2 Conclusions

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Introduction

2.1. On 9 October 2001 the DGFT announced that, following complaints from both farmers’ groups and individual consumers and evidence that prices in the UK are substantially higher than in other European countries, he was referring to the Competition Commission (CC) for investigation and report under the FTA the possible existence of a monopoly situation in relation to the supply within the UK of POMs.¹ The announcement noted that the Office of Fair Trading’s preliminary investigation gave rise to further concerns, in particular:

(a) a lack of transparency in prices—as the medicines are often dispensed in the course of treatment and may not be itemized separately; and

(b) evidence of reluctance by manufacturers to supply veterinary pharmacies.

We were asked to report within 15 months. Our terms of reference are at Appendix 1.1.

2.2. On 16 April 2002 we published a statement (see Appendix 1.2) setting out issues on which we would welcome comment, divided into four groups—those arising from:

(a) the regulatory regime;

(b) practices of manufacturers;

(c) practices of veterinary wholesalers; and

(d) practices of veterinary surgeons.

2.3. On 17 September 2002 we published a further statement (see Appendix 1.3) of provisional conclusions on complex monopoly situations and hypothetical remedies.

2.4. This chapter sets out our conclusions.

Industry background and regulation

2.5. Veterinary medicines include biologically active and other potentially harmful substances used for the prevention or treatment of illness in animals. Their manufacture, distribution, supply, prescription, dispensing, sale and administration in the UK are subject to controls primarily aimed at the protection of human and animal health and to a significant body of law, much of it made at the European level.

2.6. It is useful to distinguish three levels in the supply of the generality of veterinary medicines (for simplicity disregarding supply to research institutions, zoos and some other specialized small-scale users). The levels are:

(a) manufacturer supply to veterinary and other wholesalers, veterinary practices and some end-users such as industrial-scale poultry producers;

(b) veterinary wholesaler supply to veterinary practices, pharmacies, agricultural merchants and saddlers; and

¹These are defined as medicinal products that are subject to an order under section 58 of the Medicines Act 1968 and which may be sold only by veterinary surgeons or veterinary practitioners for administration to animals under their care or by pharmacists on a written prescription from a veterinary surgeon or a veterinary practitioner. There are a number of other types of veterinary medicines and medicated feedingstuffs that fall outside our terms of reference. They are subject to varying levels of regulation and are sold through a range of different channels (see Chapter 3).
supply by veterinary surgeons (including for administration by the veterinary surgeons themselves), pharmacies, agricultural merchants and other retailers to owners of farm, and companion, animals.

However, as explained below, the chain of supply for POMs is more restricted. In practice most POMs are supplied by manufacturers to veterinary surgeries via veterinary wholesalers, and sold by veterinary surgeons to animal owners. Our inquiry focuses on this chain of supply, and the ability of pharmacies to compete with veterinary surgeons at the retail level.

2.7. The arrangements under which veterinary medicines are regulated are described in Chapter 3. As a general rule, they may not be supplied or administered in the UK unless they have a current MA, which stipulates the indications (species and conditions) for which they may be used. An MA may not be given until the safety (embracing risk to the treated animal, people and the environment), quality and efficacy of the product have been demonstrated. The holder of an MA is under a number of legal duties (see paragraph 3.63). In addition, the holder is regulated and requires a manufacturer’s licence under the Medicines Act 1968 if he makes veterinary medicine or a wholesale licence if he buys or sells the product commercially, other than by retail.

2.8. The role of veterinary surgeons in prescribing and supplying veterinary medicines is set out in the Medicines Act 1968 and regulations made under it. Provisions relevant to POMs provide that they may be sold:

(a) by a veterinary surgeon for administration by him or her, or under his or her supervision, to an animal or herd under his or her care; or

(b) at a pharmacy by, or under the supervision of, a pharmacist, only on prescription by the veterinary surgeon that has the animal or herd under his or her care.

2.9. Where there are one or more authorized veterinary medicines for the treatment of a particular species and condition, these must be used. Where there is no such medicine, veterinary surgeons may make use of the ‘cascade’ which allows them, or persons acting under their direct responsibility, to administer:

(a) a veterinary medicine authorized in the UK for use in another animal species or for another condition in the same species;

(b) if there is no medicine such as (a) describes, a product authorized for use in the UK in a human being; or

(c) if there is no medicine such as (b) describes, a veterinary medicinal product prepared by a pharmacist in accordance with a veterinary prescription.

2.10. The need for manufacturers to obtain MAs for each veterinary medicine, requiring them to demonstrate its safety, quality and efficacy, affects the timing and costs of bringing new POMs to market. The requirement for manufacturers to supply POMs only to wholesalers licensed under the Medicines Act 1968 to deal in POMs, to veterinary surgeons or to pharmacies limits the ways in which they may be distributed. The requirement for POMs to be sold or supplied only by veterinary surgeons for animals or herds under their care, or by pharmacists from prescriptions written by veterinary surgeons having animals or herds under their care, gives veterinary surgeons a ‘gatekeeper’ role in the supply of POMs and precludes one veterinary surgeon from selling POMs prescribed by another. The requirement for veterinary surgeons to use POMs authorized for the treatment of a particular species and condition (or otherwise use the cascade) limits their choices in their ‘gatekeeper’ role. These regulatory requirements have significant effects upon competition in the supply of POMs in the UK by increasing costs of supply, raising barriers to entry, and restricting the outlets through which POMs may legally be obtained.
2.11. Entry of new POMs is further constrained by patents. Although only 13 per cent of POMs are currently under patent, they account for some 35 per cent of POM sales (see paragraphs 2.74 and 9.5).

2.12. Various aspects of the legislative framework under which veterinary medicines are controlled are under review both within the EC and in the UK. Within Europe, the European Commission has been reviewing the principal EC legislation on human and veterinary medicines and has made a number of proposals for change that are under discussion with member states (‘Review 2001’; see paragraphs 3.96 and 3.97). Separately, within the UK, a group appointed in August 2000 by the then Minister for Agriculture, Fisheries and Food and chaired by Professor Sir John Marsh looked at the regulatory aspects of providing POMs, and made several recommendations for change, which are set out in the Report of the Independent Review of Dispensing by Veterinary Surgeons of Prescription Only Medicines of May 2001 (the Marsh report). The Government issued its response on 10 December 2002 (see Appendix 3.1). Our inquiry is concerned with whether one or more monopoly situations exist under the terms of the FTA, and we are not conducting a further review of the regulatory regime governing the supply of POMs. Nevertheless, some concerns raised in the Marsh report are also relevant to us, and in conducting our review we have needed to take account of the implications for competition of tight regulatory control at all levels of the supply chain, combined with the role played by patents. We recognize that legislators and regulators face difficult choices in seeking to protect human health and animal welfare whilst preserving the scope for innovation and competition. Nevertheless, widespread concern was expressed to us over the decreasing number of veterinary medicines available to treat animals, so we have sought, in our inquiry, to identify features of the present regulatory arrangements that appear to restrict competition more than is necessary. In paragraphs 2.191 to 2.219 we recommend some changes.

Conducts and jurisdiction

2.13. We are first required to establish whether any monopoly situations exist in relation to the supply of POMs within the UK. Under section 6(1)(a) of the FTA a scale monopoly situation would exist where at least one-quarter of all the POMs supplied in the UK are supplied by, or to, one person. Under section 6(1)(c) of the FTA a complex monopoly situation would exist if at least one-quarter of POMs supplied in the UK are supplied by members of a group of persons (not being a group of interconnected companies) who, whether voluntarily or not or by agreement or not, conduct their respective affairs so as to prevent, restrict or distort competition in connection with the supply of POMs in the UK.

Findings on scale monopoly

2.14. Our assessment of the share of supply of POMs as a whole at the manufacturer level is set out in Table 4.2. Supply of POMs at the retail level is widely distributed between veterinary surgeons currently working in general practice—we estimate their number to be 9,700 (see paragraph 6.32 for an explanation of how we derived this figure)—with a very small amount supplied by pharmacies (see paragraph 9.79). At neither level does one party account for one-quarter of total supply.

2.15. Our assessment of shares of supply of POMs in the UK at the wholesaler level is set out in paragraphs 5.11 to 5.20. This shows that NVS supplied at least 35 per cent of all POMs supplied in the UK in 2001. Accordingly we conclude that NVS has a scale monopoly in the wholesale supply of POMs in the UK.
Complex monopoly: conduct

2.16. In assessing whether one or more complex monopoly situations exist in the supply of POMs in the UK, we focused our attention on evidence of conduct, by persons supplying POMs, that are not required by the regulatory structure and that prevent, restrict or distort competition. We identified several interrelated conducts engaged in by manufacturers, wholesalers and veterinary surgeons which have the effect of preventing, restricting or distorting competition:

(a) failure of veterinary surgeons to inform animal owners that they can ask for prescriptions, or discouraging requests for prescriptions, or declining to provide prescriptions on request;

(b) failure of veterinary surgeons to inform clients of the price of POMs prior to dispensing them, or to provide itemized bills;

(c) pricing of POMs by veterinary surgeons which does not reflect their cost of supply, including:

(i) mark-ups on manufacturers’ list prices that take no account of the discounts and rebates they receive from wholesalers and manufacturers, or do not reflect variations in those discounts and rebates; and

(ii) pricing POMs to subsidize, to a greater or lesser extent, professional fees;

(d) failure of manufacturers to enable pharmacies to obtain supplies of POMs on terms which would allow them to compete with veterinary surgeons; and

(e) failure of veterinary wholesalers to take reasonable steps to market to pharmacies and supply them with POMs, so that they can compete with veterinary surgeons.

Conducts of veterinary surgeons

2.17. In order to assess the extent of the relevant conducts and obtain other detailed information on veterinary practices in the UK, we commissioned BMRB International Limited (BMRB), an independent market research organization, to undertake three surveys on our behalf:

(a) a telephone and Internet survey of veterinary surgeries (BMRB1);

(b) a postal survey of veterinary surgeries (BMRB2); and

(c) a telephone survey among the general public about billing practices of veterinary surgeons (BMRB3).

2.18. BMRB1 included a telephone survey of veterinary surgeons based on a representative sample of 610 veterinary surgeries selected from an RCVS database, which lists approximately 3,500 veterinary branches and surgeries. 63 per cent of respondents were senior veterinary surgeons. There were over 1,300 responses to the postal survey (BMRB2) of surgeries where animals are treated. BMRB considered that in a self-completion survey of senior professionals, the achieved response rate of 42 per cent was very good. In 70 per cent of cases, the respondent was a senior veterinary surgeon or partner. BMRB3 surveyed a representative sample of the Great Britain population and obtained responses from 2,022 adults, 848 of whom owned companion animals.
2.19. These surveys and their results, together with a separate survey of cat and dog owners undertaken for us by Produce Studies Research Limited (PSR), are described in Appendices 6.1 to 6.3. We consider that the surveys were reliable and the results robust for the purposes of our inquiry.

2.20. The conducts identified in paragraph 2.16 were found both in relation to the supply of POMs for companion animals and for animals used for food production—though we received some evidence that they may be less common in specialist areas such as the commercial production of poultry, pigs or fish, where veterinary surgeons’ arrangements with producers—who can have considerable buyer power and, in some cases, employ veterinary surgeons on their staff—can differ from those more typically found with other animal owners. However, the numbers of veterinary surgeons involved, and the value of POMs supplied under such arrangements, were not on a scale to be significant for the purposes of jurisdiction (see paragraph 2.44 and Appendix 2.1).

2.21. In commenting on conduct relating to the provision of prescriptions (see paragraph 2.16(a)), many veterinary surgeons drew attention to the provision in the RCVS Guide to Professional Conduct, which requires them to make their clients aware that POMs may be obtained on prescription from other suppliers and states that they should not unreasonably refuse to supply prescriptions (see paragraph 3.76). They argued that only very few veterinary surgeons discouraged requests for prescriptions or declined to provide them. Similarly in commenting on conduct relating to information about prices (see paragraph 2.16(b)), many veterinary surgeons told us that the provision of itemized bills was now common practice.

2.22. Our PSR survey showed that, among dog and cat owners, only about one in six was aware that it was possible to ask for a prescription (see paragraph 6.168). Our BMRB1 survey showed (see paragraph 6.171) that 73 per cent of veterinary surgeons did not inform clients that they could have a prescription, or only did so on request. 52 per cent of companion animal owners who took part in our BMRB3 survey (see paragraph 6.174) said that they were not told the price of the medicine by the veterinary surgeon before it was dispensed. Our BMRB1 survey showed (see paragraph 6.179) that around 30 per cent of veterinary surgeons did not routinely provide itemized bills. We are clear from comments by members of the public and from individual veterinary surgeons themselves (see paragraphs 11.136 and 13.246), and from evidence provided by [Details omitted. See note on page iv.], following a mailshot it carried out in March 2001 (see paragraph 9.106), that refusal to provide prescriptions and discouraging requests for prescriptions does occur in some cases.

2.23. Some veterinary surgeons and manufacturers who commented on pricing of POMs by veterinary surgeons argued that the use of manufacturers’ list prices as a basis for mark-ups did not show that their pricing was uncompetitive or led to higher prices than would otherwise be the case. Information on mark-ups by veterinary surgeons is considered in paragraphs 6.135 to 6.149. The price at which goods are sold need not bear any fixed relationship to the cost at which the seller obtained them. However, the failure of veterinary surgeons to reflect increases in rebates, or to adjust prices for differences between rebates, may be taken as indicative of a lack of competition. The divorce of prices from costs may be significant where discounts and rebates to the veterinary surgeon are substantial. Competition at the retail level in the market for POMs is discussed in paragraphs 2.103 to 2.116.

2.24. Merial argued that the methodology used in BMRB1 was flawed and that it was unsafe to conclude, on the basis of that survey, that the majority of veterinary surgeons mark up on manufacturers’ list prices (see paragraphs 6.144, 10.388 and 10.389). We accept that the precise formulation and sequencing of the questions in BMRB1 means that the proportion of veterinary surgeons marking up from manufacturers’ list prices could not safely be estimated from that survey alone, if there were any doubt about the way in which the great majority of respondents had interpreted the question. However, we judge that reliable estimates can be
made from BMRB1 when its results are considered in the light of the evidence from the BMRB2 survey. That survey used a different approach but yielded very similar results.

2.25. BMRB1 recorded (see paragraph 6.154) that 53 per cent of veterinary surgeries questioned said that they priced POMs to subsidize professional fees, to a greater or lesser extent. Of the individual veterinary surgeons who commented on this issue, some 60 per cent agreed that they set charges for dispensing medicines to subsidize consulting fees; and some said that cross-subsidization was endemic, and described how it had grown for historical reasons (see paragraph 11.154). However, other veterinary surgeons and the British Veterinary Association (BVA) argued that there was insufficient evidence to conclude that the pricing of POMs was commonly used to subsidize professional fees, once proper allowance was made for the true costs, to veterinary surgeons, of dispensing medicines (see paragraphs 6.155, 11.154 and 11.289). We were able to obtain only limited data on veterinary surgeons’ dispensing costs and this was not of sufficient quality to allow the subsidization of fees by profits from medicine sales to be demonstrated beyond doubt. However, our analysis does tend to support the views of the many veterinary surgeons questioned, who reported that POMs were commonly priced to subsidize professional fees (see paragraphs 6.153 to 6.162).

2.26. Many veterinary surgeons raised a wider issue over the conducts. Although they did not in general dispute that in some instances the prescribing, dispensing and administration of POMs could be handled as separate activities, many argued that doing so would undermine the effective control of POMs, and so increase risks to human and animal safety, and to the environment. In their view, the conducts with which we were concerned should not be seen as preventing, restricting or distorting competition, but as being part of a system in which competition could occur, but only within controls that were necessary for the safe supply and use of potentially dangerous substances.

2.27. We do not agree that conducts cannot properly be held to prevent, restrict or distort competition if they could also be argued to offer certain wider benefits to society. However, we fully accept that the supply of POMs raises issues that go wider than competition, and that account must be taken of these both in deciding whether any complex monopoly operates against the public interest (see paragraphs 2.145 to 2.161) and when considering potential remedies (see paragraphs 2.162 to 2.189).

Conducts of manufacturers

2.28. We received complaints from the National Pharmaceutical Association (NPA) and from several pharmacies that pharmacies had been unable either to obtain supplies of POMs from manufacturers, at all, or only on terms that did not allow them to compete with veterinary surgeons. These complaints are summarized in paragraphs 12.9, 12.26, 12.30, 12.91, 12.108, 12.114 and 12.120 to 12.122.

2.29. The responses of manufacturers to these complaints are summarized in paragraphs 10.170, 10.247, 10.336 to 10.342, 10.399, 10.518 and 10.519, 10.596, 10.752, and 10.841 to 10.843. Most of them agreed that they did not at present supply pharmacies with POMs direct and responded to enquiries by inviting pharmacies to obtain POMs through a veterinary wholesaler. They argued, however, that this was for commercial reasons; was in line with their normal policy on direct supply to veterinary surgeons; and reflected the advantages to the manufacturers of distribution through a specialist wholesaler. Bayer plc (Animal Health Business Group) (Bayer), Intervet, Novartis, Fort Dodge and Virbac acknowledged that they did supply some veterinary surgeons direct, but said that this was largely a matter of history. New customers were generally expected to obtain supplies from veterinary wholesalers. All the manufacturers that we asked said that they were in principle willing to supply anyone who held a veterinary wholesaler licence, provided they met their normal business conditions.
2.30. Nearly all manufacturers offer some form of scheme under which veterinary surgeons who purchase their POMs, whether direct or through a veterinary wholesaler, may receive a rebate off the purchase cost. The details of these schemes, including the amount of rebate payable, vary greatly from manufacturer to manufacturer (see paragraphs 8.15 to 8.54). [Details omitted. See note on page iv.] and [X] told us that rebates were not paid to pharmacies. [X] told us that two veterinary practices that also operated as pharmacies were eligible for its scheme, although only one reached the threshold for receipt of rebates. The majority of these manufacturers argued that a difference in approach was justified by the different role played by veterinary surgeons in determining the medicines to be used, through their statutory monopoly of the right to prescribe. [X] and [X] said that they had no fixed policy on paying rebates to pharmacies, and if they began to buy POMs in sufficient quantities they would consider introducing a scheme—though not necessarily the same one that they offered to veterinary surgeons, because of their differing roles. [X] said that it would consider, case by case, whether to offer rebates to pharmacies. [X] said that it did not offer the same terms to pharmacies as to veterinary surgeries, in part for fear of a reaction from veterinary surgeons, and concern that pharmacies might use veterinary products as a loss leader.

2.31. Some of these manufacturers said that they sometimes made introductory offers to new veterinary practices, though in many cases these were a matter of history and were no longer significant.

2.32. It was put to us that in a competitive market the terms on which manufacturers dealt with veterinary surgeons and pharmacies should reflect their different roles in prescribing and dispensing POMs, and to offer identical terms that failed to reflect the veterinary surgeons’ central role in determining the POMs used would itself distort competition. It was further put to us that, as only some veterinary surgeons received rebates—and even many who did, collected only small amounts—any impact on pharmacies’ ability to compete was limited.

2.33. The effect of rebate arrangements on competition between manufacturers is considered further in paragraphs 2.77 to 2.88; and their effect on veterinary surgeons, in paragraphs 2.89 to 2.92. However, we have concluded that, under present conditions, pharmacies are not able to offer effective competition to veterinary surgeons in the supply of POMs at the retail level, and that their inability to obtain POMs on terms that include manufacturers’ rebates is a significant factor in this. Fort Dodge, Intervet, Merial, Novartis, Pfizer, Pharmacia, Schering-Plough and Virbac all engage in conducts that have this effect, as they pay rebates to veterinary surgeons that they do not pay, or offer, to pharmacies. We do not believe that this judgement is negated where, as is the case with [X], rebates are paid to pharmacies only when they are linked to veterinary practices. Competition between veterinary surgeons and pharmacies in the supply of POMs is considered further in paragraphs 2.110 to 2.116.

**Conducts of veterinary wholesalers**

2.34. We received complaints from several pharmacies that they had been unable to obtain supplies of POMs from veterinary wholesalers. Hyperdrug Pharmaceuticals (Hyperdrug), Laycock’s Agricultural Chemists (Laycock’s) and [X] told us that NVS had refused them an account, and another pharmacy told us that NVS had failed to reply to a request for an account. Similar complaints were made about Genus Xpress (Genus) by R M Jones, and about W & J Dunlop Ltd (Dunlops) by Hyperdrug, Jobsons Farm Health (Jobsons), Walter Davidson & Sons Ltd (Davidsons) and another pharmacy. Complaints were also made about Veterinary Surgeons Supply Co Ltd (VSSCo) and Dunnwood (VS) Ltd (Dunnwood).

2.35. The Royal Pharmaceutical Society of Great Britain (RPSGB) and the NPA told us that in wholesale supply of pharmacists ‘there are indications that punitive conditions are set in
terms of minimum turnover levels, poor discounts and short payment terms’. A pharmacy that has now changed hands told us that it was refused an account by NVS, but received supplies from a smaller wholesaler, though on inferior terms to veterinary practices. Hyperdrug said that Genus would supply to pharmacies, but at inflated prices. The pharmacists’ complaints about veterinary wholesalers are summarized in paragraphs 12.9, 12.30, 12.69, 12.82, 12.84, 12.92, 12.108, 12.117, 12.123 and 12.132.

2.36. The responses of the veterinary wholesalers to these complaints are summarized in paragraphs 10.871, 10.885 and 10.906. NVS told us that its policy was to supply pharmacies on the same terms as veterinary surgeries; it said that because most of the complaints that we had received related to requests made over a period of two and a half years, it was virtually impossible to investigate them. In the most recent case which NVS was able to identify, it told us that its decision to decline to supply was due to an internal error. Genus told us that it did not know about the dealings between Dunnwood and Davidsons, and did not have R.M Jones’ details on record. Genus denied quoting inflated prices to Hyperdrug. Dunlops told us that it did not recall dealing with Davidsons. It had not replied to Hyperdrug’s request for supply because ‘Marsh was going on and we were not really interested’. It was unable to confirm or deny Hyperdrug’s claim that a telephone call had resulted in a blunt refusal to supply pharmacies (see paragraph 9.81).

2.37. In general the veterinary wholesalers accepted that they supplied few POMs to pharmacies, but argued that this was essentially due to lack of demand; they had few enquiries from pharmacies, and those that they did receive rarely turned into orders. All those from whom we obtained evidence said that, subject to the pharmacies meeting their normal business requirements, they were willing to supply them with POMs on the terms available to veterinary surgeons for equivalent volumes. However, the provision of rebates by manufacturers was outside their control.

2.38. Given the combination of factors that have served to deter them from competing with veterinary surgeons in the supply of POMs (see paragraphs 2.110 to 2.116), we found it unsurprising that the number of reported instances of approaches from pharmacies to veterinary wholesalers that led to complaints was small and was spread over such a period that we were unable to obtain reliable information on precisely what had occurred. So, as well as examining these cases, we also sought to understand the broader picture. At that level, the evidence presented to us by the NPA, individual pharmacies and by the veterinary wholesalers was essentially consistent with a general unwillingness on the part of veterinary wholesalers to supply pharmacies.

2.39. The ways in which veterinary wholesalers compete to supply veterinary surgeons is considered in paragraph 2.97. This involves competing both on levels of discount and on levels of service in terms of speed and convenience. The latter includes ease of ordering, reliable stocking of the full range of POMs and other veterinary medicines, speed of delivery, and the ability to provide a one-stop shop covering other veterinary supplies. Veterinary wholesalers actively market themselves to veterinary surgeons on the basis of the additional services they can provide, for example supplying pet foods and providing software to facilitate ordering and to help track medicines to their end-user. The successful veterinary wholesaler becomes the ‘first port of call’ from which the veterinary surgery purchases most of its supplies across the broadest range of goods.

2.40. None of the veterinary wholesalers has sought actively to market services to pharmacies. Because few veterinary prescriptions for POMs are presented to pharmacies, and because pharmacies cannot obtain POMs on terms that include manufacturer rebates, only a few have approached veterinary wholesalers for supplies, typically for modest volumes. Against this background, and an expectation that they would continue to buy only small amounts of veterinary medicines in the future, veterinary wholesalers have seen few commercial opportunities in supplying pharmacies. They have neither canvassed pharmacies for
business, nor offered them introductory deals such as those that they have offered to new veterinary surgeries. They appear to us to have regarded approaches from pharmacies about supplying POMs as more of a nuisance than an opportunity.

2.41. Indeed, some of the veterinary wholesalers appear to perceive the entry of pharmacies as a potential threat. Dunlops expressed concern over the potential impact on its business if many pharmacies wanted to be supplied, given their large numbers, compared with veterinary practices. NVS, Genus and Dunlops further expressed concern that pharmacies might ‘cherry-pick’ some leading veterinary medicines, and human medicine wholesalers might then start to supply those medicines to the pharmacies, reducing the size of the market for veterinary wholesalers and increasing their unit costs. Dunlops noted that the few veterinary pharmacies that specialized in supplying farms obtained the bulk of their veterinary medicines, which were not classified as POM, through other routes of supply (including, in some cases, direct from manufacturers).

2.42. Pharmacies depend on the veterinary wholesalers actively competing for their business in order to enter into competition with veterinary surgeons in the supply of POMs to animal owners. In these circumstances, and in the light of the weakness we find in competition at the retail level, in our view the failure by the veterinary wholesalers actively to market to pharmacies is a failure to supply. We note moves by several wholesalers since the start of the Marsh, and of our own, inquiries to respond more positively to approaches from pharmacies. Nevertheless, the number of active accounts to supply pharmacies with POMs remains very small. So we conclude, on the evidence presented to us, that all the veterinary wholesalers—NVS, Centaur Services Ltd (Centaur), Genus, Dunlops and VSSCo—failed to take reasonable steps to supply pharmacies with POMs to enable them to compete with veterinary surgeons.

The complex monopoly situations

POMs supplied by veterinary surgeons

2.43. For a complex monopoly situation to exist, at least one-quarter of POMs in the UK must be supplied by members of the group of persons engaged in the relevant conducts, or supplied to members of the group. We have identified as a relevant group those veterinary surgeons engaged in one or more of the conducts listed under (a) to (c) in paragraph 2.16, which have the effect of preventing, restricting or distorting competition in the supply of POMs to animal owners. To establish whether that group supplies at least one-quarter of POMs supplied in the UK we used evidence from our surveys to assess the proportion of veterinary surgeons engaged in one or more of the relevant conducts and the proportion of POMs they supplied.

2.44. The relevant calculations based on responses to our surveys are in Appendix 2.1. They show that veterinary surgeons in private practice that are engaged in at least one of the relevant conducts included in (a) to (c) in paragraph 2.16 supply more than 91 per cent by value of all POMs supplied by veterinary surgeons in private practice, representing not less than 73 per cent of all POMs supplied in the UK.

2.45. So we find that a complex monopoly situation exists in consequence of veterinary surgeons engaged in one or more of:

(a) failure to inform animal owners that they can ask for prescriptions, or discouraging requests for prescriptions, or declining to provide prescriptions on request;

(b) failure to inform clients of the price of POMs prior to dispensing them, or to provide itemized bills;
(c) pricing of POMs which does not reflect cost of supply to themselves, including:

(i) mark-ups on manufacturers’ list prices that take no account of the discounts and rebates that they receive from wholesalers and manufacturers, or do not reflect variations in those discounts and rebates; and

(ii) pricing of POMs to subsidize, to a greater or lesser extent, professional fees;

being a group of persons that supply at least one-quarter of all POMs in the UK and who conduct their respective affairs in such a way as to prevent, restrict or distort competition in the supply of POMs to animal owners (hereafter referred to as the veterinary surgeons complex monopoly situation).

POMs supplied by manufacturers

2.46. We identified as a relevant group those manufacturers engaged in conduct (d) in paragraph 2.16 that has the effect of preventing, restricting or distorting competition in the supply of POMs to retailers (veterinary surgeons and pharmacies). We consider Fort Dodge, Intervet, Merial, Novartis, Pfizer, Pharmacia, Schering-Plough and Virbac to be engaged in this conduct as a result of failure to offer or pay rebates to pharmacies on the same terms as to veterinary surgeries. Shares of supply by all the main manufacturers are shown in Table 4.2. This shows that the eight named manufacturers supply around 70 per cent of POMs supplied in the UK.

2.47. We took evidence from all the large and medium-sized manufacturers of POMs supplied in the UK, plus a number of others. We are satisfied that this list includes all the manufacturers that, through the operation of their rebate schemes, have an impact on competition between pharmacies and veterinary surgeons that we regard as likely to be significant. Whilst there may be some smaller manufacturers engaged in similar conduct that we have not identified, we do not regard any impact they may have as likely to be significant.

2.48. We therefore find that a complex monopoly situation exists in consequence of Fort Dodge, Intervet, Merial, Novartis, Pfizer, Pharmacia, Schering-Plough and Virbac failing to enable pharmacies to obtain supplies of POMs on terms that would allow them to compete with veterinary surgeons. These manufacturers are a group of persons that supply at least one-quarter of all POMs in the UK and who conduct their respective affairs in such a way as to prevent, restrict or distort competition in the ultimate supply of POMs to animal owners (hereafter referred to as the manufacturers complex monopoly situation).

POMs supplied by veterinary wholesalers

2.49. We identified as a relevant group those veterinary wholesalers engaged in conduct (e) in paragraph 2.16 that has the effect of preventing, restricting or distorting competition in the supply of POMs to retailers (veterinary surgeons and pharmacies). We consider all of the veterinary wholesalers (NVS, Centaur, Genus, Dunlops and VSSCo) to have failed to take reasonable steps to supply pharmacies with POMs to enable them to compete with veterinary surgeons. Shares of supply by all the main manufacturers are shown in Table 4.2. This shows that the eight named manufacturers supply around 70 per cent of POMs supplied in the UK.

2.50. Paragraphs 4.21 to 4.23 show that around 90 per cent of all POMs currently supplied in the UK are supplied through these five veterinary wholesalers. Their individual shares of this supply are discussed in paragraphs 5.11 to 5.20.

2.51. We therefore find that a complex monopoly situation exists in consequence of NVS, Centaur, Genus, Dunlops and VSSCo failing to take reasonable steps to supply POMs to pharmacies to enable them to compete with veterinary surgeons, being a group of persons that
supply at least one-quarter of all POMs in the UK and who conduct their respective affairs in such a way as to prevent, restrict or distort competition in the supply of POMs to animal owners (hereafter referred to as the veterinary wholesalers complex monopoly situation).

**Interconnections between the conducts**

2.52. In the preceding paragraphs we identified three separate complex monopoly situations that prevent, restrict or distort competition in the supply of POMs to animal owners. These conducts are interconnected in ways that are important for a proper understanding of the lack of competition in this market.

2.53. First, through interconnections of effect, in that conducts at the different levels combine to raise barriers to entry and expansion by pharmacies. For pharmacies to be able to compete in the supply of POMs they require there to be both demand, which is dependent upon animal owners not automatically receiving their medicines from the prescribing veterinary surgeon but shopping around between alternative suppliers, and supply, which enables the pharmacies to obtain medicines at prices that do not put them at a significant disadvantage relative to veterinary surgeons. Failure by veterinary surgeons to inform animal owners that they can ask for prescriptions, discouraging requests for prescriptions, declining to provide prescriptions on request, failing to inform clients of the price of medicines prior to dispensing them and/or to provide itemized bills that would increase animal owners’ awareness of the cost of POMs, all have the effect of reducing potential demand for POMs from pharmacies. Failure of manufacturers to enable pharmacies to obtain POMs on terms that allow them to compete with veterinary surgeons, through their paying rebates only to veterinary surgeons, adversely affects the supply side of the equation. The normal route for distribution of POMs from manufacturers to retailers is through veterinary wholesalers. Most manufacturers will not supply POMs (and some veterinary medicines that are non-POM) direct, but insist that they are obtained through the veterinary wholesalers. Failure of the veterinary wholesalers to take reasonable steps to supply pharmacies with POMs to enable them to compete with veterinary surgeons therefore also adversely affects the ability of pharmacies to obtain medicines at prices that do not disadvantage them relative to veterinary surgeons, and hence also adversely impacts on the supply side of the equation (see paragraphs 2.96 to 2.98).

2.54. Second, through interconnections of relationship: the manufacturers, wholesalers and veterinary surgeons each maintain direct relationships with the others. Although the normal route of supply from manufacturer to veterinary surgeon is through the veterinary wholesalers, the manufacturers use sales teams, manufacturer rebates and other non-price incentives to market directly to the veterinary surgeons. The veterinary wholesalers all stock the complete POM ranges of all the manufacturers and receive a standard 15 per cent discount from manufacturers’ list prices. The veterinary wholesalers then sell to the veterinary surgeons using the manufacturers’ list prices, less a proportion of the 15 per cent discount they themselves received; the discount given to any veterinary surgeon depends on the total volume purchased. A manufacturer pays a rebate to veterinary surgeons based on purchase of its products. The net price paid by the veterinary surgeon thus depends both on the level of wholesaler discount and of the manufacturer rebate. The operation of the manufacturer rebate schemes depends upon the collection and provision to the manufacturers of detailed information on supplies to veterinary surgeons by the wholesalers (and in some cases administration of the rebates by the wholesaler), for which the wholesaler is paid. The ability of the wholesalers to collect and pass on that information depends on the agreement of the veterinary surgeons (which they give because the information must be provided if they are to receive rebates from the manufacturers). These relationships differ markedly from those that would occur in a supply chain where the manufacturers simply sold to the wholesalers who then sold on to the veterinary surgeons.

2.55. Third, through interconnections of justification, in that certain conducts at one level in the supply chain provide a rationale for those at other levels to maintain their conducts. The
veterinary surgeons explain and seek to justify their conduct, in part, because, as pharmacies do not stock POMs and as they can dispense them only to animals or herds under their care, their clients cannot shop around, so there is little point in providing prescriptions or information on prices. The manufacturers explain and seek to justify their conduct, in part, because, in the absence of prescriptions, there is insufficient demand for POMs from pharmacies to merit direct supply or payment of volume-related rebates—though many manufacturers also argue that it is the veterinary surgeons’ unique role in determining the product to be used that justifies different rebate arrangements, irrespective of volumes. The wholesalers explain and seek to justify their conduct on the basis that the absence both of prescriptions from veterinary surgeons and rebates from manufacturers means that pharmacies will not sell enough POMs to make it profitable for the veterinary wholesalers to extend their distribution arrangements to them, other than in exceptional circumstances.

2.56. Fourth, through interconnections of benefit, in that each of those engaged in the conduct benefits from the conduct of the others through their combined effects. Veterinary surgeons, whether themselves engaging in the conduct or not, benefit from the reduced level of competition from pharmacies, which keeps prices for POMs higher than they would otherwise be. Manufacturers benefit because veterinary wholesalers are price takers, exercising no buyer power, and because of the absence of pharmacy groups that might be expected to be able to exert greater buyer power than veterinary surgeons. They also benefit from lower costs of sales through being able to focus marketing just on veterinary surgeons. Veterinary wholesalers benefit from the lack of competition at retail level through lower distribution costs and by not having to compete with the human medicine wholesalers, who are the normal distribution channel to pharmacies (see paragraphs 2.113 to 2.115).

2.57. Fifth, through interconnections of dependence, in that certain conduct at one level of the supply chain depend upon conduct at others. Thus veterinary surgeons can sell POMs at prices which do not reflect their cost of supply because competition from pharmacies is so weak, as a result of the other conduct at all three levels in the supply chain.

2.58. We considered, therefore, whether the conduct might more appropriately be regarded not as three separate monopoly situations, but as part of single complex monopoly involving all parts of the supply chain.

2.59. When we put this to the veterinary surgeons, manufacturers and veterinary wholesalers, four manufacturers of POMs (Fort Dodge, Intervet, Merial and Pfizer) argued that the conduct of manufacturers, wholesalers and veterinary surgeons were insufficiently connected for them to be grouped in a single complex monopoly.

2.60. We take the view that persons operating at different levels in a supply chain may properly form part of a single group where, for the purposes of the FTA, there is a sufficient connection between their conduct (as specified in section 6(2)). Whether such a sufficient connection exists will depend upon an examination of the particular characteristics of the industry in question and upon a competitive analysis of the market, or markets, involved, including the dynamic features within them. A sufficient connection may well be found where there are significant structural or other links between the various levels of supply, or more generally where the conduct of those operating at one level enables, facilitates, supports, or is used to justify, the conduct of those operating at others, with the result that competition is restricted or distorted at more than one level.

2.61. For the reasons given in paragraphs 2.52 to 2.57, we believe that significant interconnections of these types are found in the present case, and accordingly take the view that it would have been open to us to find a single complex monopoly. We believe that an appreciation of the interconnections between conduct at different levels in the supply chain is important for a proper understanding of competition in the supply of POMs in the UK. However, the conduct also form the basis for complex monopoly situations at each level in the supply chain, as we concluded in paragraphs 2.45, 2.48 and 2.51.
2.62. Having found the existence of complex monopoly situations, the FTA requires us to address the matters set out in paragraph 2.126. Before doing so, however, we consider the relevant markets and competition within them.

The relevant markets

Market definition

2.63. As noted in paragraph 2.6, for the purposes of our inquiry we distinguish three levels in the supply of veterinary medicines: the manufacturer level, the wholesaler level and the retail level. Although some end-users, who employ veterinary surgeons, are supplied direct with some POMs by manufacturers, around 90 per cent of all POMs supplied in the UK are supplied by the manufacturers to veterinary wholesalers (see Table 4.5) and then by them to veterinary surgeons and—to a very limited extent—to pharmacies. They are then sold or supplied by the veterinary surgeons and pharmacies for administration by end-users or administered by the veterinary surgeon (see paragraph 6.86). The relevant geographic and product markets at each of these levels are considered in Chapter 7. Our conclusions are these.

Geographic and product markets at the manufacturer level

2.64. Costs of transport and distribution are typically low in relation to the value of veterinary medicines. However, regulation limits the potential for imports. Although POMs supplied in the UK are manufactured in a variety of locations globally, they can—if they are required to have a UK MA—only be supplied in the UK by, or with the consent of, that MA’s holder. The VMD told us that the authorization process took an average of around two years. (While there is provision for specific authority to be granted to certain parallel imports (see paragraph 7.5), these are rare in practice.) Within the UK, most manufacturers saw Great Britain and Northern Ireland as one market. Although ex-manufacturer prices of individual POMs vary between Great Britain and Northern Ireland, the price data we received suggested than on average there is no great variation in ex-manufacturer prices between them (see paragraph 8.122). We therefore treat the UK as the relevant geographic market for the supply of POMs at the manufacturer level, though the supply of fish vaccines may be an exception. Although there are differences in share of sales between Great Britain and Northern Ireland, given the limited size of the market in Northern Ireland, there is limited scope for variation in market shares between Great Britain and the UK.

2.65. As for product markets, we consider that the potential for entry, while significant, is not sufficiently immediate—given the time usually required for product development and obtaining MA—to constitute supply-side substitution (see paragraphs 7.11 and 7.12). On the demand side, price competition between two products depends on customers responding to an increase in the price of one by switching to another. If the extent of switching that would result from a price increase is sufficient to constrain it, the two products can be seen as economic substitutes. In the case of POMs, the substitutable products need not be clinically equivalent in all circumstances provided a veterinary surgeon is able to substitute, as a price response, between two products in enough circumstances for the one to act as an effective price constraint on the other—ie there may be partial substitutability.

2.66. Manufacturers and veterinary surgeons agreed that a veterinary surgeon would not choose between two medicines on the basis of price unless both were perceived to be efficacious in treating the particular condition(s) in question. However, there was some disagreement (both between manufacturers and between veterinary surgeons) about the extent to which veterinary surgeons are influenced by price (see paragraph 9.19). In general, manufacturers were more likely than veterinary surgeons to see price playing an important role in the purchasing decision.
2.67. In paragraph 7.85 we identify 30 separate product markets under five broad headings (antimicrobials, parasiticides, neurologicals, cardiac/respiratory stimulants and vaccines), and calculate market share and size in 2001 in each of them—no view was taken on markets for hormones. These calculations show that in six of the seven markets that we estimated as being worth more than £10 million, the leading supplier had a share of over 25 per cent, and in three of them its share was over 50 per cent. Two of these three (prescription-only small-animal flea treatments and poultry vaccines) were POM and one (small-animal wormers) was mainly Pharmacy and Merchants List medicines (PML). PMLs may be supplied, without prescription, by a pharmacy, by a veterinary surgeon for the treatment of an animal or herd under his or her care, by an agricultural merchant or (if a wormer for cats, dogs or horses) by a registered saddler.

2.68. When invited to comment, several manufacturers noted that precise market definition did not appear crucial to our findings, and so did not set out their views in detail. Of those that did express a view, several disagreed with the distinction between preventive and curative medicines that we made in several markets. Pfizer commented in detail, disagreeing with our judgements in several areas. We accept that there is scope for differing judgements over the precise boundaries between product markets, which may, in some cases, change over time according to the products available. So there can be a degree of uncertainty over market shares and concentration. Nevertheless, it appears to us that in most POM markets the leading manufacturer has a large share and concentration is high (see Table 7.1). For the purposes of our inquiry we do not judge it necessary to reach a definitive view on these issues, as the competition issues with which we are primarily concerned do not depend upon the precise boundaries between different product markets.

**Veterinary wholesalers**

2.69. Geographic coverage of the veterinary wholesalers and the ways in which they compete are considered in paragraphs 2.96 to 2.98. One veterinary wholesaler operates only in Northern Ireland, another only in Scotland, Wales and northern England, with the other three operating in most regions of Great Britain. Inter-product substitution is less important in defining the market at the wholesale level than at the manufacturer level because each of the veterinary wholesalers appears to stock the complete range of POMs of manufacturers that supply in the UK and not to compete on prices of individual POMs.

**Veterinary practices and other retail outlets**

2.70. Competition between veterinary practices is local. The veterinary surgery must be close enough for the animal or herd to be under the care of the veterinary surgeon. The distances veterinary surgeons will travel depend on the nature of the practice and the type of animals in which it specializes (see paragraph 9.89). In urban areas, chains of substitution may nevertheless lead to relatively large geographic markets. In principle, competition from pharmacies in dispensing some POMs could be less geographically concentrated, for example through the use of mail order or the Internet, but in practice veterinary surgeons currently face little competition from pharmacies in the supply of POMs, and where it does exist, it is local.

2.71. Inter-product substitution is less important in defining the market at the retail, than at the manufacturer, level because a veterinary practice will be able to dispense any POM for the treatment of animals under the care of one of its veterinary surgeons.

**Competition between manufacturers**

2.72. We identified 29 manufacturers that, between them, according to Martin Hamblin GfK Healthcare UK (GfK), accounted for 97 per cent of POMs sold through veterinary
wholesalers in the UK in 2001. Of these 29, 19 each sold more than £\[\text{T}\] worth of POMs in 2001. These manufacturers are described in Chapter 4 and their respective sales and shares shown in Table 4.2. In 2001 Intervet had the largest net sales by value of some £\[\text{T}\] (after deduction of manufacturer discounts to wholesalers and manufacturer rebates to veterinary surgeons) representing 13.3 per cent of all sales of POMs in the UK in that year. It was followed by Pfizer (13.1 per cent), Merial (11.8 per cent), Schering-Plough (11 per cent), Fort Dodge (8.6 per cent) and Novartis (6.3 per cent). These six were the only manufacturers with net sales of POMs greater than £\[\text{T}\] in that year.

2.73. Most of the manufacturers are part of international pharmaceutical corporations whose headquarters are in the USA or in Continental Europe. Of the six named in paragraph 2.72, only Merial Ltd, the holding company of Merial, is UK registered and that is a joint venture between a US and a French company. For most parent companies, veterinary medicines are a small part of their overall business, and the UK a small part of their wider geographical interests.

2.74. Entry, price sensitivity and buyer power are considered in Chapter 9. There are significant barriers to entry, primarily in the costs, time and uncertainty of new product development, but also in meeting regulatory requirements—most new POMs introduced into the UK in recent years have come from existing manufacturers. Patents are a factor too (see paragraph 2.11), and even where a product is not patented, or the patent has expired, the opportunity for entry by competing products may be hindered by a ‘data protection period’ (see paragraph 3.25) of up to ten years. The average reported time for development of a new product was around three and a half years, and authorization took an average of two years, but these periods may overlap (see paragraph 9.12). The number of new products launched varies from year to year, but between 1997 and 2001 the annual figure ranged from 21 to 38 (see Table 9.5).

2.75. Although veterinary wholesalers handle around 90 per cent of POMs, their main function seems to be to act as distributors, receiving standard terms from the manufacturers and stocking their full ranges of POMs. We assess that none exercises significant buyer power at present. (The veterinary wholesalers are discussed in paragraphs 2.96 to 2.98.) We similarly assess that few, if any, customers that use POMs or sell them to animal owners have buyer power, with the possible exception of some customers in the poultry, fish and pig sectors. We note that very few veterinary practices account for more than 1 per cent of GfK-recorded sales of any of the largest eight manufacturers, and none accounts for more than 5 per cent.

2.76. It is common practice in the industry for manufacturers to publish national price lists, from which wholesalers receive a standard 15 per cent discount, and to use rebates to influence the net price paid by veterinary surgeons. These rebate schemes are described in Chapter 8. Table 8.2 shows POM sales and rebates paid by 19 manufacturers in 2001. Table 8.5 shows the average rebate over gross price in each relevant product market. Table 8.4 shows the number of veterinary practices to which certain manufacturers were paying rebates. The tables show that rebates are widespread. Intervet, Pfizer, Merial and Schering-Plough, the four manufacturers with the largest POM sales in the UK, each paid rebates to [\[\text{X}\]] veterinary practices in the UK. Although the sums received will vary, the overall level of rebates is significant, amounting to between 14 and 27 per cent of gross sales [\[\text{X}\]] to all veterinary surgeons. Rebates varied considerably by product market, averaging more than 20 per cent for nine product groups and more than 30 per cent for cat and dog vaccines, for POM antibacterial soluble products for pigs and poultry, and for general anaesthetics by inhalation.

**Effect of rebates on competition between manufacturers**

2.77. We examined whether these schemes operate in such a way as to prevent, restrict or distort competition between manufacturers by creating barriers to entry or expansion. Although
we received few specific complaints from smaller manufacturers, one did tell us that the rebate scheme operated by a larger manufacturer was a major barrier to its competing in two related markets. [...] complained about the effect of the same scheme in these markets (see paragraph 9.44). It also told us that in November 2000 it had sought legal advice on the bundling practices of three of the larger manufacturers, but decided against taking any further action.

2.78. Rebate schemes exist in many industries and when operated by firms without market power are generally seen as pro-competitive or neutral. As noted in paragraph 2.67, many manufacturers have high market shares in individual markets. However, competition through rebates could be seen as taking place across a range of markets in that the relative attractiveness of each rebate scheme depends on the volume of purchases by the veterinary surgeon of different types of POM from that manufacturer.

2.79. Most manufacturers have a wide range of products operating in several different markets. If rebate schemes give some manufacturers an advantage over others, the effect is likely to be more diffuse the more products are included in the scheme. Any such effect may differ considerably from one market to another, depending on the substitutability of different products in each market, and the relative strength of different rebate schemes. In order to assess whether rebate schemes have an effect, we looked at:

(a) trends in sales of generic products; and

(b) purchasing patterns of veterinary practice accounts in different product areas.

2.80. The results of these examinations are described in paragraphs 9.30 to 9.33, and summarized below.

2.81. Over the past five years the share of the top five manufacturers’ sales of six key veterinary authorized generics has fallen, suggesting that the rebate schemes of those manufacturers have not been effective in encouraging veterinary practices to buy their products where a close substitute is available (see paragraph 9.33).

2.82. Veterinary practices with a higher-than-average share of purchases of a manufacturer’s largest product (as a proportion of their total purchases in that market) are also likely to buy a higher-than-average proportion of its second-largest product. However, this is true both of manufacturers that operate rebate schemes and of those that do not. The effect appears to be most pronounced where (as in the cases of ...) a manufacturer’s two largest products are cat and dog vaccines.

2.83. [...] all have small-animal vaccines as a separate product group for rebates, and [...] has a separate category for ‘vaccines’ of which, in practice, 90 per cent are for small animals. We also noted that, on average, rebates on small-animal vaccines are particularly large. This led us to focus on whether the linking of small-animal vaccines through rebates has an anti-competitive effect.

2.84. There are six manufacturers of cat and dog vaccines supplied in the UK. The market leader for dog (excluding bordetella and rabies) vaccines is Intervet with a 45 per cent share in 2001; the market leader for cat (excluding rabies) vaccines is Fort Dodge with a market share of 39 per cent in 2001 (see Tables 20 and 21 of Appendix 7.1). However, analysis of GfK account purchases indicates that, regardless of the total value of purchases, over 60 per cent of veterinary practices buy nearly all (90 to 100 per cent) of their cat and dog vaccines from a single manufacturer. Furthermore, nearly all practices buy at least two-thirds from a single manufacturer (see Table 9.11). This suggests that there are powerful factors causing veterinary surgeons to obtain all or most of their cat and dog vaccines from a single manufacturer.
2.85. Manufacturers and veterinary surgeons suggested a variety of reasons, other than rebate incentives, for these purchasing patterns. Reasons mentioned included the benefits of having a single source for related literature including reminders, vaccination certificates etc tailored to the individual veterinary practice, reduced risk of error in giving the wrong vaccine, and general convenience. Nor does the level of rebates necessarily depend on purchases of cat and dog vaccines from the same supplier. For example, [X] identified 98 veterinary practices or buying groups that purchased at least £2,500 worth of its cat or dog vaccines in 2000 and reduced their purchases by more than 25 per cent in 2001. It said that there were no cases in which a reduction in dog vaccine purchases led to a reduction in subsequent rebates on cat vaccines, or vice versa.

2.86. Analysis of GfK data showed that among purchasers of dog vaccines or cat vaccines generally, one in six accounts switched supplier for either one or both vaccine groups in 2001, with around a third of those switching doing so for both cat and dog vaccines (see Table 9.13).

2.87. Individual veterinary surgeons told us that manufacturers tried through their rebate schemes to incentivize single-source purchasing of cat and dog vaccines. However, some veterinary surgeons said that they chose not to single source for clinical reasons. The majority of veterinary surgeons also said that small-animal vaccines were one area in which manufacturers competed strongly. Manufacturers, including Novartis—which does not sell small-animal vaccines—tended to support this view. None of the manufacturers that supply cat and dog vaccines, but have small market shares, argued that the rebate schemes of other suppliers was a significant barrier to its competing or expanding its market share. We identified no additional manufacturers of cat or dog vaccines that had been deterred from entering the UK market.

2.88. It is clear that not all the evidence points in one direction, or allows only one interpretation. However, we are unable to conclude that in general the effects of the rebate schemes operated by manufacturers constitute conducts that prevent, restrict or distort competition between manufacturers in the supply of POMs in the UK, or that they so operate in relation to the supply of cat and dog vaccines.

Effect of rebates on veterinary surgeons

2.89. Aside from any effect on competition between manufacturers, rebate schemes may increase the difficulty veterinary surgeons have in knowing the net price at which they are buying medicines. This may be due to:

(a) Uncertainty—ie as to what rebate will be achieved in the current period. This may be greater if the rebate is calculated over a long period. However, some manufacturers base rebates on a ‘moving annual total’ of purchases, which may reduce uncertainty.

(b) Complexity—discounts from a manufacturer may depend on a combination of factors, including total purchases, purchases within specified product groups, and increases in purchases relative to the previous period. Most veterinary practices receive discounts from a number of manufacturers, calculated in a variety of different ways (see paragraph 8.50).

2.90. Many, but not all, veterinary surgeons reported difficulties in establishing net prices, and some veterinary associations claimed that failure of veterinary practices to pass on discounts reflected the complexity of, and frequent changes in, discount structures (see paragraphs 9.50 and 11.253).

2.91. Several manufacturers reported comments by veterinary surgeons that suggested concern about the clarity of rebate schemes (see paragraph 9.48). However, each manufacturer claimed that its own scheme was sufficiently clear and transparent to enable veterinary
surgens to establish, at least within a relatively small margin, the net cost of POMs to them. None accepted, therefore, that any tendency to mark up on the basis of manufacturers’ list prices, rather than net cost, was a consequence of its rebate scheme.

2.92. The rebate schemes operated by the manufacturers vary considerably, and from our own examination it is clear that the degree of complexity and uncertainty faced by any individual veterinary practice will depend upon its pattern of purchases and the number of rebate schemes with which it is involved. However, it appears to us that the combination of uncertainty and complexity may cause difficulty for veterinary practices in (a) optimizing purchases to minimize input costs or (b) marking up consistently on the basis of cost—(a) may also reduce switching to alternative suppliers, and (b) may lead to a distortion of competition at the retail level, as the price charged by the veterinary practice for a medicine may not properly reflect its net cost. We conclude that, although some veterinary surgeons may be using the rebate schemes as an excuse for conduct in which they would anyway be engaging, the schemes are, collectively, at least one factor in the prevalence among veterinary surgeons of marking up from manufacturers’ list prices. We return to this aspect of rebate schemes in paragraph 2.141.

Buying groups

2.93. Given the scale and significance of rebates and discounts—and the fact that many veterinary practices purchase too few POMs to enable them to benefit significantly from them—there might be an expectation that they would form buying groups. Among respondents to BMRB1, only 18 per cent said that they were members. The largest buying groups are London Veterinary Forum Ltd (111 members), St Francis Ltd (80), Vetcel Ltd (60) and Vetswest Ltd (30) (see paragraph 9.64).

2.94. We heard evidence that some manufacturers had refused to negotiate discounts with buying groups. However, the manufacturers that do not currently supply buying groups told us that this reflected a judgement that offering higher discounts to groups did not lead to greater sales or other advantages to the manufacturer and so were not justified commercially. The major buying groups from whom we took evidence were themselves divided about whether the behaviour of some manufacturers reflected a desire to restrict the emergence of buyer power, or a legitimate commercial decision (see paragraphs 9.67 and 9.68).

2.95. We concluded that differences between manufacturers in their dealings with buying groups were the result of normal commercial pressures and found no clear evidence of their refusal to negotiate group discounts amounting to conduct to prevent, restrict or distort competition.

Competition between veterinary wholesalers

2.96. Following the failure of Dunnwood in 2002, the wholesale supply of POMs to veterinary surgeons and pharmacies is now undertaken by five veterinary wholesalers. They are described in Chapter 5, and alternative calculations of their shares of sales in 2001 are in Table 5.5. As noted in paragraph 2.15, the largest veterinary wholesaler is NVS, which in 2001 had a market share of 44 per cent. The second largest is Centaur, a cooperative owned by veterinary surgeons. In 2001, its share of the sales of POMs by veterinary wholesalers was around 25 per cent. The three smaller wholesalers are Genus, which acquired the assets of Dunnwood during the course of our inquiry, Dunlops and VSSCo, none of which had a market share greater than 14 per cent in 2001. NVS, Centaur and Genus approach coverage throughout Great Britain, Dunlops operates in Scotland, Wales and northern England and VSSCo in Northern Ireland, where it is the only significant veterinary wholesaler of POMs.
2.97. All the veterinary wholesalers operate in a similar way, handling the products of all manufacturers and stocking their complete range of POMs. The manufacturers supply them all on identical terms, based on their list prices, less 15 per cent. The veterinary wholesalers all sell on the basis of the manufacturers’ list prices and give discounts based on the value of total deliveries, mainly in the form of prompt payment discounts—though we were told that this requirement was not always enforced. They also compete on levels of service, including frequency of delivery, ease of ordering, reliability and provision of a wide range of non-POM products with the aim of providing a ‘one-stop’ service for veterinary surgeons (see paragraph 9.86). Ease of ordering includes provision of electronic ordering and practice management software. Reliability depends upon maintaining high levels of stocks of POMs and other veterinary medicines that may be required by the veterinary surgery, and on speed of delivery. Providing a one-stop shop includes offering goods and services other than veterinary medicines, including items such as pet foods. Veterinary wholesalers seek to market themselves to veterinary surgeons on the basis of the full range of services they provide. The successful veterinary wholesaler becomes the ‘first port of call’ from which the veterinary surgery purchases most of its supplies across the broadest range of goods.

2.98. Notwithstanding the high level of concentration, we found no evidence of conducts that prevent, restrict or distort competition for supply to veterinary surgeons within the framework just described. As noted in paragraph 2.40, we did, however, find evidence of failure by the veterinary wholesalers to market POMs actively to pharmacies, amounting to a failure to take reasonable steps to supply pharmacies.

Veterinary surgeons and competition at the retail level

Veterinary surgeons

2.99. The role and scale of the veterinary profession, trends in the demographics of its members, ownership of veterinary practices and the demand for veterinary services, together with operational and financial analysis of veterinary practices and relationships between veterinary surgeons and their clients, are considered in Chapter 6. An estimated 9,700 veterinary surgeons worked in general practice in 2002 (see paragraph 6.32). According to statistics from the RCVS, this represented an increase of 70 per cent since 1988 (see Table 6.3). Veterinary surgeons typically work in practices consisting of one or more surgeries. The average surgery has around three veterinary surgeons plus five or six staff. Some 67 per cent of surgeries specialize in the treatment of small animals; around 3 per cent specialize in the treatment of large animals other than horses; 3 per cent are equine specialists; and around 26 per cent of practices are mixed. There is a trend towards specialization in the treatment of small animals (see Tables 6.4 and 6.7). In 2002, around 74 per cent of time spent in general practice was devoted to their treatment (up from 66 per cent in 1998: see Table 6.9). Factors motivating this trend have been the decline in the number of British livestock animals in recent years, and pressure on farmers to reduce costs.

2.100. Overall, we estimate the size of the veterinary market in 2002 as between £1.2 billion and £1.3 billion (see paragraph 6.55). The annual turnover of the UK veterinary profession in general practice is estimated by Mintel to have increased by over 35 per cent between 1996 and 2000, with turnover per veterinary surgeon having increased by about 16 per cent over the same period. These increases appear to have come not from a rise in animal numbers, but from veterinary surgeons selling more services to existing clients—a trend which has been facilitated by the growth in pet insurance. The increases also reflect factors such as advances in drug treatments and surgical techniques permitting dogs and cats to live longer.

2.101. Non-fee income, primarily from the sale of medicines, is particularly significant for practices specializing in large animals. Our analysis of data from BMRB2 indicates that in 2001:
(a) professional fees for practices specializing in small animals represented some 62 per cent of total income, and sales of products, including veterinary medicines, some 38 per cent on average;

(b) for mixed practices, professional fees represented some 51 per cent of total income, and sales of products, including veterinary medicines, some 49 per cent on average; and

(c) for practices specializing in large animals, professional fees represented some 37 per cent of total income, and sales of products, including veterinary medicines, some 63 per cent on average (see paragraph 6.104 and Table 6.24).

2.102. Average combined salary and profit per partner was highest for small-animal practices, at around £82,000, and lowest for ‘other’ (primarily equine and large-animal) practices, at around £62,000 (see Table 6.20).

**Competition between veterinary surgeons**

2.103. Competition between veterinary surgeons is discussed in paragraphs 9.112 to 9.117. Because veterinary surgeons may only sell veterinary medicines for administration to an animal or herd under their care, they compete with one another only in the provision of a total package, in which the supply of POMs is bundled with consulting services. Competition in the provision of veterinary services is essentially local. Choice for animal owners depends on the number of veterinary surgeries within a reasonable travelling distance (either for the animal and its owner or, more typically for large animals, for the veterinary surgeon—see paragraph 9.89). Our survey evidence suggests that owners of small animals will typically have to travel up to 5 miles to find an alternative veterinary practice, with small-animal veterinary surgeons typically willing to make a maximum one-way journey in the range 20 to 29 minutes and large-animal surgeons typically willing to make a maximum one-way journey in the range 40 to 49 minutes. There is a close correlation between location of veterinary surgeries and population density, and hence the extent of local choice will typically be greater in urban, than in rural, areas and least in sparsely populated areas. We were told that in some rural areas the lack of provision of veterinary services is a cause for concern. In the Highlands and Islands of Scotland a special scheme exists under which public subsidies are paid to some veterinary practices to enable a veterinary service to be provided to crofters and other remote small livestock farmers at an affordable cost.

2.104. 63 per cent of the veterinary surgeons who responded to BMRB1 told us that ‘quality of service’ was the main element on which they attempted to compete with their nearest neighbour, with a further 14 per cent mentioning service-related and other items. Only 10 per cent mentioned price. Some individual veterinary surgeons told us that it was important for them to maintain good relations with other veterinary surgeons in the area, with whom they may have arrangements for providing 24-hour emergency cover, and that they did not try to win clients from each other.

2.105. We considered evidence on animal owners changing their veterinary practice and whether there were any barriers to this. We were told by veterinary surgeons that it was easy for customers to switch, but received conflicting evidence on how often switching occurred. Some veterinary surgeons told us that clients valued the relationship they built up with their veterinary practice and would change only rarely. Others told us that switching was common. The National Farmers’ Union (NFU) told us that farmers were often reluctant to change veterinary practice or obtain veterinary medicines from other sources for fear of disrupting their existing relationships. Our evidence suggested that 15 per cent of the dog and cat owners who participated in our survey had tried to join a practice in the last three years (see paragraph 6.192). 13 per cent said that they would switch to another practice if their current one increased prices by 20 per cent.
2.106. When a switch does take place, the RCVS encourages veterinary surgeons to contact the previous practice to obtain an animal’s medical records, and this guidance appears to be widely followed. Our survey evidence indicated (see paragraph 6.194) that 34 per cent of veterinary surgeons who reported that they had clients who had transferred had asked whether the previous practice objected. Of these, 35 per cent said that they would reject a client if the previous practice objected to the transfer.

2.107. Given the geographic distribution of veterinary surgeons, it is likely that the extent of competition in providing veterinary services varies by location and species. Loyalty to individual veterinary surgeons or surgeries and the desire by some veterinary surgeons to maintain good relations with their neighbours may in some cases limit competition even where there are alternatives. Furthermore, veterinary surgeons told us that such competition as did occur tended to be on service and not on price.

2.108. We assess that competition between veterinary surgeons in the supply of POMs is particularly constrained as a result of bundling. This is because:

(a) Provision of professional services involves a service element in a way that dispensing POMs does not. By competing on services, veterinary surgeons are able to gain the POMs business without competing on their price.

(b) The inability of one veterinary surgeon to dispense POMs prescribed by another means that where an animal is already under the care of one veterinary surgeon anyone wishing to shop around between veterinary surgeons for POMs will in many cases incur professional fees and the cost of having the animal further examined, as well as the normal costs involved in alternative sourcing of goods.

2.109. Weak price competition enables veterinary surgeons to maintain higher mark-ups than would be possible in a competitive market. Mark-ups are lower on PMLs, which are available from a wider range of suppliers and can be bought unbundled from veterinary services (see paragraph 2.115).

**Competition between veterinary surgeons and pharmacies**

2.110. We identified around 15 specialist veterinary pharmacies, which sold mainly large-animal medicines. The NPA told us that—in addition to these specialists—about 750 community pharmacies currently sold over-the-counter (OTC) veterinary medicines, worth an estimated £2.5 million a year at manufacturers’ list prices. This implies that about 6 per cent of UK community pharmacies have an involvement in veterinary medicines.

2.111. We asked the ten largest pharmacy chains about their involvement in the supply of veterinary medicines. Six told us that they currently supplied veterinary medicines, but in very low volumes. Lloyds Pharmacy told us that it had initiated a trial of 100 pharmacies selling non-prescription pet medicines. National Co-operative Chemists told us that it had conducted a trial at one branch, which had been unsuccessful because veterinary surgeons were resistant to writing prescriptions. Safeway told us that it had tried to enter the market but had found the lack of prescriptions a significant obstacle.

2.112. Although the larger pharmacy chains have not established themselves in the market, some smaller specialists appear to have had more success, using a variety of business models often involving operating as a wholesaler as well as retailer. Brian G Spencer Ltd told us that its veterinary medicines wholesale business had grown in the last four years from ‘minimal’ to a turnover of £211,000, which included £130,000 sold through its 43 ‘Manor Pharmacy’ community pharmacies. Jobsons told us that it had recently carried out a mailshot to 200 pharmacies offering to distribute veterinary medicines, and had achieved a higher-than-
expected (7 per cent) response rate. Veterinary Drugs To Go Ltd, an Internet pharmacy that dispenses veterinary medicines prescribed by veterinary practices, told us that after nine months it was achieving online sales of over £20,000 a month, close to the turnover that would enable it to cover its costs. That said, sales of POMs via pharmacies remain very small. On the basis of information from the manufacturers and wholesalers, we estimate total sales of POMs to pharmacies in 2001 at no more than around £120,000, or less than 0.1 per cent of sales at the ex-manufacturer level (see paragraph 9.79).

2.113. For pharmacies to be able to compete in the supply of POMs, they require both demand and supply. Demand depends on animal owners not automatically receiving their medicines from the prescribing veterinary surgeon, but being able to shop around between alternative providers. Supply requires pharmacies to be able to obtain medicines on terms that do not put them at a significant disadvantage relative to veterinary surgeons.

2.114. Failure by veterinary surgeons to inform animal owners that they can ask for prescriptions, discouraging requests for prescriptions, declining to provide prescriptions on request, or failing to inform clients of the price of medicines prior to dispensing them all have the effect of reducing potential demand for POMs from pharmacies.

2.115. Failure of manufacturers to enable pharmacies to obtain supplies of POMs on terms that would allow them to compete with veterinary surgeons—through the operation of manufacturer rebates paid only to veterinary surgeons—adversely affects the supply side of the equation. The normal route for distribution of POMs from manufacturers to retailers is through veterinary wholesalers and most manufacturers do not supply direct. So failure of the veterinary wholesalers to take reasonable steps to market to pharmacies, and to supply them with POMs so that they can compete with veterinary surgeons, also adversely affects the pharmacies’ ability to obtain medicines at prices that do not disadvantage them relative to veterinary surgeons, and hence also adversely impacts on the supply side of the equation.

2.116. It is clear to us that pharmacies at present can provide only minimal competition for veterinary surgeons in the supply of POMs at the retail level. We do not accept the contention, put to us by some manufacturers and veterinary surgeons, that the market for veterinary medicines is too small and the mark-ups available on them are too low to be of any interest to pharmacies. Among dog and cat owners who responded to a survey commissioned by the RCVS, the British Small Animals Veterinary Association, the Society of Practising Veterinary Surgeons (SPVS), Fort Dodge and others (Quo Vadis), 11 per cent were very likely and 24 per cent quite likely to ask for a prescription to take elsewhere (see paragraph 9.104). As noted in paragraph 2.110, in addition to the specialist veterinary pharmacies, there are around 750 (or about 6 per cent of) community pharmacies currently selling non-prescription veterinary medicines. We obtained evidence that mark-ups on those classified PML and GSL (general sales list medicines that may be supplied, without prescription, by any retailer) sold by veterinary surgeons are lower than on POMs (see paragraph 2.119). National Co-operative Chemists told us that it was ‘looking to develop a package … focusing entirely on pet medicines’ and, as previously noted, Safeway had tried to enter the market but found lack of prescriptions the most significant obstacle. In November 2002 the NPA published a resource pack Pet Medicines in Pharmacy to help members ‘make the most of the growing opportunities in the delivery of care to pets and companion animals’. This pack concentrates on worming products and flea treatments.

Prices

2.117. We used the British Veterinary Index (BVI), a commercially-produced database owned by GfK, to look at changes in the list prices of veterinary medicines sold through wholesalers between 1996 and 2001. The average list price grew by 15 per cent, increasing steadily by around 3 per cent a year from 1996 to 2000 and by 2 per cent between 2000 and
2001. With the exception of [✱], the five largest manufacturers’ list prices grew more slowly than average (see Tables 8.9 and 8.10).

2.118. We asked the 20 largest manufacturers of POMs for data on the value of sales, net of discounts and rebates, and the volume of sales, for calendar years 1999 to 2001, and used this data to compare net average ex-manufacturer selling prices in those years. The data shows that net prices have not increased at the same rate as list prices, with net prices for POMs on average having decreased by 1 per cent in 2000 and increased by 2 per cent in 2001, whereas average list prices of the same manufacturers increased by 4.5 per cent between 1999 and 2001, indicating that rebates have increased over the period (see Table 8.11 and paragraph 8.69). Net prices of medicines for farm animals fell by 5 per cent between 1999 and 2001, whilst the net price of medicines for companion animals increased by 3 per cent during the same period (see Table 8.12).

2.119. In order to assess price competition at the retail level, we compared (a) mark-ups applied by veterinary surgeons to POMs with (b) those applied to other veterinary medicines classified PML and GSL. Unlike POMs, these—which typically comprise about 20 per cent of medicine sales by veterinary practices—are also available unbundled from professional services, from outlets other than veterinary surgeons and pharmacies, and can conveniently be obtained over the Internet, as no prescription is involved. Consequently price competition appears more robust.

2.120. Evidence from BMRB1 showed that, on average, the mark-up applied by veterinary surgeons to PML and GSL medicines is around 20 percentage points lower (see Table 6.39) than that applied to POMs. Veterinary surgeons put forward various reasons for differences in mark-ups, including special storage requirements, drug audits, disposal charges, increased wastage and increased administration charges for POMs. We were also told that veterinary surgeons were unable to obtain the same terms on PML and GSL medicines as agricultural merchants, who typically buy larger volumes. Hence mark-ups are constrained by a need to compete with alternative outlets (see paragraph 6.149).

2.121. We recognize that there are a number of reasons why higher mark-ups on POMs may not equate to higher margins. We further recognize that factors other than intensity of competition may lead to lower margins on veterinary medicines classified PML or GSL than on POMs. However, whilst not conclusive, the higher mark-ups on POMs nevertheless appear to us consistent with the idea that price competition in the sale of POMs to animal owners is weak.

2.122. We conducted two exercises to compare prices of POMs in the UK to prices overseas: one compared UK ex-manufacturer prices, the other UK retail prices, with those of other countries (see paragraphs 8.82 to 8.146). These exercises involved comparing prices for a limited selection of top-selling veterinary medicines in the UK with prices in other, primarily EC, countries. We did not attempt to construct a representative basket of veterinary medicines for each country; the purpose was to establish whether UK customers were, on average, paying more than customers in the selected countries for veterinary medicines commonly used in the UK, rather than to compare prices of veterinary medicines overall.

2.123. In summary, our results show that, for the veterinary medicines studied:

(a) Most of the best-selling POMs in the UK are substantially more expensive ex manufacturer than in all the European countries in our study. These differences are large on average and are unlikely to be attributable only to exchange rate effects.

(b) The difference in price between the UK and other European countries is greater for POMs, ex manufacturer, than for other veterinary medicines, and countries in which pharmacies play a larger role in the supply of POMs are also those with the lowest ex-manufacturer prices.
(c) Retail prices (excluding VAT) are never lower and are generally substantially higher in Great Britain. On average, pharmacies surveyed charged lower mark-ups on POMs than the veterinary practices surveyed, and average mark-ups were lowest in Spain and Belgium, where pharmacies are the only retail outlet for POMs.

(d) For those POMs for which it was possible to make a comparison of retail prices after adjusting for differences in ex-manufacturer prices, prices in Great Britain are still higher in the majority of cases.

2.124. A range of factors can account for differences in prices between countries, including differences in local market conditions, the local cost of supply and distribution, exchange rate fluctuations, and the cost of obtaining MAAs. Not all of these would lead to prices being higher in Great Britain than in other countries, and most would apply equally to POMs and non-POMs. The results from our international price comparisons can be treated as no more than indicative. They are, nevertheless, consistent with the view that the price of most commonly-used POMs in the UK, including several leading brands, are systematically lower in neighbouring countries, at the ex-manufacturer level, at the retail level, and at the retail level after adjustment for differences in ex-manufacturer prices. They are also consistent with the evidence that the DGFT mentioned in referring this inquiry to us, and with the view that a greater role for pharmacies in the dispensing of POMs may lead to their retail prices being lower.

2.125. Many of the letters we received from the public were concerned with the high price of POMs from veterinary surgeons, of which about a quarter mentioned the costs of medicines for companion animals requiring long-term use of POMs. (Two canine epilepsy organizations also wrote to us about this.) Some were about the price of POMs for which there is a cheaper human ‘equivalent’ (which may have been available to animals before the cascade was introduced (see paragraphs 13.238 and 13.239)). The NFU and the National Farmers’ Union Scotland told us that their members had been concerned for some years that they were paying higher prices for veterinary medicines than their competitors elsewhere in Europe (see paragraphs 13.78 and 13.99).

Analysis of issues

2.126. Having found the existence of a scale monopoly situation and three complex monopoly situations, the FTA requires us to consider in relation to each:

(a) in favour of what persons the monopoly situation exists;

(b) whether any steps (by way of uncompetitive practices or otherwise) are being taken by that person or those persons for the purpose of exploiting or maintaining the monopoly situation and, if so, what uncompetitive practices or in what other way;

(c) whether any action or omission on the part of that person or those persons is attributable to the existence of the monopoly situation and, if so, what action or omission and in what way it is so attributable; and

(d) whether any facts found by the CC in pursuance of its investigations under the preceding provisions operate, or may be expected to operate, against the public interest.

Issues arising from the scale monopoly situation

2.127. As shown in paragraph 2.15, NVS supplies more than one-quarter of all POMs at the wholesale level. This meets the definition of a scale monopoly in section 6(1)(a) of the
FTA. NVS conducts its business in ways that have much in common with its competitors. We consider that the conducts in which NVS engages, over which we have expressed concern, are attributable to the complex—rather than the scale—monopoly situation. We therefore conclude that, in relation to the scale monopoly situation, there are no steps, actions or omissions such as are referred to in paragraph 2.126, nor any facts which operate or may be expected to operate against the public interest.

**Issues arising from the complex monopoly situations**

*Persons in whose favour the monopoly situations exist*

2.128. We noted earlier in this report that the effect of each of the three complex monopoly situations identified is to prevent, restrict or distort competition between pharmacies and veterinary surgeons in the supply of POMs to animal owners, and to do so in a way that reinforces the impact of the other two. It follows that whoever benefits from any one of the three complex monopolies will also benefit from the others, and that therefore the persons in whose favour each operates will be the same.

2.129. Some veterinary surgeons argued that they were not in a position to benefit from any of the complex monopolies, as competition between them in the supply of veterinary services was sufficient to constrain the prices of POMs to animal owners even in the absence of competition from pharmacies.

2.130. Some manufacturers argued that the existence of any complex monopoly that resulted in higher prices at the retail level would not benefit them because effective competition between them meant that the benefits of such prices would be captured by veterinary surgeons and higher prices would tend to reduce the volumes of POMs sold, to the detriment of manufacturers.

2.131. Some veterinary wholesalers argued that the existence of any complex monopoly that resulted in higher prices at the retail level would not benefit wholesalers since competition between them was intense and their limited ability to benefit from changes to the price of POMs meant that the benefits would be captured at the veterinary surgeon and/or manufacturer level. They argued, furthermore, that veterinary wholesalers were disadvantaged by the existence of conducts by veterinary surgeons or manufacturers that limited their own ability to develop their role as suppliers to pharmacies as well as to veterinary surgeons.

2.132. We do not accept these arguments, for the reasons set out below.

2.133. We previously noted that competition between veterinary surgeons in the supply of veterinary services is variable and, where it does occur, tends to focus on service quality, not price. We further concluded that competition between veterinary surgeons in the supply of POMs is particularly constrained as a result of bundling, and that competition in their prices is weak (see paragraph 2.108). It is our judgement that competition between veterinary surgeons is not sufficient to preclude higher prices as a result of reduced competition from pharmacies, and that veterinary surgeons benefit from this reduced level of competition through being able to maintain prices for POMs higher than they would otherwise be.

2.134. Manufacturers benefit from the absence of pharmacy groups that might be expected to be able to exert greater buyer power than veterinary surgeons. NVS and Genus both told us that entry by pharmacists would increase the buyer power faced by the manufacturers. They also benefit from lower selling costs because they can focus their marketing just on veterinary surgeons. When we asked manufacturers how, if at all, their business would be affected if veterinary surgeons commonly wrote prescriptions for certain POMs, and customers had them dispensed by a pharmacy, Schering-Plough told us that it would expect its distribution and sales
support costs to increase. Pfizer said that it would have to restructure, Intervet pointed out obstacles to the change, and Merial said that it would expect end-user total costs to increase, leading to a reduction in the use of veterinary medicines. Of the five largest manufacturers, only Fort Dodge suggested the possibility that, if end-user costs were reduced, the impact on its business would be positive, but even Fort Dodge took a conservative view of any such change (see paragraph 9.58).

2.135. Veterinary wholesalers benefit from the inability of pharmacies to compete through lower distribution costs and the absence of competition from the human medicine wholesalers who are the pharmacies’ normal distribution channel. NVS, Genus and Dunlops expressed concern over the possibility that wholesalers of human medicines might supply veterinary medicines to pharmacies, reducing the volumes of POMs supplied by veterinary wholesalers and increasing their unit costs.

2.136. Veterinary surgeons and manufacturers benefit whether or not they are themselves engaged in the relevant conducts. Veterinary surgeons benefit from reduced competition from pharmacies leading to higher prices for POMs to animal owners whether or not they themselves fail to inform animal owners that they can ask for prescriptions, discourage requests for prescriptions, decline to provide prescriptions on request, fail to inform clients of the price of POMs prior to dispensing them, or fail to provide itemized bills. They similarly benefit from an ability to achieve prices higher than they would otherwise be whether or not they are using mark-ups that take account of discounts and rebates or pricing so as to subsidize professional fees. Likewise, manufacturers that supply POMs in the UK benefit in the ways described in paragraph 2.134 whether or not they are themselves failing to enable pharmacies to obtain supplies of POMs on terms that would allow them to compete with veterinary surgeons. We found that all the veterinary wholesalers failed to take sufficient steps to supply pharmacies with POMs—though, even if we had found one that had not, it too would have benefited in the ways described in paragraph 2.135.

2.137. We find that each of the three complex monopoly situations we have identified operates in favour of veterinary surgeons, manufacturers and veterinary wholesalers who supply POMs in the UK, whether or not they engage in the conducts themselves.

Steps, acts or omissions by persons in whose favour the monopoly situations exist

2.138. We now consider whether there are steps taken by persons in whose favour the complex monopoly situations exist for the purpose of exploiting or maintaining each of the complex monopoly situations we have identified or actions or omissions attributable to the existence of those monopoly situations.

The veterinary surgeons complex monopoly situation

2.139. In paragraph 2.45 we identified conducts by some veterinary surgeons that have the effect of preventing, restricting or distorting competition in the supply of POMs to animal owners (the veterinary surgeons complex monopoly situation). In our view, these conducts constitute steps by those veterinary surgeons for the purpose of exploiting the monopoly situation among veterinary surgeons (in the case of failing to inform clients of the price of POMs prior to dispensing them, failing to provide itemized bills and pricing of POMs in a way that does not reflect their cost of supply) or maintaining that monopoly situation (in the case of failure to inform animal owners that they can ask for prescriptions, discouraging requests for prescriptions, and declining to provide prescriptions on request).

2.140. In paragraph 2.48 we identified conducts by some manufacturers that have the effect of preventing, restricting or distorting competition in the supply of POMs to animal owners (the
manufacturers complex monopoly situation). In our view the failure to enable pharmacies to obtain POMs on terms that would allow them to compete with veterinary surgeons constitutes both an omission by those manufacturers attributable, in part, to the existence of the complex monopoly situation among veterinary surgeons, and a step that they have taken for the purpose of exploiting or maintaining it.

2.141. In paragraph 2.92 we considered the effect of manufacturer rebate schemes on veterinary surgeons. We have identified [Details omitted. See note on page iv.] as operating retrospective rebate schemes—without the use of moving annual turnovers, in the case of all but [Details omitted. See note on page iv.] (see Table 8.6). We have identified [Details omitted. See note on page iv.] as operating different rebates for different products or multiple types of rebate (see Table 8.8). We judge that, collectively, such schemes have an adverse effect on competition both by reducing the propensity of veterinary surgeons (a) to price POMs on the basis of mark-ups that accurately reflect their costs and (b) to switch from products of one manufacturer to another even when there are benefits for themselves and their customers in doing so (see paragraph 2.92). We take the view that the operation of complex rebate schemes involves the manufacturers that have them in taking steps for the purpose of exploiting the complex monopoly situation among veterinary surgeons.

2.142. In paragraph 2.51 we identified conducts by veterinary wholesalers that have the effect of preventing, restricting or distorting competition in the supply of POMs to animal owners (the veterinary wholesalers complex monopoly situation). The failure to take reasonable steps to supply pharmacies with POMs so as to enable them to compete with veterinary surgeons constitutes an omission by those veterinary wholesalers attributable to the existence of the complex monopoly situation among veterinary surgeons.

The manufacturers complex monopoly situation

2.143. In our view, the conduct identified in paragraph 2.16(d) and discussed in paragraphs 2.28 to 2.33 involves the manufacturers who are members of the conduct group in taking steps to exploit or maintain the complex monopoly situation resulting from that conduct. We identified no persons who are not members of the conduct group that had taken steps for the purpose of exploiting or maintaining the manufacturers complex monopoly situation, or who were responsible for actions or omissions attributable to its existence.

The veterinary wholesalers complex monopoly situation

2.144. In our view the conduct identified in paragraph 2.16(e) and discussed in paragraphs 2.34 to 2.42 involves the veterinary wholesalers who are members of the conduct group in taking steps to exploit or maintain the complex monopoly situation resulting from that conduct. We identified no persons who are not members of the conduct group that had taken steps for the purpose of exploiting or maintaining the veterinary wholesaler complex monopoly situation, or who were responsible for actions or omissions attributable to its existence.

The public interest

2.145. Under the terms of the FTA we are required to assess whether any facts that we found in pursuance of our investigations operate, or may be expected to operate, against the public interest. We have found the existence of complex monopoly situations, and steps, actions and omissions by persons in whose favour they operate, which, in our judgement,
prevent, restrict or distort competition. We judge that two consequences of this are that there is a lack of choice of supplier for animal owners and the price of POMs in the UK is higher than it would otherwise be. In reaching a judgement on the public interest, however, we must also consider whether there are any benefits arising from the conducts we have identified that would outweigh the detriments we have identified.

2.146. Many veterinary surgeons and some others argued that the public interest in the supply of POMs in the UK goes beyond the extent of competition, that the behaviours over which we have raised competition concerns serve that wider public interest, and that any attempt to introduce greater competition into the supply of POMs would not be in the public interest (see paragraphs 11.224 to 11.230). The arguments had two main strands:

(a) the public interest in the protection of public safety and animal welfare is served by effective control of the use of POMs, and the conducts over which we have raised competition concerns promote and facilitate that control; and

(b) veterinary surgeons are under a professional obligation to protect and promote animal welfare through the provision of such services as 24-hour emergency cover, the emergency treatment of suffering animals whether or not they will receive payment, and the stocking of sufficient veterinary medicines to discharge these obligations whether or not it is commercially advantageous to do so, and that these serve the public interest in animal welfare.

2.147. In support of (a) above, it was put to us that the widespread writing of prescriptions, to be dispensed elsewhere, would undermine effective control over POMs and animal welfare through:

(a) fraudulent prescriptions;

(b) greater dispensing of wrong medicines;

(c) adverse impact on pharmacovigilence;

(d) confusion of liability between the prescribing veterinary surgeon and whoever dispenses the POM;

(e) poorer administration of medicines by animal owners;

(f) increased failure to obtain and complete courses of treatment; and

(g) reduced ability of veterinary surgeons to address failure of animals to respond to treatment and/or adverse reactions to medication.

2.148. It was further put to us that the charging of low professional fees subsidized by high prices for POMs increases the likelihood of veterinary surgeons seeing animals and regularly visiting farms. This is in the interests of animal welfare, effective monitoring for disease and control and protection of the food chain.

2.149. In support of paragraph 2.146(b), it was argued that to discharge their professional obligations veterinary surgeons need their income to be subsidized from other sources, and that the maintenance of prices for POMs higher than they would be in a fully competitive market provides a mechanism for this.

2.150. Many veterinary surgeons raised concerns over the consequences for public safety and animal welfare if their right to dispense POMs were taken away, so that animal owners could obtain POMs only through pharmacies. We agree that this would be undesirable for several reasons. Not only is it necessary in certain circumstances, in the interests of animal
welfare, that veterinary surgeons can dispense and administer POMs immediately, but the removal of veterinary surgeons’ dispensing privilege would restrict consumers’ choice and their ability to take advantage of a one-stop service. The public interest requires that veterinary surgeons retain their ability to administer and dispense to animals and herds under their care.

2.151. Many veterinary surgeons, the BVA and the RCVS feared that, even if veterinary surgeons’ ability to dispense were not removed, any attempt to increase competition in the supply of POMs, through a greater role for pharmacies, would be damaging. Some veterinary surgeons argued that this would lead to higher prices to consumers: by adding costs to the supply chain, through the writing of more prescriptions, through the involvement of pharmacies and through increasing unit costs to veterinary surgeons of dispensing as a result of lower volumes. It was put to us that even if increased competition led to a reduction in the cost of some commonly used POMs, consumers would be no better off overall as veterinary surgeons would either increase their professional fees in order to remain viable or be forced out of practice. Furthermore, if veterinary surgeons did increase their professional fees this would reduce the likelihood of animal owners consulting them sufficiently early, or at all. This would be to the detriment of animal welfare and potentially, in the case of farm animals, to the detriment of disease control and protection of the food chain.

2.152. Some veterinary surgeons also worried about changes to the pattern of use of POMs in response to price changes, and implications for the development of drug resistance. For example, a lower price might lead to increased use of antimicrobials, particularly if pharmacies began to compete in their supply, but not in the supply of vaccines, so the relative price of antimicrobials fell.

2.153. The NFU told us that, although it would be concerned if the scenario foreseen by veterinary surgeons developed, it thought it unlikely. Remedies that increased competition in the supply of POMs would, in the NFU’s view, be more likely to encourage veterinary surgeons to focus on selling the benefits of professional veterinary input to farmers in order to improve the health status of farms. This would be in line with the Government’s animal health strategy and farm assurance policies. Whilst such a change would take time to bed down, it was necessary in any event, given lower livestock numbers and the changing needs of farmers (see paragraph 13.82). We considered evidence from the Department for Environment, Food and Rural Affairs (Defra) on the operation of arrangements for disease surveillance (which are currently under review) and the role veterinary surgeons in private practice play in this, both through the legal requirement on them to report suspected disease, and as paid Local Veterinary Inspectors (LVIs). Defra emphasized the importance it attached to these arrangements and the need for us to consider the impact of any recommendations on future availability of farm veterinary surgeons (see paragraph 13.16).

2.154. As stated in paragraph 2.27, we fully accept that the supply of POMs raises issues that go wider than competition and that the public interest includes protection of public safety and animal welfare. We recognize the importance of veterinary training in diagnosis and control of potentially harmful veterinary medicines, and hence the importance of the veterinary surgeons’ ‘gatekeeper’ role in prescribing POMs. We also recognize the advantages to society of effective pharmacovigilance and emergency medical services for animals. We note the importance of securing adequate veterinary supervision on farms, and that some differences between the use of POMs for farm, and for companion, animals need to be taken into account. These include differences in approach where treatment depends on an animal’s market, rather than emotional, value; pressures on farmers to contain and reduce costs; farmers’ regular, as opposed to intermittent, purchase of POMs; the higher proportion of income in large-animal practices that arises from the sale of veterinary medicines; and the importance of traceability and veterinary medicine residues in food-animal production.
2.155. However, we do not agree that continuation of the anti-competitive conducts we have identified are necessary to deliver these outcomes, nor that they self-evidently provide the most economic and effective route through which such wider benefits can be secured.

2.156. The writing of prescriptions for dispensing by a pharmacy is already established as a legal alternative in the supply of POMs, and is common in the supply of human medicines. Pharmacies offer professionalism and efficiency in the handling and dispensing of medicines.

2.157. It is, in our view, important for the future economic and effective provision of veterinary services in the UK that veterinary surgeons charge realistic rates for their professional services rather than rely on the maintenance of high prices for POMs. In this way incentives to use a sub-optimal mix of veterinary medicines and services will be avoided. If veterinary surgeons charge unrealistically low professional fees to encourage utilization of their services, then it is likely that those services will be used inefficiently, for example through unnecessary reliance on call-out rather than planned visits and whole herd management. If the prices of veterinary medicines are kept higher than they would otherwise be, to subsidize professional fees, then veterinary surgeons will face undue pressure to maintain or increase sales of POMs and animal owners will have an incentive to find alternatives or obtain POMs from lower-cost sources, including the black market.

2.158. Much of the work of veterinary surgeons to protect the food chain is already publicly funded—both through the public veterinary services and through the use of veterinary surgeons in general practice as LVIs—and the Highlands and Islands Veterinary Scheme subsidizes veterinary services for crofters in an area where full economic charging would be prohibitive. We take the view that, if there is a need—for reasons of disease monitoring or food protection—for greater veterinary input on farms than will be demanded where charges are realistic, then it is likely to be economically more efficient for this to be provided directly through public support than through hidden cross-subsidies, which depend on restriction of competition in the supply of POMs.

2.159. Similar arguments apply to the provision of 24-hour emergency services and the other professional obligations placed upon veterinary surgeons noted in paragraph 2.146. Defra, the BVA and the RCVS told us that they were not aware of any attempt to cost these or examine alternative ways of meeting the underlying need. Nor did the BVA or the RCVS know of any assessment of the incidence or pattern of demands for them, although they doubted whether discharging these obligations was particularly onerous for most veterinary surgeons. In the absence of better data it is difficult to place a value on the benefits of such services, or to assess whether they could be more efficiently and effectively provided in some other way. We do not accept, however, that there is any necessary connection between their provision and the maintenance of the uncompetitive conducts we have identified.

2.160. Increased competition usually generates consumer benefits, and we expect that animal owners will, over time, make choices that reduce their costs, or increase the benefits. Producers and consumers can be expected to adapt to increased competition so as to increase overall efficiency of supply. Increased numbers of veterinary surgeons, in the absence of growth in the animal population and changing requirements of animal owners, will in our view inevitably lead to changes in the way in which veterinary services are provided. On the basis of our investigation we believe it unlikely that current arrangements leave no opportunity for improvements in efficiency as part of those changes. Nearly all POMs are currently supplied through veterinary surgeries, each of which operates a dispensary providing the POMs that its veterinary surgeons prescribe. This is typically run by veterinary surgeons whose training and expertise are in the diagnosis and treatment of animals, not in running a supply business.

2.161. In summary, we take the view that the link between the complex monopoly situations and the wider public benefits, which they are claimed to provide, is not sufficient for these benefits to outweigh the public interest detriments that we have identified. We conclude
that the detriments identified in paragraph 2.145, in terms of loss of consumer choice and prices of POMs being higher than they would otherwise be, are not outweighed by public interest benefits, and that the three complex monopoly situations that we have identified operate against the public interest.

**Remedies and recommendations**

2.162. We now consider how the concerns that we have identified might best be addressed. As noted in paragraph 2.12, weakness in competition in the supply of POMs arises not only from the complex monopolies we have identified, but also from the impact of regulation. When considering possible remedies and recommendations, we have sought to take this into account in three ways:

(a) in assessing possible remedies for implementation under the FTA we have considered their likely impact under the existing regulatory framework;

(b) in changes to the regulatory framework that we would wish to see implemented alongside the remedies under (a), for example to remove regulatory barriers to competition between veterinary surgeons in the supply of POMs; and

(c) in regulatory changes that we believe would be desirable in order to remove other features of present regulatory arrangements which appear to us to restrict competition more than is necessary.

2.163. When considering possible remedies and recommendations under (a), (b) and (c) above, we have taken into account their likely effects, both in terms of competition and the wider public interest.

**Remedies under the Fair Trading Act**

2.164. We deal first with measures that we recommend be taken using the Secretary of State’s powers under the FTA to remedy the detriments we have identified in reaching our conclusions on complex monopoly and the public interest in paragraphs 2.15, 2.45, 2.48 and 2.51. For these to be capable of implementation under the FTA, they are required to be compatible with all existing regulatory requirements.

2.165. Effective competition in the retail supply of POMs depends on a number of factors:

— on alternative sources of supply able to offer effective competition to the veterinary surgeon who made the diagnosis and recommended the POM: under current regulations this competition can come only from pharmacies, as one veterinary surgeon may not supply POMs prescribed by another;

— on the ready availability of prescriptions from veterinary surgeons;

— on pharmacies being able to supply POMs—which, in turn, means that they must be able to obtain them on terms that do not prevent, restrict or distort competition with veterinary surgeons; and

— on the provision of transparent information to enable animal owners to understand and compare prices.

All of these elements are necessary. Action on the demand, or supply, side alone would not be sufficient to deal with the absence of competition that we have identified. In our statement of
17 September we identified a range of possible remedies to remove barriers or otherwise promote competition in relation to each of these factors (see Appendix 1.3).

**Remedies to reduce barriers to obtaining prescriptions**

2.166. In our statement of 17 September we identified the following possible remedies under this heading:

(i) a requirement to display signs in veterinary surgeries advising clients of the availability of prescriptions to enable them to obtain POMs from pharmacies if they wish;

(ii) a requirement to include on the signs envisaged under (i) above any price charged for issuing prescriptions additional to the normal consultation fee;

(iii) a requirement for veterinary surgeons to advise clients, immediately prior to any dispensing of POMs, other than POMs that need to be used immediately, of the availability of prescriptions to enable them to obtain POMs from pharmacies;

(iv) a requirement for veterinary surgeons to provide on request prescriptions for POMs whose use they have recommended;

(v) a requirement for veterinary surgeons recommending the use of POMs to provide prescriptions in every case other than for POMs used in emergency treatment, for treatments during surgical procedures or for the use of anaesthetics;

(vi) a requirement for veterinary surgeons recommending the use of POMs to provide prescriptions in every case other than for POMs that need to be used immediately at the time of consultation;

(vii) a requirement for veterinary surgeons to state on all prescriptions issued for POMs that the prescribed items may be dispensed by pharmacies;

(viii) a requirement for veterinary surgeons providing prescriptions to charge no more for issuing such prescriptions than properly reflects the incremental cost to themselves in preparing them;

(ix) a requirement for veterinary surgeons providing prescriptions to do so at no additional charge to the client beyond that of the consultation;

(x) a requirement for veterinary surgeons to display signs stating their policies on frequency of examination of animals requiring repeat prescriptions and on the fees charged for such prescriptions;

(xi) a requirement for veterinary surgeons recommending the use of POMs to state when the animal will need further examination and, where the animal requires repeat prescriptions prior to that date, to charge no more for issuing such prescriptions than properly reflects the incremental cost to themselves of preparing them; and

(xii) a requirement for veterinary surgeons recommending the use of POMs to state when the animal will need further examination and, where the animal requires repeat prescriptions prior to that date, to provide these at no further cost to the client on request.

2.167. Most of those who commented on these remedies were veterinary surgeons. The majority raised no objection to (i), (ii) or (iv). On the other hand, there was widespread objection to (v), (vi), (ix) and (xii). Reactions to the remainder were mixed, with some in
favour and some against. On the other hand, the pharmacies and pharmacy organizations that commented were concerned that animal owners would be reluctant to request prescriptions and that if veterinary surgeons were free to charge for them they would do so at levels to deter clients from obtaining POMs elsewhere. Farmers’ organizations generally supported stronger remedies than the veterinary surgeons felt were appropriate.

2.168. The most common arguments against any requirement to provide prescriptions under circumstances where they had not been requested were that this was unnecessary; would lead to large numbers of prescriptions being written where the animal owner wished to obtain the POMs from the veterinary surgeons and hence would serve no useful purpose; and would increase costs that would have to be recovered somehow. We consider the question of cost of writing prescriptions and charging in paragraph 2.173. Though there is room for debate about the true costs of writing prescriptions, there clearly is some small cost involved, and providing a prescription where the animal owner wishes to obtain the POMs from the veterinary surgeon would be wasteful. On the other hand, we share the concern of pharmacy organizations that many animal owners, even if they were aware that they could ask for a prescription to obtain the POMs elsewhere, may be reluctant to do so and risk upsetting the veterinary surgeon, particularly starting from a position in which it has not been usual to request prescriptions. We conclude that an acceptable and proportionate solution would be a requirement for veterinary surgeons to offer, and provide on request, prescriptions for POMs they have recommended, except where they are for use in emergency treatment, in treatments during surgical procedures, or as anaesthetics.

2.169. As for charges, most veterinary surgeons argued that it would be wrong in principle to require them to provide prescriptions, including repeat prescriptions, at no additional charge beyond the consultation fee. There was less agreement on what might constitute a reasonable prescription charge, or even on what costs it should cover. The SPVS identified as relevant costs those required to:

(a) choose the correct drug bearing in mind the diagnosis, species, cascade, availability and price;

(b) make a permanent entry in the clinical notes;

(c) produce a prescription—either by hand or using specialist software;

(d) explain to the owner what can be done with the prescription;

(e) explain the drug and dosage;

(f) explain and sometimes demonstrate methods of administration;

(g) explain potential side effects; and

(h) take responsibility for the drug and any potential side effects.

2.170. We do not accept that many of the eight cost elements identified by the SPVS—such as choosing the drug and explaining its administration and potential side effects to the animal owner—are relevant for inclusion in a prescription charge. In our view, only two of the eight are essential to setting the charge: item (c) producing a prescription, by hand or using specialist software; and item (d) explaining to the animal owner what can be done with it—which could easily be satisfied if the specialist software printed guidance on the prescription. The other elements seem to us to relate more to actions that would be necessary even if the medicine were to be dispensed by the veterinary surgeon, and so should properly belong in the fee for consultation, not in a prescription charge.
2.171. It is likely that, if it is left to them, veterinary surgeons will come to very different conclusions on what would be a reasonable charge in different circumstances. Some individual veterinary surgeons, who indicated what they regarded as reasonable costs, quoted figures in the range £5 to £15. This variation is confirmed by evidence from our BMRB survey on the figures being charged by veterinary surgeons for the small number of prescriptions currently being provided, in which 22 per cent of veterinary surgeons reported that they did not charge for prescriptions; 32 per cent, that they charged less than £5; 31 per cent, between £5 and £10; and 7 per cent, £10 or more (see paragraph 6.187). Most of these charges appeared to be for prescriptions for companion animals, and we were not convinced that the variations were a true reflection of differences in the costs incurred by the veterinary surgeons. (7 per cent of veterinary surgeons indicated that they did not write prescriptions, so were not able to report a price.)

2.172. If our concern were simply to establish the correct market price for prescriptions, then it might be reasonable to leave veterinary surgeons to set and sign clearly their own prices, and then rely on the market to determine the rate through clients choosing veterinary surgeons, in part, on the basis of their prescription charges. However, the prices charged for prescriptions have a major impact on competition with pharmacies. Veterinary surgeons are currently able to set the price of providing a prescription so as to deter animal owners from asking for one and so influence the terms of competition with pharmacies to their own advantage. We believe that, on average, the incremental unit cost of providing prescriptions, by which we mean those costs incurred by veterinary surgeons that would not be required if they were dispensing the POMs, will be modest to an efficient veterinary surgeon, particularly as more prescriptions are provided.

2.173. We note that the Marsh report recommended that prescriptions should be provided at no additional charge or at a fee to be determined by the RCVS acting in the public interest—and that the Government’s response leaves both options open. Four members of the Group of Commissioners charged with carrying out the present inquiry take the view that, in order to be confident that charges will not provide a continuing barrier or deterrent to animal owners obtaining prescriptions, and to encourage them to make greater use of pharmacies, it will be necessary for a period of three years for veterinary surgeons to provide prescriptions at no additional charge to their client, beyond that of the consultation. By the end of that period, we judge that there is a reasonable prospect that competition from pharmacies will be sufficiently established, and both veterinary surgeons and animal owners sufficiently familiar with the provision of prescriptions, to allow veterinary surgeons to set their own fees. We recognize, however, that there is some uncertainty over what will then happen and some risk that veterinary surgeons might seek to introduce fees at levels that would be damaging to competition, either generally or in particular areas. We recommend therefore that the DGFT, with the RCVS, monitors numbers and types of prescriptions written and the charges made for them over the 12 months following the end of the period in which prescriptions are provided without charge. If there is evidence that veterinary surgeons are charging for prescriptions so as to deter animal owners from asking for them or to influence the terms of competition with pharmacies to their own advantage, then the DGFT should take further steps to establish appropriate charges for prescriptions. The fifth member of the Group, Mr Charles Henderson, considered that such a remedy would act against the grain of market forces, and would be likely to result in veterinary surgeons seeking to recover the charges they would have levied for prescriptions by increasing their consultation fees across the board. In his view, this would adversely affect the vast majority of customers who, he thinks, will continue to opt for medicines to be dispensed by veterinary surgeons owing to the convenience of the bundled service. Although he agrees that prescription charges will act as a deterrent to the take-up of prescriptions, it is his view that this will only have a marginal impact, and that a public display of prescription charges by veterinary surgeons will tend to drive those charges down. Thus, he thinks that the potential benefit of the proposed remedy, in terms of medicine prices, will be small and substantially outweighed by the adverse impact on the majority of animal owners of the consequential increase in consultation fees. In his view, charges for prescriptions should be unconstrained at
the outset, but the monitoring and review process recommended above should be instituted immediately. He believes that this would be in accord with the Government’s response to the Marsh report, on the question of prescription charges.

2.174. Responses were mixed to the proposals in our statement of 17 September affecting veterinary surgeons recommending POMs for animals that may need repeat prescriptions or further examination (see paragraph 2.166(xi) and (xii)). Whilst many veterinary surgeons accepted that it was good practice to have, and to communicate to clients, policies on frequency of re-examination of animals requiring repeat medicines, and the associated charges, it was argued that the need for re-examination depended on clinical judgement, and the circumstances of the animal, so there could be no fixed periods. Some suggested that such matters were best dealt with in letters of engagement given to clients setting out that practice’s policies and prices on medicines and services.

2.175. We believe that greater competition in the supply of POMs has the potential to offer particular benefits to the owners of animals requiring long-term medication, as they are most adversely affected by high prices for POMs. To the extent that they purchase more POMs relative to veterinary services than average, this will be true, overall, even if veterinary surgeons increase professional fees to compensate for loss of income on POMs. They will not benefit, however, if veterinary surgeons respond by increasing the frequency with which their animals have to be examined. We accept that policies on re-examination of animals need to take account of differing needs, and that it is not possible to lay down fixed periods for re-examination in all cases. However, given the potential for manipulation and misunderstanding, we believe that it is particularly important that veterinary surgeons ensure that their policies in this area are sufficiently transparent and understood by their clients. We therefore recommend the introduction of a requirement for veterinary surgeons recommending POMs to inform clients of their policies and charges for further examination of animals that need repeat prescriptions, either by leaflet or in a letter of engagement.

Remedies to improve price transparency and the ability of animal owners to understand and compare prices

2.176. In our statement of 17 September we identified the following possible remedies under this heading:

(i) a requirement for veterinary surgeons to inform clients, on request, of the price of any POM they propose to dispense;

(ii) a requirement for veterinary surgeons to quote the price of any POM they sell to any person who asks;

(iii) a requirement for veterinary surgeons to display in the veterinary surgery the price of the most commonly-dispensed POMs;

(iv) 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;

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

(vi) a requirement for veterinary surgeons to provide itemized bills distinguishing the cost of services from the cost of POMs.
Most of those who commented on (i), (ii), (iii), (iv) and (vi) were veterinary surgeons. The majority raised no objection to (i) and (vi), commonly regarding them as good practice and something they would already do. Some expressed concern that (ii) would lead to ‘frivolous’ requests from people whom they could not supply, anyway, and increase demands on receptionists, but most saw no difficulty. They were more divided on (iii), with those who objected raising a mixture of concerns over pressure from some customers to demand POMs that were unsuitable, and practical concerns over cluttering surgeries with signs which needed to be regularly updated. A few argued that quoting or displaying prices of POMs could be unlawful. All respondents were opposed to (iv), arguing that it was not required of other businesses. Those who commented on these remedies who were not veterinary surgeons were generally in favour, except in the case of (iv).

We believe that the provision of readily available and easily understood information on prices is essential. Whilst we acknowledge the arguments of those who have concerns over the advertising of POMs (considered in paragraphs 2.185, 2.190 and 2.193), these do not, in our view, bear on the availability of price information, both for the purpose of shopping around and so that animal owners understand the charges they are asked to pay. In a market in which price competition is weak, this includes the need to display some price information in veterinary surgeries. We do not believe that quoting or displaying prices of POMs in these ways would be contrary to the Medicines Act 1968. However, we recognize that a requirement along the lines of (iv) would be an exceptional measure that would only be justified if it were essential to kick-start competition. In the light of the evidence we have received, we do not believe that a sufficiently strong case exists.

The majority of veterinary surgeons welcomed (v). However, most of the manufacturers that did comment argued either that it was unnecessary, as their schemes met the requirement already, or disproportionate, because the costs of changing rebate schemes would not be justified by the marginal increase in veterinary surgeons’ knowledge of net costs. Some disputed whether such an increase in knowledge would affect the pricing behaviour of veterinary surgeons. Wholesalers were more inclined to see the potential advantage of a simple comparison of net prices and, in some cases, envisaged a role for themselves in providing software to facilitate greater transparency.

Since, as discussed in paragraph 2.89, the uncertainties and complexities arising from discount and rebate arrangements affect veterinary surgeons rather than the manufacturers, each of which need focus only on its own scheme, we are more inclined to accept the judgements of veterinary surgeons and our own attempts to grapple with the schemes, rather than those of manufacturers. The key elements of detriment we identified arise from difficulties veterinary surgeons have in establishing net unit costs to themselves and the consequences of switching supply to the products of other manufacturers in whole or in part. We accept that it would not be reasonable to place all the burden on manufacturers by requiring them to provide information on prices net of all discounts and rebates where they have no involvement in the terms of the wholesaler discounts. We also accept that it would not be reasonable to require manufacturers to inform veterinary surgeons and pharmacies of the ex-manufacturer net prices at the time of each purchase, given that individual purchases will typically be made from wholesalers and could take place daily. However, it appears to us reasonable and proportionate to require manufacturers that supply POMs in the UK to inform veterinary practices and pharmacies, at not less than three-month intervals, of the per product ex-manufacturer unit price(s) net of any discount or rebate at which its POMs were supplied to the veterinary practice or pharmacy in the preceding period and, on request, to quote the ex-manufacturer unit price(s) net of any discount or rebate at which any stated mix and volume of products would be supplied in the next three months.
2.181. In our statement of 17 September we identified the following possible remedies under this heading:

(i) a requirement for manufacturers and wholesalers that supply POMs in the UK to supply pharmacies;

(ii) 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;

(iii) a requirement for veterinary surgeons to display the name, postal address, telephone number and web-site address of any pharmacy supplying veterinary medicines that so requests; and

(iv) 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 authorized veterinary medicines to the brand specified.

2.182. The majority of the veterinary surgeons who commented on (i) and (ii) raised no objections. Similarly, neither manufacturers nor wholesalers objected to the principle of supplying pharmacies, but were concerned that any remedy might require them to behave uncommercially, for example in supplying pharmacies directly under circumstances where they would not wish to supply veterinary practices directly.

2.183. Intervet, Merial, Pfizer, Pharcacia and Schering-Plough objected to (ii) if it were interpreted as requiring payment of rebates on the same terms to pharmacies as to veterinary surgeons. They argued that this would fail to reflect the differing roles of veterinary surgeons and pharmacies and thus tend to distort competition. Some further argued that factors other than the terms of supply would affect pharmacies’ ability to compete with veterinary surgeons. None of the wholesalers objected, provided wholesaler discounts could continue to reflect volumes and costs of supply.

2.184. We have considered the manufacturers’ rebate schemes in some detail. We recognize that they may have commercial reasons for paying different rebates to veterinary surgeons and pharmacies because of the veterinary surgeons’ greater role in determining the POMs supplied in any particular case. However, we have concluded that paying rebates to veterinary surgeons but not to pharmacies prevents, restricts or distorts competition (see paragraph 2.48). The commercial incentives faced by manufacturers arise because, while pharmacies can dispense POMs to animal owners, only veterinary surgeons also have a statutory monopoly over prescribing them—for reasons related to the protection of human and animal health. As we have already made clear (see paragraph 2.154), we do not believe that it would be in the public interest to remove veterinary surgeons’ dispensing privilege. We considered two measures for addressing the adverse effect on competition arising from the manufacturers’ response to these commercial incentives:

— requiring the supply of POMs to veterinary surgeons and pharmacies to be on the same terms for the same volumes, so as to ensure, as far as possible, that manufacturers are not in a position to differentiate between the two groups; and

— giving pharmacies a greater role in determining the POMs supplied, so as to change the incentives manufacturers face: we consider this in paragraphs 2.186 to 2.189.

2.185. Nearly all the veterinary surgeons that commented on remedy (iii) objected to it, arguing that it was both unreasonable and impracticable. It was unreasonable because it
effectively required veterinary practices to provide free advertising for their competitors. It was impracticable because it could lead to veterinary surgeries being required to display details of large numbers of pharmacies irrespective of location or their ability to supply POMs. We accept that a requirement along these lines would be an exceptional measure that would be justified only if there were no other way to address a lack of knowledge by consumers, that pharmacies could not themselves reasonably overcome through advertising. We do not believe this to be the case.

2.186. Our suggestion of a possible requirement for veterinary surgeons, when they write prescriptions for POMs, to do so on an ‘or equivalent’ basis—and thus give pharmacies a greater role in determining the POMs supplied—attracted extensive comment from both veterinary surgeons and manufacturers. Some of this reflected uncertainty about what might be meant by ‘equivalent’ POMs and a concern that this might enable pharmacies to dispense medicines outside the requirements of the cascade.

2.187. More generally, it was argued that, even where there are alternative veterinary approved medicines for treatment of particular conditions in particular species, these may be not be clinically equivalent. So it would not be safe to allow pharmacists to supply alternatives. This would be the case even where these were based on the same active ingredients, because of differences in, for example, rates of absorption, elimination of residues, means of administration or palatability. Some veterinary surgeons even argued that the substitution of an approved veterinary generic could also lead to difficulties—where animals failed to respond to treatment—which would be in the interests of neither animals nor their owners. The VMD told us that whilst alternative products, indicated for the same treatment, may not be interchangeable for a range of reasons—because of differences in active ingredients, strengths, mode of administration and additional indications—approved veterinary generics and their reference products can be regarded as interchangeable in terms of active ingredients. It provided us with a list of the limited number of veterinary approved generics available.

2.188. We conclude that although there are circumstances in which competing products may be used to equal effect, the choice of product is not one that can normally be made by anyone other than the prescribing veterinary surgeon. In view of this, and because the number of veterinary approved generic POMs, and the range of indications for which they are available, is small, there is limited scope for pharmacists to play a greater role in deciding which POM should be supplied. This adds weight to the requirement for veterinary surgeons and pharmacies to be supplied with POMs on the same terms for the same volumes, and reinforces our judgement that this is a necessary and proportionate remedy.

2.189. It remains important, however, that where an animal owner requests a prescription, veterinary surgeons should provide one in a form that will allow identification and dispensing of alternatives which, in their clinical judgement, would be equally acceptable so as to give the animal owner maximum opportunity to seek the most cost-effective solution. This is not only in the interests of consumer choice and competition, but, as it may lead to some animals being treated that would otherwise go untreated, because of cost, it may also yield benefits in terms of animal welfare. We urge the RCVS to encourage veterinary surgeons to do this and, in order to facilitate such behaviour, to consider the desirability of drawing up or endorsing lists of alternative veterinary medicines to be considered by veterinary surgeons in writing prescriptions for common conditions. However, in view of the difficulty of formulating any enforceable requirement—and the risk that any attempt to require veterinary surgeons to prescribe more than one option might be incompatible with the proper exercise of their clinical judgement—we do not propose the introduction of any legally enforceable obligation along these lines.
Recommendations for remedies under the Fair Trading Act

2.190. In the light of the comments received and of the preceding discussion, we recommend the following remedies enforceable under the FTA:

(I) A requirement for a large and prominently displayed sign in all veterinary surgeries advising clients on:

— the availability of—and charge for—prescriptions, consistent with recommendations (V) and (VI), to enable them to obtain POMs from pharmacies if they wish;

— the price of the ten POMs most commonly prescribed or dispensed by that surgery in a typical three-month period; and

— the availability of further information on prices of all POMs stocked or sold.

(II) A requirement for veterinary surgeons to inform clients, on request, of the price of any POM they propose to dispense and to quote the price of any POM stocked or sold to anyone who asks.

(III) A requirement for veterinary surgeons to provide itemized bills distinguishing the cost of services from the cost of POMs.

(IV) A requirement for veterinary surgeons recommending the use of POMs to inform clients of their policies and charges regarding further examination of animals requiring repeat prescriptions, either by provision of a leaflet or in a letter of engagement. We would encourage veterinary surgeons also to include in these leaflets or letters of engagement texts advising clients of the matters covered in remedies (I), (II) and (III).

(V) A requirement for clients of veterinary surgeons to be offered, either orally or in writing, prescriptions for POMs the veterinary surgeon recommends, except for those used in emergency treatment, for treatments during surgical procedures or as anaesthetics; and for prescriptions requested in consequence to be provided by the veterinary surgeon.

(VI) A requirement, for a period of three years, for veterinary surgeons providing prescriptions to do so at no additional charge to the client beyond that of the consultation. The DGFT, with the RCVS, to monitor the prescriptions written, and the charges made for them, over the 12 months following the end of that period. The DGFT to set charges for prescriptions (either by way of one or more fixed fees or by specifying arrangements under which charges are to be calculated) if, in his judgement, veterinary surgeons are charging for prescriptions so as to deter animal owners from asking for prescriptions or to influence the terms of competition with pharmacies to their own advantage.

(VII) A requirement for manufacturers that supply POMs in the UK to inform veterinary practices and pharmacies, not less than once every three months, of the ex-manufacturer unit price(s) net of any discount or rebate at which its POMs were supplied to the veterinary practice or pharmacy in the preceding period and, on request, to quote the ex-manufacturer unit price(s) net of any discount or rebate at which any stated mix and volume of products would be supplied in the next three months.

(VIII) A requirement for all manufacturers that supply POMs in the UK to supply pharmacies and veterinary surgeons on the same terms for the same volumes, including ensuring the same ex-manufacturer net prices whether the POMs are obtained direct or through veterinary wholesalers or other third parties.
A requirement for veterinary wholesalers that supply POMs in the UK to supply pharmacies and veterinary surgeons on the same terms for the same volumes.

**Recommendations for changes to regulation of veterinary surgeons**

2.191. As previously noted, the inability of one veterinary surgeon to dispense a prescription written by another significantly restricts the scope for competition between them in the supply of POMs. The ability of one person to dispense safely the prescriptions of another is recognized in the provisions enabling pharmacists to play such a role, and it appears to us that the limitation on veterinary surgeons doing the same represents an unnecessary restriction. Should the remedies proposed in paragraph 2.190 be implemented and lead to the more widespread use of prescriptions, it will, in our view, be highly desirable that veterinary surgeons are able to compete with pharmacies in supplying POMs to animal owners in accordance with those prescriptions. We note that the RCVS *Guide to Professional Conduct* restricts the ability of veterinary surgeons to advertise veterinary medicines in ways that would appear unduly restrictive if one veterinary surgeon were able to dispense the prescriptions of another. In our statement of 17 September we therefore consulted on two recommendations. First, a recommendation that the Secretary of State consider changing the law to allow veterinary surgeons to dispense a veterinary prescription, whether or not the animal concerned is under their care. (This retains the requirement that the prescribing veterinary surgeon must have the animal under his or her care.) Second, a recommendation that the RCVS modify its *Guide to Professional Conduct* to remove restrictions on the advertising of medicines by veterinary surgeons (except advertising that clearly brings the veterinary profession into disrepute).

2.192. Around half of those commenting favoured enabling one veterinary surgeon to dispense a prescription written by another. Some veterinary surgeons raised concerns over possible clashes of clinical judgement between the veterinary surgeon writing the prescription and the one doing the dispensing. This does not seem to us to represent a major obstacle. The one doing the dispensing, not having the animal under care nor having made a diagnosis, will be in no position to exercise clinical judgement. Where one veterinary surgeon doubts the wisdom of dispensing POMs indicated on a prescription written by another we would expect the one doing the dispensing to refer back to the prescribing veterinary surgeon or to decline to fill the prescription as a matter of responsible dispensing. The RPSGB observed that pharmacists were the only professionals specifically educated and trained to perform the dispensing function, and that the limited dispensing exemption in the Medicines Act was for health professionals treating their own patients. The RPSGB considered that any amendment to this restriction would require careful consideration and consultation. We note, however, that in practice veterinary surgeons are already dispensing nearly all the POMs supplied to animal owners in the UK.

2.193. The majority of those commenting on possible removal of restrictions on advertising of POMs did not believe that this would be desirable, raising concerns over the possible pressure from animal owners for selection of inappropriate POMs. We recognize that there are deep divisions over the wisdom of allowing advertising of POMs, and that this is a matter currently under discussion within the EC. However, we regard the ready availability of information of prices as essential to effective competition. We do not believe that an ability to compare prices from different suppliers of a POM prescribed by a veterinary surgeon raises issues over use of inappropriate POMs. If the remedies recommended in paragraph 2.190 are adopted, then veterinary surgeons will be required to display certain information on prices and to make further price information available on request. This would necessitate some change to the RCVS *Guide to Professional Conduct*.

2.194. Having considered the responses to our earlier consultation we now recommend:
— **Recommendation 1:** The Secretary of State to consider changing the law to allow veterinary surgeons to dispense a veterinary prescription, whether or not the animal concerned is under their care.

— **Recommendation 2:** The RCVS to modify its *Guide to Professional Conduct* to remove restrictions on veterinary surgeons’ publishing the prices they charge for veterinary medicines.

2.195. In our statement of 17 September we also consulted on three recommendations intended to give the RCVS a role in monitoring and enforcing our remedies and recommendations, in so far as they affect veterinary surgeons. A clear majority of those responding were against giving the RCVS such a role. The RCVS told us that it was essentially concerned with professional conduct and, although in principle failure to follow recommendations from the CC could constitute professional misconduct, depending on the recommendation and the nature of the failure, the RCVS arrangements for applying sanctions in the event of misconduct would not necessarily be well suited to enforcing the sorts of recommendations we might wish to contemplate.

2.196. We expect that adoption of our recommendations affecting veterinary surgeons in paragraph 2.190 will be by means of orders under the FTA, and would be enforceable by the DGFT. Once these orders were introduced we would look to the RCVS to modify its *Guide to Professional Conduct* so as to make it proper professional conduct for veterinary surgeons to observe them, in the same way as any other legal requirement affecting veterinary surgeons. Since these will be new requirements, we would encourage the RCVS to monitor compliance as a matter of good practice, and to take seriously any evidence of failure by veterinary surgeons to meet their legal obligations.

**Recommendations for other regulatory changes**

2.197. In our statement of 17 September we consulted on possible recommendations for other regulatory changes under four headings:

— recommendations affecting the operation of the single European market;

— recommendations on classification of veterinary medicines;

— recommendations on regulatory procedures; and

— recommendations on the cascade.

2.198. We do not make recommendations for changes to the cascade. This proved the most controversial of all the areas on which we consulted, with arguments over the role of the cascade in ensuring the safe use of veterinary medicines and in promoting innovation and availability of future veterinary medicines. Our consideration of the responses led us to conclude that changes to the cascade would require a review going beyond the scope of our inquiry. We now concentrate on the recommendations that we do wish to pursue, in the other three areas.

**Recommendations affecting the operation of the single European market**

2.199. We were concerned that there was no effective single European market in veterinary medicines. Although most POMs are manufactured by multinational companies and are used for broadly the same conditions in the same species in all member states, the existing regulatory system, defined at the European level, has sustained segregated national markets. The lack of
cross-border competition appears to be a factor in the scale of price differences found between member states. Products authorized in one may not legally be imported into, or marketed in, another without authorization from the importing country. This is so even in the case of products authorized in both member states through the decentralized procedure. Such products are pharmaceutically identical, differing only in the language of labels and inserts and in their authorization numbers. The results from our international comparisons (see paragraph 2.123) are consistent with the view that the prices of the most commonly-used veterinary medicines in the UK, including several leading brands, are systematically lower in neighbouring countries, at the ex-manufacturer, as well as at the retail, level. If it were easy for UK veterinary wholesalers and veterinary practices to obtain supplies from cheaper sources elsewhere in the EC, there would be downward pressure on prices in the UK. The present system of regulation helps to sustain price differences, with the obvious detriment that prices paid for POMs by farmers and owners of companion animals are higher in the UK than in other member states. Although this may benefit the manufacturers, they too suffer detriments because of the additional costs and delays in bringing new products to market that arise from the fragmented system of MA to which most are subject.

2.200. In our statement of 17 September we consulted on two recommendations (see Appendix 1.3, recommendations 1 and 2):

— to open up the centralized procedure for obtaining MAs as an option, without making it mandatory for any further categories of medicine; and

— to remove restrictions on cross-border trading in mutually recognized products.

2.201. The first of these was not opposed by any respondent, though the VMD noted that in practice all centrally authorized products were likely to continue to be classified POM irrespective of product characteristics. There is a risk, therefore, that opening up the centralized procedure may lead to some veterinary medicines being classified POM that would otherwise have been authorized under an alternative procedure and received a less restrictive classification. We would regard it as regrettable if the change were to lead to over-classification of some veterinary medicines in this way, but take the view that any such risk is outweighed by the advantage of increasing the number of products for which there is a single European market.

2.202. Over 80 per cent of respondents agreed with the second recommendation, though some manufacturers and the VMD considered that the existing system for authorization of parallel imports into the UK achieved the aims of the recommendation. Few products have been imported under the existing arrangements, and we believe that the extent to which they remove all unnecessary barriers in practice has still to be demonstrated. We note that in evidence to us Defra drew attention to difficulties it faced in obtaining certain vaccines for cattle, where only one product had an MA in the UK though two further products were authorized in other EC countries. We remain concerned, for example, that there may still be unnecessary barriers to labelling in the appropriate language. We believe that it may be desirable to go further in reducing regulatory hurdles.

2.203. In the light of our consideration of the comments received and evidence from the VMD, we now recommend:

— Recommendation 3: The Secretary of State to consider negotiating changes to the draft Council Regulation (proposed in COM (2001) 404 final) so as to allow all categories of veterinary medicine access to the centralized procedure, without making this mandatory for any further categories of medicine.

— Recommendation 4: The Secretary of State to consider establishing arrangements to allow any veterinary medicine authorized through the decentralized procedure in the UK
to be imported into the UK from any other EC member state in which it is also
authorized, without further individual MA but subject to:

(i) prior notification to the VMD; and

(ii) the conformity of all labelling and inserts with the UK authorization;

and to consider negotiating any changes to the Directive necessary to achieve this and to
remove barriers to relabelling for this purpose.

Recommendations on classification

2.204. The distribution classification of a veterinary medicine determines the categories of
retailer permitted to supply it, and therefore strongly influences the extent of competition at the
retail level. We are concerned that manufacturers can have a commercial interest in the choice
distribution classification (including deciding whether to seek reclassification), going beyond
questions of safety, quality and efficacy.

2.205. Some products will have mandatory POM classification simply because of a novel
ingredient. It appears to us that in time and in the absence of adverse field experience, this
should be capable of review. However, EC law does not provide a mechanism for review of the
distribution classification of a centrally authorized medicine.

2.206. We are further concerned that the VMD interprets a medicine’s efficacy narrowly, to
refer only to the welfare of animals treated with it. The price and availability of medicines
affect the welfare of all animals in need of treatment and, we believe, should be considered a
legitimate factor in the choice of distribution classification.

2.207. The European Commission has proposed that all medicines for food-producing
animals should be permanently classified POM. We are concerned that such a move would lead
to a loss of channels for distribution and supply of veterinary medicines with an adverse impact
on competition.

2.208. In our statement of 17 September we accordingly consulted on a number of possible
recommendations to address these concerns (see Appendix 1.3, recommendations 3 to 12).

2.209. The majority of respondents, both manufacturers and veterinary surgeons, thought
that it would not be reasonable to disregard the views of the manufacturer on distribution
classification. In particular, it was argued that to disregard the manufacturer’s advice on a
matter relevant to the safe handling and use of its product would be dangerous. That, of course,
was not our intention. Our concern is rather to encourage distribution classification of veter-
inary medicines at the lowest level consistent with standards of safety, efficacy and quality.

2.210. The majority of respondents, including most manufacturers, were in favour of
automatic review of distribution classification on the basis of the existing dossier. The VMD
did not oppose automatic review of classification but had doubts about exclusive reliance on
the existing dossier. We recognize that there could be circumstances in which it would be
necessary to go beyond the existing dossier, but believe that they should be circumscribed to
avoid review of distribution classification unnecessarily increasing burdens on manufacturers.

2.211. Respondents were split on the desirability of broadening the consideration of animal
welfare in the VMD’s remit, though many comments appeared to be based on a misunder-
standing of the intention behind the recommendation. This was to ensure more systematic
consideration of economic factors in decisions on distribution classification and regulation. The
VMD was opposed, arguing that cost considerations should not influence decisions on safety,
quality and efficacy and pointing to practical difficulties they would face if day-to-day economic judgements on costs and benefits were required of them. Whilst we understand the concerns that were raised, we believe that in discharging its responsibilities the VMD should take account, where relevant, of the impact on animal welfare of the availability and accessibility to animal owners of veterinary medicines, which includes consideration of cost.

2.212. The majority of respondents agreed with the need for member states to retain the freedom to set distribution classification irrespective of the channel through which the veterinary medicine had received its MA, and for a distribution classification review mechanism for centrally authorized products (as was also recommended by the Marsh report).

2.213. Respondents were more divided on a new POM sub-classification to allow agricultural merchants and others to dispense some veterinary medicines. Many of those who objected expressed concern over safety and, in particular, criticism of the existing regime governing Suitably Qualified Persons (SQPs). It is beyond our remit to assess the operation of current requirements for SQPs. However, we do not agree that concerns on that issue should be addressed by restricting the dispensing of all veterinary medicines to pharmacies and veterinary surgeons. Several respondents, including the VMD, wondered whether such a recommendation would be redundant if the European Commission were to be unsuccessful in its proposals for all veterinary medicines to be classified POMs. We do not believe this to be the case, particularly if recommendation 1 is adopted (see paragraph 2.194).

2.214. In the light of our consideration of the comments received and evidence from the VMD, we now recommend:

— **Recommendation 5:** The Secretary of State to consider amending the remits of the Veterinary Products Committee and the VMD to require them to recommend the lowest distribution classification consistent with their assessment of a product’s safety, efficacy and quality.

— **Recommendation 6:** The Secretary of State and the VMD to consider instituting automatic review of distribution classification whenever a product’s MA is renewed (or at similar intervals if the European Commission’s proposal to make MAs permanent is adopted) and, unless there is good scientific reason to require additional information, to base such reviews on the product’s existing dossier and accumulated field experience. An early benefit could result from an immediate review of the distribution classifications of ectoparasiticides (for the treatment of fleas) for companion animals, which could provide a particularly effective stimulus to competition from pharmacies in the supply of one of the most widely-used veterinary products.

— **Recommendation 7:** In discharging its responsibilities for the licensing and distribution classification of veterinary medicines against the criteria of safety, efficacy and quality, the VMD should take account, where relevant, of the impact on animal welfare of the availability and accessibility to animal owners of veterinary medicines, including considerations of cost.

— **Recommendation 8:** The Secretary of State, in negotiating the Draft Directive and Regulation, to keep in mind the importance of retaining member states’ existing right to control the channels of distribution and supply of veterinary medicines, including those authorized through the centralized procedure.

— **Recommendation 9:** The Secretary of State to consider establishing one or more new distribution 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.
Recommendations on regulatory procedures

2.215. The cost and especially the time taken in obtaining MAs are substantial (see paragraphs 9.9 and 9.10 for a discussion of the time taken to bring new products to market). So too are the costs of maintaining an authorization through continuing pharmacovigilance and five-yearly renewals. It appears to us that, partly as a result of this, new market entrants are deterred and competition is weak in some therapeutic sectors with few alternative products. In our statement of 17 September we accordingly consulted on a number of possible recommendations to address these concerns (see Appendix 1.3, recommendations 13 to 17).

2.216. The majority of respondents supported permanent MAs, as proposed by the European Commission. However, the VMD was opposed. It argued that the proposal would not reduce costs to manufacturers because dossier updates would continue to be required to keep pace with scientific advances and would have to undertake more stringent pharmacovigilance. Whilst we accept that making MAs permanent may not reduce costs to manufacturers in all cases, we are not convinced that the present uniform requirement for five-yearly renewals of MAs is necessary.

2.217. All respondents were in favour of encouraging the VMD to structure authorization procedures to minimize delays to product commercialization, and a majority were in favour of the VMD offering applicants for MAs the option of submitting their dossier in stages as one way of achieving this. The VMD pointed out that it already had in its Framework Document the objective ‘to deliver efficient cost effective and high quality services to all of VMD’s customers whilst maintaining the safeguards of the licensing system’, and argued that any requirement on the VMD to process dossiers submitted in phases would lead to more complex and less efficient management systems. Whilst it is not clear to us that submission of phased dossiers is necessarily the best way to reduce times to commercialization, we remain convinced that there should be scope for reducing the current time to commercialization, for example through improvement in the way in which the VMD interacts with manufacturers prior to receipt of complete dossiers.

2.218. A majority of respondents supported allowing Maximum Residue Limits (MRLs) for minor food-animal species to be set by extrapolation from major species data where this is scientifically justified. The VMD told us that this was already possible, and informed us that the first MRLs set in this way had recently been issued by the European Commission. We welcome this move and hope that this procedure will be used in as many cases as possible.

2.219. In the light of our consideration of the comments received and evidence from the VMD, we now recommend:

— **Recommendation 10**: The Secretary of State to support the European Commission’s proposal to make MAs permanent (in the absence of adverse field experience or other comparable grounds for review).

— **Recommendation 11**: The VMD should improve its procedures so as to minimize delays to product commercialization, including examination of the ways in which it interacts with manufacturers prior to receipt of complete dossiers.

2.220. Although none of our recommendations or remedies affects veterinary surgeons’ exclusive right to prescribe POMs for animals or herds under their care, they are all designed to encourage and increase competition in the supply of POMs. The eventual success of the measures designed to increase competition between veterinary surgeons, and between them and pharmacies, will depend on animal owners and veterinary surgeons responding to the new opportunities we have sought to create, and on the readiness of pharmacies to enter the market. This, in turn, will require that they should be able to obtain supply, on terms that will allow them to compete.