Pharmacia did not believe that this remedy alone would bring about improved price transparency. It said that the recommendations in paragraph 24(b)(iv) and (vi) of the statement would need to be implemented in parallel.

*A requirement for manufacturers and wholesalers that supply POMs in the UK to supply pharmacies (paragraph 24(c)(i) of the statement)*

10.706. Pharmacia said that animal welfare and safety was the paramount consideration. In its view, attempts to encourage pharmacists’ participation in the supply chain should be made only where there was certainty that pharmacists were available who were adequately trained in the dispensing of veterinary medicines.

10.707. Pharmacia commented that the term ‘requirement … to supply’ needed to be clarified to ensure that the requirement did not become an administrative burden on a manufacturer and did not mean that POMs would have to be supplied direct to pharmacies where that would be commercially or economically unviable, taking account of the manufacturer’s distribution network, location of the
pharmacy, volume of purchases and availability through wholesalers. At present, the only POMs that Pharmacia supplied direct were pig and poultry products, and these were supplied to a small number of pharmacies, as well as veterinary practices, where it was satisfied that the pharmacist was adequately trained and where criteria including credit checks and minimum purchasing requirements were met. Pharmacia would not support any requirement for manufacturers actively to promote products to pharmacies with a view to gaining their custom. It said that the direction of promotional activity should be left to the discretion of the individual manufacturer.

A requirement for manufacturers and wholesalers that supply POMs in the UK to supply pharmacies on terms that enable them to compete with veterinary surgeons (paragraph 24(c)(ii) of the statement)

10.708. Pharmacia said that although it would support the end-result of such a remedy, because this could be a greater customer base for itself, it would again want to clarify exactly what requirement, and burden, would be placed on manufacturers to facilitate such competition.

10.709. It commented that there was a distinction between the different functions of the veterinary surgeon and pharmacist in the supply chain. A veterinary surgeon could be responsible for both prescribing and dispensing whereas the pharmacist was responsible only for dispensing. The terms of supply to veterinary surgeons recognized both the functions they performed. Any requirement for a manufacturer to provide favourable terms to a pharmacy to allow it to compete with a veterinary surgeon needed to recognize the difference in functions, which meant that pharmacies did not compete with veterinary surgeons on all aspects of the service provided, nor add the same value to the supply chain as veterinary surgeons did. The terms of any remedy needed to accommodate this.

10.710. Pharmacia said that a pharmacy had a different set of overheads, operational expenses and commercial goals from a veterinary practice. Given those differences, it was not clear that providing a pharmacy with the same or similar terms for the purchase of POMs would actually allow it to compete. Pharmacia also commented that the volume of product bought by a pharmacy was likely to be considerably less than the volume taken by a veterinary practice: we needed to take account of this as otherwise it would raise manufacturers’ cost of doing business. In Pharmacia’s view, to ignore the difference would seem to be anti-competitive and would demand discrimination in favour of pharmacies over veterinary surgeons, at the expense of the manufacturers. Pharmacia believed that its terms and prices to veterinary surgeons were reasonable and did not yield particularly high margins. It said that it should not be expected to subsidize anti-competitive attempts to reconfigure the marketplace.

A requirement for veterinary surgeons when they write prescriptions for POMs to do so on an ‘or equivalent’ basis to enable those dispensing such prescriptions to supply alternative authorised veterinary medicines to the brand specified (paragraph 24(c)(iv) of the statement)

10.711. Pharmacia did not believe that permitting a pharmacist, even one adequately trained to dispense veterinary medicines, to substitute an alternative product to the one prescribed would be in the best interests of the animal under treatment, as the veterinary surgeon would have taken a number of factors into account in deciding to prescribe a particular product. The pharmacist would not be aware of the reasoning behind that decision and might well endanger the animal by substituting a different product even if it was indicated for the same condition.

10.712. In Pharmacia’s view, the remedy would not increase competition in the market to any great extent, because the potential liability that could attach to a pharmacist for incorrectly dispensing an unsuitable ‘equivalent’ would undoubtedly limit the number of pharmacists willing to dispense ‘equivalents’. Pharmacia did not consider that any benefit there might be to the market was worth the serious safety risks associated with the remedy. Nor did it consider that such a remedy was needed, as the cascade gave veterinary surgeons considerable flexibility in prescribing.

Regulatory issues

10.713. Regarding regulatory matters, Pharmacia said that veterinary medicine manufacturers wanted harmonization of regulatory requirements and systems across the EC and as much harmonization as possible between the USA and the EC.
10.714. We asked Pharmacia about the cost implications of the requirements of five-yearly MA renewals as against the cost of pharmacovigilance. Pharmacia said that the cost of generating data for renewals was far more significant than the renewal fee payable. It estimated that over the previous ten years, the annual cost of maintaining and defending its current MAs within the EC had been approximately US$1.5 million to $2 million (excluding staff and administration costs). It pointed out that a report produced for FEDESA in 2002 had found that companies spent around 35 per cent of their R&D budgets on defensive R&D (ie R&D required solely to keep a product on the market) and that some 50 per cent of defensive R&D was unjustified and had been requested for political or other, non-scientific reasons.

10.715. Pharmacia agreed with FEDESA’s recommendation that the five-year renewal requirements should be removed and instead the current variations system, GMP inspections and strengthened pharmacovigilance requirements should be relied on. Pharmacia understood that there was a proposal for Periodic Safety Update reports to be submitted every three years with the option for regulatory authorities to request further updates at any time—such a system would trigger actions, where necessary, at any stage of a product’s life cycle rather than just at the time of the renewal of the MA. Pharmacia estimated that if FEDESA’s recommendation were to be implemented then most of its US$1.5million to $2 million cost of maintaining MAs would be saved, although this would be dependent on the level of harmonized pharmacovigilance requirements that were agreed.

10.716. We invited Pharmacia to estimate the extra cost of regulation by considering the effects of three different hypotheses: no external regulation of veterinary medicines anywhere in the world; mutual recognition by the EC of US authorization; and UK acceptance of EC central or national authorization without further regulatory requirements. It said that it was extremely difficult to quantify the likely savings. Under the first hypothesis, it would still undertake testing for safety, quality and efficacy, but would make savings by testing to only one set of international standards instead of having to repeat tests. The most significant saving was likely to accrue from avoidance of lost sales as it would be far quicker to bring products to market on a global scale. The same considerations applied under the second hypothesis. Under the third, additional cost arising from the VMD’s stringent application of EC requirements would be avoided, together with the UK regulatory fees.

10.717. Pharmacia’s comments on regulatory matters raised in the statement of 16 April are recorded below.

*Whether the current MRL requirements restrict competition in, and availability of, veterinary medicines, particularly for minor species (Issue I(i))*

10.718. Pharmacia said that determination of MRLs increased the cost of bringing a veterinary medicine to market. This might discourage manufacturers from widening the range of species for which an individual product was authorized. Under EC law it was illegal to use a medicine in a food species for which there was no MRL for the molecule concerned. The data needed in order to obtain an MRL required substantial investment that companies could not justify to develop products for minor species—which in the EC included horses, goats and rabbits—and consequently medicines for those species had been disappearing. The European Commission’s proposal to allow extrapolation of MRLs to set MRLs for minor food species was a positive move, but if regulatory bodies still required full residues and efficacy studies to be conducted in these animals then that would still represent a significant barrier.

*Whether the inclusion of an efficacy test in the marketing authorisation procedure unnecessarily increases the barriers to introducing a veterinary medicine to the market (Issue I(ii))*

10.719. Pharmacia said that it, and most other veterinary manufacturers, would undertake efficacy testing whether or not such testing was required by law. Nevertheless, it believed that without a regulatory requirement there would be no consistency as to the meaning of efficacy, and no certainty that a product had in fact been tested.

10.720. Efficacy testing was used to determine the appropriate treatment dosage for an animal and without it a medicine could be misused or overused. This was of particular concern to Pharmacia, involved as it was in the development and marketing of antibiotic medicines, as over-exposure to ineffective antibiotics could lead to problems with resistance levels, especially in relation to food animals. The potential risk to animal and human health would greatly increase if efficacy testing were to be removed from the regulatory regime. Pharmacia believed that the risk far outweighed the benefits of a shorter regulatory procedure.
10.721. All other European markets and major markets outside the EC required defined efficacy data before an authorization could be granted. Pharmacia said that if the requirement were to be removed from the UK it would hamper attempts to harmonize the regulatory framework of the UK with those of other countries, thereby possibly limiting the potential market for certain products. It did, however, believe that the efficacy testing requirements for essentially similar veterinary medicines could be reviewed in order to reduce unnecessary animal testing, cost and time to market.

10.722. In conclusion, Pharmacia said that it believed the efficacy test was essential and, provided that it was uniformly enforced, did not unnecessarily increase barriers to entry.

Whether the absence of provision for a third party to request reclassification of a veterinary medicine, or for regular review of classification, leads to an over-classification of veterinary medicines (Issue I(iii))

10.723. Pharmacia considered that the regulatory authorities (in conjunction with the MA holder) were the proper bodies to determine the classification of a veterinary medicine. It was true that there was not a level playing field in the EC because of differences in classification systems and interpretations between member states, but Pharmacia did not believe that this led to deliberate overclassification in the UK. It could indeed be argued that there was underclassification in some other member states.

10.724. Pharmacia did not agree that a third party should be permitted to apply for a review of a medicine’s classification. A third party might request review in order to gain competitive advantage over the MA holder (by forcing it to focus its energies on defending the classification), or might submit a request based on a misunderstanding of the product and its use. Even if the applicant bore all the cost of a review, dealing with an application would still require considerable effort on the part of the MA holder and the regulatory authority. In Pharmacia’s view, the current controls were sufficient, particularly as the MA holder, as the person entitled to apply for review of a medicine’s classification within five years of its authorization, was obliged to ensure the medicine’s safety, quality and efficacy.

Whether the lack of a prescription-only sub-classification for medicines that could be prescribed by a veterinary surgeon (for animals under his/her care) without prior clinical examination restricts competition (Issue I(iv))

10.725. In Pharmacia’s view, animal safety and welfare, prudent use of veterinary medicines and public safety should be the primary concerns when considering classification issues, rather than the cost and inconvenience of veterinary consultation. Pharmacia would support greater access to veterinary medicines provided that this could be achieved safely and in the interests of animal welfare. It did not believe, however, that any of its POMs could be dispensed without some prior veterinary involvement.

Whether the length of time allowed to regulators to reach a decision on marketing authorisations is a barrier to introducing a new medicine (Issue I(v))

10.726. Pharmacia said that it would welcome any reduction in the time taken to bring a product to market, and any incentives to encourage prompt action by the regulatory authorities. It did not believe, however, that speedier decisions on MA applications would alone encourage manufacturers to increase their portfolios, or new manufacturers to enter the market. The R&D time period needed for a new product far exceeded the time taken by the regulatory authorities.
Whether the requirement that medicines on the Pharmacy and Merchants List (PMLs) may only be dispensable by veterinary surgeons, pharmacists, and Suitably Qualified Persons (SQPs) employed by agricultural merchants or saddlers restricts competition in the supply of PMLs (and hence of any POMs which may be reclassified as PMLs) (Issue I(vi))

10.728. Pharmacia considered that the current PML classification could lead to some anomalous situations that might restrict competition. For instance, it thought that it should be possible for pet shops and other retailers to be licensed to sell PML products for companion animals without having to reclassify themselves as saddlers. It agreed that the dispensing of veterinary medicines should be properly regulated, but believed that in certain situations it should be possible to increase distribution channels without sacrificing regulatory control.

Whether the current arrangements which preclude SQPs from breaking bulk in supplying veterinary medicines places them at a competitive disadvantage to veterinary surgeons (Issue I(vii))

10.729. Pharmacia said that its pack sizes were designed to meet end-users’ needs and it was unlikely that SQPs would want to split packs, as their customers did not usually require very small amounts of a product. If pack splitting was to occur, Pharmacia would not object provided that the procedure was regulated and the safety, quality and efficacy of medicines was not compromised. It would not, however, condone the splitting of aseptic preparations, because of the high risk of contamination.

Whether the conditions under which the European centralised procedure is available could restrict competition, either: by being too narrow, and therefore compelling companies to use the decentralised procedure even if this is a greater barrier to introducing the product to market, or by being too narrow, and so allowing companies to gain a POM classification for their products which cannot subsequently be revised to PML (Issue I(viii))

10.730. Pharmacia did not believe that the conditions acted as a barrier to entry in the sense of stopping veterinary medicines from being brought to market at all. It was more likely to deter veterinary manufacturers from seeking authorization in all member states. As a major market, the UK was unlikely to suffer as a result of this.

10.731. Pharmacia agreed that the classification as POM of centrally authorized products could be anti-competitive in that it might result in an over-classification relative to the other medicines in its market. For example, a novel wormer would be classified centrally as POM whereas in the UK the majority of wormers were PML or GSL.

Whether the potential for competition from extra-EU markets is prevented by the lack of mutual arrangements between the EU and other regulatory regimes (Issue I(ix))

10.732. From Pharmacia’s experience as a US-owned company, it had found that the process of bringing US-authorized medicines to European markets took an unnecessarily long time because results of tests carried out in the USA were not recognized by the regulatory authorities in the EC. This affected decisions on whether or not to introduce products into Europe. Pharmacia did not, however, consider that there should be immediate mutual recognition of authorizations: it would first be necessary to harmonize all relevant standards.

Possible recommendations for regulatory changes

10.733. Pharmacia commented on those recommendations in the statement of 17 September where it wanted to draw certain matters to our attention. Its comments are recorded below.

The Secretary of State to consider negotiating changes to the draft Directive so as to legitimise cross-border trading, without need for a further marketing authorisation, of any veterinary medicine authorised through the decentralised procedure, between member states in which it is authorised, and to remove barriers to labelling in the appropriate language (Recommendation (2))

10.734. Pharmacia did not agree with this recommendation. It said that it was essential, for animal welfare and safety reasons, for labelling to be in the language of the country in which the product was to
be used. More importantly, it believed that the product needed to be registered with the regulatory authority in the country where it was to be sold, in order to ensure adequate controls on batch number and expiration dates in case a batch recall was ever necessary. Pharmacia also believed that the changes we were suggesting would make it easier for counterfeit products to reach the market, which was clearly a danger to animal welfare and food safety.

10.735. Veterinary medicines authorized through the decentralized procedure could vary between EC member states, and any imported product should comply with the regulatory requirements of the country of import to ensure consistency and a level playing field with domestic products. Pharmacia saw no reason why imported veterinary medicines should be treated differently from parallel imported human medicines, which had to be licensed by the appropriate regulatory authority and be labelled in the language of the country where they were to be sold. Pharmacia added that the manufacturer must also be given adequate rights to protect its intellectual property in the country of import.

**The Secretary of State to consider amending the remits of the Veterinary Products Committee and the Veterinary Medicines Directorate to preclude them from taking into consideration manufacturers’ views on the classification of a product for which they are seeking marketing authorisation (Recommendation (3))**

10.736. Pharmacia did not agree that such a recommendation was necessary, since MA holders did not benefit from over-classification of their products. It thought that a change in the remit would indeed preclude a manufacturer from attempting to achieve a lower classification for its product. That would be undesirable, given the valuable data and experience that the manufacturer could contribute to the decision from its work in developing the product and researching its safety profile and intended market.

**The Secretary of State to consider widening the remits of the Veterinary Products Committee and Veterinary Medicines Directorate to take into account the welfare of animals overall (Recommendation (5))**

10.737. Pharmacia said that it would support any initiative to ensure animal welfare. However, it was under the impression that these bodies already took overall account of animal welfare of animals when classifying a product. Furthermore, it was not clear from the recommendation what our goal was in putting forward the recommendation, how it would be implemented in practice and what would be the consequences in terms of both time delays and uncertainty.

**The Veterinary Medicines Directorate to consider offering applicants for marketing authorisation the option of submitting their dossier in stages (Recommendation (15))**

10.738. Pharmacia said that it would support any initiative aimed at saving time in bringing a product to market, but it queried whether implementation of this proposal would achieve time savings overall. In addition, it said that it would be hesitant to use such a procedure if the fees payable were to increase as a result. The VMD operated on a full costs recovery basis, and it seemed to Pharmacia that submitting a dossier in stages would invariably lead to greater man-hours spent on the review, thus leading to higher fees.

**The Secretary of State to consider negotiating changes to the proposed Directive to allow provisional marketing authorisation to be given to any product for which an efficacy claim is made and which has successfully completed safety and quality assessments so that commercialisation may begin before completion of efficacy assessment (Recommendation (16))**

10.739. Pharmacia said that it did not agree with the removal of requirements for any efficacy testing, and reliance on a simple efficacy claim, unless there was a secure basis for the claim (for example, bio-equivalence with an existing licensed product) and provisional data available in support. Implementation of any proposal to the contrary could jeopardize animal welfare and bring the industry into disrepute.
The Secretary of State to consider negotiating changes to the proposed Directive to remove the ranking of cascade options in respect of non food-producing animals so that, where circumstances allow recourse to cascade, a veterinary surgeon may use whichever option he considers best (Recommendation (18))

The Secretary of State to consider negotiating changes to the proposed Directive to allow recourse to the cascade in the case of non food-producing animals where, notwithstanding the existence of an authorised medicine for the species and condition in question, the veterinary surgeon having the animal under his care considers this justified on grounds of animal welfare, including cases where the cost of treatment would otherwise cause the animal to go untreated (Recommendation (19))

10.740. Pharmacia had serious concerns about these recommendations. Whilst any prescribing decision should be left to a veterinary surgeon’s clinical judgement, Pharmacia believed that the ranking within the cascade gave structure and certainty to the prescribing decision rather than being a barrier either to competition or to an animal receiving appropriate treatment. Pharmacia was also concerned that implementation of recommendations on these lines could stifle future innovation, in that manufacturers would be less inclined to spend money developing new veterinary medicines that would then be in competition with human generic medicines. This would clearly be to the detriment of veterinary medicine, as the best treatment for an animal would always be one developed specifically for a particular disease in a particular species.

The RCVS to modify its Guide to Professional Conduct to remove restrictions on advertising of medicines by veterinary surgeons (except of advertising that clearly brings the veterinary profession into disrepute) (Recommendation (21))

10.741. Pharmacia would not support any proposal that gave veterinary surgeons free rein to advertise its products. It did not believe that our proposed exception was wide enough to prevent inappropriate advertising. It said that veterinary manufacturers were subject to a voluntary code in respect of their advertising as well as to the general legal requirements about comparative advertising etc, and in its view the same requirements would need to be applied to veterinary surgeons. It would therefore only be in favour of this type of recommendation if it were limited to use of advertising materials or messages developed by the manufacturer (and owner of the intellectual property in the product).

**Schering-Plough Ltd (Schering-Plough Animal Health (UK))**

Provisional complex monopoly situation—supply of POMs to animal owners

10.742. In Schering-Plough’s view, our provisional conclusions did not provide sufficient supporting evidence to warrant its inclusion in a complex monopoly finding. We had identified seven conducts in paragraph 9 of the statement of 17 September as the basis for the provisional complex monopoly. Only three of these related to alleged conduct by manufacturers, the other four concerning veterinary surgeons or wholesalers. As regards conducts (d), (e) and (f) alleged against manufacturers, Schering-Plough considered that there was inadequate evidence that it had engaged in such conduct to justify its inclusion in our provisional finding.

10.743. In respect of the conduct described in paragraph 9(d) of the statement (refusal/failure to negotiate discounts and rebates with buying groups), Schering-Plough said that it was not its general policy or practice to negotiate discounts and rebates only with individual veterinary practices. A significant number of its customers formed part of wider veterinary practices with whom it negotiated discounts and rebates centrally, based on the overall volume of purchases by the group. One such example was Companion Care group, which had about 40 branches across the UK. The rebate received by each practice within this wider group was based on the aggregated purchases of all 40 branches. There were, however, a few buying groups with which Schering-Plough considered it would not generally be appropriate to deal direct. These were buying groups of unconnected veterinary practices, where Schering-Plough considered that dealing with the buying group might compromise its ability to maintain a close relationship with the individual practices, and that the involvement of the buying group would not materially add value to the supply chain.
10.744. Expanding on these comments, Schering-Plough said that it had established direct links, including discount and rebate arrangements, with individual veterinary practices before buying groups came on the scene. It said that, unlike corporate practices, buying groups were unable to guarantee a particular volume of products, yet they were looking for an additional discount over and above that paid to their members. These groups still wanted Schering-Plough to deliver to the veterinary wholesalers and the wholesalers to deliver to the individual practices, and Schering-Plough still needed to direct its sales efforts to the individual practices, so there was no cost saving to be made. In general, therefore, the propositions put forward by buying groups tended not to be commercially attractive. Schering-Plough believed that, in principle, failure to supply groups that did not add value to the supply chain did not amount to conduct that prevented, restricted or distorted competition.

10.745. Schering-Plough told us, however, that it did not refuse to do business with anyone and in fact supplied three buying groups: London Veterinary Forum Ltd, St Francis and Vetcel. All members of these groups that bought Schering-Plough products were able to participate in its Vetplan rebate scheme and receive discounts on their purchases. In addition, Schering-Plough was willing to pay additional discounts to the buying group itself if it was able to give a satisfactory purchasing commitment. At the time of our inquiry, with one exception, none of the buying groups had been able to provide a sufficient commitment. The exception related to a recently-launched anti-inflammatory product for companion animals, where negotiations had been concluded with the Vetcel buying committee. Schering-Plough had decided to deal direct with Vetcel in this case because it believed that Vetcel might be in a position to improve the take-up of the product by its members.

10.746. With regard to the complaint made by Vetcel (see paragraph 11.428), Schering-Plough said that it did not generally deal with Vetcel direct because:

— to do so could undermine the close relationship that Schering-Plough enjoyed with the veterinary practices that were members of Vetcel;

— Vetcel was believed to retain for itself an element of the discount/rebate that it negotiated with manufacturers, such that its members would be unlikely to be materially better off if Vetcel took over the negotiations of discounts and rebates with Schering-Plough; and

— Vetcel did not offer any benefits to Schering-Plough that would warrant the payment of an extra discount/rebate to it.

10.747. In commenting on the conduct described in paragraph 9(e) of the statement (operation of rebate schemes that make it difficult for veterinary surgeons to ascertain at the time of purchase the cost of POMs to themselves), Schering-Plough rejected any suggestion that its Vetplan rebate scheme had this effect. Under Vetplan, the same discount applied to all Schering-Plough veterinary medicines that were purchased by the veterinary surgeon. The discount was clearly specified in the monthly statement provided to each veterinary surgeon and did not fluctuate from month to month. Consequently, the veterinary surgeon could readily ascertain the net cost of each Schering-Plough POM by deducting from the published notional professional price (NPP) (a) the Vetplan discount and (b) the settlement margin granted by the veterinary wholesaler.

10.748. As regards the conduct described in paragraph 9(f) of the statement (failure of manufacturers to supply pharmacies with POMs and/or enable them to obtain supplies of POMs on terms that enable them to compete with veterinary surgeons), Schering-Plough said that it was wholly unreasonable to expect manufacturers to supply POMs direct to pharmacies, just as it would be unreasonable to expect human pharmaceutical manufacturers to supply retail pharmacies direct. There would be logistical problems as retail pharmacies were likely to require daily deliveries whereas the few agricultural merchants supplied direct by Schering-Plough had weekly deliveries. In addition, the rebates provided to veterinary surgeons reflected their role in generating demand for Schering-Plough’s products, and in providing valuable information about both the performance of particular products and their own prescribing practices. Pharmacies did not provide similar benefits and in Schering-Plough’s view there was, therefore, no justification for requiring manufacturers to treat pharmacies and veterinary surgeons alike.

10.749. Schering-Plough said that it did not supply veterinary practices direct. It would expect any pharmacy that wanted to obtain veterinary POMs to do so via the veterinary wholesalers, which was how veterinary practices were supplied. It was entirely happy for veterinary wholesalers to supply POMs to
pharmacies. It told us that it would supply POMs to any wholesaler with an appropriate licence, including a pharmacy or pharmacy group. To date, it had not supplied any pharmacy group that was also a wholesaler because the circumstance had never arisen and it therefore could not say with certainty that it would offer any such group the same terms as it offered the veterinary wholesalers.

10.750. Commenting on the benefits provided by veterinary surgeons to manufacturers, Schering-Plough said that, unlike pharmacists, they influenced the choice and volume of product used whereas pharmacists were not in a position to have any influence over such matters. With regard to the provision of information through rebate schemes, Schering-Plough said that through its Vetplan scheme it obtained valuable data (with the consent of veterinary surgeons) about purchases of its medicines. The information was also useful to the veterinary surgeons as it enabled them to compare their purchases over a period of time and against a national average. These kinds of comparisons could, for example, suggest that some veterinary surgeons were under-diagnosing certain conditions. The information was of real value to Schering-Plough and it was concerned that it would not be so readily available if pharmacies became active in the supply chain. It feared that there would be logistical barriers and extra costs in the way of collation of information from pharmacies, possibly by a third party who would sell data to the manufacturers. Furthermore, manufacturers would prefer still to get information at the level of the prescriber rather than less precise information about medicines dispensed by pharmacies. This would require the pharmacy, or a third party, to seek the consent of veterinary practices on disclosure of the information.

10.751. In the circumstances, Schering-Plough did not believe it would be appropriate to base a complex monopoly finding on the fact that manufacturers did not supply pharmacies direct, or did not grant them equivalent rebates to those granted to veterinary surgeons.

10.752. We invited Schering-Plough to respond to a specific complaint from R M Jones, a pharmacy, that in response to its request for access to veterinary POMs Schering-Plough had indicated that it would supply only through veterinary wholesalers (see paragraph 12.117). Schering-Plough said that in its view there were entirely legitimate and appropriate reasons, as outlined in paragraph 10.748, for it to advise R M Jones to obtain its POMs through the veterinary wholesalers, even though it directly supplied this pharmacy with PML medicines.

**Provisional complex monopoly situation—supply of cat and dog vaccines to veterinary surgeries**

10.753. Schering-Plough acknowledged that purchases of cat and dog vaccines were aggregated under its Vetplan rebate scheme. However, it questioned the provisional complex monopoly finding, given that cat and dog vaccines were not the only veterinary medicines that were included in the aggregated rebate schemes of manufacturers. Although the cat and dog vaccines market segment was large, others, such as antibiotics and anaesthetics, were equally big, so it was difficult to understand why we had focused on vaccines.

10.754. Schering-Plough added that it was a relatively small supplier of cat and dog vaccines in the UK; its share of supply was only 8 per cent of cat vaccines and 10 per cent of dog vaccines. On that basis, even if we were to find that there was a complex monopoly in respect of the supply of cat and dog vaccines, it did not believe that it should be included in the finding.

10.755. So far as Schering-Plough was aware, there had been no significant changes in recent years in competition in supply of cat and dog vaccines, save for the effects of Fort Dodge’s recent production problems. It believed that Intervet and Fort Dodge had together accounted for about 70 per cent of supply of cat vaccines until some time in 2001 when Fort Dodge seemed to have become the leading supplier. Schering-Plough thought that the ranking of the other four main suppliers had not changed, although Merial had increased its market share from about 1 to 3 per cent. The picture was similar for dog vaccines: in the previous three or four years Intervet and Fort Dodge together accounted for some 70 per cent of supply and the other four suppliers had experienced only small changes in their shares.

10.756. Schering-Plough provided information about is own vaccine sales, which showed that [x] per cent of veterinary practices that bought cat or dog vaccines from it bought both kinds of vaccine, [x] per cent bought only cat vaccines and [x] per cent bought only dog vaccines. In value terms, [x] per cent of its total sales of cat and dog vaccines was from practices buying both, [x] per
cent from practices buying only cat vaccines and [\textless\_\textless\_] per cent from those buying only dog vaccines. Information on sales of cat and dog vaccines won and lost by Schering-Plough in the period January 1999 to August 2002 suggested that practices readily switched from one supplier to another.

Other issues

10.757. Schering-Plough’s comments on other matters set out in the statement of 16 April are recorded below.

Whether veterinary manufacturers tie in the sales of some or all products in their ranges with an anti-competitive effect (Issue II(i))

Whether veterinary manufacturers, via linked price promotions, use the existing market power of some products as a lever to gain share of other markets (Issue II(i)a)

Whether veterinary manufacturers operate rebate schemes which are a barrier to successful market entry, in that they encourage veterinary surgeons to buy more from larger veterinary manufacturers (Issue II(i)b)

10.758. Schering-Plough said that it did not use linked price promotions. Its price promotions were normally limited to a single veterinary medicine.

10.759. Schering-Plough told us that its Vetplan volume rebate scheme was a cross-product scheme in the sense that the rebate given to veterinary surgeons was (a) determined by their aggregate purchases of Schering-Plough products, and (b) applied to all of their purchases of such products.

10.760. Schering-Plough had introduced Vetplan in 1988 to establish a direct relationship with veterinary surgeons, who were the key drivers of demand for its products. The benefits that flowed from the scheme included marketing advantages for Schering-Plough in that when sales representatives met veterinary surgeons they could have a focused discussion because they would know which products the veterinary surgeon was already buying and in what quantities. The scheme also led to a better understanding of veterinary surgeons’ prescribing behaviour. This gave Schering-Plough an informed view on disease patterns and enabled it to adapt and develop its product range to address changes in those patterns, to the benefit of animal welfare. Schering-Plough also gained direct feedback on its products.

10.761. Schering-Plough said that if Vetplan were removed and lower net prices given to veterinary wholesalers, there would be a risk that the price reductions would not be passed on in full to veterinary surgeons. It made the following points:

— Cross-product rebate schemes were not unique to the supply of veterinary medicines and it appeared that rebates of this sort were increasingly being used as an extra element of price competition between suppliers, for example loyalty cards.

— The cost of providing support services to veterinary surgeons was a major variable cost incurred by Schering-Plough. Offering volume discounts to encourage veterinary surgeons to purchase larger volumes of products resulted in sales being less dispersed than would otherwise be the case, and consequent cost savings in respect of support services for Schering-Plough. These were reflected in the discounts paid under Vetplan.

— Vetplan was designed to be consistent and transparent. The level of rebate given to a veterinary surgeon was, in the vast majority of cases, not individually negotiated, but was set by reference to bands of purchases. The same level of rebate applied to all Schering-Plough products purchased and was calculated by reference to the NPP. It was therefore easy for a veterinary surgeon to calculate the actual price he or she paid for a particular product by deducting from the NPP both the rebate and the settlement margin received from the veterinary wholesaler.

— Vetplan did not require veterinary surgeons to purchase product exclusively from Schering-Plough nor to purchase across the range of its products.
10.762. Schering-Plough said that although it had a strong market position in respect of certain products, this was also likely to be true of most other manufacturers of veterinary medicines. These veterinary medicines comprised a large number of narrow product markets. Consequently, the competition law concern that an aggregated rebate scheme operated by a dominant supplier placed non-dominant competitors at a disadvantage was of materially less concern in this sort of sector, where most suppliers enjoyed high market shares in at least some products.

**Whether rebates have any other anti-competitive effect, apart from as a barrier to entry or expansion (Issue II(ii))**

**Whether veterinary manufacturers design their rebate schemes in such a way as to reduce price transparency (Issue II(ii)a)**

10.763. Schering-Plough believed that Vetplan did not prevent veterinary surgeons from knowing the price that they paid for its products. It added that Vetplan included a cushioning mechanism whereby a veterinary surgeon’s MAT had to have changed to a different band within the banding structure for a number of months before the rebate was altered. The fact that the rebate was based on retrospective purchases did not, therefore, cause uncertainty about the level of rebate applying to current purchases.

**Whether veterinary manufacturers’ rebate schemes are structured in such a way as to cause veterinary surgeons to charge higher prices than they would otherwise do (Issue II(ii)b)**

10.764. Schering-Plough denied that Vetplan was designed to result in higher prices to animal owners than would otherwise be the case. The suggestion appeared to be based on the misconception that it would want higher retail prices: on the contrary, it was in its interests for veterinary surgeons to charge lower, not higher, prices, because higher retail prices were a disincentive to farmers/producers and other animal owners buying veterinary medicines and tended to result in lower sales volumes and revenues. Schering-Plough told us that it had in some instances suggested to veterinary surgeons that they should base their prices on the actual cost to them of medicines (ie after rebates etc) rather than on the list price.

**Whether veterinary manufacturers who operate rebate schemes gain in informational advantage over those who do not, and whether this enables them to strengthen their position in the market in any anti-competitive way (Issue II(ii)c)**

10.765. Schering-Plough said that sales information was available to all manufacturers from NOAH and GfK. The extra information that it received from Vetplan was of benefit in terms of its marketing activities but in its view this information advantage was not anti-competitive, because the information related only to sales of Schering-Plough products and not to purchases of other manufacturers’ products. Also, Schering-Plough received the information from the veterinary wholesalers, with the consent of the veterinary surgeons. It was feasible for other suppliers to obtain similar information in the same way, and many of them did so.

**Whether veterinary manufacturers with a large market share in particular veterinary medicine sub-markets carry out anti-competitive practices to maintain their position, and in particular: whether veterinary manufacturers engage in predatory pricing (Issue II(ii)d)**

10.766. Schering-Plough said that it was not aware of any such practices by veterinary manufacturers.

**Whether veterinary manufacturers promote brand loyalty to such an extent as to limit price competition and restrict market entry (Issue II(ii)e)**

10.767. Schering-Plough commented that the speed with which generic products were able to gain market share indicated that brand loyalty was of limited value in the face of a lower-priced generic competitor. By way of example, it told us that until about two years ago Merial’s Ivomec product was by far the leading product in the ivermectin anthelmintic sector (products for the control of worms in cattle and sheep), with an estimated share of supply of more than 70 per cent. About two years ago, however, Norbrook had launched a lower-priced generic competitor product, Noromectin, which had already gained a share of about 30 per cent.
Whether veterinary manufacturers engage in anti-competitive market sharing, by jointly choosing not to launch or promote products that directly compete with those of other suppliers (Issue II(ii))

10.768. Schering-Plough said that it was not aware of any collusion between competitors (or potential competitors) on the decision to launch or promote a product. In its experience, the high costs of regulatory clearances compared with the relatively small size of most markets for particular products in the UK meant that a manufacturer would be reluctant to launch a new product in a market where there was already one or more well-established products, unless the new product had some sufficiently clear advantage (in terms of efficacy, convenience or cost) to give the prospect of significant sales.

Whether the manufacturers of veterinary medicines are protected by the provisions of the cascade from competition from substitutable human medicines, and whether they exploit this protection by charging higher prices than would otherwise be the case (Issue II(iii))

10.769. Schering-Plough said that it was frequently not financially viable for manufacturers to obtain regulatory approval for products for minority species. The cost of establishing and obtaining approval for the appropriate presentation and dosage regimes, and also withdrawal time, for each new species were significant. Similar problems arose in the case of products for the treatment of rare diseases and conditions. As a result, there was a lack of approved veterinary medicines for treating minority species or rare conditions. The cascade had been instituted to enable veterinary surgeons to address this problem. However, use of the cascade inevitably involved a compromise between considerations of safety and efficiency of the treatment, on the one hand, and the veterinary surgeons’ desire to offer some form of treatment, on the other. Where they prescribed human pharmaceuticals for animals under the cascade, they had to do so without guidance as to the appropriate dosage, prescribing regime and withdrawal times. This inevitably entailed some risk.

10.770. Schering-Plough said that certain antibiotics, eye and ear treatments and anaesthetics that were used for humans and animals were more expensive per unit when supplied in the animal formulation. The difference in price was primarily a reflection of the proportionately higher regulatory cost per unit sold, and also sales and distribution costs on account of the lower sales volumes, that the manufacturers of the animal pharmaceuticals had to bear. Removing the cascade and allowing veterinary surgeons to prescribe the human version of the product, whenever available, might reduce the unit costs but it would leave veterinary surgeons without guidance about the appropriate dosage and also without the back-up support provided with veterinary medicines. Schering-Plough said that manufacturers would not continue to bear the costs of maintaining regulatory approvals for the veterinary medicine if veterinary surgeons were able to prescribe the human product, because the demand for the animal version would rapidly disappear. The key issue was whether the additional safety and efficiency benefits secured by the regulatory regime justified the higher price of veterinary medicines.

Whether veterinary manufacturers set the price or influence the retail mark-up on veterinary medicines, and in particular whether veterinary manufacturers, through published list prices, effectively set minimum resale prices (Issue II(iv))

10.771. In Schering-Plough’s opinion it was not in the manufacturers’ interest to maximize retail prices for veterinary medicines. On the contrary, it would be in their interest if retail prices fell, with veterinary surgeons significantly reducing their retail mark-up. Schering-Plough said that the high mark-up charged by some veterinary surgeons was a significant disincentive to animal owners to buy medicines. It discouraged farmers and producers from using certain treatments with the frequency or in the quantities that effective animal husbandry would suggest. Schering-Plough would support wholesale retailers invoicing veterinary surgeons at a simple net price (rather than at list price less a settlement discount) and veterinary surgeons showing the charges for veterinary medicines and other services separately on their invoices.

Whether veterinary manufacturers otherwise set, or influence, the price at which their products are resold (Issue II(v))

10.772. Schering-Plough was not aware of this practice occurring.
Whether veterinary manufacturers request, or fail to initiate review of, classification of a medicine as prescription-only in cases where this is not necessary on grounds of safety (Issue II(vi))

10.773. Schering-Plough said that safety was its primary concern in deciding what classification to request for a new product. POM status would ensure that a product was prescribed only after diagnosis by a veterinary surgeon. In addition, the quality of the feedback on efficacy or side effects was likely to be better if the product had POM classification, again because of the involvement of veterinary surgeons in prescription and monitoring of its performance (which was especially important for new compounds). Once a product had received a POM classification, the UK regulatory regime acted as a major disincentive to manufacturers seeking reclassification for two reasons:

— Although the cost of submitting the application for reclassification was relatively inexpensive, the VMD was likely to request significant further information in order to complete its assessment. The cost of providing this information could be significant. Moreover, if the VMD did consent to reclassification, further significant costs would be incurred on such matters as new product packaging and revised directions for use.

— There was always a risk that changes in the policy of the VMD and the way applications were handled might not merely lead to refusal of the lower reclassification, but also to risk the original POM classification unless new test data was produced, at further substantial costs for the manufacturer.

For these reasons it would be unusual for Schering-Plough voluntarily to seek reclassification of a POM.

Whether veterinary manufacturers encourage veterinary surgeons to buy certain prescription-only veterinary medicines by asserting that they will not be subject to reclassification (Issue II(vii))

10.774. Schering-Plough said that it had not experienced this. However, in the past, when it had reclassified a levamisole worming product from POM to PML, veterinary surgeons complained that having helped to develop the market for the product they would in future face competition from sales by agricultural merchants.

Whether veterinary manufacturers charge differential prices to veterinary surgeons in such a way as to restrict competition (Issue II(viii))

10.775. Schering-Plough said that the price paid for its products by veterinary surgeons was a combination of:

— the price charged by the veterinary wholesaler. While the wholesaler’s net selling price might vary from one veterinary surgeon to another, Schering-Plough sold at a standard price to all veterinary wholesalers; and

— the rebate paid under Schering-Plough’s Vetplan volume discount scheme. The level of rebate varied depending on the aggregated purchase of Schering-Plough products, but the Vetplan scheme was offered on equal terms to all veterinary surgeons.

Schering-Plough told us that its sales representatives had only limited discretion to negotiate with veterinary surgeons outside the Vetplan scale (in respect of one-off and seasonal offers). It maintained that it was not charging differential prices in a way that restricted competition.

Whether veterinary manufacturers refuse to supply to certain intermediaries (wholesalers or retailers) or classes of intermediaries; supply certain intermediaries on less favourable terms than others; or fail to respond to requests for supply by certain intermediaries (Issue II(ix))

10.776. Schering-Plough said that it would supply any customer directly as long as it satisfied certain financial and business criteria, including an assertion that it would generate sufficient demand in volume terms.

10.777. As veterinary surgeons, smaller agricultural merchants and pharmacies tended to require small volumes of products, it was more appropriate for them to buy from wholesalers. Schering-Plough placed no restrictions on the type of customer to whom its wholesalers could resell its products.
Whether the provision of detailed sales information by veterinary wholesalers to veterinary manufacturers was detrimental to veterinary surgeries or customers (Issue III(iii))

10.778. Schering-Plough said that the sales information obtained from veterinary wholesalers enabled its sales representatives to have informed and focused discussions with veterinary surgeons. Meetings were likely to be of more value to both parties if the manufacturer had this information. No information was disclosed about purchases by individual farmers or other owners of animals, so it was not apparent how the disclosure of sales information by the wholesaler would be detrimental to either veterinary surgeons or consumers.

Whether veterinary surgeons fail to provide itemised invoices showing a breakdown between the cost of professional fees and the cost of medicines dispensed (Issue IV(ii))

10.779. Schering-Plough said that some, but not all, veterinary surgeons provided itemized invoices. It would strongly support the provision of itemized invoices by all of them so that the cost of veterinary medicines was clearly identifiable.

Whether veterinary surgeons by some action or omission may have indicated to veterinary manufacturers and/or veterinary wholesalers that they should refuse to supply pharmacists, or supply them on less-favourable terms (Issue IV(v))

10.780. Schering-Plough said that it was not aware of any such suggestion having been made to it. Whilst it was unlikely to deliver products direct to pharmacies because of the relatively small orders involved, it had no objection to veterinary wholesalers supplying its products to pharmacies and this would be made clear to any veterinary surgeon suggesting otherwise.

Possible remedies

10.781. Schering-Plough’s views on the possible remedies set out in the statement of 17 September are recorded below.

10.782. As a preliminary remark, Schering-Plough said that the animal health industry was experiencing difficult economic conditions and was in decline. It urged us not to recommend remedies that would increase the operating costs of manufacturers, veterinary wholesalers and/or veterinary surgeons, because this would be not only to their detriment but also to the detriment of animal welfare.

A requirement for veterinary surgeons when quoting the price at which they will dispense any POM also to state the cost of that POM to themselves (paragraph 24(b)(iv) of the statement)

10.783. In Schering-Plough’s view, there was a material risk that this remedy would result in increased price transparency between POM manufacturers and a consequent risk of reduced price competition between them. It said that if the purchase cost of a POM were disclosed, presumably in writing, by a veterinary practice to customers when quoting its selling price, then the information would inevitably find its way into the public domain. Consequently, it would be relatively easy for competing POM manufacturers to obtain the information and use it to estimate fairly accurately the level of discount being offered to particular veterinary surgeons on particular products by the supplying manufacturer. The level of discounts was not publicly known at present and was one of the elements of price competition between POM manufacturers.

10.784. Schering-Plough argued that it would be anti-competitive and in breach of Chapter I of the Competition Act 1998 for POM manufacturers to exchange information on the level of discounts they gave to veterinary surgeons, because of the greater level of price transparency that would result. Paragraph 3.21 of the DGFT’s Guidelines on the Chapter I Prohibition (OFT 401) stated that: ‘The exchange of information on prices may lead to price co-ordination and therefore eliminate any competition which would otherwise be present between the undertakings.’ The proposed remedy, although not involving any exchange of information directly between manufacturers, would nonetheless result in otherwise confidential price information becoming known to competitors. In Schering-Plough’s opinion, it would therefore create the same risk of a reduction in price competition between manufacturers and would self-evidently be counter-productive.
A requirement for manufacturers of POMs giving rebates to veterinary surgeons to provide sufficient information, either directly or through wholesalers, so as to enable the veterinary surgeon to ascertain with certainty the cost net of POMs supplied to them (paragraph 24(b)(v))

10.785. Schering-Plough said that it supported this remedy. It believed that its existing Vetplan scheme was entirely transparent and already met this requirement.

A requirement for the veterinary surgeons to provide itemised bills distinguishing the cost of services and the cost of POMs (paragraph 24(b)(vi))

10.786. Schering-Plough supported this proposal.

A requirement for manufacturers and wholesalers that supply POMs in the UK to supply pharmacies (paragraph 24(c)(i))

10.787. Schering-Plough said that it had no objection to pharmacies obtaining its POM products from veterinary wholesalers. It would not, however, be economically viable or logistically feasible for it to supply retail pharmacies direct. Its distribution structure for POMs at present was not designed to handle the rapid delivery of relatively small quantities of product and it would not be feasible to attempt to develop such systems. Schering-Plough pointed out that there were approximately 12,000 retail pharmacies in the UK, whereas it supplied POMs direct to only four veterinary wholesalers (and a small number of food producers). Although it did supply non-POMs direct to certain trade customers, there were only 80 of them and the majority were supplied by wholesalers. Schering-Plough said that it would not be able to supply any pharmacies run by its 80 trade customers with POMs directly while refusing direct supply to other pharmacies—in other words, supplying POMs to the limited number of customers it did already supply direct would open the floodgates of demand, which it lacked the logistics to meet. It was, therefore, strongly opposed to any proposal to require manufacturers to supply POMs direct to pharmacies.

A requirement for manufacturers and wholesalers that supply POMs in the UK to supply pharmacies on terms that enable them to compete with veterinary surgeons (paragraph 24(c)(ii))

10.788. Schering-Plough said that manufacturers could not control the price at which veterinary wholesalers resold products to retail pharmacies. It was therefore not feasible for manufacturers to try to ensure, through the prices that they charged wholesalers, that pharmacies obtained their products at the same prices as veterinary surgeons.

10.789. A proposal that manufacturers should pay rebates to pharmacists equivalent to those paid to veterinary surgeons would also present a number of difficulties. Schering-Plough had introduced its rebate scheme because it had wished to establish a direct relationship with veterinary surgeons in order to obtain information about disease patterns, prescribing behaviour and feedback on its products. The payment of rebates direct to veterinary surgeons reflected the benefits that Schering-Plough received in return, both in terms of such information and increasing demand for its products. The payment of volume rebates to pharmacies would not generate any equivalent benefits. Pharmacies did not drive demand, nor were they in a position to provide manufacturers with the sort of feedback that veterinary surgeons could provide. The increased costs of giving them rebates would have to be compensated for, by either an increase in prices or a reduction of discounts/rebates paid elsewhere in the distribution chain, ie to veterinary wholesalers and veterinary surgeons.

10.790. As veterinary surgeons and pharmacies did not play an equivalent role in the supply chain, Schering-Plough strongly believed that it would be inappropriate to impose equivalent financial terms in respect of the supply of POMs to them.

A requirement for veterinary surgeons when they write prescriptions for POMs to do so on an ‘or equivalent’ basis to enable those dispensing such prescriptions to supply alternative authorised veterinary medicines to the brand specified (paragraph 24(c)(iv))

10.791. Schering-Plough commented that the meaning of the term ‘equivalent’ in this context was unclear; it could be being used with a similar meaning to ‘bioequivalent’ (or generic) or to products that might be considered to be therapeutically equivalent, such as aspirin and paracetamol. It said that to allow pharmacists to dispense on the basis of therapeutic equivalence would present major potential
animal welfare and safety problems, and would be wholly unacceptable because of the fundamental differences in therapeutic performance, side-effect profile and specific indications for use in various patient groups. While a pharmacist might consider one drug to be as good as another in terms of therapeutic equivalence, he or she would not be aware that the veterinary surgeon had prescribed the particular medicine because, for example, of the animal’s age and medical condition and in the knowledge that the prescribed medicine was suitable for that class of patient whereas ‘equivalent’ alternatives were not. Medicines of the same chemical class, for example oxytetracycline and chlortetracycline, could not be regarded as ‘equivalent’, and those of different chemical classes such as paracetamol and aspirin most certainly could not be considered as such.

10.792. Schering-Plough said that in the case of food animals, the situation was more complex. For example, the drug florfenicol was prescribed in cattle for respiratory disease. An ‘equivalent product’ existed in the form of medicines containing the related active ingredient chloramphenicol, which was used in human and small-animal medicine. However, chloramphenicol was banned for use in food animals under Regulation No (EEC) 2377/90 (on the establishment of maximum residue limits). Hence, although chloramphenicol might be considered ‘equivalent’ to florfenicol, this was not the case. There were a number of other examples.

10.793. Schering-Plough said that this left open the question of precisely how similar a generic was to the treatment of choice prescribed by the veterinarian. The two might differ in terms of excipients (qualitatively and quantitatively), dissolution rates (with tablets, capsules and some bolus devices) and ultimately, in pharmacokinetic behaviour. The differences might be even greater between a human generic and the prescribed product, and a human medicine might be potentially harmful to animals.

10.794. A further problem was that in veterinary medicine, generics might be based on the same active ingredients as branded products, but would not necessarily contain the same dose—hence, the generic might not be truly ‘equivalent’ and therefore not as efficacious as the branded product, thus compromising animal welfare, or it might lead to overdose, or contain an excipient to which the animal had previously experienced an adverse reaction and which was not present in the branded drug. For food animals, the branded drug and the generic might have different withdrawal periods. If the veterinary surgeon had prescribed a medicine because it had a short withdrawal period, use of a generic with a longer withdrawal period might compromise consumer safety if the animal was likely to be slaughtered in the near future.

10.795. Schering-Plough said that the proposed remedy also raised questions of liability and responsibility. Under UK legislation the veterinary surgeon was responsible for the safety and welfare of animals under his or her care, and under EC residues monitoring legislation was responsible for ensuring that residues did not occur in food of animal origin. If a pharmacist or other person replaced the prescribed medicine with an ‘equivalent’, it was not clear who then would be responsible for the welfare of the animal and the presence or absence of residues.

10.796. For these reasons, Schering-Plough would be concerned if pharmacists were given the freedom to supply a product other than that specified by the veterinary surgeon.

Prohibition on manufacturers operating rebate schemes in which the level of rebates given on purchases of cat and dog vaccines is based on, or substantially influenced by, the combined value of purchases of those vaccines (paragraph 25)

10.797. Schering-Plough said that if this remedy were implemented, it would require manufacturers who wished to offer rebates direct to veterinary surgeons to operate at least three separate schemes, one for cat vaccines, one for dog vaccines and one for other products. It said that such a change would add an additional level of complexity to its existing Vetplan scheme and would run counter to the proposed remedy in paragraph 25(b)(v) of the statement, which was intended to make it easier for veterinary surgeons to calculate their net purchase prices. It also questioned whether it would be proportionate to require it to make such a change to its Vetplan scheme, bearing in mind that Schering-Plough was only a relatively small supplier of cat and dog vaccines.
Regulatory issues

10.798. Schering-Plough provided us with a comparison of the US and EC regulatory requirements for new veterinary medicinal pharmaceutical products. It also provided some analysis of the costs of regulation. Its conclusions were:

— In general terms, the costs associated with developing a product in the USA and the EC were comparable.

— The costs of developing and registering a veterinary medicine in the UK were not dissimilar to those of developing and registering the same product in other EC member states.

— ‘Gold-plating’ by the VMD was probably not a major issue in the decentralized (mutual recognition) procedure; it was certainly no worse than in several of the other EC countries such as Germany and France.

— ‘Gold-plating’ was, however, a serious issue at renewal in the UK, when the VMD’s demands and the ensuing defensive regulatory costs were significantly higher than in most other EC countries.

— It was unlikely that an absence of regulation for veterinary medicines would reduce costs overall, because some testing in product development was essential, as was some testing to protect the industry from product liability issues. Marketing might be brought forward by a year or so in the absence of regulation.

10.799. Schering-Plough’s comments on regulatory issues set out in the statement of 16 April are recorded below.

Whether the current MRL requirements restrict competition in, and availability of, veterinary medicines, particularly for minor species (Issue I(i))

10.800. Schering-Plough did not believe that the current MRL requirements in themselves restricted competition. It considered, however, that the following factors were problematic in terms of developing new active ingredients for food species:

— The overall costs, not just the MRL costs, of regulation had increased dramatically.

— The regulatory system, particularly in Europe, was becoming ever tighter, goalposts were shifting and individual regulators becoming more stringent and demanding (especially in [Details omitted. See note on page iv.]).

— Consumer pressures, and groups concerned about residues of pesticides, veterinary medicines, heavy metals, antibiotic resistance etc, had in effect taken away from regulators any flexibility they once had. Politicians too were concerned about residues, especially in the wake of several food-related crises, for example BSE, salmonella, and in response to constant pressure from groups such as Friends of the Earth and the Soil Association.

— Consumers (and politicians) were aware of the fallout of EC bans on hormones used for growth enhancement, bovine somatotrophin used for milk production enhancement and other compounds used for production improvement.

— As a result of BSE and FMD, consumers and other activists were calling for a return to ‘traditional’ farming, organic systems and less reliance on medicines and agrochemicals.

10.801. For all of these reasons, the industry would have to ask whether it was worth investing in new actives for food animals. Schering-Plough said that such questions would not go away and contributed to one of the worst prospects for any industry—regulatory uncertainty.
Whether the inclusion of an efficacy test in the marketing authorisation procedure unnecessarily increases the barriers to introducing a veterinary medicine to the market (Issue I(ii))

10.802. Schering-Plough said that efficacy testing rarely delayed an application; rather, it was usually safety or quality aspects. It said that efficacy testing was essential to ensure effectiveness and prove that a drug was innovative and safe. One of the major ways of demonstrating that a drug was innovative was by way of an efficacy study. Efficacy testing also protected companies from product liability claims.

Whether the lack of a prescription-only sub-classification for medicines that could be prescribed by a veterinary surgeon (for animals under his/her care) without prior clinical examination restricts competition (Issue I(iv))

10.803. Schering-Plough said that POMs were by definition those medicines which should not, largely for safety reasons, be prescribed without prior diagnosis. This would usually necessitate a clinical examination. It recognized, however, that so-called repeat prescriptions (which did not require a fresh examination each time the medicine was purchased) could sometimes be given without compromising safety. Other than that, it did not believe that POMs should be capable of prescription without prior clinical examination. As repeat prescriptions were possible under the current classification system, Schering-Plough did not believe that competition was unduly restricted.

Whether the length of time allowed to regulators to reach a decision on marketing authorisations is a barrier to introducing a new medicine (Issue I(v))

10.804. Schering-Plough said that the regulatory authorities often did not complete assessments ahead of timetables. Nevertheless, in most countries, delays were not generally a major problem and did not constitute a significant barrier to the introduction of a new medicine. Introduction of the new EC systems (centralized and decentralized) had led to fewer delays, of less duration, across Europe.

Whether the requirement that medicines on the Pharmacy and Merchants List (PMLs) may only be dispensed by veterinary surgeons, pharmacists, and Suitably Qualified Persons (SQPs) employed by agricultural merchants or saddlers restricts competition in the supply of PMLs (and hence of any POMs which may be reclassified as PMLs) (Issue I(vi))

10.805. In Schering-Plough’s view, PMLs were available from a sufficient number of sources for there to be effective competition in their supply. Schering-Plough commented that this issue was too remote from the supply of POMs for it to fall within our terms of reference.

Whether the current arrangements which preclude SQPs from breaking bulk in supplying veterinary medicines places them at a competitive disadvantage to veterinary surgeons (Issue I(vii))

10.806. Schering-Plough thought it unlikely that the inability to break bulk placed SQPs at a material disadvantage to veterinary surgeons. Customers of SQPs typically required bulk supplies whereas veterinary surgeons usually supplied to named patients only, so they needed to be able to break bulk supplies. Schering-Plough said that pack-splitting could be dangerous, and it was therefore sensible to restrict it. It was also important that when splitting occurred, medicines and product literature were not separated as this could constitute a major threat to patient and owner safety. The risk was much reduced when a veterinary surgeon split a pack as he or she would issue individual recommendations and warnings, directed at the needs of the patient concerned.

Whether the conditions under which the European centralised procedure is available could restrict competition, either: by being too narrow, and therefore compelling companies to use the decentralized procedure even if this is a greater barrier to introducing the product to market, or by being too narrow, and so allowing companies to gain a POM classification for their products which cannot subsequently be revised to PML (Issue I(viii))

10.807. Schering-Plough said that delays, or the need to withdraw from the centralized procedure to avoid major difficulties in registration, including arbitration, could make the centralized procedure attractive. Under European Commission proposals to amend the veterinary legislation (Regulation 2001), the centralized procedure would be opened up, indeed it would be compulsory, for all new chemical entities (ie active ingredients) to be registered via this route.
10.808. Under the same review of the legislation, the European Commission had proposed changes to the decentralized procedure, which would improve its effectiveness. One of the measures planned was the introduction of compulsory arbitration through the CVMP regardless of whether a manufacturer withdrew the application in the member state objecting. This would have two main effects: manufacturers would try even harder to get their applications/dossiers as ‘correct’ as possible and member states that persisted in asking minor questions, wrapped up as ‘major public health’ issues, would be subject to greater control, through the CVMP.

Possible recommendations for regulatory change

10.809. Schering-Plough said that it supported Recommendations 6, 7, 8, 11, 13, 14, 15, 16 and 17 in the statement of 17 September. It pointed out that Recommendation 1 was already supported by FEDESA in its comments on the review of the current legislation applicable to the supply of veterinary medicines. Schering-Plough’s comments on others of our possible recommendations are recorded below.

The Secretary of State to consider negotiating changes to the draft Directive (also proposed in COM (2001) 404 final) so as to legitimise cross-border trading, without need for a further marketing authorisation, of any veterinary medicine authorised through the decentralised procedure, between member states in which it is authorised, and to remove barriers to labelling in the appropriate language (Recommendation (2))

10.810. Schering-Plough said that there was no regulatory objection to this, providing linguistic difficulties and problems relating to over-labelling could be overcome.

The Secretary of State to consider amending the remits of the Veterinary Products Committee and the Veterinary Medicines Directorate to preclude them from taking into consideration manufacturers’ views on the classification of a product for which they are seeking marketing authorisation (Recommendation (3))

10.811. Schering-Plough said that the manufacturer of a veterinary medicinal product would have invested several million pounds in its development and would have extensive knowledge of the drug substance, the mode of action, any side effects, and any possible dangers to the patient, the public or the environment. It seemed sensible that the manufacturer, taking its broad knowledge of the product into consideration, should at least be able to suggest the appropriate legal category and support this with relevant data.

10.812. This was not a major issue for Schering-Plough as the majority of its products were clearly ethical in nature, for use by veterinary surgeons or under the instruction and supervision of veterinary surgeons. In its experience, the VPC and the VMD paid little regard to the wishes of the industry, and products were generally classified as they saw fit. Schering-Plough believed that the industry usually requested a classification that it knew would be satisfactory to the authorities. For example, when submitting an MA application for a veterinary anaesthetic, the only realistic legal category open to the applicant would be POM.

10.813. Schering-Plough suggested that the best guide to classification must be whether the condition for which the product was indicated needed a veterinary diagnosis. If it did, then POM classification should be mandatory as it should be for drugs that needed careful supervision (for example, antibiotics) or control (for example, narcotics/barbiturates). It thought that a POM classification was also essential if the patient was likely to require a drug on a long-term basis under veterinary supervision and management (for example, insulin for a diabetic dog or cat).

The Secretary of State and the Veterinary Medicines Directorate to consider instituting automatic review of classification whenever a product’s marketing authorisation is renewed (or at similar intervals if the European Commission’s proposal to make marketing authorisations permanent is adopted) and to base such reviews exclusively on the product’s existing dossier and accumulated field experience unless there is good scientific reason to require fresh testing to be carried out (Recommendation (4))

10.814. Schering-Plough agreed with the recommendation but said that the industry’s views should be assessed as one of the factors taken into consideration.
The Secretary of State to consider widening the remits of the Veterinary Products Committee and Veterinary Medicines Directorate to take into account the welfare of animals overall (Recommendation (5))

10.815. In Schering-Plough’s experience, both the VPC and the VMD already did this, as did the European Commission. Decisions were made on the basis of animal welfare in its widest sense, as this was also covered by the Veterinary Surgeons Act. For example, when bovine somatotrophin (BST) was under deliberation in Europe as a milk production enhancer, the expert committee gave a positive opinion on the product’s safety, quality and efficacy whereas the European Commission took the view that cattle treated with BST might, inter alia, come under greater metabolic pressure as part of the milk production enhancement process, to the extent that animal welfare would be compromised. Consequently the product was not authorized.

The Secretary of State to consider establishing one or more new classifications of veterinary medicines to allow specific categories of persons (such as agricultural merchants and saddlers as well as veterinary surgeons and pharmacists) to dispense veterinary prescriptions for medicines so classified and to make corresponding changes to the law governing the dispensing of prescriptions (Recommendation (9))

10.816. Schering-Plough strongly opposed this recommendation. It said that veterinary surgeons and pharmacists were trained for anything from four to six years in all aspects of dispensing. Poor or illegal dispensing by untrained personnel could raise major safety issues.

The Secretary of State to consider re-defining the categories of business permitted to sell PMLs so that any business may do so subject to registration of its premises (as now) and the authorisation of each sale by a Suitably Qualified Person (SQP) (Recommendation (10))

10.817. Schering-Plough did not object to this recommendation providing that those concerned had been trained to AMTRA standards.

The Secretary of State and the Veterinary Medicines Directorate to consider safe and practical extensions of the PML concept to new combinations of species and indication (Recommendation (12))

10.818. Schering-Plough supported this recommendation except in respect of products where veterinary diagnosis and veterinary support were needed.

The Secretary of State to consider negotiating changes to the proposed Directive to remove the ranking of cascade options in respect of non food-producing animals so that, where circumstances allow recourse to cascade, a veterinary surgeon may use whichever option he considers best (Recommendation (18))

10.819. Schering-Plough said that the cascade was written in such a way as to ensure that all aspects of animal welfare were given due regard: that is, that on the one hand animals did not go untreated because there was no medicine available and on the other hand they were not put at undue risk by being given unsuitable medicines as an alternative to no treatment. Schering-Plough believed that the first recourse of a veterinary surgeon, where no suitable medicine was available, should be to an authorized veterinary medicine indicated for another disease or in another species.

The Secretary of State to consider negotiating changes to the proposed Directive to allow recourse to the cascade in the case of non food-producing animals where, notwithstanding the existence of an authorised medicine for the species and condition in question, the veterinary surgeon having the animal under his care considers this justified on grounds of animal welfare including cases where the cost of treatment would otherwise cause the animal to go untreated (Recommendation (19))

10.820. Schering-Plough said that it would support this recommendation, but only where the alternative was no treatment on the grounds of cost.

Vétoquinol (UK) Ltd

10.821. Vétoquinol did not comment on the statements of 16 April and 17 September.
Competition

10.822. Vétoquinol said that the competition it faced tended to be very product specific, [Details omitted. See note on page iv.]. It was not active in SAVs and ectoparasiticides, where there was most competition.

Discounts and rebates

10.823. [Details omitted. See note on page iv.]

10.824. Although Vétoquinol considered that the discount schemes of some suppliers were a barrier to entry, it said that it had succeeded with its own products because of its emphasis on quality and efficacy.

10.825. Vétoquinol said that the trend in the industry generally was for high list prices and high discount levels, available to veterinary surgeons as either retrospective packages or special offers. Its particular concern was large discounts offered by the leading companies, based on volume of sales across the entire product range, which made it difficult for smaller suppliers, with limited ranges, to compete. This was particularly true of biologicals, where there were three or four dominant players, especially where vaccines were concerned. These companies were able to exert leverage through their vaccines and endoparasiticides for small animals, which all veterinary practices had to stock if they were to succeed, across the rest of their product range. The larger the turnover taken from a single manufacturer, the more discount would be obtained across a whole range of products. Vaccines came with a complete package of marketing support: vaccination certificates, reminders for the following year, business cards and even newsletters. In Vétoquinol’s view, these additional features acted as disincentives to veterinary practices to switch to a different supplier. Vétoquinol was also concerned about the scope for bundling by the larger suppliers, for example the offer of free antibiotics with purchases of vaccines.

10.826. [Details omitted. See note on page iv.]

Prices

10.827. Vétoquinol said that manufacturers’ price lists for veterinary surgeons provided a base line for charging their clients. Few veterinary surgeons paid the list price, the reduction obtained depending on the size of the practice and its negotiating ability. Computer software used in veterinary practices was geared to a fixed mark-up on the list price. [Details omitted. See note on page iv.]

10.828. Vétoquinol said that most owners of companion animals were not very price sensitive. Many were fully insured. On the other hand, farmers, particularly intensive farmers such as pig and poultry specialists, were much more price aware and price sensitive and would ask the veterinary surgeon for specific products. Farmers had to relate the cost of treatment to the economic value of the animal.

10.829. [Details omitted. See note on page iv.]

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10.830. [Details omitted. See note on page iv.]

10.831. Asked about international price differences, Vétoquinol said that prices of POMs were higher in the UK than elsewhere in the EC, for a number of reasons. It suggested that the difference between the UK and the Republic of Ireland was partly because veterinary surgeons in the Republic of Ireland gained some income from TB testing and so were less dependent on sales of medicines. Regulatory fees were higher in the UK than other EC countries because the VMD had to be self-financing: that was more relevant to smaller products than large ones. The broader costs of compliance were fairly similar throughout the EC. If a product was being considered for mutual recognition, the same data was required everywhere and all the regulatory authorities worked to set time schedules.

10.832. Other factors included the historical practice of the pharmaceutical companies of setting different prices in different EC countries. [Details omitted. See note on page iv.]

Another factor in relation to medicines for food animals was the economic value of the animal. If an animal was worth less in one country than another, the price of medicine would be lower, although not necessarily pro rata. Vétoquinol added that veterinary surgeons in the UK, unlike those elsewhere, had traditionally accepted higher list prices in anticipation of higher discounts.

Pharmacies

10.833. Vétoquinol said that [X] per cent of its products were sold through wholesalers, but it would supply veterinary surgeons direct in an emergency. [Details omitted. See note on page iv.]

Regulatory issues

10.834. [Details omitted. See note on page iv.]

10.835. Vétoquinol said that it would be happy to see all veterinary medicines classified as POMs. The advantage of the POM classification was that it ensured that veterinary surgeons gave clients appropriate advice on safety and the correct use of the medicine. [Details omitted. See note on page iv.]

Virbac Ltd

Provisional complex monopoly situation—supply of POMs to animal owners

10.836. Virbac had no comments on our provisional conclusion that a complex monopoly situation existed in the supply of POMs to animal owners. It questioned, however, whether such a complex monopoly situation would tend to operate in favour of manufacturers. It said that there was considerable competition between manufacturers in what was a shrinking market, and this prevented any one manufacturer from increasing prices beyond what could be justified. Virbac had no comments on our
view that it was appropriate to consider the conducts we had identified in paragraph 9 of the statement of 17 September as constituting a single complex monopoly.

10.837. With regard to the conduct identified in paragraph 9(d) (refusal or failure by manufacturers to negotiate discounts and rebates with buying groups), Virbac said that it supplied most of the existing buying groups on the same terms as it supplied veterinary practices, including discount and rebate terms.

10.838. In relation to the conduct identified in paragraph 9(e) of the statement (operation of rebate schemes by manufacturers that make it difficult for veterinary surgeons to ascertain with certainty at the time of purchase the cost to themselves of POMs), Virbac said that it operated different levels of rebate for vaccines than for other POMs. All rebates were agreed in advance with the practices, were on a specific percentage basis and were paid quarterly. Veterinary practices would get a quarterly statement showing how much they had bought, the rebate level applying and the amount of rebate they were owed. Although there were seasonal variations in purchases, the agreed rebate level did not fluctuate to reflect those variations; it would continue unchanged for at least a year and in some cases for longer. Virbac believed that it would not be difficult for any of its veterinary practice customers to calculate how much rebate they could expect to get.

10.839. Commenting on the conduct identified in paragraph 9(f) of the statement (failure of manufacturers to supply pharmacies with POMs and/or enable them to obtain supplies of POMs on terms that enable them to compete with veterinary surgeons), Virbac said that its POMs were supplied to veterinary practices via the veterinary wholesalers, with the exception of two practices that it supplied direct under historical agreements, and it would expect any pharmacies that wanted to buy its POMs also to do so from the veterinary wholesalers. Virbac did not have the infrastructure and logistics to supply small quantities of its products direct to large numbers of veterinary practices and pharmacies across the UK. It did not open new accounts for any retailers and referred any that enquired to the wholesalers that distributed its products. Virbac said that it was willing to supply POMs to wholesalers other than veterinary wholesalers, and would be legally obliged to do so provided that they held the appropriate licence.

10.840. With regard to the terms available to pharmacies, Virbac said that it did not offer them the rebates that it gave to veterinary practices. This was partly because pharmacies had wanted to buy only small volumes and had not been interested in discussing a longer-term commitment to buy from Virbac. There was also a political reason: Virbac would be frowned on by the veterinary profession if it supplied pharmacies with POMs on the same terms as it supplied veterinary practices. Virbac said that it was aware of this from its discussions with veterinary surgeons, although there was no written evidence. It told us, however, that it had been threatened with boycott by veterinary practices when it started supplying vaccination clinics and that its market share had suffered as a result. It believed that enabling pharmacies to compete with veterinary practices could have similar results. It was also concerned that pharmacies might use veterinary products as a loss leader because they would represent such a small percentage of total turnover, and that, consequently, veterinary surgeons would be put out of business.

10.841. Commenting on a specific complaint made by Hyperdrug (see paragraph 12.121), Virbac said that it was not aware of any inquiry about, or request for, POMs from Hyperdrug in the previous nine years. Hyperdrug was, however, a relatively large buyer of its PML products. Virbac had objected to Hyperdrug’s use of its promotional material for Equimax (a PML product) because Hyperdrug had pasted the material on to its web site without permission and out of context. Hyperdrug had subsequently agreed to use only Virbac’s approved promotional material in its entirety. Virbac said that it had supplied Equimax to Hyperdrug on the same terms as to other PML retailers. Geographical coverage and volume sales were the criteria, because Virbac was not equipped to supply all retailers. These criteria were applied uniformly and Hyperdrug was informed of them when it started buying Virbac’s earlier equine product, Eraquell. Hyperdrug did not get the best prices for Equimax because it did not order the necessary quantity, nor would it give a commitment to buy agreed quantities over a set period. Virbac believed that Hyperdrug was unwilling to accept its criteria in respect of Equimax because sales of Eraquell had been disappointing. In Virbac’s view, this was because Hyperdrug had priced Eraquell too high in comparison with other mail-order outlets. (A large part of Hyperdrug’s business was mail order.)

10.842. Virbac said that as far as its horse products were concerned, a retailer would qualify for a quantity discount only if it placed a firm order for a set quantity or gave a commitment to take a set quantity over a specified period. The set quantities would be customized to the individual outlet in negotiations between the sales representative and the retailer. Virbac accepted that this constituted
differential pricing, but said that it was prepared to give a better price to a retailer who actively promoted and supported its products or would carry Virbac products exclusively.

10.843. With regard to the complaint from R M Jones (see paragraph 12.117), Virbac said that the request from that pharmacy was specifically about POMs for food animals. At a meeting with Mr Jones in November 2001, Virbac had explained that those medicines were subject to a marketing agreement between itself and its distributor Bimeda. Mr Jones had been advised to contact Bimeda.

Provisional complex monopoly situation—supply of cat and dog vaccines to veterinary surgeries

10.844. Virbac had no comments on our provisional conclusion that a complex monopoly situation existed in relation to the supply to veterinary surgeries of vaccines for cats and dogs.

10.845. Virbac believed that most veterinary practices would buy their cat and dog vaccines from the same manufacturer. It said that switching between suppliers did not occur with great frequency, for technical reasons as well as for reasons of brand loyalty (once an animal had been vaccinated with a particular product its booster vaccinations needed to be the same product). Virbac thought that a veterinary practice would normally consider changing its vaccine supplier only about once every three years.

10.846. Virbac said that it was a fairly small player in cat and dog vaccines and the market was extremely competitive. It had been able to enter the market because it was the first company with a feline leukaemia vaccine in the UK: at that time it had only that one product. It had then developed standard cat vaccines and was able to win some contracts from established competitors. Its market share had fallen as a result of Fort Dodge and Pfizer introducing feline leukaemia vaccines: veterinary practices that were already buying other cat vaccines from those companies started switching to their leukaemia vaccines as well. This prompted the agreement with Intervet whereby it would supply Intervet with its feline leukaemia product and Intervet would supply Virbac with dog vaccines. The two companies would thus fill a gap in their respective portfolios.

10.847. Virbac said that one reason for wanting to be present in both markets was the leverage afforded by rebate schemes that linked the purchase of cat and dog vaccines. A further advantage of a presence in both markets was the higher turnover that could be achieved, thus making it cost-effective for a company to supply additional services to veterinary practices, such as customized vaccination certificates, reminder cards and mailings, which were a feature of competition.

10.848. With regard to its own rebate scheme, Virbac said that the discount offered to a vaccine purchaser did not depend on the total value of purchases of both cat and dog vaccines. Instead, there were separate calculations for each type of vaccine. A practice that did not buy dog vaccines from Virbac but bought a sufficiently large volume of cat vaccines would nevertheless get the highest level of rebate on the cat vaccines, and vice versa. Those that bought both cat and dog vaccines would get the rebate appropriate to their combined annual purchases: they would not get anything extra for buying both. If a practice that had bought both types of vaccine from Virbac switched to another supplier for one of them, the rebate level offered by Virbac on the other type of vaccine would remain unchanged.

Other issues

10.849. Virbac’s comments on some of the matters raised in the statement of 16 April are recorded below.

Whether veterinary manufacturers with a large market share in particular veterinary medicine sub-markets carry out anti-competitive practices to maintain their position, and in particular: whether veterinary manufacturers engage in predatory pricing (Issue II(ii)d)

10.850. Virbac said that it had not seen predatory pricing eliminate anyone from the veterinary medicines market. It had seen two or three short-term examples of what might be considered predatory pricing, but not in the previous two years or so. This might have to do with the marginal cost of the product, particularly in vaccines, being significantly lower than in other industries. Virbac had, however,
seen some fairly aggressive attempts by certain manufacturers to buy in the stock of a competitor from veterinary practices if the practices would replace it with their product. This had occurred with Virbac’s feline leukaemia vaccine: a new entrant to the market had offered to replace veterinary practices’ entire stock of this product with its new vaccine, in order to gain shelf space. Virbac did not think that this tactic was legitimate and had complained about it at the time. Other tactics used from time to time included offering products, particularly vaccines, at less than half price at regular intervals, but Virbac thought that such offers would only influence about 10 per cent of the market. Most veterinary practices would stick with their technical decision or their contract.

**Whether veterinary manufacturers promote brand loyalty to such an extent as to limit price competition and restrict market entry (Issue II(ii)(e))**

10.851. Virbac said that it was a valid tactic for a company to promote brand loyalty if it had been the patent holder and had invested in building the brand. It told us that in gas anaesthetics a number of patents were coming to an end and the brand that had had the market to itself some 18 months ago now had four competitors, which suggested that there was not a great barrier for generic entry at that point. Virbac was itself one of the entrants. It told us that the new entrants’ prices had come in at 20 per cent below that of the branded products and there was then a rapid spiral down to about 25 per cent of the price two years ago. However, the brand still held about 60 to 70 per cent market share, which indicated that investment in the brand had worked.

**Whether the manufacturers of veterinary medicines are protected by the provisions of the cascade from competition from substitutable human medicines, and whether they exploit this protection by charging higher prices than would otherwise be the case (Issue II(iii))**

10.852. Virbac would be opposed to any relaxation of the cascade because it had concerns about the ability of veterinary surgeons to make judgements about which drugs were substitutable and which human drugs could safely be used in animals. It was also concerned that allowing cost to be a factor in the veterinary surgeon’s judgement in applying the cascade would undermine the licensing system for veterinary medicines and remove the incentives for manufacturers to develop and market new products.

**Whether veterinary manufacturers encourage veterinary surgeons to buy certain prescription-only veterinary medicines by asserting that they will not be subject to reclassification (Issue II(vii))**

10.853. Virbac said that as far as medicines for food animals were concerned, where a product was classified as POM (for example, because it was a new product) but might actually be classified as PML, then retention of the POM classification would restrict the product to only some 25 per cent of its potential market. This was because other competitive products with PML classification would be available through the retail trade and veterinary surgeons would not generally be interested in promoting a product at that price level. There might be different considerations in respect of a unique pharmaceutical product in the POM sector, where reclassification to PML might well lead to loss of margin.

**Whether veterinary surgeons influence veterinary manufacturers not to reclassify prescription-only medicines to a lower classification (Issue IV(vi))**

10.854. Virbac said that veterinary surgeons occasionally lobbied them to maintain the POM classification for a product, or to ensure that a product with a lower classification was available only to veterinary surgeons. These approaches tended to be informal, in conversations with representatives, and Virbac had received no written representations from veterinary surgeons about classification of specific products. It said that lobbying did not influence its policy on classification, which took account primarily of the business potential of the product concerned.

**Possible remedies**

10.855. Virbac said that it was generally supportive of possible remedies that were intended to increase price transparency to consumers. Its specific comments on certain of the hypothetical remedies contained in the statement of 17 September are recorded below.
A requirement for veterinary surgeons to display in the veterinary surgery the price of the most commonly dispensed POMs (paragraph 24(b)(iii) of the statement)

10.856. Virbac said that there were a number of practical matters that we needed to consider. For example, there were seasonal variations in the use of some medicines: these would need to be reflected by updating the list at agreed intervals. We should also bear in mind that in practices with a number of veterinary surgeons, and particularly in mixed practices, the POMs most commonly dispensed by one veterinary surgeon could vary considerably from those most commonly dispensed by another. The remedy would need to be drafted to allow for that.

A requirement for veterinary surgeons when quoting the price at which they will dispense any POM also to state the cost of that POM to themselves (paragraph 24(b)(iv))

10.857. Virbac said that it had some concerns about this proposal, which seemed to go much further than anything that was required of other retailers.

A requirement for manufacturers of POMs giving rebates to veterinary surgeons to provide sufficient information, either directly or through wholesalers, so as to enable the veterinary surgeon to ascertain with certainty the cost net of rebates of POMs supplied to them (paragraph 24(b)(v))

10.858. Virbac did not believe that it would have to make any material change to its rebate scheme on account of this remedy. The scheme was sufficiently transparent for veterinary surgeons to work out what they were paying for any product. There were only three categories within the scheme (cat vaccines, dog vaccines and pharmaceuticals) and veterinary surgeons knew at the outset what level of rebate they would get for each. They were also given quarterly statements showing, among other things, the percentage rebate and absolute amount of rebate achieved. This statement was on an MAT basis and showed the position for the preceding five quarters as well as the most recent. Virbac believed that, in general, most veterinary surgeons had a good understanding of manufacturers’ rebate schemes and were able to calculate the cost to themselves of POMs.

A requirement for manufacturers and wholesalers that supply POMs in the UK to supply pharmacies (paragraph 24(c)(i))

A requirement for manufacturers and wholesalers that supply POMs in the UK to supply pharmacies on terms that enable them to compete with veterinary surgeons (paragraph 24(c)(ii))

10.859. Virbac said that if it agreed rebate terms with a veterinary practice then it could be reasonably certain that the practice would support its products: for example, that it would use only, or mainly, Virbac vaccines. It would be prepared to offer the same terms to pharmacies only if a similar level of support was likely to be forthcoming. It feared that pharmacies would demand the same rebate levels as veterinary practices without any commitment to buy the same volumes or to display the products on their shelves. There was also a danger that pharmacies would cherry-pick the best-selling lines and decline to stock products for which there was infrequent demand.

10.860. In Virbac’s experience, pharmacies (with the exception of a few specialist agricultural pharmacies) had shown little interest in veterinary medicines over the years and it would not expect this to change even if prescriptions became generally available. There might be a temporary increase in sales by pharmacies, but in the longer term Virbac thought that most veterinary medicines would continue to be dispensed by veterinary surgeons, as few clients would want to search out lower prices. Virbac also questioned whether lower overall prices to the consumer would necessarily follow from our possible remedies, given that veterinary surgeons might have to increase professional fees to compensate for loss of medicines sales and also charge a prescription fee, and pharmacies would have to take some margin on medicine sales.

A requirement for veterinary surgeons when they write prescriptions for POMs to do so on an ‘or equivalent’ basis to enable those dispensing such prescriptions to supply alternative authorised veterinary medicines to the brand specified (paragraph 24(c)(iv))

10.861. Virbac was concerned about the animal health and safety implications of allowing pharmacists discretion in dispensing veterinary medicines. It would be particularly worried if there were any suggestion that a pharmacist could substitute a human generic for the veterinary medicine named in a
prescription. It thought that any remedy on the lines we were proposing would need to be tightly worded and controlled.

**Prohibition on manufacturers operating rebate schemes in which the level of rebates given on purchases of cat and dog vaccines is based on, or substantially influenced by, the combined value of purchases of those vaccines (paragraph 25)**

10.862. Virbac said that the possible remedy would not affect it because the rebates given under its scheme were not based on or influenced by the combined purchases of cat and dog vaccines. It questioned whether prohibition of schemes with such a feature would bring about much change in the market: it believed that manufacturers would find ways of offering veterinary surgeons other inducements to buy cat and dog vaccines from the same source.

**Regulatory issues**

10.863. Virbac said that the regulatory authorities in the UK tended to be stringent and cautious in the application of European Commission directives. They were also quicker than other member states to implement new directives, which meant that there was not a level playing field throughout the EC at any one time in terms of the ease with which MAs could be obtained.

10.864. A particular difficulty arising from regulation was the cost of maintaining products in the marketplace through the process of MA renewal. Virbac said that considerable financial and scientific resources were needed to answer the questions put by the VMD and the level and accuracy of the scientific data required was constantly increasing. Even taking account of recent food scares, it thought that the level of precautionary questioning was now beyond a reasonable balance between risk, cost and availability of product. This affected not only the continued existence of established products but also the ability of manufacturers, particularly smaller companies, to bring new molecules to the market. Virbac supported the Regulation 2000 proposal to replace the five-yearly review with more rigorous policing of pharmacovigilance reporting. This seemed a sensible way of monitoring the ongoing safety of a product, probably at lower cost than the existing system.

10.865. Virbac said that the regulatory system in the USA compared favourably with the EC system in terms of both speed and cost. For example, it was common for a vaccine that had been developed and licensed in the USA to need up to five more years’ work on it before it would be accepted by the authorities in EC countries, and would probably have to be produced in a European plant. With regard to generics, the waiver system in the USA seemed much less onerous than the EC requirements. Virbac understood that once a product was off patent, a manufacturer had only to supply quality data to the US authorities to demonstrate that it was producing an image of the original product. This was a relatively low-cost procedure that encouraged the entry of generic products.

10.866. We invited Virbac to estimate the extra cost of regulation by considering the effects of three different hypotheses: no external regulation of veterinary medicines anywhere in the world; mutual recognition by the EC of US authorization; and UK acceptance of EC central or national authorization without further regulatory requirements.

10.867. Virbac said that under the first hypothesis, manufacturers would still have to test new molecules for efficacy, safety and stability, to satisfy their own requirements before releasing a product for sale. Trials would take three years, at an estimated cost of £350,000. This compared with the current six- to nine-year development period and a cost of £1 million. There would also be a two-year delay in obtaining an MA, at a cost of a further £1 million in lost profit. For a generic product, testing could be completed in 18 months at a cost of £75,000 compared with the current three- to four-year development time at a cost of £200,000 and a further £200,000 lost profit from a year’s delay in obtaining an MA.

10.868. The second hypothesis would have no advantage over the current situation as far as innovative products were concerned. For generic products the cost of testing would be approximately £105,000, plus a year’s delay at £200,000.

10.869. There would be no cost saving under the third hypothesis except the licence fee and annual turnover tax, because all data required by the VMD had to be assembled with regard to EC rules. Virbac said that all member states were moving towards the more stringent requirements already operating in the
UK; therefore it could not be assumed that it would be easier or cheaper to obtain an MA under this hypothesis.

10.870. Virbac said that it had no objection to a proposal that third parties should be allowed to initiate a review of the classification of any veterinary medicine, but it did not think that the MA holder should be expected to meet the costs of the review, including the costs of any data that might be needed, especially if the persons applying for the review had a commercial interest in the outcome.

Views of the veterinary wholesalers

W&J Dunlop Ltd

Provisional complex monopoly situation—supply of POMs to animal owners

10.871. Dunlops had no comments on our provisional conclusion that a single complex monopoly existed in relation to the supply within the UK of POMs to animal owners. It did, however, accept that such a complex monopoly situation would tend to operate generally in favour of wholesalers distributing POMs in the UK.

10.872. With regard to the conducts identified in paragraph 9 of the statement of 17 September, Dunlops was uncertain as to whether or not manufacturers might refuse or fail to negotiate discounts and rebates with buying groups (paragraph 9(d)) of the statement). It suspected that, while manufacturers had probably resisted dealings of this nature, the issue was not a major concern for them and that, if requested, they would accommodate buying groups and negotiate terms with them. It thought that the larger manufacturers with wide product ranges might be reluctant to deal with buying groups because they would not necessarily get the support that they were looking for across the range from each member of the group, but would be under pressure to give the same levels of rebate to all members.

10.873. Commenting on the conduct described in paragraph 9(g) of the statement (failure of wholesalers to supply pharmacies and/or enable pharmacies to obtain supplies on terms that enable them to compete with veterinary surgeons), Dunlops told us that while it was willing to supply veterinary products to pharmacies—and currently it had one or two local pharmacy customers for non-POM products—it had never been asked to supply POMs by an individual high-street pharmacy, a pharmacy chain or an agricultural pharmacy, presumably because veterinary prescriptions had not been presented to them. Dunlops said that it would have no difficulty in supplying pharmacies with POMs on the same terms, including discount terms, as those given to veterinary practices, depending on volumes required and its distribution costs. It thought that if the demand by pharmacies for veterinary POMs were to increase, the wholesalers of human medicines would be the natural suppliers as they already provided a twice-daily delivery service to pharmacies. Although Dunlops would be prepared to compete for pharmacies’ business, it lacked both the purchasing power and the logistical capability of the large human medicine wholesalers. It also believed that it would not be able to supply pharmacies that were owned by the human medicine wholesalers, which might be as many as 80 per cent of the market, because those wholesalers would wish to retain control over the supply of products to their own outlets.

10.874. Dunlops thought that the human medicine wholesalers would be interested in the high-volume veterinary products but not necessarily in the full range carried by the veterinary wholesalers. The outcome might be a reduction in the size of the market for the veterinary wholesalers and an increase in their unit costs, to the extent that one or more of them might go out of business if there was a significant shift of sales from veterinary practices to pharmacies.

10.875. We invited Dunlops to comment on complaints from several pharmacies about its failure to supply them (see paragraphs 9.80, 9.82, 12.84 and 12.123). Dunlops said that it recognized the name of Davidsons, but could not recall ever having dealt with the company. It had quoted the price of PML products to Davidsons some years ago, but no order had been placed. Dunlops had in the past traded with Portland House Veterinary Group (PHVG), whose partners also owned Veterinary Drugs to Go Limited, a pharmacy business. Dunlops had, however, ceased trading with it, primarily for commercial reasons. It was not financially viable for Dunlops to continue delivering to this business, which was its only customer located so far south and was receiving a high level of discount on a relatively small volume of purchases. Dunlops told us that veterinary surgeons and others in the industry had put it under some pressure following its decision to trade with PHVG, given the existence of the pharmacy business, but it
had not actually been threatened with loss of business from veterinary practices. Dunlops could not shed any light on the other complaints. It commented that all the complainants were agricultural pharmacies, and said that there was not a level playing field as far as the supply of PML products was concerned: these pharmacies could obtain PMLs either direct from manufacturers or from trade wholesalers at a higher discount than Dunlops could obtain from the manufacturers. In some cases they could also obtain the small range of POMs that they needed direct from manufacturers as well, because they could be delivered with the PML products. They were not, therefore, interested in buying from Dunlops except for a few items that they could not obtain from their usual sources.

10.876. Regarding the conduct identified in paragraph 9(f) of the statement (failure of manufacturers to supply pharmacies with POMs and/or enable pharmacies to obtain supplies of POMs on terms that enable them to compete with veterinary surgeons), Dunlops said that it did not know what terms the manufacturers gave to veterinary surgeons or pharmacies. It did not believe that veterinary surgeons were overcharging their clients, and suggested that if our proposed remedies were implemented then some veterinary surgeons were likely to go out of business, as they would no longer be able to subsidize professional fees through sales of medicines.

10.877. In respect of the conduct identified in paragraph 9(e) of the statement (operation by manufacturers of rebate schemes that make it difficult for veterinary surgeons to ascertain with certainty at the time of purchase the cost to themselves of POMs), Dunlops agreed that manufacturers engaged in the conduct, but said that in many cases it had no detailed knowledge of the rebate schemes and certainly had no influence on the way they operated. It did, however, provide a facility on its Internet site, and also a computerized management system, to help veterinary surgeons calculate their net prices and apply whatever mark-up they chose. Dunlops said that there had been a general shift over the years from online discounts, whereby the veterinary wholesaler gave the discount up front and claimed it back from the manufacturer, to retrospective rebates paid by the manufacturers. This had increased veterinary surgeons’ difficulty in determining net prices. Dunlops did not agree that veterinary surgeons tended to ignore the manufacturer’s rebate when they were setting the retail price of a POM. Over the previous two years, enquiries from veterinary surgeons about how to calculate net prices had increased and there seemed to be a greater awareness among them of the need to be competitive.

10.878. Dunlops was not wholly convinced that the conduct set out in paragraph 9(e) might prevent, restrict or distort competition between veterinary surgeons. Much would depend on the individual and the extent to which the practice was up to date. Those who did not fully understand the needs of the business were becoming less competitive. Dunlops argued that the greater the number of veterinary surgeons, the greater would be the competition between them, and it expressed concern that the effect of our remedies would result in a fall in the number.

10.879. Dunlops told us that it had no strong views on the conducts we had identified in relation to the way veterinary surgeons issued or did not issue prescriptions (see paragraph 9(a), (b) and (c) of the statement). It said that whilst in theory if they issued more prescriptions competition should increase, in practice the dispensing business would simply be moved around. It was concerned that pharmacies would cherry-pick the big-selling veterinary medicines, thus reducing veterinary surgeons’ turnover and ultimately leading to fewer veterinary practices.

Possible remedies

10.880. Dunlops made the following comments on the possible remedies set out in the statement of 17 September.

Possible remedies to reduce barriers to obtaining prescriptions (paragraph 24(a) of the statement)

10.881. Dunlops did not think that any of the possible remedies proposed under this heading would have a serious effect on its business. It was concerned, however, that there should be an effective mechanism in place to ensure that veterinary prescriptions presented at pharmacies were authentic. This would be particularly important in the case of mail-order pharmacies.
Possible remedies to improve price transparency and the ability of animal owners to understand and compare prices (paragraph 24(b))

10.882. Dunlops said that it was unlikely to be affected by any of the possible remedies under this heading. It said that the proposal for veterinary surgeons to disclose the cost price to themselves of POMs (see paragraph 24(b)(iv) of the statement) seemed to go beyond what was required in any other industry. It suggested that if the remedy were implemented then the same condition should be imposed on pharmacies.

10.883. Regarding the proposed requirement for manufacturers to provide sufficient information to enable veterinary surgeons to ascertain the cost, net of rebates, of POMs supplied to them (see paragraph 24(b)(v)), Dunlops said that this had already started to happen and was a valuable development. There were computer programs available that helped veterinary surgeons to calculate their net costs.

Possible remedies to reduce barriers to pharmacies competing with veterinary surgeons in the dispensing of POMs (paragraph 24(c))

10.884. Dunlops suggested that the remedies should also ensure that veterinary surgeons could compete with pharmacies in the sale of PML products. This was not the case at present because veterinary pharmacies could buy PML products at lower prices than were available to veterinary surgeons.

Prohibition on manufacturers operating rebate schemes in which the level of rebates given on purchases of cat and dog vaccines is based on or substantially influenced by the combined value of purchases of these vaccines (paragraph 25)

10.885. Dunlops said that the effect on wholesalers would be marginal. If implementation of the remedy stimulated new entry into the vaccines market then wholesalers would have to carry an increased range of vaccines, which might increase their costs. If vaccine prices fell as a result, then wholesalers’ margins would also fall.

Genus Xpress

Provisional complex monopoly situation—supply of POMs to animal owners

10.886. Genus had no comments on our provisional conclusion that a complex monopoly situation existed in relation to the supply of POMs to animal owners. Nor did it comment on our view that it would be appropriate to consider certain conducts of manufacturers, wholesalers and veterinary surgeons as a single complex monopoly situation affecting all parts of the supply chain. Genus considered that the complex monopoly situation would operate in favour of veterinary wholesalers only in so far as they formed part of a supply chain.

10.887. Commenting on the conduct described in paragraph 9(g) of the statement of 17 September (failure of wholesalers to supply pharmacies and/or enable pharmacies to obtain supplies on terms that enable them to compete with veterinary surgeons), Genus told us that in the three months to 30 September 2002 it had made sales to pharmacies to the value of over £97,000, of which some £38,500 were sales of POMs. It had traded with 26 pharmacy customers in that period.

10.888. Responding to complaints made by pharmacies (see paragraph 9.80), Genus acknowledged that it had failed to supply POMs to R M Jones. It said that internal compliance had since been tightened up and its staff were aware that they should supply pharmacies on request. It had not approached R M Jones to offer supply, but would be pleased to do so if provided with the address (if no longer held contact details on file). We passed on these details to Genus in November 2002. Genus was unable to comment on complaints made by pharmacies about Dunnwood, which it had acquired in July 2002, and in particular about its dealings with Davidsons.

10.889. Genus confirmed that it did not take active steps to seek the business of pharmacies or tell them that it was prepared to supply them.

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10.890. Regarding terms of supply, Genus denied the allegation by Hyperdrug that it supplied pharmacies at inflated prices to prevent them competing with veterinary surgeons (see paragraph 12.123). It had in fact negotiated discounts with a number of pharmacies to take account of their volume of purchases. It stated that it had never been under pressure, direct or indirect, from veterinary surgeons to refuse to supply pharmacies or supply them on terms that would make it difficult for them to compete with veterinary practices.

10.891. Genus said that its standard terms, including discounts and service levels, were the same for pharmacies as for veterinary practices, subject to purchasing volumes. Discounts started when monthly spend exceeded £2,500. The one exception was Boots the Chemist, which had an agreement with Genus that no discount would be paid whatever its spend, because of the large number of deliveries involved. For new veterinary practices, Genus would on occasion provide a start-up package, which might include deferred payment terms and/or IT assistance. Genus confirmed that it would be willing to provide similar assistance to a new pharmacy, subject to purchasing volumes, but said that the situation had never arisen.

10.892. In response to paragraph 9(e) of the statement, which refers to failure of manufacturers to supply POMs to pharmacies or enable them to obtain POMs on terms that would make it possible for them to compete with veterinary surgeons, Genus told us that it was aware that some manufacturers had put great effort into cultivating a sales channel through veterinary practices, but it was not aware of any attempts by manufacturers to prevent it from supplying pharmacies.

Possible remedies

10.893. Genus’s views on certain of the possible remedies listed in the statement of 17 September are recorded below.

10.894. Genus said that it was generally supportive of possible remedies that were intended to increase price transparency to consumers. It had reservations, however, about the proposed requirement for veterinary surgeons when quoting the price at which they will dispense any POM also to state the cost of that POM to themselves (see paragraph 24(b)(iv) of the statement). It thought that greater transparency in retail pricing should be a sufficient remedy.

A requirement for manufacturers of POMs giving rebates to veterinary surgeons to provide sufficient information, either directly or through wholesalers, so as to enable the veterinary surgeon to ascertain with certainty the cost net of rebates of POMs supplied to them (paragraph 24(b)(v) of the statement)

10.895. Genus said that it would willingly cooperate in the supply to veterinary surgeons of whatever information was needed to achieve the aim of this remedy. However, it was uncertain as to how, in practice, the remedy would operate. It suggested that manufacturers might respond by removing retrospective discounts and reducing the list prices of POMs. Assuming that manufacturers held the discount given to veterinary wholesalers at 15 per cent, the amount of money available to support the distribution model would be significantly reduced while the costs of distribution would be unchanged. Genus feared that in such a situation NVS would be able to use its scale monopoly position in a predatory manner and force Genus and other regional veterinary wholesalers out of the market.

10.896. With regard to the issue of barriers to pharmacies competing with veterinary surgeons in the dispensing of POMs, Genus said that it had considered the likely impact on its business if pharmacies were to supply a proportion of POMs. It feared that pharmacies, most of which were severely constrained by space, would cherry-pick the high-value, low-volume items and that those would be the items that the human medicine wholesalers would choose to distribute. Genus believed that this would render its business unviable and would reduce the service to the end-consumer because, if veterinary wholesalers went out of business, it was not clear who would then distribute the high-volume, low-value products such as prescription diets.
A requirement for manufacturers and wholesalers that supply POMs in the UK to supply pharmacies (paragraph 24(c)(i) of the statement)

A requirement for manufacturers and wholesalers that supply POMs in the UK to supply pharmacies on terms that enable them to compete with veterinary surgeons (paragraph 24(c)(ii) of the statement)

10.897. Genus saw no problem with these proposals, which it thought would bring about clarity and a level playing field. It suggested that, as far as the veterinary wholesalers were concerned, compliance might be monitored through regular audits. It thought that the RPSGB might be a useful channel for investigation of any complaints from pharmacies about failure to obtain supplies of POMs.

A requirement for veterinary surgeons to display the name, postal address, telephone number and website address of any pharmacy supplying veterinary medicines that so requests (paragraph 24(c)(iii) of the statement)

10.898. Genus had some reservations about the idea of a business advertising its competitors. It thought that the proposal would be more acceptable if pharmacies were required to reciprocate by advertising veterinary practices.

A requirement for veterinary surgeons when they write prescriptions for POMs to do so on an ‘or equivalent’ basis to enable those dispensing such prescriptions to supply alternative authorised veterinary medicines to the brand specified (paragraph 24(c)(iv) of the statement)

10.899. Genus thought that there were serious problems with this possible remedy, which it believed was likely to undermine the cascade. In its opinion, the cascade was not a barrier protecting the price of branded veterinary generics.

10.900. Genus considered that if the remedy were to be implemented, pharmacists would be likely to exhibit the behaviour seen in the human medicines market. In that market, pharmacists negotiated the margins for drugs with the manufacturers and dispensed the equivalent that provided them with the highest margin. This process was regulated by the annual claw-back. There was no such control in the veterinary medicines market, which made Genus fear that the behaviour that we were concerned about in veterinary surgeons could emerge among pharmacists, ie dispensing decisions would reflect the margin that the pharmacist could exploit.

10.901. Genus said that ‘or equivalent’ needed to be carefully defined and limited. It pointed out that some products were equivalent in terms of the conditions they treated (for example, flea treatments, wormers) but could be very different forms of active ingredients. It was concerned about pharmacists trying to second guess the intentions of veterinary surgeons in writing prescriptions, ie whether or not the veterinary surgeon had prescribed a specific licensed product for clinical reasons.

Prohibition on manufacturers operating rebate schemes in which the level of rebates given on purchases of cat and dog vaccines is based on, or substantially influenced by, the combined value of purchases of those vaccines (paragraph 25)

10.902. Genus supported the views of its associated manufacturing company, Animalcare, on this remedy (see paragraph 10.9).

Possible recommendations for regulatory changes

10.903. Genus endorsed Animalcare’s comments (see paragraphs 10.11 to 10.16) on certain of the possible recommendations listed in our statement. It had the following additional comment on Recommendation 9.
The Secretary of State to consider establishing one or more new classifications of veterinary medicines to allow specific categories of persons (such as agricultural merchants and saddlers as well as veterinary surgeons and pharmacists) to dispense veterinary prescriptions for medicines so classified and to make corresponding changes to the law governing the dispensing of prescriptions (Recommendation (9))

10.904. Notwithstanding its reservations about Recommendation 6, Genus would wish veterinary wholesalers to be included as a specific category of participant, were Recommendation 9 to be implemented.

National Veterinary Services Ltd

Provisional scale monopoly situation—wholesale supply of POMs in the UK

10.905. In the statement of 16 April, we came to the provisional conclusion that a scale monopoly situation existed in relation to the supply within the UK of POMs, since it appeared that NVS supplied at least one-quarter of POMs to veterinary surgeons. Dechra Pharmaceuticals PLC (Dechra) (NVS’s parent company) said it fully appreciated that a finding of scale monopoly related only to market share and did not imply the existence of any facts that operated or might be expected to operate against the public interest. It was indeed apparent from our statement that the practices of wholesalers were unlikely to have a significant effect upon the market for POMs. In the circumstances, Dechra thought it was unfortunate that NVS was the only company specifically named in our statement and that the impression had been created that it was likely to be at the centre of any difficulties within the market. This had resulted in a measurable loss of investor confidence. Dechra did not comment further on the scale monopoly situation following publication of the statement of 17 September.

Provisional complex monopoly situation—supply of POMs to animal owners

10.906. NVS had no comments on our provisional conclusion that a complex monopoly situation existed in relation to the supply of POMs to animal owners. It did not, however, accept that any such complex monopoly was operating in favour of veterinary wholesalers. It said that the existing structure of the market currently restricted it from trading in the agricultural markets (PML products). It would like to trade, for instance, in the equine market but could not do so because without the manufacturers’ rebates it was buying PMLs at a higher price than the smaller wholesalers supplying the equine trade and so could not compete on a like-for-like basis.

10.907. With regard to the conduct identified in paragraph 9(d) of the statement (refusal/failure by manufacturers to negotiate discounts and rebates with buying groups), NVS said that there were only a few buying groups that bought products at advantageous discounts and then sold them on to members. Other veterinary practices had formed more loosely organized groups that did not operate as true buying groups. NVS commented that while veterinary practices might have joined groups because they thought it would increase their buying power, in reality the only substantial beneficiary was likely to be the person organizing the group. NVS said that it offered favourable terms (i.e. a higher level of discount than an individual practice could negotiate) to all the buying groups. It had no information on manufacturers’ dealings with such groups, except in regard to its associated company, Arnolds (see paragraph 10.23).

10.908. With regard to the conduct identified in paragraph 9(g) of the statement (failure by wholesalers to supply pharmacies and/or enable pharmacies to obtain supplies on terms that enable them to compete with veterinary surgeons), NVS said that its policy was to supply pharmacies on the same terms, including discounts and frequency of service, as veterinary practices. Currently, it had four pharmacy accounts, three of which had been active during the preceding 12 months and only one of which had bought POMs from NVS. Sales were small because of limited demand from pharmacies for veterinary products.

10.909. NVS argued that the evidence we had presented was insufficient to support the provisional conclusions that wholesalers in general (and NVS in particular) failed to supply pharmacies. It pointed out that in its own case only three examples of alleged failure to supply had been presented, covering a period of some two and a half years (see paragraph 9.80). NVS had found it impossible to investigate two of the complaints, after such a time lag. In the most recent case, however, it confirmed that NVS had
declined to supply as a result of an error by a new Managing Director who was unfamiliar at that time with NVS’s trading practices.

10.910. As regards offering terms on which pharmacies might compete with veterinary surgeons, NVS made the following points:

- The veterinary wholesaler’s discount was only part of the equation. A potentially larger discount could be obtained from manufacturers through their rebate schemes. The level of rebate that an individual pharmacy might receive would be the subject of negotiations with the manufacturer in each case. Veterinary wholesalers had no influence on that process.

- In respect of the veterinary wholesaler’s discount, a veterinary practice or a pharmacy purchasing small one-off items could not obtain the same level of discount as a practice with substantial annual purchases. NVS’s standard terms required monthly purchases of at least £2,000 before any discount was given. This rose to a maximum of 12 per cent for purchases of over £12,000 a month. While NVS would not discriminate between veterinary practices and pharmacies, it could only supply on terms that made it economic and profitable to do so.

- The headline price at which veterinary wholesalers sold to veterinary practices and pharmacies was effectively set by the manufacturers. This limited the ability of the wholesalers to compete on a product by product basis. It was difficult for them to promote brands because of the unusually narrow margins available, which meant that in practice they had to give discounts based on the volume of all products supplied. Since this could be as much as 12 per cent out of the total wholesaler margin of approximately 15 per cent, there was no margin left for brand promotions. This in turn prevented wholesalers from offering pharmacies competitive terms on the relatively small number of fast-moving products that they were likely to stock. Inter-brand price competition effectively took place through the discounts and rebates offered direct by manufacturers. This also restricted inter-brand competition between veterinary wholesalers, because they were forced to stock all brands and could not make efficiency savings by limiting the number of lines carried.

10.911. NVS concluded that while veterinary wholesalers could ensure that pharmacies were not discriminated against at wholesaler level, they could not ensure that pharmacies were supplied at prices that enabled them to compete with veterinary practices, since this was largely in the hands of the manufacturers. In its view, price transparency would be achieved only if pharmacies and veterinary practices could purchase at a competitive price based on the fact that they offered a full-line service. It suggested that banning retrospective rebates might be necessary in order to bring about competition.

10.912. NVS said that it would typically support a new veterinary practice by offering extra discount or deferred payment until it had established itself. Similar support had not been offered to new pharmacy customers, but NVS said that if pharmacies started to enter the market, it would be keen to offer them favourable terms in order to avoid losing market share to other veterinary wholesalers.

10.913. NVS said that it had not been under direct pressure from veterinary surgeons not to supply pharmacies or to supply them on less favourable terms. It had, however, heard reports that some veterinary surgeons were dissatisfied with its decision to supply its Internet pharmacy customer with POMs. It had suspended the account of that customer for a short time in order to seek legal advice, but had quickly decided to continue supplying it.

10.914. Regarding the conduct identified in paragraph 9(f) of the statement (failure of manufacturers to supply pharmacies with POMs and/or enable pharmacies to obtain supplies of POMs on terms that enabled them to compete with veterinary surgeons), NVS said that manufacturers had never tried either to dissuade it from supplying POMs to pharmacies or to influence the terms of supply. It thought that there were several reasons why manufacturers might be reluctant to see pharmacies entering the market. One of them was anxiety that pharmacists might not have the expertise to dispense veterinary prescriptions. Another was that under the existing structure of the market manufacturers controlled prices, but they would lose this control if pharmacies entered the market in any number. NVS said that it would be costly for manufacturers to collect data from pharmacies and administer rebates to them, although there was no reason why the veterinary wholesalers should not eventually supply them with the information.
10.915. With regard to the conduct identified in paragraph 9(e) of the statement (operation by manufacturers of rebate schemes that made it difficult for veterinary surgeons to ascertain with certainty at the time of purchase the cost to themselves of POMs), NVS said that it had no information on individual manufacturers’ rebates scheme. It was not in a position, therefore, to comment on the detail of them. It thought that they did not help price transparency because they made it more difficult for veterinary surgeons to calculate net prices. NVS had itself developed a pricing matrix to assist veterinary practices to work out the cost of veterinary medicines, net of all discounts and rebates. The matrix was in the form of a spreadsheet into which veterinary practices could enter the appropriate levels of discount and retrospective rebate and these would be applied to the products of the manufacturer concerned and the net price automatically determined. In addition, over the past five years it had offered a facility for veterinary practices to review their purchases by product, product group or manufacturer, and to compare purchases with those of their peer group.

10.916. Commenting on the conducts we had identified with regard to veterinary surgeons (see paragraph 9(a) to (c) of the statement), NVS said that it did not disagree with our provisional conclusions. It thought that if steps were taken to make it easier for pharmacies to compete for dispensing business, then veterinary surgeons would reduce the price of their medicines in order to retain sales, as had already happened with the cost of vaccinations following the establishment of vaccination clinics.

**Provisional complex monopoly situation—supply of cat and dog vaccines to veterinary surgeries**

10.917. NVS was aware that rebate levels tended to be higher for cat and dog vaccines but questioned why we were particularly singling out these products for attention. It thought that market concentration and barriers to entry might be just as pronounced in some other areas. It recognized, however, that linked rebates might be a particular feature of SAVs. It commented that the vaccine market was difficult to enter in terms of the capital investment needed, but after that it was relatively low cost.

**Other issues**

10.918. NVS’s comments on certain of the matters set out in the statement of 16 April are recorded below.

*Whether discounts granted by veterinary wholesalers are cost related given the very narrow margins upon which wholesalers must operate (Issue III(ii))*

10.919. NVS said that discounts were given according to business need. They might be the consequence of competition between veterinary wholesalers, to which NVS had no option but to respond. Prompt payment discounts were of the utmost commercial importance given the narrow margins on which wholesalers operated, and were designed to ensure that there were no undue disruptions to cash flow. NVS thought that such discounting was likely to benefit customers without any corresponding distortion of competition.

*Whether the provision of detailed sales information by veterinary wholesalers to veterinary manufacturers is detrimental to veterinary surgeries or consumers (Issue III(iii))*

10.920. NVS said that information was made available to manufacturers by veterinary wholesalers either directly or through GfK for marketing purposes and for the purpose of paying retrospective rebates under manufacturers’ schemes. The information was potentially available to all manufacturers, even smaller players or those without rebate schemes. It was doubtful, therefore, whether any manufacturer had gained any particular advantage from its existence. As the information was useful to all in relation to marketing activities, NVS’s opinion was that it was likely to lead to increased competition between manufacturers. It said that the provision of this kind of information to manufacturers was merely an additional service by veterinary wholesalers and had no bearing upon the way in which they themselves operated in the market.
Possible remedies

10.921. NVS’s views on certain of the possible remedies listed in the statement of 17 September are recorded below.

Possible remedies to improve price transparency and the ability of animal owners to understand and compare prices (paragraph 24(b))

10.922. NVS had some concerns about the suggestion that a veterinary surgeon should be required to tell clients the net cost to the practice of a POM (see paragraph 24(b)(iv) of the statement). This would be an unusual requirement not imposed on other businesses and NVS did not see what extra stimulus it would give to competition over and above a requirement on veterinary surgeons to notify clients of their retail prices.

10.923. As regards a requirement for manufacturers to provide sufficient information for veterinary surgeons to know for certain the cost net of rebate of POMs supplied to them (see paragraph 24(b)(v)), NVS thought that except for complex multi-tiered rebate schemes it should be relatively easy for manufacturers to comply. There were systems such as its own pricing matrix that would assist with this.

Possible remedies to reduce barriers to pharmacists competing with veterinary surgeons in the dispensing of POMs (paragraph 24(c))

10.924. NVS said that if it were required to supply POMs to pharmacies, and on terms that enabled pharmacies to compete with veterinary surgeons (see paragraph 24(c)(i) and (ii) of the statement), it would have to be economically viable for it to do so. The volume bought by a pharmacy would have to be sufficient to cover NVS’s delivery costs. It would be concerned if veterinary POMs became available through the human medicine wholesalers, which already had a very large business base and would be in a position to subsidize veterinary medicines, thus making it difficult for NVS to compete. It was also possible that pharmacies and human medicines wholesalers would cherry-pick, say, the ten best-selling veterinary POMs, and use them as loss leaders, or distribute them for a very small margin. The effect could well be that prices of other POMs would be inflated, as NVS and other specialist veterinary wholesalers would probably have to cut discounts in order to remain profitable. In NVS’s experience, however, pharmacies, apart from a few specialist agricultural ones, had shown little interest in selling veterinary medicines in recent years. It thought that for most of them it would be only a marginal activity because the market was so small, and they would not want to devote valuable shelf space to a large range of veterinary products.

10.925. Commenting on the possible remedy of a requirement on veterinary surgeons to write prescriptions for POMs on an ‘or equivalent’ basis (see paragraph 24(c)(iv)), NVS said that it was potentially dangerous because there were so many variations between products that in pharmacological terms might appear to be equivalent. It cautioned particularly against any proposal that human generics might be substituted for a prescribed medicine. Any alternative that a pharmacist was permitted to dispense should be a licensed veterinary product. NVS suggested that a better way of introducing more products and greater competition in the market would be by bringing down regulatory costs and barriers.

Prohibition on manufacturers operating rebate schemes in which the level of rebates given on purchases of cat and dog vaccines is based on, or substantially influenced by, the combined value of purchases of those vaccines (paragraph 25 of the statement)

10.926. NVS believed that implementation of this remedy would have the effect of devaluing the market for cat and dog vaccines. Since NVS had a large share of the small-animal market, its profitability could be depressed. It thought it was unlikely that this would be compensated for by increased volume of sales resulting from lower vaccine prices. A more likely outcome was that veterinary surgeons would charge more for their professional time in order to retain their profitability. In reality, therefore, consumers were unlikely to be better off. In the final analysis, other than by attending a local vaccination clinic, the consumer would not benefit. NVS was also concerned that any diminution of the market would put veterinary wholesalers in a precarious position, unless they could gain some control of their gross margin. It suggested that a ban on manufacturers’ rebates would be a more effective remedy and would remove a significant distortion from the market.

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Regulatory issues

10.927. NVS said that it broadly welcomed suggestions for regulatory change since any steps to reduce the cost and accelerate the process of bringing authorized veterinary products to market would increase competition and benefit animal welfare. It was, however, concerned about the likely impact of Recommendations 18 and 19 (for amendments to the cascade) of our possible recommendations for regulatory change. It said that the cascade had clear animal welfare benefits in ensuring that proper dosage levels and delivery mechanisms were used in the treatment of a particular species. If veterinary surgeons were permitted to ignore the cascade on grounds of cost, these benefits would be lost in a large number of cases. NVS believed that the damage to animal welfare that might follow would outweigh any possible benefits to those animals for whose owners the cost of medicines would preclude treatment.

Veterinary Surgeons Supply Co Ltd

10.928. VSSCo commented on evidence we had received from pharmacists in Northern Ireland about the difficulties pharmacies were likely to face in obtaining supplies of POMs from wholesalers, or in obtaining POMs at the same prices as were available to veterinary surgeons (see paragraph 12.82). VSSCo said that it did not refuse to supply pharmacies, provided that it was satisfied that they were legally entitled to buy POMs. As far as it was aware, it had received only a few enquiries from pharmacies, all by telephone. It had offered to supply POMs to those pharmacies at its normal prices, but none of them had placed an order.

10.929. Regarding terms of supply, VSSCo said that it would expect a veterinary practice to purchase a reasonable amount to get twice-weekly free delivery; there would be a charge (currently £3) for additional next-day delivery. Even new practices would buy £250 a week and many would buy more, as VSSCo sold equipment as well as drugs and sundries. New practices were often good customers before they opened up for business and VSSCo gave all of them the same terms as larger practices operating in the same area, in order to help them become established. It agreed that this might be seen as an indirect cross-subsidy, but thought that it gave a fair and balanced deal to customers.

10.930. VSSCo’s discounts were related to speed of payment. A maximum discount of 10 per cent was available in return for immediate payment and the level dropped as payment was deferred. Some veterinary practices received no discount, either because they were beyond terms or because their purchases were of such low value as to be cancelled out by the carriage charge. VSSCo said that it did not give a 20 per cent discount to anyone (see paragraph 12.82) and did not have sufficient margin to do so.

10.931. VSSCo said that all terms offered to veterinary practices would also be available to genuine pharmacies.