

**EXPLANATORY MEMORANDUM TO THE
SUPPLY OF RELEVANT VETERINARY MEDICINAL PRODUCTS ORDER 2005**

2005 No. 2751

1. This explanatory memorandum has been prepared by the Department of Trade and Industry and is laid before Parliament by Command of Her Majesty.

This memorandum contains information for the Joint Committee on Statutory Instruments.

2. **Description**

2.1 The Order prohibits veterinary surgeons from charging a fee for the issuing of prescriptions for a period of three years. It also requires manufacturers of certain prescription-only veterinary medicines – classified as relevant veterinary medicinal products – to provide information to veterinary surgeons and pharmacists about the costs of those medicines and not to discriminate between veterinary surgeons and pharmacists in the provision of those medicines.

3. **Matters of special interest to the Joint Committee on Statutory Instruments**

3.1 None

4. **Legislative Background**

4.1 In October 2001, the Director General of Fair Trading¹, pursuant to his powers under sections 47, 49 and 50 of the Fair Trading Act 1973, made a monopoly reference to the Competition Commission in relation to the market in the supply of prescription-only medicines for veterinary use (POMs).

4.2 The Competition Commission investigated that market and a report was laid before Parliament on 11 April 2003 (Cm. 5781). The Competition Commission found that three complex monopoly situations existed in relation to POMs. The Competition Commission recommended a number of measures designed to increase competition in this market.

4.3 The purpose of the Order is to remedy or to prevent the adverse effects specified in the Competition Commission's report and is made pursuant to the powers conferred on the Secretary of State under sections 56 and 90 of, and Schedule 8 to, the Fair Trading Act 1973. Although these provisions were repealed by the Enterprise Act 2002, they continue to apply in respect of monopoly references made before 20 June 2003².

¹ The functions of the Director General of Fair Trading have been transferred to the Office of Fair Trading pursuant to section 2 of the Enterprise Act 2002.

² See paragraphs 14 and 19 of Schedule 24 to the Enterprise Act 2002 and S.I. 2003/1397 para 2(2).

4.4 Since publication of the report, the Veterinary Medicines Regulations 2005 have been laid before Parliament by Defra. These regulations widen the list of medicines that are to be classified as POMs. As a result a new definition – relevant veterinary medicinal products – is used in this Order to more accurately reflect the market considered by the Competition Commission.

5. Extent

5.1 This instrument applies to all of the United Kingdom.

6. European Convention on Human Rights

6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

7.1 The monopoly provisions of the Fair Trading Act 1973 enabled the Director General of Fair Trading or Ministers to refer a ‘monopoly situation’ to the Competition Commission for investigation. Where the Competition Commission concluded that there was a monopoly situation operating against the public interest, the Secretary of State was empowered to remedy the adverse public interest. These provisions have now been replaced by the market investigation provisions in Part 4 of the Enterprise Act 2002, but continue to apply in relation to monopoly references made before 20 June 2003.

7.2 In its 2003 report, which was laid before Parliament on 11 April 2003 (Cm. 5781), the Competition Commission found that three complex monopoly situations existed in relation to POMs.

7.3 The first complex monopoly situation involves veterinary surgeons engaged in one or more of the following conducts:

- (a) failure to inform animal owners that they can ask for prescriptions, or discouraging requests for prescriptions, or declining to provide prescriptions on request;
- (b) failure to inform clients of the price of POMs prior to dispensing them, or to provide itemised bills; and
- (c) the pricing of POMs which does not reflect their cost of supply.

7.4 The second complex monopoly situation arises from the failure of eight manufacturers to enable pharmacies to obtain supplies of POMs on terms which would enable them to compete with veterinary surgeons.

7.5 The third complex monopoly situation arises from the failure of all the veterinary wholesalers to take reasonable steps to market to pharmacies and supply them with POMs, so that they can compete with veterinary surgeons.

7.6 The Government reviewed and accepted the Commission’s findings when the report was published. The DTI consulted for 12 weeks on the remedies proposed.

7.7 Policy changes were made following the consultation process, including the transfer of implementation of a significant proportion of the remedies to the Royal College of Veterinary Surgeons, for inclusion in their Guide to Professional Conduct, as an alternative to regulation. The Government's response to the consultation can be found on the Department's website at: <http://www.dti.gov.uk/ccp/topics2/vetmeds.htm>.

7.8 In general veterinary surgeons and some manufacturers opposed the proposals while other consultees were in broad support, the consultees provided many solid comments on the detail.

7.9 In general, veterinary surgeons argued that the Order was unduly detailed and would give rise to operational difficulties in practice. As a result of these representations the Order has been simplified. This has been facilitated by the formal proposal from the Royal College of Veterinary Surgeons to implement a number of the Commission recommendations through changes to their Guide to Professional Conduct. This offer has been accepted by DTI, and as a result, the Order no longer implements many of the more detailed recommendations of the Competition Commission, for example, the requirements to provide itemized bills and to have a large and prominently displayed sign in the surgery setting out, inter alia, the price of the ten prescription only medicines most commonly prescribed.

7.10 In addition, veterinary surgeons have been hostile to the Competition Commission recommendation that they be prohibited from charging for prescriptions for three years. These representations were considered by the Commission when formulating their recommendations and by the Government both when reviewing them and when developing the final Order. However, we remain of the view that the proposal is essential to opening the market to competition from pharmacies and, as a result, Article 3 of the Regulations sets out the prohibition.

7.11 Certain manufacturers expressed concern with the draft Order and we have responded by amending the provisions in two areas. First, we removed a requirement on manufacturers to supply a POM to any veterinary surgeon or pharmacist who requested it. Second, we have limited the requirement to supply information as to prices charged by the manufacturer over the last three months to the situation where a manufacturer directly supplies a veterinary surgeon or pharmacist or has provided a rebate or discount direct to the veterinary surgeon or pharmacist. This is because certain manufacturers supply wholesalers, rather than veterinary surgeons and pharmacists direct and would have had difficulty with a requirement to supply information to veterinary surgeons and pharmacists.

7.12 The policy intention behind the Order is to increase competition in the market for relevant veterinary medicinal products by ensuring that pharmacists are better able to access the market and that both pharmacists and veterinary surgeons have better access to information on prices. The Order does this by:

- prohibiting veterinary surgeons from charging for prescriptions for a period of three years;
- requiring veterinary manufacturers who engage in some form of direct relationship with customers (either veterinary surgeons or pharmacists) to inform those customers every three months and on request the net price at

which they supplied relevant veterinary medicinal products to that customer in the previous three months;

- requiring veterinary manufacturers to inform veterinary surgeons or pharmacists on request of the price they would be willing to supply relevant veterinary medicinal products in the next three months;
- making it unlawful for veterinary manufacturers to discriminate between veterinary surgeons and pharmacists.

7.13 These provisions will complement the changes being made to the Royal College of Veterinary Surgeons' Guide to Professional Conduct. These changes will implement the CC recommendations that veterinary surgeons should publish prices of the top ten POMs; display information on prescription pricing; inform clients of the cost of veterinary medicines before offering to prescribe or dispense them; inform any reasonable enquirer of the price of POMs stocked; provide itemised bills distinguishing the cost of POMs from other services; and provide information regarding a particular veterinary practice's policy on repeat prescriptions.

7.14 Guidance has been prepared to help business. This can be found on the Department's website at: <http://www.dti.gov.uk/ccp/topics2/vetmeds.htm>.

8. Impact

8.1 A Regulatory Impact Assessment is attached to this memorandum

8.2 There is no impact on the public sector.

9. Contact

John Madill at the Department of Trade and Industry Tel: 020 7215 2132 or e-mail: john.madill@dti.gsi.gov.uk can answer any queries regarding the instrument.

dti

Regulatory Impact Assessment

The Supply of Relevant Veterinary Medicinal Products Order
2005

7 October 2005

URN 05/1613

dti

The DTI drives our ambition of 'prosperity for all' by working to create the best environment for business success in the UK. We help people and companies become more productive by promoting enterprise, innovation and creativity.

We champion UK business at home and abroad. We invest heavily in world-class science and technology. We protect the rights of working people and consumers. And we stand up for fair and open markets in the UK, Europe and the world.

ORDER REMEDYING ADVERSE EFFECTS IDENTIFIED IN COMPETITION COMMISSION REPORT UNDER THE FAIR TRADING ACT 1973 ON THE SUPPLY OF PRESCRIPTION-ONLY VETERINARY MEDICINES

NOTE

Following publication of the Competition Commission report making the recommendations covered by this Regulatory Impact Assessment, further changes to legislation relating to veterinary medicines have been laid before Parliament in the Veterinary Medicines Regulations (VMR)³. The CC report used the term POM as a catch-all for prescription-only medicines for veterinary use. However, the VMR widens the definition of POM beyond the scope of the CC recommendations and creates two new subcategories. Of these, Prescription-Only Medicine – Veterinarian (POM-V) defines the market closest to that covered by the CC report, but even this is too wide. For the purpose of the Order, a new definition – Relevant Veterinary Medicinal Product – has been used. Essentially this definition covers all POM-Vs but excludes medicated feedstuffs and specified feed additives.

For clarity, therefore, this document uses three acronyms to refer to veterinary medicines:

- RVMP – Medicines covered by the Order;
- POM – in references to the CC report; and
- POM-V – in reference to the VMR.

The Royal College of Veterinary Surgeons have not yet indicated how they will interpret the change in definition. However, unlike an Order (which, under the Fair Trading Act, may not cover a market wider than the subject of the CC report), the RCVS may choose their own definition. For the purpose of this Regulatory Impact Assessment it is assumed RCVS will use the matching definition – RVMP.

PURPOSE AND INTENDED EFFECT

Objective

1. The Competition Commission (CC) report on the supply of POMs⁴ concluded that competition in the market was not fully effective. It identified practices carried out by manufacturers, wholesalers and veterinary surgeons which restrict or distort competition in the supply of POMs and operate against the public interest.

2. The CC recommended a series of remedies which they believe, in time, will encourage stronger competition. Manufacturers and wholesalers will have to supply both pharmacies and veterinary surgeons on the same terms for the same volumes supplied over the same time period. Manufacturers will also have to make available the net prices of the RVMPs they supply to veterinary surgeons and pharmacists. Veterinary surgeons will have to inform clients of the prices they charge for RVMPs and offer clients prescriptions which clients can take away if they wish. The remedies should, over time, lead to reduced prices of POMs ex-manufacturer, more equal terms of supply throughout the sales chain, reduced costs of medicines to veterinary surgeons and their clients, and more choice and transparency in the supply of RVMPs.

³ Further details are available on the VMD website (www.vmd.gov.uk). At the time of going to press no SI number is available for the VMR.

⁴ Competition Commission : A report on the supply within the United Kingdom of prescription-only veterinary medicines, CM 5781. Available from The Stationery Office or www.competition-commission.org.uk

3. This Regulatory Impact Assessment covers the proposals (including the Order) which are intended to remedy or prevent the adverse effects on the public interest, and implement the remedies identified by the CC.

Background

4. The CC's report found that three complex monopoly situations existed in relation to the supply of POMs, which these proposals address. The CC found each of the three complex monopoly situations to operate in favour of all veterinary surgeons, manufacturers and wholesalers who supplied POMs in the UK (whether or not they engaged in the monopoly conducts themselves). They also concluded that this results in effects detrimental to the public interest in that they lead to a lack of choice of supplier for animal owners and to the prices of POMs being higher than they would otherwise be.

5. The first complex monopoly situation was found to involve veterinary surgeons engaged in one or more of the following conducts:

- failure to inform clients that they can ask for prescriptions, or discouraging requests for prescriptions, or declining to provide prescriptions on request;
- failure to inform clients of the price of POMs prior to supplying them, or to provide itemised bills;
- pricing of POMs which does not reflect their cost of supply, including mark-ups on manufacturers' list prices that take no account of the discounts and rebates they receive from wholesalers and manufacturers, or do not reflect variations in those discounts and rebates; and
- pricing POMs to subsidise, to a greater or lesser extent, professional fees.

6. The second complex monopoly situation arises from the failure of eight manufacturers (Fort Dodge Animal Health Ltd, Interveterinary surgeon UK Ltd, Merial Animal Health Ltd, Novartis Animal Health UK Ltd, Pfizer Ltd, Pharmacia Ltd (Pharmacia Animal Health), Schering-Plough Ltd (Schering-Plough Animal Health (UK)), and Virbac Ltd) to enable pharmacies to obtain supplies of POMs on terms which would enable them to compete with veterinary surgeons.

7. The third complex monopoly situation arises from the failure of all the veterinary wholesalers to take reasonable steps to market to pharmacies and supply them with POMs, so that they can compete with veterinary surgeons.

8. As a result of these issues the CC made a number of recommendations.

Rationale for Intervention

9. The CC's report, and several years previously the Marsh Report⁵, both found that the veterinary profession tended to understate the true cost of their professional services and subsidise this by higher medicines pricing. Unfortunately, this practice is not simply a harmless mis-posting of costs, because the CC found that it has resulted in inadequate pressure on POM prices in the manufacturing and supply chain. The high prices – for instance compared with those available in neighbouring countries – result in detriment to animal owners and potentially the welfare of their animals. Owners may be inhibited from

⁵ Report of the Independent Review of Dispensing by Veterinary Surgeons of Prescription-only Medicines, published May 2001.

presenting their animals for examination because of cost. This also has potential consequential implications for prompt disease control and monitoring. There has been much comment about the merits of allowing cross-subsidy between POM sales and professional fees to continue. However, the fact remains that it has resulted in UK animal owners having to pay higher charges for POMs than those in neighbouring countries and this is not good for animals or their owners. It is worth emphasising that the overall thrust of the CC's recommendations is to secure an overall reduction in the totality of the cost to animal owners and not, simply a redistribution of costs.

10. In the absence of an open market price, few if any veterinary practices have been large enough to exert any credible pressure on the POM supply chain – and in the main they have become “price takers” with much of the “benefit” of those higher charges being taken by the medicine manufacturers and the supply chain. Each veterinary practice will need to make its own decisions on whether to realign its professional fees in the light of steps to open up RVMP supply to competition. There is no reason to believe that any increase in professional fees need be greater than the actual profit foregone on lost RVMP sales. The availability of free prescriptions should open up the market, generating scope for pharmacies to significantly increase their involvement. More importantly, the CC felt that the buying power of pharmacy operations would be likely to have direct and indirect benefits for animal owners as it would have the potential to apply very real pressure on the POM manufacturers and wholesalers, allowing them to offer lower prices. This, they argued, would in turn exert pressure on existing suppliers to veterinary surgeries who, to protect their market share, would need to lower their prices and exert increased pressure on their supply chain and ultimately the POM manufacturers – again to the benefit of the animal owner. However, such developments will not happen overnight – hence their proposed transitional measures.

11. It is important to recognise that neither the CC nor the Government is saying that veterinary surgeons should not be paid for the work they do. Nevertheless, the temporary requirement to supply free prescriptions is an important step to rectify the distorting effects arising from the tendency to use elevated prices for POMs to subsidise undercharging for their professional services. Hence the CC recommendation that for three years prescription charges be absorbed within their overall charge for professional services, whilst this new market place is being established. This would allow animal owners to become used to the availability of free prescriptions and help moderate any decisions to introduce charges after the three-year period.

12. In the following year veterinary surgeons will be free to apply a prescription fee if they so wish. At the same time, the Office of Fair Trading (OFT) have been invited to closely monitor such charges and, if they conclude that such charges were likely to act as a deterrent to people seeking a prescription so that they can obtain RVMPs from other sources, the CC recommended that steps be taken to stipulate a maximum prescription fee. In any event, even after the three-year period has elapsed, veterinary surgeons will not be able to discriminate between clients to whom they give prescriptions and clients to whom they do not give prescriptions. This will be the case in both the prices and fees they charge (other than the fees they charge for prescriptions).

13. The complex monopoly situations found by the CC lead to significant consumer detriment. The current lack of competition means that animal owners are paying too much for veterinary medicines. The CC noted that the mark-up applied to POMs was on average 20 per cent higher than the mark-up on other medicines, although they noted that some of this difference may be accounted by the different storage and other requirements for POMs. The

CC also noted that prices for POMs are generally substantially higher in the UK than in other European countries studied, and are never lower.

14. The annual turnover in the veterinary medicines market was £389 million⁶ in 2003. The lack of competition means that animal owners (including farmers) have been paying a higher price for POMs than they would in a fully competitive market. Pharmacies have been unable to establish a presence in the market as an alternative supplier because the lack of prescriptions has meant that most animal owners bought POMs from their veterinary surgeon.

CONSULTATION

Within Government

15. When analysing the CC report, the DTI took advice from the OFT and worked closely with the Veterinary Medicines Directorate (VMD)⁷ within the Department for the Environment, Food and Rural Affairs. We have continued to work closely with both of these organisations in developing the final Order.

16. As a result of the close discussions with VMD, implementation of this Order has been delayed until wide-ranging changes to the legislation affecting veterinary medicines as a result of EU law are also implemented, to minimise the effect on the sector of having to relearn guidance.

Public Consultation

17. The CC carried out a detailed investigation lasting around fifteen months before publishing its report. During its investigation, the CC consulted widely and took into account evidence and views from manufacturers, wholesalers of veterinary medicines, veterinary surgeons, consumer bodies, pharmacists, the Chief Veterinary Officer, the VMD, animal charities and individuals. The CC held hearings with the British Veterinary Association (BVA), the VMD, Bayer, Fort Dodge, Genus, Intervet, Merial, Novartis, NVS, Pfizer, Schering-Plough, Virbac, the National Farmers Union and the Royal College of Veterinary Surgeons (RCVS). There was also a public hearing held in London on 26 April 2002 attended by many interested individuals and organisations. On 16 April 2002 the CC sent an Issues Statement⁸ to manufacturers, veterinary wholesalers and veterinary surgeons. On 17 September 2002, the CC issued a statement of hypothetical remedies and provisional conclusions⁹ as it wished to consult parties on possible remedies.

18. After publication of the CC's report on 11 April 2003, the OFT held an informal consultation with interested parties including the RCVS, the BVA and the British Small Animal Veterinary Association. The DTI has also met with those organisations to discuss the Order.

19. On 18 February 2005, DTI launched a formal public consultation. This received 105 responses, the majority from veterinary surgeons. The majority of the respondents opposed

⁶ Figure from the National Office of Animal Health which represents the UK animal medicines industry. This figure is the value of the market from manufacturer to wholesaler and does not include sales to veterinary surgeons and pet owners

⁷ The Veterinary Medicines Directorate is an executive agency of the Department for Environment, Food & Rural Affairs. It is responsible for assessing, issuing and maintaining national marketing authorisations for veterinary medicines in accordance with EC and UK legislation. See www.vmd.gov.uk for more details.

⁸ Appendix 1.2, Vol 2, Competition Commission report

⁹ Appendix 1.3, Vol 2, Competition Commission report

the provisions, in particular the restriction on charging for prescriptions, feeling that the CC had interfered unfairly in the market, and the remedies were unnecessary. However, the majority of those respondents who acknowledged the problem addressed by the CC did feel that some measures were necessary.

OPTIONS

I. Do Nothing

20. The annual turnover in the veterinary medicines market was £389 million in 2003. The CC found that the lack of competition means that animal owners and farmers pay a higher price for POMs than they would in a fully competitive market. Pharmacies are unable to establish themselves as an alternative source of supply where animal owners cannot obtain prescriptions.

II. Self Regulation and a reduced scope Order

21. The RCVS¹⁰ has offered to implement most of the remedies directly aimed at veterinary surgeons through changes to their Guide to Professional Conduct¹¹. The amended Guide would potentially include provisions which mean that veterinary surgeons would be required to:

- Prominently display a large sign in all veterinary surgeries to which clients have access, advising clients on:
 - the availability of – and charge for – prescriptions, to enable clients to obtain RVMPs from pharmacies if they wish;
 - the prices of the ten RVMPs most commonly supplied by the veterinary surgeon in the previous three-month period; and
 - the availability of further information on prices of all RVMPs stocked.
- Quote the price of any RVMP stocked to anyone who makes a reasonable request.
- Before supplying RVMPs:
 - advise clients of the price of any RVMP they propose to supply;
 - offer clients, either orally or in writing, prescriptions for RVMPs and advise them of the charge for prescriptions; and
 - where relevant and possible, tell clients of their policies and charges relating to repeat prescriptions. This could be orally or in a leaflet or letter.

22. These requirements are subject to the exemption for urgency mentioned in paragraph 36 (below). This means that veterinary surgeons are not required to comply with the obligations to advise clients of the price of RVMPs, the availability of, and charge for, prescriptions and the costs relating to repeat prescriptions in urgent situations where, in the view of the veterinary surgeon, it would not be reasonable on the grounds of animal health or welfare to delay the supply and administration of the RVMP until such advice could be given. Further, veterinary surgeons are not required to comply with the obligation to advise clients of the availability of, and charge for, prescriptions where the RVMP to be supplied is to be administered by injection and is only available in packs containing multiple doses.

¹⁰ The Royal College of Veterinary Surgeons is the statutory regulatory body for the veterinary profession. It supervises veterinary undergraduate education, maintains a register of qualified veterinary surgeons and oversees their conduct. More information can be found on their website www.rcvs.org.uk

¹¹ The RCVS Guide to Professional Conduct can be found on www.rcvs.org.uk. The RCVS would not be able to prohibit veterinary surgeons from charging for prescriptions for 3 years so this remedy would stay in the Order.

23. In addition, veterinary surgeons are not to be required to comply with the obligation to advise clients of the availability of, and charge for, prescriptions where the client has confirmed in writing (such confirmation to be valid for up to one year) that he does not want the veterinary surgeon to give such advice or the client has confirmed that he wants the veterinary surgeon to administer the RVMP (for example, where a RVMP is to be administered during surgery or during a consultation).

24. The RCVS will not stop veterinary surgeons from charging for prescriptions for three years and therefore this remedy must be implemented by Order. Additionally, it is envisaged the parts of the Order applying to manufacturers and wholesalers will be retained.

25. The Government is in favour of proceeding with this Option.

III. Undertakings

26. The Fair Trading Act 1973 allows for two ways of introducing remedies: undertakings and orders. Undertakings can only be put in place with the agreement of the party or parties concerned, whereas an order may be imposed on the parties. Once signed, undertakings are legally binding in the same way as an order. Given that at the time of publication of the CC report there were around 9,700 veterinary surgeons in the UK (and this number is increasing) it is not practical to seek an undertaking from each one. Although the number of wholesalers and manufacturers is smaller, it would remain impractical to seek individual undertakings.

IV. Full Order

27. An order can be imposed under the Fair Trading Act 1973 on parties and therefore does not pose the same difficulties as using undertakings. The Government believes that implementing these remedies by way of changes to the RCVS guide and an Order is a sensible way forward given the large numbers of veterinary surgeons involved.

28. The Government consulted on a draft Order containing the following requirements:

- A requirement for veterinary surgeons to display prominently a large sign in all veterinary surgeries to which clients have access, advising clients on:
 - the availability of – and charge for – prescriptions, to enable clients to obtain RVMPs from pharmacies if they wish;
 - the prices of the ten RVMPs most commonly supplied by the veterinary surgeon in the previous three-month period; and
 - the availability of further information on prices of all RVMPs stocked.
- A requirement for veterinary surgeons to quote the price of any RVMP stocked to anyone who makes a reasonable request.

29. Before supplying RVMPs, all veterinary surgeons should:

- advise clients of the price of any RVMP they propose to supply;
- offer clients, either orally or in writing, prescriptions for RVMPs and advise clients of the charge for prescriptions; and
- where relevant and possible, advise clients of their charges relating to repeat prescriptions (this could be orally, in a leaflet or in a letter).

30. Either before or after supplying RVMPs, all veterinary surgeons should provide invoices distinguishing the cost of RVMPs from the cost of other goods and services.

31. In addition to the proposals above which may be implemented by self-regulation, the Government also consulted on legislation to achieve the following, which we are not convinced can be achieved by self-regulation or undertakings.

32. For three years after the Order comes into force, veterinary surgeons will not be able to charge clients for prescriptions. But they will be able to recover the costs they incur in giving prescriptions (for example, by including an amount in their consultation fees) provided they do so without discriminating between clients to whom they give prescriptions and clients to whom they do not. Even after the three-year period has elapsed, veterinary surgeons will not be able to discriminate between clients to whom they give prescriptions and those to whom they do not in the prices and fees they charge (other than the fees they charge for prescriptions).

33. The Order also proposes to require manufacturers of RVMPs to provide veterinary surgeons and pharmacists with certain price information in relation to RVMPs (for animal use only):

- At least once every three months, manufacturers who have any form of direct relationship with veterinary surgeons and pharmacists are required to provide price information to those veterinary surgeons and pharmacists with whom they have a direct relationship either as a result of supplying the RVMPs or as a result of agreeing to provide the veterinary surgeon or pharmacist with a discount or rebate. The price information that manufacturers are required to provide consists of the net price (taking into account discounts and rebates) of the RVMPs supplied in the three-month period. The net prices should not take into account any discounts or rebates given to or by a wholesaler as this information can be provided separately by the wholesaler; and
- On written request, manufacturers are required to inform veterinary surgeons or pharmacists of the net price at which they would be willing to supply, directly or indirectly via a wholesaler, a RVMP (for animal use only) in the next three months.

34. Additionally, the Order makes it unlawful for manufacturers and wholesalers to discriminate unreasonably between pharmacies and veterinary surgeons in the prices charged for RVMPs or any discount offered in relation to them or in the other terms or conditions of supply.

RISK ASSESSMENT

Animal health and welfare

35. There will be no change in the current requirement that prescriptions for POM-Vs can only be issued by a veterinary surgeon who has the animal in question under their care. It will still be for that veterinary surgeon to determine whether repeat prescriptions and consultations are required and, if so, what frequency is appropriate taking into account all relevant factors. However, the CC have recommended that veterinary surgeons be allowed, if they wish, to supply RVMPs in accordance with prescriptions given by other veterinary surgeons and thereby potentially gain additional sales within the new market place being created. This recommendation is permissive – it would be for individual veterinary surgeons to decide whether or not they wish to supply RVMPs in this way. The VMD is implementing this

recommendation as part of the new Veterinary Medicines Regulations (VMR). The VMD have confirmed that veterinary surgeons opting to supply POM-Vs in accordance with another veterinary surgeon's prescription would participate solely in the role of supplier. Like pharmacists, they would be expected simply to supply the identified medicines after satisfying themselves that the prescribed medicine seemed appropriate to the animal and diagnosed illness. Should they consider that the prescribed medicine was inappropriate they would have a duty to contact the prescribing veterinary surgeon to resolve the matter.

Urgently supplied and administered RVMPs

36. The changes proposed by the CC, and which will be set out in the RCVS Code of Practice, recognise and maintain the existing position in relation to any potential requirement to administer RVMPs urgently. If a veterinary surgeon has an animal in their care and it is necessary to administer a RVMP as a matter of urgency during an examination in circumstances where, in the professional opinion of the veterinary surgeon, there is not sufficient time to inform the client of the price of the RVMP, the availability of, and charge for, a prescription and the costs relating to repeat prescriptions, then, by way of an exception to the proposed regime, the veterinary surgeon may supply the RVMP without having to provide the client with this information.

Duty to comply with Medicines Act / Cascade¹² rules

37. Any persons wishing to supply, within the UK, any medicines falling within the ambit of the VMR will still need to meet the requirements of the VMR. POM-Vs will continue to be available only in accordance with a prescription of a veterinary surgeon. This will apply regardless of whether the actual POM-V is obtained from a veterinary surgeon or from a pharmacy (including internet-based operations). It is important to emphasise that this opening up of the RVMP supply process to competition does not in any way alter the current Cascade process. Consequently, pharmacists and any veterinary surgeons who choose to supply POM-Vs prescribed by another veterinary surgeon who has that animal under their care will still be strictly required to supply the POM-V specified on the prescription. They cannot offer a substitute medicine.

38. A number of respondents to the consultation queried whether pharmacists were sufficiently well trained to understand the cascade principles; the Government is content they will need to be aware of their liabilities and the National Pharmaceutical Association offers training for those who wish to take it up – low take-up is likely to be attributable to the small market that currently exists for pharmacy-dispensed POMs. We would hope that as the market develops, more pharmacists avail themselves of this opportunity.

Disease Monitoring

39. We anticipate that by combining their own medicine supply data with data from the prescriptions they have issued, veterinary surgeons will continue to have access to the same data as they currently do to carry out disease surveillance and reporting activity.

COSTS AND BENEFITS

¹² Sometimes there is no authorised veterinary medicine for the treatment of a particular combination of species and condition. In those circumstances a veterinary surgeon can use the "cascade". This means that they can administer (a) a veterinary medicine authorised in the UK for use in another animal species or for another condition in the same species; (b) if there is no such veterinary medicine as described in (a), a product authorised for use in the UK in a human; or (c) if there is no such human medicine as describe in (b), a veterinary medicinal product prepared by a pharmacist or a veterinary surgeon who has the animal in their care. If the animal concerned is food producing, the medicine may only contain substances found in a veterinary medicine already authorised in the UK for such animals and the veterinary surgeon must specify an appropriate withdrawal period.

Sectors and Groups affected

40. For either Options II or IV, the main beneficiaries of more effective competition in the market will be animal owners; whether pet owners or farmers. It is anticipated that it will be of particular benefit to owners of animals requiring long-term medication, as customers will be offered greater choice and lower prices.

41. The direct effect of the CC recommendations will fall on veterinary surgeons, manufacturers and wholesalers. The majority of administrative costs on veterinary surgeons will apply in respect of the changes to the RCVS Guide to Professional Conduct, rather than this Order, but all will fall as a result of implementing the CC recommendations.

42. We do not anticipate that any of the options will have a disproportionate effect, positive or negative, on any ethnic group, either as business or consumers.

Benefits

43. It is anticipated that the expected benefits of implementing the CC's recommendations will fall to the large proportion of customers of veterinary surgeons who purchase RVMPs. According to the CC report, in 80 per cent of consultations a POM was administered, and in 75 per cent of consultations a POM was dispensed for administration by the animal owner. This implies that in around 50 per cent of cases POMs are both administered during the consultation and dispensed for administration by the owner. The CC report illustrated how POMs are substantially more expensive for UK consumers than they are for their counterparts in other EU countries. The CC found, when comparing the UK prices of some commonly-used POMs with those in other European countries:

- Most best-selling POMs in the UK are substantially more expensive, ex-manufacturer, than in all the European countries in their study.
- The difference in price between the UK and other European countries is greater for POMs, ex-manufacturer, than for other veterinary medicines, and countries where pharmacies play a larger role in their supply have the lowest ex-manufacturer prices.
- Retail prices for POMs (excluding VAT) are never lower and are generally substantially higher in Great Britain.
- For those POMs for which it was possible to make a comparison of retail prices after adjusting for differences in ex-manufacturer prices, prices in Great Britain are still higher in the majority of cases.

44. Overall, the CC found that, on average, prices of the POMs that they looked at are 21 per cent higher in the UK than in each of the five European countries that they analysed. They also found that the average mark-up applied to POMs was 68 per cent, over 20 per cent higher than the average mark-up on other medicines. While we do not have sufficient information to estimate the scale of the potential benefits to consumers arising from increased competitive pressure on RVMP prices, it is very likely, given the information cited above, that prices will fall significantly and that consumers benefits will be accordingly large.

45. Other beneficiaries will include pharmacies, who will have improved access to the market for RVMPs. The scale of the benefits to pharmacies, and thereby the scale of the eventual consumer benefits, will depend in large part on the extent to which pharmacies are willing to take advantage of the new opportunities which will become available to them. The

consultation received responses from the National Pharmaceutical Association and two other pharmacy companies expressing support as they felt the provisions would increase pharmacy participation in the market.

Costs for manufacturers

46. Every three months, manufacturers will have to provide veterinary surgeons and pharmacists, to whom they have supplied RVMPs direct or granted a discount or rebate, with information about the net prices charged for RVMPs purchased by those veterinary surgeons and pharmacists in the preceding 3 months. This obligation will extend to providing such information to all veterinary surgeons or pharmacists who buy their product whether directly or indirectly via a wholesaler. Manufacturers should already hold details of such veterinary surgeons or pharmacists in order to operate their discount or rebate schemes. Manufacturers need not take into account discounts or rebates offered to or by wholesalers in calculating net price. Further, the manufacturers will not be obliged to provide net price information in relation to medicines that can also be used for the treatment of humans. On request, manufacturers will also have to advise veterinary surgeons and pharmacists of the net price at which they would be willing to supply (either directly or indirectly) a RVMP in the following three-month period.

47. Manufacturers will not be permitted to discriminate unreasonably between pharmacies and veterinary surgeons on price, discounts or other terms and conditions. In their response to the CC, the majority of the manufacturers claimed that the requirement not to discriminate would increase costs, as new channels for distribution would need to be set up¹³.

Costs for wholesalers

48. In the same way, wholesalers will not be permitted to discriminate unreasonably between pharmacies and veterinary surgeons on price, discounts or other terms and conditions. It is anticipated that this is likely to result in a very small administrative cost of monitoring their prices.

Costs for veterinary surgeons

49. Both Options II and IV impose similar costs for veterinary surgeons. They will have to put up signs in their surgeries with information including the prices of their top ten RVMPs. In identifying their top ten RVMPs, veterinary surgeons may use whatever criteria they reasonably consider appropriate to provide clients with a fair and representative illustration of their prices. The list of top ten medicines will have to be updated at least once every 3 months. The Government considers that making such signs should not involve substantial resources or expense, and this was backed up in the consultation, where the maximum costs given were up to £150 which would equate to significantly less than £1 on the cost of a consultation.

50. Veterinary surgeons will have to provide customers with itemised bills which at least distinguish the costs of other goods and services from the costs of the RVMPs. In a recent survey, 69% of veterinary surgeons that responded said they always provide itemised bills. More already had computer systems that would allow them to calculate consulting and dispensing charges. One respondent estimated a one-off cost of up to £25,000 and associated additional costs per annum of around £5,000, while another suggested £18,000. However, the first respondent noted that switching to itemised bills would reflect best practice regardless of the provision in the Order.

¹³ Para 9.58, pg 261 Competition Commission report

51. However, Option II also imposes a separate cost on veterinary surgeons. The RCVS is funded through subscription payments by members. Out of these payments, RCVS meets all its administrative and enforcement costs. Under Option II, any enforcement of the CC recommendations would therefore be paid indirectly by veterinary surgeons. Under Option IV, this cost is borne by the taxpayer through the OFT.

Policy Costs

52. In response to the consultation, one veterinary surgeon estimated a likely loss of around £12.90 per consultation through lower POM prices. Others estimated the loss in profit as between 5 and 30 per cent although two veterinary surgeons claimed that consultation costs could increase by 300-400 per cent.

53. Under the part of the Order that would be retained, veterinary surgeons will not be allowed to charge for writing a prescription for a period of three years. Currently around four-fifths of veterinary surgeons charge for prescriptions. The CC estimated the mean price for those making a charge to be £5.24¹⁴. Evidence in the CC report suggests very few prescriptions are currently written out. However, veterinary surgeons will be able to recover the costs they incur in giving prescriptions (for example, by including an amount in their consultation fees) provided they do so without discriminating between clients to whom they give prescriptions and clients to whom they do not.

54. Responses to the consultation gave a wide range of charges for prescriptions. The CC's estimate that around 20% of practices do not charge was backed up, and other costs were estimated as being between £2 and £30, with £5-£6 as the most common. However, several of the respondents included the costs of providing prescriptions for medicated feedstuffs. As these were not considered by the CC, they will not be included in the final Order. The anticipated increase in consultation costs was estimated to be up to 30%.

55. It is difficult to analyse the detail of the responses, as many veterinary surgeons argued that their prescription charges included the cost of determining the appropriate treatment for animals. The Government recognises that veterinary surgeons may pass on to their clients the costs incurred in determining the appropriate treatment and providing the prescription. This will be reflected in the guidance issued with the final Order, but it leads us to believe the likely cost will be at the lower end of the proposed range.

SMALL FIRMS IMPACT TEST

56. Most veterinary practices are small businesses. The costs for them are discussed above. To ensure the views of small businesses are adequately taken into account we asked that the veterinary profession's trade associations place details of our consultation on their websites. As a result, we received a significant number of responses from veterinary surgeons.

57. Individual costs are dealt with above, but one veterinary surgeon argued that competition policy in general favoured larger businesses, who were able to achieve lower costs through economies of scale. While this may be the case to some extent, it is limited by the fact that any organisation in a dominant position may be subject themselves to competition investigation.

¹⁴ Para 6.187, pg 175 Competition Commission report

58. Additionally, the BVA expressed concern that lower margins for veterinary surgeons could have an effect on the level of provision of rural services. However, the National Farmers' Union, which represents small farmers, supported the proposals and felt the impact suggested by the BVA was unlikely.

COMPETITION ASSESSMENT

59. The competition filter test has been conducted and this indicates that the proposed remedies will not negatively affect competition.

60. The remedies reviewed in this RIA are intended to reduce the barriers faced by pharmacies in the supply of RVMPs to animal owners. These barriers currently favour veterinary practitioners, to the disadvantage of pharmacies and animal owners.

61. The markets affected are for the sale of RVMPs by manufacturers to wholesalers, their sale by wholesalers to veterinary practices and to pharmacies and their sale by veterinary practices and pharmacies to animal owners.

62. The proposed remedies will not have a differential impact between manufacturers, between wholesalers, between vets or between pharmacies. All firms within each sector will be affected equally, except in the case of small veterinary practices which may face relatively higher costs compared to larger practices. This aspect is covered above in the Small Firms Impact Test.

63. It is intended that competition between veterinary practices and pharmacies will be affected. The proposed remedies will lower the barriers that pharmacies face in entering the RVMPs market and increase their ability to compete effectively with vets.

64. Scale economies enjoyed by pharmacies will allow them to apply pressure upwards to wholesalers and manufacturers and will encourage cost-cutting and greater efficiency in all the sectors affected.

ENFORCEMENT, SANCTIONS AND MONITORING

65. Civil proceedings for an injunction or any other appropriate relief may be brought in respect of a failure to comply with the terms of the Order. The breach of any injunction or other order of the Court obtained as a result of such proceedings would constitute a contempt of court. Further, any person may be able to bring civil proceedings for a breach of the Order against the person responsible.

66. The OFT will monitor compliance with the Order.

67. The RCVS is responsible for enforcing breaches of its Guide to Professional Conduct. This is done by means of the arrangements for regulating professional conduct which are set out in the Veterinary Surgeons Act 1966 (the 1966 Act). The system is essentially complaints-based but all complaints are investigated to identify potential issues of misconduct or “disgraceful conduct in a professional respect”, in accordance with the 1966 Act. Where such issues are found, a case is referred to a formal hearing before the RCVS Disciplinary Committee which has powers to remove or suspend a veterinary surgeon from the Register of those legally allowed to practice in the United Kingdom. The Committee also has power to

issue a warning or to postpone judgment on conditions, which, for example, may relate to a requirement for retraining or for health treatment and perhaps an undertaking not to carry out certain procedures until certain conditions have been satisfied.

68. Where issues of misconduct are not found, the investigation may nevertheless result in advice being given to the veterinary surgeon. If a further complaint reveals that advice has not been heeded that would be a significant factor in determining whether a case should be referred to the Disciplinary Committee. Although all cases would be considered on their merits, the RCVS would expect that initial or minor breaches of the CC requirements would be dealt with by way of advice but that subsequent or flagrant breaches could raise issues of misconduct for the Disciplinary Committee.

69. In addition to the statutory arrangements for regulating misconduct, the RCVS has recently introduced a scheme for setting and monitoring practice standards. At this stage the scheme is voluntary, but since it was launched to the profession in January 2005 approximately a third of all practice premises have joined. As part of the Scheme, practices are inspected and, in addition to the routine inspections, unannounced visits are made on a 'spot check' basis. These visits will give the RCVS an additional means of monitoring compliance with the CC recommendations.

IMPLEMENTATION AND DELIVERY PLAN

70. Detailed draft guidance was issued 10 weeks in advance of the implementation date of the Order, to allow preparation time. This guidance will be revised when the Order is in force. Once this and the VMD legislation are in place, RCVS will work towards revising their Guide to Professional Conduct for reissue in January 2006.

POST-IMPLEMENTATION REVIEW

71. The OFT will, from time to time, review the effectiveness and benefits of the Order to see whether relevant parties should be released from the Order or whether the Order needs to be varied or superseded by a new Order. The OFT will advise the Secretary of State of its findings. If it is considered that the Order is no longer appropriate, the Secretary of State may revoke the Order. In accordance with the Enterprise Act 2002, it is envisaged that, in due course, responsibility for enforcing the Order will be transferred to the OFT and the CC. As part of this process the power to release or vary the Order will be transferred to the CC.

SUMMARY AND RECOMMENDATION

72. The Government's preference is for a combination of Option II (self-regulation) and a reduced version of Option IV (legislation), as RCVS have demonstrated that their proposal will remedy the adverse effects on the public interest identified by the CC and implement the CC's recommendations effectively.

73. The CC's adverse findings were made against eight manufacturers (Fort Dodge Animal Health Ltd, Interveterinary surgeon UK Ltd, Merial Animal Health Ltd, Novartis Animal Health UK Ltd, Pfizer Ltd, Pharmacia Ltd (Pharmacia Animal Health), Schering-Plough Ltd (Schering-Plough Animal Health (UK)), and Virbac Ltd) and against all veterinary wholesalers and veterinary surgeons.

74. The CC’s recommendations are aimed at addressing the complex monopoly problems identified in their report and the resulting adverse effects. The recommendations affect many elements of the industry including those involved in the manufacture, wholesale and supply of POMs.

75. To address the complex monopoly problems and the resulting detriment to animal owners and the potential welfare of their animals, the CC recommendations focus on opening up the supply of POMs to market forces. For the early stages, while the new market develops, the CC considered it important that animal owners/consumers were made aware of, and were not deterred by prescription charges from exercising choice in the sourcing of POMs. Hence they specifically recommended that for a period of three years there should be no charge for prescriptions. Whilst this requirement is to be lifted after three years, the level of prescription charges applied will be monitored to assess the level of charges and the effect on competition.

76. Competition is not a devolved matter, and responsibility rests with the Government of the United Kingdom. This order will apply to England, Scotland, Northern Ireland and Wales.

Summary costs and benefits table		
Option	Total benefit per annum: economic, environmental, social	Total cost per annum: - economic, environmental, social - policy and administrative
1	Zero – Although following publication of CC report there may be some competitive pressure this is likely to be minimal.	Zero
2	Up to 20% drop in RVMP prices; increased competition from pharmacists able to enter market.	Manufacturers may face some increased costs but could not quantify. Veterinary surgeons may face costs of up to £150 pa for information provision and some will face one-off costs of up to £25,000 to allow itemised bills. On average up to 30% may be added to the cost of consultation for 3 years, a lower figure after that. Some cost to veterinary surgeons may arise if there is significant breach of RCVS Guide and resulting enforcement cost.
3	As Option 2	As Option 2, plus significant additional cost to OFT in obtaining undertakings and likely risk of inability to secure from all veterinary surgeons
4	As Option 2	As Option 2, although cost of enforcement would be borne by public sector (DTI/OFT) rather than by RCVS and funded through professional fees.

DECLARATION AND PUBLICATION

I have read the regulatory impact assessment and I am satisfied that the benefits justify the costs

Signed *Gerry Sutcliffe*

Date 4th October 2005

Gerry Sutcliffe
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