

To those organisations on the attached list

10 December 2002

Dear Sir/Madam

**THE GOVERNMENT'S FORMAL REPOSE TO THE RECOMMENDATIONS  
CONTAINED IN THE REPORT OF THE INDEPENDENT REVIEW OF DISPENSING BY  
VETERINARY SURGEONS OF PRESCRIPTION ONLY MEDICINES**

The purpose of this letter is to inform you that the Government has now published its formal response to the recommendations in the Report of the Independent Review of Dispensing By Veterinary Surgeons of Prescription Only Medicines – the so-called Marsh Report. A copy of the response is enclosed at Annex A.

The independent review formed part of the package of long-term measures and short-term financial aid for British farming announced at the Agriculture Summit on 30 March 2000

In July 2000 the then Minister of Agriculture appointed Professor Sir John Marsh CBE, Dr Jeremy Lucke, Mr John Moffitt CBE and Lady Patsy Yardley as Chairman and members respectively, of the Independent Review Group.

The Review Group was given the following terms of reference:

“To review the procedures by which prescription only medicines (POMs) for veterinary use are classified and sold in the United Kingdom and the impact current practices may be having on availability and prices.

To make recommendations to the Minister of Agriculture, Fisheries and Food by 31 March 2001.”

The Group concluded its investigations and presented its Report to Ministers in March 2001. The Report was published in May and a total of 245 interested parties were consulted on the Government's interim responses in December 2001.

The Government's interim responses were welcomed and supported by most of the 39 respondents. Of those 39 responses, 11 were received from the veterinary profession, 10 from the farming industry, 4 from pharmacists, 3 from distributors of veterinary medicines, 1 from the pharmaceutical industry and 10 from other interested organisations or individuals. Only one recommendation “to allow veterinarians to prescribe generic treatments for companion animals” brought any real divergence of views.

You will see from the response that of the Report's 14 recommendations:

8 are agreed (Recommendations 1, 3,5-7, 9,10 and 12);

1 is rejected (Recommendation 8);

3 await the outcome of the European Commission's proposals to amend the veterinary medicines directive (Review 2001) (Recommendations 14, 2 and 4); and

2 await the outcome of the Competition Commission's inquiry into the cost of veterinary medicines (Recommendations 11 and 13).

The Government will issue its formal response to five outstanding Recommendations when the Competition Commission has reported or the Review 2001 negotiations have been completed, as appropriate.

The effect of accepting the 8 recommendations will be to:

encourage veterinary surgeons to issue prescriptions for Prescription Only Medicines and to improve their business practices;

encourage farmers and veterinary surgeons jointly to introduce farm health plans, which should lead to improved flock/herd health and a reduction in the amount of medicines used;

improve the availability of training for those employed in the care of animals;

increase the range of medicines available to treat minor species;

increase the number of outlets authorised to dispense cat and dog wormers classified as PML; and

increase the range of medicines available to treat horses not intended for human consumption.

I have also enclosed at Annex B, for information, initial regulatory impact assessments for recommendations 3, 5, 6 and 9. Regulatory impact assessments are not required for the other accepted recommendations.

Copies of the Report are available from the Veterinary Medicines Directorate, Woodham Lane, New Haw, Addlestone, Surrey, KT15 3LS, and on its website [www.vmd.gov.uk](http://www.vmd.gov.uk).

John FitzGerald  
Director of Policy

**THE GOVERNMENT'S FORMAL REPOSE TO THE RECOMMENDATIONS CONTAINED IN THE REPORT OF THE INDEPENDENT REVIEW OF DISPENSING BY VETERINARY SURGEONS OF PRESCRIPTION ONLY MEDICINES:**

**1. RECOMMENDATIONS AGREED**

**Recommendation 1. Issue Of Prescriptions**

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

**Interim Response**

The Government accepts that the client should be able to choose where he/she buys a POM for their animals. To achieve this the client should be offered a written prescription by the veterinary surgeon. The Government would prefer to introduce this change by strengthening the professional guidance, rather than by legislation.

The Government accepts that veterinary surgeons should be able to charge for providing a prescription in the same way as they can charge for any other service they provide. Fees are normally set between the veterinary surgeon and the client and this would apply to a fee for writing a prescription.

**Formal Government Response**

**The Government welcomes the general acceptance that the client should be able to choose where he/she buys a POM for their animals and that the client should be offered a written prescription by the veterinary surgeon. The Government has said it would prefer to introduce this change by strengthening the professional guidance, rather than by legislation and is pleased to see that the RCVS has now strengthened their “Guide to Professional Conduct” to this effect. Veterinary surgeons will need to publicise this change so that their clients can take advantage of it.**

**The VMD will monitor the situation, including the prices charged, for a year and then re-consider whether legislation is required.**

### **Recommendation 3. Efficient Operations of Pharmacy Services**

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

#### **Interim Response**

The Government supports this recommendation, which is aimed at the veterinary profession. The professional bodies are keen to promote good pharmacy practice and the Government hopes that they will develop codes of practice as necessary. It encourages veterinary surgeons to take up the training available in order to help them improve their provision of pharmacy services.

#### **Formal Government Response**

**The Government welcomes the general acceptance of this recommendation, which is for the professional bodies and individual veterinary practices to implement. The VMD will be discussing with the professional bodies how they propose to take it forward.**

### **Recommendation 5. Health Plans For Farm Animals**

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

#### **Interim Response**

This recommendation does not require any legislation or regulatory action. The Government would encourage the various interests involved to work together to stimulate the development of farm health plans with the objective of improving the health of flocks and herds thereby reducing the need for therapy.

#### **Formal Government Response**

**The Government welcomes this recommendation, which should make farmers full participants in the management of animal health and medication on their farms. The VMD will work alongside Defra colleagues dealing with animal health and the disposal of farm waste, including medicinal waste, to discuss with the farmers' and professional organisations how this idea can be taken forward.**

## **Recommendation 6. CPD for Prescribing, Dispensing and use of Medicines**

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

### **Interim Response**

The Government acknowledges the benefits that are gained from CPD. However, making CPD a requirement raises a number of issues on which it would welcome the views of interested groups.

### **Formal Government Response**

**The Government acknowledges the benefits that are gained from CPD and encourages its use by all *those employed* in the care of animals. The VMD will speak to representative groups about implementing this recommendation in conjunction with farm animal health plans rather than introducing a legal requirement to show competence in animal handling as a pre-requisite for the purchase of veterinary medicines for food producing animals.**

## **Recommendation 7. Extrapolation of MRLs for Minor Species**

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

### **Interim Response**

The Government proposes to support this recommendation.

### **Formal Government Response**

**The Government supports extrapolation of MRLs to minor food producing species. The UK supported proposals by the EU’s Committee for Veterinary Medicinal Products for a range of extrapolated MRLs for minor species and hopes they will lead to an increased number of medicines available for those species.**

### **Recommendation 9. Dispensing of Cat and Dog Wormers in Pet Shops**

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

#### **Interim Response**

The VMD was already working to make the changes proposed by this recommendation. It plans to consult on changes to the PML Order, which would implement this recommendation later in 2001. Subject to comments, the earliest implementation date would be 1 April 2002.

#### **Formal Government Response**

**The Government accepts this recommendation and the VMD will continue to develop proposals to amend the PML Order. A consultation on the proposed changes will take place shortly.**

### **Recommendation 10. Written Records of Medicines for Horses**

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

#### **Interim Response**

The Government has a long-standing objective of securing a wider range of authorised products to treat horses not intended for human consumption. It supports the development of effective controls, which will permit this. The VMD will continue the process of discussion and negotiation on this issue, which is currently taking place in Brussels.

#### **Formal Government Response**

**The Government welcomes the support for increasing the availability of medicines for horses. It supports European Commission proposals to amend EU legislation to increase the availability of medicines for horses. These will complement the horse passport arrangements, which allow more medicines to be used on horses not for food production.**

## **Recommendation 12. Support for Mutual Recognition Procedures**

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

### **Interim Response**

The Government is committed to making the European authorisation systems work. The VMD was instrumental in establishing the VMRFG and continues to play an active role in its work. The Government will support continuing assessment of the performance of the mutual recognition procedure through regular surveys.

### **Formal Government Response**

**The Government continues to support the mutual recognition process and will support continuing assessment of the performance of the mutual recognition procedure through regular surveys.**

## **2. RECOMMENDATION REJECTED**

### **Recommendation 8. Prescribing Generic Treatments for Companion Animals**

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

### **Interim Response**

EC law requires that, whenever it is available, an authorised product will be used and any change will require a negotiated amendment to this legislation. Because of the importance of having products authorised for the species in which it is used the Government is minded to reject this recommendation.

### **Formal Government Response**

**The Government recognises that cost of medicines is an important factor in the treatment of companion animals. But there is a difficult balance to be drawn between cost, safety and the availability and development of veterinary medicines. The assessment of the safety of a veterinary medicine is made on its use in the target species. There is no general read across between human and the various animal species. The future availability of existing medicines and the development of new ones could be adversely affected by allowing this use of human generic medicines. Consultees were divided on this issue. On balance, the Government believes that the increased risk to target animal safety and the added disincentive to the development of new animal medicines outweighs the benefits of possibly reduced costs.**

### **3. RECOMMENDATIONS AWAITING THE OUTCOME OF REVIEW 2001**

#### **Recommendation 14. Classification of POMs**

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

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

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

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

#### **Interim Response**

The present classification and distribution system in the UK has worked well for many years. There is no evidence that it has led to abuse of veterinary medicines or to residue violations that would harm the consumer. As part of its proposals following the review of medicines legislation in Europe (Review 2001), the European Commission has subsequently proposed changes to the distribution system for veterinary medicines, most significantly, that all medicines for food producing animals should be classified POM. If this was accepted by a majority of member states then the independent review team's proposal could serve as a model and retain the benefits of the current distribution arrangements. The Government will however argue for more flexibility in the Commission's proposals so that member states can take advantage of existing arrangements as long as consumer protection and animal welfare can be demonstrably assured.

## **Formal Government Response**

**The Government acknowledges the general support for this recommendation but will defer any decision until negotiations on the Commission proposals to amend EU pharmaceutical legislation (Review 2001) have been concluded.**

### **Recommendation 2. Dispensing of Prescriptions**

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

## **Interim Response**

The Government supports this recommendation, which would give the client the widest choice of appropriately qualified people to dispense a prescription. Implementation would require amending legislation.

## **Formal Government Response**

**Although the Government can support this recommendation its implementation is dependent on the outcome of negotiations in Brussels on Review 2001 and the decision on whether to implement Recommendation 14.**

### **Recommendation 4. Importation of Medicines Licensed in other EU States**

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

## **Interim Response**

This recommendation seeks to improve the availability of veterinary medicines. The VMD already uses the flexibilities allowed in the current legislation and will continue to do so. The Commission has made proposals under Review 2001 to introduce additional flexibility by extending the so-called cascade arrangement to allow the use by veterinary surgeons of a product authorised in another member state. The Government will be seeking clarification from the Commission on how it would operate in practice.

## **Formal Government Response**

**The Government will continue to support the proposal in negotiations on Review 2001 and to take account of the practical concerns raised in UK implementing legislation if the change is agreed in Brussels.**

#### **4. RECOMMENDATIONS AWAITING THE OUTCOME OF THE INQUIRY BY THE COMPETITION COMMISSION**

##### **Recommendation 11. Centralised Authorisation Procedure**

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

##### **Interim Response**

The Government acknowledges the concerns of industry on this issue whilst recognising the benefits that can be gained from using the centralised procedure and from POM status for newly authorised novel products. It is, therefore, minded to argue that an appropriate classification should be decided on a case-by-case basis and that a mechanism should be available for reviewing a product’s classification.

##### **Formal Government Response**

**The Government acknowledges general agreement with its interim response but awaits the Competition Commission Report before deciding what action to take.**

##### **Recommendation 13. Review of Classifications**

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

##### **Interim Response**

The Government accepts that the classification of veterinary medicinal products should be open to review on the same grounds under which the initial classification was set ie. safety, quality and efficacy.

##### **Formal Government Response**

**The Government acknowledges general agreement with this recommendation but confirms its view that classification should be on a product-by-product basis. It will await the Competition Commission Report before deciding what action to take.**

## REGULATORY IMPACT ASSESSMENT

### IMPLEMENTATION OF THE RECOMMENDATIONS MADE IN THE REPORT OF THE INDEPENDENT REVIEW OF DISPENSING BY VETERINARY SURGEONS OF PRESCRIPTION ONLY MEDICINES (THE MARSH REPORT)

1. **TITLE: Recommendation 3 - That veterinary practices apply improved business practice in the operation of their pharmacy services with a view to reducing costs.**

2. **Purpose and intended effect**

- i) **Objective:** To reduce the cost to clients of prescription only medicines.
- ii) **Background:** During its evidence gathering sessions the Review Group became aware that many veterinarians appeared to be unaware of the cost of providing a pharmacy service and the impact this was having on their operating costs.
- iii) **Risk Assessment:** There is no perceived risk in this recommendation which could increase the animal owner's willingness to seek the advice of their veterinary surgeon.
- iv) **Business sectors affected:** All veterinary practices would be encouraged to adopt good business practice.
- v) **Issues of Equity or Fairness:** The proposal is for good business practice to be employed by all veterinary practices.

3. **Identify Options**

Two options have been identified:

**Option 1:** To continue current practice. Veterinary surgeons may not be running their practices in line with best practice and may not therefore be operating efficiently. The result is high running costs (including storage and wastage), which have to be passed on to clients through charges, including an increased mark-up on veterinary medicines sold.

**Option 2:** To discuss with the professional bodies how they can provide advice and encouragement to their members to introduce good business practice into their pharmacy operations. Encouraging veterinary surgeons to adopt good business practice will lead to an awareness of the costs in providing the pharmacy service and the impact this is having on their clients, and should help to identify areas where savings can be made.

#### 4. **Benefits**

**Option 1:** This will have no benefit to veterinary surgeons or to clients and would result in no reduction to the charges to clients.

**Option 2:** Adopting good business practice will enable veterinary surgeons to run their practices more efficiently and should identify areas where savings can be made, leading to a reduction in the overall running costs of the veterinary practice, including a reduction in the costs in providing a pharmacy service. These savings could be passed on in the form of reduced charges to clients.

#### 5. **Costs for Business, Charities and Voluntary Organisations Business sectors affected**

##### i) **Compliance costs**

**Option 1:** None

**Option 2:** None, the introduction of good business practice would reduce costs.

##### ii) **Compliance costs for a typical business**

None.

#### 6. **Consultation with small business: “The Small Firms Impact Test”**

The Government has consulted widely on this recommendation. Representative organisations have indicated their agreement to take it forward.

#### 7. **Competition Assessment**

The recommendation will not affect/distort competition. All veterinary practices would be encouraged to adopt good business practice and those that do will be able to pass on the benefits in the form of reduced costs to clients.

#### 8. **Enforcement and Sanctions**

This recommendation is for the professional bodies to implement.

#### 9. **Monitoring and Review**

The VMD will be discussing with the professional bodies how they propose to take forward the recommendation and will report on progress to Ministers.

10. **Consultation**

Consultation on the Government's interim response to this recommendation has taken place and all the professional bodies concerned have indicated their agreement to take this forward.

11. **Summary and recommendation**

It has been indicated that veterinary practices could improve their efficiency by adopting good business practice and that savings could result. It is recommended that this option be adopted.

12. **Declaration**

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

Signed: .....

Date: .....

Minister's name: .....

Title : .....

Department: .....

13. **Contact Point**

Heather Oliver, Veterinary Medicines Directorate, tel: 01932 338316 (GTN 3046 8303) e-mail [h.oliver@vmd.defra.gsi.gov.uk](mailto:h.oliver@vmd.defra.gsi.gov.uk)

The competition filter	
<b>Q1:</b> In the market(s) affected by the new regulation, does any firm have more than 10% market share?	No
<b>Q2:</b> In the market(s) affected by the new regulation, does any firm have more than 20% market share?	No
<b>Q3:</b> In the market(s) affected by the new regulation, do the largest three firms together have at least 50% market share?	No



<b>Q4:</b> Would the costs of the regulation affect some firms substantially more than others?	No
<b>Q5:</b> Is the regulation likely to affect the market structure, changing the number or size of firms?	No
<b>Q6:</b> Would the regulation lead to higher set-up costs for new or potential firms that existing firms do not have to meet?	No
<b>Q7:</b> Would the regulation lead to higher ongoing costs for new or potential firms that existing firms do not have to meet?	No
<b>Q8:</b> Is the market characterised by rapid technological change?	No
<b>Q9:</b> Would the regulation restrict the ability of firms to choose the price, quality, range or location of their products?	No

## REGULATORY IMPACT ASSESSMENT

1. **TITLE: Recommendation 5 - That farmers and veterinarians join with pharmacists, agricultural merchants and farm management advisors to create health plans for farm animals, within which medicines can be supplied at least cost.**
2. **Purpose and intended effect**
  - i) **Objective:** To reduce the cost of veterinary medicines to farmers.
  - ii) **Background:** In its evidence gathering sessions the Review Group noted that, in some other member states, veterinary medicines are prescribed within an overall animal health plan for the farm. Within the plan medicines can be obtained from appropriate sources without reference to a veterinarian. The Review Group considered that this combines a positive approach to animal health with the efficient use of professional resources. It allows veterinarian expertise to be accessed, sometimes at a distance and where it is needed, without necessarily requiring a visit to the farm concerned.
  - iii) **Risk Assessment:** There is no perceived risk in this recommendation, which should help to reduce farmers' overheads.
  - iv) **Business sectors affected:** All livestock farmers and large animal veterinary practices.
  - v) **Issues of Equity or Fairness:** The benefits will apply to all livestock farmers who create health plans for their stock.
3. **Identify Options**

Two options have been identified:

**Option 1:** To continue current practice. However, as the availability of veterinary services for farm animals in several parts of the UK declines and the economic value of each animal falls to the point where the cost of individual treatment may not be justified, there is the likelihood of an increase in the incidence of animal welfare problems.

**Option 2:** For colleagues in Defra to work with and encourage farmers, veterinarians, pharmacists, agricultural merchants and farm management advisors to create health plans for farm animals. It has been shown that health plans for farm animals are employed successfully in a number of other member states. They are drawn up by veterinarians in consultation with individual farmers and other professionals. Farmers introducing health plans for their animals will be able to obtain medicines from appropriate sources without further reference to the veterinarian. It also

allows veterinarian expertise to be accessed without the necessity for frequent visits to the farm.

#### 4. **Benefits**

**Option 1:** No perceived benefit.

**Option 2:** Farm health plans improve the health management of flocks and herds, reducing the need for therapy. They will reduce the frequency of farm visits by the veterinary surgeon and allow the farmer to source his veterinary medicines at least cost. Additional benefits will be to help farmers meet new waste requirements, including safe disposal of medicinal waste.

#### 5. **Costs for Business, Charities and Voluntary Organisations Business sectors affected**

##### i) **Compliance costs**

**Option 1:** The cost of option 1 will be that the farmer is unable to take advantage of the benefits of reduced farm visits by veterinary surgeons and least cost sourcing of veterinary medicines.

**Option 2:** None: compliance will lead to a reduction in overheads.

##### ii) **Compliance costs for a typical business**

None.

#### 6. **Consultation with small business: “The Small Firms Impact Test”**

The Government has consulted widely on this recommendation. Representative organisations have indicated their agreement to take it forward.

#### 7. **Competition Assessment**

The recommendation will not affect/distort competition. All livestock farmers would be encouraged to work together with their veterinary surgeons, pharmacists, agricultural merchants and farm management advisers to develop health plans, and those that do will benefit in the form of reduced costs.

#### 8. **Enforcement and Sanctions**

This recommendation does not require any legislation or regulatory action.

9. **Monitoring and Review**

The VMD will work alongside Defra colleagues dealing with animal health including the disposal of farm waste and medicinal waste, to discuss with farmers and professional organisations how this idea can be taken forward.

10. **Consultation**

Consultation on the Government's interim response to this recommendation has taken place and all the professional bodies concerned have indicated their agreement to take this forward.

11. **Summary and recommendation**

By adopting health plans for their animals, livestock farmers will become full participants in the management of animal health and medication on their farms, which could help to reduce their costs. It is recommended that this option be adopted.

12. **Declaration**

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

Signed: .....

Date: .....

Minister's name: .....

Title: .....

Department: .....

13. **Contact Point**

Heather Oliver, Veterinary Medicines Directorate, tel: 01932 338316 (GTN 3046 8303) e-mail [h.oliver@vmd.defra.gsi.gov.uk](mailto:h.oliver@vmd.defra.gsi.gov.uk)

The competition filter	
<b>Q1:</b> In the market(s) affected by the new regulation, does any firm have more than 10% market share?	No
<b>Q2:</b> In the market(s) affected by the new regulation, does any firm have more than 20% market share?	No
<b>Q3:</b> In the market(s) affected by the new regulation, do the largest three firms together have at least 50% market share?	No
<b>Q4:</b> Would the costs of the regulation affect some firms substantially more than others?	No
<b>Q5:</b> Is the regulation likely to affect the market structure, changing the number or size of firms?	No
<b>Q6:</b> Would the regulation lead to higher set-up costs for new or potential firms that existing firms do not have to meet?	No
<b>Q7:</b> Would the regulation lead to higher ongoing costs for new or potential firms that existing firms do not have to meet?	No
<b>Q8:</b> Is the market characterised by rapid technological change?	No
<b>Q9:</b> Would the regulation restrict the ability of firms to choose the price, quality, range or location of their products?	No

## REGULATORY IMPACT ASSESSMENT

1. **TITLE: Recommendation 6 - That continuous professional development should be required of all involved in the prescription and dispensing of animal medicines and for all who have responsibility for the care of animals. A formal record of training undertaken and the level reached should be available on request. When courses are available, the requirement for training should be extended to farmers and farm workers with responsibility for animals, and sales of medicines to them should be subject to written evidence of competence in their use.**

### 2. Purpose and intended effect

- i) **Objective:** To make all distributors and users of veterinary medicines aware of the risks to food safety and/or animal welfare, including development of resistance, their responsibilities and the guidance available.
- ii) **Background:** Many witnesses stressed to the Review Group the danger that the misuse of veterinary medicines could lead to the development of resistance.
- iii) **Risk Assessment:** There is no perceived risk in this recommendation, which will be seen by consumers and food retailers as a significant step forward in demonstrating that veterinary medicines are being used responsibly on farms.
- iv) **Business sectors affected:** Veterinarians, pharmacists, agricultural merchants and, ultimately, farmers and those employed in the care of animals.
- v) **Issues of Equity or Fairness:** Continuous Professional Development is already available to veterinary surgeons, pharmacists and agricultural merchants dispensing veterinary medicines. This recommendation is aimed at making it available to farmers and those employed in the care of animals.

### 3. Identify Options

Three options have been identified:

**Option 1:** To continue current practice. Continuous professional development is already a requirement for the professional bodies (i.e. pharmacists and veterinarians) involved but not for farmers and those employed in the care of animals. There is a danger that there is a gap in training which could lead to the misuse of veterinary medicines and an increase in resistance to, say, antibiotics or anthelmintics.

**Option 2:** To introduce new legislation to make Continuous Professional Development a requirement for all those employed in the care of animals. Continuous Professional Development is already a requirement for the professional bodies. Extending this requirement to farmers and those employed in the care of animals would improve animal welfare and there would be a reduction in the misuse of veterinary medicines. However, new training courses would need to be established and there are likely to be constraints on the ability of individual farmers to access training because of the remoteness of training providers, lack of money or the ability to take time off from work.

**Option 3:** To discuss with representative groups how continuous professional development can be encouraged amongst farmers, farm workers and those employed in the care of animals. Used in conjunction with farm animal health plans continuous professional development would improve animal welfare and there would be a reduction in the misuse of veterinary medicines. However, new training courses would need to be established and there are likely to be constraints on the ability of individual farmers to access training because of the remoteness of training providers, lack of money or the ability to take time off from work.

#### 4. **Benefits**

**Option 1:** No perceived benefit.

**Option 2:** Will improve the welfare of animals and be seen by consumers and food retailers as a significant step in demonstrating that veterinary medicines are being used properly on farms.

**Option 3:** Will improve the welfare of animals and be seen by consumers and food retailers as a significant step in demonstrating that veterinary medicines are being used properly on farms.

#### 5. **Costs for Business, Charities and Voluntary Organisations Business sectors affected**

##### i) **Compliance costs**

**Option 1:** None. Continuous professional development is already practiced amongst veterinary surgeons, pharmacists and agricultural merchants involved in dispensing veterinary medicines.

**Option 2** When training courses are available there will be additional costs for farmers and those employed in the care of animals.

**Option 3** When training courses are available there will be additional costs for farmers and those employed in the care of animals.

ii) **Compliance costs for a typical business**

There would be additional costs for attendance at training courses, which would fall to the business concerned.

6. **Consultation with small business: “The Small Firms Impact Test”**

The Government has consulted widely on this recommendation which met with general agreement from those involved in the prescribing and dispensing of veterinary medicines. However, there were concerns about funding and there were some suggestions that the Government should pay. The Government has therefore decided to implement this recommendation so that, when continuous professional development training is available, farmers, farm workers and others employed in the care of animals are encouraged to undertake it.

7. **Competition Assessment**

The recommendation will not affect/distort competition.

8. **Enforcement and Sanctions**

Because any requirement to show competence in animal handling as a prerequisite to buying medicines would require new UK legislation, it is recommended that training should be made available to farmers, farm workers and those employed in the care of animals.

9. **Monitoring and Review**

The practical implementation of the recommendation will require further discussion with representative groups.

10. **Consultation**

Consultation on the government's interim response to this recommendation has taken place and met with general agreement from those involved in the prescribing and dispensing of veterinary medicines. However, although the farmers unions agreed in principal, they raised concerns about the practical implementation.

11. **Summary and recommendation**

There are benefits to be gained from Continuous Professional Development but implementation should be in conjunction with farm animal health plans rather than by the introduction of a legal requirement.

12. **Declaration**

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

Signed: .....

Date: .....

Minister's name: .....

Title: .....

Department: .....

13. **Contact Point**

Heather Oliver, Veterinary Medicines Directorate, tel: 01932 338316 (GTN 3046 8303) e-mail [h.oliver@vmd.defra.gsi.gov.uk](mailto:h.oliver@vmd.defra.gsi.gov.uk)

The competition filter	
<b>Q1:</b> In the market(s) affected by the new regulation, does any firm have more than 10% market share?	No
<b>Q2:</b> In the market(s) affected by the new regulation, does any firm have more than 20% market share?	No
<b>Q3:</b> In the market(s) affected by the new regulation, do the largest three firms together have at least 50% market share?	No
<b>Q4:</b> Would the costs of the regulation affect some firms substantially more than others?	No
<b>Q5:</b> Is the regulation likely to affect the market structure, changing the number or size of firms?	No
<b>Q6:</b> Would the regulation lead to higher set-up costs for new or potential firms that existing firms do not have to meet?	No

<b>Q7:</b> Would the regulation lead to higher ongoing costs for new or potential firms that existing firms do not have to meet?	No
<b>Q8:</b> Is the market characterised by rapid technological change?	No
<b>Q9:</b> Would the regulation restrict the ability of firms to choose the price, quality, range or location of their products?	No

## REGULATORY IMPACT ASSESSMENT

1. **TITLE: Recommendation 9 - That the role of registered agricultural merchants and saddlers in the dispensing of cat and dog wormers classified as PML medicines be extended to suitably registered pet shops, provided that all sales in these outlets are made by people who are suitably qualified having passed courses established by AMTRA. We see no need for the pet shop to register as a saddler as is currently the case.**

### 2. Purpose and intended effect

i) **Objective:** To include cat and dog wormers classified as PML in the range of products available from pet shops that employ suitably qualified persons.

ii) **Background:** In its evidence gathering sessions, the Review Group was made aware of the important role played by agricultural merchants in the distribution of veterinary medicines. The medicines involved do not require a specific diagnosis and include medicated animal feedingstuffs and anthelmintics. Dispensing is the responsibility of a 'Suitably Qualified Person' (SQP). Agricultural Merchants who sell medicines in this way are subject to inspection by the Royal Pharmaceutical Society of Great Britain (RPSGB) and their employees have to pass courses to standards agreed by the representative bodies. Farmers have welcomed this facility. Pet shops have been unable to provide a similar service to the owners of companion animals, except in so far as they are classified as 'saddlers' and are permitted to sell a limited range of medicines.

iii) **Risk Assessment:** There is no perceived risk in this recommendation.

iv) **Business sectors affected:** Agricultural merchants, saddlers and pet shops.

v) **Issues of Equity or Fairness:** It will open up the range of medicines that a registered pet shop or other suitable retailer (pet shop) is able to sell.

### 3. Identify Options

Two options have been identified:

**Option 1:** To continue current practice which is that, under the Medicines (exemptions for Merchants in Veterinary Drugs) Order 1998 (the 'PML Order') registered pet shops are allowed to sell cat and dog wormers classified as PML if the person in charge of the sale has successfully completed a course run by AMTRA for saddlers. The pet shop would also be able to sell horse wormers, but in many inner city areas such trade is non-existent.

**Option 2:** To amend the PML order to allow suitably registered pet shops to dispense cat and dog wormers classified as PML, provided that PML sales in these

outlets are made by people who are suitably qualified having passed courses established by the Animal Medicines Training Regulatory Authority (AMTRA).

#### 4. **Benefits**

**Option 1:** No perceived benefit.

**Option 2** This would improve animal health and welfare, and public health by increasing the availability of products used to control worms and fleas in companion animals.

#### 5. **Costs for Business, Charities and Voluntary Organisations Business sectors affected**

##### i) **Compliance costs**

**Option 1:** None.

**Option 2:** There would be some cost to those pet shops that wished to sell PML products for cats and dogs, in registering their premises with the RPSGB and in training the SQP.

##### ii) **Compliance costs for a typical business**

Suitable training course for those pet shops that wished to sell PML medicines for dogs and cats would be developed. The current cost of such training is £340 plus an annual registration fee of £16.

#### 6. **Consultation with small business: “The Small Firms Impact Test”**

The Government has consulted widely on this recommendation which has met with the agreement of farmers, pharmacists, distributors and veterinary surgeons, subject to the availability of suitable training and the inspection and registration of premises.

#### 7. **Competition Assessment**

The recommendation will introduce competition in the sales of PML medicines for cats and dogs between agricultural merchants and registered pet shops.

8. **Enforcement and Sanctions**

The VMD will continue to develop proposals to amend the PML Order and will undertake a consultation exercise with interested organisations on the proposed changes.

9. **Monitoring and Review**

The RPSGB, which is currently responsible for registration and inspection of merchants and saddlers, has indicated that it would assume responsibility for inspection and registration of pet shops.

10. **Consultation**

Consultation on the Government's interim response to this recommendation has taken place and all the professional bodies concerned have indicated their agreement to take this forward.

11. **Summary and recommendation**

Allowing registered pet shops or other suitable retailer to sell PML products for cats and dogs will improve animal health and welfare, and public health by increasing the availability of, and controlling the cost of products used to control worms and fleas in companion animals. The PML Order should therefore be amended.

12. **Declaration**

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

Signed: .....

Date: .....

Minister's name: .....

Title: .....

Department: .....

13. **Contact Point**

Heather Oliver, Veterinary Medicines Directorate, tel: 01932 338316 (GTN 3046 8303) e-mail [h.oliver@vmd.defra.gsi.gov.uk](mailto:h.oliver@vmd.defra.gsi.gov.uk)

The competition filter	
<b>Q1:</b> In the market(s) affected by the new regulation, does any firm have more than 10% market share?	No
<b>Q2:</b> In the market(s) affected by the new regulation, does any firm have more than 20% market share?	No
<b>Q3:</b> In the market(s) affected by the new regulation, do the largest three firms together have at least 50% market share?	No
<b>Q4:</b> Would the costs of the regulation affect some firms substantially more than others?	No
<b>Q5:</b> Is the regulation likely to affect the market structure, changing the number or size of firms?	No
<b>Q6:</b> Would the regulation lead to higher set-up costs for new or potential firms that existing firms do not have to meet?	No
<b>Q7:</b> Would the regulation lead to higher ongoing costs for new or potential firms that existing firms do not have to meet?	No
<b>Q8:</b> Is the market characterised by rapid technological change?	No
<b>Q9:</b> Would the regulation restrict the ability of firms to choose the price, quality, range or location of their products?	No