EXPLANATORY MEMORANDUM TO

THE VETERINARY MEDICINES REGULATIONS 2007

2007 No. 2539

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.

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

2. Description

2.1 The Regulations revoke and replace the controls and procedures concerning the authorisation, manufacture, supply and use of veterinary medicines 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

Background

3.1 These Regulations provide a single comprehensive set of controls on all aspects of veterinary medicines, other than residues. They revoke and replace the Veterinary Medicines Regulations 2006 (hereon referred to as the 2006 Regulations), which consolidated legislative provisions previously contained in the Medicines Act 1968 and approximately 45 statutory instruments.

3.2 Provisions related to residues of veterinary medicines in food are not included in the 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.

3.3 As proposed at the time the 2005 Regulations came into force, it was considered that to maintain the simplified format, and thereby to reduce administrative burdens, the Regulations should be revoked and replaced when amendments are required rather than being amended with an additional piece of secondary legislation.

3.4 During the consultation period for the previous amendments, made in 2006, a number of additional regulatory issues were raised by consultees which could not result in changes to the legislation without a further, full, consultation exercise being undertaken. These issues, a necessary inflationary increase to the fees schedule and the implementation of two new pieces of European legislation formed the basis of the proposed amendments for the 2007 Regulations.

3.5 The principal changes to the 2006 Regulations are as follows.

- The new Regulations introduce a requirement for the registration of veterinary premises for the supply and storage of veterinary medicinal products.
- They implement Commission Directive 2006/130/EC and enforce Commission Regulation (EC) No 1950/2006.
- They permit the advertising of POM-V medicines to veterinary nurses.
- They extend the provision that the holder of a Marketing Authorisation for an immunological product must submit to the Secretary of State the results of all tests carried out on each batch of the product before he places the product on the market, to require that the holder must wait for confirmation from the Secretary of State before the product is placed on the market.
- They control exports to other member States.
- They update fees.

Fees

3.6 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. To continue to achieve this it is necessary to increase the existing fees to recover inflation.

3.7 The additional revenue raised against industry by the inflationary increases introduced by these Regulations is estimated to be in the order of £175,000 for fees related to the authorisation of veterinary medicines, and £12,000 for fees related to medicated feeds and feed additives. This is equivalent to approximately 2.5% of the total take from industry in 2006/07. These changes will have a significant impact on some individual companies. However there are decisive arguments on fairness, transparency and predictability underpinning the changes. The impact on business will depend on the number of applications made in a year and business turnover.

3.8 Fees were last increased in 2006, resulting in an estimated 2.5% increase in total VMD income from industry. A table comparing the old and new fees is attached at Annex 1.

4. Legislative Background

4.1 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).

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

4.3 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.

4.4 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. Extent

5.1 This instrument applies to all of the United Kingdom.

6. European Convention on Human Rights

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

7. Policy background

7.1 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 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. Generally 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.

7.3 While the proposals were being developed a series of informal consultations and presentations 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. 12 weeks were allowed for comment and the 32 respondents generally supported the proposals but provided comments on particular issues, many of which sought clarification or raised points of detail.

7.4 The accompanying Regulatory Impact Assessment (RIA) covers in detail the costs and benefits of the proposed changes and the main issues raised by consultees.

7.4 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. The fees are provided in the 2006 Regulations, rather than in separate fees legislation. The proposed changes for the fees elements contained within the 2007 Regulations include changes to the amounts charged, full details are provided in the attached RIA.

8. Impact

8.1 A Regulatory Impact Assessment is 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) can answer any queries regarding the instrument.

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 2007

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 31
Article 24	Schedule 2 paragraph 12
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 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 12
Article 44(4)	Administrative measure; nothing to implement
Article 45	Schedule 2 paragraph 3
Article 46	Administrative, but covered by Schedule 2 paragraph 7(1)
Article 47	Schedule 2 paragraph 2(1)
Article 48	Schedule 2 paragraph 2(2)
Article 49	Regulation 31(2)
Article 50(a)	Schedule 2 paragraph 9(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 33 and 34
Article 50(e)	This is a necessary implication of Schedule2 paragraph 12
Article 50(f)	Schedule 2 paragraph 9(3)
Article 50(g)	Regulation 21
Article 50 (a)(1)	Achieved by the power of entry in regulation 33(7)
Article 50(a)(2)	Administrative measure; nothing to implement
Article 51	Administrative measure; nothing to implement
Article 52	Schedule 2 paragraph 9(2)
Article 53 and 54	Schedule 2 paragraph 10; 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 12(1)
Article 55(1)(b) first paragraph	Schedule 2 paragraph 12(2)
Article 55(2)	Schedule2 paragraph 12(3)
Article 55(3)	Schedule 2 paragraph 12(4)
Article 56	Schedule 2 paragraph 11(1)
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 32 to 35
Article 80(1) second paragraph	Regulation 33(7)
Article 80(1) third paragraph	Regulation 33(8)
Article 80(1) fourth paragraph	Nothing to implement; this is a voluntary inspection
Article 80(1) fifth paragraph	Regulation 34
Article 80(2)	Schedule 1 paragraph 2(5)
Article 80(3)	Schedule 2 paragraph 8
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 7
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
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 30
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)

Final Regulatory Impact Assessment

1. Title: The Veterinary Medicines Regulations 2007

INTRODUCTION

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.

Following a complete review of the previous regulatory regime for veterinary medicines in the UK during 2005, the Veterinary Medicines Regulations 2005 came into force on 1 October 2005. We indicated that we would review, revoke and re-make the Regulations annually to keep them and our fees up to date and to maintain transparency and simplification by avoiding a raft of amending Statutory Instruments. This was accomplished in 2006 with the Veterinary Medicines Regulations 2006 coming into force on 1 October that year.

A review of the 2006 Regulations, with key stakeholders, identified the need for amendments to provide increased clarity and to ensure that the Regulations remain fit for purpose. In addition, two new pieces of European legislation relating to veterinary medicines came into force during 2006 and needed to be implemented in the UK legislation. Changes were also necessary to the fees elements of the Regulations.

2. PURPOSE AND INTENDED EFFECT

(i) Objective

To revoke and replace the Veterinary Medicines Regulations 2006 (SI 2006/2407) with updated Regulations that are fit for purpose.

This measure is required to:

i. Maintain and strengthen existing safeguards and to promote the safe, effective and responsible use of veterinary medicines, whilst minimising the necessary burdens on industry as far as possible.

ii. Continue to encourage the development and availability of veterinary medicines and make the UK an attractive base for the research and development of new products.

iii. Retain the position of the UK as a leading regulatory authority in respect of European authorisation procedures.

iv. Introduce revised fees to recover the projected annual costs of assessing applications for veterinary medicinal product Marketing Authorisations (MAs) and associated services, including inspections of premises and pharmacovigilance.

v. Introduce revised fees to recover the projected annual costs of the registration and inspection of manufacturers and distributors of medicated feed and feedingstuffs and premises for supply by suitably qualified persons.

The changes will primarily affect veterinary surgeons and the veterinary pharmaceutical industry, which includes the companies marketing and manufacturing veterinary medicinal products. However, because they permeate the entire regulatory regime, which applies to all aspects of veterinary medicines including manufacture, marketing, distribution, supply, administration and post authorisation monitoring of suspected adverse reactions, aspects of the Regulations may potentially affect a wide range of interests including:

- registered pharmacies and pharmacists;
- agricultural merchants and saddlers;
- owners and keepers of food-producing animals (including farmers and beekeepers);
- owners and keepers of companion and other non-food producing animals (including owners of horses and exotic animals);
- veterinary medicines wholesalers;
- animal charities providing veterinary treatment;
- other retailers of veterinary medicines, such as pet shops.

The majority of changes are outlined below. There are some minor modifications of current procedures that, although necessary, will have a negligible impact on current practice. The changes in respect of fees are set out separately in detail in Annex 1.

Devolution

The Regulations will apply to the UK as control of medicines is reserved to Westminster, apart from enforcement, which is devolved to the territorial administrations.

(ii) Background and Rationale for Government intervention

No medicinal product can be considered completely risk free and many are potentially harmful if not used responsibly. In view of this, there is a need to maintain a robust system to regulate the safety, quality and efficacy of

veterinary medicinal products placed on the market, as well as their distribution, supply and use, in order to safeguard the public, including consumers of animal produce, the environment, and the health and welfare of animals.

The regulatory system, which has existed in the UK since the Medicines Act 1968, is based on an evaluation of the risk/benefit balance (the beneficial effect of the medicine against possible harmful effects) of each medicinal product at the authorisation stage and subsequent monitoring of safety during its manufacture and use.

The coming into force of the Veterinary Medicines Regulations in 2005 was a significant milestone in the development of the regulatory regime for veterinary medicines in the UK. The new Regulations were written and presented clearly and without the tendency towards confusing 'legalese' that was apparent in the legislation that they replaced. In recognition of this significant change, the VMD has maintained open channels of communication with key stakeholders following the coming into force date. Although the format of the Regulations was widely appreciated by stakeholders, one consequence of the simplification exercise was that some areas of the new legislation now require amendment to improve clarity of interpretation. In some areas it is also necessary to add provisions to address minor regulatory gaps that have arisen unintentionally as a result of the simplification exercise. If no action is taken to address these issues the Regulations will not provide sufficient legislative control in respect of the safe manufacture, marketing, supply and use of veterinary medicinal products.

We therefore propose to implement a number of amendments to the legislation at the same time as the necessary adjustments to the fees are made, to ensure that the Regulations remain up to date and that they reflect the minimum level of regulation that is required.

Key Changes

In addition to the proposed changes in respect of fees, which are outlined separately in Annex 1, the following issues are proposed for inclusion in the Veterinary Medicines Regulations 2007:

i. Registered premises for Veterinary Surgeons

Introduce a requirement for the registration of premises used by veterinary surgeons for the storage and supply of veterinary medicinal products. This will enable controls on veterinary medicinal products, including controlled drugs, to be enhanced and will bring veterinary surgeons in line with other Registered Qualified Persons (RQPs).

ii. Exemption criteria for POM food-producing animals

Implement the Commission Directive 2006/130/EC, implementing Directive 2001/82/EC of the European Parliament and of the Council as regards the establishment of criteria for exempting certain veterinary medicinal

products for food-producing animals from the requirement of a veterinary prescription. This was published as Directive 2006/130/EC in the Official Journal (OJ L349, p15, 12/12/06) on 12 December 2006.

iii. List of essential substances for horses

Introduce the requirements resulting from the Commission Regulation (EC) No 1950/2006 of 13 December 2006 establishing, in accordance with Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products, a list of substances essential for the treatment of equidae. This came into force on 25 December 2006.)

iv. Advertising of POM-V medicines to Veterinary Nurses

Introduce a provision to permit the advertising of POM-V medicines to Veterinary Nurses.

v. Batch release system for Immunological Veterinary Medicinal Products

Extend the provision that the holder of a Marketing Authorisation for an immunological product must submit to the Secretary of State the results of all tests carried out on each batch of the product before he places the product on the market, to require that the holder must wait for confirmation from the Secretary of State before the product is placed on the market.

vi. Export of Veterinary Medicinal Products

Introduce a provision that requires a person authorised to supply veterinary medicinal products in the UK to ensure that if they export an authorised veterinary medicinal product from the UK to another EU Member State, they will comply with the legislation of the importing Member State.

CONSULTATION

3. The formal consultation package included the draft 2007 Regulations, proposals for Schedule 7 (fees), a partial Regulatory Impact Assessment and revised Guidance Notes to accompany the Regulations. All the associated documents were made available electronically on the VMD website (www.vmd.gov.uk) and sent to consultees by e-mail (or CD ROM when requested).

The consultation period ran for 12 weeks, from 5 March to 28 May 2007 and 32 written responses were received. An open meeting was held on 30 May 2007 to enable stakeholders to discuss the proposals with VMD officials. The following groups were consulted:

(i) Within government

Defra
Department of Health
Food Standards Agency
Environment Agency
Medicines and Healthcare products Regulatory Agency
Health and Safety Executive
Scottish Executive Environment and Rural Affairs Department
Dept of Agriculture & Rural Development for Northern Ireland
Welsh Assembly Government – Department of Environment, Planning and Countryside
Department of Health & Social Security Northern Ireland
UKREP

(ii) Public consultation

A wide range of interested parties were consulted, including all of the VMD's pharmaceutical industry customers, stakeholders from the veterinary and pharmacy professions, SQPs, farming organisations, veterinary charities, pet owners, owners and keepers of horses, feed merchants, saddlers and consumer organisations.

4 OPTIONS
5 COSTS AND BENEFITS { TAKEN TOGETHER

As a general principle, for each significant issue consideration has been given to retaining the current position (i.e. doing nothing), adding to, or modifying, relevant Codes of Practice, or putting detailed requirements in guidance notes as alternatives to including provisions in legislation. Where legislative provisions are considered to be required, two basic options were considered:

(a) to amend the existing legislation to include the provisions; or

(b) to revoke the existing legislation and replace it with new legislation including the new provisions.

It was considered that option (a), whilst initially being administratively simpler for the Department, would be more complicated for those having to work with the legislation. It was therefore decided to proceed with option (b) to maintain the simplified form of the Regulations within one document.

There are drafting amendments throughout the Regulations to improve clarity without changing the legislative requirement. The options for the main proposed regulatory changes are outlined below:

i. Registered premises for Veterinary Surgeons

We propose to introduce a requirement for the registration of premises used by veterinary surgeons for the storage and supply of veterinary medicinal

products. This will enable controls on veterinary medicinal products, including controlled drugs, to be enhanced and will bring veterinary surgeons in line with other Registered Qualified Persons (RQPs).

EU legislation requires retail suppliers of POM veterinary medicines to maintain records and the Member States' authorities to inspect these records. This cannot be done in the UK for all veterinary surgeons as there is no comprehensive register of the premises where they store and from which they supply these products. Enhanced controls on the storage and supply of controlled drugs have also been introduced for human medicines following the Shipman Inquiry. These require a complete audit trail from manufacture to use or disposal. Veterinary surgeons use controlled drugs and the registration of veterinary premises is a first step towards enhancing the current controls by implementing a proportionate system within the veterinary sector.

OPTION 1 - Do nothing

If we do nothing this would maintain the current uneven playing field between veterinary surgeons and other registered qualified persons who are required to work from registered premises. This is particularly apparent in relation to website shops set up by veterinary surgeons; many such websites have been set up since 2005 and without a premises register it is difficult to locate where these businesses are or to undertake records inspections. Additionally, it is essential that traceability of controlled drugs on the veterinary side is improved. It is not possible to enforce the rigorous new legislation relating to such drugs in use for treatment of humans because of the absence of the National Health Service infrastructure so a different but a proportionate regime must be introduced to manage the risks of the use of these substances. **This option is not viable.**

OPTION 2 - Industry self regulation

It is considered that industry self-regulation would not be effective because there would not be sufficient motivation to comply. The RCVS currently runs a voluntary practice register which already has 90+% of practices registered. This is very positive; however, we need to know where all veterinary surgeons supply medicines from and without a legislative requirement it is unlikely that the final 10% of veterinary surgeons will comply on a voluntary basis. **This option is not viable.**

OPTION 3 - Introduce the requirement

It is proposed that the Regulations would require all premises which are used by a veterinary surgeon to store or supply POM-V, POM-VPS and NFA-VPS veterinary medicines to be registered with the Secretary of State. Premises would be defined to allow veterinary surgeons to continue to supply veterinary medicines from their cars while visiting clients. A transitional period would be 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. We have held exploratory talks with interested bodies on how the registration scheme will be implemented. In order to minimise the additional cost and administrative burden associated with statutory premises registration we are working with the Royal College of

Veterinary Surgeons (RCVS) so that we can use their existing systems. The RCVS voluntary practice register already has 90+% of practices registered. This would clearly present a good start for premises registration. Also, the RCVS voluntary practice standards scheme already includes a medicines inspection and we would not duplicate this work. Those premises not in the practice standards scheme would require a medicines inspection at a frequency determined by the level of risk posed.

Consultation Comments
14 comments were received from representatives of the veterinary, pharmacy and pharmaceutical industry bodies as well as pet owners. Whilst many of the respondents requested more information on how the scheme would operate in practice and how costly it would be, the proposal itself was accepted.

The RCVS Council discussed the issue and it was agreed by their Council members that there should be an official register of veterinary practices, particularly of premises where controlled drugs are stored. The RCVS Council also took the view that to reduce duplication the College would be the right body to set up and keep the register and agreed to work with VMD to further develop the proposal, to enable the 2009 implementation date to be met. We expect to continue discussions with the RCVS over the next few months so that a detailed scheme can be agreed and further consultations with stakeholders can be progressed

a) Sectors and groups affected by the change
The proposed change will not have any race equality impacts and will not affect any particular social group in relation to issues of ethnicity, gender, age, health, disability, rural communities or income. Veterinary surgeons prescribing and supplying veterinary medicinal products will be affected by the proposed change.

b) Analysis of Costs and Benefits
It is anticipated the costs to the Department of implementing the legislative change would be minimal.

The RCVS has offered to handle the operation of the register in a self-regulatory fashion and as a result of this there will be a significant reduction in new burdens placed on the industry. The RCVS voluntary practice register already has 90+% of practices registered and therefore the additional costs to businesses of completing a register of premises are not expected to be great and have yet to be fully quantified. In order for the administration of this provision to be funded it is likely that there will be a fee chargeable at the time of registration.

If the RCVS does take responsibility for the register, it will be responsible for setting its own fees to achieve full cost recovery; it is not yet clear whether those practices already registered (90% of an estimated 2200 practices within the UK) would need to pay an additional fee to the RCVS. Whilst the level of fees is not known at this stage and will be further discussed during 2008, it is anticipated that the total administrative cost to industry for a one-off

registration would be £200, or less, for each veterinary practice. Compliance is likely to be high because the existing RCVS register can be used as the starting point.

Sustainable development

i. Social – recognition of needs of everyone

The Social benefits of the proposed change relate to providing a clear list of veterinary premises which will provide information to animal owners and enhance the safe and responsible use of veterinary medicines. The provision will also increase benefits by enabling risk based inspections of the medicines records to be carried out in all cases.

ii. Environmental

The environmental impact of the change is negligible.

iii. Economic

The economic impact is not expected to be high but will potentially be more significant for those veterinary practices who are not currently part of the RCVS register or Practice Standards Scheme (see table below).

Summary of Costs and Benefits:

Option	**Total benefit per annum: social, environmental, economic**	**Total cost per annum: - economic, environmental, social - policy and administrative**
1 – Do Nothing	No increase in administrative burden on the industry	- Uneven level of legal requirements for premises between retailers - Risk of medicines being illegally supplied or stored by veterinary surgeons in unknown premises - Inability of Government to check record keeping in line with EU legislation -inability of Government to identify Illegal supply from veterinary surgeons premises -Lack of traceability of Controlled Drugs stored by veterinary surgeons -Risk of inability to

Option	Total benefit per annum: social, environmental, economic	Total cost per annum: - economic, environmental, social - policy and administrative
		control the use of Controlled Drugs by Veterinary surgeons.
2 – Industry Self-Regulation	-No legislative requirement to be registered.	- Uneven level of legal requirements for premises between retailers - Risk of non-compliance leading to incomplete register
3 – Introduce the Requirement in Legislation	**-** Greater traceability of controlled drugs - Opportunity to improve inspection regime on a risk/benefit basis - Greater consumer reassurance and transparency over where vets are in practice. - Existing RCVS schemes can be used to minimise new burdens	- anticipated costs not yet defined.

ii. Exemption criteria for POM food-producing animals

Implement the Commission Directive 2006/130/EC, implementing Directive 2001/82/EC of the European Parliament and of the Council as regards the establishment of criteria for exempting certain veterinary medicinal products for food-producing animals from the requirement of a veterinary prescription. This was adopted on 11 December 2006 and published as Directive 2006/130/EC in the Official Journal on 12 December 2006. There are 168 products currently authorised for use in food animals in the UK that do not require a veterinary prescription and this Regulation enables their current distribution arrangements to be maintained.

OPTION 1 - Do nothing

Implementation of the Directive is optional for the Member States, however, if the option is not taken up in the UK, all products for food-producing animals that are currently on general sale in the UK will have to be restricted so that they are only available only on prescription. If a prescription from a veterinary surgeon were required for these products it would significantly increase costs and inconvenience to farmers and other owners of food animals who use

these products, with no resulting benefit in respect of the safe use of the products. **This option would be very damaging to the farming as well as some sectors of the veterinary pharmaceutical industry and is not viable.**

OPTION 2 - Industry self regulation
Member States' competent control authorities determine the distribution category for veterinary medicinal products **and therefore this is not a possible option**

OPTION 3 - Introduce the requirement
It is proposed that the provision will be implemented by the Regulations. The Directive sets out stringent criteria to exempt certain veterinary medicinal products for food-producing animals from the requirement of a veterinary prescription. In practice this means that food-producing animal products that are currently distributed through the AVM-GSL category will be able to remain on the general sales list.

Consultation comments
3 comments were received from consultees, all of which supported the introduction of the exemption criteria.

a) Sectors and groups affected by the change
The proposed change will not have any race equality impacts and will not affect any particular social group in relation to issues of ethnicity, gender, age, health, disability, rural communities or income.
Farmers will benefit from the implementation of this Directive as easy availability of some current veterinary medicines will continue. Veterinary pharmaceutical manufacturers will also be affected by this change, as will veterinary medicine retailers and other customers purchasing veterinary medicinal products.

b) Analysis of costs and benefits
The benefit of this addition to the legislation is that there will be no change to current product classifications in use. There are, therefore, no additional costs.

c) Compliance and administrative costs for business
Not applicable as we are already fully complying with the new Directive.

d) Sustainable development, impacts
i. Social – recognition of needs of everyone
Not applicable as we are already fully complying with the new Directive.

ii. Environmental
Not applicable as we are already fully complying with the new Directive.

iii. Economic
Not applicable as we are already fully complying with the new Directive.

Summary of Costs and Benefits:

Option	Total benefit per annum: economic, environmental, social	Total cost per annum: - economic, environmental, social - policy and administrative
1. Do Nothing	No benefit	- 168 medicines for farm animals would become available on prescription only - Costs of these medicines would increase to cover extra admin required - high risk that availability of these medicines would reduce - medium risk that animal health could suffer
2. Industry Self-Regulation	Not applicable	Not applicable
3. Introduce the Requirement in Legislation	Maintain the status quo re availability of medicines for farm animals	No costs

iii. Establish a list of essential substances for horses

Enable the enforcement of Commission Regulation (EC) No 1950/2006 of 13 December 2006 establishing, in accordance with Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products, a list of substances essential for the treatment of equidae. This came into force on 25 December 2006.

EU legislation limits the veterinary medicines that can be used to treat food animals to those medicines which have been tested for consumer safety and have defined withdrawal periods. Horses are considered to be a food-producing species within the EU and the purpose of the Regulation is to provide a wider range of medicines for them than other food-producing species because many horses are kept solely as pets. The regulatory change allows veterinary medicines containing a specific range of active substances not normally used in food-animals to be used in the treatment of horses, with a standard minimum withdrawal period of 6 months applying for those individual animals that have been declared as intended for human consumption on its Horse Passport.

OPTION 1 - Do nothing
This option is not applicable. This is a Council Regulation so it is therefore immediately applicable throughout the EU. However, it is necessary to

provide for enforcement of the Regulation so that action can be taken should the provisions be abused.

OPTION 2 - Industry self regulation

This option is not applicable. The controls on medicines used in food-producing species are already contained within the existing Veterinary Medicines Regulations and therefore implementing this enforcement requirement outside of the regulatory framework would not be possible.

OPTION 3 - Introduce the requirement

For the purposes of enforcement we propose to provide that the Secretary of State is the enforcement authority for this Regulation in the Veterinary Medicines Regulations 2007.

a) Sectors and groups affected by the change

The proposed change will not have any race equality impacts and will not affect any particular social group in relation to issues of ethnicity, gender, age, health, disability, rural communities or income.

Veterinary surgeons prescribing and supplying veterinary medicinal products and horse owners will primarily be affected by this change.

b) Analysis of costs and benefits

The benefit of this change is increased availability of veterinary substances for use in the treatment of horses by veterinary surgeons. There are no new costs to the Department of enforcing this requirement, which will continue to be done through routine retailer's records inspections.

c) Compliance and administrative costs for business

We do not anticipate that there will be an increased cost to industry. No issues relating to costs were raised by consultees.

d) Sustainable development, impacts

i. Social – recognition of needs of everyone

The social impact of the proposed change is not considered to be significant, although veterinary surgeons and horse owners will have increased availability of veterinary substances for the treatment of horses. This could in turn improve the health and wellbeing of horses in the UK, the majority of which are kept for the pursuit of leisure interests.

ii. Environmental

The environmental impact of the change is negligible.

iii. Economic

The economic impact of the change is negligible.

Summary of costs and Benefits

iii. Establish a list of essential substances for horses		
Option	**Total benefit per annum: economic, environmental, social**	**Total cost per annum: - economic, environmental, social - policy and administrative**
1 Do Nothing	Not applicable	Not applicable
2 Industry Self-Regulation	Not applicable	Not applicable
3 Introduce the Requirement in Legislation	Increased availability of medicines to treat horses	No new costs

iv. Advertising of POM-V medicines to Veterinary Nurses

Introduce a provision to permit the advertising of POM-V medicines to Veterinary Nurses. The coming into force of the new Regulations in 2005 greatly clarified the legislation controlling the advertising of veterinary medicines, which previously formed part of the Medicines Act 1968. The restrictions on advertising were already in existence in the previous legislation, but were not as clearly written and therefore not well understood. The current situation is that advertisements for POM-V medicines cannot be aimed at veterinary nurses, for example these products cannot be advertised in veterinary nursing journals or at training events aimed at veterinary nurses. As a result we have received a large number of letters from veterinary nurses who are unhappy with the current restrictions. This is because in the course of their work veterinary nurses need to be familiar with a wide range of POM-V products and the restrictions prevent them receiving beneficial 'educational' advertising material from MA holders.

OPTION 1 - Do nothing
There has been a continued call for a change in the legislation from industry representatives and therefore **this option is not viable**.

OPTION 2 - Industry self regulation
It is a provision of EU legislation that POM veterinary medicines may not be advertised to the general public therefore industry self-regulation is not considered to be appropriate . **This option is not viable**

OPTION 3 - Introduce the requirement
The Veterinary Medicines Directorate (VMD) has met with representatives of interested parties, to gain a clearer picture of the current roles and responsibilities of a qualified veterinary nurse. After discussing these issues with representatives from the concerned bodies we consider that a change in

the legislation regarding the advertisement of POM-V medicines is relevant to a qualified veterinary nurse's role.

Consultation Comments
6 comments were received from consultees representing veterinary nurses and the pharmaceutical industry, all of whom supported the proposed change. No increased costs to industry were identified.

a) Sectors and groups affected by the change
The proposed change will not have any race equality impacts and will not affect any particular social group in relation to issues of ethnicity, gender, age, health, disability, rural communities or income.
Veterinary nurses, veterinary surgeons employing veterinary nurses, manufacturers and publishers of veterinary nursing journals will be affected by the change.

b) Analysis of costs and benefits
The benefits of this change are that veterinary nurses will be better informed, encouraging further discussion between a veterinary surgeon and a veterinary nurse when deciding which veterinary medicines are appropriate for the practice. We anticipate an increase in the number and type of advertisements aimed at veterinary nurses. This will help to maintain the dedicated journals that are currently available that are aimed at veterinary nurses by increasing their possible sources of revenue.

The costs to the Department of enforcing this change are negligible and would be covered by existing arrangements for monitoring advertising of veterinary medicines.

c) Compliance and administrative costs for business
Compliance is likely to be high and the administrative costs low. Whilst we do not have specific figures for estimated administrative costs or savings for business, it is not expected that there will be an increased financial burden on industry resulting from the change.

d) Sustainable development, impacts
i. Social – recognition of needs of everyone
The social impact of the proposed change relates to the ability of veterinary nurses to easily maintain their knowledge, be aware of new medicines and changes to the authorisations of currently authorised products. However, there is not considered to be a significant wider social impact.

ii. Environmental
The environmental impact of the change is negligible.

iii. Economic
It is not considered that there will be a significant economic impact as a result of the change.

Summary of costs and Benefits

iv. Advertising of POM-V medicines to Veterinary Nurses		
Option	**Total benefit per annum: economic, environmental, social**	**Total cost per annum: - economic, environmental, social - policy and administrative**
1 Do Nothing	No benefit	- Reduced product knowledge amongst veterinary nurses
2 Industry Self-Regulation	Not applicable	Not applicable
3 Introduce the Requirement in Legislation	Improved product knowledge amongst veterinary nurses	No costs identified

v. Changes to batch release system for Immunological Veterinary Medicinal Products

Amend the provision to require the holder of a Marketing Authorisation (MA) for an immunological product to submit to the Secretary of State the results of all tests carried out on each finished batch of the product and to wait for written confirmation from the Secretary of State before placing the batch of product on the market.

A batch release checking system is already in place in existing legislation, whereby the MA holder submits the results to the Secretary of State and then waits for a period of 15 days before placing the product on the market. However, there is a risk of batches of immunological product being released on to the market without any official confirmation that the appropriate checks have been completed. It is also difficult for both industry and the authorities to work within a system that is open ended.

OPTION 1 - Do nothing
The current system is that companies must 'tell, wait and do' without obtaining prior approval and does not ensure that the approval of product batches can be traced. The current system is also difficult to manage both within the authorities and industry. **This is not a viable option.**

OPTION 2 - Industry self regulation
This is a possible option, however, the UK have implemented the requirement for official administrative batch release for immunological products within existing legislation in order to maintain control of individual products and

ensure they will be safe and efficacious in use. The proposed change will amend this piece of legislation and therefore it is considered that industry self-regulation would not be appropriate. **This option is not viable.**

OPTION 3 - Introduce the requirement
The implementation of this change would make it an offence to put batches of immunological product onto the market without receipt of written approval and would ensure that only approved batches would be released on to the market. Although it is not anticipated that it will take any longer to obtain the written approval that the current permitted time of 15 days, the VMD will publish performance standards, following consultation with the industry, so that the time taken can be monitored easily and batch releases would not be delayed unacceptably.

Consultation comments
No comments were received from consultees.

a) Sectors and groups affected by the change
The proposed change will not have any race equality impacts and will not affect any particular social group in relation to issues of ethnicity, gender, age, health, disability, rural communities or income. Marketing Authorisation holders will be affected by the proposed change.

b) Analysis of costs and benefits
At present it is difficult for both the authorities and industry to be sure that the appropriate checks have been carried out in each case before the batch is released on to the market. The implementation of the new requirement will provide a simple mechanism for improved clarity. Also although in reality the current checking process is normally completed within the 15 day period, there is an avoidable risk of unsatisfactory or potentially unsafe batches of product being on the market after 15 days, which would have to be recalled. A product recall exercise can be costly for the industry. The benefit of the proposed change would be to remove this risk.

c) Compliance and administrative costs for business
The proposed legislative change clarifies general current practice. We do not anticipate that there will be any increased cost to industry because the written confirmation will be sent to the company within the 15 day period that they currently wait for.

There will be no additional costs to the Department of enforcing this requirement which will continue to be done through the systems in place.

d) Sustainable development, impacts
i. Social – recognition of needs of everyone
The social impact of the proposed change is not considered to be significant.

ii. Environmental
The environmental impact of the change is negligible.

iii. Economic

It is not considered that there will be any economic impact as a result of the change.

Summary of Costs and Benefits

v. Changes to batch release system for Immunological Veterinary Medicinal Products		
Option	**Total benefit per annum: economic, environmental, social**	**Total cost per annum: - economic, environmental, social - policy and administrative**
1 Do Nothing	No benefit	-Risk of product recall being required if a batch is placed on the market before test result checks reveal a problem
2. Industry Self-Regulation	Not applicable	Not applicable
3. Introduce the Requirement in Legislation	- Only approved batches can be released for sale -Greater traceability of batch release approval	No new costs identified

vi. Export of Veterinary Medicinal Products

Introduce a provision that requires a person authorised to supply veterinary medicinal products in the UK to ensure that if they export an authorised veterinary medicinal product from the UK to another EU Member State, they will comply with the legislation of the importing Member State.

At present there is nothing to require a person, authorised to supply a veterinary medicinal product in the UK, to ensure that, if they export an authorised veterinary medicinal product from the UK, they will comply with the legislation of the importing country. This has created enforcement problems where the exporter has not committed an offence in the UK but exported products are then placed illegally on the importing country's market. There have been examples where UK exporters have deliberately flouted the laws of the importing country and it has not been possible to take any action against them. If the requirement is introduced it will enable the UK Government to prosecute those breaking the law and enhance the European single market for lawful veterinary medicinal products.

OPTION 1 - Do nothing

The current situation is not acceptable because illegally imported products originating from the UK are being made available in other Member States and there is no legislative control in place to prevent the products being exported. **This is not a viable option.**

OPTION 2 - Industry self regulation
Due to the requirements of the single market and the consequent need to have greater legislative control over exported products **this is not a viable option.**

OPTION 3 - Introduce the requirement
The proposed provision would clarify the existing legislation by requiring that anyone who exports a veterinary medicinal product for use in another Member State must ensure that the veterinary medicinal product exported can be lawfully supplied or administered in the importing country. If the requirement is introduced it will enable the UK to assist other Member States in controlling the legal supply of veterinary medicines to their market by prosecuting those supplying products from the UK illegally.

Consultation Comments

5 consultees commented on this proposal and a number of concerns were raised about the original draft of the provision being too restrictive because the amendment required that an offence would be committed if an exported product did not have a marketing authorisation in the importing country. The consultees' concerns related to the possible prevention of legitimate export of unauthorised products through the use of exemption schemes or import provisions specific to individual Member States. The potential for a significant increase in resources being required to meet the new requirement was also raised by one consultee, who did not currently adhere to any legislation in other countries and who considered that a high level of staff time would be spent checking the legal status in other Member states of the products they intended to export.
As a result of these comments, an amended draft was circulated to all the consultees concerned, which removed the requirement for a marketing authorisation, but still required that the product could be legally supplied or administered in the importing country. All those consulted on the new draft indicated that they were satisfied with the new wording.

a) Sectors and groups affected by the change
The proposed change will not have any race equality impacts and will not affect any particular social group in relation to issues of ethnicity, gender, age, health, disability, rural communities or income.
Any person authorised to supply veterinary medicinal products could be affected by the proposed change.

b) Analysis of costs and benefits

We have yet to determine the costs of enforcing this requirement, but it is considered that the existing inspection and enforcement systems will absorb any additional enforcement work resulting from the change. The issue of whether additional departmental resources are required will remain under review once the amendment is implemented, although it is anticipated that compliance is likely to be high. The benefit of the change will be that the

legitimate export of veterinary medicinal products from UK to other Member states will be unchanged whilst the export and subsequent import of illicit products will be preventable. This will maintain the single market within the UK while ensuring that enforcement action can be taken when required where deliberate flouting of the law occurs.

c) Compliance and administrative costs for business

As mentioned above, in response to the initial draft a consultee raised the issue of increased administrative costs relating to checks required to be made before a product can be exported. However, it is considered that the information required to fulfil the requirement is readily available from UK MA holders and from other Member States' regulatory authorities and that these checks should be part of the normal current procedures for responsible exporters. Authorised wholesale dealers have supported this provision.

d) Sustainable development, impacts

i. Social – recognition of needs of everyone

The social benefits of the proposed change centre on improved awareness in terms of what import legislation is required for the responsible supply of veterinary medicines.

ii. Environmental

The environmental impact of the change is negligible.

iii. Economic

The economic impact of the change is negligible. We are not introducing any new controls; the proposed legislative change clarifies current good practice. We do not anticipate that there will be any increased cost to industry.

There will be no additional costs to the Department of enforcing this requirement which will continue to be done through the systems in place.

Summary of Costs and Benefits

vi. Export of Veterinary Medicinal Products		
Option	**Total benefit per annum: economic, environmental, social**	**Total cost per annum: - economic, environmental, social - policy and administrative**
1 Do Nothing	No benefit	- Continued export of unauthorised products into other Member States - Lack of understanding of the required controls on export
2. Industry Self-Regulation	Not applicable	-Not applicable
3. Introduce the	- Better clarification of the responsibilities	-No new compliance costs identified

vi. Export of Veterinary Medicinal Products		
Option	**Total benefit per annum: economic, environmental, social**	**Total cost per annum: - economic, environmental, social - policy and administrative**
Requirement in Legislation	placed on exporters of veterinary medicines.	

OTHER REGULATORY ISSUES RAISED DURING CONSULTATION

The following new issues were raised by consultees. Where a legislative change has been made in response to the issue only where the current legislation is considered to be significantly unclear and where no new burden would result from the change being made:

Authorised Products used under Animal Scientific Procedures Act (ASPA)

A response to the consultation raised the problem of animals under ASPA that only receive authorised medicines in accordance with their MAs still being required to obtain an Animal Test Certificate before they can legally enter the food chain. For example, an animal under ASPA for the testing of a surgical procedure not involving any unauthorised medicines could be treated with an authorised anaesthetic or antimicrobial medicine and therefore should be able to enter the food chain following the authorised withdrawal period for the product used. It would be impossible for VMD to issue an ATC in this case as no medicines would be 'tested' so the animals would not be able to be slaughtered for human consumption.

It was considered that this was a valid point and an amendment was made to the restrictions relating to animals under ASPAs.

Supply of 'cascade' products by SQPs

At present the SQP Code of Practice and Animal Medicines Training Regulatory Authority (AMTRA) advice does not allow SQP's to supply veterinary medicinal products other than for the purposes for which the products are authorised. However this also prevents SQPs from supplying a customer with a product prescribed by their veterinary surgeon for its use 'off-label' under the prescribing cascade. In some cases an SQP is more likely to stock particular medicines for farm animals than a veterinary surgeon and therefore it is considered that this change is necessary to allow optimum availability of medicines.

Consultees requested that a change be made to the legislation to this effect. However the current legislation does not prevent this activity so the change will be implemented through amendments to existing guidance documents.

Small Animal Exemption Scheme

A request was received for an addition to the labelling requirements for veterinary medicines exempted from the need to hold a marketing

authorisation under Schedule 6 of the Regulations. The point of the scheme is to exempt small businesses who manufacture treatments containing restricted quantities of active ingredients specifically for use in certain small pet animals from the need to meet all the requirements of a full marketing authorisation. It was suggested that all the products marketed under this scheme should be labelled to clarify that they were not for use in animals intended for human consumption.

The proposal was discussed with other consultees at the Open Meeting held on 30 May and it was generally considered that a label change was a costly exercise and that the suggested amendment would place a new burden on a small industry that was disproportionate to the minimal benefit to human health that might result from the change. It is clear that the products marketed under this scheme may only be used in the types of animals listed within the Scheme and may never be used in animals intended for human consumption so that the proposal was felt to be unnecessary and burdensome and was therefore not accepted.

Specialist Input – lawyers, economists etc

The Veterinary Medicines Regulations 2007 have been drafted by a dedicated Defra lawyer. Departmental economists and Better Regulation experts have scrutinised the proposals and any resulting feedback has been taken on board.

6. SMALL FIRMS IMPACT TEST

At the time of the introduction of the 2005 Regulations a series of presentations were held, attended by a range of interested organisations and individuals, including those representing small businesses. At these meetings feedback was sought and the key issues that have continued to be raised in correspondence to the VMD have been incorporated in the 2007 Regulations. Further meetings have been held this year with interested groups and individuals to ensure as far as possible that issues could be raised and so taken into account.

7. COMPETITION ASSESSMENT

Overall, the proposed Regulations are likely to affect a number of markets related to veterinary medicines. However, as explained in paragraph 3 above, it is considered that most of the proposed changes are unlikely to have any significant impact. The competition filter test was completed in respect of 4 markets considered to be most affected:

A – the veterinary pharmaceutical industry;
B – veterinary practices;
C – agricultural merchants;
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 2000 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 2006 indicates that there are some 3,685 veterinary practices and branches in the UK. The British Veterinary Association has estimated that there are approximately 2,200 separate practices. The RCVS Report indicates that 51% of practices focus mainly on small (i.e. non-food) animals, 1% on farm animals, 45% on mixed animals (i.e. small animals and food animals), and 3% 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 1 site, 30% from 2 sites, 16% from 3 sites and a smaller proportion from more than 3 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 9 people - in round terms 3 veterinary surgeons, 3 veterinary nurses and 3 other staff. The Report indicates that practice branches average approximately 4 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 is 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

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.

It is considered that a simple competition assessment, rather than a detailed assessment is required. On this basis no significant competition issues have been identified.

8. ENFORCEMENT AND SANCTIONS

While responsibility for controls on veterinary medicines remains with the Westminster Parliament, responsibility for the enforcement of those controls has been transferred to the devolved administrations under devolution arrangements. The enforcement responsibilities will remain as under the existing legislation and will include the use of Improvement and Seizure Notices, where appropriate, in addition to further legal action resulting in fines or imprisonment.

9. IMPLEMENTATION AND DELIVERY PLAN

In line with Better Regulation best practice, we have produced revised guidance documents to take into account the changes to the legislation. To assist consultees in considering the implications of the changes within the new Regulations, and to ensure that the guidance is finalised in time for publication three months before the Regulations come into force the draft guidance documents were issued as part of the initial consultation package. They have since been updated to include additional guidance requested during the consultation period and made available from 2 July.

It is proposed that the Veterinary Medicines Regulations 2007 will come into force on 1 October 2007, in accordance with the Government-wide adoption of Common Commencement dates.

10. POST-IMPLEMENTATION REVIEW

The effectiveness of the new Regulations will be monitored and reviewed within the ongoing VMD customer satisfaction surveys and feedback from stakeholders. The operation of the procedures and requirements set out in the legislation will be subject to ongoing monitoring and any issues arising or raised will be considered to determine whether any changes are required. It has been decided that the Regulations will not be amended but, when changes are required, they will instead be revoked and remade so that they remain as a single comprehensive and current piece of legislation. The inclusion of fees provisions means that these will need reviewing annually to take account of inflation and any other relevant changes. This will provide a regular annual basis for reviewing the operation of all the provisions of the Regulations and making any changes necessary.

11. SUMMARY AND RECOMMENDATION

It is recommended that the regulatory changes discussed in this RIA and in the attached Annex 1 are implemented.

The proposed changes have been fully outlined above and, whilst necessary to maintain the coherence and suitability of the existing regulatory framework, they are not considered to represent a significant departure form the current regime.

12. DECLARATION

I have read the Regulatory Impact Assessment and I am satisfied that the benefits justify the costs.

Signed.....Jeff Rooker.....

Date.....25th July 2007.....

Jeff Rooker
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ANNEX 1

REGULATORY IMPACT ASSESSMENT - FEES

1. Title

The Veterinary Medicines Regulations 2007 – fees relating to veterinary medicines.

2. Purpose and intended effect

(i) Objective

This measure is required to introduce revised fees to recover the projected annual costs of:

- assessing applications for veterinary medicinal product Marketing Authorisations (MAs) and associated services, including inspections of premises and pharmacovigilance;

- the registration and inspection of manufacturers and distributors of medicated feed and feedingstuffs and premises for supply by suitably qualified persons; and

- carrying out follow-up inspections after routine controls have found non-compliance. New provisions are included to make persons liable for the cost of the re-inspection either through specified fees or for the full economic cost of any additional inspection necessarily carried out as a result of the issue of an improvement notice to that person;

- expand the existing fees menu to include applications for Provisional Marketing Authorisations instead of the previous flat rate fees. The fees menu was introduced by the 2006 Regulations as a means of achieving a more transparent link between application fees and the underlying costs for this work.

The charges under this legislation apply in the UK.

(ii) Background

These Regulations will amend the fees currently charged in accordance with the Veterinary Medicines Regulations 2006, which established the fees for applications and inspections relating to authorisations and certificates issued under those Regulations. With effect from 1 October 2007 the Veterinary Medicines Regulations 2007 will come into force and the Veterinary Medicines Regulations 2006 will be revoked.

The fees proposed within the updated Schedule 7 take account of the need to revise the current fees in respect of inflation and to ensure that they continue

to reflect the cost of the work being carried out. The proposals are intended to achieve full cost recovery.

(iii) Risk assessment

If the revised fees are not introduced, full cost recovery will not be achieved.

3. Options

Option 1: To leave general fee levels unchanged – the VMD will be unable to achieve full cost recovery. Some of the costs of the VMD will have to be met out of existing public funds.

Option 2: To increase the fees as proposed in order to fully recover the cost of the VMD's services from the customers/parties benefiting from those services.

Option 3: Any other option falls between Options 1 & 2 above.

4. Benefits

The VMD aims to ensure the safety, quality and efficacy of all aspects of veterinary medicines. With adequate financing of its Authorisations Division it is able to attract and retain scientific personnel of the appropriate quality and experience to carry out its work to high standards and in acceptable timescales. In this regard, maintaining the VMD's first class reputation within the world veterinary pharmaceutical industry is of paramount importance in attracting applications for new products to the UK.

The Business Sectors and the number of firms affected within the pharmaceutical industry are shown in paragraph 11. No records are available on the absolute size of these firms, only information on sales of veterinary medicinal products.

5. Costs

(i) Compliance costs

The additional revenue raised against industry by these Regulations is estimated to be in the order of £190,000, equivalent to approximately 1.25% of the total take from industry in 2006/07.

To put the charges in context, the costs of authorising a veterinary medicinal product represent a small proportion of the total costs of developing a product and bringing it to the market, which can run to up to £10 million.

(ii) Other Costs

As these Regulations increase fees for work done, there are no other costs.

(iii) Costs for a"typical" business

There is no such thing as a typical company in this sector. The effect of this proposal will depend on how often a company makes an application to the VMD, how many Marketing Authorisations they currently have and the size of their annual turnover in veterinary medicines.

Additional recurring costs for a typical business in the above sectors are difficult to assess because of the disparity in size, complexity, geographical spread of sites and numbers of products handled by the companies in question. All of these factors can affect the level of fees charged and hence the costs likely to be incurred by individual businesses.

There should be no non-recurring costs.

6. Equity and fairness

The proposed fee increase and other listed charges will apply evenly to all types of customer, except that Marketing Authorisation holders with turnover of less than £225,000 will pay a reduced fixed annual fee.

7. Consultation with small business: Small Firms' Impact Test

The large veterinary pharmaceutical companies hold most Marketing Authorisations but there are also a number of small operators in the market. Measures proposed should not favour one category as against another. Small operators will, however, tend to make proportionately fewer applications than large companies, whereas large companies' turnover can reach proportionately higher levels. This means that increases in application fees have a greater effect on large companies whilst increases in Graded Annual Fees tend to protect new products that have not yet reached the peak of the product sales cycle.

8. Competition assessment

We have assessed this against the competition filter and have concluded that these changes will have no impact on competition between existing or new members of the market.

9. Enforcement and sanctions

It is not anticipated that these proposals will change existing arrangements for enforcement and sanctions. The VMD retains, as a last resort, the right to suspend or revoke Marketing Authorisations and continues to seize illegal products.

10. Monitoring and review

It is not anticipated that these proposals will change existing arrangements for monitoring and review.

11. Consultation

i. Within government

The following governmental bodies were consulted:

Department of Health
Medicines and Healthcare products Regulatory Agency
Scottish Executive Environment and Rural Affairs Department
Dept of Agriculture & Rural Development for Northern Ireland
Welsh Assembly Government – Department for Environment, Planning and Countryside
Department of Health & Social Security Northern Ireland
UKREP

ii. Public consultation

All of the VMD's pharmaceutical industry customers and other interested parties were consulted on these proposals. There were approximately 1,050 organisations and individuals directly consulted and the documents were published on the VMD web site so that they were available to any interested party. The VMD quarterly publication highlighted the consultation and it was brought to the attention of enquirers during the consultation period.

Summary of Additional Costs as a result of the Veterinary Medicines Regulations 2007

Description	Group Affected	Additional annual cost	Rationale
Fees related to applications for the authorisation of veterinary medicines	Pharmaceutical Industry - including Manufacturers and Marketing Authorisation holders	£160,000 (2.5 % increase)	Inflationary increase to cover increased Departmental costs
Fees related to the Animal Medicines Inspectorate	Merchants, Saddlers and on-farm Feed Compounders	£12,000 (2.5% increase)	Inflationary increase to cover Animal Medicines Inspectorate Departmental costs
Fees related to manufacturers	Manufacturers of veterinary medicinal products for use by small pet animals	£16,000	The 2007 Regulations will require this group to hold manufacturing authorisations.
Fees relating to an improvement notice	Any person served an improvement notice under these Regulations	The full economic cost of an inspection is borne by the person on whom a notice is served	A new requirement to ensure that individual operations pay for inspections resulting from their non-compliance, rather than being funded by industry as a whole.