13 Views of other parties

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Introduction

13.1. At the start of the inquiry, we wrote to a range of other interested parties to seek their views, including government bodies, trade associations, trade unions and animal charities. We also invited people to submit their views by advertising in eight specialist publications, aimed respectively at veterinary surgeons, farmers and owners of companion animals, and through the CC’s website. This chapter summarizes the views put to us in writing and in hearings by organizations and individuals other than those covered in Chapters 10, 11 and 12, which reported the views of veterinary manufacturers and wholesalers, veterinary surgeons, veterinary organizations and pharmacists.

Government bodies

Animal Medicines Training Regulatory Authority

13.2. AMTRA is responsible for the training and registration of SQPs who undertake the sale and supply of medicines outside the POM category. In AMTRA’s view there were around 30 POM products that could be classified as PML. Widening the system of supply would bring greater competition to the market.

13.3. AMTRA’s comments on some of our possible recommendations for regulatory change, as set out in the statement of 17 September, are shown below. The statement is at Appendix 1.3. AMTRA said that it would be counterproductive to preclude manufacturers from putting forward views on the classification of medicines for which they sought authorizations, although it agreed that there were situations where manufacturers might seek a POM classification for commercial reasons. However, manufacturers did sometimes ask for a PML classification and there had been instances when the VPC imposed a POM classification despite the manufacturers’ arguments in favour of PML. AMTRA proposed that our recommendation should be that the VMD and the VPC should classify a product in the least restrictive category possible, consistent with animal welfare and safety of the animal and the person administering the medicine.

13.4. AMTRA supported our possible Recommendation (5) which would widen the remits of the VMD and the VPC to take into account the welfare of animals overall. It opposed the EC’s proposal that all medicines for food-animal species should be POM (Recommendation 6). It supported Recommendations (7) and (8). In relation to Recommendation (10), it observed that the present need for a pet shop to register either as an agricultural merchant or a saddler in order to sell PML medicines reduced the incentive for manufacturers to seek more PML classifications, since outlets for their sale and supply were limited. AMTRA fully supported proposed Recommendations (11) and (12) but pointed out that the RPSGB was already fully involved in the development and extension of AMTRA training through its membership of AMTRA and its board of directors.

13.5. Opposing possible Recommendation (19) about the cascade, AMTRA said that the incentive for seeking MAs would be greatly diminished or eliminated if a medicine without a specific authorization could be prescribed or administered.

Department for Environment, Food and Rural Affairs

13.6. The Chief Veterinary Officer (CVO) at Defra referred to the belief advanced by some people that the marketplace in veterinary practice should operate by allowing supply and demand eventually to come into equilibrium, so that efficient veterinary practices survived and the inefficient ones went to the wall. He expressed some concern about this proposition in relation to Defra’s involvement with veterinary practices in dealing with disease, disease surveillance, and animal welfare.

13.7. He explained that Defra did not employ enough veterinary surgeons to undertake all the work it needed to do on clinical diseases. The Great Britain Veterinary Service had traditionally operated with a core State Veterinary Service of around 230 frontline VOs, plus 5,000 to 6,000 veterinary practitioners working on farms on Defra’s behalf in their capacities as LVIs. Generally, the work the LVIs did on Defra’s behalf was on their clients’ farms.
13.8. In some cases private practice veterinary surgeons acting as LVIs worked directly for Defra. An example would be if there was a case of anthrax on a farm and an animal was found dead from the disease, the LVI would contact the Animal Health Office and he/she would then be authorized to investigate, take samples and serve the relevant notices.

13.9. LVI work also included testing animals for diseases, such as tuberculosis and brucellosis, for which Defra ran regular programmes. For example, cattle herds had to be tested for tuberculosis at intervals which varied in different parts of the UK (once a year, once every two years, etc).

13.10. An additional area of responsibility for the LVI related to animal welfare on the farm, during transport, at slaughterhouses and in livestock markets. On a market day, for example, the divisional veterinary manager, who was a government official, would arrange for an LVI to undertake a market inspection, checking for any abuses of animals. If there was a welfare problem, Defra would expect the LVI to deal with it by giving appropriate advice. If further action were needed, Defra would expect this to be reported to it, since LVIs lacked enforcement powers.

13.11. LVIs (both individual veterinary surgeons and practices) had to be on a panel, for which they qualified by being in practice and receiving appropriate training. There were a range of different panels with responsibilities for large animals, tuberculosis, rabies, small animals, and export certification, and other types of work. The majority of LVIs were large-animal practitioners but some were also small-animal practitioners, dealing with export certification, rabies, and pets’ travel schemes (under which animals could travel to and from the UK without going into rabies quarantine).

13.12. The CVO said that LVIs were paid for their services in different ways. Defra paid them for specified tasks, such as testing for tuberculosis, brucellosis and anthrax. The cost to Defra was between £12 million and £15 million a year in England, Wales and Scotland. A second source of payment for an LVI was the client, in circumstances when an export certificate was needed; a health certificate had to be provided by the veterinary surgeon, signing as an official veterinary surgeon on behalf of the Government, and the client would generally pay for that service. Payment rates were negotiated with the BVA and were linked in general to the pay which government VOs received. There were different rates of payment for different jobs.

13.13. In amplification, the CVO said that, whilst most practising veterinary surgeons engaged in farm work were LVIs, all general practitioners—including those who were not LVIs—were required by law (and by the RCVS) to report suspect notifiable diseases if they came across a case. In this respect, all veterinary surgeons, including some not receiving payment from Defra, played an important role in national disease surveillance.

13.14. The CVO explained that, under the Animal Health Act 1981 and its subsidiary Orders, everybody was under an obligation, if they suspected that animals had a disease such as FMD, swine vesicular disease or swine fever, to report it to the police or the Divisional Veterinary Manager. However, in practice, it would usually be the veterinary surgeon who detected anything unusual.

13.15. Whilst there was no legal obligation on veterinary surgeons to report non-notifiable diseases, they would normally report to the Veterinary Laboratory Agency (part of Defra) any suspicions of new or emerging diseases. BSE first came to light in this way from reports coming into the agency from some veterinary surgeons. The published inquiries into FMD emphasized the importance of private veterinary surgeons in disease surveillance. Increasingly, Defra recognized them as a critical partner in this area.

13.16. The CVO said that Defra’s concern in relation to our inquiry was that any outcome that damaged the viability of veterinary practice, particularly in the rural areas, would have an impact on all the work described above. It was in Defra’s interest to retain viable large-animal practice, particularly in those parts of the country where there were potential financial problems. Whilst this concern mainly centred on rural (including equine) practices, Defra was responsible for all animal welfare and there was at least one notifiable disease affecting small animals which Defra needed to monitor.

13.17. The CVO said that, if there were to be a major outbreak of disease, Defra would need the assistance of practising veterinary surgeons. To deal with the FMD outbreak in 2001, Defra started with around 230 veterinary surgeons working in Government. They were augmented by an additional approximately 1,600 veterinary surgeons working as temporary veterinary inspectors, some of whom were from overseas, including a number who had come to the UK specifically to work for Defra. In
addition, the practising veterinary surgeons who remained in the practices had a major role in licensing
the movements of animals; they had issued some 250,000 such licences.

13.18. The CVO stated that if practices were lost in some areas the question would be: who would
do the work? He cited the example of the Highlands and Islands Veterinary Services Scheme. This long-
standing scheme was designed to ensure that crofters and farmers of similar economic status in the
Highlands and Islands of Scotland received veterinary services at prices they could afford. The scheme
also had the virtue of maintaining a level of large-animal surveillance, local disease-testing capability
and protection of animal welfare in the remoter parts of the Highlands where coverage by veterinary
practices would otherwise be in serious jeopardy. If some other areas did not have veterinary practices
because they were not economically viable, Defra would lose considerable capacity to carry out anthrax
investigations; if an animal died on a farm there would be no veterinary surgeon—normally the first port
of call in such situations—to go out and examine it, to check whether or not it had BSE or other
notifiable disease. Defra would also lose the veterinary surgeons’ welfare monitoring role. Also there
would be no veterinary practice to undertake the clinical treatment of the animals. Although this was a
private issue between the veterinary surgeon and client, the absence of a veterinary service would raise
the question of how the welfare of animals on farms would be dealt with. Defra had looked at what it
would have to do, in terms of numbers of veterinary surgeons, to provide that service, and as it did not
currently deal with clinical work, had concluded that it would become an expensive and complex
business. The CVO’s concern was whether any change would have an impact on rural practices in
England and Wales, and other areas of Scotland, and make them non-viable. In this case Defra could
well have to consider a new system of providing veterinary service in those areas. Put in other terms, if
anything happened to make practice non-viable locally, the issues that had arisen in the Highlands and
Islands Scheme would arise in those localities.

13.19. The CVO could not speculate on what form of help might be provided, since this would be a
matter for ministerial decision. He noted that the Highlands and Islands Scheme was a call on the
Scottish Executive’s budget. The determination of any form of help would involve discussions on a
range of professional questions, including the veterinary surgeons’ obligation to provide 24-hour cover.

13.20. He made it clear that the State Veterinary Service would not undertake clinical work. The
question had arisen some time ago in relation to the Highlands and Islands Scheme, and the conclusion
reached was that Defra would not do clinical work, because it would then have to assume all the complex
arrangements for running practice. Defra nonetheless emphasized that it was not suggesting that it
wanted, in any way, to support rural practices financially. The CVO emphasized that the Highlands and
Islands Scheme was unique in a unique area where there were huge distances to travel. Defra’s view was
that it would not support such a scheme in other parts of the country; it was not currently needed but the
issue was that Defra wanted to avoid a situation where it was needed.

13.21. In response to questions on the specific conducts and remedies set out in our statement of
17 September, the CVO said that his concerns were at a general level only. Defra recognized that it
would be a complex exercise to look into the economics of veterinary practice, and it had not done so for
any part of England, because it was not its role to look into how private practice worked. The economics
of practice were issues for the BVA and the SPVS.

13.22. Defra thought that much would depend on how veterinary surgeons responded to the CC’s
hypothetical remedies, were these to be implemented. They could do so in a number of different ways; it
did not think it was easy to predict the response.

13.23. On the specific issues of cross-subsidization between fees and income from POMs’ sales, the
CVO said that this had been under debate for some time. It was a question of where the practice got its
income from: whether it should make it largely from the professional charges, which would have to
increase considerably to achieve this, or whether it was made from sales of drugs, or whether the package
as a whole created a reasonable charge to the client and provided a reasonable income for the veterinary
surgeon. One of the difficulties had always been the raising of professional charges and the acceptability
of that increase to the customers. If the CC’s remedies were to affect this balance between sources of
income, a major issue would be the speed with which they were implemented and the speed at which the
practices could readjust to them.

13.24. Asked whether there was a quality control mechanism which all livestock farmers had to
operate, the CVO said that this rather depended on species. In many cases the farmer needed access to a
veterinary surgeon; if there was a requirement by Defra for tuberculosis and brucella tests, the farmer had to nominate an LVI to do the work. But as to how often the veterinary surgeon visited a farm was dependent on the farmer requesting a visit; there was no obligation to visit, for example, once a year or every six months. If the farmer did not call the veterinary surgeon in, the veterinary surgeon had no legal right to go to the farm, except when specifically doing work on Defra’s behalf. In general, the veterinary surgeons tended to go to a dairy farm, under private dairy herd assurance schemes, to control mastitis, lameness and reproductive problems. Veterinary surgeons went less often to beef farms, and still less often to sheep farms. There was, at present, no legislation which required a farmer to call out a veterinary surgeon. Farms could operate almost completely independently of veterinary input until they required veterinary drugs (and then they required a veterinary surgeon who had the animals under his or her care). However, the farmer had responsibilities under animal welfare legislation. If animals were suffering, the farmer was expected to deal with them, and in many cases that would require the farmer to call on the services of a veterinary surgeon.

13.25. Following the FMD outbreak, Defra was developing a strategy of greater involvement of practising veterinary surgeons in dealing with disease surveillance. There were negotiations under way in Brussels in relation to food and hygiene legislation. One of the issues under discussion was to what extent should the history of the farm, and its disease history, be known before the animals went to the abattoir. The general thrust of meat hygiene and food safety issues in these negotiations was that more decision-taking should be based on action at farm level—that is, further down the chain from the inspections currently made at abattoirs. The CVO noted that the poultry industry already required inspections early in the production chain.

13.26. Defra said that the mid-term review of the Common Agricultural Policy, aiming at ‘decoupling’ direct payments to farmers from the amount they produced, would also require some kind of inspection of the farms to make sure they were being run in an environmentally friendly way. To that had been added the idea that farmers should also be securing animal welfare, which generally meant complying with the European law about animal welfare standards on farms. There might be official ‘advisory visits’ to farms, which, among other tasks, would check on animal welfare. The UK Government believed that an animal welfare assessment should be undertaken by a veterinary surgeon. The review was at an early stage. Many steps remained to be taken, but eventually a rather more formal system might emerge than at present, whereby farmers would be expected to be subject to occasional veterinary inspection visits. Defra’s preferred way of achieving that would be to have what might be called a farm ‘health and welfare plan’ drawn up by the veterinary surgeon in conjunction with the farmer. If a private veterinary practitioner made an advisory visit, he or she could see that there was a plan in place and could tick boxes in checking on the health and welfare points. The issue of whether the member state or the European Commission would finance this scheme was yet to be resolved. Defra added that the health and welfare plan would not necessarily be written into European Commission proposals but might be adopted by the UK as the way of complying with an audit requirement. It would be a familiar experience for farmers in the UK, who were accustomed to farm assurance schemes.

13.27. Looking at trends in the veterinary profession, the CVO said that his general impression was that an increasing number of veterinary students were graduating. There were also many graduates from other countries being registered in the UK but they appeared to go into general practice and not the areas where there were shortfalls in supply. For example, it was difficult to persuade veterinary surgeons to go into public health, food safety, meat hygiene service, or the State Veterinary Service although there had been a good response to recent advertisements for VO vacancies with the State Veterinary Service. There was equally a problem getting veterinary surgeons to go into research. Whilst it seemed some large-animal practices could recruit veterinary surgeons easily, others found it difficult to do so. In short, whilst there were more veterinary surgeons around, they seemed to go into small-animal practice and not into other areas. If the number increased and over-supply occurred in small-animal practice, this would be likely gradually to spill over into the other areas. But the question then arose as to whether large-animal practice could afford to pay them.

13.28. We asked Defra if it could provide cost/benefit studies of four subjects relating to veterinary practice: the 24-hour emergency cover function; services in respect of wild or unowned animals or animals whose owners were unable to pay; the veterinary surgeons’ role in disease surveillance on farms; and their role in ensuring safe and appropriate use of veterinary medicines. Defra said that it had not produced, nor was it aware of, cost/benefit analyses in these areas.

13.29. The CVO noted that the desirability of maintaining the 24-hour cover provision was debated from time to time. His own view was that if an animal was suffering and required immediate treatment, it
should be treated; that the 24-hour cover was a reasonable requirement. Defra had not made any cost benefit analysis on disease surveillance, but was preparing a surveillance strategy which would be using veterinary practice more and would develop stronger partnership between the Government and veterinary practices to collect surveillance information. Defra had no information on the cost benefits associated with the role of veterinary surgeons in ensuring safe and appropriate use of veterinary medicines. However, it did monitor veterinary practices to ensure that they correctly recorded, stored and used medicines. This task fell to the State Veterinary Service on behalf of the VMD.

13.30. Turning to the requirements of the Government Veterinary Service for POMs, the CVO said that at present it did not use many, since its major use for drugs currently was for destroying animals, as part of a disease eradication policy, rather than treating them clinically. For the role of animal destruction, Defra used Euthatal, Pentobarbitone derivatives. However, Defra was just moving into the area of vaccinations. If compulsory vaccination programmes went ahead, there would be a large requirement for vaccines.

13.31. The CVO said that this had raised interesting questions. The previous policy was to kill animals and there was a contingency plan to vaccinate and kill: if there was a major outbreak of disease, Defra would use a vaccine and then kill the animals. The reason for using the vaccine would be to limit the spread of the disease and thus enable Defra to control the way in which it destroyed the animals. The status of the vaccine was immaterial because the animals were going to be killed. Now Defra had moved on to a policy which would involve vaccination to preserve life. It was going to have to use vaccines with MAs and had to buy and stockpile vaccines from companies prepared to go through an MAs process. So far Defra had purchased 15 million doses of the FMD strain that would give immunity to the cause of the outbreak in 2001.

13.32. Because of the large volumes involved, Defra had been looking to buy direct from manufacturers. It had looked at three major manufacturers but only one had an MA for the UK. Defra could not contemplate using a vaccine that did not have an MA. Therefore, the question arose as to whether MAs in one country should automatically be applicable in another, because there were two vaccine manufacturers producing vaccine in Europe for use in other European countries, which did not have MAs in the UK. Whilst the VMD had encountered this problem before, for example where vaccines for poultry diseases had been used in other countries in Europe, but were not licensed in the UK, this had been the first occasion when the issue had impacted on the Government Veterinary Service’s work. Defra was still exploring the issues of which vaccines it could use, what status they would have to have and how it would use them.

13.33. The CVO agreed that the problem would apply to other countries as well, and that, if there was a need for large-scale vaccination in the event of an emergency, the inability to move vaccines across European borders would be extremely unhelpful. Moreover, he noted that applications for MAs depended on the manufacturing company being ready to make the application, and the Government could not insist on this.

13.34. Defra outlined the timetable for possible legislation on animal health and welfare. A document on an Animal Welfare Bill had been issued for wide consultation. Defra hoped to publish a draft of this bill in autumn 2003 for pre-legislative scrutiny. A possible Animal Health Bill would revise and amend the Animal Health Act 1981, but thinking about this was still inchoate. Defra was considering how such a bill might respond to the reports on FMD and various other documents yet to be published, including an animal health and welfare strategy, and a seminar paper on sustainable agriculture. One of the issues on the animal health and welfare strategy was an attempt to deal with disease without using medicines, on the basis of husbandry systems. There was also a view that veterinary care should be moving towards vaccines rather than prophylactic continuous treatment.

13.35. Defra said that it faced a problem of resources in addressing a new Veterinary Surgeons Act, not least the shortage of time to take the various bills through Parliament. There was therefore no timetable for a review the Veterinary Surgeons Act 1966, although Defra recognized that a review was necessary since the Act was well out of date. Much of it needed to be updated in terms of human rights and professional discipline and conduct, as well as in relation to the way the profession was organized and run. There was a large issue regarding the appropriate balance between the interests of the profession and the interests of the consumer of the profession’s services. But no view had yet been formed. Another area to be looked at was the use of paraprofessionals, that is non-veterinary surgeons undertaking some of the work which veterinary surgeons had done in the past. There would be a review of all the Articles.
in the Act, but it was unlikely to be brought forward until well after the Animal Welfare Bill had been enacted.

**National Assembly for Wales**

13.36. Mr Carwyn Jones AM, Minister for Rural Affairs, said that any move that reduced the costs of medicine to industry was welcome. However, because of the nature of POMs, any changes in their supply and any associated cost reduction must not be at the expense of the level of control over their use.

**Veterinary Medicines Directorate**

13.37. The VMD explained that in its handling of applications for MA it acted as executive arm of the licensing authority (the Ministers responsible for health and agriculture in the UK as a whole, Scotland and Northern Ireland). It also played a central role in the surveillance of adverse reactions to veterinary medicines and in the monitoring of medicines residues in food. It advised the Government on policy matters arising from the availability, use and regulation of veterinary medicines and prepared regulatory impact assessments as inputs to decision-making. Further advice to Ministers on both scientific and policy issues was given by the independent VPC. Its staff participated in relevant international expert committees, including those of the EC through which it had influence on European policy formulation as well as on individual MA applications under the centralized procedure.

13.38. The VMD told us that, in regard to veterinary medicines, the primary concern of its parent government department, Defra, was the control of disease in farm animals and in their welfare. Corresponding concern for companion animals was secondary. The VMD told us that economic considerations, including effects upon price, were not taken into account when reaching decisions on the authorization of individual veterinary medicinal products. In the context of any specific medicine, animal welfare was, for the VMD, the welfare of the animal treated with it. The extent to which animals needing that treatment would go untreated for reasons of cost was not taken into account and in the VMD’s view ought not to be.

13.39. The availability of a sufficient overall range of medicines was of concern to the VMD which believed there were gaps in the armoury of veterinary medicines. The pattern of availability of veterinary medicines in the UK was fairly stable. For the past three to four years the numbers of medicines withdrawn from the UK market had been in broad balance with the numbers of new authorizations (total MAs in force fluctuating around an average of 1,950). Out of an average of some 80 MAs a year, the VMD said that fewer than ten were of novel medicines incorporating molecules new to veterinary medicine, and that this number was declining.

13.40. In accordance with EC legislation, the ‘three pillars’ of safety, efficacy and quality were the basis for the VMD’s assessments of applications for MA. It told us that it considered classification, as POM or otherwise, to be an aspect of the control of risk. Prescription-only classification was seen as the least risky of the options available and, where the law allowed other choices, the VMD’s policy was to regard it as the default, especially where the medicine contained a new active substance, to be applied if the applicant made no other suggestion. It told us that a company making an application for prescription-only classification would be likely to receive it. It noted that in its experience, lower-classified medicines tended to have higher turnovers, giving manufacturers a commercial incentive towards the lower classifications.

13.41. Early in our inquiry the VMD saw choice of classification not as a matter for itself but one for the MA applicant and for the VPC. More recently it said that acceptance of our hypothetical recommendation that manufacturers’ views should not be taken into account in classification decisions was subject to consideration of possible legal liabilities and the applicant’s retaining the right of appeal.

13.42. The VMD opposed the European Commission’s proposal that all medicines for food animals should be permanently classified prescription-only. It was also opposing the European Commission’s proposal that five-yearly renewals should no longer be required and MAs should have permanent validity, provided the product was marketed within a rolling two-year period. This proposal was linked to more frequent reporting on strengthened pharmacovigilance and retention of the existing requirement
that dossiers be updated as scientific understanding advanced. The VMD regarded this as more uncertain and just as onerous as the existing requirement for five-yearly renewal of MAs.

13.43. The VMD told us that in the case of medicines initially, but not necessarily permanently, authorized as prescription-only (for example, medicines containing an active ingredient new to veterinary medicine and therefore required to be classified POM for five years), it did not automatically review classification when MA renewal became due after five years. It considered it to be for the MA holder to request any review of classification. However, it told us that, bearing in mind the implications of imposing a change to the test of product labelling in the event of a forced classification change, it might accept our hypothetical recommendation that each medicine’s classification should be regularly reviewed, subject to clarification of the legal liabilities it could incur. In particular it considered it logical, where a product was legally required to be classified POM because it was novel, to review its classification when the legal requirement expired after five years.

13.44. The VMD said that it kept the efficiency of its procedures under review (as it was required to do by Ministers). It also set itself publicly available target timings for the completion of the stages of MA assessments and monitored their achievement. On the basis of practical experience and discussion with companies, the VMD did not accept that the US practice of carrying out regulatory procedures in stages led to earlier outcomes than in Europe where complete dossiers must be submitted before assessment could begin. It opposed our hypothetical recommendation to allow, as an option, the submission of dossiers in stages, arguing that this would bring no improvement in efficiency. It also considered dangerous our hypothetical remedy to allow provisional MA to be given as part of normal procedure before the manufacturer’s efficacy claims had been verified. It could be at legal risk, for example if harm were attributed to a veterinary medicine which it was alleged the VMD had authorized after insufficiently rigorous assessment.

13.45. The VMD was alert to the views of manufacturers. It had three regular meetings each year with NOAH (the trade association representing the majority of manufacturers of veterinary medicines). However, the VMD accepted that, despite these and other meetings and seminars, misunderstandings with manufacturers still occurred.

13.46. Commenting on the operation of the European decentralized procedure, the VMD said that applications under that procedure amounted to a growing proportion of the total, and that it acted as reference member state in some 60 per cent of the decentralized cases in which it was involved. It believed that only one member state had acted as reference member state in more cases.

13.47. The VMD was aware of criticisms that the decentralized procedure was not applied uniformly by the national authorities of all EC member states. In its view there had been differences in the ways in which existing products were dealt with in the transition from previous national procedures to those now in force throughout the EC. The VMD told us that a sustained effort, in the training of assessors and otherwise, was bringing about a common understanding across Europe. It considered that applications for new authorizations were now being treated with greater consistency by all member states’ authorities. The VMD agreed in theory with the argument that MA given by any member state should require no substantive re-examination for the product to be marketed in any other part of the EC (though it would be important to ensure that traceability was not jeopardized). In practice, however, the risk assessments underlying regulatory decisions were intrinsically judgemental and it would be very ambitious to ask national scientific experts to accept such judgements unquestioningly.

13.48. The VMD contrasted the decentralized and centralized procedures. In the former, member state authorities carried out separate assessments in isolation, followed as necessary by reconciliation of differences. Under the centralized procedure a single assessment was first scrutinized by co-rapporteurs and then made the basis of a collective opinion by the CVMP, on which all member states had expert representation. Agreement was just as difficult but it had the potential to be reached more quickly. The VMD considered that all types of veterinary medicine should qualify for authorization through the centralized procedure though this should be optional in all cases. It also pointed out that, following discussion by the CVMP, the European Medicines Evaluation Agency had begun to extrapolate MRLs for minor species from major-species data in cases where this was scientifically justified.

13.49. We were told by the VMD that the cascade was widely used in the UK. The authorities of other member states regarded its use as exceptional. Adoption of the European Commission’s proposed changes to the cascade, in particular its placing of a veterinary medicine authorized in another EC
member state at the same level as a human medicine, would be likely to reduce the UK’s veterinary use of human medicines. The VMD considered that relaxation of the cascade to allow much wider use of human medicines as alternatives to authorized veterinary medicines would remove manufacturers’ incentive to obtain or renew veterinary authorizations and would increase the safety risk for the target animal. To remove the rankings of the options provided by the cascade would, in its view, create risks that were avoidable and therefore unacceptable.

13.50. As regards access to the cascade on cost grounds, the VMD pointed to the guidance given in paragraph 23 of its document AMELIA 8, which went as far as was legally possible towards the needs of owners, unable to afford treatment, to evade specific authorized products.

13.51. The VMD told us that in its view there were relatively few examples of veterinary medicines that were directly interchangeable and could be regarded as substitutes for one another in all circumstances. Although alternative treatments for particular species and conditions were not uncommon in some therapeutic categories, these products often differed pharmacologically and in aspects of presentation, including palatability. They could not, in the VMD’s view, be regarded as direct substitutes. Alternative products indicated for the same treatment might not be interchangeable for a range of reasons: because of differences in active ingredients, strengths, mode of administration and additional indications. Both veterinary generics and their reference products, and ‘copycat’ products (the same product marketed under a different name) and their parent products, might be regarded as interchangeable in terms of their active ingredients. However, even in these cases, the authorized indications might differ between products, and they were not therefore always interchangeable in terms of authorized treatments for a particular condition in a particular species.

Other bodies

Animal Health Distributors Association

13.52. The Animal Health Distributors Association (AHDA) told us that there were around 1,000 agricultural merchants premises registered for the sale of PML animal medicines. The AHDA represented the owners of some 70 per cent of these. Farmer cooperatives were among its larger members. There were a few pharmacists who registered their premises as agricultural merchants, rather than pharmacies.

13.53. Commenting on the role of pharmacies, the AHDA thought it was unlikely that existing pharmacies would choose to expand to cope with any increased demand for dispensing prescriptions.

13.54. The AHDA did not know whether agricultural merchants generally thought that prices of veterinary medicines were higher in the UK than in other European countries. It was not aware of any firm evidence except in the case of certain products from the Republic of Ireland, which were cheaper. Many of these were intramammaries, available through milk cooperatives in Ireland without prescription. It was possible that this different distribution route had an effect on prices.

13.55. The AHDA said that although the use of all medicines carried a risk if used incorrectly, there was generally a greater safety margin with PML medicines than with POMs. AHDA members were involved in the campaign to prevent the development of anthelmintic resistance by promoting rotation and the prevention of under-dosing.

13.56. The AHDA said that there was healthy competition among agricultural merchants. It felt that manufacturers had contributed to some distortion in the market by charging customers different prices.

13.57. It said that since it was set up in 1985 it had maintained that some medicines currently classified as POM could safely and appropriately be reclassified as PML and thus made more widely available. This would almost certainly increase competition and lead to significant price reduction for the end-user.

13.58. It said that several factors might influence a manufacturer’s decision not to apply for a change of classification, including a wish to avoid upsetting its commercial relationship with the veterinary profession and the cost of producing the evidence that would be needed to support an application.
13.59. The AHDA believed that agricultural merchants could provide animal medicines economically and efficiently because they were able to spread their overheads across their whole merchanting business, which the veterinary profession was unable to do.

13.60. The AHDA was concerned about the EC proposal, which would force all medicines for food animals to be classified as POM. Implementation of this would create a total monopoly, leading to significantly higher prices for medicines, which were now PML. It would effectively put the AHDA’s members out of business. From monitoring that had been done in the UK, there was no evidence of PML residues in food or any food safety problem. The AHDA therefore totally supported our possible Recommendation (6) in the statement of 17 September. It would welcome a wider recommendation, namely to encourage the Secretary of State to persuade other member states to support the UK’s opposition to the European Commission’s proposed amendment to Article 67.

13.61. In its comments on our other possible regulatory recommendations, the AHDA said that manufacturers certainly had a commercial interest in the classification of a medicine, which worked against the interests of agricultural merchants, animal owners and competition. There was a bias in the system towards the most restrictive classification. Nevertheless, it would be counterproductive totally to preclude manufacturers from putting forward a view on the classification of medicines for which they sought authorizations (Recommendation (3)). There were situations where manufacturers sought a PML classification. Indeed, there had been instances when the VPC imposed a POM classification despite the manufacturers’ arguments in favour of a PML classification. The AHDA proposed that our recommendation should be that the VMD and the VPC should classify a product in the least restrictive category possible, consistent with animal welfare and safety to the animal and the administrator.

13.62. The AHDA agreed with the proposal that the VMD should be asked to consider instituting automatic review of a product’s classification whenever its MA was renewed etc (Recommendation (4)) which it had proposed for many years. It would like to see the VMS’s remit widened to take account of the welfare of animals overall (Recommendation (5)). It supported possible Recommendation (7) noting that, although all centrally-authorized animal medicines had been classified POM, there was no legal obligation for this under EC law. More flexibility within the regulations should be exercised by the authorities. The AHDA supported Recommendation (8).

13.63. The AHDA supported possible Recommendation (10), stating that the absence of PML-registered pet shops reduced the incentive for the classification of more pet medicines as PML medicines, since the outlets for their sale and supply did not exist.

13.64. The AHDA supported possible Recommendations (11) and (12) but pointed out that, like AHDA, the RPSGB was already fully involved in the development and extension of AMTRA training.

British Equestrian Trade Association

13.65. BETA said that it represented equestrian-related industries and included companies that manufactured, supplied and retailed PML products. Almost 400 of its 650 members were retailers.

13.66. It was concerned about the apparent domination of veterinary surgeons in the supply of POMs. Only through a more open market would usage and availability increase.

13.67. BETA said that PML medicines sold by saddlers and agricultural and feed merchants were mainly equine anthelmintics but included a few cat and dog wormers. PML products were purchased initially through animal health wholesalers. PMLs were sold through premises registered with the RPSGB and each individual sale had to be authorized by an SQP. It was only over the last ten years that equine retailers and saddlers merchants had had the right to sell PML wormers. Formerly, these products could be purchased only through veterinary surgeons. The change had led to a more competitive market, widened the availability of the product and in the long term reduced prices to the consumer. The overall health of the equine population had increased dramatically.

13.68. BETA said that many saddlers and feed merchants now relied on the sale of PML products, which represented up to 40 per cent of revenue, to maintain their turnover. The return to a monopoly situation would be devastating for many businesses, which would lose out both in direct sales and loss of customers for other products. There would be an adverse effect on animal welfare.
13.69. BETA disagreed with the proposed amendment to the EC code, which would classify all medicines for food animals as POM. Horses were considered as food animals in the rest of Europe. If the PML category disappeared, distribution of products would again be limited to veterinary surgeons, strengthening a current monopoly. Prices to the consumer would rise.

13.70. BETA argued that products such as topical wound dressings and external parasite treatments, which were POMs, should be reclassified as PML, to free up the market and increase the controlled access of animal owners to appropriate medicines.

13.71. Commenting on rebate and discount schemes, BETA had no evidence to suggest that the financial incentive provided by discount schemes led to overuse of medicines. It noted that because veterinary surgeons’ prices were not transparent, it was difficult to compare them with those of other retailers. It thought that prices had been driven down in areas where agricultural merchants and saddlers were in direct competition with each other.

13.72. BETA believed that pharmacies were unlikely to be interested in stocking veterinary products, either POM or PML. It would not be economically viable for agricultural merchants or saddlers to establish pharmacies within their premises.

13.73. BETA could not comment on whether UK prices of equine medicines were higher in the UK than elsewhere in Europe, except to note that it had occasionally seen imports from the Republic of Ireland, which indicated that prices there were lower. Manufacturers’ prices seemed to be lower, but the exchange rate also gave a price advantage. One example was Spot-on for cattle, which had a slightly different pack and presentation but arrived in the UK 10 or 15 per cent cheaper than the UK-licensed product. BETA was also aware of mail-order supplies of horse wormers from the Republic of Ireland that were cheaper than the same products in the UK.

Canine Epilepsy Support Group

13.74. The Canine Epilepsy Support Group was concerned at the high cost of POMs for the treatment of epilepsy. The group said that it had received many calls from distressed owners who had seen the cost of medication for their pets rise dramatically.

Lincolnshire Rescue Kennels

13.75. Lincolnshire Rescue Kennels (LRK) said that it was contracted by the Lincolnshire Constabulary, Lincoln City Council and other district councils to receive, care for and rehome all the stray dogs from Lincoln, Newark, Gainsborough and large tracts of rural areas in Lincolnshire. It handled 1,000 dogs a year. Since the vast majority of stray dogs had not been vaccinated and some carried infectious diseases, the obvious precaution would be to inoculate them immediately they were taken in. LRK said that for the last eight years it had tried to instigate such a programme, similar to those run by charities such as the RSPCA and National Canine Defence League, which had their own in-house veterinary surgeries. The drug companies sold the required vaccine for £2 or less, but they could only sell them to veterinary surgeons, who increased the price to between £20 and £30. Veterinary surgeons were allowed to train lay people to administer vaccines, but LRK told us that it was not aware of any who were willing to forgo what it perceived as vast profits to retail vaccines at a reasonable price. Some drug companies had even offered to supply some free vaccines to LRK if it could source a prescription, but that had proved impossible to achieve.

13.76. LRK observed that, in the Republic of Ireland, the USA and many other western countries, vaccines were available to the general public OTC. To vaccinate all its dogs would cost up to £35,000 a year under the present system, but in the Republic of Ireland it would cost £3,000. LRK said that there were many breeders who vaccinated a significant number of dogs and who would also benefit from a less restrictive system.
13.77. The NFU said that it represented some 65,000 commercial farmers in England and Wales (around 70 per cent of farms) and the interests of a further 80,000 countryside members.

13.78. The NFU had three areas of concern about veterinary medicines: safe and responsible use, particularly in relation to food safety; ready availability, in the interests of animal health and welfare; and costs. High prices of medicines had been a source of concern to its members over some years, particularly in view of the lower prices that appeared to be available outside the UK. There was anecdotal evidence that drugs were cheaper elsewhere in the world. Republic of Ireland price differences had caused particular concern, but for New Zealand, South America and North America price differences were to be seen on the Internet. The NFU said that farmers were badly placed to negotiate either with veterinary surgeons or with manufacturers and wholesalers.

13.79. It was concerned about the lack of transparency in the prices charged by manufacturers and veterinary surgeons. Wholesalers were effectively distributors for the manufacturing companies, working on low margins, and were not particularly important in considering price issues.

13.80. The NFU thought that the veterinary profession was not sufficiently aware of the financial problems facing farmers. Unless veterinary surgeons took steps to help reduce costs of medicines, for example through buying cooperatives, the profession would face serious consequences. Farmers who could not afford veterinary services had no choice but to resort to the humane killing of sick animals.

13.81. The NFU observed that there were local monopolies in parts of the country where there were no other veterinary practices for a considerable distance. Even if choice existed, farmers were often reluctant to change veterinary practice or obtain medicines from other sources. The farmers’ relationship with professional practitioners was long-term and personal, which made negotiation about prices difficult. Veterinary surgeons were reluctant to provide quotations when asked or to compete for new clients.

13.82. Commenting on the 17 September statement of provisional findings and hypothetical remedies, the NFU welcomed the provisional finding that a complex monopoly operated and believed that all the possible remedies listed would help to improve transparency and competition. Although it would be concerned if the scenario foreseen by veterinary surgeons developed as a result, it believed that 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, given lower livestock numbers and the changing needs of farmers.

13.83. The NFU said that veterinary surgeons should have a more inventive approach to providing services—for example, by cooperating with each other to provide emergency cover. Some had already made changes, developing lower charges for planned visits, herd health plans and regular attendance, but more competitiveness was necessary. The effect of the CC’s recommendations would depend partly on a constructive dialogue between the NFU and the veterinary associations on the way forward. Veterinary surgeons should develop business-marketing skills rather than continue with the present ways of operating, which appeared to discourage efficiency. Farmers also needed to develop their business skills.

13.84. The NFU said that veterinary bills were usually itemized, but lacked transparency because the dispensing function was not separated from service provision. More transparency on the costs of dispensing would encourage a more competitive and less complacent attitude by veterinary surgeons towards purchasing policies.

13.85. The NFU considered that farmers were not generally aware of their rights to request prescriptions for dispensing elsewhere. Competition would be introduced if veterinary surgeons issued prescriptions but the NFU thought a maximum price should be set. It was aware of a veterinary surgeon who, on being asked for a prescription, said that he would issue a separate prescription for every item and charge £15 per item.

13.86. The NFU was not in favour of the suggestion that veterinary surgeons should be enabled to write prescriptions on an ‘or equivalent’ basis, leaving the choice to the pharmacist. A better way
forward would be if farmers had list prices from the veterinary surgeon and from the pharmacy for equivalent products, which they could discuss with the veterinary surgeon.

13.87. Commenting on regulatory suggestions, the NFU was concerned at the small number of veterinary medicines that could be traded across EC borders and supported the CC’s proposals to widen the categories of medicines eligible for the centralized register. It fully supported the proposal to improve competition by legitimizing cross-border trade between member states without the need for further MAs for medicines approved through the decentralized procedure.

13.88. The NFU supported the possible recommendations for regulatory change in relation to the manufacturers’ role in the classification of animal medicines (Recommendations (3), (4) and (5)). It said that it would welcome amendments to the remits of the VMD and the VPC as part of the effort to ensure an impartial assessment of product classification.

13.89. The NFU welcomed the CC’s suggestion that the Secretary of State might oppose the European Commission’s proposal to classify all medicines used for food animals as POM. The PML classification system had been satisfactory and any move in the other direction would discourage competition. Compared with POMs, there was more competition in PML medicines, even those bought through veterinary surgeons, because they had to compete with agricultural merchants.

13.90. If, following adoption of the EC Directive, most medicines were to be POM, the NFU said that it was essential that rights were given to registered agricultural merchants and saddlers to dispense veterinary prescriptions for medicines that would have otherwise been classified as PML.

13.91. The NFU supported changes to the draft Directive on the classification of animal medicines to ensure that member states controlled channels of distribution and supply of veterinary medicine.

13.92. The NFU stated that it was essential to have a classification review mechanism for centrally authorized regulations under the draft EC Regulation, as indicated in the CC’s Recommendation (8).

13.93. It agreed with the CC’s analysis that recommendations to counter the over-narrow definition of POMs would fail if there remained unjustified barriers to entry into the retailing of PMLs. The NFU said that it welcomed possible Recommendations (10), (11) and (12) in principle but would need to consider these proposals.

13.94. The NFU stated that, subject to the caveats noted by the CC, it welcomed the proposal to make MAs permanent to reduce costs and encourage applications, to streamline the application process, to provide PMAs and to provide for extrapolations for MRLs for minor food species from large food species (Recommendations (13), (14), (15), (16) and (17)).

13.95. The NFU said that the small number of generic products on the market meant that price competition from them was relatively weak. It therefore supported the proposed changes to the cascade to improve this situation (Recommendations (18) and (19)). In its view, severe problems were emerging about the availability of medicines and an undesirable increase in the use of the cascade. An example of a product that had been withdrawn because manufacturers thought it not worth their while to renew the authorization was lignocaine, used as a bovine anaesthetic.

13.96. The NFU fully supported Recommendation (20) asking the Secretary of State to consider changing the law to allow veterinary surgeons to dispense prescriptions for animals not under their care.

National Farmers’ Union Scotland

13.97. The NFUS said that it represented Scottish farmers, growers and crofters. It had some 12,000 members, some 80 per cent of all farmers in Scotland. Most were livestock producers.

13.98. The NFUS said that the livestock industry had been adversely affected since 1996 by BSE, FMD and the effects of a strong pound. The industry had reviewed its cost base in the light of renewed government pressure to become more competitive and this had focused attention on the price of veterinary products.
13.99. The NFUS said that livestock producers in Scotland had to pay more for POM products than producers in other EC member states. Differentials in prices between the UK and other countries, most notably the Republic of Ireland, encouraged the development of a highly undesirable black market in illegally imported veterinary products, the efficacy and safety of which could be highly questionable. This jeopardized the health, welfare and provenance of Scottish livestock and undermined the competitive position of the livestock industry in Scotland, where its predominance made the cost of veterinary products a particularly important and sensitive issue.

13.100. The NFUS said that, whilst it agreed with the manufacturers that monetary exchange rates, the high cost of licensing, and supply and distribution arrangements in the UK all had a bearing on the ultimate cost of veterinary medicines, it believed that the pricing policy in different countries was also based on what the manufacturers believed the market would bear. But manufacturers had misjudged this; although livestock values had declined over the last few years, there had been no reduction in prices.

13.101. The NFUS said that veterinary product manufacture in the UK was dominated by a small number of large companies. Whilst greater competition between veterinarians and pharmacies might go some way towards reducing the prices to producers of POM products, the real solution lay with the manufacturers and their dominance of the UK market.

13.102. The NFUS said that it was difficult to identify the true cost of a product to veterinary surgeons because their prices included an amount to cover or subsidize call-out costs. The NFUS supported greater transparency in prices, to improve competition. But it observed that a reduction in veterinary surgeons’ margins on medicines would necessarily result in a corresponding increase in call-out fees. Any disruption to the financial viability of veterinary practices would jeopardize the health and welfare of farmed livestock and was the last thing livestock producers wanted. Large-animal veterinary practices were already scarce in the more remote areas of Scotland. The NFUS said that north of Inverness there were only five scattered veterinary practices, which were subsidized by the Highlands and Islands Veterinary Service.

13.103. In commenting on the provisional conclusions and hypothetical recommendations, the NFUS expressed surprise that the CC had focused possible remedies so heavily on the veterinary profession and not paid more attention to the pricing policies of manufacturers.

13.104. The NFUS would support moves aimed at ensuring that those manufacturers that gave rebates provided sufficient information to veterinary surgeons to enable them to ascertain the net cost of POMs. This was an essential starting point for calculating a realistic retail price to the client.

13.105. The NFUS would support a requirement for manufacturers and wholesalers to supply pharmacies. Competition could not work if one section of potential suppliers was unable to obtain the product.

13.106. It supported the proposed remedy that veterinary surgeons should offer prescriptions for POMs. It also agreed that the price charged for writing a prescription should be clearly indicated to the client. It suggested that clients should be informed about dispensing options and about the price of writing a prescription by a notice in the surgery waiting room and verbally by the veterinary surgeon at the start of the consultation. Veterinary surgeons answering a call-out request to a farm could similarly be required to inform the farmer at the start of the visit that he or she could ask for a prescription, and to advise the farmer of the charge that would be made. This information could also be communicated to farmer clients by post.

13.107. The NFUS stated that, for clients to be able to make meaningful comparisons between the prices charged for POMs by competing practices and pharmacies, a requirement for veterinary surgeons to provide clients with itemized bills was essential. It agreed with the proposal that veterinary surgeons should inform clients of the price of any POM they proposed to dispense. Whilst displaying lists of the prices of the most commonly dispensed POMs in the surgery would be helpful for clients attending surgeries, it would be of little benefit to farmer clients. The NFUS suggested that veterinary surgeons could provide product price information, using both proprietary brand and generic names, on a price list posted out to farmer clients, once or twice a year, with their invoices.

13.108. Whilst in agreement with most of the CC’s hypothetical remedies, the NFUS stated its concern that single-minded attention to price alone could benefit high-volume products at the expense of products with lower volumes and potentially higher prices, with possibly unfortunate implications for animal health and welfare. To avoid clients being misled by price in considering the suitability of a product, and to
highlight other considerations, price lists should include a simple star rating or tick-box system for each product to draw attention to its strengths or weaknesses in these fields.

13.109. The NFUS would support a requirement for veterinary surgeons, when writing a prescription for POMs, to do so on an ‘or equivalent’ basis: this would introduce much-needed flexibility to the system.

13.110. Commenting on regulatory matters, the NFUS recommended that the present costly veterinary product licensing and MRL arrangements in the UK should be subjected to a risk assessment analysis to ensure that they were all necessary. Manufacturers were deterred by the costs from seeking to license and establish MRLs for products for which there was a limited market. That restricted both competition and access to these products. The excessive length of time regulators took to reach a decision about MAs was a barrier to new products and made the cost of products more expensive.

13.111. The NFUS said that moves aimed at freeing up the availability of veterinary medicines throughout the European single market were important to encourage competition and for the achievement of greater price convergence throughout the EC. It therefore supported the proposal which would allow all categories of veterinary medicine access to the European centralized procedure, so that they could be traded across EC borders.

13.112. The NFUS would support a proposed change to the EC draft Directive to legitimize cross-border trading, without the need for a further MA, of any veterinary medicine authorized through the decentralized procedure, between member states in which it was authorized. Barriers to labelling in the appropriate language should also be removed.

13.113. The NFUS was strongly opposed to the European Commission’s proposal that all veterinary medicines for food animals should be classified POM. If, however, the European Commission’s proposal on POMs were eventually realized, the NFUS would support the CC’s possible recommendations for dealing with the new situation, particularly Recommendation (9).

13.114. The NFUS would favour moves to review the classification of veterinary products currently classified as POM, with a view to making those used for routine disease prevention—other than antibiotics—available under a different and potentially less costly classification. This would improve access and reduce bureaucracy and cost, without compromising standards of health, welfare or safety.

13.115. It supported the suggested recommendations for reducing the cost and time taken in obtaining and maintaining MAs for veterinary products, which appeared to be excessive in the UK. Such moves should help reduce the cost of the product to the client, and potentially help competition by reducing the cost deterrent to new market entrants.

13.116. The NFUS had concerns about possible Recommendation (16). Releasing a product on to the market without completion of its efficacy assessment could result in farmers and others wasting money on a product which might turn out to be ineffective. If new products were to be marketed without an efficacy assessment, its absence must be clearly indicated on the product packaging, so that purchasers knew that they might be taking a risk in using it.

13.117. The NFUS suggested that commercial exotic species and fibre-producing animals should also be eligible for the cascade arrangements envisaged in Recommendation (18).

13.118. The recommendation which would allow a veterinary surgeon to dispense a veterinary prescription, whether or not the animal concerned was under his or her care, had the support of the NFUS.

National Office of Animal Health

13.119. NOAH said that it was a trade association representing companies which researched, manufactured and held MAs for animal medicines in the UK. Of its 48 members, 36 were corporate members—manufacturers who were MA holders. The 12 associate members provided services to the industry.

13.120. NOAH observed that, with a UK turnover of only £352 million, the veterinary medicines industry was very small. Its corporate members sold, by value, about 95 per cent of all animal medicines
in the UK. About one-quarter of them also manufactured human medicines, a lower proportion than ten years ago.

13.121. NOAH pointed out that the discovery and development of new products was an uncertain process. Most potential products failed to progress to full registration and their costs had to be covered through the sales of successful marketed products. Manufacturers had to recoup the initial costs before generic equivalents reached the market.

13.122. NOAH said that it was not in a position to make direct comparisons between UK and non-UK manufacturing costs, but noted that price differentials were caused by a number of factors, including R&D and transport costs. In the UK, 94 per cent of MAs were wholly national—neither mutually recognized nor centralized. UK subsidiaries had to bear the costs of authorization and reflect them in the UK price. Prices were also influenced by what the local market could bear.

13.123. It was NOAH’s view that effective competition existed in the veterinary medicines market. Whilst price was a significant feature, technical efficacy, perceived differences in speed of action and individual preference (for example, related to the method of application) also influenced the veterinary surgeon’s choice of product. A reduction in price would not necessarily lead to greater sales.

13.124. NOAH was not aware of any barriers to entry. While mergers continued among larger companies, new smaller companies from both the UK and elsewhere were entering the UK market. The practice of discounting did not appear to discourage new entrants. There was evidence that small and medium-sized companies were enjoying growth.

13.125. NOAH said that the principle of retrospective discounts had been created by the nature of distribution. There was no infrastructure for dealing with hundreds of small outlets and rebates and discounts could not be calculated until the details of completed transactions were known.

13.126. NOAH considered that there was a case for more transparency in the charges made by veterinary surgeons and merchants which could be achieved through itemized billing. However, historically, veterinary surgeons had covered much of their costs through a mark-up on medicines and if that were reduced, their business operating costs would need to be recovered in other ways.

13.127. Commenting on the alleged difficulty which pharmacists experienced in obtaining veterinary medicines, NOAH said that manufacturers did not normally supply direct to any retail outlets, whether high-street pharmacies or veterinary practices, and any enquiries from retailer pharmacists would tend to be referred to wholesalers.

13.128. NOAH said that the effects of increased sales by pharmacists would differ according to the animal species, type of area, and the nature of illness and whether the animal was in the food chain or was a companion animal. However, it believed that the inconvenience to clients of obtaining prescriptions and having them dispensed at a high-street pharmacy could reduce compliance, to the detriment of animal health.

13.129. NOAH was particularly concerned about the burden of regulation on manufacturers. It considered that the animal medicines supply chain in the UK was more highly controlled and burdened by regulation than any other industry in Europe. The VMD required a detailed dossier of data on the quality, safety and efficacy of a new product, which could take months to be assessed. NOAH was also concerned about the detail required by the Home Office for licensing laboratory work and considered that the Health and Safety Executive was far more enthusiastic than its counterparts in other countries. R&D was being driven out of the UK because multinational companies tended to undertake trials in other countries with lower regulatory costs.

13.130. NOAH thought that until the guidelines for licence renewal procedures were enforced more rigorously in other EC countries, there would continue to be higher cost implications for UK manufacturers. In product categories which had a turnover of less than £1 million a year, there had been 60 licence withdrawals in the past five years, the reason being primarily the cost of maintaining the product or renewing the licence.

13.131. The cost of maintaining a product on the market was not only the known cost of annual licence renewal but the possibility of further studies requested either under new EC directives or by the
UK authorities. There were also ongoing major costs of generating new data for old products at their five-year renewal intervals. The requirement to update dossiers for products with a proven safety and efficacy record appeared to be unique to the UK. For low turnover niche products, the investment needed to meet these requirements was often not commercially justified: a possible example of ‘gold plating’ of regulations in the UK.

13.132. NOAH commented on our possible recommendations for regulatory change. It welcomed proposals to open the centralized procedure to more products but agreed that companies should not be compelled to use this route, which was not appropriate for all circumstances. It did not agree with possible Recommendation (2) because, it said, a perfectly acceptable, rapid and inexpensive system existed; it was important that the MAPI system remained in place to ensure that products which did not have identical formulation between member states but which might have similar names were not imported erroneously. Furthermore, it was important that regulatory agencies continued to control this situation so that, should prompt pharmacovigilance action be necessary, a product could be recalled from all countries.

13.133. NOAH did not agree with possible Recommendations (3) and (4) concerning classification of medicines. It said that the VMD and the VPC should always consider arguments put forward by manufacturers, which knew more about the product than anyone else. The regulatory process had a tendency to favour POM classification over PML/GSL, and by ignoring the arguments of the manufacturer, the CC’s proposals might be counterproductive. Moreover, some companies might only have a sales, marketing and technical support infrastructure that operated in a specific market (veterinary surgeons only or merchant trade only). If such a company were forced to launch a product under a specific licence category that dictated distribution routes, through a market sector where it did not have a presence, it would either have to identify and adopt another marketing partner or invest in additional sales and marketing staff. That might not be economically viable.

13.134. To review all 2,000 authorized products every five years would be quite disproportionate, given that only about 20 products had been identified as ‘wrongly’ classified POM by organizations such as the AHDA. It would increase costs for manufacturers, ultimately inflating the cost of UK-authorized medicines. A more appropriate review would be that which NOAH had supported in proposals put forward by the VMD in a public consultation in 2000, allowing third parties to initiate a review of individual products, provided this was at no cost to the primary authorization holder.

13.135. NOAH supported possible Recommendations (5), (6), (7), (8), (10), (11) and (12). It opposed the EC proposal to classify all medicines for food animals as POMs; that would be counterproductive and probably lead to increased prices. At present, farmers were able to shop around to get the best price from merchant outlets for PML medicines. But if this EC proposal went through, NOAH would support our suggested Recommendation (9).

13.136. NOAH supported possible Recommendations (13), (14) and (15). It opposed possible Recommendation (16), which would allow commercialization to begin before efficacy assessment was completed. It said that the PMA system already worked well. Animal welfare could be compromised by permitting products on to the market without proven efficacy.

13.137. NOAH fully supported the aims of possible Recommendation (17) but pointed out that the problem was not with the Directive, but with the practice of the CVMP. The Directive and MRL Regulation did not require MRLs to be set for specific species: indeed, that was scientifically a very dubious concept. NOAH said that the process for extrapolating current MRLs needed to be much simplified. Another useful change that could be made in the draft Directive would be to allow certain groups of animals not destined for the food chain (such as horses or rabbits) to be considered by individual member states as non-food animals. That would allow medicines for such animals to be authorized without the need for an MRL or residue studies to determine a withdrawal period.

13.138. NOAH opposed possible Recommendation (18), which would allow veterinary surgeons to choose whichever options they considered best where non-food animals were concerned. Cats and dogs had as much right as food animals to properly researched and specifically formulated animal medicines.

13.139. It was very important to differentiate between veterinary generics (which were perfectly legitimate, and already came at the ‘top’ of the cascade where the veterinary surgeon chose the most appropriate authorized veterinary product from those available) and human generics. Whilst human
products might have the same active ingredient at the same concentration (though this was often not the case with tablets), the excipients used might not be suitable for all species. NOAH was also concerned that adverse reactions to human medicines used in animals were not adequately monitored.

13.140. NOAH said that the amount of new and innovative research for establishing the use and dosage of existing medicines in human pharmaceuticals for use in the veterinary field was limited, as companies could not justify the high costs and relative short recouping periods. This was causing a ‘new animal medicines’ availability crisis, as there was little incentive for a company to conduct research if it knew that human generics could be used with impunity as soon as its licence had been granted and used under the dosage recommendations established by a veterinary manufacturer. Therefore, possible Recommendation (18) could be very damaging to the future development of the animal medicines market.

13.141. On possible Recommendation (19), which, on the grounds of animal welfare, would allow veterinary surgeons recourse to the cascade, notwithstanding the existence of authorized medicine, NOAH felt that such a provision could easily be abused and was not appropriate for private veterinary practice.

**People’s Dispensary for Sick Animals**

13.142. The PDSA said that it was the largest veterinary charity in the UK. Its objective was to provide a free veterinary service for sick and injured animals for people who, in its opinion, could not afford private veterinary fees. It did not currently carry out preventive treatments such as vaccinations.

13.143. The PDSA said that it had 45 animal hospitals and around 240 veterinary practices contracted to provide services on its behalf. It also provided financial support for some customers not covered by these services, helping with private veterinary bills. In order to avoid the administrative costs of means testing, it restricted its service to people in receipt of means-tested benefits. The organization treated mainly small, domestic companion animals.

13.144. In the last financial year, the PDSA’s pharmaceutical expenditure amounted to £2.5 million, with an additional £0.5 million for consumables such as bandages, injections and syringes.

13.145. It expressed concern that margins on drugs were determined by reference to list prices, although actual costs to veterinary surgeons were reduced by discounts given by both manufacturers and wholesalers. It felt that the result was a disproportionately high cost to the end-user, with adverse financial consequences particularly for people with chronically ill pets. It accepted that customers were reluctant to pay consultation fees, especially in circumstances where medication had not been provided. It believed, however, that a more practical approach to charging for professional services, which took a realistic account of overheads, would result in lower drug costs and better consumer understanding.

13.146. The PDSA said that its drug purchases were made centrally. It conducted periodic competitive tendering exercises with manufacturers and wholesalers, taking into account both volume discounts and service and quality considerations. Levels of settlement discounts from wholesalers were in the region of 12 per cent, and from manufacturers between 2 and 46 per cent. A decision to deal with only one wholesaler had been taken to strengthen the PDSA’s buying power. Lower administrative costs were an added benefit.

13.147. Whilst there was considerable overlap in products from different manufacturers, some also had their own unique and valuable products, which were continually updated. The PDSA expressed concern that branded products were considerably more expensive than identical generics. It was disappointed that the Government had not pursued the Marsh report’s recommendation that the cascade system should be renegotiated for companion animals. It noted that the veterinary profession in general had never viewed the use of generics with enthusiasm because it felt under pressure to use licensed products, having been advised by the RCVS that, if the pharmaceutical industry were not used, it would disappear, with disastrous consequences, including the loss of R&D. The PDSA’s own approach was influenced more by a need to seek maximum value for money on behalf of both consumer and provider.

13.148. The PDSA said that, because of the small size of the veterinary market, there were relatively few drugs specifically tailored for it. It pointed to the physiological differences between small and large
animals and noted that it was easier to adapt human drugs to the former. There was a stronger argument for protecting veterinary medicines for larger animals.

13.149. In the PDSA’s view, the safety of the animal and the efficacy of the product were paramount in any medical treatment. Sometimes there could be doubt by the owner about how, when and why any medicine needed to be given. It accepted that pharmacists were in a position to offer advice to the public and said that it preferred that to the open-ended nature of supermarket purchases. It felt, however, that even if prescriptions were made more widely available through pharmacies, most pet owners would continue to obtain medicines from veterinary surgeons.

13.150. When invited to comment on the cascade, the PDSA used as an example the product Rapinovet. If the PDSA purchased the licensed product at list price, it would cost £40,000 a year, whereas the generic (Propofol) cost £8,000. In another example, the branded veterinary antibiotic Amoxycillin would cost £55,000 at list price and the generic £25,000. Therefore, the PDSA used the generic product.

The Phyllis Croft Foundation for Canine Epilepsy

13.151. The Phyllis Croft Foundation for Canine Epilepsy (PCFCE) said that it had over 400 members. Its objectives were to bring support and comfort to owners of dogs suffering from epilepsy, to increase public and professional awareness of the condition and to challenge the outdated yet widespread view that euthanasia was the inevitable outcome.

13.152. The PCFCE said that whilst its members had been concerned for some time about the steeply rising costs of long-term anti-epileptic drugs, it did not seek to diminish or undermine the important role played by veterinary surgeons. It sought consistent national standards for drug charges, and medication for life at lowest possible cost. With medication, dogs with primary epilepsy could live a normal and happy life for many years, but owners unable to afford some very high charges had been forced to consider euthanasia for their animals.

13.153. The PCFCE referred to surveys it had conducted among its members about the costs of phenobarbitone or Epiphen (the veterinary licensed product). These had demonstrated an extremely wide variation in charging. The problem was compounded by an effective monopoly held by veterinary practices in dispensing medication.

13.154. In the experience of the PCFCE’s members, veterinary surgeons imposed a huge mark-up, very often in excess of 100 per cent, on manufacturers’ prices. It was aware of the argument that, if a large practice with modern facilities charged a higher price, that was justified by the quality of what was on offer, but that argument ignored the fact that there would be a greater number of clients.

13.155. The PCFCF said that Vétoquinol had incurred the high costs of licensing phenobarbitone for animal use and this would explain why the prices paid by clients had risen significantly. However, prices had continued to vary extensively between veterinary practices. Additionally, the PCFCE felt that there was no justification for those veterinary surgeons still dispensing human generic phenobarbitone to do so at prices equivalent to Epiphen when, despite the introduction of blister packaging, the generic product was very significantly (up to ten times) cheaper to buy retail in Boots.

13.156. The PCFCE also said, however, that there were indications that a number of the excessive increases had levelled out and that the licensed product had, bizarrely, become cheaper for the client than the generic one in some cases.

13.157. The PCFCE’s view was that, if it was accepted that prices of drugs to pet owners were excessive, then charges for written prescriptions should be regulated in order to prevent veterinary surgeons penalizing owners by this means. Should extra revenue be needed to cover any shortfall, the PCFCE felt that charging higher professional fees would mean that pets on lifelong medication would no longer be excessively penalized.
Pig Production Development Committee

13.158. The Pig Production Development Committee thought that a monopoly existed in respect of both POMs and vaccines but could not offer evidence to support its view.

Royal Association of British Dairy Farmers

13.159. The RABDF said that it represented and promoted the interests of specialist dairy farmers and others working in related service industries. It told us that the vital role played by veterinary surgeons in maintaining good health and welfare was well recognized by dairy farmers. It was essential that the veterinary profession remained profitable.

13.160. The dairy industry was undergoing considerable structural change. The number of milk producers had declined over the last 60 years, particularly in recent years because of economic factors, including the effects of FMD. The prices received for milk were often lower than the costs of production. Any measure to reduce the price of medicines would benefit the profitability and competitiveness of the dairy-farming industry.

13.161. The RABDF said that it was difficult to generalize about how much farmers spent on veterinary bills since different producers recorded some products, for example disinfectants, in different ways. Prices of medicines varied considerably between veterinary practices. Most veterinary surgeons made a large profit on medicines and undercharged on fees. It estimated that, on average, total veterinary costs in a well-managed herd were probably between 3 and 5 per cent of the milk cheque.

13.162. The RABDF believed that livestock producers were at a disadvantage with most competitors outside the UK because they had to pay more for medicines, although its evidence about price differences was anecdotal. It referred to the Marsh report’s finding that the price and availability of medicines influenced the growth of the black market. Illegally imported products had implications for animal health and welfare.

13.163. The RABDF said that greater transparency in costs was essential. Producers had no access to information about the prices along the chain between manufacturer and point of use. Many believed that the market was dominated by a small number of manufacturers but, without greater transparency, the true picture was not clear.

13.164. Farmers were not generally aware that they could have medicines supplied through a source other than a veterinary practice. Pharmacies were not usually conveniently placed for farmers, and veterinary surgeons carried supplies for immediate application. However, the RABDF was in favour of introducing a requirement for veterinary surgeons to issue prescriptions. More use of pharmacies for dispensing would increase price transparency and competition. The RABDF said that many veterinary surgeons in large-animal practices presented itemized bills.

13.165. It believed that income from medicine sales had a large influence on profitability for veterinary practices and country-based veterinary practices faced a challenging future. Whilst producers needed to access cheaper animal medicines to reduce their production costs, they were aware of the need to maintain veterinary services. It was a difficult balance, which must be addressed by the Government, the veterinary profession and the farming industry.

13.166. In the view of the RABDF, some existing POMs could be declassified to reduce costs. It was concerned about EC proposals that all medicines for food animals should be POM. That would place unacceptable burdens on an already struggling industry, with no benefit to animal health or consumer safety.

Royal Society for the Prevention of Cruelty to Animals

13.167. The RSPCA said that its interest in the inquiry was both as an animal welfare organization and as a provider of veterinary services to those unable to afford the full cost. In general, it would support any action which reduced the total cost of veterinary care and oppose anything which made it less available.
13.168. It said that its veterinary care was provided both in wholly RSPCA-owned and -run veterinary practices and in clinics which offered a limited service, with the work being contracted to a local practice. Because care was heavily subsidized by it, the cost of treatment to the client was not directly related to the cost of providing the treatment. Inevitably the cost of medicines prescribed would be greater at a pharmacy than from an RSPCA practice.

13.169. Commenting on the hypothetical remedies, the RSPCA pointed out that the major factors influencing whether an animal received care in a timely manner were the cost and availability of treatment, together with the inclination of the animal’s keeper to act responsibly. The current provision of a one-stop shop by veterinary surgeons encouraged proper care. If it were necessary for the client to make two journeys (one to the veterinary surgeon for consultation and another to the pharmacist for dispensing), inevitably a number of owners would fail to collect drugs prescribed. This could apply both to owners of companion animals and to farmers.

13.170. The RSPCA believed that, if some of the hypothetical remedies were put into practice, some veterinary practices would find it uneconomic to continue to dispense and would prescribe only. That would endanger animal welfare.

13.171. It believed there was a significant risk that the hypothetical remedies would have the effect of increasing the overall cost of treatment to the client, which would further damage the welfare of animals whose owners had difficulty affording treatment.

13.172. Commenting on our possible recommendations for regulatory change, the RSPCA particularly welcomed Recommendations (1) to (5), relating to the licensing of medicines. The current restrictive rules which governed licensing left no freedom for input other than from the pharmaceutical industry. The RSPCA considered that some medicines were over-regulated, especially flea remedies.

13.173. It disagreed with possible Recommendation (16). Licensing authorization in the UK had been very effective in excluding from the market medicines whose efficacy was poor. This proposal would potentially allow licensing of medicines which did not work.

13.174. In earlier comments, the RSPCA noted that any reduction in the cost of medicines would have to be very significant to effect an overall reduction in the total cost of veterinary services.

13.175. Referring to itemized billing, it said that it dealt with over 2,000 veterinary practices, and the great majority of invoices, including those from practices which did not use computers, detailed the cost of drugs.

**Royal Welsh Agricultural Society Ltd**

13.176. Royal Welsh Agricultural Society Ltd told us that it was very concerned by the fact that its members were being charged at a higher rate for POMs than almost any other food producer in Europe. The monopoly situation created by the POM label had three major effects on users and potential users. First, it increased the cost of production in the UK compared with other countries, leading to an unlevel playing field. Second, it reduced the viability of production systems which had to use such products, further squeezing farm profits which were already at a catastrophically low level. Third, it could lead to animal welfare problems where there was reluctance by the producer to use expensive drugs for economic reasons or where the use of drugs was delayed.

13.177. The Society said that opening up the supply chain for POMs would reduce prices and thereby lower costs of production of all meat and dairy products produced in the UK.

**Scottish Landowners’ Federation**

13.178. The Scottish Landowners’ Federation said that whilst it strongly opposed any anti-competitive practice that disadvantaged the farming industry, it had neither the expertise nor the mandate to provide evidence in this inquiry.
Scottish Society for the Prevention of Cruelty to Animals

13.179. The Scottish Society for the Prevention of Cruelty to Animals said that the welfare of animals should be paramount when considering changes to current practice. It was concerned that a loss of income from the sale of POMs might force veterinary practices to charge more for their services, with resulting delays in the treatment of sick and suffering animals, especially in poorer areas.

13.180. The Society said that POMs should be sold in conjunction with current, safe and correct advice regarding their use. Veterinary surgeons were best placed to provide this service. It believed the RCVS should be encouraged to intervene in circumstances where clients were being exploited.

Women’s Food and Farming Union

13.181. The Women’s Food and Farming Union said that under the present system for dispensing POMs there was a lack of choice and insufficient competition to force any price reductions. Veterinary surgeons did not bulk buy in the same way that agricultural merchants did and were not passing on lower prices; they only supplied a few items at a discount.

13.182. If UK prices continued to be out of line with those of its competitors, there were obvious dangers from a black market in medicines smuggled from abroad or bought over the Internet.

13.183. The Union said that a move to POM-only medicines would result in increasingly higher costs in the UK and more animal welfare problems as farmers under financial pressure deferred calling out expensive veterinary surgeons. There was also the possibility that a veterinary surgeon might not be available, leading to further delays in treatment. The PML and GSL categories worked well in the UK and led to competition, consumer choice and prices lower than would be the case if distribution were left to veterinary surgeons.

Industry commentators

Dr Gerald Coles

13.184. Dr Coles, of the Department of Clinical Veterinary Medicine at the University of Bristol, said that anthelmintics and ectoparasiticides were the most important group of animal health products in the UK, essential for the health and welfare of both farm and companion animals. However, an inevitable result of the use of chemicals to kill infectious organisms was the development of resistance.

13.185. In Dr Coles’s opinion, any step taken to increase the availability of these products direct to farmers, horse owners and pet owners would be very retrograde as it would encourage greater use of the products and enhance the development of resistance. The full extent of resistance in the UK was not known for any group of products or parasites. In many cases no good tests for resistance were available and there was relatively little research even on a worldwide basis. The result of the recent lack of interest in funding agencies in drug resistance in veterinary parasites was that no one knew how close we were to being unable to control major parasites in the UK. Dr Coles was most concerned about the control of nematodes and scab mites in sheep.

13.186. He said that he had long been critical of the policy of making valuable drugs available to the general public without a veterinary prescription. He said he knew that his views were opposed by a powerful industrial lobby who believed that restrictions would reduce sales. He fully supported the European Commission’s view that products given to food animals should be POM, because of his concerns about resistance. He believed availability by prescription only should be extended to products for horses and probably pets.

13.187. Dr Coles pointed out that making products available only via prescription did not mean that they had to be sold only by veterinary surgeons. It did mean that there would have to be extensive retraining of veterinary surgeons so that they understood the latest ideas on parasite control and were fully familiar with the necessary diagnostic techniques. Trying to maximize production by removing nematodes in animals was not sustainable. With permanent external parasites, the target should be ‘on-farm’ eradication.
13.188. Dr Coles hoped that the CC would ensure that good science overruled the pressures to make parasiticides more freely available.

Mr Roger Cook

13.189. Mr Cook responded to the statement of provisional conclusions and hypothetical remedies in a personal capacity, as an independent consultant. He explained that he had recently retired from NOAH after 16 years as Director and for 15 years had been a board member of AMTRA. The views expressed were his own and should not be attributed to either organization.

13.190. Mr Cook said that a proper separation in veterinary surgeons’ bills of the components of veterinary costs would be welcome but the overall cost of treatment would not necessarily fall. Veterinary surgeons would still have to balance their books to stay in business, whilst animal medicine companies had to make a profit if they were to survive to develop the next generation of animal medicines.

13.191. He welcomed the recognition that there were many mini-markets for POM products. The small size and specialist nature of some markets made it inevitable that only a few companies would participate. He said that in some markets mentioned, the animal owner’s choice was widened by the availability of licensed animal medicines, which had a PML or GSL category.

13.192. Mr Cook thought that the biggest single obstacle to choice and hence competition was the licensing system itself, particularly overcautious interpretation of the law by UK and EC regulatory officials. Because this had massively increased the cost of placing and keeping a product on the market, only larger companies, operating at European or even global scale, could justify and afford the required research. Even large companies had been forced by regulatory demands to prune their product lists and concentrate on the major animal species and on diseases and parasites that commonly occurred in a number of countries.

13.193. This regulatory excess had had many anti-competitive consequences. For example, by accelerating mergers and the rationalizing of product ranges it reduced choice while the veterinary surgeons’ professional monopoly was further strengthened as only they had the legal right to prescribe ‘off label’.

13.194. The high cost of veterinary consultation encouraged animal owners to move outside the regulated system and opt for unregulated, potentially illegal, alternative products, which carried no regulatory costs or consultation fees. The existence of so many alternative products, unlicensed and widely available, introduced considerable distortion in the market and exposed the purveyors of authorized products to grossly unfair competition, which was exacerbated by the authorities’ inaction in controlling this illegal sector.

13.195. Commenting on the alleged refusal or failure of manufacturers to negotiate discounts or rebates with veterinary buying groups, Mr Cook said that veterinary surgeons were already in a most powerful position because they alone could sanction use of POM products.

13.196. On the allegation that manufacturers’ rebate schemes made it difficult for veterinary surgeons to ascertain the costs of POMs to themselves, Mr Cook suggested that the calculations were not difficult but that the veterinary profession had, collectively, been very lax over many years in not ensuring that there was an element of business training in the professional syllabus.

13.197. Mr Cook said that on a number of occasions over the last 15 years member companies within NOAH had broached the idea that NOAH should take action to discourage the increasing complexity of rebate systems and so improve transparency. NOAH was advised against so doing on the grounds that it would have breached competition law.

13.198. On the alleged conducts by manufacturers and wholesalers in relation to pharmacies, Mr Cook understood that fewer than 200 of some 12,000 retail pharmacists were members of the RPSGB’s agriculture and veterinary group, and fewer still held the relevant diploma. Although there was a wide range of GSL and PML products that could be obtained and sold by pharmacists, very few had taken them up. Retail pharmacies were supplied by specialist pharmacy wholesalers. Mr Cook was not
aware of any pharmacy wholesalers having approached or been rejected by a manufacturer for the supply of POMs.

13.199. Manufacturers had organized their business so as only to supply wholesalers and so it was entirely reasonable that a manufacturer, approached by a potential new retail client, would refuse to open a new account with them, whether they were a pharmacy or veterinary practice.

13.200. The widespread view in the manufacturing industry was that the recent revival of interest in POMs among high-street pharmacists was linked to the arrival of a range of highly profitable, widely advertised and hence easily sold, POM flea products for dogs and cats. It was alleged that pharmacists were not interested in stocking the full range of obscure and low-profit products necessarily stocked by veterinary practices.

13.201. Mr Cook agreed that there were very great differences between the more industrial poultry, pig and fish sectors or the highly specialized equine sector and general practice. With the growing trend to specialization in all sectors, the structures and pressures were sufficiently different to require separate treatment of each sector if the CC’s findings were to be relevant.

13.202. Mr Cook said he agreed that, because some rebates were supplied direct from manufacturers to veterinary practices, commercial relationships and the net price paid could become confusing. There was a good case for ending retrospective discounts and the payment of rebates direct by manufacturer to retailer. In his view, such a change would be welcomed by manufacturers, who were locked into a system which they did not like but found it difficult to change, not least because of the commercial naivety of many in the veterinary profession.

13.203. Commenting on the provisional finding of a complex monopoly relating to dog and cat vaccines, Mr Cook agreed that there were barriers to companies wishing to enter the market for the first time, but these were principally technical, regulatory and financial. The rebate system was not one of the main reasons. He thought that the pet vaccine market was one of the most competitive.

13.204. Turning to our hypothetical remedies, Mr Cook said that he was sceptical about the basic premise that the market for POMs was sufficiently coherent for remedies to be applied across the board. Commenting on hypothetical remedies to reduce barriers to obtaining prescriptions from veterinary surgeons, he agreed with those about veterinary surgeons providing information about prescriptions and providing prescriptions on request ((a)(i), (ii), (iii) and (iv)). He disagreed with (a)(v) and (vi), which would require veterinary surgeons to issue prescriptions. He thought (a)(vii) was excessive but harmless. He did not agree with the proposed remedies relating to charges for prescriptions ((a)(viii), (ix) and (xii)). He agreed with (a)(x) and (xi).

13.205. On possible remedies to improve price transparency, he agreed with (b)(i), (ii) and (vi) relating to veterinary surgeons, but disagreed with (b)(ii), which would require veterinary surgeons to state the costs to themselves of POMs they dispensed. He agreed with the hypothetical remedy that manufacturers should be required to provide sufficient information about any rebates to enable the veterinary surgeon to ascertain the net cost of POMs.

13.206. Of the two remedies concerning manufacturers and wholesalers and supply to pharmacies ((c)(i) and (ii)), Mr Cook said that these seemed to be interfering in the market. Moreover, as worded in the statement they would remove any discretion by manufacturers over the creditworthiness or other unsuitability of a pharmacy. He agreed with (c)(iii).

13.207. Mr Cook objected to hypothetical remedy (c)(iv), which would require a veterinary surgeon to write ‘or equivalent’ on a prescription. This would give an individual pharmacist the power to gainsay the work and expertise of European legislators, company scientists, the regulatory authorities and the veterinary surgeon who prescribed the product. The proposal was seriously flawed and potentially damaging to the long-term availability of properly researched and authorized medicines. Mr Cook questioned whether the average pharmacist had the necessary veterinary expertise to judge what was the appropriate or equivalent product for the species and condition being treated, and whether savings would be passed on by the pharmacist to the customer.

13.208. He said that the use of ‘equivalent’ medicines would have to be based on the information, advice and indications contained in the NOAH Compendium of Data sheets, provided free of charge to
all veterinary practices and paid for by the licence-holding companies. Introduction of such a system would create a new form of unfair competition by allowing manufacturers, possibly from outside the veterinary sector, who had not gone to the trouble and expense of obtaining a licence to benefit from pirating the intellectual property of their competitors.

13.209. The effect on the future supply of new medicines for the UK market was likely to be detrimental. Unlike human medicine, the animal sector was entirely ‘private’. The profit of current sales financed future research and UK animal medicine divisions of international companies had to compete internally with rival divisions for research funds and capital investment.

13.210. Mr Cook agreed with the CC’s possible Recommendation (1) which would open up the EC centralized procedure to all types of medicine, but said that this would be counterproductive unless possible Recommendations (6), (7), (8) and (9) concerning classification were also introduced.

13.211. He supported the theory behind possible Recommendation (2), unrestricted cross-border trading of mutually recognized products; indeed, true mutual recognition would remove the need for the central registration of medicines or the EMEA. However, he noted that it was not necessarily correct to assume that products available in different member states were ‘pharmaceutically identical’, nor was the wording of labels identical in different countries, even where there was a common language. Withdrawal periods were still set by the individual member state and EC law permitted additional labelling, for example to cater for national transport or environmental legislation.

13.212. Mr Cook particularly welcomed the CC’s recognition that ‘the price and availability of medicines affect the welfare of all animals’. It was true that the manufacturer had a commercial interest in the choice of classification, but the reasons for this could be entirely practical. POM products were normally supplied to veterinary surgeons by a few veterinary wholesalers; merchants were normally supplied direct by manufacturers and serviced by separate sales teams. In a situation where the manufacturer had no merchant customers, reclassification of a product from POM to PML could impose large additional costs, probably for little increase in sales.

13.213. Mr Cook asked what evidence the CC had that the VMD and the VPC gave undue consideration to manufacturers’ views at present. He disagreed with the suggested automatic review of classification (Recommendation (4)) because reclassification could impose considerable extra cost for no additional income. Moreover, the product was the manufacturer’s intellectual property: it would be a breach of natural justice to deny the holder of an MA the opportunity to be consulted on a proposed change.

13.214. He fully supported Recommendation (5), which would broaden the meaning of animal welfare in the VMD’s remit. This concern should also be used as a test of the CC’s own recommendations. He fully supported the following recommendations, which he said were also the policies of FEDESA, NOAH and many non-veterinary UK organizations: opposing the EC food-animal POM-only proposal (Recommendation (6)); allowing member states to classify a medicine irrespective of how it was authorized through the centralized procedure (Recommendation (7)); provision for classification review for centralized authorizations (Recommendation (8)).

13.215. Commenting on suggested Recommendation (9), introducing a POM sub-classification for dispensing by agricultural merchants, Mr Cook said that it should be reworded to make it clear that it was a fall back position which would only apply if suggested Recommendation (6) failed. Mr Cook agreed with Recommendations (10), (11) and (12) but found the wording extremely vague and opaque.

13.216. Mr Cook welcomed Recommendations (13), (14), (15), (16), and (17), for which NOAH had campaigned over many years. On MRLs, it had long argued that there was no scientific justification, nor a requirement in EC law, to have separate MRLs, even for major species. The MRL related to the toxicity of the substance; it was the withdrawal period, which linked the MRL to the metabolism of a particular species. This was a prime example of regulatory excess. Sadly, the damage in terms of massive costs and loss of products had already been done and little could be undone. There was no need to change EC law as proposed in Recommendation (17), but only for the CVMP to reverse its previous administrative decision.

13.217. Mr Cook disagreed with Recommendations (18) and (19) concerning the cascade, which raised the same problems as ‘equivalent’ dispensing. These would do enormous long-term damage both
to the welfare of animals and to competition and choice in the retail market. Authorized products were specifically formulated for the species and disease to be treated. To use generics (even if they were appropriately formulated), either the supplying company or the prescribing veterinary surgeon would have to depend on the label or data sheet of the original manufacturer: a form of intellectual piracy. The long-term result of these recommendations would be to deter investment in future research and so cause veterinary surgeons and animal owners either to survive on increasingly aged products or to rely on the veterinary surgeon’s professional (monopoly) right to prescribe off-label. Previous incidents where individual veterinary surgeons had allegedly used the cascade to prescribe cheap generics, while charging the full price to the client, should also be considered.

13.218. Mr Cook supported all the comments and proposed recommendations relating to the professional regulation of veterinary surgeons (Recommendations (20) to (24)) but said that the proposal to remove the restriction on advertising medicines by veterinary surgeons would need to be accompanied by some form of guidance or code, to ensure the suitability and accuracy of the advertisement.

13.219. Mr Cook summarized by saying that there were many recommendations that he was pleased to support, but he was very surprised to find that the CC had given no evidence to support its assertions and little reasoning to justify some of the recommendations. The statement of provisional conclusions and hypothetical recommendations at times appeared lazy, making naive generalizations about a complex, sophisticated group of ‘mini-markets’ with very different characteristics. But if one outcome of the CC’s work were a restoration of balance in the regulatory system and a return to the view that animal medicines were a benefit rather than a threat, then the inquiry would have been most worthwhile.

Livestock producers

13.220. A few livestock producers, around 20, sent us written representations. The main points made were as follows. Regulations governing the supply of veterinary medicines should be relaxed. Current regulations had had the effect of putting animal husbandry back into the 19th century and veterinary surgeons had compounded the problem by pricing themselves out of the sheep market in particular.

13.221. Veterinary surgeons had a monopoly in the supply of animal medications to a far greater extent than elsewhere in Europe. This situation disadvantaged hard-pressed British farmers, who were paying more than their European competitors for identical veterinary medicines. The cost of medicines in Great Britain was much higher than in New Zealand. There was a lack of competition in the UK. Livestock producers had no means of comparing prices, or obtaining veterinary products from elsewhere.

13.222. Generally, veterinary surgeons applied a 95 per cent mark-up on medicines, which they tried to justify by arguing that fees would be much higher otherwise. Annual costs for veterinary medicines had risen disproportionately compared with the sales value of animals.

13.223. There were comments about prescriptions. It was said that livestock producers were paying about double the cost for medicines for their dairy herds because some veterinary surgeons would only write prescriptions if farmers subscribed to a herd health plan. Veterinary surgeons were reluctant to write prescriptions in cases where animal owners wished to obtain medicines from other, cheaper sources. In one instance, the farmer had been told by his veterinary surgeon that the fee for writing a prescription would be doubled to £25.

13.224. The high cost of veterinary fees (in one case £1,000 a month) might be due in part to current regulations. This situation might encourage unscrupulous people to avoid veterinary treatment because of the costs involved. What the industry needed was more realistic prices.

13.225. Farmers should have alternative sources for the supply of POMs, for example animal pharmacies, so that they could obtain value for money. A number of examples were given of significant savings that were achieved when buying medicines from sources other than from veterinary surgeons.

13.226. The drug companies were fleecing British farmers. It was time that the issue was addressed and fairness brought into the equation.

13.227. Concern was expressed that, following this investigation, the monopoly which veterinary surgeons had would be transferred to pharmacists.
Owners of companion animals

13.228. We received written representations from around 200 owners of companion animals. Although most were critical of the price of medicines, and mentioned the role of veterinary surgeons in this respect, comments were not universally negative. One animal owner, for example, expressed support for veterinary surgeons, stressing that they had to earn a living and that people could choose whether or not to keep pets.

13.229. There were many general comments about the high price of veterinary medicines and some references to a lack of competition among veterinary surgeons. The points made included the following. Veterinary surgeons, pharmaceutical and insurance companies were holding pet owners to ransom and owners did not get good value for money from any of them. The fact that only veterinary surgeons could dispense medicines encouraged higher pricing. The market was small and over-regulated; this stifled competition and increased costs. More free choice in the supply of veterinary medicines would allow owners of companion animals to make their own decisions about treating their animals. The restricted market for POMs operated against the public interest, by enabling veterinary surgeons to overcharge for prescribed products. If greater competition existed, veterinary surgeons would be obliged to reduce their charges.

13.230. We were informed that people were being ‘ripped off’ for treatments that could not possibly be worth the price and that veterinary surgeons routinely overcharged for veterinary medicines and treatment, knowing that caring owners would do anything to help their pets. In a crisis, owners were unable to query the cost or to shop around. Owners of companion animals were put off by the high cost of treatment and their animals suffered as a result. Some owners of companion animals had had to consider euthanasia for their pets because they could not afford treatment. Veterinary surgeons’ ever-increasing fees made the ownership of pets prohibitive to all but the better off. Owners should refuse to pay large bills as veterinary surgeons could not cure many of the small animals. British animal owners had no choice but to pay inflated prices. The standard of veterinary care had not kept pace with rising costs.

13.231. Animal owners who did not have Internet access should not be forced to pay inflated prices by greedy veterinary surgeons. The veterinary profession had animal keepers over a barrel; it had to bear some responsibility for the fact that many thousands of animals went untreated in the UK.

13.232. Fees for treating insured animals were inflated since veterinary surgeons were aware that the client was not paying. Veterinary surgeons appeared to charge more for treatment when a pet was insured; animal owners were always asked if the animal was insured when they registered with a new veterinary practice.

13.233. Whilst it was acknowledged that veterinary surgeons had to cover their overheads, massive mark-ups were extortionate and insupportable. Veterinary surgeons did not offer alternatives that could be bought OTC.

13.234. Veterinary practices were very much a closed shop, and there was no easy way to compare prices between veterinary surgeons. Since people tended to use a particular practice, it was unlikely that they would take their animal to a different practice just to obtain a cheaper medication. This led to an uncompetitive environment.

13.235. There was insufficient discussion with clients about the cost of treatments and medicines. Veterinary surgeons failed to provide information about cheaper alternatives.

13.236. There were huge differences in the price of POMs throughout the UK, ranging from wormers to special shampoos. The more competition there was in a city, the cheaper the price.

13.237. The level of mark-ups by veterinary surgeons was the subject of a number of comments. One suggested that these ranged from 100 to 150 per cent. A doctor commented that ‘the cost of medicines from the veterinary surgeon is far higher than the drug tariff price for equivalent human medicines’. Two people said that the cost price of vaccines was £5 a shot, but one of them was charged £26 a shot by the veterinary surgeon and the other ‘a minimum of £35’. Other examples given were: Fuciderm cream (cost price £2.80, veterinary surgeon’s price £10.74); and Galastop (cost price around £4 for 15ml, veterinary surgeon’s price £28.75).
13.238. 50 per cent of those who contacted us commented on the prices paid for individual products. Most complaints concerned the cost of flea treatments and wormers which, it was noted, could be bought much cheaper over the Internet. Among the most frequently mentioned products were Frontline, Rimadyl, Metacam, Soloxine and prescription diet food. (These are all POMs.) Drontal, pet shampoos and toothpastes were also mentioned frequently.

13.239. About one-quarter of complainants said that treatment could be very expensive for animals on long-term medication. There were complaints that veterinary surgeons did not offer cheaper drugs which were not on prescription. It was difficult to find out about alternative products. Some owners complained that pets with long-term conditions, such as dogs with epilepsy or Cushing’s disease, could not be treated with human generics, as had been possible in the past.

13.240. It was said that if flea treatments were to be made available OTC, the cost would fall dramatically because of competition. These treatments required no supervision by veterinary surgeons, and could therefore be sold without a prescription.

13.241. Owners of companion animals were being overcharged for vaccinations and boosters. One correspondent said that owners were being persuaded by veterinary surgeons to buy very expensive prescription diet foods, which suggested that commission on these products was very attractive.

13.242. Several owners of companion animals gave examples of medicines that were available cheaper from pharmacies than from a veterinary practice. The sources mentioned included mail-order services, web sites, mobile veterinary surgeons and health-food stores.

13.243. We were told that it was impossible to find a competitive price for annual vaccinations, because there was no variation in price between veterinary surgeons. On the other hand, there were comments on the different prices charged by veterinary surgeries in the same area. Examples included: a difference of £200 between veterinary surgeons for the same treatment; breeders’ rates for routine booster vaccinations varied between veterinary surgeons from £17 to £34; an animal owner was charged 50 per cent more for Rimadyl compared with other veterinary surgeons and has now changed to another surgery. He calculated that over the lifetime of the animal, which was on long-term medication, he would have been overcharged by £2,000. One veterinary surgeon charged £30 for a month’s supply for feline hyperthyroidism, while another charged £11 for exactly the same product. Triple booster vaccinations varied from £18 to £32.60 in the same area. The cost of two worming tablets at one practice was £6 compared with £2 at another practice. Another comment was that prices had risen by up to 100 per cent when a local surgery was taken over by a group practice.

13.244. A number of owners of companion animals commented on the difference between the price of POMs in Great Britain compared with other countries. These comparisons mostly concerned the price of Frontline and other products, which it was said could be bought more cheaply in many European countries and the USA, in some cases 50 per cent cheaper, and without a prescription. It was said that breeders and owners had a very raw deal in the UK in the cost of veterinary products, which was not in the interests of animals, particularly horses and ponies. However, one person commented that it was difficult to compare UK prices with those in the rest of Europe because a higher standard of small-animal care and facilities were available in the UK. Another said that the prices charged by pharmaceutical companies were higher in the UK than the rest of Europe because of complex licensing issues, the costs of which were passed on through wholesalers and veterinary surgeons.

13.245. There were comments about the availability of written prescriptions. It was said that some veterinary surgeons were deliberately obstructive when pet owners tried to buy medicines from another source, by charging excessively for writing a prescription. One person said that the veterinary surgeon charged the difference between his usual price and that of the pharmacy as an administration fee. In one case, a veterinary surgeon refused to write a prescription for flea treatment because the pet owner wanted to buy the product from a pharmacy. In another, the prescription was given only after the veterinary surgeon consulted the RCVS. A number of people said that their veterinary surgeon was reluctant to provide a prescription or did so with bad grace.

13.246. Some owners of companion animals complained about the expense of obtaining repeat prescriptions and the requirement for animals to be seen by a veterinary surgeon periodically, for which a consultation fee was charged. It was felt that repeat medication should be available from pharmacies or pet shops.
13.247. Examples of prescription fees which pet owners had been charged ranged from £3.41 to £15. A number of people commented that the veterinary surgeon set the fee at such a level that it was not worth the client going to a pharmacy, even though the pharmacist charged less for the medicine.

13.248. Those who submitted comments on the level of veterinary fees said that they were too high and deterred owners of companion animals from seeking treatment for their animals, and that lower fees would result in fewer abandoned animals. Some of the examples given included: £80 for a blood test; £140 to have a dog’s tooth extracted (including anaesthetic and antibiotics); £350 to keep a cat in surgery overnight, and £70 for a routine saline drip; £130 for two cats having boosters and annual check-ups, including worming and flea treatment; £263.68 for a dog’s dental treatment, and £231.30 for an X-ray of the same dog.

D P B KINGSMILL  (Chairman)

G H HADLEY

A HAMLIN

C E HENDERSON

T S RICHMOND

R FOSTER  (Chief Executive and Secretary)

8 January 2003