

**INQUIRY INTO SUPPLY OF PRESCRIPTION-ONLY VETERINARY MEDICINES:
STATEMENT OF PROVISIONAL CONCLUSIONS ON COMPLEX MONOPOLY AND
HYPOTHETICAL REMEDIES**

The Competition Commission has today sent the attached statement to manufacturers and wholesalers of prescription-only veterinary medicines (POMs). The statement is also being sent to all veterinary surgeons with addresses in the UK. It gives the Commission's provisional conclusions on the existence of complex monopoly situations in relation to supply of POMs to animal owners and in relation to supply to veterinary surgeries of vaccines for dogs and cats.

This statement of hypothetical remedies is being made public to inform all interested persons, should they wish to comment or to raise further points with the Commission. In particular, comments are invited on the likely effectiveness, costs and practicability of the remedies that have been set out. Any such comments should reach the Commission by Friday 4 October 2002.

The complete statement of provisional conclusions on complex monopoly and hypothetical remedies may be obtained from the Competition Commission web site: www.competition-commission.org.uk/pressreleases/46-02.htm or, in writing, from the Reference Secretary (Veterinary Medicines), Competition Commission, Room 565, New Court, 48 Carey Street, London, WC2A 2JT.

Notes to Editors

1. The reference was made by John Vickers, Director General of Fair Trading, under sections 10(3), 10(4), 47(1), 49(1) and 50(1) of the Fair Trading Act 1973 (see OFT Press Notice 41/01).

2. No conclusions will be reached about whether any matters operate or may be expected to operate against the public interest until the Competition Commission submits its report to the Secretary of State for Trade and Industry on 8 January 2003.
3. Denise Kingsmill, a Deputy Chairman of the Commission, is heading the inquiry. The other members of the group are Graham Hadley, Alan Hamlin, Charles Henderson, and Tim Richmond.
4. Further information can be obtained from the Commission website at www.competition-commission.org.uk/inquiries/vetmed.htm
5. Enquiries should be directed to:
Francis Royle, Press Officer Tel: 020 7271 0242

Supply of Prescription Only Veterinary Medicines in the United Kingdom

Statement of Provisional Conclusions on Complex Monopoly and Hypothetical Remedies

1. In its 'statement of issues' released on 16 April 2002 the Competition Commission (the Commission) provisionally concluded that a scale monopoly situation exists in relation to supply within the United Kingdom of prescription only veterinary medicines (POMs) since it appears that National Veterinary Services Ltd., a wholly owned subsidiary of Dechra Pharmaceuticals plc, supplies at least one-quarter of prescription only veterinary medicines to veterinary surgeons. The statement made clear that this provisional finding does not imply the existence of any facts which operate, or may be expected to operate, against the public interest. (For a definition of scale monopoly and of certain terms used in this statement see the issues statement of 16 April 2002).
2. The Commission has now further provisionally concluded that one or more complex monopoly situations as defined in section 11 of the Fair Trading Act 1973 exists by

reason that the conditions specified in section 6(1)(c) are fulfilled in relation to the supply of POMs in the United Kingdom. Under section 6(1)(c) a complex monopoly situation arises if at least one quarter of POMs in the United Kingdom are supplied by, or to, members of a group of persons (not being a group of interconnected companies) who, whether voluntarily or not and whether by agreement or not, conduct their respective affairs so as to prevent, restrict or distort competition in connection with the supply of POMs. This finding relates to certain conducts of some veterinary surgeons and some manufacturers and wholesalers of POMs (see paragraphs 9 and 21). Under the terms of the Fair Trading Act the finding does not require or imply that all veterinary surgeons or manufacturers or wholesalers engage in the conducts identified, and would be consistent with a finding that no veterinary surgeon or manufacturer or wholesaler engages in all of them.

3. The Commission is still pursuing its investigation and has as yet reached no final conclusion on these matters. It has reached no conclusion, provisional or otherwise, on whether any matter operates or may be expected to operate against the public interest. To assist the Commission in taking forward its investigation and to assess the wider implications of any recommendations it might wish to propose if it did reach adverse public interest findings, we set out below our provisional conclusions on whether one or more complex monopoly situations exist and invite comments on the practicality and effectiveness of certain hypothetical remedies. The Commission is not, however, at this stage proposing any of the remedies set out below, which are for comment and discussion, and suggestions for alternative remedies are also invited.

The Commission's View of the Markets

4. Before discussing the provisional conclusions on whether one or more complex monopoly situations exist or possible recommendations it may be useful to put these in the context of the Commission's current view as to market definition and the main characteristics of the markets.

5. The Commission's current view is that:
 - (a) There are several relevant product markets primarily reflecting the therapeutic indications of the different POMs, the animal species they are licensed for and whether they are curative or preventive. Some of the more important examples of these, in terms of value of sales, are the markets for small animal flea treatments, the market of oral and injectable antimicrobials, the market for small animal wormers, and the markets for dog vaccines, for sheep vaccines, for cattle vaccines and for cat vaccines.
 - (b) The United Kingdom excluding Northern Ireland forms a single geographic market. Northern Ireland, where distribution is primarily in the hands of a single co-operative wholesaler controlled by the veterinary surgeons and which some manufacturers supply through operations in the Republic of Ireland, forms a separate geographic market. The system of regulation results in a series of national markets for POMs in the EU rather than a single European market.
6. The supply of POMs in the United Kingdom displays several features that limit competition. POMs are subject to certain requirements under both European and UK law that increase costs of supply, raise barriers to entry and restrict the outlets through which POMs can be obtained legally. Manufacturers must obtain marketing authorisations for each medicine, requiring demonstration of safety, quality and efficacy, which affects the time and costs of bringing veterinary medicines to market. Manufacturers may only supply POMs to wholesalers licensed under the Medicines Act 1968 to deal in veterinary POMs, to veterinary surgeons or to pharmacies, which limits the ways in which they may be distributed. POMs may only be dispensed by veterinary surgeons for animals or herds under their care or by pharmacists from prescriptions written by veterinary surgeons having animals or herds under their care.

This gives veterinary surgeons a unique role in the supply of POMs and precludes one veterinary surgeon from dispensing POMs prescribed by another. (The main features of the way in which the supply of prescription-only veterinary medicines in the UK is regulated was set out in Appendix C to the issues statement of 16 April 2002.) These requirements are primarily aimed at the protection of human and animal health. They affect competition in the supply of POMs in the United Kingdom both directly and through the emergence of behaviours that, while not required by regulation, may be seen as a response to the regulated market in which they occur.

7. It appears to the Commission that certain features of this regulated market are of particular significance for competition. Veterinary surgeons serve both as ‘gatekeepers’, since only they may prescribe POMs, and as dispensers of POMs. There is therefore an asymmetry between their role in supplying POMs and that of pharmacies, which provide the only alternative route through which POMs can be dispensed but which can only dispense items prescribed by a veterinary surgeon. One consequence is that veterinary surgeons are uniquely able to provide animal owners and others responsible for the care of animals (hereafter referred to as animal owners) with a ‘one stop’ service. Because one veterinary surgeon may not dispense POMs prescribed by another, they compete with each other only in the provision of a total health-care package in which the supply of POMs is bundled with provision of services. Since veterinary surgeons play a key role in the choice of POM in cases where there is more than one competing product, manufacturers have a clear commercial incentive to focus their marketing activities such as rebate schemes and other promotions on veterinary surgeons. Whilst the provision of bundled services may be seen as a benefit by clients of veterinary surgeons in many circumstances, from a competition perspective these market features raise issues both on the demand and on the supply side, in terms of barriers to animal owners exercising effective consumer choice and over the availability and terms of supply of POMs to pharmacies.

8. To analyse competition in the supply of POMs it has been necessary for the Commission to consider both regulatory and non-regulatory factors that bear on this. However, in assessing whether one or more complex monopoly situations exists in the supply of POMs in the United Kingdom the Commission has focused its attention on evidence of conducts by persons supplying POMs that prevent, restrict or distort competition going beyond conducts required by the regulatory framework.

Provisional finding on complex monopoly in relation to supply of POMs to animal owners.

9. The Commission has provisionally concluded that inter-related complex monopoly situations exist amongst persons engaged in one or more of the following conducts:
 - (a) failure of veterinary surgeons to inform animal owners that they can ask for prescriptions, and/or discouraging requests for prescriptions, and/or charging excessive prices for prescriptions, and/or declining to provide prescriptions on request;
 - (b) failure of veterinary surgeons to inform clients of the price of POMs prior to dispensing them and/or provide itemised bills;
 - (c) pricing of POMs by veterinary surgeons in such a way as does not reflect costs of supply to themselves, including
 - the use of mark-ups on manufacturer list prices that take no account of either the existence of, or variations in, discounts and rebates from wholesalers and manufacturers;
 - pricing POMs so as to subsidise, to a greater or lesser extent, professional fees;
 - (d) refusal/failure of manufacturers to negotiate discounts and rebates with buying groups formed by, or acting on behalf of, veterinary surgeons;

- (e) operation by manufacturers of rebate schemes that make it difficult for veterinary surgeons to ascertain with certainty at the time of purchase the cost to themselves of POMs supplied to them either directly by the manufacturer or through a wholesaler;
 - (f) failure of manufacturers to supply pharmacies with POMs and/or enable pharmacies to obtain supplies of POMs on terms that enable them to compete with veterinary surgeons;
 - (g) failure of wholesalers to supply pharmacies and/or enable pharmacies to obtain supplies on terms that enable them to compete with veterinary surgeons.
10. It appears to the Commission that these conducts have the effect of preventing, restricting or distorting competition in the supply of POMs in the United Kingdom to animal owners (described hereafter as supply at the retail level). In the Commission's view, the setting of retail prices for POMs higher than they would otherwise be, which may be associated with setting prices at levels to cross-subsidise professional charges, distorts competition even where the price of complete treatments, involving the provision of care plus the provision of POMs, is no higher. Whilst recognising that any animal for whom POMs are supplied must be under the care of a veterinary surgeon, the Commission takes the view that the prescribing of medicines, dispensing of those medicines and their administration are activities that are in many instances capable of separation. It further takes the view that animal owners wishing to obtain POMs separate from their procurement of the other services must be able so to do wherever this is practicable if competition in the supply of POMs at the retail level is to be effective, and that any action that inhibits their ability to do so prevents, restricts or distorts competition. Competition is inhibited by barriers to animal owners obtaining prescriptions to be dispensed elsewhere or comparing prices between alternative sources of supply, including informational barriers. In markets

characterised by the features noted in paragraph 7, the use of mark-ups based on list prices which do not reflect discounts or rebates or prices that include cross-subsidies between POMs and professional fees further weakens the role that price signals play, and may indicate that benefits of competition between manufacturers and wholesalers in the supply of POMs to veterinary surgeons are not passed on to consumers. Competition at the retail level is distorted by practices that restrict the ability of smaller veterinary practices to benefit from buying groups. It is further inhibited by practices that place pharmacies at a disadvantage relative to veterinary surgeries in obtaining supplies of POMs.

11. The Commission has not taken a view at this stage of its inquiry on the extent to which the provision of bundled professional services and POMs by veterinary surgeons offers wider advantages to the public interest, for example in terms of animal welfare and the prudent use of veterinary medicines.

12. The first three of the conducts ((a) to (c) in paragraph 9) involve behaviour by certain veterinary surgeons, the second three ((d) to (f) in paragraph 9) involve behaviour by certain manufacturers and the final conduct ((g) in paragraph 9) involves behaviour by certain wholesalers. The Commission has considered carefully whether these are more appropriately viewed as part of a single complex monopoly situation involving all parts of the supply chain whose effect is to prevent, restrict or distort competition at the retail level, or as conducts potentially constituting three separate complex monopoly situations. The Commission believes that the relevant conducts by the manufacturers and wholesalers involved are most readily understood in terms of the dynamics of the supply chain as a whole and interaction with the conducts of veterinary surgeons. The Commission has in previous reports taken the view that a single complex monopoly can involve conducts at different levels in a supply chain¹, and takes the view that in the present case the commercial realities are such that conceptually these conducts are also more appropriately considered as part of a single

¹ For example, see the MMC's reports on *Supply of films for exhibition in cinemas in the UK*, HMSO, Cm 2673, October 1994 and *Domestic Electrical Goods I*, HMSO, Cm 3675-I, July 1997.

complex monopoly situation. However, in order to establish whether the Commission's provisional finding on the existence of complex monopoly in relation to the supply of POMs to animal owners is dependent on this view, we have considered as an alternative whether the relevant tests would be met should we treat the conducts as defining three separate groups for the purpose of establishing the existence or otherwise of complex monopoly situations (see paragraph 18).

Evidence on conducts

13. There are more than 13,000 veterinary surgeons registered to dispense POMs in the UK. It has not been practicable for the Commission to assess the conduct of each veterinary surgeon individually, and thus list those that it believes engage in one or more of the conducts specified above. However this is unnecessary provided that the Commission can be satisfied that two or more persons are engaged in one or more of the relevant conducts and that the group engaged in one or more of the conducts supplies, or is supplied with, at least 25 per cent of POMs in the UK. Such conducts appear to occur both in relation to the supply of POMs for use in companion animals and in relation to the supply of POMs for use in animals for food production. We have received some evidence that these conducts may be less common in more specialist areas such as the supply of POMs for use in commercial production of poultry, pigs or fish, where arrangements between veterinary surgeons and producers can differ from those more typically found between veterinary surgeons and the owners of the animals they treat. We do not, however, believe that it is ultimately necessary for the purposes of jurisdiction to distinguish between types of veterinary surgeon along these lines. The Commission's primary means of assessing the extent of the relevant conducts has been by means of surveys conducted by BMRB, an independent market research organisation, involving interviews with practitioners at over 610 UK veterinary surgeries drawn from a list provided by the Royal College of Veterinary Surgeons to provide a random sample. In addition to the telephone surveys, veterinary surgeons not selected for interview were invited to complete a similar survey via the Internet.

14. Evidence presented to the Commission by some of the larger buying groups indicates that several major manufacturers of POMs have refused or failed to negotiate discounts and rebates with them despite these being available to veterinary surgeries purchasing outside of such groups, and/or have withdrawn from such arrangements where they have taken over manufacturers which previously supplied those buying groups. Evidence presented to the Commission by individual pharmacists, by the National Pharmaceutical Association, and by some manufacturers themselves indicates that a significant number of manufacturers do not supply pharmacies with POMs directly or on terms allowing pharmacies to participate in rebate schemes operated by those manufacturers in relation to the supply of POMs to veterinary surgeries. Since rebates can be substantial (representing up to 40 per cent of the list price on some POMs, in addition to the smaller discounts obtainable from wholesalers) rebate schemes and other promotional arrangements appear to play a significant role in determining the price at which POMs are supplied. Part of the rationale for these schemes depends upon the fact that whilst, in some cases, clinical considerations will point to a preferred product such that considerations of cost will play little role, in other cases there will be more than one competing product which the veterinary surgeon could choose. The privileged position of veterinary surgeons in this respect appears to be reflected in the behaviour of manufacturers in their different approaches to supplying veterinary surgeries, and to supplying pharmacies, and in the targeting of rebate schemes on veterinary surgeries alone.

15. Although most manufacturers operate national price lists, the system of rebates results in a wide variety of prices being paid for POMs by veterinary surgeons. Some of these schemes are so complex as to make it difficult or impossible for veterinary surgeons purchasing POMs covered by such schemes to know the price they paid when they subsequently sell them to animal owners. The multiplicity of these schemes adds to the complexity faced by veterinary surgeons. This lack of transparency encourages the use by veterinary surgeons of mark-ups on list prices, with the consequences noted in paragraph 10.

16. It additionally appears to the Commission on the evidence provided by individual pharmacies and the National Pharmaceutical Association that two or more wholesalers may have declined to supply some pharmacies with POMs when approached to do so.
17. For a complex monopoly situation to exist at least one quarter of POMs in the United Kingdom must be supplied by members of the group, or to members of the group. If the veterinary surgeons, manufacturers and wholesalers engaged in the identified conducts are treated as separate groups then it is necessary to assess whether in each case the relevant group supplies, or is supplied with, 25 per cent of POMs in the United Kingdom. If, on the other hand, they are treated as members of a single complex monopoly then the group must be considered as a whole. The Fair Trading Act 1973 allows the assessment to be by reference to a wide range of criteria including value, cost, price, quantity, capacity, number of workers employed or such other criteria or combination of criteria as appears most suitable in the circumstances. This could include assessment of shares of supply at each stage in the chain as would be the case if they were treated as a series of separate complex monopoly situations.
18. On the basis of the data from the BMRB survey and data on sales and purchases supplied to the Commission by manufacturers and wholesalers of POMs supplied in the UK the Commission provisionally finds that veterinary surgeons, manufacturers and wholesalers engaged in one or more of the conducts identified in paragraph 9(a) to (g) that prevent, restrict or distort competition satisfy the supply test, whether they are viewed as a group involved in a single complex monopoly situation or as three separate groups involved in three separate complex monopoly situations.
19. It appears to the Commission that such a complex monopoly situation or complex monopoly situations, to the extent that these lead to less competition and higher prices for POMs at the retail level, will tend to operate generally in favour of veterinary surgeons supplying POMs, rather than only in favour of those engaged in the conducts that prevent, restrict or distort competition. It appears to the Commission

likely that such complex monopoly situation(s) also operate in favour of manufacturers supplying POMs in the UK, and/or of wholesalers distributing POMs in the UK, through lower competition and higher prices at the retail level reducing competitive pressure on prices further up the supply chain.

Provisional finding on complex monopoly in relation to supply to veterinary surgeries of vaccines for cats and dogs.

20. The Commission has further provisionally concluded that a complex monopoly situation exists amongst certain manufacturers of POMs by virtue of the structure of rebates given by those manufacturers to veterinary surgeons on purchases of vaccines for cats and dogs.

21. Most of the major manufacturers of POMs supplied in the United Kingdom operate rebate schemes. The schemes differ in scale and structure. Many of the largest rebates are paid on purchases of dog and cat vaccines. The markets for both dog and cat vaccines are highly concentrated and supplied by the same six manufacturers (Fort Dodge, Intervet, Merial, Pfizer, Schering Plough and Virbac). Fort Dodge is the market leader in cat vaccines, and the second largest supplier of dog vaccines. Intervet is the market leader in dog vaccines, and the second largest supplier of cat vaccines. Some of the rebate schemes have in common the feature of giving rebates based on, or substantially influenced by, the combined value of purchases of small animal vaccines within particular periods. They therefore give veterinary surgeons a commercial incentive to purchase both cat and dog vaccines from the same supplier. As a result manufacturers seeking to enter the market for the first time, or smaller manufacturers seeking to expand sales, face increased barriers, most notably where they offer a competitive cat vaccine or dog vaccine but not both. It appears to the Commission that the effect of such schemes is to prevent, restrict or distort competition between manufacturers by raising barriers to entry or expansion and maintaining higher market concentration than would otherwise be the case.

22. From sales data supplied by the manufacturers the Commission provisionally finds that manufacturers who operate schemes giving rebates based on, or substantially influenced by, the combined value of purchases of cat and dog vaccines supply at least 25 per cent of POMs in the UK.
23. It further appears to the Commission that the complex monopoly situation identified in paragraphs 21 and 22 operates in favour of the manufacturers who operate such schemes.

Possible remedies

24. In this paragraph we list a number of remedies that we might wish to consider, either individually or in combination, in the event that we were to conclude that the conducts identified in paragraph 9 in relation to the supply of POMs at the retail level were against the public interest.

(a) Possible remedies to reduce barriers to obtaining prescriptions

- (i) A requirement to display signs in veterinary surgeries advising clients of the availability of prescriptions to enable them to obtain POMs from pharmacies if they wish.
- (ii) A requirement to include on the signs envisaged under (i) above any price charged for issuing prescriptions additional to the normal consultation fee.
- (iii) A requirement for veterinary surgeons to advise clients, immediately prior to any dispensing of POMs, other than POMs that need to be used immediately, of the availability of prescriptions to enable them to obtain POMs from pharmacies.
- (iv) A requirement for veterinary surgeons to provide on request prescriptions for POMs whose use they have recommended.
- (v) A requirement for veterinary surgeons recommending the use of POMs to provide prescriptions **in every case** other than for POMs used in emergency treatment, for treatments during surgical procedures or for the use of anaesthetics.

- (vi) A requirement for veterinary surgeons recommending the use of POMs to provide prescriptions **in every case** other than for POMs that need to be used immediately at the time of consultation.
- (vii) A requirement for veterinary surgeons to state on all prescriptions issued for POMs that the prescribed items may be dispensed by pharmacies.
- (viii) A requirement for veterinary surgeons providing prescriptions to charge no more for issuing such prescriptions than properly reflects the incremental cost to themselves in preparing these
- (ix) A requirement for veterinary surgeons providing prescriptions to do so at no additional charge to the client beyond that of the consultation.
- (x) A requirement for veterinary surgeons to display signs stating their policies on frequency of examination of animals requiring repeat prescriptions and on the fees charged for such prescriptions.
- (xi) A requirement for veterinary surgeons recommending the use of POMs to state when the animal will need further examination and, where the animal requires repeat prescriptions prior to that date, to charge no more for issuing such prescriptions than properly reflects the incremental cost to themselves of preparing these.
- (xii) A requirement for veterinary surgeons recommending the use of POMs to state when the animal will need further examination and, where the animal requires repeat prescriptions prior to that date, to provide these at no further cost to the client on request.

(b) Possible remedies to improve price transparency and the ability of animal owners to understand and compare prices

- (i) A requirement for veterinary surgeons to inform clients, on request, of the price of any POM they propose to dispense.
- (ii) A requirement for veterinary surgeons to quote the price of any POM they sell to any person who asks.

- (iii) A requirement for veterinary surgeons to display in the veterinary surgery the price of the most commonly dispensed POMs.
- (iv) A requirement for veterinary surgeons when quoting the price at which they will dispense any POM also to state the cost of that POM to themselves.
- (v) A requirement for manufacturers of POMs giving rebates to veterinary surgeons to provide sufficient information, either directly or through wholesalers, so as to enable the veterinary surgeon to ascertain with certainty the cost net of rebates of POMs supplied to them.
- (vi) A requirement for veterinary surgeons to provide itemised bills distinguishing the cost of services from the cost of POMs.

(c) Possible remedies to reduce barriers to pharmacies competing with veterinary surgeons in the dispensing of POMs

- (i) A requirement for manufacturers and wholesalers that supply POMs in the UK to supply pharmacies.
- (ii) A requirement for manufacturers and wholesalers that supply POMs in the UK to supply pharmacies on terms that enable them to compete with veterinary surgeons.
- (iii) A requirement for veterinary surgeons to display the name, postal address, telephone number and website address of any pharmacy supplying veterinary medicines that so requests.
- (iv) A requirement for veterinary surgeons when they write prescriptions for POMs to do so on an 'or equivalent' basis to enable those dispensing such prescriptions to supply alternative authorised veterinary medicines to the brand specified.

25. In this paragraph we list a further remedy that we might wish to consider in the event that we were to conclude that the conducts of manufacturers identified in paragraph 21 in relation to the supply of cat and dog vaccines to veterinary surgeries were against the public interest:

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

Possible recommendations for regulatory changes

26. Paragraph 6 noted the extent to which requirements under European and UK law, primarily aimed at the protection of human and animal health, increase costs of supply, raise barriers to entry and restrict the outlets through which POMs can be legally obtained. In a report published in May 2001 ‘Report of the Independent Review of Dispensing by Veterinary Surgeons of Prescription Only Medicines’ a Group appointed by the then Minister for Agriculture, Fisheries and Food chaired by Professor Sir John Marsh looked at the regulatory aspects of the provision of POMs and made several recommendations for change. The Government issued an interim response for consultation in December 2001 and is expected to issue a final indication of the way in which it proposes to move forward later this year. Our terms of reference require us to investigate and report on whether one or more monopoly situations exist under the terms of the Fair Trading Act 1973, and we are not conducting a further review of the regulatory regime governing the supply of POMs. Nevertheless in conducting our review we have noted that there are features of the present arrangements which appear to restrict competition to a greater extent than is necessary, on which we may wish to make recommendations. We accordingly invite comments on the following.

European single market

27. The regulatory system, defined at European level, has not led to the growth of a single European market in most veterinary medicines. This lack of cross-border competition appears to the Commission to be a factor in the scale of price differences found between member states of the EU.
28. The small number of veterinary medicines authorised through the European centralised procedure can be traded across EU borders. The Commission welcomes

the European Commission's proposal to widen the categories of veterinary medicine eligible for the centralised procedure but notes that some would remain ineligible.

29. Marketing authorisations obtained through the centralised procedure are normally given only after agreement is reached in a committee of experts from all member states. In certain cases, for example niche products with geographically limited markets, national authorisation procedures may be of more benefit to competition, say by allowing speedier commercialisation of new products. It therefore appears to the Commission better that the exclusivity of the centralised procedure should not be extended and it is therefore considering the following recommendation:

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

30. Products authorised in one Member State may not legally be imported into or marketed in another without authorisation from the importing country. This is so even in the case of products authorised in both countries through the decentralised procedure. Such products are pharmaceutically identical, differing only in the language of labels and inserts and in their authorisation numbers. The Commission does not question that labels and inserts must be in the language of the country in which the product is marketed. But it appears to the Commission unnecessary for imported product, with regulated textual matter replaced so as to conform to the wording of the importing country, to undergo any regulatory procedure.

31. Manufacturers can sometimes impede re-wording by an importer of their products by asserting copyright over the relevant text. In the cases considered here no question of counterfeiting arises and it appears to the Commission that such recourse to copyright is a restriction of competition. It is therefore considering the following recommendation:

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

Classification of veterinary medicines

32. Veterinary medicines are classified in order to reduce the risk that misuse will cause harm to people, animals and the environment. The classification of a veterinary medicine determines the categories of retailer permitted to supply it, and therefore strongly influences the extent of competition at retail level. The Commission notes that the regulation of veterinary medicines recognises the need to balance efficacy against safety.

33. It appears to the Commission firstly that manufacturers can have a commercial interest in the choice of classification (including deciding whether to seek re-classification), going beyond scientific questions of safety and efficacy and that this may add to the restriction of competition inherent in classification. Secondly it appears to the Commission that the regulator interprets a medicine's efficacy narrowly, to refer only to the welfare of animals treated with it. The price and availability of medicines affect the welfare of all animals in need of treatment and could be considered a legitimate factor in the balance between safety and efficacy, including the choice of classification. It is therefore considering the following recommendations:

- (3) The Secretary of State to consider amending the remits of the Veterinary Products Committee and the Veterinary Medicines Directorate to preclude them from taking into consideration manufacturers' views on the classification of a product for which they are seeking marketing authorisation.
- (4) The Secretary of State and the Veterinary Medicines Directorate to consider instituting automatic review of classification whenever a product's Marketing

Authorisation is renewed (or at similar intervals if the European Commission's proposal to make Marketing Authorisations permanent is adopted) and to base such reviews exclusively on the product's existing dossier and accumulated field experience unless there is good scientific reason to require fresh testing to be carried out.

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

34. The European Commission has proposed that all medicines for food-producing animals should be permanently classified POM. In respect of food animal medicines classified POM in the UK, but not so required by law, the proposal would negate the Commission's Recommendations on classification. The Commission is therefore considering the following recommendation:

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

35. All veterinary medicines so far authorised through the centralised procedure have been classified POM. This is because the eligibility criteria for access to this procedure place them within the definition of veterinary medicines for which POM classification is mandatory. This may not remain true if the proposed widening of the centralised procedure is implemented, and especially if Recommendation (1) above is put into effect. It appears to the Commission that the UK authorities would have freedom to apply a UK classification to centrally-authorized veterinary medicines if no stipulation regarding distribution were made in the central authorisation itself and that competition in the UK would be enhanced if this freedom were available and used. The Commission is therefore considering the following recommendation:

(7) The Secretary of State to consider negotiating changes to the draft Directive to make it clear that the procedure through which an MA is given has no bearing on

the scope of member states' freedom to control channels of distribution and supply of veterinary medicine.

36. Some products will have mandatory POM classification simply because of a novel ingredient, though in time and in the absence of adverse field experience, it appears to the Commission that this should be capable of review. However EC law does not provide a mechanism for review of the classification of a centrally-authorised medicine. The Commission is therefore considering the following recommendation:

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

37. Implementation of the European Commission's proposals would lead to an increasing proportion of veterinary medicines classified POM and, as matters stand, subject to limited competition at retail level. The Commission notes that the well-established pattern of competition in supply of food animal medicine by agricultural merchants, and of certain other PML medicines by saddlers, could be lost. It also notes that it could be very largely restored if registered agricultural merchants and saddlers gained rights (corresponding to their present ability to supply PML medicines) to dispense veterinary prescriptions for medicines that, but for the European Commission's proposals, would have been classified PML (or possibly GSL). It appears to the Commission that this limited extension of dispensing rights would not impair safety. It is therefore considering the following recommendation (which resembles the Marsh Report's Recommendation 14):

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

36. The PML classification provides an alternative to POM suited to situations where, because the animal is kept by way of business, the owner or keeper can be presumed to have a corresponding degree of expertise. It appears to the Commission that its recommendations aimed at curbing over-narrow classification as POM will not achieve their full potential if there remain unjustified barriers to entry into the retailing of PMLs. It is therefore considering the following recommendations:

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

(11) The Royal Pharmaceutical Society of Great Britain, the Pharmaceutical Society of Northern Ireland and the Animal Medicines Training Regulatory Authority to work together to develop and promote SQP training tailored to new market niches/segments.

(12) The Secretary of State and the Veterinary Medicines Directorate to consider safe and practical extensions of the PML concept to new combinations of species and indication.

Regulatory procedures

37. The cost and especially the time taken in obtaining marketing authorisation are substantial. So too are the costs of maintaining an authorisation through continuing pharmacovigilance and 5-yearly renewals. It appears to the Commission that, partly as a result of this, new market entrants are deterred and competition is weak in some therapeutic sectors with few alternative products. It is therefore considering the following recommendations:

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

- (14) The Secretary of State to consider changes to the Veterinary Medicines Directorate's remit to encourage it to seek out ways to structure authorisation procedures to minimise delays to product commercialisation.
- (15) The Veterinary Medicines Directorate to consider offering applicants for marketing authorisation the option of submitting their dossier in stages.
- (16) The Secretary of State to consider negotiating changes to the proposed Directive to allow provisional marketing authorisation to be given to any product for which an efficacy claim is made and which has successfully completed safety and quality assessments so that commercialisation may begin before completion of efficacy assessment.
- (17) The Secretary of State to consider negotiating changes to the draft Directive so as to allow Maximum Residue Limits for minor food-animal species to be set by extrapolation from major-species data where this is scientifically justifiable.

The cascade

38. The Commission notes that there are relatively few authorised generics equivalent to authorised branded veterinary medicines. Price competition from generics is therefore relatively weak. The 'cascade' whilst allowing the administration of unauthorised medicines and off-label use of authorised veterinary medicines, does so only on a very limited scale. In respect of companion animals the Commission considers that there is a case for allowing veterinary surgeons to use the cascade more flexibly and in certain situations where an authorised veterinary medicine is available. The Commission is therefore considering the following recommendations:

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

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

Regulation of veterinary surgeons

39. The inability of one veterinary surgeon to dispense a prescription written by another significantly restricts the scope for competition between veterinary surgeons in the supply of POMs. The ability of one person to safely dispense the prescriptions of another is recognised in the provisions enabling pharmacists to play such a role, and it appears to the Commission that the limitation on veterinary surgeons doing the same represents an unnecessary restriction. The Commission is therefore considering the following recommendation:

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

40. The Commission notes that the conduct of veterinary surgeons in the exercise of their profession is governed in part by specific legal obligations and in part by the Royal College of Veterinary Surgeons' Guide to Professional Conduct. The Guide restricts the ability of veterinary surgeons to advertise medicines in ways that would appear unduly restrictive if one veterinary surgeon was able to dispense prescriptions of another. The Commission is therefore considering recommending:

(21) The RCVS to modify its Guide to Professional Conduct to remove restrictions on advertising of medicines by veterinary surgeons (except of advertising that clearly brings the veterinary profession into disrepute).

41. The Guide contains few provisions on aspects of professional conduct relevant to the inquiry. The Commission is therefore considering recommending:

(22) The RCVS to review and modify its Guide to Professional Conduct so as to draw attention to the Competition Commission's recommendations regarding veterinary surgeons and make compliance a matter of professional conduct.

42. The Guide is enforced mainly through a formal complaints procedure which, apart from criminality and fraud, is confined to "disgraceful professional conduct". Lesser misconduct, including isolated instances of unethical conduct, may lead to criticism but not to formal disciplinary procedures. Few aspects of professional conduct are subject to compliance monitoring, making the Guide a relatively weak means of curbing uncompetitive practices. The Commission is considering the following recommendations:

(23) The Royal College of Veterinary Surgeons to revise its Guide to Professional Conduct to make clear that single breaches of the provisions of the Guide are capable of being considered disgraceful professional conduct.

(24) The RCVS to institute regular monitoring of compliance with its Guide to Professional Conduct.

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