EXPLANATORY MEMORANDUM TO

THE VETERINARY MEDICINES REGULATIONS 2008

2008 No. 2297

1. This explanatory memorandum has been prepared by the Department for Environment, Food and Rural Affairs and is laid before Parliament by Command of Her Majesty.

2. Description

2.1 The Regulations revoke and replace the controls and procedures concerning the authorisation, manufacture, supply and use of veterinary medicines in the UK to ensure that the legislation remains up to date. They include provisions on medicated feeds and feed additives and a revised fee structure.

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

3.1 None

4. Legislative Background

4.1 These Regulations provide a single comprehensive set of controls on all aspects of veterinary medicines, other than residues and controlled drugs. They revoke and replace the Veterinary Medicines Regulations 2007 (hereon referred to as the 2007 Regulations).

4.2 Provisions related to residues of veterinary medicines in food are not included in these Regulations because the European Commission has made proposals to revise the associated EC legislation. These changes will be incorporated into the Regulations when they are agreed, so that there will continue to be a single instrument. This approach is strongly supported by our industry stakeholders.

4.3 Provisions related to controlled drug use by veterinary surgeons are currently in Home Office legislation. The possibility of moving these provisions (not the definition of a controlled drug) to the Veterinary Medicines Regulations to improve transparency for stakeholders received strong support during the consultation and is under consideration
.

4.4 To ensure that the legislative provisions remain consolidated and in a simplified format, the Regulations are revoked and replaced when amendments are required.

4.5 During the consultation period for the previous amendments, made in 2007, a number of additional regulatory issues were raised by consultees that could not result in changes to the legislation without a further, full, consultation exercise being undertaken. These issues formed the basis of the proposed amendments for the 2008 Regulations and are listed below.

4.6 The principal changes in the 2008 Regulations are as follows:

- Provide rights of appeal to an appointed person when applications for the authorisation or approval of manufacture or retail premises are refused;

- Clarify the supply of blood products from blood banks to reflect current practice;

- Introduce new controls on the collection and supply of equine stem cells;

- Introduce compulsory variations for manufacturers and wholesale dealers where there is a serious non-compliance problem in a localised area of the business;

- Allow Suitably Qualified Persons to supply veterinary medicines to retail customers from pharmacies or registered veterinary premises without dual registration;

- Introduce a new type of animal test certificate for small-clinical trials;

- Clarify the controls on Medicated Feeds and Feed Additives relating to supply and possession to reflect current practices:

    - Allow more flexible labelling of premixtures or feedingstuffs containing a veterinary medicinal product;

    - Allow Suitably Qualified Persons to supply medicated premixtures and medicated feed for domestic use without having to be registered as distributors;

    - Introduce an exemption for premises at which ornamental fish are kept to mix medicated feed for these fish without the need for an authorisation to do so.

- Introduce record-keeping requirements in relation to adverse reactions to products marketed under the Small Animal Exemption Scheme;

- Introduce more flexible labelling requirements for manufacturers of products marketed under the Small Animal Exemption Scheme;

- Introduce above-inflation fee increases for certain applications whilst maintaining the existing fee levels for the majority of them;

- The text is now gender-neutral.

Fees

4.7 The VMD is required by Ministers to recover the full cost of the authorisation of veterinary medicines, medicated feeds and feed additives from its customers, principally the veterinary pharmaceutical industry. The increased volume of applications in 2007, combined with increased efficiencies introduced, permitted the VMD to restrict application fee increases for 2008. There is no need to apply an "across the board" 2.5% fee increase this year in order to achieve cost recovery, as was the case last year. The estimated savings to industry from cancelling the proposed 2.5% general fee increase is £100,000. The VMD is maintaining application fees at existing levels with the exception of fees for pharmacologically-equivalent applications for marketing authorisations received under European procedures. This increment is being applied to correct under-recovery of existing costs and will represent an estimated additional cost to the industry of £15,000. The fees for applications and inspections for manufacturers and wholesale dealers will also need to be increased above inflation to recover costs incurred by the Department and will result in an estimated extra cost for the industry of £15,000.

A new category of animal test certificate has been created to regulate small scale clinical research carried out by veterinary surgeons. This type of research is necessary for scientific advancement but may not be of commercial significance and therefore a fee of £30 was determined to cover governmental costs.

A new inspection fee of £250 to cover estimated costs for the routine inspection of veterinary practice premises is included in the Regulations.

European legislation

4.8 The Regulations implement Directive 2001/82/EC of the European Parliament and of the Council on the Community Code relating to veterinary medicinal products (OJ No. L311, 28.11.2001, p.1), as amended by Directive 2004/28/EC (OJ No. L136, 30.4. 2004, p.58).

4.9 They implement Commission Directive 2006/130/EC and enforce Commission Regulation (EC) No 1950/2006.

4.10 They also identify the competent authority for, and provide for enforcement of, Regulations (EC) No. 178/2002 (OJ No. L31, 1.2.2002, p.1), (EC) No. 1831/2003 (OJ No. L268, 18.10.2003, p.29), (EC) No. 882/2004 (corrected version at OJ No. L191, 28.5.2004, p.1) and (EC) No. 183/2005 (OJ No. L35, 8.2.2005, p.1), in so far as they apply to veterinary medicinal products used in feedingstuffs, and to the following additives used in feedingstuffs:

(a) coccidiostats;

(b) histomonostats;

(c) all other zootechnical additives except —

(i) digestibility enhancers;

(ii) gut flora stabilisers; and

(iii) substances incorporated with the intention of favourably affecting the environment.

4.11 In addition they implement Council Directive 90/167 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community (OJ No. L92, 7.4.90, p.42) so far as they are not rendered spent by Regulation (EC) No. 183/2005.

5. Territorial Extent and Application

5.1 This instrument applies in the United Kingdom.

6. European Convention on Human Rights

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

7. Policy background

7.1 Controls on veterinary medicines are necessary to ensure they are of consistently acceptable quality and are safe and effective when used in accordance with the manufacturers' directions. This includes the safety of consumers of produce from treated animals and of the environment. Since the coming into force of the Medicines Act 1968, UK legislation has regulated many aspects of veterinary medicines including their manufacture, distribution, supply and administration. However, the need for controls has to be balanced against the need for sufficient medicines to be available to ensure the health and welfare of animals. There is a need for new medicines to be developed in response to new and evolving disease patterns and it can take 10 years to develop a new medicine and bring it to the market. A well-established regime of controls exists based on the fundamental principle that veterinary medicines must be authorised before they may be placed on the market. Over the years these controls have been increasingly

based in European legislation as authorisation and many related requirements have been harmonised across the EU. This has made it easier for companies producing the medicines to market their products across the Member States.

7.2 In 2005, following a detailed consolidation exercise and widespread consultation with industry, the veterinary medicines sections of the Medicines Act 1968 and approximately 45 statutory instruments were revoked and replaced with the Veterinary Medicines Regulations 2005. To maintain the resulting simplification of the regulatory regime, the Regulations are revoked and replaced annually to incorporate any changes required.

7.3 Because the regime of controls on veterinary medicines is well-established, the changes contained in the new Regulations largely amount to fine-tuning of established systems and procedures. The proposed changes have not attracted particular public or media attention but have been of interest to those directly involved – primarily the companies producing and marketing the products, veterinary practices, pharmacies, agricultural merchants, veterinary wholesalers and owners of food-producing animals.

7.4 While the proposals were being developed informal consultations were held with a wide range of interested organisations and individuals. A formal consultation package was published on the Veterinary Medicines Directorate (VMD) website and letters were sent to over 800 interested organisations and individuals. Twelve weeks were allowed for comment and the 29 respondents generally supported the proposals providing comments on particular issues, many of which sought clarification or raised points of detail.

7.5 The accompanying Impact Assessments (IAs) cover in detail the costs and benefits of the proposed changes and the main issues raised by consultees. One IA covers the changes to the Regulations and a separate IA specifically covers the expected impact of the compulsory registration and inspection of veterinary surgeon's practice premises.

7.6 The VMD is the UK Regulatory Authority for veterinary medicines. It is required to recover the costs of its authorisation and related activities through fees charged to the industry. Because we are able to update the Regulations annually the fees are provided within the Regulations, rather than in separate fees legislation. Full details of the proposed changes for fees in the 2008 Regulations are provided in the attached IA.

8. Impact

8.1 Two Impact Assessments are attached to this memorandum.

8.2 No significant impact on the public sector is anticipated.

9. Contact

John FitzGerald at the Veterinary Medicines Directorate of the Department for Environment, Food and Rural Affairs, tel: 01932 338303 or e-mail: (j.fitzgerald@vmd.defra.gsi.gov.uk).

IMPLEMENTATION TABLE FOR DIRECTIVE 2001/82/EC (AS AMENDED BY DIRECTIVE 2004/28/EC) ON THE COMMUNITY CODE RELATING TO VETERINARY MEDICINAL PRODUCTS BY THE VETERINARY MEDICINES REGULATIONS 2008

PROVISION OF AMENDED DIRECTIVE	IMPLEMENTATION
Article 1	Regulation 2 and in the body of the Regulations
Article 2	Nothing to implement
Article 2(2)	Regulation 2(4)
Article 2(3)	Largely nothing to implement, but inspectors have powers to inspect starting materials
Article 3(1)(a)	Excluded from the Directive but included in Schedule 5 of the Regulations
Article 3(1)(b)	These are excluded under regulation 15(2) except for vaccines administered to other animals, which are regulated under Part 2 of Schedule 2
Article 3(1)(c)	Regulation 3(1)
Article 3(1)(d)	Although not covered by this Directive, these are regulated by other Community legislation and are dealt with in Schedule 5
Article 3(1)(e)	This contradicts Article 9. Trials are controlled under animal test certificate under Schedule 4 paragraph 9.
Article 3(2)	Schedule 3 paragraph 13 (2) and Schedule 4 paragraph 1
Article 4(1)	This derogation is not being exercised
Article 4(2)	Schedule 6
Article 5	Regulations 4 and 6
Article 6(1)	Schedule 1 paragraph 23
Article 6(2)	Action by Member State
Article 6(3)	Schedule 1 paragraph 23

Article 7	Schedule 1 paragraph 16
Article 8 first paragraph	Schedule 4 paragraph 4
Article 8 second paragraph	Community competence
Article 8 third paragraph	Schedule 4 paragraph 5
Article 9	Schedule 4, paragraph 9.
Articles 10 and 11	The cascade under Schedule 4 paragraphs 1 and 2
Article 12(1) first paragraph	Schedule 1 paragraph 1
Article 12(1) second paragraph	Schedule 1 paragraph 5
Article 12(1) third paragraph	Schedule 1 paragraph 23(2)
Article 12(2)	Schedule 1 paragraph 18
Article 12(3)	Schedule 1 paragraph 2
Article 13	Schedule 1 paragraphs 10 to 12
Article 13(a)	Schedule 1 paragraph 7
Article 13(b)	Schedule 1 paragraph 8
Article 13(c)	Schedule 1 paragraph 9
Article 13(d)	Schedule 1 paragraph 10
Article 14	Schedule 1 paragraph 3
Article 15	Schedule 1 paragraph 2(4)
Article 16(1) and (2)	Schedule 1 paragraphs 63, 66 and 67
Article 16(3) and 16(4)	This is already permitted under the cascade in Schedule 4
Article 17	Schedule 1 paragraph 63
Article 18	Schedule 1 paragraph 64
Article 19	Schedule 1 paragraph 63
Article 20	Schedule 1 paragraph 63
Article 21.1	Schedule 1 paragraphs 17 and 44
Article 21.2	Schedule 1 paragraph 44
Article 22	Schedule 1 paragraph 20

Article 23 (1), (2) and (3)	Administrative measure; nothing to implement
Article 23(4)	Regulation 32
Article 24	Schedule 2 paragraph 11
Article 25(1)	Schedule 1 paragraph 22
Article 25(2)	Regulation 6
Article 25(3) and 25(4)	Schedule 1 paragraph 25
Article 26(1)	This is the general provision on labelling, which is dealt with in more detail in Title V of the Directive. Labelling is dealt with in Schedule 1 Part 7.
Article 26(3)	Schedule 1 paragraph 26
Article 27(1)	Schedule 1 paragraph 36
Article 27(2)	Schedule 1 paragraph 27
Article 27(3)	Schedule 1 paragraph 28
Article 27(5)	This is achieved by Regulation 6
Article 27(a) first paragraph	Schedule 1 paragraph 31 (1)
Article 27(a) second paragraph	Schedule 1 paragraph 31(2)
Article 27(a) third paragraph	Schedule 1 paragraph 31(3)
Article 28(1)	Schedule 1 paragraph 32(1)
Article 28(2) first paragraph	Schedule 1 paragraph 32(2)
Article 28(2) second paragraph	Schedule 1 paragraph 32(4) and (5)
Article 28(3)	Schedule 1 paragraph 32(6) and (7)
Article 28(4)	Schedule 1 paragraph 32(8)
Article 28(5)	Schedule 1 para 32(9)
Article 28(6)	Schedule 1 paragraph 32(10)
Article 29	The Department considers that Article 29 adds nothing to the general law and that there is nothing to implement
Article 30 first paragraph	Schedule 1 paragraph 24(1)
Article 30 second paragraph	Schedule 1 paragraph 24(2)

Article 30 third paragraph	Schedule 1 paragraph 24(3)(a)
Article 30 fourth paragraph	Regulation 4(2)
Article 31	Administrative measure; nothing to implement
Article 32(1) first paragraph	Schedule1 paragraph 42(2) and (4)
Article 32(1) second paragraph	Schedule 1 paragraph 42(3) and (5) and paragraph 43(1)
Article 32(1) third paragraph	Schedule 1 paragraph 42(5)
Article 32(2)	Schedule 1 paragraph 42(1) and (5) and paragraph 43(1)
Article 32(3)	Schedule 1 paragraph 44(2)
Article 32(4)	Schedule 1 paragraphs 42(6), 43(2) and 44(3)
Article 32(5)	Schedule 1 paragraph 42(9) and 44(7)
Article 33(1) first paragraph	Schedule 1 paragraph 42(6) and 44(3)
Article 33(1) second paragraph	Administrative measure; nothing to implement
Article 33(2)	Administrative measure; nothing to implement
Article 33(3) to 5	Administrative measure; nothing to implement
Article 33(6)	Schedule 1 paragraph 42(10) and 44(8)
Article 34	Administrative measure; nothing to implement
Article 35	Administrative measure; nothing to implement
Article 36	Administrative measure; nothing to implement
Article 37	Administrative measure; nothing to implement
Article 38 (1) and 38(2)	Administrative measure; nothing to implement
Article 38(3)	Schedule 1 paragraph 42(10), 43(4) and 44(8)
Article 39	Variations where a product is authorised in more than one member State are dealt with by Regulation (EC) No. 1084/2003, which is enforced in Schedule 1 paragraph 33. The rest of the paragraph is administrative measure; nothing to implement
Article 40	Schedule 1 paragraph 39
Article 41	Administrative measure; nothing to implement

Article 42	Administrative measure; nothing to implement
Article 43	Administrative measure; nothing to implement
Article 44(1)	Regulation 5
Article 44(2)	Regulation 5
Article 44(3)	Schedule 2 paragraph 11
Article 44(4)	Administrative measure; nothing to implement
Article 45	Schedule 2 paragraph 3
Article 46	Administrative, but covered by Schedule 2 paragraph 6 (1)
Article 47	Schedule 2 paragraph 2(1)
Article 48	Schedule 2 paragraph 2(2)
Article 49	Regulation 32(2)
Article 50(a)	Schedule 2 paragraph 8(2)
Article 50(b)	This refers to other domestic legislation; there is nothing to implement
Article 50(c)	A holder can only manufacture in accordance with his authorisation.
Article 50(d)	Regulations 34 and 35
Article 50(e)	This is a necessary implication of Schedule 2 paragraph 11
Article 50(f)	Schedule 2 paragraph 8(3)
Article 50(g)	Regulation 21
Article 50 (a)(1)	Achieved by the power of entry in regulation 34(7)
Article 50(a)(2)	Administrative measure; nothing to implement
Article 51	Administrative measure; nothing to implement
Article 52	Schedule 2 paragraph 8(2)
Article 53 and 54	Schedule 2 paragraph 9; the Directive requirement is unworkable and the Department has tried to come up with a sensible interpretation, which also reflects current practice
Article 55(1)(a)	Schedule 2 paragraph 11(1)

Article 55(1)(b) first paragraph	Schedule 2 paragraph 11(2)
Article 55(2)	Schedule2 paragraph 11(3)
Article 55(3)	Schedule 2 paragraph 11(4)
Article 56	Schedule 2 paragraph 10
Article 57	The provisions relating to homoeopathics in Part 9 of Schedule 1 do not disapply the requirement for a manufacturing authorisation; Schedule 1 paragraph 64(1)(c)
Article 58(1) to (3)	Schedule 1 paragraph 45 and 48
Article 58(4)	Schedule 1 paragraph 47(1)
Article 58(5)	This refers to authorisations granted by the European Medicines Agency and so is administrative.
Article 59(1)	Schedule 1 paragraph 51
Article 59(2)	Schedule 1 paragraph 52
Article 59(3)	Schedule 1 paragraph 47(1)
Article 60	Schedule1 paragraph 48(2)
Article 61	Schedule 1 paragraph 48 and 50
Article 62	Schedule 1 paragraph 38
Article 63	Administrative measure; nothing to implement
Article 64	Schedule 1 paragraph 53
Article 65(1)	Regulation 13 and Schedule 3 paragraph 2 and paragraph 17.
Article 65(2)	Schedule 3 paragraph 18(4)
Article 65(3) first and third paragraph	Regulation 22
Article 65(3) second paragraph	Schedule 3 paragraph 22(3)
Article 65(3)(a)	Schedule 3 paragraph 18(4)(b)
Article 65(4)	Schedule 3 paragraph 2
Article 65(5)	Regulation 9(4)(b) and Schedule 1 paragraph 13
Article 66(1)	Schedule 3 paragraph 3

Article 66(2) first paragraph	Regulation 23
Article 66(2) second paragraph	Schedule 3 paragraph 15
Article 66 third paragraph	Regulation 23(4)
Article 66(3)	Schedule 3 paragraph 14
Article 67 first and third paragraph	Schedule 3 paragraph 1
Article 67 second paragraph	Schedule 3 paragraph 7(c)
Article 68(1)	This is achieved though the classification of the veterinary medicinal products
Article 68(2) and (3)	The lists are published by the Department and the appropriate professional bodies. The records are in the record-keeping requirements at Regulations 17 to 24.
Article 68(3)	Administrative measure; nothing to implement
Article 69	Regulation 17, 19 and 20
Article 70	Schedule 4 paragraph 6
Article 71	The Department has not exercised this derogation
Article 72(1)	This "encouragement" is done by means of circulars and does not appear in legislation
Article 72(2)	The Department has not exercised this power
Article 73	Administrative measure; nothing to implement
Article 73(a)	Administrative measure; nothing to implement
Article 74 first paragraph	Schedule 1 paragraph 55
Article 74 second paragraph	Schedule 1 paragraphs 55 and 56
Article 75(1) to 75(4)	Schedule 1 paragraphs 57 and 58
Article 75(5)	Schedule 1 paragraph 59
Article 75(6)	Administrative measure; nothing to implement
Article 75(7)	Schedule 1 paragraph 59(4)
Article 75(8)	Schedule 1 paragraph 60
Article 76(1)	Administrative measure; nothing to implement
Article 76(2) and (3)	Schedule 1 paragraph 58(3)

Article 77(1) first and third paragraphs	Administrative measure; nothing to implement
Article 77(1) second paragraph	Schedule1 paragraph 57(4)
Article 77(2)	Administrative measure; nothing to implement
Article 78	Schedule 1 paragraph 61
Article 79	Administrative measure; nothing to implement
Article 80(1) first paragraph	Regulations 33 to36
Article 80(1) second paragraph	Regulation 34(7)
Article 80(1) third paragraph	Regulation 34(8)
Article 80(1) fourth paragraph	Nothing to implement; this is a voluntary inspection
Article 80(1) fifth paragraph	Regulation 35
Article 80(2)	Schedule 1 paragraph 2(5)
Article 80(3)	Schedule 2 paragraph 7
Article 89(4)	If a third country manufacturer refuses to be inspected he is not accepted as a manufacturer for the purposes of a marketing authorisation
Article 80(5), (6) and (7)	Schedule 2 paragraph 6
Article 81(1)	Schedule 1 paragraph 30 and Schedule 2 paragraph 9(5)
Article 81(2)	Schedule 1 paragraph 30
Article 81(2) second paragraph	Schedule1 paragraph 27 and Schedule 2 paragraph 9(7)
Article 82(1)	Schedule1 paragraph 27 and Schedule 2 paragraph 9(7); this part of the Directive is repetitive, and requires for immunologicals what is already required for all products
Article 82(2) first paragraph	Schedule 1 paragraph 27
Article 82(2) second paragraph	Administrative measure; nothing to implement
Article 82(2) third paragraph	Schedule 1 paragraph 41(3)
Article 82(3) to (5)	Administrative measure; nothing to implement

Article 83(1) and (2)	Schedule 1 paragraphs 38 and 40. The list in the Directive is insufficient and the Regulations add additional grounds for revocation, eg the fact that a product does not comply with the Marketing Authorisation.
Article 84	Schedule1 paragraph 39(4),41.
Article 85(1) and (2)	Schedule 2 paragraph 5. The Department has included a clause for a compulsory variation to the manufacturing authorisation, to avoid the need for to suspend the whole authorisation when this is unnecessary to address a localised issue.
Article 85(3)	Regulation 11
Article 86	This is not disapplied by Schedule1 Part 9 and accordingly applies to homoeopathics.
Article 87	This is "encouragement" and will be achieved by circulars
Article 88 to 90	Administrative measure; nothing to implement
Article 91(1)	Schedule 1 paragraph 61
Article 91(2)	Schedule 1 paragraph 28
Article 91(3)	Administrative measure; nothing to implement
Article 92	This is not disapplied by Schedule1 Part 9 and accordingly applies to homoeopathics.
Article 93	Regulation 31
Article 94 first paragraph	Administrative measure; nothing to implement
Article 94 second paragraph	Schedule1 paragraph 25
Article 95	Regulation 3(2)
Article 95a()	Disposal is covered by the marketing authorisation
Article 95 (a) and (b)	Administrative measure; nothing to implement
Article 2 of Directive 2001/28	Schedule 1 paragraphs 11(3) and 12(2)

Summary: Intervention & Options		
Department /Agency:	**Title:** **Impact Assessment of The Registration of Veterinary Surgeon's Practice Premises**	
Stage: Final	**Version:** 2	**Date:** 12 August 2008
Related Publications: Public Consultation on Changes to the Veterinary Medicines Regulations 2007 and 2008 Including a Partial Impact Assessment published March 2008		

Available to view or download at:

http://www.vmd.gov.uk

Contact for enquiries: Martha Spagnuolo-Weaver **Telephone:** 01932 338319

What is the problem under consideration? Why is government intervention necessary?

The Veterinary Medicines Regulations 2007 introduced a requirement for veterinary surgeons who supply and store veterinary medicinal products to register their premises. The requirement will come into effect on 1 April 2009. Details of how to operate the scheme have now been finalised and are the subject of this IA. **Therefore, this IA only deals with the charging regime associated with the registration requirement.** An IA dealing with the registration requirement itself is at http://www.opsi.gov.uk/si/si2007/em/uksiem_20072539_en.pdf

What are the policy objectives and the intended effects?

Objective:

To ensure compliance with the Regulations in line with the procedures already in place for pharmacies and premises from where Suitably Qualified Persons (SQPs) supply veterinary medicinal products.

Effect:

Comprehensive registration of veterinary surgeon's practice premises throughout the UK enables the department to implement a proportionate inspection regime and improve the traceability of drugs.

What policy options have been considered? Please justify any preferred option.

There is no new policy being considered, but the charging regime associated with the already existing policy has now been agreed in consultation with stakeholders. Minor changes to the Regulations have been made to reflect that the Royal College of Veterinary Surgeons (RCVS) will hold the register of veterinary surgeon's practice premises, and to introduce a fee for inspections in order to enable cost recovery.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects? There is a process of annual review for all of the policy objectives within the Veterinary Medicines Regulations, with newly updated Regulations coming into force every 1 October.

Ministerial Sign-off For final proposal/implementation stage Impact Assessments:

"I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) the benefits justify the costs."

Signed by the responsible Minister:

Jonathan Shaw ..... Date: 26th August 2008

Summary: Analysis & Evidence	
Policy Option:	**Description:**

COSTS

ANNUAL COSTS		Description and scale of **key monetised costs** by 'main affected groups'
One-off (Transition)	**Yrs**	(i) Registration fee for veterinary practices not currently registered with RCVS (£160,000)
£176,000	1	(ii) Time cost for veterinary practices of completing registration form (£16,000)
Average Annual Cost (excluding one-off)		**Total Cost** (PV) **£1,648,000**
£315,000	5	

Other **key non-monetised costs** by 'main affected groups'

Nil

BENEFITS

ANNUAL BENEFITS		Description and scale of **key monetised benefits** by 'main affected groups'
One-off	**Yrs**	This IA does not deal with a new policy, only with the charging regime associated with an agreed policy. The policy itself yields social benefits by improving the traceability of controlled drugs, which are not included here. The benefits estimates presented here
£176,000	1	
Average Annual Benefit (excluding one-off)		**Total Benefit** (PV) **£1,648,000**
£315,000	5	

Other **key non-monetised benefits** by 'main affected groups'

Nil

Key Assumptions/Sensitivities/Risks

It is assumed that there are about 4,000 practice premises to be registered with the RCVS.

Price Base Year 2008	Time Period Years 5	**Net Benefit Range** (NPV) **£0**	**NET BENEFIT** (NPV Best estimate)

What is the geographic coverage of the policy/option?				UK	
On what date will the policy be implemented?				1 April 2009	
Which organisation(s) will enforce the policy?				VMD, Defra	
What is the total annual cost of enforcement for these organisations?				£ 250,000 (full cost	
Does enforcement comply with Hampton principles?				Yes	
Will implementation go beyond minimum EU requirements?				No	
What is the value of the proposed offsetting measure per year?				£ Nil	
What is the value of changes in greenhouse gas emissions?				£ Nil	
Will the proposal have a significant impact on competition?				No	
Annual cost (£-£) per organisation (excluding one-off)	Micro	Small	Medium	Large	
Are any of these organisations exempt?	No	No	N/A	N/A	

Impact on Admin Burdens Baseline (2005 Prices)			(Increase - Decrease)
Increase of £16,000 (year 1	Decrease £	**Net Impact**	£16,000 (year 1 only)

Key: **Annual costs and benefits:** **(Net) Present**

Evidence Base (for summary sheets)

[Use this space (with a recommended maximum of 30 pages) to set out the evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Ensure that the information is organised in such a way as to explain clearly the summary information on the preceding pages of this form.]

Registration of Veterinary Practice Premises

Background

The requirement for veterinary surgeons to register premises from which veterinary medicines are supplied or stored was introduced in the Veterinary Medicines Regulations, which came into force on 1 October 2007. A transitional period was allowed until 31 March 2009 to provide ample opportunity for all veterinary surgeons who wished to continue to supply veterinary medicines after that date to register their premises. Therefore the legislation will take effect from April 2009. The purpose of the register is to bring veterinary surgeons into line with other retailers who are currently required to have registered premises, to improve traceability of Controlled Drugs and to enable a risk-based inspection regime to be developed to ensure compliance with the Regulations. It is proposed that once the register is up and running veterinary practices will be regularly inspected to ensure compliance with the Regulations – this already happens for pharmacies and premises from where Suitably Qualified Persons (SQPs) supply veterinary medicinal products.

There are no new policy options discussed here because the provision is already within legislation and has been accepted in principle by the industries and groups affected. However, a detailed cost analysis was not available at the time of the previous consultation in March 2007 because the practicalities of how the register would operate had not been finalised. For full details of the previous consultation on the Internet – please go to http://www.vmd.gov.uk/publications/consultations/vmr07.htm.

Responsibility for the Register

It has been agreed that the Royal College of Veterinary Surgeons (RCVS) will be responsible for setting up and running the register. The RCVS already operates a voluntary register of practices and a Practice Standards Scheme (PSS) which enables practices to have the opportunity to be assessed against best practice standards through routine inspections:

"The RCVS Practice Standards Scheme is a voluntary initiative to accredit veterinary practices in the UK. Through setting standards and carrying out regular inspections, the Scheme aims to promote and maintain the highest standards of veterinary care.
It offers peace of mind to clients of accredited practices and more informed choice to the animal-owning public.
To become accredited, practices volunteer for rigorous inspection every four years and will have met a range of minimum standards including hygiene, 24-hour emergency cover, staff training, certain types of equipment and cost estimation procedures. More specific criteria apply for practices accredited at different levels. Accredited practices also undergo spot-checks to ensure standards are maintained between inspections." *Information from the PSS pages on the RCVS website.*

Scope of the register

The RCVS has suggested to the VMD that the 2008 Regulations should provide for a register of 'veterinary practice premises' at which medicines are stored or supplied. This tighter wording should help to make clear that, for instance, it is not necessary to register a client's farm simply because a veterinary surgeon is storing medicines there from the practice for future use on the farm.

The type of practice premises that will be included on the register will include:

a. Premises from which the veterinary surgeons of a practice provide veterinary services.

b. Premises advertised or promoted as premises of a veterinary practice.

c. Premises open to members of the public to bring animals for veterinary treatment and care.

d. Premises not open to the public, but which are the base from which a veterinary surgeon practises or provides veterinary services to more than one client.

e. Premises to which medicines are delivered wholesale, on the authority of one or more veterinary surgeons in practice.

Information on currently registered practice premises

- 2055 practices are currently registered in the voluntary RCVS Directory of Practices.
- There are an additional 1959 practice premises currently registered as part of the voluntary Practice Standards Scheme (PSS):
    - Since the start of the PSS in January 2005, 33 practices have been removed. The reasons for removal range from voluntarily, non-payment of fees and on the instruction of the Practice Standards Review Group (PSRG). The PSRG would only direct removal following inspection and subsequent failure to meet all requirements of the standards.
    - Between 1/1/07 and 31/12/07 23 new practices joined the scheme (data is not currently available on how many premises this represents).
    - In 2008 from 1/1/08 to 31/5/08, 13 new applications representing 23 premises were processed and inspected. Also in this period a further 35 application packs in hard copy were sent out on request and additional enquiries received from practices who were able to download the packs from the RCVS website.

It is estimated that there are up to 2000 other practice premises not currently registered in any way. The estimate of 2000 is based on the number of practising veterinary surgeons in the UK who are not already accounted for on either the voluntary practice register or the PSS (approximately 4000 out of a total of 16,137), and is based on the assumption that these veterinary surgeons will be working alone from their own private premises or in small unregistered practices with one or two other veterinary surgeons.

Therefore, it is estimated that there will be an approximate total of 6,000 registered premises when the register is completed in 2009. Of these, 2000 are not currently registered with the RCVS in any form.

Proposals for the set-up of the register by RCVS

- An application form is currently under development. The basic information for the register will be the practice name and the addresses of all premises used for the storage and supply of veterinary medicinal products. In addition, contact details for the person supplying the information, and a billing address for the fee will be required.

- A fee of £40 for the initial registration will be charged, with an annual fee of £40 to remain on the register. These fees will cover the cost to RCVS of managing the register. No additional fees will be charged to practices in the PSS.

- Veterinary practices that are already members of the PSS, or on the RCVS voluntary Directory of Practices register, will be sent a note of the information already held on their premises and asked to confirm that it should be included in the register.

- The register will be held by the RCVS and published on the VMD website.

Registration Costs

- Initial registration of 4,000 veterinary practices at a fee of £40 per practice (£160,000).

- The registration requirement will impose a new administrative burden. For practices in the PSS or the existing RCVS Directory of Practices, the RCVS would expect to use the form pre-printed with the information they already have and ask for any amendments to it. If there are no changes to be made this should be a matter of reading the information and ticking a box, so the administrative burden will be negligible.

- The 2,000 practices that are not currently registered with the RCVS will have to complete the form in full. The size of the practice (number of premises) will affect how long it takes to complete the form but an estimate has been used of 30 minutes. The administrative burden is estimated to be about £16,000 (see following table).

Estimated new administrative burden from the requirement to register:

Activity	**Population**	**Estimated time taken/year**	**Estimated Hourly Rate**	**'Business as Usual' Reduction**	**Total Admin Burden**
Completing Application for register	2,000	0.5 hours	£16.23[1]	N/A	£16,230

Background to requirement for Inspections

Some, but not all, veterinary surgeons have in the past been periodically inspected by Defra officers from the State Veterinary Service (now Animal Health) to observe compliance with a range of EU legislatory requirements affecting the veterinary sector, including medicines. The SVS inspection regime did not include every practice in the UK and it was recognised that the routine inspection of all veterinary practices to check compliance with medicines regulation was hampered by the absence of a central register of premises. Changes were made in the way that the Department operated in 2005 and routine medicines inspections could no longer be incorporated within the new remit of Animal Health once it replaced SVS. Since this time there have been no routine inspections of veterinary surgeons to check compliance with veterinary medicines controls.

Following an FVO (European Commission's Food and Veterinary Office) Mission to the UK in 2005 to check compliance with the Veterinary Medicines Directive 2001/82 EC as amended, there was criticism of the effectiveness of the UK's overall inspection regime for veterinary practitioners to control the proper distribution and use of VMPs. The FVO's recommendation to the VMD was that the inspection systems should be strengthened and the frequency of inspections adequately increased. As a result the VMD has been working towards the development of a central register so that an effective inspection programme could in turn be developed and implemented.

Consultation Comments

[1] Based on the average hourly rate of a employee who has management responsibility, taken form the Government Standard Cost Model for measurement of Administrative Burdens

Five consultees responded to the information circulated, representing the pharmaceutical industry, the animal welfare sector, a veterinary industry body and two individual retailers of veterinary products.

Four consultees welcomed the registration of veterinary surgeons and the introduction of an inspection regime, although questions were raised about the scope and frequency of any such inspection scheme, and it was requested that such inspections would be undertaken by trained and competent inspectors with relevant and pragmatic understanding of veterinary practice and the market place. One consultee opposed the introduction of inspections commenting that they were already being inspected by the RCVS through membership of the PSS. It was stated that duplication of existing schemes should be avoided and the inspection should be advisory in the first instance with the provision of improvement notifications should they be required.

It was requested that inspections should also consider how the impact and recommendations on the handling of Controlled Drugs following the Shipman Inquiry could be incorporated to ensure that additional imposition of burdensome regulation is avoided.

It was suggested by one consultee that the potential costs of inspections would be significant for their business. Another consultee felt that the costs would not be significantly burdensome to compliant retailers.

VMD Response: The inspection of veterinary premises to monitor compliance with the Regulations is not currently being done by the Government and will begin after April 2009. The method and timing of the inspections is still being finalised and the consultation feedback has been taken on board.

It is clear that approximately 2,000 practices that are PSS members will already be subject to a medicines inspection by the RCVS as part of the much broader PSS inspection programme covering all areas of veterinary practice. The VMD is working with the RCVS to draw up a medicines inspection regime for the remaining 4,000 practices that is proportionate, risk-based and prevents duplication of effort. It is anticipated that these veterinary practices will be inspected by VMD inspectors and the inspection itself will cover record keeping, prescribing duties and storage. The use and disposal of Controlled Drugs by veterinary surgeons is also not currently subject to any statutory routine checks. Although there is clear guidance on this available from industry bodies, the Government has a responsibility following acceptance of the recommendations of the Shipman Inquiry to ensure that the use of Controlled Drugs is effectively monitored.

We are exploring with the Home Office the possibility of transferring the provisions of the Controlled Drugs from the Misuse of Drugs Regulations to the Veterinary Medicines Regulations. Therefore the responsibility for compliance would fall within the VMD's remit and could be included in the inspection regime that will be introduced in 2009 without additional burden to the industry.

Inspection Costs

- It is anticipated that there will be a maximum time period of four years between inspections. There are 4,000 new practices to be inspected. It is therefore estimated that 1,000 practices will be inspected each year.

- A fee will be charged to cover the costs of carrying out the inspection and this fee has been set at £250 per inspection, based on the current estimate of the amount of resources (staff time, overheads, travel and subsistence) that will be required. Total cost of inspection fees is therefore £250,000 per year.

- Based on our experience of SQP premises inspections, it is anticipated that each inspection may take up a maximum of 4 hours of a business's time, to include preparation and availability of a member of staff on the day. The total administrative burden of complying with inspections is therefore £65,000 per year (see following table).

Activity	**Population**	**Estimated time taken/year**	**Estimated Hourly Rate**	**'Business as Usual' Reduction**	**Total Admin Burden**
Preparation for Inspection	1,000	4 hours	£16.23[2]	N/A	£64,920

The proposed fee has been reached using the current costs to the Department of SQP retail premises inspections as a base line, with an estimated increase to reflect additional inspector resource due to the much wider range of products that a veterinary surgeon would be able to supply compared to an SQP, and the additional records to be checked for supply of (POM-V) prescription medicines. As with all fees within the Veterinary Medicines Regulations, the fee for inspections of veterinary surgeon's practice premises will be subject to annual review to ensure full cost recovery and any proposed decreases or increases to the fee will be preceded by a full 12-week public consultation exercise.

It is intended that further informal consultation with industry on the inspection procedures will be held in the first quarter of 2009, prior to the start of the inspections.

Benefits

- There are no additional benefits as such because this IA only deals with the implementation of the registration requirement that was introduced under the Veterinary Medicines Regulations 2007.
- The registration requirement itself has benefits stemming from all retailers operating from registered premises and harmonisation between pharmacists, SQPs and veterinary surgeons retailers.
- The traceability of Controlled Drugs will be enhanced in the future to bring veterinary medicines regulation in line with the recommendations of the Shipman Inquiry, thereby strengthening the likelihood of veterinary surgeons being able to continue to use these drugs without the imposition of further burdensome regulation.
- Consumers can be reassured that veterinary medicinal products with a distribution category above AVM-GSL can only be supplied by registered retailers, all of whom will be subject to regular inspection to check that these products are being supplied responsibly.

[2] Based on the average hourly rate of a employee who has management responsibility, taken from the Government Standard Cost Model for measurement of Administrative Burdens

Specific Impact Tests: Checklist

Use the table below to demonstrate how broadly you have considered the potential impacts of your policy options.

Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.

Type of testing undertaken	***Results in Evidence Base?***	***Results annexed?***
Competition Assessment	Yes	Yes
Small Firms Impact Test	No	Yes
Legal Aid	No	Yes
Sustainable Development	No	Yes
Carbon Assessment	No	Yes
Other Environment	No	Yes
Health Impact Assessment	No	Yes
Race Equality	No	Yes
Disability Equality	No	Yes
Gender Equality	No	Yes
Human Rights	No	Yes
Rural Proofing	No	Yes

Annexes

ANNEX 1

Competition Assessment

Veterinary Practices

The Royal College of Veterinary Surgeons (RCVS) Annual Report 2007 indicates that there are some 6,000 veterinary practices and branches in the UK. The RCVS report indicates that 53.5% of practices focus mainly on small (i.e. non-food) animals, 1.5% on farm animals, 41.6% on mixed animals (i.e. small animals and food animals) and 3.4% on equines (horses and ponies). The Competition Commission Report on the Supply within the UK of prescription-only Veterinary medicines, published in April 2003, suggests that approximately 40% of practices operate from one site, 30% from two sites, 16% from three sites and a smaller proportion from more than three sites (Table 6.2 on p.142 of the Report). The Competition Commission Report also suggested that the average main veterinary practice is staffed by approximately nine people - in round terms three veterinary surgeons, three veterinary nurses and three other staff. The Report indicates that practice branches average approximately four staff and that a small number of veterinary hospitals average 20 staff. The Report also noted as major trends that numbers of large animal practices are in decline while small animal practices have increased in recent years. The Report also indicated that approximately 40% of practices are owned by a sole principal veterinary surgeon, 55% by a partnership of veterinary surgeons and 5% by a company or corporate body. More recent data are not available on this sector.

The sector is not characterised by rapid technological change although the use of the internet by veterinary surgeons to offer services and supply medicines has increased rapidly within the last 3 years.

The provisions in the Regulations that impact upon veterinary practices will apply to all practices. They are not considered likely to affect the market structure or to impose higher costs for new companies than for existing ones. The requirement to register will not affect the current position in respect of a veterinary practices' ability to choose price, quality, range or location of their products.

ANNEX 2
Outcome of Impact Tests not referred to in the Evidence Base

Small Firms Impact Test
As a result of a continual process of informal consultation with our stakeholders on proposed legislative developments (such as stakeholder meetings, regular industry liaison and attendance by key personnel at high profile industry events throughout the year) the VMD feels that the proposed change will not have a significant impact on small firms.

Legal Aid
The proposal does not introduce any new offence or other legal sanction.

Sustainable Development
This proposal will have very little impact on sustainable development.

Carbon Impact Assessment
The proposals will have no significant effect on carbon emissions.

Other Environmental Issues
It is considered that there will be negligible impact in relation to climate change, waste management, landscapes, water and floods, habitat and wildlife or noise pollution.

Health Impact Assessment
The proposals will not directly impact on health or well being and will not result in health inequalities.

Race /Disability/Gender
There are no limitations on meeting the requirements of the proposal on the grounds of race, disability or gender. The proposal does not impose any restriction or involve any requirement which a person of a particular racial background, disability or gender would find difficult to comply with. Conditions apply equally to all individuals and businesses involved in the activities covered by the proposals.

Human Rights
The proposals are consistent with the Human Rights Act 1998.

Rural Proofing
The proposals are considered to have an equal effect in both rural and urban areas.

Summary: Intervention & Options		
Department /Agency:	**Title:** **Impact Assessment of** **Veterinary Medicines Regulations 2008**	
Stage: Final	**Version:** 2	**Date:** 11 August 2008
Related Publications:		

Available to view or download at:

http://www.vmd.gov.uk

Contact for enquiries: Martha Spagnuolo-Weaver **Telephone:** 01932 338319

What is the problem under consideration? Why is government intervention necessary?

The Veterinary Medicines Regulations came into force in 2005 and aimed to simplify the previous regulatory regime in the UK and also to implement the requirements of EC Directive 2004/28/EC. Since then the VMD reviews, revokes and re-makes the Regulations annually to keep them and the fees up to date, clarifying existing policy points and adding new provisions when necessary. VMD's stakeholders request changes to the Regulations, these requests are compiled and submitted for general consultation. If agreed they are incorporated into the legislation. The main points proposed for 2008 are listed in the Evidence Base section.

What are the policy objectives and the intended effects?

The Veterinary Medicines Regulations are intended to establish controls on the supply and use of veterinary medicinal products. These controls are required in order to protect the safety of treated animals, people handling the medicine, consumers of produce from treated animals, and the environment. The policy objectives are:

-to produce updated and fit-for-purpose legislation that is simple to use for both stakeholders and the regulators and to achieve full cost recovery where appropriate

The intended effects are:

- to fine tune the regulatory regime that is already in place since 2005 and has been subjected to annual review since that date. The Veterinary Medicines Regulations transpose the requirements of Directive 2001/82/EC as amended by Directive 2004/28/EC and other European legislation relating to Medicated Feeds and Feed Additives.

What policy options have been considered? Please justify any preferred option.

Policy options have been designed to address identified problems using a range of approaches, such as clarifying existing legislation, introducing new controls, or reducing duplication by widening the scope of existing provisions. A number of options are considered during the consultation stage and the final chosen option is considered here. This option includes the introduction of new controls on the collection and supply of Equine Stem Cells (regulatory controls for stem cell use in humans were introduced in 2007 by EC legislation but there is no corresponding legislation for the use of stem cells in animals. It is expected that these controls will be developed at European level in due course).

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects? The Veterinary Medicines Regulations are reviewed on an annual basis. Public consultation for the 2008 review has been carried out and it is intended that the updated Regulations will come into force on 1 October 2008.

Ministerial Sign-off For final proposal/implementation stage Impact Assessments:

"I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) the benefits justify the costs."

Signed by the responsible Minister:

Jonathan Shaw ..... Date: 26th August 2008

Summary: Analysis & Evidence

Policy Option:	Description:

COSTS

ANNUAL COSTS		Description and scale of **key monetised costs** by 'main affected groups'
One-off (Transition)	**Yrs**	(i) Registration fee and inspection costs for companies supplying equine stem cells
£6,640	1	(ii) Increases to certain fees relating to pharmacologically-equivalent products
Average Annual Cost (excluding one-off)		
£30,000	1	**Total Cost** (PV) **£36,640**

Other **key non-monetised costs** by 'main affected groups'

Cost to veterinary surgeons of applying for new type of Animal Test Certificate (unit cost £30)

BENEFITS

ANNUAL BENEFITS		Description and scale of **key monetised benefits** by 'main affected groups'
One-off	**Yrs**	(i) Remove registration requirement for Suitably Qualified Persons to supply veterinary medicinal products from pharmacies and registered vet premises
£100,000	1	(ii) Remove registration requirement for outlets supplying ornamental fish
Average Annual Benefit (excluding one-off)		
£4,910	1	**Total Benefit** (PV) **£104,910**

Other **key non-monetised benefits** by 'main affected groups'

(i) Enable an animal blood donation to benefit more animals by separating blood into its constituent parts

(ii) Remove registration requirement for outlets supplying ornamental fish

Key Assumptions/Sensitivities/Risks

Price Base Year 2008	Time Period Years 1	**Net Benefit Range** (NPV) **£68,270**	**NET BENEFIT** (NPV Best estimate)

What is the geographic coverage of the policy/option?			UK	
On what date will the policy be implemented?			1 October 2008	
Which organisation(s) will enforce the policy?			VMD,Defra	
What is the total annual cost of enforcement for these organisations?			£36,380 (all	
Does enforcement comply with Hampton principles?			Yes	
Will implementation go beyond minimum EU requirements?			No	
What is the value of the proposed offsetting measure per year?			£ Nil	
What is the value of changes in greenhouse gas emissions?			£ Nil	
Will the proposal have a significant impact on competition?			No	
Annual cost (£-£) per organisation (excluding one-off)	Micro	Small	Medium	Large
Are any of these organisations exempt?	Yes/No	Yes/No	N/A	N/A

Impact on Admin Burdens Baseline (2005 Prices) (Increase - Decrease)

Increase of £260 Decrease of £780 **Net Impact** **£-520**

Key: **Annual costs and** **(Net)**

Evidence Base (for summary sheets)

[Use this space (with a recommended maximum of 30 pages) to set out the evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Ensure that the information is organised in such a way as to explain clearly the summary information on the preceding pages of this form.]

Background

The Veterinary Medicines Regulations (hereafter referred to as 'the Regulations') implement the requirements of Directive 2001/82/EC, as amended by Directive 2004/28/EC (hereafter referred to as 'the Directive'), which governs the controls on veterinary medicinal products throughout the Europe Union. The Regulations also implement the following Directive and Regulations relating to medicated feeds:

- Council Directive 90/167/EEC laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community
- Regulation (EC) 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
- Regulation (EC) 1831/2003 on additives for use in animal nutrition
- Regulation (EC) 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare
- Regulation (EC) 183/2005 laying down the requirements for feed hygiene.

The Regulations first came into force in October 2005 to implement the Directive and consolidate all the controls on veterinary medicines that were previously part of the Medicines Act 1968 and over 45 amending Statutory Instruments.

To minimise regulatory burden on industry wherever possible, the Regulations are written in plain English and revoked and remade annually to include any necessary changes following a process of review and public consultation. This system is a radical approach for Defra that has received acclaim from industry stakeholders and the House of Lords Select Committee on the Merits of Statutory Instruments. It is beneficial to all those affected by the legislation because there is only ever one statutory instrument in force, rather than a complex Act of Parliament with many consequential amendments. Another key benefit of the annual 'revoke and remake' procedure supported by our stakeholders is the ability of the Department to consult on and make a legislative change relatively quickly if necessary.

Consultation on options

A full written public consultation on the draft statutory instrument "The Veterinary Medicines Regulations 2008" took place between March and June 2008, preceded by informal consultation with key stakeholders. The formal consultation, which included a partial Impact Assessment, considered 11 proposed changes to the Regulations with the options for each of "doing nothing", "amending guidance where possible", or "amending the legislation".

In addition, key consultees were contacted individually during the consultation period and invited to provide more information via informal teleconferences on how the proposals relating to their sector might affect them. At the end of the consultation an open meeting was held to discuss the proposed changes and was attended by 26 stakeholders.

A total of 29 responses to the consultation were received, three of which were obtained through the use of teleconference discussions. The pertinent information gained from consultees is included in the narrative for each proposal on the following pages of this Impact Assessment.

Summary of changes

The following new provisions will be introduced in the 2008 Regulations. These are discussed further in the analysis of costs and benefits, and summarised in the table of groups and sectors affected:

- Provide comprehensive rights of appeal to an appointed person when applications for the authorisation or approval of manufacture or retail premises are refused.
- Clarification of the supply of blood products from blood banks, to reflect current practice.
- Introduce controls on the collection and supply of Equine Stem Cells.
- Introduce compulsory variations by the Secretary of State for manufacturers where there is a serious non-compliance issue.
- Introduce compulsory variations by the Secretary of State for wholesale Dealers where there is a serious non-compliance issue.
- Allow Suitably Qualified Persons to supply veterinary medicines to retail customers from pharmacies or registered veterinary premises without dual registration.
- Introduce a new type of Animal Test Certificate for small-scale clinical trials by research veterinarians.
- Clarification of the controls on Medicated Feeds and Feed Additives relating to supply and possession to reflect current practice.
- Allow Suitably Qualified Persons to supply domestic premises with medicated premixtures and medicated feeds under certain conditions.
- Under labelling conditions on premixtures containing a veterinary medicinal product, to allow those products considered to be "complementary feeds" to be labelled in accordance with EU legislation.
- Make it an offence to supply a product which is intended for unauthorised use.
- Introduce more flexible labelling requirements for manufacturers of products marketed under the Small Animal Exemption Scheme.
- Introduce additional requirements for reporting of Suspected Adverse Reactions to products marketed under the Small Animal Exemption Scheme to reflect current practice.
- Introduction of below inflation fee increases for the majority of applications and above-inflation fee increases for certain applications.

Costs and benefits

The costs and benefits of the above provisions are outlined below.

1. Provide appeal procedures for refusal of applications for Non-Food Animal Blood Banks (NFABBs), Autogenous Vaccine Authorisations (AVAs) and Approved Premises (retail).

Background

For NFABBs, AVAs and retail premises that require approval and registration with the Secretary of State (e.g. agricultural merchants or pet shops employing Suitably Qualified Persons), there is currently no appeal process if the application for approval is refused. This is inconsistent with other legislative provisions in the Regulations where there is a right of appeal to an appointed person whenever the Secretary of State makes the decision to refuse an application for authorisation or approval of a business premises.

Policy option

An additional provision will be added to the Regulations to cover all of the authorisations or approvals for which there is a right of appeal to an appointed person against the Secretary of State's refusal to grant the authorisation or approval. Similar provisions for

appealing against the refusal of any new types of authorisation or approval will also be included in future

Consultation Comments
No comments were received from consultees in relation to this proposal.

Costs
There are no additional costs associated with this policy as it is anticipated that any additional administrative cost to the Department of setting up future appeals to appointed persons would be absorbed within the normal budget allowances for administration of manufacturing authorisations. No applications have been rejected outright in recent years.

Benefits
The benefit is that the regulatory regime will have consistent routes of appeal to all applicants who are affected by the Secretary of State's decisions in relation to refusal of authorisations or approvals. The current legislation for appeals is incomplete and unfair and the proposed change is needed to ensure that the provisions within the Regulations do not exclude certain parties from their legal right to lodge an appeal against the Secretary of State.

2. Clarification of supply of blood products from blood banks to reflect current practice.

Background
The current Regulations contain provisions which cover the controls on businesses that operate a non-food animal blood bank (NFABB) facility providing veterinary surgeons with blood for use in transfusions for treatment of anaemia and blood losses in dogs.

The NFABB scheme has only been in existence since 2005 and the purpose of this legislation is to allow the collection and storage of blood from donor animals in a controlled and ethical way, so that it can be made available quickly to veterinary surgeons on demand. The blood is sold to veterinary practices across the UK. There are restrictions put in place to ensure the welfare of donor dogs. In general donors can donate between 3 to 4 times per year. There are currently two businesses authorised to carry out this service. In one company the blood is taken from dogs with the consent of the client and in the other the blood is taken from greyhounds in a rescue centre. The authorisations are granted following inspection of the NFABB sites to ensure compliance with recognised quality standards, but without the need to achieve full compliance with Good Manufacturing Practice (GMP) principles.

An amendment to the legislation is required because the current provision refers only to the collection and storage of blood, but in practice the collected blood can be used more efficiently if it can also be separated into its constituent parts (such as plasma and white blood cell). This activity is considered acceptable within the scope of the NFABB scheme as long as the separation technique uses a closed-bag system, individual to each donation, and does not involve practices that would be considered to fall under the definition of manufacture of a product – for which a full Marketing Authorisation would be required.

Policy Option
The legislation will be amended as above to clarify the purpose and limitations of the NFABB authorisation scheme and reflect current practice and guidance.

Consultation Comments
Two consultees responded - one representing a UK-wide charitable veterinary organisation and supporting the change to reflect current practice without overburdening

this sector of the industry, or increasing costs to the end user. The other consultee, representing a business manufacturing equine immunotherapy blood products under a full Marketing Authorisation (MA), did not support the change because they did not feel that the quality of the blood products supplied through the NFABB route would be of a sufficiently high standard to be consistently safe. It is possible that this consultee is also concerned about the likelihood of a competitor business being set up to provide equine blood from a NFABB without the need to have a full MA and therefore with less regulation.

This will not be possible under the current system because the scope of the NFABB scheme is restricted in that the blood products produced are not authorised veterinary medicinal products; they are not quality tested and the veterinary surgeons using them are aware that there is an element of risk associated with their use. However since these products are often used in situations where otherwise a dog may die (e.g. emergency transfusion), the risk to the animal from receiving an unauthorised product has to be considered proportionately.

The NFABB authorisation stipulates that sites are inspected every two years and that 10% of all donations must be tested for bacterial and fungal contamination and the Department considers that to enforce more testing would be too burdensome. It is not easy to find donor dogs and the current system has a limited range that is adequately regulated. There is currently insufficient evidence to support the need to increase the regulatory burden in relation to operation of blood banks or supply of blood products derived from them.

Costs
There are no additional costs to businesses as they already process blood in this way. The change in the legislation will simply reflect acceptable current practice.

Benefits
There are no additional financial benefits to businesses as they already process blood in this way. Changing the legislation will:

- Provide improved clarity on the existing legislative controls.
- Provide increased assurance for authorisation holders over what their authorisation permits.
- Reinforce animal welfare, as allowing the blood to be processed into various blood products rationalises its use, so that each donation taken from these pets and rescue animals can be used to treat more than one animal. It is estimated that by fractioning the blood, 1 donor can help 2-4 animals depending on their sizes and the condition to be treated.

3. Introduce controls on the collection and supply of Equine Stem Cells.

Background
Stem cells are a novel development used for the treatment of injuries and disease in humans and more recently animals. Following an injury or disease, stems cells are implanted into the donor animal with the expectation that they will improve the healing and repair of damaged or diseased tissues by differentiating into specialised cell types of other tissues. The use of stem cells derived from the same animal to which they are subsequently administered for treatment of injury or disease is known as autologous treatment. Stem cells are derived from two sources:

Donor animal derived stem cells from the adult animal or the umbilical cord of newly born animals. These are the preferred source of stem cells used for the treatment of animals.

Embryonic stem cells derived from embryos are subject to ongoing ethical and technical issues and are not part of this proposal.

In 2004, 115,000 new thoroughbred foals were registered worldwide, for whom orthopaedic injuries will be the most common cause of lost training days or premature retirement. Traumatic osteoarthritis (OA) is estimated to constitute 60% of all equine lameness issues making it the leading cause of equine lameness. Osteochondrosis (OC) lesions are other important causes of joint disease in the horse[3]. It is estimated that the number of European performance horse tendon/ligament injuries is over 150,000 per annum. It is known that the average cost to the end user for each stem cell treatment is approximately £1,500 and that horses used in National Hunt racing cost £40,000 or more.

The use of stem cells to treat tendon injuries in horses is an emerging area of veterinary science that is, at present, still in an investigational phase with little research available into its efficacy as a treatment option. There is strong support from within the industry for further research resulting from wider use of the technology. Historically in Europe autologous treatments and autogenous vaccines (killed vaccines derived from pathogens isolated from a group of animals and administered to the same group of animals) have been considered to fall outside the Directive controlling veterinary medicinal products. With the emergence of novel advanced cell therapies, such as autologous treatments using stem cells, the EU's Committee on Veterinary Medicinal Products recently concluded that stem cells were veterinary products and should be regulated.

The Veterinary Medicines Directorate (VMD) has visited two companies (one in the UK and one in Ireland) that offer a stem cell collection, storage and implantation service for horses. It was noted that the quality of the processes was high.

Consultation Comments

A total of five consultees responded on this option, none of whom opposed the introduction of regulatory controls in this new area of veterinary science. A number of points of clarification were raised with regard to the wording of the legislation and the scope of the proposed regulatory regime; these have been taken on board and worked into the revised text of the legislation and guidance where appropriate.

A consultee representing the racing industry supported the introduction of the regulatory controls because tendon injuries were common to racehorses, costly to the industry both in terms of horse welfare and financial losses and there are few options for treatment. It was felt that reassurance would be given by the fact that horses receiving stem cell treatment would receive a substance produced in controlled conditions and would have to be treated under the responsibility of a veterinary surgeon, in contrast to other emerging experimental treatments for tendon injuries that were not always instigated by veterinary intervention and could ultimately result in a horse being excluded from racing.

Two consultees expressed concern that whilst the proposed regulation would place controls on the manufacture and supply of equine stem cells there would be no restriction on how they were administered by veterinary surgeons – for example there is no 'approved' administration site for the stem cells into the horse, which could result in the

[3] Isolation of mesenchymal stem cells from equine umbilical cord blood,

Report by **Thomas G Koch**, **Tammy Heerkens**, **Preben D Thomsen** and **Dean H Betts**[1]

treatment itself being unsuccessful. It was suggested however that this would be unlikely to cause any additional suffering to the animal. The possibility of using such treatment for enhancing performance rather than treating injury would be opposed as unethical and concerns were raised over how this could be prevented. It is considered that these issues are subject to the professional judgement of the veterinary surgeon administering the treatment, as with any other novel or 'off-label' veterinary treatment that is allowed in accordance with the Regulations.

The Department recognises that because this is a relatively new sector of the industry there will probably be a need for changes to the legislation in future, arising from the experiences gained from initial enforcement of this proposed Regulation.

Policy option

Doing nothing would allow the collection, storage and supply of stem cells to go unregulated in the UK. This option was considered during consultation but not accepted because there is a risk that deficient practices could go unchecked, potentially leading to suffering in animals.

The chosen option in the short term is therefore to control the manufacturing and supply activities of companies offering this service through an adaptation of the UK's Non-Food Animal Blood Bank (NFABB) scheme. The legislation will be amended to control the manufacturing and supply activities of companies offering this service for equines, through an adaptation of the UK's NFABB scheme. This option would allow the current practice, valued by race horse owners and vets, to continue but in a controlled and proportionately regulated fashion. It is also in line with the controls in place on similar products for human use. It is anticipated that, following the introduction of these legislative controls, the Department will be in a better position to monitor the use of equine stem cell technology within the UK, and any regulatory developments required in future will be subject to further extensive public consultation.

In addition, the UK will press for European legislation to be developed to control stem cell therapies in animals. Regulatory controls for stem cell use in humans were introduced in October 2007 by EC legislation on advanced therapy medicinal products which amends the human medicinal products Directive (2001/83/EC). There is no corresponding legislation for the use of stem cells in animals. For human products produced on a non-routine basis the controls are on manufacture and quality and require adverse reaction reporting. We can press the Commission to introduce similar controls to those for humans but this will take a long time.

Costs

- The introduction of proposed regulation on the use of stem cells in animals would increase the regulatory burden on those involved. There will be a requirement to apply for an authorisation which will be subject to an initial inspection, followed by risk based inspections every two years to confirm continued compliance. In addition to the administrative burdens associated with completion of application forms and preparation for inspections there will be a fee structure based on the fees charged for businesses operating a NFABB.

  The fee for registration of an equine stem cell centre will be £3,190, including an initial inspection, with the same fee for each inspection after that. It is estimated that each inspection will cost the business one day of a senior manager's time.

  There are currently two sites that will become regulated and therefore the new cost associated with the proposal is:

Description	Annual cost in £
Authorisation fee (including initial inspection)	£6,380
Cost of complying with initial inspection (£16.23 per hour x 8 hours x 2)	£260
Total one-off/transition cost	£6,640
Annual cost of inspection fees (one site inspected per year)	£3,190
Cost of complying with inspection	£130
Annual cost	£3,320

There are no additional costs to government as the fees have been set at levels that allow for full cost-recovery. The Department is anticipating that the cost to government of authorising these businesses will be equivalent to the costs applicable to NFABB businesses. The fee amount is based on the requirements for cost-recovery of inspection and administration by the Department - the current NFABB fee of £3,110 is equivalent to approximately 5 inspection hours (including preparation, travel and reporting). When blood bank inspections were first introduced, the estimated time was the same as for an autogenous vaccine inspection. The fee amount has been linked ever since. The fees will be subject to annual review.

Our consultees supported the view that the proposed regulatory controls on the manufacture of equine stem cells were proportionate to the type of work that is currently involved and both businesses operating existing services supported the introduction of the new Regulation.

Evidence from the consultation process suggests that the standards required by the proposed legislation are close to those already being applied within the existing businesses and that there would not be any significant increase in costs to these businesses in relation to attaining these standards because they are already doing so.

Benefits

This legislation is likely to lead to an increase in the number of horses successfully treated with stem cell therapy, due to the quality assurance provided by VMD regulation and inspection. However, it is not possible to monetise this benefit as the technology is still at a nascent stage and it is not possible to predict how uptake will increase in future, or how many horses will remain in use as a result of the change in regulation.

There is strong support from the pioneer companies, who have expressed the view that they would welcome VMD regulation and inspection to provide assurances on the quality of their products. There is strong support from the racing and animal welfare sectors for the introduction of this legislation as a first step in regulating the use of stem cell technology in the treatment of animals. Veterinary surgeons that use stem cell products to treat horses under their care would be reassured that the production processes used meet required standards to ensure the quality of the stem cell products and safety for the end user. This will help maintain animal health and welfare.

4. Introduce compulsory variations for manufacturers where there is a serious non-compliance issue.

Background

The veterinary pharmaceutical industry comprises approximately 140 companies who between them hold Marketing Authorisations (MAs) for some 2,000 veterinary medicinal

products authorised in the UK. Manufacture of pharmaceutical products is strictly regulated in the UK and all manufacturers are required to comply with Good Manufacturing Practice (GMP) guidelines. Whilst the standard of compliance is generally high there are occasions when urgent enforcement action is needed to address serious or persistent non-compliance. Within human medicines regulation there is the ability for the regulatory authority to partially suspend a manufacturing authorisation through the use of a compulsory variation issued on behalf of the Secretary of State. Since the veterinary sections of the Medicines Act 1968 were revoked in 2005 a similar provision has not existed in the Regulations and it is considered necessary to re-introduce it.

An example of where this option would be desirable for veterinary medicines is where a serious non-compliance issue affects production of only some of the products produced by a manufacturer. Under the current Regulations the Secretary of State may only suspend or revoke the entire authorisation and there may be an animal health and welfare need to allow other unaffected products to continue to be manufactured from the site in question.

This is not a common problem but problems encountered with a vaccine manufacturer during 2007 have raised the profile of this issue. For example, a high profile animal safety issue occurred that could have resulted in the prolonged closure of an entire manufacturing site. The complete closure of the site was avoided only because the manufacturer voluntarily ceased production of all live vaccine work so that killed vaccines could continue to be developed. This situation enabled vital research and development work to continue but there was no formal mechanism to outline the responsibilities of the site owner in terms of the work that continued to be done, and in reality the full manufacturing authorisation was still in force.

Policy option
The preferred option is to amend the legislation as above. This new provision will not be applicable to all cases of non-compliance but will ensure that a more measured approach to enforcing manufacturing requirements is used.

Consultee Comments
Three consultees representing the pharmaceutical industry, the manufacturing sector and the animal welfare sector unanimously supported the change in legislation. It was considered that the proposal would minimise the impact of regulation on the supply and distribution of veterinary medicinal products.

It was stated by consultees that this change would bring the UK regime into line with practices used in other member States, which are currently applied without such clear legal standing, and would therefore reduce the disadvantage to UK industries when compared to their European competitors.

Costs
- The costs are negligible to the Government and for compliant businesses.
- Based on the experiences of the human medicines regulator (MHRA) it is anticipated that the cost to the Department of introducing compulsory variations will be minimal.

Benefits
- The potential benefit of the legislation is that, in the event of non-compliance for one product, the company may still be able to continue manufacture of other products. End users will benefit as the policy would reduce the possibility of disrupting supply of product to the market. It is however not possible to monetise this benefit, as this is not a common problem and there are few instances to draw upon. In the one case that has occurred within the last 12 months, the company voluntarily stopped part of their operation - thereby effecting the partial suspension we would have formally applied.

5. Proposal to introduce compulsory variations for Wholesale Dealer Authorisations where there is a serious non-compliance issue.

Background
This issue is similar to the one discussed above in point 4, but is being addressed separately because it affects a different sector of the industry.

Approximately 160 wholesalers are authorised to deal in veterinary medicinal products. These include enterprises dealing solely in veterinary medicines as well as others that wholesale deal both human and veterinary medicines. Authorisation holders include smaller companies operating from single sites as well as larger businesses operating from a number of sites. Some companies who hold Marketing Authorisations also hold wholesale dealer authorisations. Individuals, partnerships, limited companies and corporate bodies are all eligible to hold wholesale dealer authorisations provided they meet the necessary requirements. These primarily relate to having sufficient and suitable staff, premises, equipment and facilities for the handling, storage and recording of the products concerned. Individual authorisations specify the categories of product (i.e. POM-V, POM-VPS, NFA-VPS and AVM-GSL) and types of product (e.g. ointments, tablets, sterile liquids etc…) that they relate to as well as listing all sites at which the relevant activities may be carried out.

Within human medicines regulation there is the ability for the regulatory authority to partially suspend a wholesale dealing authorisation through the use of a compulsory variation issued on behalf of the Secretary of State. Since the veterinary sections of the

Medicines Act 1968 were revoked in 2005, a similar provision has not existed in the Regulations and it is considered necessary to re-introduce it.

An example of where this option would be desirable is where a serious non-compliance issue affects only some of the products distributed by the wholesaler (for example failures in refrigerated storage for temperature sensitive medicines where non-temperature sensitive stock could continue to be distributed without risk). Under the current Regulations the Secretary of State may only suspend or revoke the entire authorisation and there may be an animal health and welfare need to allow other unaffected products to continue to be distributed from the site in question. Non-compliance problems encountered during 2007 in relation to a wholesaler's cold-chain processes, but not affecting other products, have raised the profile of this issue. On this occasion the problem was rectified without the need to enforce suspension of the entire authorisation because the business voluntarily ceased their cold-chain activities, whilst continuing their other distribution functions, and were given ongoing advice from inspectors over how to rectify the problem. However we could not presume that all future situations would have a similar outcome.

Policy option
The preferred option is to amend the legislation as above. This new provision will not be applicable to all cases of non-compliance but will ensure that a more measured approach to enforcing the requirements of the wholesale dealer's authorisation is used.

Consultee Comments
Two consultees commented on this proposal in conjunction with the proposal at point 4 relating to manufacturers. As mentioned in the narrative for point 4, both consultees supported the change in legislation and felt it was necessary to minimise the impact of regulation on the supply and distribution of veterinary medicinal products whilst bringing the UK legislative control into line with that of other Member States.

Costs
- No new costs have been identified for compliant businesses or for Government in relation to this change.
- Based on the experiences of the human medicines regulator (MHRA) it is anticipated that the cost to the Department of introducing compulsory variations will be minimal.

Benefits
- It is not possible to estimate a financial saving because there are too many variables in terms of the size and scope of WDA business and the range of products and customers each one would have. In the one example of this problem that was experienced in the last 12 months the company voluntarily ceased part of their operation, thereby effecting the partial suspension to their authorisation that we wanted to formally apply.
- As a result of the proposed change the VMD will have the option to quickly restrict the type of authorisation held by a wholesaler that is found to be non-compliant with the requirements of the Regulations, rather than to completely suspend all wholesale dealing. There is a benefit to industry because distribution may, in these cases, be able to continue in a limited way. This would result in a financial saving for the wholesale dealer.
- The benefits are similar to those indicated above in relation to manufacturing activities, in that wholesale dealers would be able to carry on their businesses. This would reduce the possibility of having a disruption in the supply of product to the market.

6. Allow Suitably Qualified Persons to supply veterinary medicinal products to the public from pharmacies and registered veterinary premises

Background

A Suitably Qualified Person (SQP) is a person registered with a body approved by the Secretary of State (currently the Animal Medicines Training Regulatory Authority - AMTRA- is the only approved body) and who is recognised as qualified to supply a limited range of veterinary medicines to the public (POM-VPS and NFA-VPS). SQPs often work within agricultural merchants, pet shops or saddleries, selling medicines such as flea and worming treatments that do not require a clinical assessment by a veterinary surgeon but do require advice to the purchaser before they can be prescribed or supplied.

At present an SQP may only supply veterinary medicines from premises that have been registered with the Animal Medicines Inspectorate (AMI), which is a part of the VMD. This means that if a veterinary surgeon or pharmacist wishes to employ an SQP they must also register their premises with the AMI. Pharmacies are already registered with, and inspected by, the Royal Pharmaceutical Society of Great Britain (RPSGB) and from April 2009 veterinary surgeon's premises will have to be registered with the Secretary of State under the Regulations. Therefore the current situation results in a duplication of administrative burden in meeting the requirements of the Regulations.

There are currently 5 Pharmacy businesses that are dually registered. There are currently 19 veterinary practices registered with the AMI and without the amendment these premises would also be subject to dual registration after April 2009.

Policy option

The existing provisions will be amended to reduce duplication of administrative burden by recognising registered pharmacies and veterinary surgeon's premises and removing the requirement for them to register with AMI as well.

Consultation Comments

Six consultees responded on this proposal, five supported the amendment and one opposed it on the grounds that dual registration was required to fully audit and track the personnel involved. No additional information was provided to support this view and it was not reflected in the comments received from the other five respondents.

Costs

- No new costs to industry or Government have been identified in relation to this change.

Benefits

- Duplication of administrative burden for Pharmacies that are already dually registered will be removed - the proposed amendment to the Regulations will mean that they will no longer have to prepare for or pay for VMD inspections or annual fees, representing a new reduction in administrative burden.
- There are a total of 24 affected premises - 19 approved SQP retailers/vets' practices and 5 approved SQP retailers/pharmacies. Each of these premises is currently charged an annual fee of either £90 or £180, depending on the range of medicinal products supplied. The proposed amendment will prevent additional administrative burden for these businesses by ensuring they will no longer be charged an annual fee by the VMD.
- Pharmacies employing SQPs will no longer be subject to inspection by VMD.
- Veterinary practices employing SQPs will only be charged for inspections if these are undertaken by the VMD.

- SQP premises are inspected on average every 2 years (so 12 premises inspected per year) and there would be a saving in half a day's administrative time in preparing for these inspections - a saving of 4 hours at £16.23/hour.
- The proposed change to the Regulations represents annual potential savings to industry of :
    - 19 Merchants annual fees@ £180
    - 5 Companion animal only retailers annual fees @ £ 90
    - 12 half day's preparation for inspection @ £ 65

    TOTAL £4,650

7. Introduce a new type of Animal Test Certificate (ATC) for small-scale clinical trials by veterinary surgeons.

Background

In order to investigate the efficacy and safety of veterinary medicines and to develop new products, it is necessary to conduct clinical trials in animals. Trials carried out by pharmaceutical companies wishing to generate data to obtain a marketing authorisation for a product require authorisation by the Secretary of State. This type of trial is controlled under the Regulations through the granting of ATCs.

Veterinary surgeons can on their own initiative compare the results of UK authorised products to treat animals under their care without regulation. In such trials the investigations are carried out using the product in accordance with the terms of the marketing authorisation (i.e., authorised species, indications, etc) or under the provisions of the cascade. It is considered that this type of investigation does not carry a particular risk to the animal welfare of the animals in the trial.

Veterinary surgeons may also wish to carry out trials to advance knowledge in a particular area, using products outside the terms of their marketing authorisation. For example, the veterinarian might wish to test anaesthetics with a dosage regimen different from that for which the product has been authorised. This has potential animal welfare implications.

The current ATC system has been designed for the trials carried out by the pharmaceutical companies. The costs, timescales and data requirements involved are considered to be overly burdensome for veterinary researchers and investigators wishing to conduct smaller scale clinical trials which are necessary for scientific advancement but may not be of commercial significance. The cost of an ATC under the existing system ranges from £340 - £805 per application, depending on the type of products being tested.

Following meetings with industry representatives, particularly in relation to anaesthetics, we were aware that trials carried out by veterinary surgeons outside the terms of the marketing authorisation are currently being conducted without regulation. It is not possible to estimate how many of these trials are being carried out in the country at the moment. All parties indicated that they wished to find a way of allowing the practice to continue within a proportionate control system that promotes animal welfare and sharing of research findings. In December 2007 a focus group of key stakeholders was set up to facilitate the development of the new scheme to ensure that it would be proportionate in terms of regulatory burden and would reflect the needs of both the industry and the Department in regulating these small-scale trials. Several meetings were held to discuss the proposal in early 2008 and the group approved the final version of the scheme before it was included in the public consultation.

Policy option

The preferred option is to amend the legislation and the guidance. The legislation will be amended to introduce a new type of ATC for the regulation of small-scale trials by veterinary surgeons. A proportionate fee of £30 will be charged for this type of trial.

In addition, the guidance to the legislation will be amended to outline the scope of the new ATC type, to clarify what type of trial it would apply to and the data requirements.

Costs

The total cost to industry of applying for ATCs cannot be estimated because it is not possible to estimate the number of small-scale trials that are currently being conducted. The level of the fee proposed for ATCs for small scale trials is £30 per application. This would just cover the cost to government. With the help of the focus group the Department has set up a trial of the new ATC system, with no charge, to enable the robustness and feasibility of the new system to be tested.

Benefits

The proposed change requires veterinary surgeons to apply for ATCs for small-scale trials that they are currently conducting without regulation. This is expected to have the following effects:

- Ensure safeguards for animals involved in small-scale trials, users, consumers and the environment.
- Veterinary surgeons will have independent scrutiny of their proposed clinical trials for a nominal fee.
- Consideration could be given to the VMD making publicly available the outline of approved small scale trials (subject to data protection and commercial confidentiality). This information would be a resource for researchers and veterinary surgeons.
- Researchers could be encouraged to publish their findings.
- When applicable, pharmaceutical companies could also take advantage of any change to the system if the data obtained from small scale trials are published.
- Expanding the ATC system could lead to improved pharmacovigilance for unauthorised products. This information could also be made publicly available (subject to commercial confidentiality).

Therefore, there will be benefits in terms of improved animal welfare standards for the animals undergoing trial and the possibility of sharing the advance knowledge on animal treatments derived from the trials. However, it has not been possible to monetise these benefits.

8. Clarification of the controls on Medicated Feeds and Feed Additives relating to supply and possession.

i) Mixing Feed for Ornamental Fish

Background

In the consultation on the 2007 Regulations and subsequently, fish veterinary surgeons raised concerns about them supplying in-feed medication to retail premises to treat ornamental fish. These premises (such as aquarium and pond shops in garden centres) were required to be approved to mix small quantities of veterinary medicinal products into ornamental fish feed when using in-feed medications to treat unhealthy fish prior to sale. The veterinary surgeons were concerned that they would be prescribing and mixing veterinary medicinal products into fish feed illegally if the premises were not approved. Feed mills, which are authorised to prepare in feed-medication, would not be interested in preparing the small amounts required to treat these fish. In-feed medication is often the most effective way of treating disease in fish and diseased fish require immediate treatment.

Only two retail premises had registered. Thus, to identify how best to address whether ornamental fish retailers' premises should be approved to mix medicated feeds, the VMD met with veterinary surgeons, an ornamental fish industry representative and the Veterinary Products Committee (VPC) fish expert in 2007. During this meeting it was concluded that, although EU legislation requires commercial feed mixers to be approved, when assessing risk, it is disproportionate to require approval where these particular manufacturers use small quantities of a veterinary medicinal product (VMP) in small quantities of feed for use in ornamental fish. As a result of these discussions it was proposed that a derogation should be introduced to cover circumstances where ornamental fish retailers used less than one kilogram of a VMP per year.

Information from the Ornamental Aquatic Trade Association website indicates that there are around 140 million pet fish in the UK and the average fish keeper has 22 fish at home. The price of ornamental fish varies but the average cost of a koi carp is £200.

Policy option

To amend the legislation and the guidance to allow veterinary surgeons to supply small quantities of in-feed medication to retail premises to treat unhealthy ornamental fish prior to sale.

Consultation Comments

As noted above, the proposal itself is the result of informal consultation with interested parties in response to concerns that the existing legislation was too restrictive. Two consultees responded on this proposal and both supported the amendment to the legislation.

Costs

- There are no costs to the industry. There are no costs to Government. VMD charge a fee for approved premises on a full cost recovery basis. A small amount is allocated to overheads, but the saving of inspector time would be utilised on other projects.

Benefits

- Veterinary surgeons can continue to supply in-feed medication for ornamental fish to be mixed at non-approved premises without acting illegally. Retailers will benefit from easier access to rapid medication, therefore reducing mortality and the cost of restocking.

- During consultation, an ornamental fish expert suggested that 50-60 businesses would make use of this change to the legislation and set up this service.
- There is a benefit to the two outlets that supply ornamental fish and have already had their premises approved. They will no longer need to be registered and will save the current cost of approval (which requires an annual fee to be paid) and will be subjected to one less inspection reducing regulatory burden.

  Annual Fee relating to premises approval = £130.00
  2 x 130 = £260.00

ii) New offence relating to supply of medicated feed/feed containing specified feed additives.

Background
Currently the Regulations state that it is an offence to feed an animal with, to buy or to posses any feedingstuff containing a veterinary medicinal product or a specified feed additive (SFA) for use in a species for which it is not approved. The **supply** of such products is not illegal, however. This gap in the legislation was identified as a result of an incident in which an inspector found a manufacturer to be supplying a poultry feed additive to a game bird breeder without a prescription. The poultry feed additive was not authorised for use in game, but, because of the legislative gap it was not an offence to supply such a product for this use. This incident did not result in animal suffering but it could have led to food safety problems (i.e. residues in meat or eggs), if a product was supplied without a prescription for use in a species for which it is not approved.

Correcting this anomaly will not affect supplies made in accordance with a prescription under the cascade, which allows a veterinary surgeon to prescribe treatment using a veterinary medicinal product not authorised for the species involved if it is necessary to avoid unacceptable suffering in an animal.

Options
It is proposed to introduce an offence in Schedule 5 regarding the supply of feed containing a VMP or SFA to be fed to any animal if the VMP or SFA is not authorised for that species of animal (unless it has been supplied under the cascade). This aims to ensure that a feed mill does not supply premises with a product which results in illegal purchasing, possession or use of that product.

Consultation Comments
No consultees commented on this amendment.

Costs
- No new costs have been identified for stakeholders or the Department.

Benefits
- The company who market the VMP will be saved the income lost by another illegal product being supplied in place of their own.
- The loophole in the legislation will be corrected and each component of the chain, from supplier to end user, will be legally responsible for the misuse of VMPs or specified feed additives incorporated to feedingstuffs.
- The main benefit is to ensure the safety of the foods that enter the human food chain.

Two new issues relating to Medicated Feeds and Feed Additives were raised through the consultation process and following further liaison with the stakeholders affected these

have now been incorporated in the amended Regulations. The new issues are discussed in iii) and iv) below.

iii) Scope and Interpretation of 'premixture'

Background and Consultee Comments

By definition feed (and premix) manufacturers are primarily governed by Feed and Feed Additive legislation. As a service to their customers (secondary to their primary function of producing safe and legal feeds) the manufacturers incorporate in-feed veterinary medicines as well, and for this part of the business they work in compliance with the Regulations. However, the Feed Regulations and the Regulations have two completely different definitions for a particular type of feed component (premixture), and this creates confusion and uncertainty at end-user level whilst providing no benefit in terms of animal or food safety.

A consultee representing the agricultural industry asked for the definition of 'premixture' within the Regulations to be reviewed.

Options

To amend the legislation to indicate that the product can be labelled as medicated premixture, or if it to be labelled as "complementary feedingstuffs" under the Feed Regulations, as "medicated complementary feedingstuffs**".**

Costs

- No new costs have been identified.

Benefits

- The manufacturers of products will benefit from some potential savings in the cost of dual labelling, but the main benefit is for the end-user, who will have clear information on the contents of the feedstuff, thus decreasing the risks of misinformation.

iv) Introduction of a derogation allowing Registered SQP retailers to supply premixtures and medicated feed intended for domestic use without the additional need to be approved as a Distributor.

Background and Consultee Comments

The current legislation requires that in order to supply veterinary medicinal products, retail outlets must be registered as SQPs. The current legislation also requires that in order to supply premixtures and feeds containing veterinary medical products suppliers must be registered as a distributor.

Therefore, should an SQP wish to supply a premixture or a medicated feedingstuff which contains a veterinary medicinal product, this will entail additional inspection and a further fee which is outlined under paragraph 44(b) of Schedule 7. This would cost £108.75 per year per establishment in GB and £48.75 in Northern Ireland

A manufacturer of a VMP of one of the most needed medications in the domestic market (a wormer) has developed a premixture which is sized and aimed specifically at the domestic market. However, the suppliers which the domestic keeper would visit for their normal purchases, i.e. pet shop, merchant, etc. are only registered as SQPs and not distributors. Such suppliers have indicated that they would not want to spend time and

money on being registered as a distributor just to sell small tubs (e.g. 60 g) of wormers and other similar products to the domestic market.

The VMD has already allowed smallholdings to mix their own feeds on the premises but they currently have to purchase large amounts of products, sold by large suppliers that cater for commercial enterprises, to treat small numbers of animals in domestic premises. Many smallholders choose not to treat their animals to avoid the expense of buying large bags of medicines. Some may buy these large bags and keep them longer than recommended for future use. In both cases there is a possible animal welfare problem: untreated animals, or animals treated with a product that has deteriorated due to long storage.

A consultee from the manufacturing industry requested that a derogation be introduced to the legislation so that SQPs in retail premises such as pet shops or agricultural merchants, could legally supply a premixture for domestic use (i.e. use in animals for personal consumption) without the premises having to be separately registered as a distributor.

The VMD decided to extend the derogation to medicated feeds as well as premixtures, as other companies may, in the future, decide to market small packs of medicated feed as well.

Policy option

It is proposed to allow SQPs to supply medicated premixtures and medicated feed to premises for domestic use, provided the supply is under a prescription, is supplied in accordance with the same conditions as for a veterinary medicinal product and provided the total weight of feed supplied does not exceed 30kg at any one time.

Costs

- No new costs have been identified.

Benefits

- Retail outlets will be able to supply premixtures aimed specifically at the domestic market at a proportionate cost.
- The domestic keeper would also benefit in that they would have easy access to supplies of product of appropriate size for mixing on their premises, and so preventing the cost of wastage.
- There is a benefit for animal welfare due to increased availability of a product designed for domestic use through a regulated supply route.

9. Introduce more flexible labelling requirements for manufacturers of products marketed under the Small Animal Exemption Scheme.

Background

The Regulations permit veterinary medicinal products for exotic animals, cage birds and small mammals to be marketed without a marketing authorisation, subject to specific conditions being met. The Small Animal Exemption Scheme (SAES) was set up by the VMD in 2005 to facilitate the exemption allowed under Article 4 (2) of the Directive. Many of the products available under the SAES have no authorised equivalent and were being widely sold and used illegally prior to the introduction of the scheme. It enables a range of products for small animals to be marketed legally providing that they have been manufactured by an authorised manufacturer.

There are a number of specific requirements for the labelling of these products and this includes the manufacturer's authorisation number, and the name and address of the manufacturer, being shown on the label. We have received feedback from the industry

that the requirement to show the manufacturer's name and address is problematic because some companies contract manufacture from others, and in some cases the companies marketing the products prefer not to publicise this fact for commercial reasons. The main reason, however, is that in some cases the manufacturer is located overseas whilst the distributor is based in the UK. In situations like this it makes sense that the end-user has access to the local distributor, in case of queries for advice or reporting of suspected adverse reactions. In addition, having the details of the local contact facilitates a batch recall if this is necessary.

Policy option
The preferred option is to amend the legislation to allow the name and address of either the manufacturer or distributor on the label. The product's traceability will not be compromised in a batch recall situation because the manufacturer's unique authorisation number is still required and this provides a means for the VMD of tracing the manufacturer anyway.

Consultee Comments
Three consultees representing the SAES manufacturing industry responded and all were in favour of the proposed change. The consultation responses confirmed that those companies who contract out the manufacture of their SAES products but are responsible for distribution already have their own systems in place to deal with product recall.

Costs
- No new costs to industry or government have been identified for this change.

Benefits

- Benefits are that companies may maintain their confidentiality as part of a marketing strategy, thereby improving conditions for competition, whilst product traceability is not compromised.
- The main benefit is to the end user who can have access to the local distributor instead of having to try to contact an overseas manufacturer, in some cases. This change will improve the pharmacovigilance for products marketed under the SAES.

10. Introduce additional requirements for reporting of Suspected Adverse Reactions to products marketed under the Small Animal Exemption Scheme to reflect current practice.

Background
Although products covered by the SAES are exempted from the requirements to hold a marketing authorisation, they are still legally classified as veterinary medicinal products and manufacturers are required to notify the VMD of any serious adverse reactions (e.g., death, abortion, blindness etc) within 15 days of receiving a report.

Marketing authorisation holders of product fully authorised are also required to report non-serious adverse reactions in Periodic Safety Update Reports (PSURs), submitted at intervals specified in the Marketing Authorisation. These reports contain a summary of all serious and non-serious cases received by the company in a given time-frame.

There is a long-term plan to bring the pharmacovigilance requirements for SAES products in line with those for fully authorised veterinary medicines. Since the introduction of the SAES scheme the industry have been told informally that the requirement for them to keep a record of all suspected adverse reactions, including non-serious reports would be introduced.

The recording and reporting of suspected adverse reactions is a vital way of monitoring ongoing product safety. The proposal is to modify the legislation to make it a legal requirement that the companies record non-serious suspected adverse reactions in their databases. In the future it is intended that the Regulations will be amended again to require SAES companies to submit Periodic Safety Update Review (PSUR) data to the VMD, which will include the records of all SARs.

Consultation Comments

Four consultees representing the SAES manufacturing industry responded on this proposal and all were in favour of the proposed amendment. Strong support was given for bringing this sector into step with holders of Marketing Authorisations, resulting in more effective detection of potentially unsafe products and therefore greater reassurance over the overall safety of the SAES products.

Policy option

An amendment will be made to the legislation requiring all suspected adverse reactions to be recorded by manufacturers, retailers and importers of SAES products.

Costs

- No new costs were identified by consultees. The consultee responses received suggested that the majority of businesses producing and marketing these products already have systems in place to record reports of suspected adverse reactions as part of their 'business as usual' practices, to enable them to assess whether any reports they receive should be classified as serious and therefore reported to the VMD.

Benefits

Non-monetised benefits include:

- Improved animal welfare because a system for recording suspected adverse reactions permits the companies to carry out trend-analysis and consequently detect any safety problems related to their products.
- There is a key benefit to the industry because the development of an effective system for monitoring suspected adverse reactions is vital to maintain the reputation of the exemption scheme and ensure its continuation – without the scheme those products manufactured under its remit would be considered to be illegal and would be removed from the market.
- There is a benefit to consumers, who can be reassured that a system to monitor the safety and efficacy of these products is in place.

11. Application fees

Background

The VMD's veterinary medicines regulatory function is funded by fees in connection with the manufacture, sale and supply of veterinary medicines. The fees charged by the VMD are monitored and reviewed annually to ensure, as far as possible, that the fee charged for a particular service reflects the cost of the work undertaken.

The consultation proposed a general below inflation increase of 2.5% for application fees apart from two fee areas where a higher than inflation increase was needed to achieve cost recovery. The general fee increase is no longer considered necessary in the light of VMD's 2007/08 results and projected business for 2008/09.

The current fees relating to pharmacologically-equivalent applications for marketing authorisations under the Decentralised or Mutual Recognition procedures are based on early estimates of the likely costs. With the benefit of increased historic data it is now apparent that an above-inflation increase is necessary to these fees in order to accurately reflect the costs to the VMD in processing these applications.

The Regulations require Manufacturers and Wholesale Dealers of veterinary medicines to be authorised and regularly inspected by the regulatory authority. To avoid duplication of effort and cost to the industry, all authorisation and inspection activity, except inspection of sites where immunological veterinary products or products exempt under the Small Animal Exemption Scheme are involved, is performed by the Medicines and Healthcare Products Regulatory Agency (MHRA). The MHRA do very similar work for the regulation of human medicines and combine inspection visits where possible which lead to efficiency savings.

The MHRA has increased the fees it charges for carrying out this work and in order to fully recover the cost of the work performed by the MHRA on behalf of the VMD, we propose to increase Manufacturer's and Wholesale Dealer's:

- application fees by 8%;
- variation fees by 7%;
- annual fees by 11%; and
- inspection fees by 3.25%.

There will be no increase in inspections fees for manufacturing sites where only immunological veterinary products are involved.

For manufacturing sites where only products exempt under the Small Animal Exemption Scheme are involved, we propose to introduce separate inspection fees of £2,280 for a minor site and £4,230 for a standard site.

Policy option

There is no longer a case for a generally-applied 2.5% fee increase this year in order to achieve cost recovery. The increased volume of applications in recent years is forecast to continue and, combined with increased efficiencies introduced by the VMD, it is likely that VMD will be able to absorb its increased costs for 2008/09.

The preferred option is therefore to maintain fees at the existing level with the exception of some targeted above-inflation increases and to introduce some new fees to ensure that only essential and unavoidable costs can be recovered.

Costs

It is assumed that a total of 13 applications for pharmacologically-equivalent marketing authorisations will be received next year, of which half are for non-food animal products and half are for food-animal products. The additional charges are £750 and £1,500 respectively. This means that the estimated additional costs to industry will be £15,000.

The estimated additional costs to manufacturers and wholesale dealers resulting from above-inflation fee increases is £15,000. This assumes the same volume of inspections and applications as in the previous year. No comments from consultees were received relating to the proposed increases.

There are no additional costs to government as the charges are being altered to permit full cost recovery. Charges for food animal products have been set at a higher level to reflect the higher cost to the Department for assessment and administration for these applications. This is because more extensive data is required supporting applications for food-animal medicinal products to ensure medicines residue levels in food products derived from the treated animal are within acceptable limits.

Description	**Group affected**	**Total increased annual cost or savings**	**Rationale**
Fees relating to pharmacologically-equivalent applications for Marketing Authorisations under the Decentralised or Mutual Recognition procedures.	Pharmaceutical industry – Applicants for new Marketing Authorisations.	£15,000 (Forecast estimate of 10-15 applications per year, each application will cost £1,500 or £750 more than currently, depending on whether the target animal is food or non-food producing respectively).	Above-inflation increases to correct under-recovery of existing costs.
Inspection fee Iicreases for Manufacturers and Wholesalers	Manufacturers Wholesalers	£15,000 (Forecast estimate based on the previous year's volumes at the higher fee amounts)	Above inflation increases to recover above-inflation costs incurred.
Fees relating to Marketing Authorisations	Pharmaceutical industry – Applicants for new Marketing Authorisations, variations, extensions, renewals and Animal Test	Saving of £100,000	Maintaining fees at their existing level while absorbing inflationary cost increases represents an efficiency saving from which industry benefits.

	Certificates.		

Benefits

- The estimated saving to industry from cancelling the proposed 2.5% general fee increase is £100,000.
- The VMD aims to ensure the safety, quality and efficacy of all aspects of veterinary medicines. Controls on veterinary medicines are required to ensure their safe, effective and responsible use, in particular to protect the safety of treated animals, people handling the medicine, consumers of produce from treated animals and the environment. It is also important that sufficient medicines are available to treat and prevent disease in the wide variety of different species present in the UK and that new medicines are developed to counter new and evolving disease patterns.
- With adequate financing of its Authorisation and Inspection operations, the VMD is able to attract and retain scientific and other personnel of the appropriate quality and experience to carry out its work to high standards and in acceptable timescales.

SUMMARY OF THE PROPOSALS SHOWING SECTORS AFFECTED

Proposed change	Industry Sector that will be affected by the proposal	Consumers and other Stakeholder groups who may benefit from the proposal	Key Benefits	Summary of New Costs to Industry
Appeals to an appointed person	Applicants for Blood Banks Applicants for AVA authorisation SQP Retailers		i) Fairer system of approval	None identified
Supply of Blood Products from Blood Banks	Manufacturers Blood Bank operators Veterinary Surgeons	Pet owners	i)Clearer controls on supply of blood products ii) Fewer blood donations required as one donation can be used to treat 2-4 animals instead of 1 animal.	None identified
Stem Cell Regulation	Manufacturers Veterinary Surgeons Racing yards Racehorse owners	Pet owners	i)Proportionate control of new technology, ensuring quality and safety	One-off cost = £6,640 Annual cost = £3,320
Compulsory Variations to Manufacturer's authorisations	Manufacturers	Farmers, pet owners	i) More flexibility to the regulator ii)Less impact on the supply of VMPs	None identified
Compulsory Variations to Wholesale Dealer's authorisations	Wholesale Dealers	Farmers, pet owners	i)More flexibility to the regulator ii)Less impact on the supply of VMPs	None identified
SQP Premises – Supply from other registered premises	SQPs Pharmacists Veterinary Surgeons Professional keepers of animals (e.g. farmers)	Pet owners	i) Removal of duplication burden and costs ii) Saving of up to £4,650 per year across the industry	None identified

Proposed change	Industry Sector that will be affected by the proposal	Consumers and other Stakeholder groups who may benefit from the proposal	Key Benefits	Summary of New Costs to Industry
Supply and Possession of Medicated Feeds	Marketing Authorisation Holders Medicated Feed Distributors Veterinary Surgeons Feed mills On farm manufacturers Professional keepers of animals (e.g. farmers) Retailers selling ornamental fish 'Back garden' keepers of ornamental fish who sell fish.	Ornamental fish owners/keepers Owners/keepers of domestic food-producing animals	i)Llegalises existing acceptable practice ii) Cost saving of £260 per year in fees across the industry	None identified
Reporting of Suspected Adverse Reactions to SAES products	Manufacturers	Pet Owners	i) Increased parity with requirements for other authorised medicines ii) Will lead to improved knowledge of SARs	None identified
Labelling Change for SAES products	Manufacturers Retailers Wholesale Dealers	Pet Owners	i)Greater flexibility for the industry ii) Potential cost reductions	None identified
No general inflationary increase in fees	Manufacturers Marketing Authorisation holders		Cost savings to the industry of £100,000	
Above-inflation fee increases for certain applications and authorisations	Manufacturers Marketing Authorisation Holders		Better cost recovery for the regulator	Expected increase in fees is = £30,000

Specific Impact Tests: Checklist

Use the table below to demonstrate how broadly you have considered the potential impacts of your policy options.

Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.

Type of testing undertaken	***Results in Evidence Base?***	***Results annexed?***
Competition Assessment	Yes	Yes
Small Firms Impact Test	No	Yes
Legal Aid	No	Yes
Sustainable Development	No	Yes
Carbon Assessment	No	Yes
Other Environment	No	Yes
Health Impact Assessment	No	Yes
Race Equality	No	Yes
Disability Equality	No	Yes
Gender Equality	No	Yes
Human Rights	No	Yes
Rural Proofing	No	Yes

Annexes

ANNEX 1

Competition Assessment

Overall, the proposed Regulations are likely to affect a number of markets related to veterinary medicines. The proposed changes to the Regulations are not considered likely to affect the market structure or to impose higher costs for new Companies than for existing ones, or to affect the current position in respect of Companies' ability to choose price, quality, range or location of their products. The competition filter test was completed in respect of four markets considered to be most affected:

A – the veterinary pharmaceutical industry;

B – veterinary practices;

C – SQP retailers;

D – veterinary wholesale dealers.

A. Veterinary Pharmaceutical Industry

The veterinary pharmaceutical industry comprises approximately 140 Companies who between them currently hold Marketing Authorisations (MAs) for some 2,000 veterinary medicinal products authorised in the UK. In some cases two or more of these may be owned by a "parent" company. The companies range from large multinationals to small businesses. Approximately 90% of sales in the £450 million animal medicines market are attributable to approximately 25% of the 140 current MA holders. A period of 10 years is accepted as an illustrative norm for the time taken to develop and bring to the market a new product. The provisions of the Regulations that impact upon the veterinary pharmaceutical industry will apply across the board and are not considered to affect some companies substantially more than others. The provisions are not considered likely to affect the market structure or to impose higher costs for new companies than for existing ones. The changes to the Regulations will not affect the current position in respect of companies' ability to choose price, quality, range or location of their products.

B. Veterinary Practices

The Royal College of Veterinary Surgeons (RCVS) Annual Report 2007 indicates that there are some 6,000 veterinary practices and branches in the UK. The RCVS Report indicates that 53.5% of practices focus mainly on small (i.e. non-food) animals, 1.5% on farm animals, 41.6% on mixed animals (i.e. small animals and food animals) and 3.4% on equines (horses and ponies). The Competition Commission Report on the Supply within the UK of prescription-only veterinary medicines, published in April 2003, suggests that approximately 40% of practices operate from one site, 30% from two sites, 16% from three sites and a smaller proportion from more than three sites (Table 6.2 on p.142 of the Report). The Competition Commission Report also suggested that the average main veterinary practice is staffed

by approximately nine people - in round terms three veterinary surgeons, three veterinary nurses and three other staff. The Report indicates that practice branches average approximately four staff and that a small number of veterinary hospitals average 20 staff. The Report also noted as major trends that numbers of large animal practices are in decline while small animal practices have increased in recent years. The Report also indicated that approximately 40% of practices are owned by a sole principal veterinary surgeon, 55% by a partnership of veterinary surgeons and 5% by a company or corporate body. More recent data are not available on this sector.

The sector is not characterised by rapid technological change. The provisions in the Regulations that impact upon veterinary practices will apply to all practices. They are not considered likely to affect the market structure or to impose higher costs for new companies than for existing ones. The Regulations will not affect the current position in respect of a veterinary practices' ability to choose price, quality, range or location of their products.

C. Agricultural Merchants, Pet shops and other SQP retailers

Approximately 1,300 premises in the UK are registered for the supply of veterinary medicines by SQPs. These vary in size from small, single outlet businesses to larger chains owning several outlets. Typically, agricultural merchants will be based in rural areas and will supply farming requisites which may range from animal feed and protective clothing through to agricultural machinery. To sell POM-VPS and NFA-VPS veterinary medicines, merchants need to register with the VMD (or the Department of Health, Social Services and Public Safety in Northern Ireland). To be registered they need to have suitable premises and staff, to have the services of a Registered Qualified Person to authorise each sale of medicines and to comply with specified operational requirements. Registration is annual and premises are subject to inspection. Some veterinary surgeries and some registered pharmacies are also registered as agricultural merchants. The Competition Commission Report referred to above indicates that animal health products account for between 15% and 25% of the business of a typical agricultural merchant. The sector is also not characterised by rapid technological change.

The changes to the Regulations are not considered likely to affect the market structure or to impose higher costs for new companies than for existing ones, or to affect the current position in respect of companies' ability to choose price, quality, range or location of their products.

D. Veterinary Wholesale Dealers

Approximately 160 wholesalers are authorised to deal in veterinary medicines. These include enterprises dealing solely in veterinary medicines as well as others that wholesale deal both human and veterinary medicines. Authorisation holders include smaller Companies operating from single sites as well as larger businesses operating from a number of sites. Some companies who hold Marketing Authorisations also hold Wholesale Dealer Authorisations. Individuals, partnerships, limited companies and corporate bodies are all eligible to hold wholesale dealer authorisations provided they meet the necessary requirements. These primarily relate to having sufficient and suitable staff, premises, equipment and facilities for the handling, storage and recording of the products concerned. Individual authorisations specify the categories of product (i.e. POM-V, POM-VPS, NFA-VPS and AVM-GSL) and types of product (e.g. ointments, tablets, sterile liquids etc) that they relate to as well as listing all sites at which the relevant activities may be carried out. The sector is not characterised by rapid technological change.

The changes to the Regulations are not considered likely to affect the market structure or to impose higher costs for new companies than for existing ones, or to significantly affect the current position in respect of Companies' ability to choose price, quality, range or location of their products.

ANNEX 2:
Outcome of Impact Tests not referred to in the Evidence Base

Small Firms Impact Test
As a result of a continual process of informal consultation with our stakeholders on proposed legislative developments (such as stakeholder meetings, regular industry liaison and attendance by key personnel at high profile industry events throughout the year) the VMD feels that the proposed changes will not have a significant impact on small firms.

Legal Aid
The proposals include a new criminal sanction relating to supply of medicated feeds. This might have a small impact in the legal aid budget although it is not possible at the moment to estimate the size of this impact. We expect that the majority of persons who could be charged under this offence wouldn't qualify for legal aid.

Sustainable Development
This proposal will have very little impact on sustainable development.

Carbon Impact Assessment
The proposals will have no significant effect on carbon emissions.

Other Environmental Issues
It is considered that there will be negligible impact in relation to climate change, waste management, landscapes, water and floods, habitat and wildlife or noise pollution.

Health Impact Assessment

The proposals will not directly impact on health or well being and will not result in health inequalities.

Race /Disability/Gender
There are no limitations on meeting the requirements of the proposal on the grounds of race, disability or gender. The proposal does not impose any restriction or involve any requirement which a person of a particular racial background, disability or gender would find difficult to comply with. Conditions apply equally to all individuals and businesses involved in the activities covered by the proposals.

Human Rights
The proposals are consistent with the Human Rights Act 1998.

Rural Proofing
The proposals are considered to have an equal effect in both rural and urban areas.