

dti

Prescription-only veterinary medicines –
consultation on proposed Order

Consultation by the Department of Trade and
Industry on draft legislation to implement the
remedies recommended in the 2003
Competition Commission report on the supply of
prescription-only veterinary medicines.

FEBRUARY 2005

URN 05/832

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.

ABOUT THIS CONSULTATION

This consultation concerns an Order which the Secretary of State for Trade and Industry intends to make in relation to the supply of prescription-only medicines for veterinary use (“POMs”) within the UK.

In particular, the draft Order requires:

- veterinary surgeons to provide certain information to their clients (including price information) when supplying POMs and by displaying a notice in their surgeries;
- veterinary surgeons not to charge for writing prescriptions for three years;
- manufacturers of POMs to provide veterinary surgeons and pharmacists with information about the prices of POMs; and
- veterinary manufacturers and wholesalers to supply POMs to pharmacies and veterinary surgeons on the same terms for the same volumes supplied over the same time period .

The draft Order follows on from the Competition Commission’s report: “A report on the supply within the United Kingdom of prescription-only veterinary medicines” (CM 5781) (“the CC Report”) which was presented to Parliament by the Secretary of State for Trade and Industry and published on 11 April 2003.

Before the Secretary of State makes the Order she is required, under section 91(2) of the Fair Trading Act 1973 (the “Act”), to publish a notice of her intention to make the Order, indicating the nature of the provisions to be included in the Order and inviting written representations from anyone with an interest in the matter.

Accordingly, the Secretary of State hereby gives notice that she intends to make an Order under sections 56(2) and 90(2), (4) and (7) of, and paragraphs 1, 4, 6, 9, 10 and 12A of Schedule 8 to, the Act, for the purpose of remedying or preventing the adverse effects on the public interest specified in the CC Report.

The Order will make provision about the supply of POMs in the UK. The nature of the proposed provisions to be included in the Order are set out in a draft Order at Annex A. The final provisions the Order will be subject to the Secretary of State considering any representations that she receives. Further, the draft Order in Annex A is based on the current regulatory regime for veterinary medicines. The final Order will take into account any changes made to this regime¹.

Any person whose interests are likely to be affected by the Order, and who wishes to make representations, should do so in writing to Mr Yuen Cheung, Consumer and Competition Policy Directorate, Department of Trade & Industry, Room 413, 1 Victoria Street, London SW1H 0ET, stating what their interest in the matter is, and the grounds on which they wish to make representations, before **13 May 2005**.

Issued 18 February 2005

Respond by 13 May 2005

Enquiries to Yuen Cheung, DTI, Bay 416, 1 Victoria Street, London, SW1H 0ET, monopannounce@dti.gsi.gov.uk

¹ Note the Veterinary Medicines Directorate is currently consulting on draft Veterinary Medicines Regulations details of which are available from www.vmd.gov.uk under “Consultations

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ABOUT THE CONSULTATION AND HOW TO RESPOND

- 1.1 This consultation is primarily of relevance to manufacturers, wholesalers and distributors of prescription-only medicines for veterinary use (“POMs”), persons directly or indirectly involved with the veterinary profession throughout the UK, as well as farmers and other animal owners. However, it is open for any interested person or organisation to contribute to this consultation.
- 1.2 The consultation is specifically intended to secure views on the scope, timing and form of the Order which is intended to remedy or prevent the adverse effects on the public interest identified in the Competition Commission’s report “A report on the supply within the United Kingdom of prescription-only veterinary medicines”¹ (“the CC Report”) and to implement the remedies suggested in the CC Report. Details of the content of the proposed Order are set out in section 2.
- 1.3 Paragraphs 1.6 to 1.12 below explain how to respond to this consultation document. We are particularly keen to receive any views from manufacturers and wholesalers of POMs and veterinary surgeons on the following areas:
- **Views on potential costs or savings for individual businesses of the proposed remedies; and**
 - **Views on whether or not some or all of the proposed remedies affecting veterinary surgeons could be implemented through amendments to the Royal College of Veterinary Surgeons Guide to Professional Conduct instead of through legislation.**
- 1.4 The case for change was set out in the CC Report which was published on 11 April 2003. The Government has already reviewed and accepted the findings of the Competition Commission (“the CC”) and the package of remedies proposed by the majority of the CC. The CC carried out a detailed investigation lasting around fifteen months, under the Fair Trading Act 1973. During its investigation, the CC consulted widely and took into account evidence and views from manufacturers, wholesalers of POMs, veterinary surgeons, consumer bodies, pharmacists, the Chief Veterinary Officer, the Veterinary Medicines Directorate, animal charities and individuals. The CC held hearings with the British Veterinary Association, the Veterinary Medicines Directorate, Bayer, Fort Dodge, Genus, Intervet, Merial, Novartis, NVS, Pfizer, Schering-Plough, Virbac, the National Farmers Union and the Royal College of Veterinary Surgeons. 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 Statement² to manufacturers, veterinary wholesalers and veterinary surgeons. On 17 September 2002, the CC issued a statement of hypothetical remedies and provisional conclusions³ as it wished to consult parties on possible remedies. This consultation

¹ CM 5781. Available from The Stationery Office or from www.competition-commission.org.uk

² Appendix 1.2, Vol 2, Competition Commission report on the supply within the United Kingdom of prescription-only veterinary medicines, CM 5781 II

³ Appendix 1.3, Vol 2, Competition Commission report on the supply within the United Kingdom of prescription-only veterinary medicines, CM 5781 II

therefore focuses primarily on the implementation of the package of remedies identified in the CC Report.

Closing date

- 1.5 Interested parties have until Friday 13 May 2005 to respond to this consultation. To ensure your views are considered, please make sure that any responses reach the DTI by no later than that date.

How to respond

- 1.6 Your response can be sent by any of the following routes:

By email to:

monopannounce@dti.gsi.gov.uk

By post to:

Yuen Cheung

Room 413

Department of Trade and Industry

1 Victoria Street

London SW1H 0ET

Or by FAX to:

020 7215 2837

- 1.7 Please make clear where your response is being made acting on behalf of an organisation rather than in a personal capacity.

Outcome

- 1.8 All responses will be considered. The outcome of this consultation will be published on the DTI website later in 2005, and as appropriate reflected in the final Order which will be presented to Parliament.

Additional copies

- 1.9 If you wish to obtain additional copies of this consultation, or are aware of other interested parties who may wish to respond, they can be obtained from the above address, or copies can be downloaded from www.dti.gov.uk/ccp/topics2/vetmeds.htm

- 1.10 Further printed copies of the consultation document can be obtained from:

DTI Publications Orderline

ADMAIL 528

London SW1W 8YT

Tel: 0870 1502 5000

Fax: 0870 1502 333
Minicom: 0870 1502 100
www.dti.gov.uk/publications

Confidentiality

- 1.11 Please note that responses to this consultation document will be made publicly available in summary, in whole or in part at the Department's discretion. If you do not wish all or part of your response (including your identity) to be made public, you must state in the response which parts you wish us to keep confidential.
- 1.12 Where confidentiality is not expressly requested, responses may be made public to any enquirer, including enquirers outside of the UK, or published by any means including the internet. Please note that any email response sent from a corporate system may carry an automatically generated notice stating that the contents of the message should be treated as confidential. Where you do not wish your views to be treated as confidential, please make it clear that such an automatically generated message does not apply.

Consultation Code of Practice

- 1.13 A copy of the DTI Code of Practice on Consultation is in Annex C.
- 1.14 If you have any questions or are unhappy about the way this consultation is being run please contact:

Nick Van Benschoten
Consultation Co-ordinator
Department of Trade and Industry
1 Victoria Street
London
SW1H 0ET
nick.vanbenschoten@dti.gsi.gov.uk

WHAT IS BEING CONSULTED ON AND WHY THIS CHANGE IS NEEDED

Background

- 2.1 Following complaints by animal owners and farmers about what they perceived as the high price of POMs, the Director General of Fair Trading formally asked the CC to investigate the market on 9 October 2001⁴. The CC Report was published on 11 April 2003. The CC found that three complex monopoly situations existed in relation to POMs. It found that each of the three complex monopoly situations operates in favour of all veterinary surgeons, manufacturers and wholesalers who supply POMs in the UK (whether or not they engage in the monopoly conducts themselves) and has 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.
- 2.2 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) pricing of POMs which does not reflect their cost of supply, including:
 - (i) mark-ups on manufacturers' list prices that take no account of the discounts and rebates they receive from wholesalers and manufacturers, or do not reflect variations in those discounts and rebates; and
 - (ii) pricing POMs to subsidise, to a greater or lesser extent, professional fees.
- 2.3 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, Schering-Plough Ltd and Virbac Ltd) to enable pharmacies to obtain supplies of POMs on terms which would enable them to compete with veterinary surgeons.
- 2.4 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.
- 2.5 The Government reviewed and endorsed the CC's findings. Subsequently the Office of Fair Trading undertook an informal consultation on a draft proposal with

⁴ Terms of reference of the inquiry are set out in Appendix 1.1, Vol 2, Competition Commission report on the supply within the United Kingdom of prescription-only veterinary medicines, CM 5781 II

interested parties such as the Royal College of Veterinary Surgeons (RCVS), the British Veterinary Association and the British Small Animal Veterinary Association. The DTI followed this with more informal discussions working closely with the Veterinary Medicines Directorate, of the Department for the Environment, Food and Rural Affairs, in taking this forward. This consultation document and proposed Order takes account of valuable input secured in response to both those informal consultations. As a result, DTI has been able to address specific animal health and welfare issues in particular.

Proposals

2.6 To remedy the adverse effects on the public interest identified by the CC and implement the CC's recommendations, the draft Order contains the following measures:

- 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 POMs from pharmacies if they wish;
 - the price of the ten POMs most commonly supplied by the surgeon in the previous three-month period; and
 - the availability of further information on prices of all POMs stocked.
- A requirement for veterinary surgeons to quote the price of any POM stocked to anyone who makes a reasonable request.

2.7 Before supplying POMs, all veterinary surgeons should:

- advise clients of the price of any POM they propose to supply;
- offer clients, either orally or in writing, prescriptions for POMs 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).

2.8 Either before or after supplying POMs, all veterinary surgeons should provide itemised bills distinguishing the cost of POMs from the cost of other goods and services.

2.9 In the light of the animal health and welfare issues identified in the informal consultations with interested parties mentioned in paragraph 2.5 above, the draft Order contains the following exemptions:

- Veterinary surgeons are not required to comply with the obligations to advise clients of the price of POMs, the availability of, and charge for, prescriptions and the costs relating to repeat prescriptions in emergency 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 POM until such advice could be given;

- Veterinary surgeons are not required to comply with the obligation to advise clients of the availability of, and charge for, prescriptions where the POM to be supplied is to be administered by injection and is only available in packs containing multiple doses. This exemption is intended to deal with the fact that a pharmacist may only be able to supply POMs for injection in pack sizes that are larger than required and there are safety concerns that arise from this.
- However, veterinary surgeons can and should inform clients of the prices of POMs for injection so that clients can see how much they are paying for these medicines. If a veterinary surgeon wishes to give a prescription to a client (who has had training in giving injections) then they can do so at their own discretion.

2.10 In addition, veterinary surgeons are not required to comply with the obligation to advise clients of the availability of, and charge for, prescriptions where:

- The client has confirmed in writing that he does not want the veterinary surgeon to give such advice (such confirmation may be valid for up to one year);
- The client has confirmed that he wants the veterinary surgeon to administer the POM. This would cover the case where a POM is to be administered during surgery or a consultation, for example.

2.11 For three years, veterinary surgeons will not be able to charge a client for writing a prescription. 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 those 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).

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

- At least once every three months, manufacturers are required to provide price information to veterinary surgeons and pharmacists to whom they have supplied POMs (for animal use only), either directly or indirectly through a wholesaler, at a discount or rebate within the last three months. The price information that manufacturers are required to provide consists of the net prices (taking into account discounts and rebates) of the POMs 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;

- 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 POM (for animal use only) in the next three months.
- 2.13 Additionally, the draft Order imposes certain other duties on manufacturers and wholesalers of POMs. In particular, manufacturers and wholesalers should supply POMs to pharmacies and veterinary surgeons on the same terms for the same volumes supplied over the same time period.⁵
- 2.14 Explanatory notes explaining the provisions in the draft Order in detail are also provided at the end of the draft Order (see Annex A).
- 2.15 A draft Regulatory Impact Assessment has been produced and we would welcome any views on the analysis of costs and benefits, and the extent to which these might alter if some of the proposed measures were subsumed within professional regulations. We would also welcome views on whether the proposals might give rise to unforeseen consequences. This is attached at Annex B.

Alternatives

- 2.16 Reflecting its Better Regulation agenda, the Government is willing to consider alternative proposals for securing the objectives that the draft Order is intended to achieve. The Department would consider all such representations carefully, particularly any from professional bodies such as the RCVS⁶ to incorporate elements of the proposed remedies directly affecting veterinary surgeons in their Guide to Professional Conduct⁷. Potential changes may include provisions which mean that veterinary surgeons would be required by their professional rules 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 POMs from pharmacies if they wish;
 - the price of the ten POMs most commonly supplied by the veterinary surgeon in the previous three-month period; and
 - the availability of further information on prices of all POMs stocked.
 - Quote the price of any POM stocked to anyone who makes a reasonable request;
 - Before supplying POMs:
 - advise clients of the price of any POM they propose to supply;
 - offer clients, either orally or in writing, prescriptions for POMs and advise them of the charges relating to repeat prescriptions; and

⁵ The draft statutory instrument also includes an article prohibiting manufacturers and wholesalers from refusing unreasonably to supply POMs to pharmacists or veterinary surgeons.

⁶ 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 at www.rcvs.org.uk

⁷ 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.

- where relevant and possible, tell clients of their charges relating to repeat prescriptions. This could be orally or in a leaflet or letter.

(These requirements could be subject to the exemptions mentioned in paragraphs 2.9 and 2.10 above.); and

- Before or after supplying POMs, provide itemised bills distinguishing the cost of POMs from the cost of other goods and services;

2.17 If the Government can be satisfied that any such alternative proposals will remedy the relevant adverse effects on the public interest identified by the CC and are enforceable, then the Government would be prepared to revise the draft Order to reduce its scope accordingly. However, it is envisaged that the proposal measures to stop veterinary surgeons from charging for prescriptions for three years will need to be implemented by means of an Order.

Regulatory Recommendations

2.18 The CC also made several recommendations relating to the system of regulation of veterinary medicines. The Veterinary Medicines Directorate (VMD) is consulting separately on the implementation of these recommendations. The VMD's consultation is part of a wider package of measures implementing changes following the review of European medicines legislation and the recommendations from the Marsh Report as well as a Better Regulation Review of existing UK legislation on veterinary medicines. The VMD is currently consulting interested parties on draft Veterinary Medicines Regulations. The VMD began consulting formally on the new legislative package on 4 January 2005. The consultation will run for 4 months until 5 May 2005. The new package will be implemented in November 2005 to comply with the timescale required for implementing the amending EU directive. The timetable for the VMD's work will also mean that, if adopted, the CC's recommendation to allow a veterinary surgeon to be able to supply POMs in accordance with another veterinary surgeon's prescription will not come into force until November 2005. Further details are available on the VMD website (www.vmd.gov.uk) under "Consultations", "Review 2001". We intend the changes made as a result of this consultation to come into force at the same time, in October 2005.

2.19 The changes to the veterinary medicines legislation are likely to have an impact on these proposals which are based on the current regulatory regime for veterinary medicines and do not take into account the VMD's proposed changes. For example, the definitions of terms such as "prescription only medicine" in the draft Order will need to be revised. The final version of the Order will, as appropriate, be modified to ensure it conforms with any changes made by VMD following their consultation.

Useful Links

2.20 Relevant background documents including the CC report can be found on <http://www.dti.gov.uk/ccp/topics2/monopolies.htm>

2005 No. xxxx

COMPETITION

**The Supply of Prescription Only Medicines (Veterinary Use)
Order 2005**

<i>Made</i> - - - -	2005
<i>Laid before Parliament</i>	2005
<i>Coming into force</i> - -	2005

Whereas the Director General of Fair Trading⁽¹⁾, in exercise of the power conferred on him by sections 10(3), 10(4), 47(1), 49(1) and 50(1) of the Fair Trading Act 1973⁽²⁾ (“the Act”), made a monopoly reference on 9 October 2001 and, in response to the reference, the Competition Commission made a report entitled “Veterinary Medicines: A report on the supply within the United Kingdom of prescription-only veterinary medicines”⁽³⁾ (“the Competition Commission Report”);

Whereas the Secretary of State, in accordance with section 91(2) of the Act⁽⁴⁾, published a notice on [****2005] stating her intention to make this Order, indicating the nature of the provisions to be embodied in it and stating that any person whose interests were likely to be affected by it and who was desirous of making representations in respect of it should do so in writing before [****2005];

And whereas the Secretary of State has considered the representations received;

Now, therefore, the Secretary of State, being the appropriate Minister under section 56 of the Act, in exercise of the powers conferred on her by sections 56(2) and 90(2), (4) and (7) of, and paragraphs 1, 4, 6, 9, 10 and 12A of Schedule 8 to, the Act⁽⁵⁾, and for the purpose of remedying or preventing the adverse effects specified in the Competition Commission Report, hereby makes the following Order:

Citation and commencement

1. This Order may be cited as the Supply of Prescription Only Medicines (Veterinary Use) Order 2005 and shall come into force on [****].

⁽¹⁾ Pursuant to section 2 of the Enterprise Act 2002 (c. 40) the functions of the Director General of Fair Trading have now been transferred to the Office of Fair Trading and the office of the Director has been abolished.
⁽²⁾ 1973 c.41. Section 50 was repealed by Schedule 26 to the Enterprise Act 2002.
⁽³⁾ Cm. 5781.
⁽⁴⁾ Section 91(2) was repealed by Schedule 26 to the Enterprise Act 2002 but, pursuant to paragraphs 14 and 19 of Schedule 24 to the Enterprise Act 2002 and SI 2003/1397 (“the saving provisions”), it continues to apply in respect of monopoly references made before 20 June 2003 under section 50 of the Fair Trading Act 1973.
⁽⁵⁾ Sections 56 and 90 and Schedule 8 were repealed by Schedule 26 to the Enterprise Act 2002 but, pursuant to the saving provisions, they continue to apply in respect of monopoly references made before 20 June 2003 under section 50 of the Fair Trading Act 1973.

Interpretation

2. In this Order—

“animal” includes any bird, fish or reptile;

“client” means any person with whom a veterinary surgeon makes an agreement to supply veterinary services;

“medicated feeding stuff” has the same meaning as in section 130(3B) of the Medicines Act 1968⁽⁶⁾;

“medicinal product” has the same meaning as in section 130 of the Medicines Act 1968 but shall not include medicated feeding stuff;

“OFT” means the Office of Fair Trading;

“parenteral administration” means administration by breach of the skin or mucous membrane;

“pharmacist” means—

(a) a person who is a pharmacist within the meaning of section 132 of the Medicines Act 1968; or

(b) any other person who is lawfully conducting a retail pharmacy business in accordance with section 69 of the Medicines Act 1968;

“prescription” means a prescription for the purposes of section 58(2)(a) of the Medicines Act 1968;

“prescription only medicine” means a medicinal product of a description or falling within a class that has been specified by order under section 58(1) of the Medicines Act 1968 which, in relation to the description or class, states that veterinary surgeons are to be appropriate practitioners for the purposes of section 58;

“prescription only veterinary medicine” means a prescription only medicine which is manufactured, supplied, imported or exported for the purpose of being administered to animals, but not for the purpose of being administered to human beings;

“supply” includes sale (including retail sale) or supply in circumstances corresponding to retail sale;

“veterinary manufacturer” means any person who is required to hold a manufacturer’s licence under section 8(2) of the Medicines Act 1968;

“veterinary services” means the services supplied by a veterinary surgeon in his capacity as such and related services supplied by other persons, and includes—

(a) giving a prescription; and

(b) supplying a prescription only medicine;

“veterinary surgeon” means a person registered in the register of veterinary surgeons kept under section 2 of the Veterinary Surgeons Act 1966⁽⁷⁾ or a person registered in the supplementary veterinary register kept under section 8 of the Veterinary Surgeons Act 1966;

“veterinary surgery” means any premises—

(a) which are used primarily for the provision of veterinary services; and

(b) to which clients have access;

“veterinary wholesaler” means any person who is required to hold a wholesale dealer’s licence under section 8(3) of the Medicines Act 1968;

“writing” includes text that is—

(a) transmitted by electronic means;

(b) received in legible form; and

(c) capable of being used for subsequent reference.

⁽⁶⁾ 1968 c.67; section 130(3B) was inserted by section 13(2) of the Animal Health and Welfare Act 1984 (c.40).

⁽⁷⁾ 1966 c.36.

Requirement for a veterinary surgeon to publish information

3.—(1) A veterinary surgeon must publish the information referred to in paragraph (2) by means of a notice of the kind specified in paragraph (3) displayed in his veterinary surgery.

(2) The information is as follows—

- (a) the prices of the 10 prescription only medicines that are most commonly supplied by the veterinary surgeon;
- (b) subject to article 6(1), any fee for giving a prescription; and
- (c) information to the effect that—
 - (i) a prescription only medicine may be supplied by a pharmacist in accordance with a prescription;
 - (ii) except in circumstances provided for by law, where a prescription only medicine is recommended for the treatment of his animal, a client will be offered a prescription for it;
 - (iii) where a prescription only medicine is recommended for the treatment of his animal, a client will be informed of its price; and
 - (iv) where any person makes a reasonable request for the price of any prescription only medicine that is usually stocked in the veterinary surgery, he will be notified of it.

(3) The notice must be sufficiently large and conspicuous so as to be easily read by clients.

(4) Where two or more veterinary surgeons supply veterinary services in partnership from the same veterinary surgery—

- (a) the requirement in paragraph (1) will be met where one veterinary surgeon publishes on behalf of the partnership the information referred to in paragraph (2) by means of a notice of the kind specified in paragraph (3) displayed in the veterinary surgery;
- (b) for the purposes of paragraph (2(a)), the 10 prescription only medicines may be the 10 prescription only medicines that are most commonly supplied by the partnership.

(5) For the purposes of selecting the 10 prescription only medicines that are most commonly supplied under paragraph (2(a))—

- (a) a veterinary surgeon may use such criteria (which may include the number of units of product supplied, the monetary value of units of product supplied and the target species of the product) as he reasonably considers appropriate to provide clients with a fair and representative illustration of his prices or, if the veterinary surgeon is publishing information on behalf of a partnership under paragraph (4), the partnership's prices; and
- (b) a veterinary surgeon must review, and if necessary update, the selection of prescription only medicines at intervals of 3 months or less.

Requirement for a veterinary surgeon to notify price information on request

4. Where any person makes a reasonable request to a veterinary surgeon to be notified of the price of any prescription only medicine that is usually stocked in the veterinary surgery from where the veterinary surgeon supplies veterinary services, the veterinary surgeon must comply with that request.

Prohibition of agreements to supply prescription only medicines

5.—(1) It shall be unlawful for a veterinary surgeon to make or carry out an agreement to supply a prescription only medicine to a client except in circumstances where the conditions specified in paragraphs (3) to (7) are satisfied.

(2) The conditions specified in paragraphs (3) to (6) must be satisfied prior to the supply of the prescription only medicine to the client.

(3) The veterinary surgeon has informed the client of the price of the prescription only medicine.

(4) The veterinary surgeon has made an offer to the client to give a prescription for the prescription only medicine and, subject to article 6(1), the veterinary surgeon has informed the client of the fee, if any, for giving the prescription.

(5) If the client accepts the offer made in accordance with paragraph (4) and agrees to pay any fee of which he has been informed under paragraph (4), the veterinary surgeon has not failed or refused to give the prescription.

(6) Where the veterinary surgeon recommends a prescription only medicine for the treatment of an animal in circumstances which he considers are likely to require the further administration of the same or similar prescription only medicine for the further treatment of the animal, the veterinary surgeon has provided the client with information relating to the cost to the client of that further treatment.

(7) The veterinary surgeon has provided the client with an invoice that distinguishes the price of the prescription only medicine supplied or to be supplied from the price of other goods or services supplied or to be supplied.

(8) Paragraphs (3) to (6) do not apply where, in the opinion 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 prescription only medicine until the conditions in paragraphs (3) to (6) could be satisfied.

(9) Paragraphs (4) and (5) do not apply where—

- (a) the client has confirmed to the veterinary surgeon in writing after the day on which this Order comes into force that, for any specified period lasting no longer than one year, he does not require the veterinary surgeon to offer to give prescriptions for all or any specified prescription only medicines;
- (b) the client has confirmed to the veterinary surgeon that he wishes the veterinary surgeon or a person acting on behalf of the veterinary surgeon to administer the prescription only medicine; or
- (c) the prescription only medicine is for parenteral administration and only available in packs containing multiple doses.

(10) For the purposes of providing the client with information mentioned in paragraph (6), the veterinary surgeon must, where possible and relevant, inform the client of the following matters—

- (a) the number and frequency of any further examinations by the veterinary surgeon that are likely to be required and the fee for such further examinations;
- (b) the number and frequency of occasions on which it is likely that the veterinary surgeon will be required to review his records of the animal's veterinary care and the fee for such reviews; and
- (c) the number and frequency of occasions on which the veterinary surgeon is likely to recommend the same or similar prescription only medicine, the price of the prescription only medicine and the fee, if any, for giving a further prescription.

(11) Where a veterinary surgeon has provided a client with information under paragraph (6) on one occasion, on subsequent occasions when the veterinary surgeon recommends the same or similar prescription only medicine for the further treatment of the animal, the veterinary surgeon need only provide the information mentioned in paragraph (6) to the extent that it is necessary to update or correct the information he has already provided under paragraph (6).

Prescription fees and prohibition of discrimination

6.—(1) Subject to paragraph (2), during the relevant period a veterinary surgeon must not charge a client a fee for giving a prescription.

(2) During the relevant period a veterinary surgeon may pass on to his clients the costs incurred in giving prescriptions, provided that he does so in a manner that does not discriminate between clients to whom he gives prescriptions and clients to whom he does not.

(3) It shall be unlawful for a veterinary surgeon to discriminate between a client to whom he gives prescriptions and a client to whom he does not, in—

- (a) the price he charges for a prescription only medicine; and
- (b) the fee he charges for supplying veterinary services other than giving a prescription.

(4) In paragraphs (1) and (2), “relevant period” means the period of 3 years beginning with the day on which this Order comes into force.

Requirement for a veterinary manufacturer to notify price information

7.—(1) At intervals of not more than 3 months, a veterinary manufacturer must notify in writing—

- (a) a relevant veterinary surgeon of the net price at which it supplied a prescription only veterinary medicine to the relevant veterinary surgeon during the preceding 3 months; and
- (b) a relevant pharmacist of the net price at which it supplied a prescription only veterinary medicine to the relevant pharmacist during the preceding 3 months.

(2) In paragraph (1)—

- (a) “relevant veterinary surgeon” means a veterinary surgeon to whom the veterinary manufacturer supplied a prescription only veterinary medicine during the preceding 3 months and to whom the veterinary manufacturer has given or agreed to give a discount or rebate in connection with the supply of that prescription only veterinary medicine; and
- (b) “relevant pharmacist” means a pharmacist to whom the veterinary manufacturer supplied a prescription only veterinary medicine during the preceding 3 months and to whom the veterinary manufacturer has given or agreed to give a discount or rebate in connection with the supply of that prescription only veterinary medicine.

(3) In paragraphs (1) and (2), “preceding 3 months”, means the 3 month period ending with the day on which the veterinary manufacturer notifies the information.

(4) In paragraph (1) and article 8(1), “net price” means the list price less any discount or rebate which the veterinary manufacturer has given or agreed to give to the veterinary surgeon or pharmacist in connection with the supply of the prescription only veterinary medicine, but does not include any discount or rebate given to, or by, a veterinary wholesaler. The veterinary manufacturer shall state whether the net price is inclusive or exclusive of VAT and all other taxes.

(5) In paragraph (4) “list price” means the price set and quoted by the veterinary manufacturer as the price at which a prescription only veterinary medicine may be supplied to a veterinary surgeon or pharmacist, without taking into account any discount or rebate. The list price may be inclusive or exclusive of VAT and all other taxes.

(6) In paragraphs (1), (2) and (5), and article 9(2), “supplied” includes supplied indirectly via a veterinary wholesaler and, in paragraphs (2) and (4), and articles 8(1), 9(1) and (3), “supply” includes indirect supply via a veterinary wholesaler.

Requirement for a veterinary manufacturer to notify price information on request

8.—(1) Where a veterinary surgeon or pharmacist makes a request to a veterinary manufacturer to be notified of the net price at which the veterinary manufacturer would be willing to supply a prescription only veterinary medicine during the next 3 months, the veterinary manufacturer must comply with that request by notice in writing.

(2) A veterinary manufacturer is not obliged to comply with a request made under paragraph (1) unless that request—

- (a) is in writing;
- (b) identifies the prescription only veterinary medicine in respect of which price information is requested;

- (c) states the name of the veterinary surgeon or pharmacist making the request and his address for correspondence; and
- (d) where the veterinary surgeon or pharmacist making the request intends to purchase the prescription only veterinary medicine from one or more veterinary wholesalers, states this circumstance and gives their names.

(3) In paragraph (1), “next 3 months” means the 3 month period beginning with the day on which the veterinary manufacturer notifies the information.

Prohibition of discrimination by a veterinary manufacturer or a veterinary wholesaler

9.—(1) It shall be unlawful for a veterinary manufacturer or a veterinary wholesaler to discriminate unreasonably between veterinary surgeons and pharmacists in—

- (a) the price that they charge for the supply of a prescription only medicine;
- (b) any discount and rebate that they give in connection with the supply of a prescription only medicine; or
- (c) the other terms and conditions upon which they supply a prescription only medicine.

(2) In determining whether discrimination is reasonable in any particular case under paragraph (1), regard shall be had to factors including the quantity of the prescription only medicine to be supplied and the period over which the prescription only medicine is to be supplied.

(3) It shall be unlawful for a veterinary manufacturer or a veterinary wholesaler unreasonably to withhold or agree to withhold or threaten to withhold from a veterinary surgeon or a pharmacist the supply of a prescription only medicine.

Requirement to furnish information to the OFT

10.—(1) The OFT may require, on reasonable notice given in writing, any person mentioned in paragraph (2) to furnish the OFT with such information mentioned in paragraph (3) as the OFT may require for the purposes of monitoring compliance with this Order.

(2) The persons are—

- (a) a veterinary surgeon;
- (b) a pharmacist;
- (c) the Royal College of Veterinary Surgeons;
- (d) a veterinary manufacturer; and
- (e) a veterinary wholesaler.

(3) The information is information held by or in the control of the person who is required to furnish the information under paragraph (1).

Directions by the Secretary of State as to compliance

11. The Secretary of State may give directions to a person specified in the directions, or to the holder for the time being of an office so specified in any company or association—

- (a) to take such steps within his competence as may be specified or described in the directions for the purposes of carrying out, or securing compliance with, this Order; or
- (b) to do or refrain from doing anything so specified or described which he might be required by this Order to do or refrain from doing.

(2) In paragraph (1), “steps” includes steps to introduce and maintain arrangements to ensure that any person carries out or secures compliance with this Order.

(3) The Secretary of State may vary or revoke any directions given.

Address

Date

Gerry Sutcliffe
Parliamentary Under Secretary of State for
Employment Relations, Competition and Consumers
Department of Trade and Industry

draft

EXPLANATORY NOTE

(This note is not part of the Order)

This Order sets out remedies to the adverse effects on the public interest specified in the Competition Commission report entitled “Veterinary Medicines: A report on the supply within the United Kingdom of prescription-only veterinary medicines” published in April 2003 (Cm. 5781). Copies of the report may be obtained from The Stationery Office.

Article 3 requires a veterinary surgeon to publish by way of a notice displayed in his surgery information about the prices that he charges for prescription only medicines and other information concerning prescription only medicines and prescriptions.

Article 4 requires that, in response to a reasonable request, a veterinary surgeon must notify any person of the price of a prescription only medicine that he usually supplies.

Article 5 makes it unlawful for a veterinary surgeon to make or carry out an agreement to supply a prescription only medicine except in circumstances where specified conditions are satisfied. The specified conditions are primarily concerned with the provision of information to clients about the price of, and the availability of prescriptions for, prescription only medicines.

Article 6 prevents a veterinary surgeon from charging a fee for giving a prescription for a period of 3 years from the coming into force of this Order, although during this time a veterinary surgeon is permitted to recover from his clients the costs he incurs in prescribing provided he does so in a way that does not discriminate between clients to whom he gives a prescription and those to whom he does not.

Article 7 requires a manufacturer of prescription only medicines, at least once every three months, to notify in writing price information to veterinary surgeons and pharmacists to whom it has supplied prescription only medicines (for animal use only) directly or via a wholesaler at a discount or with a rebate in the previous 3 months. The price information consists of the net prices (taking into account discounts and rebates) of prescription only medicines supplied to the veterinary surgeon or pharmacist in the previous 3 months.

Article 8 requires a manufacturer, on written request, to notify in writing a veterinary surgeon or pharmacist of the net price at which the manufacturer would be willing to supply directly or via a wholesaler a prescription only medicine (for animal use only) in the next three months.

Article 9 makes it unlawful for the manufacturers and wholesalers of a prescription only medicine to discriminate between veterinary surgeons and pharmacists in the prices they charge, the discounts and rebates they offer and the other terms and conditions upon which they supply a prescription only medicine. This provision also makes it unlawful for a manufacturer or wholesaler unreasonably to withhold from a veterinary surgeon or pharmacist the supply of a prescription only medicine.

Article 10 requires specified persons to provide the OFT on request with information that they hold or control and the OFT requires for the purpose of monitoring compliance with this Order.

Article 11 gives the Secretary of State powers to give directions in order to secure compliance with this Order.

A full regulatory impact assessment of the effect that this Order will have on the costs of business has been prepared and is available from [.....]. Copies can also be found at *[web address]*.

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

DRAFT REGULATORY IMPACT ASSESSMENT

PURPOSE AND INTENDED EFFECT

Issue

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

Objective

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 POMs they supply to veterinary surgeons and pharmacists. Veterinary surgeons will have to inform clients of the prices they charge for POMs 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 POMs.

3. This draft Regulatory Impact Assessment covers the draft Order which is 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 this proposal addresses. Each of the three complex monopoly situations operates in favour of all veterinary surgeons, manufacturers and wholesalers who supply POMs in the UK (whether or not they engage in the monopoly conducts themselves) and has 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. The first complex monopoly situation involves 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

¹ 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

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.

5. 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.

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

RISK ASSESSMENT

Rationale

8. The CC's report, and several years previously the Marsh Report², 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 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 the existing cross subsidy between POM sales and professional fees to continue. However the fact remains that it has resulted in the 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 not, simply a redistribution of costs.

9. Currently in the absence of an open market place, few if any veterinary practices are 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 medicines 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 POM 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 POM sales. The availability of free prescriptions should open up the market, generating scope for pharmacies to significantly increase their involvement. More importantly, the buying power of pharmacy operations is likely to have direct and indirect benefits for animal owners as it has the potential to apply very real pressure on the POM manufacturers and wholesalers, allowing them to offer lower prices. This in turn will exert pressure on existing suppliers to veterinary surgeries who, to protect their market share, will 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.

² Report of the Independent Review of Dispensing by Veterinary Surgeons of Prescription-only Medicines, published May 2001.

However such developments will not happen overnight – hence their proposed transitional measures.

10. It is important to recognise that neither the CC nor the Government are saying that veterinary surgeons should not be paid for the work they do. However the temporary requirement to supply free prescriptions is an important step to rectify the distorting effects arising from the current 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.

11. In the following year veterinary surgeons will be free to apply a prescription fee if they so wish. However the 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 POMs from other sources the CC have 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 those to whom they do not in the prices and fees they charge (other than the fees they charge for prescriptions).

12. 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 note that the mark-up applied to POMs (which are the subject of the Order) are on average 20 per cent higher than the mark-up on other medicines, although they note that some of this difference may be accounted by the different storage and other requirements for POMs. The CC also note that prices for POMs are generally substantially higher in the UK than in other European countries studied, and are never lower.

13. The annual turnover in the veterinary medicines market was £389 million³ in 2003. The lack of competition means that animal owners (including farmers) pay a higher price for POMs than they would in a fully competitive market. Pharmacies are unable to establish a presence in the market as an alternative supplier because the lack of prescriptions means that most animal owners buy POMs from their veterinary surgeon.

Animal health and welfare

14. There will be no change in the current requirement that prescriptions for POMs 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 POMs 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 POMs in this way. The Veterinary Medicines Directorate⁴ (“VMD”), part of the Department for the Environment, Food and Rural Affairs, is currently consulting on whether to implement this recommendation as part of its consultation on

³ 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

⁴ 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.

proposed new Veterinary Medicines Regulations⁵. The VMD have confirmed that veterinary surgeons opting to supply POMs 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 the prescribed medicine was inappropriate they would have a duty to contact the prescribing veterinary surgeon to resolve the matter.

Urgently supplied and administered POMs

15. The changes proposed in the consultation document recognise and maintain the existing position in relation to any potential requirement to administer POMs urgently. If a veterinary surgeon has an animal in their care and it is necessary to administer a POM 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 POM, 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 POM without having to provide the client with this information.

Duty to comply with Medicines Act / Cascade⁶ rules

16. Any persons wishing to supply, within the UK, any medicines falling within the ambit of the Medicines Act 1968 will still need to meet the requirements of the Act⁷. POMs will continue to be available only in accordance with a prescription of a veterinary surgeon. This will apply regardless of whether the actual POM 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 POM supply process to competition does not in anyway alter the current Cascade process. Consequently pharmacists and any veterinary surgeon who chooses to supply POMs prescribed by another veterinary surgeon who has that animal under their care will still be strictly required to supply the POM specified on the prescription. They cannot offer a substitute medicine.

Disease Monitoring

17. 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.

POMs for Injection

18. Following discussions by DTI and the VMD and consultation with veterinary organisations, we have accepted that veterinary surgeons should not be required to comply with the proposed obligation to advise clients of the availability of, and charge for, prescriptions where the POM to be supplied is to be administered by injection and is only available in packs containing multiple doses. This exemption is intended to deal with the fact that a pharmacist may only be able to supply POMs for injection in pack sizes that are larger than required and there are safety concerns that arise from this.

⁵ Further details are available on the VMD website (www.vmd.gov.uk) under "Publications", "Review 2001".

⁶ 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.

⁷ Subject to any changes made by new Veterinary Medicines Regulations.

19. However, veterinary surgeons can and should inform clients of the *prices* of POMs for injection so clients can see how much they are paying for these medicines. If a veterinary surgeon wishes to give a prescription to a client (who has had training in giving injections) then they can do so at their own discretion.

OPTIONS

I. Do Nothing

20. The annual turnover in the veterinary medicines market was £389 million in 2003. 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 Royal College of Veterinary Surgeons⁸ has suggested that most of the remedies directly aimed at veterinary surgeons might be implemented by appropriate changes to their Guide to Professional Conduct⁹. We are willing to consider this. 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 POMs from pharmacies if they wish;
 - the price of the ten POMs most commonly supplied by the veterinary surgeon in the previous three-month period; and
 - the availability of further information on prices of all POMs stocked.
- Quote the price of any POM stocked to anyone who makes a reasonable request
- Before supplying POMs:
 - advise clients of the price of any POM they propose to supply;
 - offer clients, either orally or in writing, prescriptions for POMs 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 in orally or in a leaflet or letter;

(These requirements would be subject to the exemptions mentioned in paragraphs 27 and 28 below); and

22. If the Government can be satisfied that any such alternative proposals will remedy the adverse effects on the public interest identified by the CC and are enforceable, then the Government would be prepared to revise the draft regulation to reduce its scope accordingly. It is envisaged that the RCVS would not stop veterinary surgeons from charging for prescriptions for three years and therefore this remedy would have to be implemented by Order. Additionally, it is envisaged the parts of the Order applying to manufacturers and wholesalers will be retained.

⁸ 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

⁹ 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.

III. Undertakings

23. 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 there are around 9,700 veterinary surgeons in the UK it is not practical to seek undertakings from each one. Although the number of wholesalers and manufacturers is smaller, it would remain impractical to seek individual undertakings.

IV. Full Order

24. 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 an order is a sensible way forward given the large numbers of veterinary surgeons involved.

25. The draft Order contains 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 POMs from pharmacies if they wish;
 - the price of the ten POMs most commonly supplied by the veterinary surgeon in the previous three-month period; and
 - the availability of further information on prices of all POMs stocked.
- A requirement for veterinary surgeons to quote the price of any POM stocked to anyone who makes a reasonable request.

26. Before supplying POMs, all veterinary surgeons should:

- advise clients of the price of any POM they propose to supply;
- offer clients, either orally or in writing, prescriptions for POMs 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).

27. These requirements are subject to the exemptions mentioned in paragraphs 15 (urgency) and 18 (POMs for injection) above. This means that veterinary surgeons are not required to comply with the obligations to advise clients of the price of POMs, 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 POM 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 POM to be supplied is to be administered by injection and is only available in packs containing multiple doses.

28. 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 POM (for example, where a POM is to be administered during surgery or during a consultation).

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

30. For three years after the Order comes into force, veterinary surgeons will not be able to charge a client for a prescription. 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).

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

- At least once every three months, manufacturers are required to provide price information to veterinary surgeons and pharmacists to whom they have supplied POMs (for animal use only), either directly or indirectly through a wholesaler, at a discount or rebate within the last three months. The price information that manufacturers are required to provide consists of the net prices (taking into account discounts and rebates) of the POMs 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 POM (for animal use only) in the next three months.

32. Additionally, the draft Order imposes certain other duties on manufacturers and wholesalers of POMs, in particular:

- manufacturers and wholesalers should supply POMs to pharmacies and veterinary surgeons on the same terms for the same volumes supplied over the same time period.; and
- Manufactures and wholesalers will not be able to unreasonably withhold supplies from pharmacies or veterinary surgeons.

ISSUES OF EQUITY AND FAIRNESS

33. The Government's preference is for either Option IV (full Order) or Option II (self-regulation and a reduced Order) if it can be demonstrated that Option II would remedy the adverse effects on the public interest identified by the CC and implement the CC's recommendations effectively.

34. 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), all veterinary wholesalers and veterinary surgeons.

35. 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.

36. To address the complex monopoly problems and the resulting detriment to the animal owner and the potential welfare of their animal, 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. (See paragraph 51)

BENEFITS

37. 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 will be of particular benefit to owners of animals requiring long-term medication, as customers will be offered greater choice and lower prices. The CC evidence shows UK veterinary medicine prices are systematically higher than neighbouring countries and POMs have a higher mark-up than other veterinary medicines. However, under the current situation, professional/consultancy costs are often subsidised by higher POM charges, and veterinary surgeons may just respond by raising their consultation charges, which would make little difference to animal owners.

38. Other beneficiaries will include pharmacies, who will have improved access to the market for POMs.

COSTS

Costs for manufacturers

39. Every three months manufacturers will have to provide veterinary surgeons and pharmacists to whom they have supplied POMs at a discount or rebate with information about the net prices charged for POMs purchased by that veterinary surgeon 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, they Manufacturers will not be obliged to provide net price information in relation to POMs 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 POM (for animal use only) in the following three month period.

40. Manufacturers will have to supply pharmacies and veterinary surgeons on the same financial terms for the same volumes supplied over the same period of time. In their response

to the CC, the majority of the manufacturers claimed that this would increase costs as new channels for distribution would need to be set up¹⁰.

Costs for wholesalers

41. Wholesalers will have to supply pharmacies and veterinary surgeons on the same terms for the same volumes supplied over the same period of time.

Costs for veterinary surgeons

42. Veterinary surgeons will have to put up signs in their surgeries with information including the prices of their top ten POMs. In identifying their top ten POMs, 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. Making such signs should not involve substantial resources or expense.

43. Veterinary surgeons will have to provide customers with itemised bills which at least distinguish the costs of other goods and services from the cost of the POMs. 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.

We would be interested to hear views, in particular from individual veterinary surgeons as to what they think these measures will cost them to implement.

44. 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 mean charge for those making a charge is £5.24¹¹. 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.

This may result in the biggest cost to veterinary surgeons. We would be interested in estimates from veterinary surgeons and veterinary practices of how much this measure is likely to cost per year.

We would also be interested in obtaining estimates of the likely effect on the number of prescriptions that will be given by veterinary surgeons.

SMALL FIRMS IMPACT TEST

45. 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 have asked that the veterinary profession's trade associations place details of our consultation on their websites.

¹⁰ Para 9.58, pg 175 Competition Commission report

¹¹ Para 6.187, pg 175 Competition Commission report

CONSULTATION

46. 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 Veterinary Medicines Directorate, animal charities and individuals. The CC held hearings with the British Veterinary Association, the Veterinary Medicines Directorate, Bayer, Fort Dodge, Genus, Intervet, Merial, Novartis, NVS, Pfizer, Schering-Plough, Virbac, the National Farmers Union and the Royal College of Veterinary Surgeons. 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 Statement¹² to manufacturers, veterinary wholesalers and veterinary surgeons. On 17 September 2002, the CC issued a statement of hypothetical remedies and provisional conclusions¹³ as it wished to consult parties on possible remedies.

47. After publication of the CC's report on 11 April 2003, the Office of Fair Trading (OFT) held an informal consultation with interested parties including the Royal College of Veterinary Surgeons, the British Veterinary Association and the British Small Animal Veterinary Association. The DTI has also met with those organisations and the VMD to discuss the Order.

COMPETITION

48. The aim of the remedies is to encourage stronger competition in the supply of POMs. The remedies should encourage more pharmacies to begin selling POMs and animal owners to shop around for their POMs. This should result in lower prices for POMs, benefiting animal owners.

DEVOLUTION

49. 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.

We are aware that there are concerns about the provision of veterinary services in rural areas, especially in the Devolved Administrations, and the impact this Order might have upon them. We would be interested in hearing the views from veterinary surgeons in the Devolved Administrations and who provide services in rural areas.

ENFORCEMENT AND SANCTIONS,

50. 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.

¹² Appendix 1.2, Vol 2, Competition Commission report

¹³ Appendix 1.3, Vol 2, Competition Commission report

MONITORING AND REVIEW

51. The OFT will monitor compliance with the Order and 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 need to be varied or superseded by a new Order. The OFT will advise the Secretary of State of its findings. Where 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 and the power to release or vary the Order, will be transferred to the CC.

draft

ANNEX C

The DTI Consultation Code of Practice Criteria

1. Consult widely throughout the process, allowing a minimum of 12 weeks for written consultation at least once during the development of the policy.
2. Be clear about what your proposals are, who may be affected, what questions are being asked and the timescale for responses.
3. Ensure that your consultation is clear, concise and widely accessible.
4. Give feedback regarding the responses received and how the consultation process influenced the policy.
5. Monitor your department's effectiveness at consultation, including through the use of a designated consultation co-ordinator.
6. Ensure your consultation follows better regulation best practice, including carrying out a Regulatory Impact Assessment if appropriate.

The complete code is available on the Cabinet Office's web site, address <http://www.cabinet-office.gov.uk/servicefirst/index/consultation.htm>

Comments or complaints

If you wish to comment on the conduct of this consultation or make a complaint about the way this consultation has been conducted, please write to Nick Van Benschoten, DTI Consultation Co-ordinator, 1 Victoria Street, London SW1H 0ET or email nick.vanbenschoten@dti.gsi.gov.uk