



**Report of the  
Independent Review  
of Dispensing by Veterinary  
Surgeons of Prescription  
Only Medicines**

**Ministry of Agriculture,  
Fisheries and Food**



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Independent Review  
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Ministry of Agriculture, Fisheries and Food

May 2001



## Independent Review of Dispensing

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The Rt. Hon Nick Brown MP

Minister of Agriculture, Fisheries and Food

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16 March 2001

Dear Minister,

You appointed us in August 2000 to carry out an independent review of dispensing by veterinary surgeons as part of the Government's Action Plan for Farming. We were given the following terms of reference:

- To review the procedures by which prescription only medicines (POMs) for veterinary use are classified and sold in the United Kingdom and the impact current practices may be having on availability and prices.
- To make recommendations to the Minister of Agriculture, Fisheries and Food by 31 March 2001.

We now have pleasure in enclosing our report.

The time we were given to carry out our review meant that we needed to collect information quickly. We were therefore extremely grateful to the organisations and individuals who provided us with information and evidence against what were at times very tight deadlines. In addition to meeting representatives from all the interested groups in the United Kingdom we also visited the European Commission and some member states. We are grateful for the help given by the British Embassy staff in arranging these visits. We carried out these visits because we felt it was essential for us to understand how veterinary medicines were made available elsewhere in the European Union.

We have tried to open our review to public scrutiny and as much as possible of our evidence has been made available on the Independent Review Group website. Our oral evidence sessions and two workshops were open to the public and we posted transcripts of these on the website as quickly as possible afterwards. The workshops provided an opportunity for key issues to be discussed in public by the stakeholders.

The perceived threat to the veterinarians' privilege to dispense prescription only medicines caused widespread anxiety within the veterinary profession. Some of the recommendations we have made in our report imply that the veterinary profession will need to look very carefully at their current practices. In the course of our enquiry we were glad to note that the veterinary professional organisations were already examining current practice. We believe that the recommendations contained in our report will, if taken forward, result in prescription-only veterinary medicines becoming more widely available through appropriate channels and at lower prices than is currently the case.

Finally, we would like to record our thanks to the Veterinary Medicines Directorate who released staff to provide us with an independent secretariat service. We are most grateful to all the team involved. Their patience, skill and thoughtfulness has enabled us to take an in-depth look at many complex issues despite the short time available. Especially we would wish to record our admiration and indebtedness to our Secretary, Chris Bean. He has opened doors on our behalf, guided us through the convolutions of legislation applicable to animal medicines and allowed us to use his drafting skills in the preparation of this report. This allowed the Group to take its own, independent view of the issues we were asked to examine.



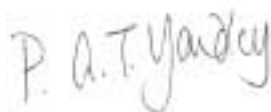
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# Chairman's Introduction

This task force was set up to look at the classification, pricing and availability of veterinary medicines as part of the Action Plan for Farming announced by the Minister of Agriculture in March 2000. The Action Plan is a response to the precipitous decline which has taken place in United Kingdom farm incomes since the mid 1990s.

That decline affects not only farmers but also all those who provide services or sell to farmers. A growing number of veterinary practices no longer offer large animal services. In some parts of the country they may no longer be able to meet traditional standards of availability.

Against this background farmers expressed concern that the prices they paid for animal medicines were substantially higher than those paid by their competitors in other European Community member states. This put them at a competitive disadvantage and also encouraged illegal imports of medicines. Given the growing importance attached to traceability, and the public concern to ensure adequate control in the use of animal medicines, this threatened to undermine the measures taken to justify consumer confidence in livestock products originating in the United Kingdom.

The supply and use of veterinary medicines affects a very diverse group of people. Not only are there farms of many differing sizes and types but owners of companion animals, ranging from ponies and riding horses, to dogs and cats, reptiles and birds. In addition there are other animal owners with more specialist requirements such as zoos and the owners and trainers of racehorses. Veterinary services are required to meet the needs of all these animal owners and to do so effectively, and in the interests of animal welfare should do so at the lowest possible cost.

Price plays a central role in allocating resources. It reflects their value to buyers of goods or services. If prices are artificially high, society loses because less use will be made of the product or service than is justified by its cost. If prices are too low the product will be used in situations in which its cost is greater than the benefit which results. We were asked to look at the prices of veterinary medicines and in doing so we have had to explore the circumstances in which prices are determined. If these are satisfactory the price which results will be just sufficient to cover the continued cost of producing and delivering the medicine.

If veterinary medicines are used wrongly human and animal health may suffer and damage could occur to the environment. To protect the public and build confidence in the use of medicines they are made available within a closely regulated system. Whilst the underlying principles of Community law are applied in all member states, national governments are responsible for their implementation. In this country the Veterinary Medicines Directorate has this responsibility. Regulations, which determine what products can be sold and how they reach the final user, have an important influence on price and availability.

Within the common framework of European Community law differences exist among members in the classification of medicines and rules relating to the terms on which they are available to users. This helps to explain variations in price and in availability. From a livestock producer's perspective, although livestock products move freely within the Single Market, there is not a single market in animal medicines. Farmers faced with tighter regulations or higher prices suffer a competitive disadvantage. In an ideal world the present arrangements would be rapidly replaced by a system which allowed medicines to move freely through the whole of the European Community. Although mechanisms exist to achieve this, through the centralised system and mutual recognition procedures they cover a minority of animal medicine products. Where

regulatory processes prevent trade, companies can increase total revenue by setting prices differently according to the market situation within each of the member states.

Medicines for animals are made available through manufacturers, wholesale distributors, pharmacies, agricultural merchants and veterinary surgeons. Medicines placed on the General Sale List may also be sold through ordinary retail outlets. For each of these businesses to continue to provide the service they offer, the revenues realised must be sufficient to cover their costs. The prices available depend on competition. If markets change as a result of new technology or a shift in demand, some businesses may not be able to survive and others may grow to replace them. This is painful for those whose living depends on the businesses that disappear, but it does not represent a failure of the system as a whole, or a price level that is inappropriate. All the enterprises to which we talked saw themselves as facing intense competition. However within the system that delivers animal medicines, there are several points at which competition may be frustrated. This made it essential that the task force examined the processes by which the prices of veterinary medicines were determined.

The development of new medicines involves costly processes of research, development, market authorisation and market launch. These costs are so high that manufacturers need a large market to justify the investment – with consequent problems for minor species and for uncommon ailments. They also have to recoup the initial costs through the selling price of their product before generic equivalents, which have not had to face the full costs of research, development or authorisation, reach the market. Without a price sufficient to cover these costs the supply of new animal medicines would cease resulting in avoidable economic losses to farmers and a less satisfactory range of treatments to ensure welfare for all animals. Patent law and the medicine authorisation process are designed to allow an innovator to recoup his costs and, during this period the price at which the medicine is available is necessarily higher than the direct cost of its manufacture. The regulations, which protect new products, affect both the price and availability of competitive products. The task force had to consider whether existing rules struck the right balance between the longer term public interest in the development of improved medicines and access by animal owners to suitable, older generic medicines at much lower prices.

The distribution of medicines is tightly controlled in all member states. Prescription Only Medicines (POMs) can only be supplied to the instructions of a veterinarian. This ensures that professional judgement is exercised before they are administered. In the United Kingdom most POMs are dispensed by veterinary practices. Pharmacies can also supply POMs if they are presented with a prescription. In addition, registered agricultural merchants can supply a limited range of PML medicines. To the user the price of the medicine depends on its cost to the veterinary practice, the pharmacy or the merchant plus the margin added to cover the provision of the service. Animal medicines constitute an important element in the revenue of most veterinary practices. If sales of medicines should decline practices would have to cut costs or increase charges for other services, or accept a reduction in income. Despite this, if the market is to work in the public interest it is important that all parts of the system should be able to compete to deliver those packages, which in the eyes of users represent best value.

Such a system would ensure that medicines were available at as low prices as possible to users. This is an important consideration in terms of animal welfare. Veterinary charges may deter many animal owners from seeking professional advice and thus impair the welfare of their animals. For some owners of companion animals who live on low incomes, animal charities provide a service that can ease this problem. For those who are not eligible or who do not have access to such assistance, the cost of medicines may still represent a substantial burden. It is therefore essential to ensure both that there is a competitive market and that the processes of classification do not unnecessarily raise the cost or restrict access to supplies of medicines. The task force looked at

practices in other member states where some effective 'routine' treatments, such as flea sprays, seemed to be more freely available than in the United Kingdom.

It is clearly of importance that the system of distributing veterinary medicines should encourage their responsible use. This requirement extends to all those involved. The classification of medicines as POMs is designed to ensure that their use is based on informed professional judgement. The expertise of the pharmacist in the distribution of medicines is designed to ensure that they are used safely, whether for humans or animals. Agricultural merchant businesses and co-operatives<sup>1</sup> which are registered by the RPSGB can sell only a restricted list of medicines and must employ Suitably Qualified Persons (SQPs) trained to standards agreed by the industry. At the point of use the animal owner has special responsibility. On a farm the recognition of problems, the administration of medicines and the subsequent monitoring of withdrawal periods generally depends upon the person who has care of the animals. Errors at this point can create risks for the public.

In the light of these responsibilities the task force considered the processes by which those involved acquired and developed their professional skills. The RCVS and RPSGB play a critical role in maintaining standards. Not only do they supervise professional training but they seek to ensure that members attend courses to promote continuous professional development. AMTRA, which is governed by members representative of the industry as a whole, set the syllabus and regulate standards for the basic training of SQPs. The task force discussed these activities and the extent to which they were responding to changes in the industry. The increased scale of modern livestock husbandry places increasing burdens on those whose responsibility it is to care for farm animals. There is a need to ensure that all those handling medicines on the farm should have access to adequate training. Eventually this might be recognised in formal training courses that would provide evidence that could entitle trained animal carers to readier access to some animal medicines.

The task force undertook its work in an economic environment in which substantial long-term changes were taking place. These may be overshadowed by the immediate crisis facing farmers, but in thinking about the adequacy of the present system of classification, pricing and availability it seemed to its members necessary to consider how satisfactory these systems were likely to be in the world of the future. The Group sought to explore with those involved the extent to which they recognised the need for change.

The difficulties of moving to a single system of veterinary medicine authorisation within the European Community must not be allowed to disguise the importance of making progress in this direction. An effective Community-wide system would make a major contribution to the removal of illegal imports and unauthorised use of medicines. Not only would this promote a more competitive medicines market but it would also increase consumer confidence in the products of its farming industry. To make progress in such a direction will require compromise and a willingness to adapt by all member states. The task force considered what the United Kingdom might do to demonstrate its readiness to make progress in this direction.

The changes taking place in the economics of farming and veterinary practice are making it increasingly difficult to retain the level of veterinary service regarded as essential in the past. In part this is a result of the decline in the number of farm animals and related production and the resultant effect on large animal practices, not least in some of the more remote areas of the United Kingdom. In part it is an outcome of increasing specialisation within the profession where a

<sup>1</sup> A wide variety of structures exist for the supply of farm requisites. These include traditional commercial merchant businesses, co-operatives that may include farmers and other members registered under the IP Acts, and joint buying arrangements by farmers operating as limited companies. In this text the term agricultural merchants and co-operatives is used to cover all those businesses that may supply PML medicines by the employment of an SQP.

'general practitioner practice' may need to call in specialist assistance from a distance. In this situation the profession, and its regulator the RCVS, need to examine carefully how best to safeguard animal welfare by using all the skills available including pharmacists, merchants and those who have direct responsibility on the farm. They will also need to explore the potential of electronic communication. This can include the maintenance of readily accessed clinical records, the production of prescriptions and the creation of written veterinary directions for dispensing. It can also assist in the rapid dissemination of new relevant information to all parties.

The electronic age presents new responsibilities. Animal owners can access information and supplies from novel channels, including sources outside this country. There is more difficulty in corroborating the validity of this information, and a danger that misuse of medicines might result. Given that access to such information cannot be prevented, those who provide medicines will have to be able to explain to their clients the relevance or otherwise of the information they have received and the pros and cons of particular treatments recommended.

The distribution of medicines, like all other products, is affected by the advent of e-commerce. Via the Internet customers can access a much wider range of potential suppliers, the effective competitors for their money are greatly increased and the market facilitated. However for medicines as with other products, the customer has to be aware of the risk that the products offered may not be identical with those with which he is familiar. We learned of examples of e-commerce being developed by veterinary pharmacies in the United Kingdom. We were also concerned to hear of impediments placed in the development of this practice by some members of the veterinary profession.

Throughout our enquiry we have been immensely grateful for the readiness of those involved to discuss relevant issues with us. We were particularly heartened by the welcome we received as we visited several partner countries in the European Community and the European Commission itself. We recognised as we talked how existing practices had been shaped by the diverse cultural characteristics of the countries concerned and how such deep-seated preferences could not be rapidly transformed. Nevertheless there was universal recognition that we needed to move forward together. We hope that this report will be made freely available and will assist the process of mutual understanding out of which we have to jointly fashion better means of regulating the supply, distribution and use of veterinary medicines within the Community to which we belong.



Professor Sir John Marsh CBE

# Summary and Recommendations

**Note:** Numbers in parenthesis refer to the main body of the Report

## 1. Prices for veterinary medicines

It has been reported to us that some animal medicines are more expensive in the United Kingdom than in some other member states of the European Community. The explanation for this may lie in part in the strength of sterling relative to the euro, in part in the ability of manufacturers to maximise their revenues by selling at different prices in markets which remain differentiated by regulatory procedures, and in part by the pricing policies of veterinarians.

For a market to work efficiently it is important that customers should be aware of prices charged by all suppliers, that it should be transparent. It is also important that purchasers should have access to least cost supplies of both medicines and services. There is a lack of transparency in the prices paid by clients for animal medicines. Many clients are unaware that they may request a prescription from a veterinarian that can be dispensed by a pharmacy. Many veterinarians appear to be unaware of the cost of their pharmacies. Treatments have traditionally been paid for in single bills, which cover the cost of medicine and the cost of providing professional services. Within the distribution system there exist complex systems of discounts and these may not be open on the same terms to all distributors, veterinary practices and pharmacists.

We believe that this lack of transparency leads to avoidably high costs of animal medicines. It may also distort the use made of medicines, discouraging clients who are anxious about the cost of a prescription, from visiting their vet. We welcome the Office of Fair Trading enquiry into the practices of animal medicine manufacturers.

### **Recommendation 1**

We recommend (5.33) that veterinarians having made a diagnosis and prescribed medicine, should be required to provide a written prescription, at either no additional charge or at a fee to be determined by the RCVS acting in the public interest. Clearly this recommendation would not apply where emergency treatment is needed, for treatments during surgical procedures or for the use of anaesthetics.

### **Recommendation 2**

We recommend (5.29) that once recommendation 14 below is implemented, prescriptions written by veterinarians should be dispensed by any suitably qualified person, including the prescribing veterinarian, other veterinarians, pharmacies and, in the case of POM (C) products, by persons holding AMTRA, SQP qualifications and employed by registered agricultural merchants or other registered retail outlets.

### **Recommendation 3**

We recommend (4.18) that veterinary practices apply improved business practice in the operation of their pharmacy services with a view to reducing costs.

## 2. The existence of black markets

Illegal sales of animal medicines arise because of differences in access to medicines, an outcome of national regulatory procedures, and differences in price, attributable in part to exchange rates but also to the policies of manufacturing companies. We are unable to measure the extent of this illegal trade but have listened with concern to suggestions that, in some parts of the United Kingdom, it may represent a serious threat to the proper control of animal medicines.

The most effective solution to this problem would be the substitution of a single system of regulation. This would enable the legal import of all medicines among all member states. Differences in price could then be no greater than the cost of movement. Our discussions in other member states reveal a consensus that such a solution would be beneficial, but encountered differing views about what such a system should require. We note that the European Commission is aware of this problem and is taking steps to make progress. However there seemed to be a marked lack of urgency and no single system seems likely to be in place in the immediate future.

In this situation the United Kingdom government has the opportunity to use, to the maximum extent possible, its freedom of action to secure a legal and open market in animal medicines in this country. All member states of the European Community are required to operate systems designed to protect the consumer, the environment, and to maintain access to medicines for animals to standards approved by the European Commission. The proper use of medicines which fulfil these requirements should not present a problem within the United Kingdom, or any member state. Most animal medicines are authorised as prescription-only. Their use within the United Kingdom should therefore be subject to professional veterinary supervision. This requirement for professional advice will ensure that differences in the ingredients contained within medicines, which have broadly similar contents and functions, are fully taken into account.

### Recommendation 4

We recommend (5.13) that the VMD should permit the import of medicines authorised in other member states, provided that they are properly labelled in English and sold via the approved distribution system within the United Kingdom.

## 3. The availability of medicines

Several problems relating to the availability of medicine were drawn to our attention. These included the continued provision of veterinary services for large animals in several parts of the United Kingdom; the availability of medicines for minority species, and the rules which prevent the use of lower cost generic medicines rather than authorised drugs for the treatment of companion animals.

The declining availability of veterinary services for large animals is a reflection of the changed economics of agriculture. Not only has the number of animals fallen but the value of each animal has also declined. For many farmers the economic value of the animal no longer justifies the cost of individual veterinary treatment. Veterinarians have often responded to this by keeping bills to a minimum. However the declining value of livestock is a long running problem. It is therefore necessary to reduce, as far as possible, the real cost of providing services. This will sometimes mean not providing treatments that are technologically possible for individual animals. Given the high fixed cost of providing veterinary services, there is a pressing need to use to the maximum possible the skills of those already involved in the care of animals. This includes all competent suppliers of medicines, pharmacists and merchants as well as veterinarians, the greater use of 'para-veterinary services' (e.g. veterinary nurses), and improved levels of skill among all who look

after animals on the farm. There is a need to encourage the continuing upgrading of skills by all those involved.

We noted that in some other member states veterinary medicines are prescribed within an overall animal health plan for the farm. Within the plan medicines can be obtained from appropriate sources without further reference to a veterinarian. This approach combines a positive approach to animal health combined with the efficient use of professional resources. It allows veterinarian expertise to be accessed, sometimes at a distance, as and where it is needed, without necessarily requiring a visit to the farm concerned. To operate a similar scheme within the United Kingdom may require some redefinition of the concept of 'animals under their care' which currently restricts the rights of vets to prescribe.

### **Recommendation 5**

We recommend (5.19) that farmers and veterinarians join with pharmacists, agricultural merchants and farm management advisors to create health plans for farm animals, within which medicines can be supplied at least cost.

Many witnesses stressed the danger that the misuse of medicines could lead to the development of resistance. We received reports indicating that for some antibiotics and for some anthelmintics resistance, in farm animals, was already a problem. We regard this as a serious loss to society and recognise a clear responsibility on all those using medicines to do so in ways that minimise the chances of resistance emerging. We do not accept that the only way to achieve this is to make all medicines POMs. Good practice depends on those who prescribe, those who dispense, but above all on those who administer medicines to animals. We regard it as essential that all distributors and users of animal medicines should be aware of the risks, their responsibilities, and have access to the necessary guidance as medicines are used. We welcome the suggestion from AMTRA that it extends its programme to include suitable training courses for farmers and farm workers.

### **Recommendation 6**

We recommend (5.19) that continuous professional development should be required of all involved in the prescription and dispensing of animal medicines and for all who have responsibility for the care of animals. A formal record of training undertaken and the level reached should be available on request. When courses are available, the requirement for training should be extended to farmers and farm workers with responsibility for animals, and sales of medicines to them should be subject to written evidence of competence in their use.

The lack of medicines for minority species is a growing problem as medicines which have been used successfully in the past are withdrawn because manufacturers cannot justify the cost of establishing Maximum Residue Levels (MRLs) for products for which the market is relatively small. Within the category of 'minority species' are animals commonly used for food production such as goats, sheep and many types of poultry. The result is that authorised treatments may be unavailable but, because of long withdrawal periods before an animal can be sold for food, the use of medicines 'off-label' results in delays so long that production becomes unprofitable.

### **Recommendation 7**

We recommend (5.16) that the Minister supports the proposals made by the European Commission to allow the extrapolation of MRLs for major species to be used to calculate MRLs for minor food-producing species and so increase the availability of veterinary medicines on the market.

We recognise the need to encourage research and development of new medicines for companion animal species. However the rule that, when an authorised medicine is available no unauthorised alternative may be prescribed has the effect of greatly increasing the cost of treatment for some chronic conditions. This may result in a loss of welfare for the animals concerned. We believe that animal owners should be able to discuss the alternative courses of treatment with their veterinarian and balance the advantages of the more up to date and effective treatment against the added cost of shifting from older drugs, including generic drugs developed for use in human medicine. Whilst this may result in some loss of market in the United Kingdom for new medicines, we believe this would be minor compared with the global market and of substantial benefit to pet owners living on low incomes.

### **Recommendation 8**

We recommend (4.28) that the Minister encourages the European Commission to amend the existing legislation to allow veterinarians to prescribe generic treatments for companion animals where, after consultation with the owner, they come to the conclusion that this is the best treatment for the animal concerned.

Within the United Kingdom agricultural merchants play an important part in overall medicine supply, through the sale of PML medicines. In this role they fulfil a function discharged by agricultural co-operatives in some other member states. The medicines concerned do not require a specific diagnosis; they include medicated feeds and anthelmintics. Dispensing is the responsibility of an SQP who must attend and pass a course developed by AMTRA. Merchants who sell medicines in this way are subject to inspection by the RPSGB and their employees have to pass courses agreed by a body representative of all the interests involved. Farmers have welcomed this facility, and in general PML medicines seem to have been sold with lower margins than those dispensed as POMs. Pet shops have not been able to provide a similar service for companion animal owners, except in so far as they are classified as 'saddlers' and are permitted to sell a limited range of medicines.

### **Recommendation 9**

We recommend (6.5) that the role of registered agricultural merchants and saddlers in the dispensing of cat and dog wormers classified as PML medicines be extended to suitably registered pet shops, provided that all sales in these outlets are made by people who are suitably qualified having passed courses established by AMTRA. We see no need for the pet shop to register as a saddler as is currently the case.

We were made aware of a serious difficulty in accessing medicines for horses within the United Kingdom. In many countries the horse is regarded as a source of food as well as a sporting animal and a companion animal. In the United Kingdom horses are seldom eaten; however, a significant number of British horses are exported and may subsequently enter the food chain. We noted that

there is a trade in horses for food-production, without controls similar to those applicable to other food-producing species. We were concerned at this anomaly. Because horses may be eaten there is a requirement that authorised medicines should have MRLs. Providing this data for horses is extremely expensive and as a result some commonly used medicines may become unavailable.

### **Recommendation 10**

We recommend (4.29) that the Minister encourages the European Commission to develop a proposal for a written record to be kept of medicines administered to a horse by its keeper. This could be in the form of a 'horse passport'. It would allow medicines, for which an MRL had not been established, to be administered to a companion, recreational or sporting horse. It would also enable a starting date to be determined to ensure that an adequate withdrawal period could to be set should it, at some time in the future life of the horse, become destined for human consumption.

## **4. The classification of medicines**

The availability of medicines is linked to the way in which they have been classified. In the United Kingdom the present system allows some medicines to be sold through any outlet (GSL); others (POM) are subject to prescription and may be sold only by pharmacists or prescribing veterinarians. A further, small group (P) can be dispensed by pharmacists without a prescription and still others (PML) may be sold by suitably qualified persons through agricultural merchandising businesses. Classification is undertaken by the Veterinary Medicines Directorate (VMD), advised by the Veterinary Products Committee (VPC). This is a highly technical task and we are satisfied that the VMD and VPC are well equipped to undertake it.

Many of those who gave evidence indicated that they found the existing system satisfactory and did not wish to see any change. However there were conflicting calls from some witnesses. Some veterinarians wanted some or all PMLs to be POMs. The representatives of agricultural merchants proposed that a number of medicines and inactivated vaccines which were currently POM should become PML and they also pointed to inconsistencies in the current distribution category allocated to some medicines. The pharmacists wished to see more medicines classified as P. We believe that the authorities should examine existing classifications to ensure that anomalies are identified and, where not justified by other considerations, corrected.

The allocation of a medicine to a class involves the submission by the manufacturer of a substantial amount of evidence, including (for medicines to be used in food animals) experimental data to establish MRLs. Providing these data to the required standard is costly. Some witnesses argued that the procedure to obtain authorisation was also too costly. The effect was to deter manufacturers from offering new medicines for minority species. We are satisfied that the costs of launching new medicines are greatly increased by the requirement to provide separate MRL data for each species and believe that once the necessary data is available for one major species MRLs for minor species should be ascertained by extrapolation. This emphasises the importance we attach to recommendation 7 above. We were further satisfied that, whereas in some other member states part of the cost of licensing was borne by the state, the licence fee charged by the VMD to defray its cost was not a major impediment to the introduction of new medicines.

All medicines developed using biotechnology have to be classed as POMs. For other products the category awarded is decided by the VMD with, if appropriate, advice from the VPC. Manufacturers will normally indicate the category they think is appropriate. This is likely to be part of a marketing strategy. However the decision is taken by the VMD alone. The VMD may

review any classification in the light of experience of the product's use but such reviews, where they extend beyond a monitoring function, are generally only undertaken on the basis of a request from the manufacturer, who has to supply the data. It was suggested to us that there should be a wider access to the right to request a review. We agree with this but believe that the costs of an appeal, including providing the evidence needed, should be borne by the appellant.

### **Recommendation 11**

We recommend (5.6) that if, as a result of its review of the operation of the centralised procedure the European Commission should open it up to a wider range of products, the Minister should urge that it also introduces a mechanism for reviewing the classification given to authorised products.

### **Recommendation 12**

We recommend (5.9) that the VMD examine closely its own procedures for dealing with applications under the decentralised procedure, to ensure that no obstacles are placed in the path of mutual recognition.

### **Recommendation 13**

We recommend (5.22) that the VMD should set in train a review of existing classifications applied to therapeutic product groups of medicines to ensure their consistency and that it should be willing to consider requests for the revision of a product's classification from any party which offers evidence of the appropriate nature and quality.

Differences in national rules concerning the prescription and distribution of animal medicines obscure market transparency and undermine the efficient use of resources within the single market of the European Community. We explored briefly the national rules adopted in a number of fellow member states of the European Community. It was clear that they resulted in substantial differences in the cost at which animal medicines were available to users and the ease with which they could be acquired. Many of these differences reflected profound cultural characteristics of the countries concerned. In some countries highly restrictive, costly systems were accepted because of public anxiety about the danger of medicine misuse. In others even the legal regulations were difficult to enforce because of deep-seated attitudes expressed in past rights to buy medicines, like other farm inputs, without restriction.

We accept that it will take a considerable time to bring about a consensus which would lead to an agreed system of classification and distribution for all member states. We also accept that any such system will require some measure of compromise by all member states. The existing United Kingdom system differs from that in most member states both in the list of medicines which are classified as POM and in the existence of categories of medicine sold by agricultural merchants and saddlers (PML). In some countries all medicines, even those classified as GSL in the United Kingdom, can only be bought from pharmacies.

If the United Kingdom is to facilitate the introduction of a single system, we need to ensure that its system of prescription and distribution reassures our partners that there is adequate control of medicines. For this country and for the European Community as a whole there is a pressing need to avoid imposing avoidable costs on agriculture faced with the prospect of increased competition. In particular we need to make full use of the resources that already exist in this field. To do this the

level of expertise employed should be no greater than that necessary to ensure that medicines are used safely and effectively. To introduce new costs by requiring all medicines to be dispensed by either pharmacists or veterinarians would run counter to this principle.

The role of agricultural merchants and farmers co-operatives in the distribution of medicines is of particular importance. Where routine treatments, which form part of the normal management systems of well-run farms, are required, it is sensible that these should form part of an integrated farm plan. We explain more fully what we mean by this in paragraphs 5.24 and 5.25 of our Report. At the same time it is appropriate that they should be accessible to the farmer via his merchant. In essence the animal health plan represents a prescription for a group of animals: this is a practice already common among poultry and pig herds where individual animals seldom receive separate medication. We regard the availability of PML medicines as falling into this category, and suggest that this should be recognised in any revision of the existing classification system within the United Kingdom.

### **Recommendation 14**

We recommend (5.28) that the Minister should consider moving in the longer term towards adopting a system of classification that has two major categories Prescription Only Medicines and General Sale List products. We would suggest that the POM category should be divided into three sub-groups as follows:

POM (A) – medicines which may be administered only by veterinary surgeons or under their direct supervision. In the latter instance the veterinary surgeon should be present at the time of administration and in a position to render assistance if necessary.

POM (B) – medicines which may be sold or dispensed by veterinary surgeons to animals under their care after a prior clinical examination of the animal or animals; or sold or dispensed in a pharmacy in response to a written veterinary prescription.

POM (C) – medicines which may be sold or supplied by veterinarians for administration to animals under their care, or by pharmacists or, providing the purchaser can demonstrate evidence of competence in their use, by registered agricultural merchants. For this group of products a prior clinical examination of the animal(s) is not a requirement, however in cases where no evidence of competence is available the products in this category should only be made available by pharmacists, registered agricultural merchants or other registered outlets against a written prescription from a veterinarian.

# Chapter 1: Introduction

## Terms of reference

- 1.1 This chapter sets out our terms of reference and describes how we went about our work.
- 1.2 The Independent Review of Dispensing by Veterinary Surgeons' terms of reference were:
  - To review the procedures by which prescription only medicines (POMs) for veterinary use are classified and sold in the United Kingdom and the impact current practices may be having on availability and prices.
  - To make recommendations to the Minister of Agriculture, Fisheries and Food by 31 March 2001.
- 1.3 We were appointed in August 2000 which meant that we had about seven months to complete our review. Inevitably, therefore, we needed to collect information quickly. We are extremely grateful to the organisations and individuals who provided us with information and evidence, both written and oral, to what were at times very tight deadlines.

## Background to the Review

- 1.4 Our review forms part of the package of long term structural measures and short term financial aid for British Farming announced by the Minister of Agriculture, Fisheries and Food at the Agricultural Summit held at 10 Downing Street on 30 March 2000. Although our review forms part of the overall strategy for United Kingdom agriculture, because of the concerns expressed to Ministers about the high cost of veterinary treatments for companion animals we were asked to encompass within our terms of reference the impact that current practices were having on the availability and price of prescription only medicines in that sector.

## Approach

- 1.5 In carrying out our review we have tried to be as open and transparent as possible. For example we published our terms of reference, work programme and summaries of our formal meetings on our web-site. We have also made available on this site as much as possible of the written evidence we have received from individuals and organisations.
- 1.6 The following paragraphs describe the main ways in which we collected evidence.

## Written evidence

- 1.7 We issued a written request for evidence to assist our work on 11 August 2000 inviting responses by 6 October. This request was sent to 236 organisations and was also placed on our web-site. We were told that this relatively short period of time created difficulties for some organisations who needed to consult their members so we therefore agreed to accept submissions of evidence up to 30 November 2000. We received written evidence from 81 organisations and 113 individuals. A list of those who submitted written evidence to us and who indicated their willingness for their submission to be made publicly available is attached at Appendix 1. The bulk of this evidence, excluding material such as published reports, codes of practice etc. was placed on our web-site. These are also available on a CD-rom attached to this report. Appendix 2 contains an analysis of the written evidence submitted to us.

## Oral evidence

- 1.8 In our initial request for evidence we invited contributors to supplement their written evidence by making an oral presentation to us. Twenty-two organisations expressed an interest in doing so and we set time aside for this in December 2000 and January 2001. These sessions were made open to the public, and the transcripts of the evidence given were placed on our web-site. These transcripts are also included on the CD-rom. Appendix 3 contains a list of those organisations who presented oral evidence to us.

## Visits

- 1.9 European Community legislation sets minimum criteria for classifying medicines which are subject to a prescription written by a veterinarian. We were made aware that differing criteria had been used by member states to implement these and that this had impacted on the way in which veterinary medicines are distributed throughout Europe. We therefore considered it important to visit a number of member states to familiarise ourselves with the range of distribution systems operated. We visited Belgium, Denmark, France, Germany, Portugal and the Republic of Ireland where we met government officials and representatives of manufacturers, veterinary surgeons and farmer organisations. We are extremely grateful to the individuals for the welcome that we received and the information they provided. We would also like formally to thank officials in the British embassies in the countries visited for making the arrangements for our visits so ably.
- 1.10 We also met representatives from the European Commission (DG Enterprise and SANCO) and the European Medicines Evaluation Agency (EMEA) both to discuss the purpose of the review and to hear their views on the future of veterinary legislation in this area. We met the Chief Executive and some departmental heads of the United Kingdom's VMD, and the Chairman and members of the United Kingdom's VPC. These meetings provided us with an insight into the procedures and methodologies used in considering an application for a marketing authorisation for a veterinary medicinal product, the factors affecting the legal distribution category applied to a product and aspects of pharmacovigilance.
- 1.11 As part of our familiarisation process we visited two veterinary practices, an agricultural merchant, a pharmacy involved in the sale of veterinary medicines and a manufacturer of these products. We met officials and representatives of the farming associations during visits to Scotland, Wales and Northern Ireland. We also attended and made presentations to conferences held by the British Veterinary Association (BVA), the Royal Pharmaceutical Society of Great Britain (RPSGB) Agriculture and Veterinary Group, the National Office of Animal Health (NOAH) and the Animal Health Distributors Association (AHDA). We also made a presentation at an evening meeting of the Northern and Scottish Veterinary Action Committee (NASVAC) whilst we were in Edinburgh.

## Workshops

- 1.12 We felt that it was important, before drawing conclusions and making recommendations, to discuss in open forum the key issues which had been raised with us in the written and oral evidence. We therefore held two workshops in London during January 2001. The first workshop considered the economic factors that influence the pricing of veterinary medicines at each stage of the supply chain. The second considered the impact that the regulations and classification system had on availability, animal welfare and prices. Both workshops were attended by over 70 participants and observers. Copies of the transcripts of the workshop sessions were placed on our web-site and are also included on the CD-rom attached to this report.

# Chapter 2:

## Classification and dispensing of veterinary Prescription Only Medicines

- 2.1 The main purpose of this chapter is to describe the procedures by which veterinary medicines are classified and sold in the United Kingdom. We also give a brief description of the legal position. Finally, we comment on the way veterinary prescription only medicines are dispensed within the United Kingdom and make a brief comparison with the systems adopted in other member states.

### Introduction

- 2.2 The authorisation of veterinary medicines in the United Kingdom is controlled by legislation made first under the Medicines Act 1968 and, increasingly since 1 January 1995, under legislation relying directly upon the provisions of European Community law. The primary purpose of this legislation is to ensure that veterinary medicines meet criteria which establish their safety, quality and efficacy. The underlying aim is to ensure that authorised veterinary medicines are manufactured to a high quality and are efficacious against the specific disease or condition in the species of animal being treated. Regulations must also ensure the safety of the person administering the product and of the consumer, through the avoidance of any harmful residues, and the environment.
- 2.3 There are three routes under which veterinary medicines may be authorised within the European Community. Two of these, the 'Centralised' and the 'Decentralised' or mutual recognition procedures, came into effect on 1 January 1995. Both are intended to facilitate the authorisation of veterinary medicines throughout the European Community and ensure the smooth functioning of the internal market in the pharmaceutical sector. These two authorisation routes sit alongside the 'National' authorisation arrangements. There are in the United Kingdom some 1980 authorised veterinary medicines of which 39 are authorised under the 'Centralised' and 76 under the 'Decentralised' procedures respectively. The remainder, 1865 (c.94%) hold United Kingdom 'National' authorisations. We noted that since 1 January 1998 if a veterinary medicinal product was already authorised in one member state, no marketing authorisation could be granted under the 'National' procedure by another member state – the 'Decentralised' procedure is obligatory. A brief description of the three authorisation routes is set out in Appendix 4.
- 2.4 Within the United Kingdom the distribution of veterinary medicines is controlled by assigning the authorised product into one of four categories. The criteria applying to prescription only medicines (POM) are described in detail in paragraphs 2.5 and 2.6 below. General Sale List (GSL) products may be sold without any controls in any retail outlet, such as a pet shop or supermarket. Products may also be categorised as being for sale in a pharmacy (P), or by a registered agricultural merchant or saddler (in a more limited range). Such products are classified as Pharmacy and Merchants' List products (PML). The criteria applied to determine which of these categories should be applied to a specific product are set out in Appendix 5.

## Legal position

2.5 Article 4(3) of Council Directive 81/851/EEC requires a prescription for the dispensing to the public of all veterinary medicinal products which have the following characteristics:

- those products subject to official restriction on supply or use such as:
  - the restrictions resulting from the implementation of the relevant United Nations conventions on narcotic and psychotropic substances;
  - the restrictions on the use of veterinary medicinal products resulting from Community law.
- those products in respect of which special precautions must be taken by the veterinarian in order to avoid any unnecessary risks to:
  - the target species;
  - the person administering the product to the animal;
  - the consumer of foodstuffs obtained from the treated animal;
  - the environment.
- those products intended for treatments or pathological processes which require a precise prior diagnosis or the use of which may cause effects which impede or interfere with subsequent diagnostic or therapeutic measures.
- magistral<sup>2</sup> formula intended for animals.

2.6 In the United Kingdom a POM classification is established for any product which meets one or more of the criteria described in paragraph 2.5 above and, in particular:

- when diagnosis of the condition for which the product is intended would be beyond the competence of the livestock owner or accurate diagnosis (including in particular differential diagnosis) is required so that the medication appropriate to the circumstances can be administered and the necessary veterinary advice given;
- when the product needs to be administered by the veterinary surgeon in person or under his supervision, e.g. because it is a therapeutic antimicrobial agent or an injectable preparation for small animals; or because of other legal provisions; or when the method of administration is novel;
- when the drug's toxicity may present a safety hazard in animals or man; when the risk/benefit ratio of using the product is finely balanced; when the substance has a significant activity on the central nervous system e.g. anaesthetics, tranquillisers or where it significantly alters the animal's physiology;
- when careful monitoring of the use of the product is required (this would normally apply to all new active ingredients for up to five years and could apply to known active ingredients authorised for administration by a new route);
- when the substance is controlled under the Misuse of Drugs Act 1971 or allied legislation, or the active ingredient is classified as a POM for human use.

## Dispensing of veterinary POMs

2.7 The Medicines Act 1968 provides that the normal channel for the sale or supply of medicines should be through a pharmacy. There is an exemption for authorised veterinary medicinal

<sup>2</sup> Any medicinal product prepared in a pharmacy in accordance with a prescription for an individual animal.

products, which are classified as GSL and may be sold freely. There is a further exemption for veterinary surgeons who are allowed to supply products, classified as POM, P or PML, to animals under their care. A further exemption from the pharmacy provision of the Act provides for veterinary medicines classified as PML to be sold by registered agricultural merchants and saddlers.

- 2.8 There is no definition in either Community or National legislation of the term 'Animals under his/her care'. The Royal College of Veterinary Surgeons (RCVS) has interpreted the meaning of the term in its Guide to Professional Conduct as follows:
- (i) the veterinarian must have been given responsibility for the health of the animal or herd by the owner or the owner's agent;
  - (ii) that responsibility must be real and not merely nominal;
  - (iii) that the animal or herd must have been seen immediately before prescription and supply, or
  - (iv) recently enough<sup>3</sup> for the veterinary surgeon to have personal knowledge of the condition of the animal or current health status of the herd or flock to make a diagnosis and prescribe;
  - (v) the veterinary surgeon must maintain clinical records of that herd/flock/individual.
- 2.9 In effect therefore the Medicines Act extends a privilege to veterinary surgeons to dispense veterinary medicines to animals under their care. This privilege is acknowledged by the RCVS, which has reminded veterinary surgeons that they should not unreasonably refuse to supply a prescription if their client wishes to purchase the medicine prescribed from a pharmacist.
- 2.10 Under European Community legislation<sup>4</sup> no person may administer any veterinary medicinal product to an animal unless it has been granted a marketing authorisation for the treatment of the particular condition in the species being treated. These Regulations apply to both food-producing and companion animals. Under these Regulations, where no authorised veterinary medical product exists for a condition in a particular species, a veterinarian (or a person acting under his/her supervision) may administer to a particular animal or a small number of animals on a particular holding:
- (a) a veterinary medicinal product authorised in the United Kingdom for use in another animal species or for another condition in the same species; or
  - (b) if there is no such product as described in (a) above, a product authorised for use in the United Kingdom in a human being; or
  - (c) if there is no such product as described in (b) above, a veterinary medicinal product prepared by an authorised person in accordance with a veterinary prescription.
- 2.11 The procedure described in paragraph 2.10 above is generally referred to as the prescribing 'cascade'. Where a product is administered to a food-producing animal under the cascade there is an additional requirement that the product administered must contain only substances found in veterinary medicinal products authorised for use in such animals. In addition the veterinary surgeon concerned must indicate a withdrawal period for the treated animal which must not be less than the standard withdrawal periods listed in the

<sup>3</sup> 'Recently enough' must be a matter for the professional judgement of the veterinary surgeon in the individual case.

<sup>4</sup> Transcribed into UK legislation by the Medicines (Restrictions on the Administration of Veterinary Medicinal Products) Regulations 1994, as amended.

Regulations. In all such cases the veterinary surgeon must maintain records of all medicines administered to animals under the cascade.

## The position in Europe

- 2.12 As we have indicated in paragraph 2.5 above, European Community legislation establishes minimum criteria which determine whether or not a prescription is required before a product can be dispensed to the public. For authorised products which are not categorised as POM member states are free to determine how they may be distributed.
- 2.13 We were made aware that the European Commission had been examining national distribution systems, through its Distribution Working Group (a sub-committee of the Veterinary Pharmaceutical Committee). The purpose of this Working Group was to identify differences between member states and to consider whether there was a possibility for the harmonisation of current divergent practices. This Working Group is, we understand, a follow-up to an earlier report published by the European Commission in September 1992 on the Distribution of Veterinary Medicines within the European Community. This report was not taken forward by the European Commission and the present Distribution Working Group, which last met in February 1999, has to date concentrated its efforts on the interpretation and application within member states of the criteria established for POMs by article 4(3) of Council Directive 81/851/EEC. The intention being to harmonise the interpretation of the POM requirements to remove the current situation where some authorised veterinary medicinal products can be sold without prescription in some member states but only on prescription in others.
- 2.14 During our visits to other member states we noted that the way in which veterinary medicines were classified and sold had, not surprisingly, evolved to meet the specific needs of the country concerned. In the Republic of Ireland a system very similar to that operating in the United Kingdom had been established. As in the United Kingdom, POMs could be sold or supplied by a pharmacist against a written prescription prepared by a veterinary surgeon. A veterinarian could also dispense directly for an animal under his/her care. However, in the Republic of Ireland, 'Animals under the care of a veterinary surgeon' had recently been defined in law. In addition the animals concerned were required to have been clinically examined immediately prior to the issue of a prescription. Non-POM veterinary products were also available without veterinary involvement from pharmacies, licensed merchants and licensed companion animal medicine sellers. Irish legislation also provides for a category of product which may be sold by a veterinarian for administration to an animal under his/her care, or directly under a pharmacist's supervision but without a veterinary prescription. Such products are classified as POM(E) (exempt) and include inactivated vaccines and a limited range of pharmaceutical products.
- 2.15 In Denmark the legislation is designed to ensure that the distribution of veterinary medicines goes through authorised pharmacies. Since 1990 veterinarians in Denmark have not been able to dispense veterinary medicines, although they may hold stocks of products obtained from a pharmacy, and they may supply these directly to a farmer. Most veterinary products, with the exception of vitamins and certain ectoparasiticides and minerals, are prescription medicines.
- 2.16 In France we were informed that approximately 90% of veterinary medicines were classified as POM, the remainder being non-prescription products which were available through pharmacies. We were also told that a derogation within French legislation provides for external anti-parasiticides intended for use in companion animals to be sold without

restriction. Within the prescription only category of products some can be dispensed by a *groupement* to its members without direct veterinary supervision but within the framework of a health plan agreed and under the control of a veterinarian. The products available through the *groupement* are laid down in secondary legislation. These include anti-parasiticides, antibiotics (in the form of medicated feeds or pre-mixes), mastitis treatments, vaccines and products to synchronise oestrus. We were told that farmers who were not members of a *groupement* and did not have an agreed health plan for their holding could only obtain these products with a veterinary prescription.

- 2.17 In Germany the main distribution route for veterinary medicines is via the veterinarian and the majority of products are classified as POMs. The veterinarian has the right under German legislation to sell and supply directly to his/her client and may obtain medicines directly from the manufacturer. A few products are available without prescription from a pharmacy.
- 2.18 The position in Belgium is that between 90 and 95% of all veterinary medicines are classified as POM – the remaining products being available over the counter at pharmacies without prescription. No sales of veterinary medicinal products are permitted through other outlets, and the veterinarian is required by legislation to obtain his/her supplies from a pharmacy. We were informed that a veterinarian could decide whether to dispense directly to his/her client or issue a prescription to be filled by a pharmacist.
- 2.19 In Portugal all veterinary medicines are classified as POM. We were informed that manufacturers or importers could sell to a wholesaler, pharmacy or other legally authorised entity. This latter group included veterinarians, who could only administer products to animals under their care, and also farmer groups which had been approved by the Ministry of Agriculture, Fisheries and Food. One of the conditions for approval is that the farmer groups have to employ a veterinarian.
- 2.20 In our meeting with officials at the European Commission we were informed that Council Regulation EEC/2309/93, which established the ‘Centralised’ and ‘Decentralised’ procedures for the authorisation of veterinary medicines, was being reviewed. We were informed that the European Commission was required by the Regulation to undertake a review of these procedures, within six years of its entry into force, on the general operation of the procedures laid down in it. The European Commission officials could not anticipate the outcome of this review and said that any recommendations made by the consultants would need to be considered by the Council of Ministers and the European Parliament under the co-decision procedure. No changes to the legislation covered by this regulation were expected to come into effect before 2005. We discussed the classification of veterinary medicines and the operation of the cascade in general terms. On classification the European Commission officials took the view that, providing the minimum criteria of article 4(3) of Directive 81/851/EEC were observed, the distribution of veterinary medicines was a matter for member states. The officials did however consider that this was an area where some harmonisation was required, and indicated their intention to re-activate the Working Group on Distribution in the near future. With regard to the operation of the cascade, we were told that the European Commission were considering how it could be modified to improve the availability of veterinary medicines, in particular for minor species. However, it was also indicated that there was a general tendency to seek tighter regulations rather than to ease access to medicines. We were given to understand that a proposal in this area was being developed within DG Enterprise and was awaiting the views of DG SANCO.

# Chapter 3:

## Pricing and availability of veterinary Prescription Only Medicines

- 3.1 The purpose of this chapter is to describe the way in which the distribution of veterinary prescription only medicines in the United Kingdom impacts on the price of those products to the end user. We also discuss a number of areas which have affected the availability of veterinary medicines in the recent past. Finally we comment on the extent to which a black market has developed. In referring to a 'black market' we mean the importation and sale of veterinary medicines which do not hold United Kingdom marketing authorisations.
- 3.2 The latest figures from the National Office of Animal Health (NOAH)<sup>5</sup> for the year ending 30 June 1999 based on returns from their member companies, show that the total value of sales of veterinary medicines in the United Kingdom was £342m of which £182.4m was in respect of sales for food-producing animals and £159.6m for companion animals. Of these figures, sales of POM products amounted to £74.5m and £130m for food-producing and companion animals respectively.
- 3.3 All manufacturers, or importers of veterinary medicines from outside the European Union, are required by Community legislation to hold a manufacturer's licence. Licensed manufacturers, including those with manufacturing premises outside the European Community, and importers are subject to regular inspections by the competent authorities in the member states to ensure that they continue to manufacture their products in accordance with Community requirements. Although manufacturers, in the United Kingdom, do not generally sell their products directly to veterinary practices or other end users, we were made aware that many routinely visit veterinary practices to advise on their products. We were also informed that it was a regular practice for veterinary practices to be given 'volume' discounts directly from the manufacturer which reflected both the quantity ordered and/or the range of that manufacturers' products purchased.
- 3.4 Manufacturers in general sell their products to wholesale dealers, although we were told that several large poultry and a few large pig units have negotiated supply contracts directly with manufacturers. Under European Community legislation wholesale dealers are required to be licensed, and are subject to regular inspection to ensure their compliance with the legislation. A wholesale dealer is able to seek a licence to deal in veterinary-only products, veterinary and human products or human-only medicines. Wholesale dealers supply veterinarians, pharmacists, agricultural merchants and saddlers directly<sup>6</sup> who in turn supply the products to the end user. We were informed that discounts of the order of 5% were also given by wholesale dealers to the majority of their customers, again based on the quantities of drugs supplied by them.

<sup>5</sup> In 1999 NOAH members provided approximately 95% of all authorised medicines in the UK for both farm and companion animals covering every legal category i.e. POM, P, PML and GSL.

<sup>6</sup> There are a wide range of businesses trading with farmers, some privately owned or PLC's, other farmer owned co-operatives, limited companies partnerships. Some of these market veterinary medicines and, for a proportion, medicine sales are a major element in business turnover. Saddlers traditionally provide requisites of all sorts for horses. In many cases, however, in order to sell cat and dog wormers, pet shops register as saddlers although their horse trade is minimal.

- 3.5 The charges made by veterinarians for providing a professional service must cover the cost of running the practice and provide an acceptable return on their investment in the business. In determining the cost of the medicine supplied by veterinarians to their clients the starting point is of course the cost of the product as supplied to the practice. Medicines are supplied by veterinarians only to animals under their care. Supply of the medicine by the veterinarian is inextricably linked to the provision of a professional service. There may however be an element of distortion in the overall cost of this service if the overhead costs of running the practice are loaded excessively on to the cost of the medicines. It is becoming increasingly common for veterinarians to itemise their invoices to clients to show, at the least, a breakdown between the cost of professional services and advice and the cost of the veterinary medicines dispensed. The margin which a veterinary practice adds to the price at which it bought medicines is not visible to the client. As with most other transactions the purchaser simply sees the final price of the medicine supplied.
- 3.6 We have already alluded, in paragraph 2.9, to the fact that under the Medicines Act 1968 veterinarians are given a privilege to dispense medicines to animals under their care. Additionally we have noted that the RCVS has reminded the profession that they should not unnecessarily refuse to supply a prescription to their clients. So far as we can establish from the evidence we have received the issue of a prescription is unusual, except perhaps in the occasional use of an authorised human medicine to treat a companion animal under the cascade. We were therefore most concerned to learn, towards the end of our review, of an obstructive attitude being taken by some veterinarians to a commercial e-pharmacy which had offered to dispense veterinary medicines (particularly those products used to manage herd health) to farmers who obtained a prescription from their veterinarian. The pharmacy was of course quite legally entitled to offer this service. The obstruction amounted to pressure being applied by some veterinarians to their wholesalers who were put in a position of having to consider refusing to supply the pharmacy concerned. It is not surprising that if such impediments are being placed in the way of quite legal operations very few pharmacies will maintain supplies of POM veterinary medicines. We discuss the implications of this in Chapter 4.
- 3.7 Availability of the veterinary medicines to the end user is not only determined by the distribution category applied to it. Account must also be taken of the extent to which existing products cease to be available and the rate at which new products are entering the market.
- 3.8 Community legislation requires all veterinary medicines administered to food-producing animals to contain only active ingredients for which a maximum residue limit (MRL) has been determined by the EMEA. Based on this an appropriate withdrawal period is set to ensure that this maximum limit will not be exceeded in any foodstuff sent for human consumption. This requirement came into effect for all new veterinary medicinal products on 1 January 1997. For those products already on the market at that date companies were allowed to continue to maintain their marketing authorisations so long as a documented application to establish an MRL for the active ingredient(s) in their product had been lodged with the EMEA by 1 January 1996. The EMEA was required to establish an MRL by 1 January 2000 or the marketing authorisation would have to be withdrawn.
- 3.9 MRLs are set for each active ingredient by individual species and tissue e.g. muscle, liver, kidney, skin and fat, milk. The cost of undertaking the necessary work to establish an MRL for each species/tissue is considerable. NOAH told us that the cost of assembling the data

package to establish an MRL was in the order of £250,000<sup>7</sup>. This cost needs to be weighed against the fact that approximately 60% of the authorised veterinary products on the market have an annual turnover of less than £100,000 and approximately 30% have less than £25,000. These costs have proved to be a significant economic deterrent for many pharmaceutical companies, particularly where the proposed uses for the product included a minor food-producing species; this includes for example, in the European context, sheep, goats, rabbits and horses. For some older products where marketing authorisations were held by several companies there was an understandable reluctance to be the first company to incur the costs of establishing an MRL because this would be seized upon by the holders of other marketing authorisations containing that active ingredient to maintain 'their' product on the market too. As a result a significant number of products were either withdrawn completely from the market or the indications of use curtailed to exclude minor species. We discuss the implications of this further in Chapter 4.

- 3.10 The cost of developing a new molecule for use solely in an animal species is very high when considered against the potential return from the market. This is the case particularly for new products intended for use in food-producing species where the animals concerned have a finite economic value. There is also the cost of establishing an MRL to be considered before an application for a marketing authorisation can be considered. We were informed that the R&D investment necessary for a novel veterinary medicine to be developed was now unlikely to be justified unless it could be utilised for a major species or to access a global market. In recent years the development of 'new' veterinary pharmaceutical medicines has concentrated on the development of existing human medicines for use in animals, particularly in the field of companion animals. We were however informed that the development of veterinary immunological products was an increasingly active area particularly in the poultry and pig sectors. Many of these new immunological products would involve some element of genetic modification in their manufacture. We noted some concerns being expressed by the veterinary profession and manufacturers that future availability of these products on the United Kingdom market might be affected by public anxieties over the use of genetically modified products generally.
- 3.11 The price and availability of veterinary medicines influence the growth of a black market. We were made aware from a number of sources that some products – particularly mastitis treatments and some flea treatments for companion animals – were available in other member states without a prescription although they were classified as POM products in the United Kingdom. The strength of sterling against currencies linked to the euro has reduced the price of products purchased in those countries. Together, lower prices and ready access have resulted in reports (which we were unable to quantify) of considerable quantities being imported illegally into parts of the United Kingdom. It is difficult to put a figure on the quantities involved because of the nature of such imports. Farmers expressed concern about this and indicated that the conditions of quality assurance schemes tended to limit the use of illegal medicines. We were also told that the VMD and officials in the Republic of Ireland were working closely together to investigate the way in which products (including intramammary products) were being sold in Ireland and exported illegally to the United Kingdom. We also noted that the Irish Medicines Board had undertaken a study on the availability of intramammary products during 1999 which, we understand, remains under consideration by the Irish government.

<sup>7</sup> The cost of establishing MRLs is especially high for large animals. The process involves experimentation to determine that the residual level of a medicine administered to an animal falls below the maximum daily intake regarded as safe for humans. In the light of this information withdrawal periods are calculated.

3.12 There appear to be differences in the price of what are essentially similar products being marketed or imported into member states by pharmaceutical companies. These differing prices reflect marketing strategies in relation to actual, or anticipated, sales volumes in the member states. We were told that a number of manufacturers were now pricing their products in euros. This may result in a balancing of prices across the euro-zone. There was some illegal movement of medicines across borders because of the differing pricing policies of the pharmaceutical companies. This included movement between the Republic of Ireland and Northern Ireland, but the extent was subject to fluctuation dependent on the strength of currencies and the local culture of cross-border trade. What was an exporting country one day could become an importing country the next. We discussed in all the member states we visited the extent to which a black market had become established. We were reassured to learn that, as we perceive the case to be in the United Kingdom, there was no large scale organised illegal trade.

# Chapter 4:

## Economic and business aspects

- 4.1 The sale of veterinary medicines in the United Kingdom is mainly by veterinary practices and is seen as part of a total service including diagnosis, prescription and dispensing. We received abundant evidence that most clients, farmers and companion animal owners were well satisfied with the service they received and had established good relationships with their veterinarians. We were also well aware that, whilst veterinary practices are businesses which have to make a profit, they are manned by people with a genuine concern for animal welfare. We recognised that the veterinary profession acknowledges that society is changing and we were grateful to receive a copy of the RCVS' *Quo Vadis* report. This examines veterinarians' attitudes, beliefs and lifestyle objective from the point of view of the profession as well as their clients. Thus, whilst in this chapter we examine the evidence we received concerning the business aspects of the supply and use of veterinary drugs we appreciated that this normally took place within continuing relationships which were valued by both parties.
- 4.2 This chapter examines the evidence we received concerning the economic and business aspects of the supply and use of veterinary medicines and their place in the farm economy.
- 4.3 NOAH informed us, that during 1999 farm medicine sales amounted to £165m. This was compared to the value of farm gate sales of livestock and livestock produce over the same period of £8.25bn or approximately 2% ex-manufacturer. It was also drawn to our attention that the average livestock farmer's veterinary bill was only of the order of 5% of turnover. It was suggested therefore that even if a major reduction in medicine costs could be achieved by this Review, it was unlikely to have a significant impact on farm businesses.
- 4.4 This view needed to be considered against the current economic conditions for farmers in the United Kingdom. When farming businesses are operating on very low margins, as they are at present, even small changes in input costs can have proportionately large impacts on farm incomes. All aspects of input costs need to be examined closely to see whether economies can be achieved. Against this background the cost of veterinary medicines to the farmer remains an important factor. Most farmers are deeply concerned about the welfare of their animals but, in the long term, they cannot survive unless they ensure that their costs, including medicines, will be at least matched by the added value of the products they sell.
- 4.5 We noted that the British Cattle Veterinary Association (BCVA) undertook a survey in 2000 of farmers' views in some key areas for the development of the veterinary profession. We were grateful to receive a copy of this survey and to the BCVA for discussing it with us. Farmers responding to this survey were primarily interested in improving the health of their stock through education and preventative medicine. Health plans were seen as a useful development. The service provided by the veterinarian was highly valued and the majority of farmers appeared to want to retain the same fee structure and quality of service. Medicine prices appeared to be a sensitive area and there was a division between those farmers who felt that lowering drug charges at the expense of higher fees would be a good option. Transparency in the overall billing was seen as valuable. Livestock farming cannot however be considered solely in such global terms. We therefore considered each livestock sector separately.

## Poultry

- 4.6 In poultry production, birds are rarely treated as individuals, as treatment is generally given to the flock as a whole. The poultry industry is highly intensive and is also relatively concentrated. We were informed that broiler production was in the hands of perhaps six major producers. As far as egg production was concerned there were four or five major producers. Most United Kingdom turkeys came from two major producers who operated at an international level.
- 4.7 Veterinary care for these flocks was either through veterinarians employed by the companies themselves or by specialist dedicated poultry private practitioners. Because of the intensive nature of this sector, costs of all inputs into the production process were monitored closely. The cost of veterinary medicines was tightly controlled within this process and was not seen as a major issue. Concern was however expressed about the lack, or non-availability, in the United Kingdom of certain vaccines that were available in other member states. This had led, we were told, on occasion to day-old chicks being transported across the Channel to be vaccinated and subsequently returned. We were also informed that chicks vaccinated with products which were authorised in another member state, but not in the United Kingdom, could legally be imported although the vaccine itself could not.
- 4.8 Concern was also expressed about the limitations placed on the availability of medicines for turkeys, ducks and geese because of the lack of MRL data for these species. As a result only some products authorised for use in chickens are available for other birds under the provisions of the cascade. In such cases a standard withdrawal period of 28 days was applied, which in some cases made treatment uneconomic given the short life-span of the birds. Poultry veterinarians considered that urgent steps needed to be taken to address the possibility of extrapolation of MRL data established for one species to others, in order to increase the availability of products and reduce withdrawal periods.

## Pigs

- 4.9 Pig production mirrors the poultry sector in some aspects. In this sector pigs too are generally treated on a herd basis. Production of pigs is more diverse than poultry although there is undoubtedly a move towards centralisation of production in the hands of a relatively few large companies. Some of these will have their own 'in-house' veterinarians. There has been a severe reduction in the number of pigs produced in the United Kingdom over the last two years. This has led to a reduction in the client base for pig veterinarians. We were told this had forced veterinary practices to become more competitive. As a result margins in these practices had fallen, and veterinary and medicines costs now represented less than 4% of total pig production costs.
- 4.10 The availability of medicines for pigs had reflected a decline in feed medication usage in recent years and a switch towards the use of vaccines to control disease, particularly respiratory disease. There was some concern that immunological products which were apparently available elsewhere within the European Community were not available in the United Kingdom.

## Beef

- 4.11 Beef production has been affected dramatically by the BSE crisis and stock values have fallen. One of the consequences of this is that the client base for veterinarians has declined. On the face of it this should have led to increased competition between practices, but this had in general only arisen in areas of high stock density. In other areas there has been a

reduction in the number of veterinarians who are prepared, or can afford, to provide large animal services. Cost of treatment remains a significant factor in the uptake of veterinary services, but we were not informed of any specific problems relating to the availability of medicines.

## Dairying

- 4.12 Dairy farming has experienced a severe reduction in prices since the mid-nineties. There has been a sharp reduction in the number of milk producers within the industry although the average United Kingdom herd size at 80 cows remains approximately double the European Community average. Dairy cow numbers have fallen, too, since markets have not grown to match increased milk yields. This trend seems likely to continue.
- 4.13 In this sector veterinary input and medicines are a substantial proportion of production costs. The costs United Kingdom dairy farmers pay for medicines are higher than in some other member states which is currently a matter of serious concern since it puts United Kingdom milk producers at a competitive disadvantage in the international milk and dairy produce market. We were informed by the industry that prices of several medicines were two or three times, and in some cases much more, than those paid by the United Kingdom's main dairy farming competitors. No problems of availability were drawn to our attention; nevertheless the ease with which products at significantly lower prices, particularly dry cow therapies from the Republic of Ireland could be obtained, provided an incentive and the means necessary to develop illegal imports.

## Sheep and goats

- 4.14 We were not made aware of any specific issues surrounding the availability of veterinary medicines for sheep, or the impact the costs of such products had on the economics of sheep production. However, the falling value of sheep meant that it was uneconomic to treat some animals. Concern was expressed to us about limited availability of veterinary medicinal products for goats within the United Kingdom compared to elsewhere in the Community.

## General

- 4.15 The farming community has always taken a pragmatic view of the cost of veterinary involvement against the benefit in terms of added value. Nevertheless the cost of seeking treatment for an animal has increasingly become an issue for livestock farmers. In today's economic climate the cost of a visit by a veterinarian and any required procedure or medication is being closely weighed against the lower price which could be realised for the animal. Where it would be unprofitable to treat an animal it is more likely to be left to recover. If this fails it will die, be slaughtered, or perhaps treated with an unauthorised or inappropriate product. This position is unsatisfactory: not only are there grounds for concern about animal welfare but there is a risk that overall the health of the national herd will diminish. Concerned as we are by this position we do not feel that our terms of reference enable us to comment further or make recommendations in this area. We do however consider that the realities of lower value stock and less frequent visits to farms by veterinarians means that farmers have to ensure that they and their stockmen are adequately trained and knowledgeable in animal welfare. It is also most important that they know when their level of competence makes it essential to call in the veterinarian.

## Service charges

- 4.16 We also needed to consider the ways in which owners are charged for the medicines that they buy from veterinary practices. As we have described in Chapter 3 veterinary practices obtain their supplies through veterinary wholesalers. We understand it is normal for veterinary practices to hold sufficient stocks of veterinary medicines in their pharmacies to meet possible emergencies and likely demands. We were somewhat surprised at the high level of stocks being held, particularly given the ability of the specialist veterinary wholesaler to give a same day or next day service even to remote areas.
- 4.17 There is, of course, a real cost involved in running a pharmacy within veterinary practices and these costs must be recovered from the client. In their evidence to us the BVA indicated that in many cases the operating costs of a pharmacy have not been fully appreciated by the profession. Indeed, it would appear to us that animal owners are unaware of the various costs underlying the price they pay for medicines. We were pleased therefore to note that the BVA had undertaken a pilot study in this area. In the pilot study it was found that practice expenditure on veterinary medicines was an average 38% of business turnover and that the value of stock in hand averaged £41,000 or 46 days' supply. The costs of providing the pharmacy service were categorised and included staff, buildings and storage, equipment, wastage, financing, insurance etc. In aggregate terms the cost of providing a pharmacy was of the order of £68,000 per annum or 20% of the annual expenditure on veterinary medicines purchased by the practices surveyed. The BVA recognises that, because of the limited size of the pilot survey, care needs to be exercised in interpreting the results. We welcome the steps it has taken to commission a wider study.
- 4.18 There is, however, no doubt in our minds that veterinary practices need to become more aware of the costs of providing a pharmacy service and the impact this is having upon their operating costs. We consider there is scope for a greater proportion of veterinary practices to apply improved business practices in the operation of their pharmacy service and **we so recommend**. We would question, in particular, the need to hold such large volumes in stock as is apparently the case. We believe that savings could be achieved in this area which could be passed on to clients.
- 4.19 It was also clear from the evidence provided that veterinarians derive a significant part of their overall income from the sale of veterinary medicines. Measurement of margins may be either as a proportion of the price to the customer or as a percentage of the cost to the veterinary practice. The evidence we received included both approaches. A survey undertaken by the British Market Research Bureau for the BVA revealed that the average margin by veterinarians, as a percentage of the retail price, varied between 33% and 52%. All the practices taking part in the BVA survey applied a margin of 50% on the list price of POMs. However, competition from agricultural merchants and others meant that similar margins could not be made on PMLs or GSLs where margins were respectively of the order of 20% and 29% of list prices. Other evidence we received confirm these figures in broad terms.
- 4.20 We have alluded, in Chapter 3, to the fact that veterinary practices receive discounts on list prices from wholesalers based on quantities delivered and, additionally, 'volume' payments or other incentives are made directly to the practice by manufacturers. We have no accurate figures on these discounts because they are not published information. Such discounts do, of course, reduce significantly the list price of the drugs purchased to the practice. We were, however, unable to establish whether these volume discounts were reflected in the base price of the medicines on to which the margins referred to in paragraph 4.19 were subsequently

added, or whether these margins were added to the retail list price. In the latter case the cost of the medicine to the client would be significantly increased.

- 4.21 We were also made aware that it was considered accepted practice within veterinary practices for professional fees for diagnosis to be ‘underpriced’ (set below the true cost of the service) and for the cost of the medicines supplied to be ‘over-priced’ to compensate. It was suggested to us that this practice had become established because historically farmers were, in general, reluctant to pay for advice but were willing to accept relatively high costs for medicines. It was further suggested to us that, since the overall aggregate invoice was the same, no benefit would come from reflecting the real cost of professional advice at the expense of reducing medicine costs. Conversely it was implied that such a course of action could reduce either the number of visits made to farms or, indeed, the time spent on the farm with consequential adverse financial effects on farmers.
- 4.22 We are not convinced that this would necessarily be the case. It implies a paternalistic attitude to farmers. In a genuinely competitive market farmers should be allowed to make their own judgement about the value of professional services, and medicines should be available at prices which correspond better to their true cost. At present the farming community have little or no scope for obtaining supplies of prescription-only medicines from anyone else but their veterinarian. If steps were taken to provide a degree of choice, through the issue of a prescription by a veterinarian, farmers would, we believe, be able to test the market for alternative sources of supply. We accept however that it would, in such circumstances, be unrealistic for veterinarians’ fees for professional advice to remain unchanged.

## Companion animals

- 4.23 So far in this Chapter we have considered the factors affecting the price and availability of veterinary medicines to owners of food-producing animals. In relation to companion animals many of the same factors apply. As with food-producing animals, veterinary practices dealing with companion animals derive their income from professional fees for advice and services and also through the dispensing of veterinary medicines. In some practices additional income is derived from other pet-related services, e.g. sales of specialist and life-stage pet foods and pet care products. From the evidence we received we learnt that sales margins on medicines in small animal practices ranged from 25% to 100%, dependent upon whether the product was a POM, PML or GSL. Stock levels and rate of turnover also impacted on these margins. The average margin on purchase price in a recent survey undertaken by the British Small Animal Veterinary Association (BSAVA) was found to be between 43% and 61%. This had to cover the cost of running the practice pharmacy.
- 4.24 We also established from the submissions of written evidence and our discussions during the oral evidence sessions that professional services and advice were under-priced although it was clearly felt that companion animal owners are more willing, in general terms, to pay the real cost for the services received. Surveys undertaken by the BSAVA and BVA indicate that owners of companion animals are generally content with the level and cost of service provided to them. However, on the basis of the evidence received, costs of medicines remain a significant cause of concern to companion animal owners, particularly to those whose animals suffer from chronic conditions and to those on low incomes.
- 4.25 We have already drawn attention in Chapter 2 to the fact that it has always been open to clients to request a prescription from their veterinarians. Despite this few owners appear to be aware of this option nor are many willing to ask their veterinarian for a written

prescription. The convenience of the 'one-stop service' suggests that few clients would wish to change where they buy their medicines. However, the lack of transparency in this area prevents companion animal owners from having any real option but to obtain the necessary medications from their veterinarian. It also makes it uneconomic for pharmacies to hold stocks of veterinary medicines.

- 4.26 Two main issues were raised concerning the range of veterinary products available for companion animals: first, the legal distribution classification applied to certain groups of companion animal products, including flea and tick treatments and wormers. We discuss the factors affecting the classification of veterinary medicines in Chapter 5. Second, the requirement under European Community legislation for only the authorised veterinary medicine to be used, even though a cheaper authorised human generic medicine was available, had an impact on animal welfare. We have some sympathy for the arguments put forward that this can compromise animal welfare. We were also distressed to learn that one of the commonest causes of prosecutions by the RSPCA on welfare grounds, was flea dermatitis. In some cases the costs of treatment may mean that the only affordable route known to the animal owner is the euthanasia of the animal concerned.
- 4.27 Article 4 of Directive 81/851/EEC requires, in the first instance, that only an authorised veterinary medicine for the specific condition in the species should be administered. That Article goes on to describe the circumstances in which alternative products may be used and only permits, under the terms of the prescribing 'cascade', the use of authorised human medicines where no authorised veterinary medicine is available. Veterinarians are therefore tied to the use of the authorised veterinary medicinal product as a first choice, irrespective of whether there is a cheaper authorised generic human product readily available.
- 4.28 We recognise the necessity for this requirement in food-producing animals, but we see no valid reason for its application to the companion animal sector. Apart from the probability that medicines authorised for specific conditions in the species concerned are likely to be more effective, it is also the case that existing rules encourage manufacturers to undertake the considerable cost of developing such products. We felt that owners of companion animals who could afford the authorised veterinary medicine would wish their veterinarian to use them. However, where the cost of these was much higher than the human generic medicine, it was important that those for whom this proved too costly should have access to generic products. It would be the responsibility of veterinarians to explain the situation to their clients. We accept that this cannot be done legally at present but this measure would be of particular value to the charitable organisations serving the less affluent companion animal owners. **We recommend** that the Minister encourages the European Commission to amend the existing legislation to allow veterinarians to prescribe generic treatments for companion animals where, after consultation with the owner, they come to the conclusion that this is the best treatment for the animal concerned.
- 4.29 Finally in this Chapter we also need to consider the availability of medicines for the horse. The horse is defined in European Community legislation as a food-producing animal despite the fact that many are kept for sport and recreation or companion purposes throughout the European Community. Because of its classification as a food-producing animal products cannot now be authorised for use in this species unless or until an MRL has been established for the active ingredient. We have already referred to the high cost of establishing MRLs for minor species and this requirement has reduced the number of products available for horses. During the course of our review we were informed that the problems surrounding the status of the horse and the availability of products for it were being considered at European Community level. There appears to be no equivalent method of recording the administration

of veterinary medicines to that applied to other food-producing species. A possible solution had been proposed through an extension of the Horse Passport scheme that would have introduced a declaration as to whether or not the horse was intended for human consumption. This would have ensured that a companion, recreational or sporting horse could not have been slaughtered for human consumption unless a six-month withdrawal period had elapsed. We understand however that this proposal has run into legal difficulties that require a change in Community law. We are aware that, in the interim, the European Commission is actively seeking an alternative solution to this matter. **We recommend** that the Minister encourages the European Commission to develop a proposal for a written record to be kept of medicines administered to a horse by its keeper. This could be in the form of a 'horse passport'. It would allow medicines, for which an MRL had not been established, to be administered to a companion, recreational or sporting horse. It would also enable a starting date to be determined to ensure that an adequate withdrawal period could be set should, at some time in the future life of the horse, it become destined for human consumption.

# Chapter 5:

## The impact of regulations and classification of veterinary medicines on availability, animal welfare and price

5.1 In this chapter we consider and make recommendations on the basis of the evidence that we have received relating to regulation and classification of veterinary medicines and the impact that this has on availability, animal welfare and price.

### Background

5.2 The regulation of veterinary medicines seeks to ensure that they are available to treat diseases or other conditions with proper regard to the safety and welfare of both the animals and the person administering the product, of the environment and, in the case of food-producing animals, to minimise the risk of consumers being exposed to medicine residues. Regulations seek to ensure that proper control can be exercised over the products used by establishing the distribution channels through which the authorised medicine may be made available.

5.3 Our terms of reference required us to review the procedures by which prescription only medicines for veterinary use are classified and sold in the United Kingdom and the impact that the current practices may be having on availability and price. In the evidence we have received concern has been expressed that:

- the present regulatory system is unnecessarily restrictive, and that it limits the availability of some veterinary medicines with consequential or potential adverse effects on animal welfare;
- that medicines cost too much to the end user; and
- that the regulations are ineffective in securing accountability, in particular that they have not prevented the illegal import of veterinary medicines into the United Kingdom.

In the following paragraphs we discuss these issues.

### The regulatory system

5.4 We have reviewed the regulatory mechanisms put in place in the first instance by the Medicines Act 1968, and subsequently extended and reinforced by legislation made which reflects the requirements of Council Directive 81/851/EEC and Council Regulation EEC/2309/93.

5.5 We do not consider that the centralised procedure is at present having any significant impact on the availability of veterinary medicines in the United Kingdom. The rationale for its introduction was to create conditions in which a single scientific evaluation would lead to rapid access to an integrated market for innovative and good value treatments. This has not happened. The relative paucity of applications coming forward under this procedure is probably because, in the veterinary sector, the patterns of disease across the Community are such that many products simply do not have a European Community-wide market that

would justify a centralised application. In practice all products authorised under the centralised procedure are classified as prescription only products, even if they are already available as a human authorised medicine. It was also suggested to us that if a product is rejected via the centralised procedure it cannot then be reintroduced through the mutual recognition procedure. It is a matter of concern that there is no mechanism in place for this classification to be reviewed at some future date.

- 5.6 We acknowledge the above concern. However, in the light of the fact that in a majority of member states the preponderance of products are classified as prescription only there seems little scope for seeking the introduction of any change to the existing procedure. Should, as an outcome of the current review (see paragraph 2.20) being undertaken by the European Commission on the operation of the centralised procedure be opened up to a wider range of product types than is currently the case. **We recommend** that in such a situation the Minister should urge the European Commission to introduce a mechanism to provide a more flexible approach at the initial authorisation stage, and for a regular review of the initial classification of products holding a centralised marketing authorisation.
- 5.7 The decentralised procedure is also intended to facilitate access to the single market by relying on the principle of mutual recognition under which a marketing authorisation granted in one member state is recognised by one or more other member states. In principle this procedure should increase the availability of veterinary medicines by providing for a relatively quick and inexpensive access to a wider market. For pharmaceutical companies it provides the opportunity to develop a market in one member state before expanding into others. Moreover it avoids the perceived risk of failure to gain access to the whole Community market as is the case under the centralised procedure.
- 5.8 We were therefore disturbed by the evidence we received that the pharmaceutical industry did not make much use of this mechanism. We noted too that, in its recent report to the European Commission on the *Operation of the Community procedures for the authorisation of medicinal products*, Cameron McKenna had indicated that the basic principles underlying the decentralised system were being undermined by many member states' authorities who continue to exhibit an extreme reluctance to accept the assessment of the reference member state. The competent authorities do not seek to disguise the fact that there is an unwillingness of member states to abide by the principles of mutual recognition. This flouts the principles of mutual recognition and frustrates the development of a Single Market.
- 5.9 We note the initiative taken by the United Kingdom government during its last Presidency of the European Community to instigate the Veterinary Medicines Mutual Recognition Facilitation Group (VMRFG). The aim of this Group, as its name implies, is to facilitate the passage of a decentralised application through the assessment procedure. **We recommend** that the VMD examine closely its own procedures for dealing with applications under the decentralised procedure to ensure that it does not place any unnecessary obstacle in the path of mutual recognition or is, in any way, 'gold plating' its requirements.
- 5.10 Although the centralised and decentralised procedures have been in place since 1 January 1998, most products were authorised under national procedures in the United Kingdom and in other member states. Whilst it is possible for a pharmaceutical company holding national marketing authorisations for the same or essentially similar products in several member states to seek to harmonise these through the decentralised procedure, there is no incentive for the company to do so. Similarly a company holding a national marketing authorisation for a product or group of products in a member state where there is a reasonable return from that market has no incentive to seek to gain access to other markets, including those of

fellow member states, where the return from the product would be minimal. The effect can be that, to avoid unnecessary suffering to animals, the veterinarian is forced to administer another authorised product indicated for a similar condition in a different species.

- 5.11 It is possible, where a product is authorised in two or more member states, for it to be purchased by a wholesaler in one member state and imported into another as a parallel import. We understand that the ability to do so has been tested in the European Court of Justice<sup>8</sup>. Essentially the Court concluded that parallel imports need a marketing authorisation before they can be marketed in the importing member state but that some of the normal rules for granting such an authorisation need not apply. We noted that the VMD had made provision for parallel imports to take place through a Marketing Authorisation Parallel Import procedure. Whilst this procedure offers the potential at least to increase the availability of authorised veterinary medicines on the United Kingdom market and to exert a competitive element into the pharmaceutical companies pricing policies, so far as we are aware no such authorisations have been granted by the VMD. We can only conclude that at present the potential returns to the parallel importer are not seen as being sufficient to justify an interest into these arrangements.
- 5.12 We understand that the European Commission is seeking to improve the availability of products, particularly for minor species, by seeking to amend the 'cascade' to allow the use of products authorised in other member states rather than just in the member state concerned. The European Commission sees this relaxation of the existing requirements as forming part of a general process for the revision of the marketing authorisation system as a whole. It intends to finalise its proposals during 2001. Unfortunately, the whole revision process will take several years to complete once the proposals are published and no immediate solution is foreseen, despite the recognition that the lack of availability of medicines for minor species is a significant problem.
- 5.13 We have given this matter careful thought in view of the concerns expressed to us about the lack of available products. We note that article 4.1 of Council Directive 81/851/EEC provides *inter alia* that '*where the health situation so requires, a member state may authorise the placing on the market or administration to animals of veterinary medicinal products which have been authorised by another member state in accordance with this Directive.*' We understand that the VMD already takes advantage of this derogation through its Special Treatment Authorisation procedure. We suggest that the VMD should examine the derogation provided by article 4.1 closely to see whether it can be more fully utilised in the short/medium term to increase the availability of medicinal products for minor species. **We recommend** that the VMD should permit the import of medicines authorised in other member states, provided they are properly labelled in English and sold via the approved distribution system within the United Kingdom.
- 5.14 The availability of authorised veterinary medicines for food-producing animals (many of which hold national marketing authorisations) has also been adversely affected by the need to establish MRLs. We have already mentioned in paragraphs 3.8 and 3.9 that holders of marketing authorisations for products intended to treat food-producing animals are required to lodge an application and supporting data with the EMEA to support an MRL for the active ingredient contained within them. The cost of developing MRLs for products for which the market return is small, or for minor food-producing species, led many manufacturers either to limit the work done to establish an MRL to the major use or to

<sup>8</sup> Ref CJEC 20.5.76, Case No 104/75 De Peijper. 1976 Report page 613.

remove the product from the market altogether. We understand that the EMEA has identified more than 100 pharmacologically active substances which had been used in veterinary medicines for many years but for which no MRL had been established by the cut-off date of 1 January 2000. The products containing these active ingredients were consequently removed from the market.

- 5.15 The European Commission has recognised the problem of availability of veterinary medicines and in its Communication to the Council and European Parliament of 5 December 2000 reference COM(2000)806 final it has proposed short-term and medium-term measures to alleviate the situation. The short-term solution is a proposal to use guidelines, to be established by the CVMP, which would allow for the extrapolation of data generated to justify an MRL in a major species to calculate an MRL for a relevant minor species. We welcome this initiative, however it may be a case of too little too late insofar as it will not result in the lost products regaining access to the market. In the medium term the European Commission proposes to adapt existing European Community legislation, with the objective of making a company's financial investment prior to marketing a new product more attractive, and allowing the use of products authorised in other member states. The paper also indicates that the European Commission is continuing to reflect on the possibility of developing a scheme which would enable financial support to be given to maintain essential, but unsupported, veterinary medicines on the Community market.
- 5.16 We support these initiatives, however we are concerned at the time scale being proposed which, we understand, may be in excess of five years. **We recommend** that the Minister supports the proposals to allow the extrapolation of MRLs for major species to calculate MRLs for minor species and so increase the availability of veterinary medicinal products on the market.

## Classification

- 5.17 Veterinary medicines are potent products that have the potential to support animal health and welfare. But they are also potentially hazardous substances if used inappropriately or without adequate supervision. For this reason the legal distribution category, or classification applied to a product has an impact on its availability. Our terms of reference required us to consider the classification of prescription only medicines. It is not surprising that the evidence we received expressed conflicting views about the need to reclassify products which are currently POM to a less restrictive category i.e. P or PML and *vice versa*. On the one hand it was suggested to us that availability to the end user would be improved considerably if more products were categorised as either P or PML; on the other it was suggested that if such a move should take place there would be a risk that these products would be over-used or administered either inappropriately or incorrectly. Some veterinarians expressed the views that the products currently classified as PMLs should be redefined as POMs. It was suggested to us that if a veterinarian dispenses as well as prescribes a POM this would provide a greater degree of certainty that it will be used correctly.
- 5.18 We needed to consider whether, in the case of veterinary medicines which are left either on the farm or with a companion animal owner, they are any more likely to be administered correctly than if the medicines had been obtained from either a pharmacy or a registered agricultural merchant.

- 5.19 This is a complex area. However the system as a whole depends upon assumptions about the competence of people using the medicines whether they are dispensed by the veterinarian, a pharmacist or a registered agricultural merchant. The need for professional training and continuous professional development is well recognised in all these fields and it is important that this continues to be the case. Sales of veterinary medicines, other than GSL products can only be made by suitably qualified persons – in the broadest sense. In providing medicines, those dispensing can give advice on their use. Veterinarians can not only advise but demonstrate how they are to be administered. Pharmacists can ensure that the prescriptions they dispense include the necessary instructions about use. The SQPs employed by agricultural merchants can, for example, discuss the appropriate wormer to be used if resistance is to be avoided. **We recommend** that continuous professional development should be required of all involved in the prescription and dispensing of animal medicines and for all who have responsibility for the care of animals. A formal record of training undertaken and the level reached should be available on request. The requirement for training should be extended to those on farms who have animals under their care when appropriate courses are available. Sales of medicines to livestock farmers should increasingly be subject to written evidence of competency in their use. These measures would, we believe, be seen by consumers and food retailers alike as a significant step in demonstrating that veterinary medicines were being properly used on farms. **We further recommend** that farmers and veterinarians join with pharmacists, agricultural merchants and farm management advisors to create health plans for farm animals within which medicines can be supplied at least cost. In making these recommendations we recognise and acknowledge the valuable work already being undertaken by the Responsible Use of Medicines in Agriculture (RUMA) Alliance and in the various Farm Assurance Schemes which are being developed throughout the industry. We see our recommendation and these initiatives running concurrently.
- 5.20 It has been pointed out to us that, once a veterinary medicinal product has been granted a distribution category through the issue of a marketing authorisation, it normally retains that category until and unless the holder of the marketing authorisation seeks a change to that category. It remains open to the VMD at any time to require a change in the distribution category should the results of pharmacovigilance suggest that a more restrictive distribution category is needed. It has been suggested to us, particularly in the case of products which are classified as POM, that leaving the decision on whether or not to seek a re-categorisation of the product in the hands of the marketing authorisation holder may reduce the availability of that product. We were asked to consider whether it would be appropriate for the distribution category assigned to a product to be determined by an independent body.
- 5.21 In considering this suggestion we were made aware that the VMD has recently agreed with the VPC a procedure for changing the legal classification of an authorised veterinary medicinal product. This new system, which is currently the subject of a formal consultation, would enable the holder of the marketing authorisation or other interested organisations/individuals to request a change in the legal category of a product or group of products. Such requests would be considered by the VMD and the advice of the VPC sought. However as it will be necessary to amend the relevant secondary legislation before a product's legal classification can be changed, it will be for Ministers finally to determine, in the light of the responses received during the formal consultation process, whether the relevant Orders should be amended.

- 5.22 We welcome the initiative taken by the VMD, which will introduce a degree of openness into the classification procedure. Irrespective of the actual distribution category assigned to a product it will however remain for the holder of the marketing authorisation to determine how the product should be retailed. We understand that some companies have a policy of marketing their products through veterinary practices only whereas, others will market only through registered agricultural merchants. These decisions are essentially commercial ones for the companies concerned. We do not consider it necessary or appropriate for us to seek to influence their marketing strategies. However, concerns were expressed to us that some products appear to be anomalously classified. **We recommend** that the VMD should set in train a review of existing classification applied within therapeutic product groups to ensure their consistency and that it should be willing to consider requests for the revision of a product's classification from any party who offers evidence of an appropriate nature and quality.
- 5.23 There is no doubt in our minds that the present arrangements for the classification and distribution of veterinary medicines in the United Kingdom have served the interests of the British farmer and companion animal owner well. The POM, P, PML and GSL categories have in the main ensured that the end user can obtain products with the appropriate degree of advice and under suitable controls. It must however be recognised that the United Kingdom's distribution arrangements remain something of an anomaly in terms of the way in which veterinary medicines are classified elsewhere within the European Community where the majority of products are categorised POM (as prescription only medicines).
- 5.24 We were impressed by the approach to the supply of medicines in France. There the *groupement* system enabled medicines to be supplied directly to farmers as part of a health plan developed in consultation with a veterinarian. In the United Kingdom the development of Assurance Schemes, where farmers produce to agreed and monitored standards, provides a basis for developing similar arrangements for the supply of medicines without a requirement for a specific prescription in each case. We believe that this approach can provide a starting point for developing integrated farm plans which encompass the health of farm animals, safeguards for the environment, assurance to customers and the need to ensure that the farm itself is profitable. It is an approach which brings together expertise from several disciplines and which supports the farmer and the person responsible for the care of farm animals. Where farmers can show that they have such a plan in operation, which will include the prescription by a veterinarian of necessary medicines that do not require specific diagnosis, they could access these medicines without requirement for specific additional prescription. Such medicines could be bought from agricultural merchants and other registered retailers.
- 5.25 There is a need in all circumstances for assurance that the person handling the medicines on the farm is competent. In due course we believe that this assurance should be demonstrated by qualifications resulting from attendance at approved courses. Once such systems can be put in place, farmers who do not have animal health plans for their farms or who cannot demonstrate their competence to use medicines would only be able to access medicines with a veterinary prescription. We believe that such an approach would increase assurance to consumers that medicines used on United Kingdom farms were handled in a responsible way. It would assist farmers to minimise the need to use medicines and also to make efficient use of them. It would make use of existing expertise in medicine handling among agricultural merchants and justify some increase in the range of medicines they were allowed to sell. United Kingdom farming faces intense competition. Meeting public concerns about animal welfare, environmental values and food safety will remain important. An

approach, which integrates and makes efficient use of available and proven skills, building them into workable and viable systems of animal production, can strengthen the place of agriculture both in the market and in public confidence. We also believe that a system, which can demonstrate that the control of medicines in the United Kingdom is rigorous, efficient and effective, will help to pave the way for replacement of national systems by one that can be accepted throughout the European Union.

- 5.26 We were made aware that both FEDESA – the European body which represents veterinary pharmaceutical manufacturers and COPA / COGECA which represents Community farmers and co-operatives have indicated their support for a three tier distribution system being established within Europe. This would involve a first tier of products that would be made available only under a veterinary prescription and following an examination and diagnosis of the animal concerned by a veterinarian. A second tier would enable products, to treat conditions which did not require a prior veterinary examination or diagnosis, to be made available without prescription from a veterinarian, a pharmacist and those trained specifically in animal medicine distribution on a controlled basis. Finally a third category of product would be available on a free sale basis. We do not disagree with this approach, which in some ways recognises a distribution system pattern which has become established within the European Community already. We recognise however that the proportion of products falling within any one of these distribution tiers will differ widely between member states. The majority of products would appear to fall into the first tier, i.e. available only under prescription and some member states do not appear to have a free sale tier.
- 5.27 We consider however that the existence in the United Kingdom of the PML category may even be seen by other member states and the European Commission as obstacles to the establishment of a harmonised system throughout the European Union. In the long term therefore we consider it would be advantageous for the United Kingdom to examine the feasibility of moving to a system which contained just POM and GSL products. We envisage that the POM category would include veterinary medicines which might be dispensed/sold by veterinarians and pharmacists (against a prescription). In the case of registered agricultural merchants/saddlers and in the future also by registered pet shops a limited range of POMs could be sold to animal owners and their agents who can demonstrate that they are competent by holding sufficient qualifications, have an agreed health plan which has included veterinary advice and are sufficiently experienced to administer the products properly and safely. This POM category would need to be subdivided into those requiring a lesser degree of control and subject to regular review but we believe it would enable a more flexible approach to be taken to the availability of veterinary medicines and fit less abrasively into a European model.
- 5.28 **We recommend** that the Minister should consider moving in the longer term towards adopting a system of classification that has two major categories: Prescription Only Medicines and General Sale List products. We would suggest that the POM category should be divided into three sub-groups as follows:
- POM (A) – medicines which may be administered only by veterinary surgeons or under their direct supervision. In the latter instance the veterinary surgeon should be present at the time of administration and in a position to render assistance if necessary.
  - POM (B) – medicines which may be sold or dispensed by veterinary surgeons to animals under their care after a prior clinical examination of the animal or animals; or sold or dispensed in a pharmacy in response to a written veterinary prescription.

- POM (C) – medicines which may be sold or supplied by veterinarians for administration to animals under their care, by pharmacists or, providing the purchaser can demonstrate evidence of competence in their use by registered agricultural merchants. For this group of products a prior clinical examination of the animal(s) is not a requirement, however in cases where no evidence of competence is available the products in this category should only be made available by pharmacies, registered agricultural merchants or other registered outlets against a written prescription from a veterinarian.

5.29 **We further recommend** that prescriptions written by veterinarians should be dispensed by any suitably qualified person, including the prescribing veterinarian, other veterinarians, pharmacists and, in the case of POM (C) products, by persons holding AMTRA, SQP qualifications and employed by registered agricultural merchants or other registered retail outlets.

## The cost of veterinary medicines

- 5.30 In the following paragraphs we consider the cost of veterinary POMs to the end user. In principle medicines that can be safely used by the general public should be readily available through normal retail outlets. This would certainly require clear instructions from the manufacturer that could be in three or four languages. In such cases competition is likely to determine the cost to users.
- 5.31 In the evidence we received considerable concern was expressed about the cost of POM veterinary medicines in the United Kingdom compared to elsewhere in the European Community. These views were most strongly expressed by owners of companion animals, particularly those with animals requiring long-term treatments e.g. for heart conditions or epilepsy. In the food-producing sector producers were also concerned about prices being higher than in other countries. However they also wished to see greater transparency in the billing process so that competition could help to hold down costs. Despite the RCVS having recently reminded the profession of the need to supply a prescription if requested to do so, very few clients seemed to be aware of this fact. As a consequence dispensing of POMs and other veterinary medicines by veterinary practices had become the normal situation.
- 5.32 For competition to work well there needs to be transparency so that the customer, in this case the client, can choose what packet of services they value most. It has been suggested to us that healthy competition already exists between veterinary practices and a client is free to move from one to another if he/she considers that the costs of treatment at a practice is too high. Whilst this may be true we do not believe that it is sufficient. It may be that the majority of clients do not want to disturb the special relationship they have with their veterinarian, often developed over many years. By default they may believe that they can only obtain veterinary medicinal products from the practice and they may well consider that their veterinarian is the best qualified person to supply those products, valuing the 'one-stop-shop' that the practice provides. Nevertheless we believe that some transparency needs to be introduced to ensure that clients are fully aware of the options they have. One step in the right direction would be for veterinary practices to encourage their clients to understand the background to the prices of veterinary medicines by providing price lists for the more widely used veterinary medicines and the routine procedures undertaken in their practices.
- 5.33 We consider however that it should be regarded, as required practice for veterinarians to provide a written prescription at the end of the initial clinical examination, when prescribed medicines have to be dispensed. There should be either no additional charge for this or for routine repeat prescriptions which do not require further clinical examination, a fee, to cover

no more than administrative costs, to be determined by the RCVS acting in the public interest. In the oral evidence given to us the RCVS suggested that £2.50 would be an appropriate charge. **We so recommend.** It would then be for the client to decide whether to have the medicine dispensed directly or to take the prescription to a pharmacy for dispensing. We do not see this procedure as precluding the immediate administration of a veterinary medicine either to stabilise a condition in an emergency or to commence a course of treatment. Clearly it could not apply where emergency treatment is needed, for treatments during surgical procedures or for the use of anaesthetics. We do however see the issue of a written prescription as a required procedure when medication is required as necessary to ensure that the necessary element of choice is placed in the hands of the client. Above all our other recommendations we see this as being fundamentally important in allowing market forces to determine the cost of veterinary medicines to the end user.

- 5.34 We believe that if our recommendations relating to the classification of veterinary medicines, training, increased competition to dispense prescriptions and adequate monitoring by professional bodies are taken into account, then an extended list of medicines should be developed which can be responsibly sold through registered agricultural merchants and other suitably registered outlets.

## Illegal imports

- 5.35 We have already referred in paragraph 3.12 to the fact that the illegal movement of products across borders is not unique to the United Kingdom. We were pleased to note that the perception in all those member states we visited was that this appears to be an opportunist trade carried out largely by individuals rather than a large-scale black market. Nevertheless, the fact that it is occurring at all is a matter of some concern. We have discussed the United Kingdom situation with the VMD and officials in Northern Ireland, and we are satisfied that rigorous action is being taken where cases that merit prosecution are detected. There is no doubt in our minds however that the lack of harmonisation in the classification of veterinary medicines coupled with limited availability of products, perceived high United Kingdom prices and the strength of sterling are all factors which aggravate the position. We can do nothing about the strength of sterling, but we believe that the recommendations we have made earlier in this chapter will go some considerable way to ameliorating the current situation and remove over time the incentive for such illegal trade.

# Chapter 6:

## Other issues

6.1 In this short concluding chapter we draw attention to four specific topics which were drawn to our attention during the course of our review. Although they are not directly within our terms of reference we believe that it was important to draw the Minister's attention to them for the sake of completeness.

### Advertising of POMs

6.2 A number of veterinarians who provided information to us during the course of the review commented adversely on the increasing numbers of advertisements appearing in publications and in public places advertising POM veterinary medicines. Many but not all of these advertisements related to products for companion animals. There was a feeling amongst the veterinary profession that such advertisements raised clients' expectations and/or introduced an element of confusion into what was or was not the most appropriate treatment.

6.3 Unlike human medicines there is no Community or United Kingdom legislation that specifically covers this form of advertising. The NOAH Code of Practice for the Promotion of Animal Medicines includes advice to its members. The Code has a requirement to the effect that when promoting a POM to a lay user, a form of words should be included which clearly indicates that advice should be sought from a veterinarian. We welcome this guidance. With the increasing use of the internet the public already has access to a wide range of information much of which is from unchecked sources. Media advertising is now very much an accepted part of our daily lives and we feel it would be inappropriate to consider placing restrictions on the advertisement of POM animal medicines. We recognise that there is a danger that this may sometimes result in misunderstanding by consumers, but we are considering POMs which can only be prescribed by a veterinarian and it draws him/her into advising on the appropriate use of medicines. It emphasises the important role veterinarians have to play in giving advice and guidance to clients on the appropriate use of the advertised product or whether it would be in the best interests of the patient. This should be seen as promoting the service veterinarians provide for their clients.

### Sales of certain veterinary medicines through pet shops

6.4 During the course of our review we were informed that under the Medicines (Exemption for Merchants in Veterinary Drugs) Order 1998 registered pet shops are allowed to sell cat and dog wormers classified as PML medicines. They were however permitted to do so only if the person in charge of the sale had undertaken and successfully completed a course run by AMTRA for saddlers. Successful completion of the course permits the pet shop to sell horse wormers too, but we were informed that in many city areas such a trade was non-existent. We understand that AMTRA and the Pet Care Trust are developing a course specifically for those selling medicines in pet shops and that they are pressing the VMD to correct the anomaly in the current legislation. We believe that it is important that this present inconsistency in the legislation is corrected soon. It is in the interests of good animal health and welfare, and public health, to increase availability and control the cost of products used to control worms and fleas in companion animals. There would appear to be few, if any, risks

as long as those selling the products are appropriately trained and the instructions for use on the product packaging are easy to read and understandable.

- 6.5 **We recommend** that the role of registered agricultural merchants and saddlers in dispensing cat and dog wormers classified as PML medicines be extended to suitably registered pet shops, provided that all sales in these outlets are made by people who are suitably qualified having passed courses established by AMTRA. We see no need for the pet shop to register as a saddler as is currently the case.

## Out of hours cover

- 6.6 A significant number of veterinarians who submitted evidence stressed the importance of the 24-hour, 365-day cover they were required to provide. They considered that if, as a result of any recommendation made by this Review, they would be no longer able to dispense veterinary medicines animal welfare out of hours would be compromised because pharmacists would either be unwilling or unable to provide the necessary products in time. We made it quite clear early on in the review process that we had no intention of recommending the removal of the veterinarian's privilege to dispense medicines. We believe that it would be appropriate for us to comment on the need for each practice to provide 24-hour 365-day cover. We accept that out of hours cover remains essential to ensure that appropriate emergency treatment can be given to animals. We recognise this puts both financial and personal strains on small practices and those located in or serving isolated areas of the country. We were nevertheless pleased to learn during the course of our review that in many towns and cities veterinary practices have made arrangements to work together out of hours to ensure that a full 24-hour cover can be provided. We fully support this approach and suggest that it may also be feasible to provide a 24-hour pharmacy service along similar lines. The veterinary profession will need to continue to adapt the services it provides in order to meet the changing needs and requirements of its clients.

## Delegation to paraprofessionals

- 6.7 The cost of veterinary treatments tends to rise both because of the demands of clients and the increased sophistication of the treatments now available. This can have serious consequences for people who find it hard to pay veterinary bills and for farmers who may have to cope with fewer veterinary practices and with falling real values for livestock. This may make it imperative to consider ways in which the real costs of maintaining an adequate service to clients can be provided. One route may be to increase the role for the paraprofessional. We welcome the initiative taken by the RCVS to encourage the development of personnel trained to fulfil this role under the supervision of a veterinarian and we believe that that this will require the profession to examine carefully the notion of 'animals under their care'. The Government, as part of its Action Plan for Farming, should support this development.

# Appendix 1:

## Organisations and individuals who submitted written evidence

All organisations and individuals submitting evidence were asked to indicate whether they agreed to their evidence being publicly available.

Those who have submitted comments to the Review Group and have indicated their willingness for their submission to be made publicly available including nil returns are listed below in alphabetical order:

### A

Aberlour Veterinary Centre  
Albyn Veterinary Centre  
Allen and Matthews, Veterinary Surgeons  
Anderson, Jo (Consumer)  
Anderson, T (Consumer)  
Animal Health Distributors Association (UK) Ltd  
Animal Medicines Training Regulatory Authority  
ANIMED, Veterinary Hospital and Equine Unit  
Armac Veterinary Group  
Association of Veterinary Anaesthetists  
Association of Veterinarians in Industry  
Association of Veterinary Surgeons in Northern Ireland  
Association of Wholesalers to the Veterinary Profession

### B

Bainton, C M (Consumer)  
Baybut, Oranie (Consumer)  
Bayer plc, Animal Health Business Group  
Beatty, J (Consumer)  
Blue Cross  
British Association of Homoeopathic Veterinary Surgeons  
British Cattle Veterinary Association  
British Egg Industry Council  
British Equine Veterinary Association  
British Pharmacological Society  
British Poultry Meat Federation  
British Small Animal Veterinary Association  
British Veterinary Association  
British Veterinary Association (Galloway and Dumfries Division)  
British Veterinary Association (North of Scotland Division)  
British Veterinary Association (Scottish Branch)  
British Veterinary Hospitals Association  
British Veterinary Poultry Association

British Veterinary Zoological Society  
Buckland, David P (Veterinary Surgeon)  
Burgess, Keith (Veterinary Surgeon)

## C

Carmichael, Alistair (Consumer)  
Celtic Dimensions  
City Hospital NHS Trust  
Clarke, T (Consumer)  
Collier and Brock, Veterinary Surgeons (6 individual letters)  
Collingborn, J & R (Consumers)  
Consumers in Europe Group  
Costen, Sally (Consumer)  
Cox, C E (Consumer)  
Craig Robinson and Partners, Veterinary Surgeons  
Cross Dr J K, Dental Surgeon

## D

Dalriada Veterinary Surgery  
Davies, V (Consumer)  
Drohan, Barry (Consumer)  
Dundas Veterinary Group

## E

Eddy, R G (Veterinary Surgeon)  
Edwards, Carole and Tom (Consumers)  
Edwards, B (Consumer) (two individual letters)  
Elliot, Owen (Consumer)  
Equuleus Falabella Stud  
ESK Veterinary Practice  
Essex, J (Consumer)

## F

Farmers Union of Wales  
Federation of Veterinarians of Europe  
F.A.I.T.H Animal Rescue  
Falconbridge, C (Consumer)  
Fish Vet Group  
Frame, Swift and Partners, Veterinary Surgeons

## G

General Public, Low Farm  
Goat Veterinary Society  
Golf Veterinary Group (three individual letters)  
Guy, Therese (Consumer)

**H**

Hall, K (Consumer)  
 Hampden and Simonside Veterinary Group  
 Harris, Alison (Consumer)  
 Harrison, Joe (Consumer)  
 Henderson, A C (Consumer)  
 Hewitt, Steve (NPTC)  
 Hi Health Ltd  
 Huckle, John and Saunders, Edwina (Consumers)  
 Hyperdrug Ltd

**J**

James, J (Consumer)  
 Jenkins, Barbara (Consumer)  
 Jobsons Farm Health

**L**

Last, Dr Rex (Consumer)  
 Lawson, R T (Consumer)  
 Line, Michelle (Consumer)  
 Lhermette, P (Consumer)

**M**

Macamgus, C (Consumer)  
 Mackay and Taylor  
 MacNeill, Katie (Veterinary Surgeon)  
 McConnachie, John (Veterinary Surgeon)  
 McClure, Annette (Consumer)  
 McCormick Smith, J (Consumer)  
 McGrandles, Wendy (Veterinary Surgeon)  
 McGregor, Donald and Partners, Veterinary Surgeons  
 Merlin Veterinary Group  
 Milne, Cynthia (Consumer)  
 Moar, J (Veterinary Surgeon)  
 Moore, R (Consumer)  
 Murphy, Carla (Veterinary Surgeon)

**N**

National Canine Defence League  
 National Cattle Association  
 National Farmers Union of England and Wales  
 National Farmers Union of Scotland  
 National Office of Animal Health  
 National Pharmaceutical Association  
 National Seal Sanctuary  
 North of Ireland Veterinary Association  
 Northern Ireland Agricultural Producers Association

Northern and Scottish Veterinary Action Committee  
Northvet Veterinary Group

**O**

Oakley, Ann (Consumer)

**P**

Parkside Veterinary Group  
Parsons, V (Consumer)  
Pedigree Masterfoods  
People's Dispensary for Sick Animals  
Pet Care Trust  
Pet Health Council  
Pharmaceutical Society of Northern Ireland  
Phyllis Croft Foundation for Canine Epilepsy  
Pig Veterinary Society  
Prior, M (Consumer)

**R**

Reed, Brown and Cameron, Veterinary Surgeons (four individual letters)  
Responsible Use of Medicines in Animals (RUMA)  
Riddleston, K (Consumer)  
Rigby, S (Consumer)  
Robb, W A (Consumer)  
Royal Association of British Dairy Farmers  
Royal College of Veterinary Surgeons  
Royal Society for the Prevention of Cruelty to Animals (RSPCA)  
Royal Welsh Agricultural Society Ltd

**S**

Sanford, Dr J (Veterinary Surgeon)  
Schering Plough Animal Health  
Scottish Environment Protection Agency  
Scottish Landowners Federation  
Scottish Society for the Prevention of Cruelty to Animals (Scottish SPCA)  
Shannon, E (Consumer)  
Sharp, Jean (Consumer)  
Sheep Veterinary Society  
Shetland Agricultural Association  
Shetland Islands Council  
Society of Practising Veterinary Surgeons  
Smith, W Ainslie M (Veterinary Surgeon)  
Sprinz, Joe (Veterinary Surgeon)  
Stramongate Veterinary Centre  
Stevens, J M (Consumer)  
Strathbogie Veterinary Centre  
Struthers and Scott, Veterinary Surgeons (four individual letters)

**T**

Taylor, Simon and Caroline (Pharmacists)  
Thackray, E (Consumer)  
Thoroughbred Rehabilitation Centre  
Thistle Veterinary Health Centres  
Thrums Veterinary Group  
Torbridge Veterinary Centre

**U**

Ulsters Farmers Union  
Union of European Veterinary Practitioners

**V**

Veterinary Cat Clinic  
Veterinary Centre (four individual letters)

**W**

West Port Veterinary Clinic  
Wishart, Dr D (Veterinary Surgeon)  
Wishart, James and Associates, Veterinary Management Consultants  
Women's Food and Farming Union  
Wykes, Lesley (Pharmacist and Consumer)

## Appendix 2:

# Analysis of the written evidence

This appendix summarises the evidence we have received from the main interest groups and examines the sometimes divergent views that have emerged.

We received very few comments directly from farmers, which is perhaps surprising given the underlying background to our review. Those that did respond were concerned at the high cost to them of POM products. They felt that there was also a case for some POMs to be made more widely available and affordable. The farming organisations who submitted evidence considered that the answer to concerns about the high cost of POM products lay in a modification to the existing system rather than replacing it with another. The service provided by large animal veterinary practices was seen to go far beyond the simple prescribing of drugs. Nevertheless, it was felt that there was a need for transparency about the way prices were divided down the distribution chain, particularly at the level of the veterinary practice. There was some concern that any changes proposed to the existing system should not, in any way, compromise farm animal health and welfare. Several organisations sought the removal of the POM classification used for routine preventative and management purposes, although this view was tempered by the need to ensure that consumer confidence in the quality of produce was maintained.

The majority of pet owners who wrote to us were concerned about the high cost of POM medicines supplied by their veterinary practice. In particular concerns were expressed about the cost of long-term treatment e.g. heart conditions and epilepsy. A number suggested that POM ectoparasiticides should be made available off-prescription as was the case elsewhere in Europe. Medicines were generally seen as being over-priced and expensive when obtained from a veterinary practice. It was suggested on a number of occasions, that the ability to have a prescription filled by a pharmacist offered the potential at least of reducing costs. A somewhat different view emerged from the pet charities. Whilst they too expressed concern at the high mark-up that were applied to veterinary medicines they were concerned that any changes proposed by this Review should not impact adversely on the availability of medicines to the pet owner. It was felt that there was a risk that if veterinarians operating within the charities were required to issue prescriptions to their client to be filled elsewhere this could result in additional costs for the client and compromise the completion of the treatment for the animal concerned. That being said some of the charitable organisations felt that there was a case for some small animal anti-parasitidal products which were currently classified as POM to be re-classified.

Individual veterinarians and their professional bodies stressed the value of the current system for dispensing POM veterinary medicines. Individual veterinarians within this group pointed to the convenience of the 'one-stop' shop for farmers (particularly those in remote areas) and companion animal owners. They pointed to the detailed knowledge they had of many species, of farm enterprises and, in the broadest sense, their impact on monitoring the disease situation in the United Kingdom herd. The veterinary societies and associations reinforced the value of the 'one-stop' service which had for many years given good value for money and provided a reasonably simple and conveniently accessible distribution system to the client. It was pointed out that farmers do not in general appear dissatisfied with either veterinarians or the cost of veterinary practices. It was recognised that steps needed to be taken within the profession to bring home to practitioners the need to apply good business practice to their dispensing activities. Finally it was pointed out that it has always been open to clients to obtain a prescription from their vet and obtain medicines

from a pharmacist if they were unhappy with the veterinarians medicines charges, but they have chosen not to do so.

The Royal Pharmaceutical Society of Great Britain recognised that specialist veterinary pharmacies were relatively undeveloped because there was little incentive for this to take place. The main reason seen was the lack of veterinary prescriptions being presented to pharmacies, except for some high value products for companion animals prescribed under the 'cascade' by veterinarians. It was also suggested to us by individual pharmacists that veterinary wholesalers were reluctant to supply either prescription or non-prescription medicines to pharmacies, and that the discount rates given to veterinarians by both the manufacturer and wholesaler could not be obtained by pharmacies. Individual pharmacists and the professional bodies representing them argued that an increase in the dispensing of veterinary prescriptions through pharmacies could bring real benefits to animals and their owners through increasing accessibility of products (both prescription and non-prescription) to purchasers linked with professional advice on their storage and use. It was also felt that increasing the number of potential outlets would increase competition and lead to a downward pressure on prices, thus reducing the potential for black-market trading. It is acknowledged by pharmacists that POM medicines requiring administration by a veterinarian should remain on the POM list. However, it was considered that there were many products that could safely be re-classified into the Pharmacy (P) category, particularly products for which a specific diagnosis is not required. Additionally a suggestion was made to us for the establishment within the United Kingdom of a POM(E) category of product which although not requiring a prescription could only be dispensed personally by the pharmacist in charge of the pharmacy (a similar system operates in the Republic of Ireland). The individual pharmacists who submitted written and oral evidence to us supported the views expressed by their professional bodies and supplemented this with detailed background information. In addition, it was proposed that the prescribing and dispensing function be separated through the requirement of a written prescription which would allow the client a choice. They also proposed that a number of products for companion animals, to treat flea and worm infestations and mange, which are currently POM, could safely be de-regulated to the P category.

The National Office of Animal Health (NOAH) which represents manufacturers of about 95% of all authorised veterinary medicinal products in the United Kingdom took the view that the current arrangements were fundamentally sound and not in need of radical reform although some fine tuning would be appropriate. In considering dispensing, NOAH felt that consideration should be given to the potential negative effects of any changes in the access to medicines and animal welfare might make to the ability of the Authorities to remain fully informed of the use and effects of animal medicines in the UK. It was felt that there was scope for improving the transparency of veterinary charges to clients and that it should be made a requirement for veterinarians to offer a prescription. With regard to classification NOAH considered there was a need for the system to be reviewed and revised in order to ensure that each product is classified scientifically according to its own merits and within the UK system of distribution and for any bureaucratic constraints to be minimised. The individual veterinary pharmaceutical companies who submitted evidence to us broadly supported these views.

Agricultural merchants are permitted, by legislation, to sell veterinary medicines classified as PML products. Their trade association, the Animal Health Distributors Association (AHDA), took the view that there was no need for a separate pharmacy (P) category of veterinary medicines as all veterinary medicines could be classified as POM, PML or GSL. AHDA believed that it is right for veterinarians to retain their privilege to dispense their own prescription but considered that there should be a greater degree of transparency between the cost of the professional services and the prices charged for the medicines dispensed. The Association believed that there are a number of

animal medicines which could quite safely be re-classified as PML – this was particularly the case for medicines administered to farm livestock by farmers. Specifically, it was considered that the onus for a change in the legal category should be taken out of the hands of the manufacturer and/or marketing authorisation holder to ensure that medicines are not held in the POM category for purely commercial reasons. These views were supported fully by the Animal Medicines Training Regulatory Authority (AMTRA) the independent regulatory body established to ensure that the marketing and distribution of animal medicines in the United Kingdom is undertaken in a responsible manner by suitably qualified persons.

# Appendix 3:

## Organisations who gave oral evidence to the review

British Small Animal Veterinary Association.

Society of Practising Veterinary Surgeons.

British Veterinary Poultry Association.

Pig Veterinary Society.

Goat Veterinary Society.

Royal Society for the Prevention of Cruelty to Animals.

Union of European Veterinary Practitioners.

Animal Medicines Training Regulatory Authority.

British Cattle Veterinary Association.

British Equine Veterinary Association.

Animal Health Distributors Association (UK) Ltd.

Brian G Spencer Limited.

Royal Pharmaceutical Society of Great Britain.

Royal College of Veterinary Surgeons.

British Veterinary Zoological Society.

Phyllis Croft Foundation.

Jobsons Farm Health.

Royal Association of British Dairy Farmers.

People's Dispensary for Sick Animals.

National Farmers Union.

National Office of Animal Health Ltd.

# Appendix 4:

## Authorisation routes for veterinary medicinal products

### The Centralised procedure

This applies to high technology products defined in the Annex to Council Regulation EEC/2309/93. It is obligatory for certain biotechnological products and novel growth promoters and optional for other novel products. Applications for such products must be made to the European Agency for the Evaluation of Medicinal Products (EMA). The assessment of the dossier will be co-ordinated by one of the members of the Committee for Veterinary Medicinal Products (CVMP) which provides scientific and technical advice to the EMA. Authorisations granted under the centralised procedure are valid in all member states and, in practice all products authorised under this route are classified as POMs. There is no mechanism for this categorisation to be reviewed at a later stage in the product's life.

### The Decentralised procedure

This route enables a manufacturer to seek authorisation through the national competent authorities of individual member states. Under this procedure an applicant wishing to market a veterinary medicinal product in more than one member state may ask a second or subsequent member state mutually to recognise, within a period of 90 days, the marketing authorisation granted by the first member state (the reference member state). The objective of this procedure is to facilitate access to a single market by relying on the principle of mutual recognition under which a marketing authorisation granted in one member state ought, in principle, to be recognised by the competent authority of another member state. Mutual recognition of the reference member state's authorisation does not however extend to the distribution classification applied to the product unless, of course, it is caught by the minimum criteria prescribed under Community law requiring the product to be made available only under a veterinary prescription.

### The National procedure

A manufacturer may also apply for an authorisation which is valid in one member state. This is the normal precursor to further applications being lodged under the decentralised procedure described in the preceding paragraph, but there is no requirement to do so. Marketing authorisations granted under this procedure are granted by the member state concerned and are valid in that country only. With effect from 1 January 1998 however, if the product is already authorised in another member state, no marketing authorisation may be granted under the national procedure and the decentralised procedure is obligatory. Prior to the establishment of the 'centralised' and 'decentralised' procedures all authorisations for veterinary medicinal products were granted, in member states, on the basis of national procedures. The majority of authorised veterinary medicines on the United Kingdom market (and indeed in other member states) hold authorisations granted under the national procedures.

# Appendix 5:

## Criteria used for establishing the GSL, P and PML distribution categories

The following is an extract from a guidance note published by the VMD on the criteria used by the Veterinary Products Committee in determining the distribution category for a veterinary medicinal product.

**Note:** The criteria used for determining POM status is set out in the main body of the report.

### General Sale List (GSL)

The legal criterion for classifying a product as GSL is established by section 51 of the Medicines Act as being a product that ‘can with reasonable safety be sold or supplied otherwise than by, or under the supervision of a pharmacist’. For veterinary products, this would also include those products which can with reasonable safety be sold or supplied other than by a registered agricultural merchant. All aspects of the safety of the product are relevant factors to be considered. In general terms therefore a product can be classified as GSL when it neither requires any specific advice concerning its method of use nor poses any significant risk to the animal being treated, the person administering the product, the consumer or the environment. In considering whether the category GSL is appropriate, account should be taken of, for example, the nature of the active ingredient, its concentration in the finished product, the excipients used, the target species and the fact that the product will be available ‘off the shelf’ and selected by the end user without advice. Although it is the active ingredient which is classified as GSL, there is scope for restricting classification based on a substance’s maximum strength and dose and its methods of use. Consequently, a different product containing the same active ingredient may appear in a more restrictive category.

### Pharmacy (P)

Products which are P can only be sold by or under the supervision of a pharmacist in a registered pharmacy. The P category will be appropriate for substances or products which, for non-food-producing species, are not suitable for sale as a GSL product but which do not meet the criteria for classification as a POM medicine.

Products for food-producing animals which do not need a POM classification will be classified as P where the following conditions apply:

- a) when advice is needed on the potential risks to the person administering the product;
- b) when advice is needed on the probability of undesirable interaction with other widely used veterinary medicines;
- c) when point of sale advice on the method of use or the preparation of a product prior to use may be needed;
- d) when unusual storage conditions or unusual requirements for safe disposal should be brought to the user’s attention.

## Pharmacy and Merchants' List (PML)

Products in the PML category are those which meet the criteria for P products but, by way of a legal exemption provided for in the Medicines (Exemptions for Merchants in Veterinary Drugs) Order 1998, can be sold by a registered agricultural merchant or, if appropriate, a registered saddler as well as by a pharmacist. The Order places conditions on the premises from which such medicines may be sold and requires them to be registered annually with the Registration Authority – the RPSGB. The Order also requires that a suitably qualified person (SQP) shall authorise each sale of veterinary drugs to which the Order applies. An SQP is a person whose name is included in an annual list maintained by the Registration Authority. A person cannot be entered on this list unless he has successfully completed an approved course of training relating to the composition, storage, use, purchase and sale of animal medicines *or* is a qualified pharmacist or veterinary surgeon who has applied to join the register.

In addition the following conditions must be complied with:

- a) if the product is a cat, dog or horse wormer, the sale may only be made to a person who the *registered merchant or saddler* knows or has reasonable cause to believe has in his charge a cat if the product is a cat wormer, a dog if the product is a dog wormer or a horse or pony if the product is a horse wormer and will use that product for the treatment of the animal concerned.
- b) if the product is not a cat, dog or horse wormer, the sale is to a person whom the *registered merchant* knows or has reasonable cause to believe has animals under his control for the purpose of, and in the course of carrying on, a business, either as his sole business activity or as part of his business activities, and
- c) if the product is an organophosphorus sheep dip, or after 30 December 1998, is a sheep dip, not intended for export, the sale is to a person whom the *registered merchant* knows or has reasonable cause to believe is the holder, or the employee of or a person acting on behalf of the holder, of a Certificate of Competence, and the agricultural merchant keeps a record of the Certificate number for three years from the date of sale.
- d) each veterinary drug sold must be in the container in which it was made up for sale by the manufacturer and which has not been opened since; it must bear the manufacturer's label and may not be sold after the expiry date on its label.

The PML category will therefore be appropriate for substances or products which are not suitable for sale as a GSL product, do not need a POM classification and to which the conditions set in subparagraphs a) to d) apply but which can, in addition, be sold to a person who a registered merchant or saddler has reasonable cause to believe meets the criteria set out in a) to c) above.

# Appendix 6:

## Glossary

### AHDA

Animal Health Distributors Association.

### AMTRA

Animal Medicines Training and Regulatory Authority.

### Agricultural merchant

A person who carries on a business involving the sale of agricultural requisites, being things used for soil cultivation or keeping of animals for production of food or game, equipment for collecting produce from animals kept for production of food, things for the maintenance of that equipment and protective clothing.

### BVA

British Veterinary Association.

### Centralised marketing authorisation

A marketing authorisation which is valid in all member states.

### Companion animals

Animals normally kept as domestic pets e.g. dogs, cats, horses, rabbits, small rodents, ornamental fish etc.

### Council Directive 81/851

Council Directive 81/851/EEC of 28 September 1981 on the approximation of laws of the Member States relating to veterinary medicinal products as amended by Council Directives 90/676/EEC and 93/40/EEC. (*OJ no L 317 of 6 November 1981, p.1*).

### Council Regulation (EEC) 2309/93

Council Regulation (EEC) 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products. (*OJ No L 214 of 24 August 1993, p.1*).

### Council Regulation (EEC) 2377/90

Council Regulation (EEC) 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin. (*OJ No. L 67 of 7 March 1997, p. 1*).

### CVMP

The European Communities Committee for the Veterinary Medicinal Products.

### **Decentralised marketing authorisation**

A marketing authorisation which is valid in one or more member states.

### **Distribution Working Group**

A working group of the EC's Veterinary Pharmaceutical Committee charged with examining national classification systems for veterinary medicines.

### **MRL**

Maximum Residue Limit: the maximum concentration of residue resulting from the use of a veterinary medicine that is legally permitted or recognised as acceptable in or on a food.

### **National marketing authorisation**

A national marketing authorisation is valid only in the member state of issue. With effect from 1 January 1998 no national marketing authorisation can be granted if the product is already authorised in another member state – the decentralised procedure must be followed.

### **NOAH**

National Office of Animal Health.

### **P**

Pharmacy veterinary medicines may be sold under the supervision of a pharmacist and by veterinarians to animals under their care.

### **PML**

Pharmacy and Merchants' List veterinary medicines. These may be sold to keepers of animals by an agricultural merchant or saddlers (on the basis of a restricted list of products) who have been suitably trained and are registered with the RPSGB. PML products may also be sold by a pharmacist and by veterinarians to animals under their care.

### **POM**

Prescription only veterinary medicines. May be sold only by veterinarian to animals under their care or by pharmacists on a written prescription from a veterinarian.

### **RCVS**

Royal College of Veterinary Surgeons.

### **RSPCA**

Royal Society for the Prevention of Cruelty to Animals.

### **RPSGB**

Royal Pharmaceutical Society of Great Britain.

### **Saddler**

A person carrying on a business involving the sale of saddlery requisites, being products and equipment and things for the maintenance of that equipment, for keeping horses and ponies, including human clothing for that purpose.

## SQP

Suitably qualified person. A person whose name is included on a list kept for persons carrying on a business in England and Scotland or Wales by the RPSGB and for businesses in Northern Ireland by the Department of Health and Social Services for Northern Ireland.

## Withdrawal period

The period following the cessation of treatment during which residues are allowed to deplete to acceptably low concentrations which provides as assurance of public safety. During the withdrawal period an animal or its products should not be used as food.

## VMD

Veterinary Medicines Directorate.

## VPC

Veterinary Products Committee: established in 1970 under Section 4 of the Medicines Act 1968 with the following terms of reference:

- To give advice with respect to safety, quality and efficacy in relation to the veterinary use of any substance or article (not being an instrument, apparatus or appliance) to which any provision of the Medicines Act is applicable.
- To promote the collection of information relating to suspected adverse reactions for the purpose of enabling such advice to be given.

The terms of reference have been extended to include veterinary medicinal products to which relevant European Community legislation applies and which come before the committee for consideration.

## Veterinary Pharmaceutical Committee

The European Communities Veterinary Pharmaceutical Committee was established in 1995 to examine any questions relating to the application of legislation or any other questions in the field of veterinary medicinal products brought up by its Chairman (DG Enterprise) or at the request of a member state.



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