EXPLANATORY MEMORANDUM TO

THE VETERINARY MEDICINES REGULATIONS 2009

2009 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. Purpose of the instrument

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 *or* the Select Committee on Statutory Instruments]

3.1 None

4. Legislative Context

4.1 The Veterinary Medicines Regulations (VMRs) implement the requirements of Directive 2001/82/EC, as amended by Directive 2004/28/EC. This Directive outlines the rules and requirements for the regulation of medicines for animal use. The VMR 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.

4.2 The VMRs 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 50 amending Statutory Instruments (SIs). The VMR have been updated annually since 2005.

4.3 The annual cycle to revoke and remake the VMR allows the VMD to respond quickly to the demands of the veterinary sector and therefore to formulate fit-for-purpose legislation that is meaningful to stakeholders. We consulted stakeholders in an open meeting in June 2009 whether or not they wished the VMD to continue with the annual update of the VMR and there was a positive response to this question.

5. Territorial Extent and Application

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

- ***What is being done and why***

7.1 The VMRs 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 2008. During the consultation period for the previous amendments, made in 2008, 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 formed the basis of the proposed amendments for the 2008 Regulations. The principal changes to the 2008 Regulations are as follows:

- They remove the requirement to publicise a seizure notice in the case of a common carrier who does not own the seized goods;
- They create a new type of authorisation (a limited marketing authorisation);
- They create an offence of altering a written prescription without authorisation.

7.2 Fees amendments

7.2.1 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.

7.2.2 The HM Treasury's latest "GDP Deflator" figures predict general inflation of 1.5% for 2009/10. To ensure that the VMD fully recovers the costs of its work done under the Regulations, it is necessary to introduce a general increase of 1.5% to all application fees. Application fees were last increased in October 2007, when a 2.5% general inflation increase was applied.

7.2.3 The 1.5% increase will not be applied to inspection fees as the VMD anticipates efficiency savings as a result of a review of how inspections are performed. These efficiency gains are expected to cancel the effect of inflation on inspection costs in 2009/10.

7.2.4 The VMRs introduce a new fee structure for variations to European Marketing Authorisations from 1 January 2010, necessary as a result of the adoption of Commission Regulation 1234/2008, which harmonise the handling of variations to products authorised via the national or the European procedure (for both veterinary and human medicinal products); the aim is to streamline current procedures and reduce administrative burdens, in line with the objectives of Better Regulation.

7.2.5 For the purposes of variations to marketing authorisations granted under the national procedure the classifications in Commission Regulation (EC) No 1084/2003 will continue to be used.

7.2.6 The VMRs remove the fees for on-line applications for import certificates as a consequence of enhancements to the on-line system which have resulted in efficiency savings.

7.2.6 The VMRs introduce an annual renewal fee of £750 per product imported under wholesale dealers import certificates. The products involved are not subject to the Graded or Fixed Annual Fees that apply to all UK Marketing Authorisations. To ensure that this fee does not prohibit the importation of products with limited markets, it will not apply when the number of import certificates issued in the 12 months prior to the annual renewal, for the relevant product from the relevant wholesalers, is 100 or less. This fee is necessary to cover the cost of work involved in the pharmacovigilance activities that are required for products imported from the EU and Third countries under the import schemes.

- ***Consolidation***

7.3 None

8. Consultation outcome

8.1 A full public consultation on the draft VMRs 2009 took place between 5 May and 28 July 2009 and was preceded by informal consultation with key stakeholders.

8.2 This public consultation aimed to seek stakeholders' views on the costs and benefits that the proposed changes would impose on business. In addition, an open meeting was held on 9 June 2009 to offer further opportunity for stakeholders to discuss the proposed changes; there were 24 atendees. The summary of the discussions that took place at that meeting and the VMD presentation are in our website:
http://www.vmd.gov.uk/publications/consultations/current.htm

8.3 In addition to the changes to the VMR, we have also consulted on amendments that we are proposing to the Misuse of Drugs Regulations 2001. We wish to implement three Shipman Inquiry recommendations regarding controlled drugs for veterinary use. Whilst these changes will be implemented by the Home Office, we felt it was appropriate to consult with our stakeholders on them.

8.4 A total of 28 responses were received to the formal consultation. Overall consultees were receptive to the changes proposed, subject to some minor changes. Evidence provided by the consultation exercise has been taken into account when preparing this final Impact Assessment.

9. Guidance

9.1 In line with Better Regulation best practice, we have produced revised guidance documents to take into account the changes to the legislation. There are 30 guidance notes.

10. Impact

10.1 The impact on business, charities or voluntary bodies are fully discussed in the Impact Assessment.

10.2 The impact on the public sector is negligible.

10.3 An Impact Assessment is attached to this memorandum.

11. Regulating small business

11.1 The legislation applies to small business.

11.2 To minimise the impact of the requirements on firms employing up to 20 people, the approach taken is to take into account turnover when calculating the graded annual fees.

11.3 The basis for the final decision on what action to take to assist small business is to continuously consult with our stakeholders on proposed legislative developments. The VMD feels that the proposed changes will not have a significant impact on small firms.

12. Monitoring & review

12.1 The VMRs are reviewed on an annual basis. This means that the changes accepted will come into force on 1 October 2009. The effects of the changes will be felt from that date onwards and will be reviewed for the VMR 2010, or during subsequent remakes of the legislation

13. Contact

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Annex 1 Implementation of EU legislation – Transposition note

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)	Regulation 3(2). Trials are also 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)	Schedule 2 paragraph 4 (3)
Article 50(d)	Regulations 34 and 35
Article 50(e)	Schedule 2 paragraph 8(2)
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)

Commission Directive 2009/9/EC

The VMRs 2009 implement Commission Directive 2009/9/EC amending Directive 2001/82 of the European Parliament and of the Council on the Community code relating to medicinal products for veterinary use (annex I).

In order to be placed on the European Community market, a veterinary medicinal product must be granted a marketing authorisation by a competent authority. For this purpose, an application dossier containing data relating to the results of tests and trials carried out on product must be submitted. The purpose of Annex I to Directive 2001/82/EC is to lay down detailed scientific and technical requirements regarding the authorisation of veterinary medicines. Annex 1 to directive 2001/82 has now been updated; it has been replaced as Commission Directive 2009/9 and must be implemented in national legislation. The changes to the annex are mainly to provide legal clarity to procedures and adjust the legislation to current practices. These two changes to the application process will allow the

pharmaceutical industry to react more promptly to address emerging risks to animal health, should the need arise.

Commission Regulation (EC) No 1234/2008

The requirements for the regulation of veterinary medicines are outlined in Directive 2001/82/EC as amended. This Directive sets out the procedures for obtaining an authorisation from a Member State and describes the various manufacturing and post-authorisation requirements for ensuring the continued safety and quality of the medicine once marketed. Veterinary medicinal products can be authorised via European or national procedures.

If the manufacturers of a veterinary medicinal product wish to introduce any changes to the product's authorisation they have to submit a variation application. The variation procedure differs depending on whether the product was authorised via a European procedure or the national procedure. This means that a company may have to comply with different procedures in each of those Member States, adding to the complexity of the procedure for industry and the administrative burden. The Variations Regulation 1234/2008 will harmonise the handling of variations to products authorised via the national or the European procedure; the aim is to streamline current procedures and reduce administrative burdens, in line with the objectives of Better Regulation.

The VMRs 2009 implement Commission Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products. Member States must apply the new Regulation 1234/08 to variations to marketing authorisations obtained through European Procedures (i.e. Mutually Recognition, Decentralised or Centralised) by 1 January 2010. However, for the purposes of variations to marketing authorisations granted under the national procedure the classifications in Commission Regulation (EC) No 1084/2003 will continue to be used.

Council Regulation (EC) No 470/09

The VMRs 2009 replace references to Council Regulation (EC) No 2377/90 on establishing maximum residue limits for pharmacologically active substances with Regulation (EC) 470/2009 of the European Parliament and of the Council (Regulation (EC). Regulation 470/2009 repeals and replaces Council Regulation (EC) No 2377/90 but the Annexes to Regulation 2377/90 are preserved pending the adoption of a Commission Regulation replacing them.

Summary: Intervention & Options		
Department /Agency: Veterinary Medicines Directorate	**Title:** Impact Assessment of the changes to the Veterinary Medicines Regulations 2008	
Stage: Final	**Version:** 1	**Date:** 5 August 2009
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 implement the requirements of EC Directive 2001/82 as amended by Directive 2004/28/EC and other EU legislation. They establish controls on the production, 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 Regulations are revised annually to incorporate necessary changes to the legislation, both clarifying existing policy and adding new provisions. The main points for 2009 are listed in the Evidence Base section of this report.

What are the policy objectives and the intended effects?

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 maintain the existing regulatory regime whilst transposing the requirements of Directive 2001/82/EC as amended and European legislation relating to Medicated Feeds and Feed Additives.

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

Policy options were considered for each problem identified by the regulators, taking into consideration comments received from stakeholders during consultation. The final options for each problem are considered in this Impact Assessment.

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. This means that the changes accepted will come into force on 1 October 2009. The effects of the changes will be felt from that date onwards and will be reviewed for the VMR 2010, or during subsequent remakes of the legislation.

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

On behalf of the Chief Economist, the Deputy Director for Food and Animal Health Economics has been consulted on this final stage Impact Assessment. He notes the main quantified benefits arise from efficiency savings at VMD being passed on and that the costs to industry, though difficult to quantify, are largely negligible. In terms of other costs, he notes that the IA confirms these changes (and especially: 1 - changed incentives of carriers of veterinary medicines; and 2 - a more flexible approval system requiring lower levels of efficacy) do not increase the risk of medicine misuse and therefore offer positive net benefits. He therefore approves the overall approach to the cost-benefit analysis and advises that, given the available evidence, the IA represents a reasonable view of the likely costs, benefits and impacts.

Summary: Analysis & Evidence	
Policy Option: 2	**Description: Amend the regulation**

COSTS

ANNUAL COSTS		Description and scale of **key monetised costs** by 'main affected groups' (i) Industry costs of new charges for WDICs (change 7):£3k p.a. (Views were sought from affected groups on additional costs during the consultation – please see Annex 1 Evidence Plan)
One-off (Transition)	**Yrs**	
£	1	
Average Annual Cost (excluding one-off)		
£ 3k	1	**Total Cost** (PV) **£ 3,000**

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

i) Potentially increased enforcement costs to Government from making tampering with prescriptions a criminal offence (Change 3); ii) increase in costs to pharmaceutical companies of

BENEFITS

ANNUAL BENEFITS		Description and scale of **key monetised benefits** by 'main affected groups' (i) Benefits to industry from not increasing inspection fees in line with inflation (change 4): £15k; (ii) Costs savings to industry from not charging for online repeat applications for SIC/STCs (change 5): £30k. (Views were sought from affected groups on additional costs during the consultation – please see Annex 1 Evidence Plan)
One-off	**Yrs**	
£ N/A	1	
Average Annual Benefit (excluding one-off)		
£ 45k	1	**Total Benefit** (PV) **£ 45,000**

Other **key non-monetised benefits** by 'main affected groups' A fairer system for carriers (change 1), greater product availability benefiting owners, vets, animals and pharmaceutical companies (change 2), greater control of prescription drugs (changes 3, 6 and MDR amendment), decreased admin burden for the industries resulting from the new processes to apply for variations (change

Key Assumptions/Sensitivities/Risks	As the VMRs are amended on an annual basis, the time period considered is one year only.

Price Base Year 2009	Time Period Years	**Net Benefit Range** (NPV) **£**	**NET BENEFIT** (NPV Best estimate) **£42,000**

What is the geographic coverage of the policy/option?			UK	
On what date will the policy be implemented?			1 October 2009	
Which organisation(s) will enforce the policy?			VMD, Defra	
What is the total annual cost of enforcement for these organisations?			£ Negligible	
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?				
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 £	Decrease of £	**Net Impact**	**£ Nil**

Key:	**Annual costs and benefits: Constant Prices**	**(Net) Present Value**

Evidence Base (for summary sheets)

1 Title of the proposal

Changes to the Veterinary Medicines Regulations 2008.

2 Purpose and intended effect

2.1 The Veterinary Medicines Regulations (VMR) implement the requirements of Directive 2001/82/EC, as amended by Directive 2004/28/EC. This Directive outlines the rules and requirements for the regulation of medicines for animal use. The VMR also implement the following Directive and Regulations relating to medicated feeds:

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- 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.

2.2 The VMR 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 50 amending Statutory Instruments (Sis). The VMR have been updated annually since 2005.

2.3 The annual cycle to revoke and remake the VMR allows the VMD to respond quickly to the demands of the veterinary sector and therefore to formulate fit-for-purpose legislation that is meaningful to stakeholders. We consulted stakeholders in an open meeting in June 2009 whether or not they wished the VMD to continue with the annual update of the VMR and there was a positive response to this question.

3 Consultation

3.1 A full public consultation on the draft VMRs 2009 took place between 5 May and 28 July 2009 and was preceded by informal consultation with key stakeholders.

3.2 This public consultation aimed to seek stakeholders' views on the costs and benefits that the proposed changes would impose on business. In addition, an open meeting was held on 9 June 2009 to offer further opportunity for stakeholders to discuss the proposed changes; there were 24 atendees. The summary of the discussions that took place at that meeting and the VMD presentation are in our website: http://www.vmd.gov.uk/publications/consultations/current.htm

3.3 In addition to the changes to the VMR, we have also consulted on amendments that we are proposing to the Misuse of Drugs Regulations 2001. We wish to implement the Shipman Inquiry recommendations for the supply, storage, record keeping and disposal of Controlled Drugs for veterinary use. Whilst these changes will be amended through Home Office Legislation, we felt it was appropriate to consult with our stakeholders on these changes, which are set out in Annex 4. We also held a meeting on 18 June 2009 with the Royal College of Veterinary Surgeons (RCVS), Royal Pharmaceutical Society for Great Britain (RPSBG) and the British Veterinary Association (BVA) to discuss the current controls on CDs in the veterinary sector, and to seek their opinion on the changes proposed.

3.4 A total of 28 responses were received. Overall consultees were receptive to the changes proposed, subject to some minor changes. Evidence provided by the consultation exercise has been taken into account when preparing this final Impact Assessment.

4 Summary of changes

4.1 The following new provisions will be introduced to the VMR 2009. They are discussed in detail elsewhere in this Impact Assessment:

1. Amendment to exempt seizure notices issued to common carriers from the requirement to publication (paragraphs 4.2.1 – 4.2.6);

2. Amendment to create a new type of authorisation (Limited Marketing Authorisation) (para. 4.3.1 – 4.3.18);

3. Amendment to make tampering with a prescription an offence (para. 4.4.1 – 4.4.7).

Fee amendments

4. Introduction of inflation-only fee increases to all application fees (para. 4.5.1 – 4.5.8);

5. Amendments to remove the fees for on line Special Import Certificates and repeat Special Treatment Certificates and Research Import Certificates (para. 4.6.1 – 4.6.14);

6. Introduction of a new fee for the annual renewal of wholesale dealer import certificates (para. 4.7.1 – 4.7.6);

7. Introduction of a new fee structure for variations to European marketing authorisations from 1 January 2010, necessary as a result of the adoption of Commission Regulation 1234/2008 (para. 4.8.1 – 4.8.10);

8. Transposition of Commission Directive 2009/9 (para 4.9.1-4.9.14)

Change 1: Amend Regulation to exempt common carriers from the requirement to publication of a Seizure Notice

4.2.1 Veterinary medicinal products are extensively transported within the country and also legally shipped between countries – but it is an offence to import or possess unauthorised veterinary medicinal products except in circumstances set in the VMR. The VMR give designated inspectors powers to seize unauthorised products and in this case a seizure notice is provided to the person from whom the product was seized. The VMD publishes all seizure notices issued on its website.

4.2.2 The current legislation requires that seizure notices given in relation to supply of unauthorised products are issued to those appearing to be in charge of the seized product. This leads to officers issuing seizure notices to common carriers e.g. couriers, who do not own the illegal goods. As the legislation also requires that the notice be made public, this implicates the carrier and can lead to subsequent reputational damage to them.

4.2.3 There were 39 instances of seizures from common carriers in 2007.

Consultation comments
4.2.4 Six consultees indicated that they were favourable to this change and one consultee requested no change to the legislation, on the basis that it is a duty of the carrier to implement some form of due diligence to prevent the carriage or importation of illegal goods.

Policy option
4.2.5 We will change the text of the VMR to exempt seizure notices issued to common carriers from the requirement to publish. Not implementing this change would lead to common carriers being issued with seizure notices even though they have no knowledge that they are transporting unauthorised goods.

Costs and benefits
4.2.6 The main stakeholders involved are carriers. There are no estimated costs to carriers, resulting from the implementation of this policy change; the benefit is that carriers will not be penalised for offences that they have not committed and their reputation will not be damaged.
The couriers still have the obligation to take all possible measures to ensure themselves of the legality of the materials they carry and the VMD will still investigate any incidents of carriers caught carrying unauthorised products.

Change 2 Proposal to introduce procedures for a Limited Marketing Authorisation (LMA)

4.3.1 A veterinary medicinal product must be the subject of a valid UK marketing authorisation (MA) in order to be legally placed on the market. Directive 2001/82 allows exceptions to this rule where there is a disease control requirement.
The current VMRs allow the VMD to issue a Provisional Marketing Authorisation (PMA) when there are no suitable medicines available to treat a particular disease or to treat a new disease in the UK. This authorisation allows a product to be placed on the market in specific and restricted circumstances, where the data show the safe use of the product but without all the comprehensive data on therapeutic effects (efficacy data) which are normally required for an MA. There are currently 10 products authorised in the UK through the PMA procedure. In 2008 there were 5 applications for PMAs (immunologicals). On average, the cost of a PMA application was £12 000 per application.

4.3.2 An application for a PMA has to be assessed and determined (issued or refused) within a maximum of 210 clock days of receipt of the application. The cost for the VMD for processing PMA applications is dependent on several factors, for example the number of species and indications covered within the application and the fees charged aim to recover these costs. A fees menu system is available on the VMD website (link: http//www.opsi.gov.uk/si/si2008/uksi_20082297_en_24) and is used to calculate the fees.

4.3.3 The current scheme states that a PMA is only valid for one year. If the exceptional circumstances persist, a renewal of the authorisation can be obtained but it is dependent on compliance with the conditions of the authorisation, on the results of suspected adverse reaction reports and on any additional data submitted. If a full MA is issued for a product effective against the disease then the PMA will not be renewed. It is expected that the pharmaceutical company responsible for the PMA will provide sufficient data in subsequent years to upgrade the PMA into a full MA.

4.3.4 The VMD has carried out an informal consultation on whether the current scheme is effective in providing suitable products to treat animals in exceptional circumstances in the UK.

4.3.5 The results of this informal consultation suggested that stakeholders would like to see a wider use of PMAs in the UK, in particular to increase the availability of products for minor use/minor species markets (such as products for ferrets or goats). The lack of availability of products to these minor markets is due to market forces (low levels of commercial return). A discussion on the informal consultation can be seen by following the link:
(http://www.vmd.gov.uk/publications/consultations/PMA.pdf)

4.3.6 The VMD accepted these comments and is now proposing a change to the current PMA scheme (which has been re-named Exceptional Marketing Authorisation). We are widening its scope. There will be 2 types of Exceptional Marketing Authorisations:

4.3.7 Provisional Marketing Authorisations – these will follow the current system. The authorisations will cover situations where there is no fully authorised veterinary medicine in the UK available to prevent or treat a particular condition. These authorisations will be issued whilst a company continues to generate the full supporting data required to obtain a full MA. PMAs are usually applied for and issued in order to address an urgent situation, for example as a result of a new disease e.g. Bluetongue, or because the nature of an existing disease has changed. These authorisations are intended to exist only in the short term and are expired when a full MA is issued.

4.3.8 Limited Marketing Authorisations (LMA) – this will be a new procedure. These authorisations are intended to be used in the case of veterinary medicines which, by the nature of the indicated species or the nature of the condition they are preventing or treating, are not expected to be sold in large quantities – so called limited market products.

4.3.9 We feel that this new type of authorisation is needed because, as a result of the costs involved in generating complete data packages, and the anticipated low level of returns on the sales of such products, pharmaceutical companies are not prepared to generate complete data packages for limited market products. Therefore, minor species such as ducks or goats, for example, are currently treated off label with products developed for major species. No specific safety or efficacy data are available and therefore veterinarians cannot provide firm advice on safety issues or on the correct dosage for the animal. LMAs are intended to help fill existing therapeutic gaps in the UK.

4.3.10 Whilst still providing sufficient quality, safety and efficacy data to the product to maintain safety to the animal, the consumer, the use and the environment, there will be no compulsory requirement to upgrade the product into a full MA. However, should a company wish to generate the necessary data and apply to convert a LMA to a full MA they may do so. It is expected that an application for a LMA would take the same time to process as a PMA.

4.3.11 On the anniversary of issue, Exceptional Marketing Authorisations will be the subject of annual reassessment triggered and performed by the VMD. In the case of LMAs, companies will only be required to submit renewal applications where this is specified as a condition of the authorisation. It is envisaged that in some cases renewal applications will not be required.

Consultation comments

4.3.12 We have received 7 comments on this proposal and they were all favourable. Consultees indicated that LMAs will encourage manufacturers to register products that otherwise may not be viable in commercial terms. One consultee in particular indicated that they do not envisage any cost implications for veterinary surgeons but foresee many benefits.

Policy option

4.3.13 The legislation will be amended to create a new type of authorisation, LMA, with reduced data requirements to encourage companies to develop products for use in minor markets. We aim to improve the availability of veterinary medicines in the UK, with an appropriate level of control which is beneficial to the end users – if more products are legally available to users, it is less likely that they will treat animals with unauthorised products that may potentially have a detrimental effect on the animal, on the user and on the environment.

Costs and benefits

4.3.14 We expect that the costs associated with the introduction of this new option to authorise products in the UK will be negligible because pharmaceutical companies already deal with PMA applications - they will simply need to adapt their systems to be able to apply for LMAs as well. We have not received any indication from the consultation that any additional costs are expected in relation to the creation of LMAs.

4.3.15 The costs for the VMD for dealing with LMAs will be the same as for PMAs. It is difficult to forecast the volume of LMA applications that the VMD is likely to receive in the next years, but as a full cost recovery agency we will be required to recover the costs of dealing with these applications.

4.3.16 It is highlighted that the existing PMA scheme will remain as it is, that is, PMAs will only be issued under exceptional circumstances when a full authorisation is not supported by the available data. The PMA will be valid for one year, with an annual renewal based on the submission of suitable data supporting the continued need for the product in the UK. We do not intend to increase fees for PMA applications.

4.3.17 Products authorised under the LMA scheme will still be assessed by the VMD for quality, safety and efficacy. This means that the VMD will still ensure that their quality is adequate, and that the products will not harm treated animals and the operators. Assessors will also check that measures are in place to ensure that the environment will not be damaged. For products for food-producing species, active substances must comply with residues legislation so that consumer safety is guaranteed. However, for products authorised under the LMA scheme a reduced efficacy package could be accepted and there will be no compulsory requirement to upgrade the authorisation to a full MA as it is the case within the current system. It is expected that the use of products authorised under the LMA scheme will decrease the need for use of unauthorised products that may present safety risks to the animal, the user or the environment. Veterinarians, pet owners and farmers will benefit from the creation of the LMA, as it will increase the availability of products to the end user. This was confirmed by the positive responses received during consultation.

4.3.18 Pharmaceutical companies will also benefit from a more flexible scheme that will allow them to launch new products in the UK (for example medicines for rabbits or bees).

Change 3 Changes to make tampering prescriptions an offence

4.4.1 We have been contacted by veterinarians and pharmacists on at least 10 occasions reporting scripts that have been tampered with or that have been re-submitted. Reports of prescription tampering involve clients altering the quantities of the prescribed veterinary medicinal product. We have also received reports of animal owners offering to 'lend' prescriptions to one another.

4.4.2 Whilst we do not have an accurate idea of the scale of the problem, we believe that the problem is wider than current evidence suggests. It is possible that veterinarians do not report tampering with prescriptions to us because they know that this is not currently an offence under the VMR. Additionally not all instances of tampering will be noticed by those who dispense the products. We consider that a criminal offence should be created in the VMR to allow us to prosecute those who illegally tamper with prescriptions to obtain these medicines.

Consultation comments

4.4.3 There were 9 comments on this change. The overall response supported the creation of an offence for tampering with prescriptions under the VMRs; and indeed some consultees requested additional regulation on mail order dispensing of prescription medicines as a means to improve this problem. One consultee questioned the need for this change and one consultee was against it; in both cases the consultees felt that there are already sufficient penalties available to deal with fraudulent prescriptions.

Policy option

4.4.4 Tampering with a prescription leads to unauthorised and therefore potentially unsafe use of veterinary medicinal products. The amendment proposed is to change the legislation to make tampering with a prescription a criminal offence; this will enable enforcement action, including prosecution, to be taken by the VMD.

Costs and benefits

4.4.5 We expect that the change proposed will not lead to any additional costs to the industry. We have not received any indication from the consultation exercise on possible monetised costs or benefits of making it a legal offence to tamper with prescriptions.

4.4.6 However, the change will create a new criminal offence which will require enforcement action by the VMD. This will probably either result in a loss of man-hours from other enforcement issues or may require the employment of more inspectors, depending on the scale of the problem. It is difficult to assess the magnitude of the issue and hence the size of enforcement action that will be required. It has been assumed, for cost calculation purposes, that these costs will be negligible.

4.4.7 The potential benefits of the change to the legislation are that, in the event of a prescription being forged, enforcement officers will be able to bring a prosecution and seize veterinary medicinal products that have been obtained illegally. Also, knowing that altering with the script is a criminal offence is likely to deter people from doing so, thus reducing the potential for the unsafe use of prescription drugs in this context.

FEE AMENDMENTS:

Change 4 Introduction of inflation-only fee increases to all application fees.

4.5.1 HM Treasury's latest "GDP Deflator" figures predict general inflation of 1.5% for 2009/10. To ensure that the VMD fully recovers the costs of its work done under the Regulations, it is necessary to introduce a general increase of 1.5% to all application fees. Application fees were last increased in October 2007, when a 2.5% general inflation increase was applied.

4.5.2 The 1.5% increase will not be applied to inspection fees as the VMD anticipates efficiency savings as a result of a review of how inspections are performed. These efficiency gains are expected to cancel the effect of inflation on inspection costs in 2009/10.

4.5.3 We propose to amend the inspection frequencies for manufacturers of autogenous vaccines and special products administered under the cascade, blood banks, and for equine stem cell centres to reflect the level of risk identified at previous inspections. However, we do not propose to change the fees schedule for these inspections this year as the operational plan needed to determine the frequency of inspections on a risk basis has not been completed yet.

Consultation comments

4.5.4 We have received no comments about this change.

Policy option

4.5.5 The current policy is to increase fees in line with inflation on an annual basis. If the existing fees continued to apply then the VMD would under-recover the costs of application-related work performed under the Regulations. As the VMD is a net-running cost controlled agency with a target of 100% cost recovery, this is not viable. On the other hand increasing all fees in line with inflation could lead to over-recovery of costs due to efficiency gains associated with the introduction of risk-based inspections.

4.5.6 We will therefore amend the legislation to only increase application fees, keeping inspection fees constant. This will avoid under-recovering the costs of application-related work and possibly over-recovering the costs of inspection based work.

Costs and benefits

4.5.7 The total increased cost to industry of a 1.5% application fee increase is estimated to be £20,000 per year. Considering the size of the pharmaceutical veterinary industry, this will have a negligible impact on individual applicants. However it is important to note that such an increase reflects current policy and hence is not included in the overall estimates of costs to industry.

4.5.8 The VMD will not increase the fees to cover the inflation for inspections, the effect of which would have been a cost of £15,000 per year to the industry. As the current policy is to increase fees in line with inflation, this change in policy would lead to benefits of £15,000 per year to the industry.

Change 5 Removal of fees for on-line Special Import Certificates and Repeat Special Treatment Certificates applications, and Research Import Certificates

4.6.1 Where there is no suitable authorised product in the UK to treat a particular condition and when the health situation so requires, a veterinary surgeon may apply for an import certificate to obtain a veterinary medicinal product authorised either in another EU Member State (Special Import Certificate or "SIC") or outside the EU (Special Treatment Certificate or "STC").

4.6.2 Where a product or substance is required for use in research performed under an Animal (Scientific Procedure) Act (A(SP)A) Licence, the appropriate project licence holder may apply, on-line, for a Research Import Certificate ("RIC") to import that product or substance.

4.6.3 A total of 2631 SICs and 4605 STCs applications were determined in 2008. From 31/12/07 to 01/01/09, only 9 RICs were issued.

4.6.4 To speed-up the process of applying for and obtaining these certificates the VMD introduced an on-line web-based service in April 2007. Approximately 60% of SIC applications are now made on-line. Fewer STC repeats are currently progressed on-line.

4.6.5 The current cost for an RIC, on-line SIC or on-line STC repeat application is £15. However enhancements to the on-line system have resulted in efficiency savings that now make the charging of a fee unnecessary.

4.6.6 Rather than wait for the next changes to the Veterinary Medicines Regulations in October 2009, the VMD have waived the £15 fee for all on-line applications, including those for SICs, repeat STCs and for RICs, made on or after 1 November 2008.

4.6.7 It will remain possible to obtain SICs and repeat STCs from the VMD by post, but it is necessary to charge a fee for the additional administration that this requires.

4.6.8 Paper based applications continue to be a requirement where an SIC is requested for a product for the first time and for new and renewed STCs; these applications are examined by VMD scientists and fees are required to recover the cost of this work.

4.6.9 The fees for paper based applications will continue to be £15 for SICs and RICs and £30 for STCs.

Consultation comments
None received.

Policy option

4.6.10 The viable option is to implement this change**:** if the exiting fees continue to apply then the VMD risks over-recovering the costs of administering SICs, STCs and RICs. The VMD is a net-running cost controlled agency with a target of 100% cost recovery.

4.6.11Therefore we will remove the fees for on-line applications for SICs, repeat STCs and RICs the VMD will avoid over-recovering the costs of administering SICs, STCs and RICs.

Costs and benefits

4.6.12 There are no expected costs.

4.6.13 As a result of waiving the fees for on line SIC applications and repeat STC applications from November 2008, we have already passed savings to veterinarians in the region of £12,000 from that date to March 2009. We anticipate that annual savings of around £30,000 for veterinarians applying on line for SICs and repeat STCs, assuming that the volume of these applications will remain the same. This figure may be a conservative estimate as it is possible that the volume of on-line applications will increase as a consequence of the proposed change.

4.6.14 The number of applications that we receive annually for RICs is very small. Applications for this type of import certificate are always made on-line and the estimated total annual savings for project licence holders applying for them, based on our records for 2008, will be negligible (£150).

Change 6 Introduce a fee for the annual renewal of Wholesale Dealer Import Certificates (WDIC)

4.7.1 The SIC and STC systems permit a veterinary surgeon to import veterinary medicinal products authorised elsewhere into the UK to treat an animal or group of animals (for example, a herd) under his/her care. To facilitate this wholesale dealers are permitted to import a batch of the product and hold it before distribution to veterinarians. In this case, the wholesale dealer must apply for a WDIC, which will allow the importer of a veterinary medicinal product to hold and supply it to the holder of a valid SIC or STC. This has advantages in terms of animal health, as in case of an urgent need for the product the veterinarian can obtain it from the wholesale dealer at short notice.

4.7.2 At the moment we do not charge for the WDIC applications but wish to introduce an annual renewal fee of £750 per product imported. It is necessary to introduce this fee to cover the cost of work involved in the pharmacovigilance activities that are required for products imported from the EU and Third countries under the import schemes. The products involved are not subject to the Graded or Fixed Annual Fees that apply to all UK Marketing Authorisations. The VMD does however have to record and follow-up as appropriate any adverse events that occur in the UK and are reported to the VMD for these imported products.

Consultation comments

4.7.3 A consultee requested the non-implementation of this proposal, on the basis that this would deter the importation of niche products, which could compromise animal health and welfare. We have received no comments from wholesale dealers**.**

Policy option

4.7.4 The viable option is to create a fee to cover WDIC applications as the VMD is a net-controlled agency with a target of 100% cost recovery.

Costs and benefits

4.7.5 We estimate that the costs for wholesale dealers paying for the annual renewal of WDICs from 1 October 2009 will be around £3,000 per year, if the volume of WDIC applications and import certificates remain the same as in 2008. We have not received any response from this sector on the change proposed.

4.7.5 If the VMD does not introduce this fee then we will not be able to recover the costs of work involved in the pharmacovigilance activities. This work is required for products imported from the EU and Third countries under the import schemes and is essential to monitor their safety.

4.7.6 To ensure that this fee does not prohibit the importation of products for niche markets, the above fee will not apply when the number of import certificates issued in the 12 months prior to the annual renewal, for the relevant product from the relevant wholesalers, is 100 or less. The VMD is a cost-recovery agency and reviews their fees annually: any over-recovery will be re-passed to the Industry in a subsequent change to legislation.

Change 7 Introduction of a new fee structure for variations to European marketing authorisations from 1 January 2010

4.8.1 The rules and requirements for the regulation of medicines for veterinary use are outlined in Directive 2001/82/EC as amended. This Directive sets out the procedures for obtaining an authorisation from a Member State and describes the various manufacturing and post-authorisation requirements for ensuring the continued safety and quality of the medicine once marketed. Veterinary medicinal products can be authorised via European or national procedures.

4.8.2 If the manufacturers of a veterinary medicinal product wish to introduce any changes to the product's authorisation, due to technological progress or new scientific data or even to introduce simple administrative changes such as change of manufacturing address, they have to submit a variation application. The variation procedure differs depending on whether the product was authorised via a European procedure or the national procedure. This means that a company wanting to change an aspect of a medicine authorised nationally in a number of EU Member States may have to comply with different procedures in each of those Member States, adding to the complexity of the procedure for industry and the administrative burden. The Variations Regulation 1234/2008 (OJ No L 334, 12.12.2008, p. 7) will harmonise the handling of variations to products authorised via the national or the European procedure (for both veterinary and human medicinal products); the aim is to streamline current procedures and reduce administrative burdens, in line with the objectives of Better Regulation.

4.8.3 Commission Regulation 1084/03 concerning granting of variations to the terms of a marketing authorisation granted by a competent authority of a Member State is currently in force and will be superseded by Regulation 1234/08. Member States must apply the new Regulation 1234/08 to variations to marketing authorisations obtained through European Procedures (i.e. Mutually Recognition, Decentralised or Centralised) by 1 January 2010. However, for the purposes of variations to marketing authorisations granted under the national procedure the classifications in Commission Regulation (EC) No 1084/2003 will continue to be used.

4.8.4 The Commission will extend the scope of this Regulation to include marketing authorisations issued on a national only basis. This requires an amendment to Directive 2001/82/EC. Work has begun at Commission level but this has yet to be finalised. This change will have an implementation date of 18 months following publication of the amendment in the Official Journal. It is not yet known when this will be published but it is expected that it will be in the Spring of 2009, and therefore changes concerning national authorisations will have to be implemented in Autumn 2010 (and therefore will be included in the next round of VMRs, coming into force in 1 October 2010 – VMRs 2010).

4.8.5 The existing fee structure for variations to Marketing Authorisation obtained through European Procedures is designed to recover the costs of application-related work performed according to the requirements of Directive 2001/82/EC. It will be necessary to introduce a revised fee structure from 1 January 2010 in order to adequately recover the cost of application-related work performed according to the requirements of Regulation 1234/2008, on variations to marketing authorisations granted under the European procedure. The fee structure for products authorised via the national procedure will be reviewed in a future consultation, when Regulation 1234/08 becomes applicable to national variations.

4.8.6. The main changes to the variations are outlined in an information sheet prepared by the VMD (http://www.vmd.gov.uk/General/AppsPage/Variations_information.pdf). This paper also explains the principles of the Variations Regulations. In summary, these are:

- Common variations will have a classification and this will be specified. Nevertheless it will not be possible to cover all eventualities from the outset and therefore, if a variation has not been specified, the industry or National Competent Authorities can submit a request to the EMEA or to the CMDv asking for a recommendation on how it should be classified.

- If a variation has not been specified in the classification guideline, the default will be moved from that variation being considered automatically as a Type II variation to it being a Type IB.

- Type II variations will be listed in the classification guideline.

- It will be possible to submit one single application for a number of changes relating to the same marketing authorisation.

- It will be possible to submit a single work-sharing application which covers one or more changes to a number of products, authorised on an EU basis. If one product has been authorised using the centralised procedure, the EMEA will take the lead. In other cases where products involve more than one Member State the CMDv will co-ordinate the procedure (once the scope of the Regulation has been expanded, work-sharing could also include nationally authorised products).

- It will be possible to implement a number of minor changes, Type IA, where the change has no requirement for immediate notification. Notification may be made on an annual basis. Only one annual application will need to be submitted and this can cover a number of changes to a number of products.

4.8.5 The VMD has consulted last year on the European Commission's proposal, together with the MHRA (http://www.vmd.gov.uk/publications/consultations/CIONletter.pdf). This consultation aimed to estimate the overall impact of this change on stakeholders. The figures obtained were hypothetical and based on the data for the human sector, as we could not obtain concrete estimates for the veterinary sector. We hope that the current consultation, on the practical implementation of this change and taking into consideration a revised fee schedule, will help to provide more accurate data on costs and benefits for the industry.

Consultation comments

4.8.6 We have received no comments about this change.

Policy option

4.8.7 The VMD has an obligation to implement Commission Regulation 1234/08, concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products. We are a net-running cost controlled agency with a target of 100% cost recovery, and amending the national legislation to introduce fee changes will ensure that the agency recovers the costs of its work on variation applications.

Costs and benefits

4.8.8 We have already consulted on the implementation of the Variations Regulations (http://www.vmd.gov.uk/publications/consultations/IA.pdf). Please refer to that document for detailed information on the IA. Neither that consultation, on the implementation of the variations regulations, nor the present one has led to the VMD receiving with any monetised estimates of possible costs or benefits from implementing the changes to the variations procedures.

4.8.9 Based on the human sector, the best estimate one-off administrative cost to companies to set up systems to deal with the new way of dealing with applications for variations was around £0.45m with annual savings ranging from £0 to £2.7m. These figures were estimated in a previous consultation (http:www.vmd.gov.uk/publications/consultations/CIONletter.pdf) and are not included in the summary table to this IA.

4.8.10 For the purpose of this IA, the amendment of the fee structure for variations to European Marketing Authorisations is a radical departure from current practice. In particular it is envisaged that the possibility of grouping variations, for example, and the other changes could lead to substantial reductions in the costs of variations to pharmaceutical companies. However, we could not obtain information from the consultation as to the number of applications that will benefit from the changes introduced by the new Regulations. The total income from European variation fees in 2008/09 was approximately £0.4m.

Change 8: Transposition of Commission Directive 2009/9

4.9.1 In order to be placed on the European Community market, a veterinary medicinal product must be granted a marketing authorisation by a competent authority. For this purpose, an application dossier containing particulars and documents relating to the results of tests and trials carried out on the veterinary medicinal product must be submitted.

4.9.2 The purpose of Annex I to Directive 2001/82/EC is to lay down detailed scientific and technical requirements regarding the testing of veterinary medicinal products against which the quality, safety and efficacy of the veterinary medicinal product should be assessed. It also gives instructions concerning the presentation and content of the application dossier.

4.9.3 Annex 1 to directive 2001/82 has now been updated; it has been replaced as Commission Directive 2009/9 and must be implemented in national legislation.

4.9.4 The changes to the annex are mainly to provide legal clarity to procedures and adjust the legislation to current practices, with the exception of two points:

- introduction of the concept of a vaccine antigen master file, a stand-alone part of the marketing authorisation application dossier for a vaccine, which contains all relevant information on quality of the active ingredients. This stand-alone part may be common to one or more monovalent and/or combined vaccines presented by the same applicant or marketing authorisation holder;

- introduction of the concept of a multi-strain dossier for some vaccine applications (i.e. foot and mouth disease, avian influenza and bluetongue).

4.9.5 These two changes to the application process will allow the pharmaceutical industry to react more promptly to address emerging risks to animal health, should the need arise. These are optional changes.

Consultation comments

4.9.11 One consultee commented on this change, indicating that any changes that facilitate the rapid response to emerging risks to animal health are desirable. No monetised information on cost or benefits was provided.

Policy option

4.9.12 The VMD has a legal obligation to implement Commission Directive 2009/9, amending Directive 2001/82 of the European Parliament and of the Council on the Community code relating to medicinal products for veterinary use.

Costs and benefits

4.9.13 The main stakeholders involved are pharmaceutical companies. The pharmaceutical industry already works to the principles of the amended annex 1 (with the minor exception of antigen master files and multi-strain dossiers) and we estimate that there will be no negative impact on the industry as a consequence of the changes.

4.9.14 The amendment of annex 1 is not likely to lead to significant benefits to the pharmaceutical industry as the industry is already working to the principles of the new legislation. However, the introduction of the concepts of a vaccine antigen master file and a multi-strain dossier for some vaccines will give the pharmaceutical industry the opportunity to react promptly to threats of infectious diseases in animals, with a positive impact to animal health and also allowing companies to bring products to the marketplace earlier so allowing them to collect returns on their investment at an earlier time. The consultation response, albeit limited, corroborated this.

5 Consultation on veterinary controlled drugs under the Misuse of Drugs Regulations 2001

5.1 Controlled drugs are defined in the Misuse of Drugs Regulations (MDR) 2001. They are dangerous substances such as ketamine, morphine, pethidine, that can kill either intentionally or unintentionally or may be used inappropriately by people for recreational purposes. These medicines are widely and routinely used in veterinary medicine, as well in human medicine. Therefore, veterinary surgeons have a responsibility to ensure that these medicines are stored, supplied, dispensed and destroyed safely.

5.2 The Misuse of Drugs Legislation is under the Home Office's remit as they are the UK competent authority for controlled substances. The Shipman Inquiry made a number of recommendations designed to strengthen the controls on the monitoring and inspection, prescribing and audit trail of controlled drugs. These recommendations have not been implemented yet in the Misuse of Drugs Legislation.

5.3 The VMD consulted on 3 Shipman's recommendations in relation to use of controlled drugs in the veterinary sector. These changes were also discussed with the Advisory Council on the Misuse of Drugs and the Home Office, the RCVS, the BVA and the RPSGB.

5.4 The changes specific to the veterinary sector are:

1. Inspections (Shipman Recommendation No. 1)

   As of April 2009, all veterinary practice premises must be registered with the Royal College of Veterinary Surgeons (RCVS) and inspected. Currently, there are no structured arrangements for inspecting veterinary surgeons for compliance with controlled drugs legislation. Registered veterinary practice premises will be inspected for compliance with the VMR by the Animal Medicines Inspectorate (AMI – part of the VMD inspectorate) or RCVS Practice Standards Scheme Inspectors and the AMI will carry out enforcement visits as required. It would be sensible to give the AMI inspectors powers to inspect compliance with the misuse of drugs legislation to avoid additional inspections and costs for the veterinary profession. Our proposal is that these inspectors are permitted to require veterinary surgeon or practitioners to furnish information to them with respect to controlled drugs pursuant to Regulation 26 of MDR.

2. Witnessing of Destruction (Shipman Recommendation No. 1)

   Under Regulation 27 of the MDR, those required to maintain a Controlled Drugs Register are not allowed to destroy Schedules 1 - 4 controlled drugs without the destruction being witnessed by a person authorised by the Secretary of State (although this does not prevent veterinary practitioners and surgeons destroying drugs returned to them for destruction without a witness where they have been supplied on prescription). For veterinarians these will be predominantly Schedule 2 controlled drugs. Currently, the authorities issued by the Secretaries of State for Health and the Home Office (to those including Inspectors of the Royal Pharmaceutical Society of Great Britain, Compliance Officers of the Drugs Licensing and Compliance Unit at the Home Office and police constables) are not related to the veterinary sector. This has made it difficult for veterinary surgeons to dispose of surplus or out-of-date controlled drugs and has led to a build-up of these medicines in some veterinary practices.

   The resources that are available in the human healthcare setting which have enabled a significant increase in the number of persons that are authorised to witness destruction are not available in veterinary setting. We, therefore, wish that the Secretary of State use their powers under the Misuse of Drugs Act 1971 to authorise a veterinary surgeon or veterinary practitioner who is independent of the practice concerned, an Inspector authorised under the VMR and a RCVS Practice Standards Scheme Inspector to witness destruction. "Independent of the practice" will specifically exclude locums who have or are acting in the practice.

3. RCVS Registration Number (Shipman Recommendation No. 11)

We propose that the veterinary surgeon's name and RCVS registration number should be included on each written prescription for a veterinary controlled drug, to improve the traceability of the controlled drugs. This will require an amendment to the Misuse of Drugs Regulations 2001.

Consultation comments

5.5 We received 4 comments on this change. Overall the comments from consultee and interested professional bodies supported the proposals and requested further controls on the prescription and supply of controlled drugs. There was a concern that the witness of destruction of controlled drugs might incur in extra costs to veterinary surgeons.

Policy option

5.6 The option is to implement the changes proposed:

- To permit VMD and RCVS Practice Standards Scheme inspectors to require veterinary surgeons or practitioners in veterinary practice premises to furnish information to them with respect to controlled drugs;

- To authorise a veterinary surgeon or veterinary practitioner who is independent of the practice concerned, a VMD or a RCVS Practice Standards Scheme inspector to witness destruction of controlled drugs;

- To amend the Misuse of Drugs Regulations 2001 so that they require that the veterinary surgeon's name and RCVS registration number be included on each written prescription for a veterinary controlled drug.

Costs and benefits

5.7 It is recognised that the veterinary sector needs to be better regulated regarding the supply, storage and disposal of controlled drugs.

5.8 The changes discussed above, regarding allowing VMD and RCVS inspectors to request information on supply, storage and destruction of controlled drugs, and to act as a witness for the destruction of controlled drugs, represent an expansion to the current inspection regime in the veterinary sector. This expansion is not considered to represent a new cost to veterinary practices because it will be part of the inspection of veterinary practice premises, which has commenced from 1 April 2009.

5.9 A consultee expressed concern that the requirement for a witness to be present for destruction of controlled drugs may represent an additional burden to the veterinary profession. However, this legislative requirement already exists under the Misuse of Drugs Regulations. The change to allow a veterinary surgeon or veterinary practitioner who is independent of the practice concerned, a VMD or a RCVS Practice Standards Scheme inspector to witness destruction of controlled drugs simply offers alternative arrangements for legislative compliance, tailored to the veterinary sector.

5.10 The amendment to require that the veterinary surgeon's name and RCVS registration number be included on each written prescription for a veterinary controlled drug will need to be implemented in the Misuse of Drugs Regulations. We feel that these new requirements do not bring additional costs to stakeholders affected by this change. No perceived costs have been highlighted in the consultation exercise.

5.11 Regarding benefits, all the changes proposed refer to controls on the storage, supply, use and disposal of veterinary controlled drugs in line with the Shipman Inquiry recommendations. We aim to

improve compliance with the Misuse of Drugs Regulations and provide better controls on the way veterinary surgeons handle controlled drugs, thus ensuring its safe use and disposal, and minimising the risks that these substances can be diverted and misused.

5.12 In addition to the changes proposed we are also creating a specific guidance note on veterinary controlled drugs (VMG Note 29), which is available on the VMD website www.vmd.gov.uk.

The guidance note will also include 2 requirements, as good practice, which resulted from the Shipman Inquiry:

- controlled drugs in Schedules 2-4 to be prescribed only in amounts needed to treat an animal for up to 28 days (Shipman Recommendation 14).

- to make it the responsibility of the prescribing veterinary surgeon to make every effort to recover and destroy any remaining product if the animal dies before completing a treatment. The veterinarian must record the return in the controlled drugs register and arrange for the destruction to be witnessed and verified by an independent person in accordance with the MDR. (Shipman Recommendation 31).

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
Amendment to exempt carriers from the requirement to publish a seizure notice	Commercial carriers	Commercial carriers	Fairer system. *	None.*
Amendment to create a new type of authorisation (Limited Marketing Authorisation)	Pharmaceutical industry (veterinary)	Pharmaceutical industry (veterinary), pet owners, farmers, vets	To improve the availability of medicines for limited markets. *	Negligible.*
Amendment to make tampering with a prescription an offence	Pet owners, farmers	Veterinarians, pet owners, farmers, pharmacists, SQPs	To minimise the risks of use of incorrect and potentially dangerous medicines in animals. *	Negligible.*
Introduction of inflation-only fee increases to all application fees	Pharmaceutical industry	Veterinarians, pet owners, farmers, pharmacists, SQPs	Savings = £ 15,000	None (application costs increased in line with inflation)
Removal of fees for on-line Special Import Certificates and Repeat Special Treatment Certificates applications, and Research Import Certificates	Veterinarians	Veterinarians, pet owners, farmers	Savings = £ 30,000	None
Introduction of a new fee for annual renewal of wholesale dealer import certificates	Wholesale dealers	Pet owners, farmers	Continued control on products imported for use under the cascade.	£ 3000
Introduction of a new fee structure for variations to European marketing authorisations from 1 January	Pharmaceutical industry (veterinary)	Pharmaceutical industry	Implementation of European legislation. The aim is to simplify the handling of variations for	Costs: 0.45 m*[#]

2010			veterinary medicinal products. Savings: 0-2.7 m* [#]	
Transposition of Commission Directive 2009/9	Pharmaceutical industry (veterinary)	Pharmaceutical industry (veterinary), pet owners, farmers, vets	Rapid response to possible threats to animal health.	Negligible.
Amendment to the Misuse of Drugs Regulation 2001	Veterinarians, pharmacists, wholesale dealers	Veterinarians, pharmacists, wholesale dealers, pet owners, farmers	To improve traceability of controlled drugs used in veterinary medicine. *	None.

* We hoped to be able to monetise costs and benefits for these changes but stakeholders were unable to provide us with any further information to that effect.

[#] These figures were estimated in a previous consultation (http:www.vmd.gov.uk/publications/consultations/CIONletter.pdf) and are not included in the summary table to this IA.

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	No	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 – Gathering of further information

There was considerable uncertainty about the costs and the benefits of many of the policies proposed by this IA. A key objective of the consultation process is to gather more information on the costs and benefits of the proposed policy options and we hoped that stakeholders would provide the necessary information by responding to the questions posed during consultation (listed below).

Despite our efforts no information on monetised costs and benefits to that effect was forthcoming. Information on non-monetised costs and benefits is discussed under the Evidence Based section of this Impact Assessment.

1 Amendment to exempt seizure notices issued to common carriers from the requirement to publication

Should the legislation be changed to remove the publication requirement of seizure notices issued to common carriers who are not the owners of unauthorised veterinary medicines?

What are the costs or benefits that this change to the legislation will present to your business, directly or indirectly?

2 Amendment to create a new type of authorisation (Limited Marketing Authorisation)

We propose to introduce Limited Marketing Authorisations for veterinary medicines which, by the nature of the indicated species or the nature of the condition they are preventing or treating, are not expected to be sold in vast quantities – so called limited market products (please see VMG 5 for further details on the proposed scheme). What is your opinion about this new type of authorisation?

What are the costs or benefits that this change to the legislation will present to your business, directly or indirectly?

3 Amendment to make tampering with a prescription an offence

Should tampering with prescription be made a criminal offence under the VMR?

What are the costs or benefits that this change to the legislation will present to your business, directly or indirectly?

4 Introduction of inflation-only fee increases to all application fees

What are the costs or benefits that this change to the legislation will present to your business, directly or indirectly?

5 Introduction of a new fee for wholesale dealer import certificates

What are the costs or benefits that this change to the legislation will present to your business, directly or indirectly?

6 Introduction of a new fee structure for variations to European marketing authorisations from 1 January 2010, necessary as a result of the adoption of Commission Regulation 1234/2008

What are the costs or benefits that the change to the fee structure for variations for European marketing authorisations will present to your business, directly or indirectly, including any likely administrative costs associated with implementing the measures?

7 Transposition of Commission Directive 2009/9

What are the costs or benefits that this change to the legislation will present to your business, directly or indirectly?

Amendment to implement the Shipman Inquiry recommendations specific to veterinary medicine (inspections, witnessing of destruction, inclusion of veterinary surgeon's name and RCVS number on written prescription)

Are the changes proposed to implement the Shipman Inquiry recommendations practical?

What are the costs or benefits that this change to the legislation will present to your business, directly or indirectly? In particular regarding the requirement for the veterinary surgeon to add his/her name and RCVS registration number to each written prescription, do you estimate that this will represent any additional cost to your practice?

Annex 2

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 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 £480 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.

It is possible that the changes to introduce a new type of exceptional marketing authorisation may encourage small and medium size veterinary pharmaceutical companies to place more products in the market.

B. Veterinarians

The Royal College of Veterinary Surgeons (RCVS) estimates that there are some 6000 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. 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. However, it is expected that at medium term the changes to introduce a new type of exceptional marketing authorisation may improve the availability of products for limited markets.

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. 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. The proposed new fees for WDICs will not apply when import certificates issued in the 12 months prior to the annual renewal amount to 100 or less, so that the fee does not prohibit the importation of products for limited markets.

Overall, we expect that the proposed changes will not affect competition. It is possible that the changes to introduce a new type of exceptional marketing authorisation may encourage small and medium size veterinary pharmaceutical companies to place more products in the market, therefore increasing the availability of medicinal products for minor species.

Annex 3

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
We are introducing a new penalty (making tampering with prescriptions an offence and it is possible that this may affect legal aid budget. However, we expect that the majority of persons who could be charged under this offence wouldn't qualify for legal aid. We do not consider that this change will require any special training for Judiciary or Court staff.

Sustainable Development, Carbon Impact Assessment, Other Environmental Issues
We do not expect that the changes proposed will affect greenhouse emissions, climate change, waste management, landscapes, water and floods, habitat and wildlife or noise pollution or will affect sustainable development.

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

Race /Disability/Gender and Human Rights
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

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

ANNEX A

RELATED SHIPMAN RECOMMENDATIONS FOR INFORMATION

RECOMMENDATIONS	GOVERNMENT REPONSE
1. A controlled drugs inspectorate should be created, comprising small multidisciplinary inspection teams, operating regionally but co-ordinated nationally. Each team would include pharmacists, doctors, inspectors and investigators, at least some of whom would have a law enforcement background.	**We agree in principle.** The Government proposes to strengthen and coordinate existing arrangements for monitoring and inspection through local networks centred on a named officer in each PCT. There would be a corresponding duty of collaboration on other local agencies. Staff who would be involved in this work would include PCT prescribing advisors and clinical governance leads, RPSGB inspectors, inspectors from the Healthcare Commission and CSCI, and police officers with appropriate skills (see Chapter 2).
The inspectorate would be responsible for inspecting the arrangements in pharmacies, dispensaries and surgeries, as to both the safe keeping of stocks of controlled drugs and the maintenance of controlled drugs registers (CDRs) and other records.	**We agree in principle.** The new monitoring and inspection regime would cover all these sectors (and also the hospital and private healthcare sectors and care homes). The intensity of inspection will depend on assessment of relative risk. It could be responsible for the supervised destruction of controlled drugs.
It could be responsible for the supervised destruction of controlled drugs.	**We agree in principle.** Local NHS organisations (PCTs and NHS or Foundation Trusts) would be responsible for ensuring that all destructions of controlled drugs were appropriately witnessed and recorded (see Recommendation 32).
The inspectorate would also be responsible for the monitoring of the prescribing of controlled drugs by means of examination of prescribing analysis and cost (PACT) data, which would include information derived from NHS and private prescriptions and requisitions.	**We agree in principle.** Audit tools would be devised centrally but applied locally by PCT or hospital clinical governance leads. They would draw on

	information on both NHS and private prescriptions and requisitions and also on movement on stock movements (see Chapter 4 for details).
It might be responsible for the issue of special controlled drug prescription pads.	**We disagree.** This will not be needed (see Recommendation 9).
If thought appropriate it might also assume many of the inspecting and other functions currently performed by Home Office drugs inspectors.	**We disagree.** The Home Office Drugs Inspectorate will continue to issue licences and inspect manufacturers and wholesalers, sharing information as appropriate with the local networks.
Inspectors and investigators would require access to background information about a doctor or pharmacist under scrutiny. There must be the facility to investigate expertly any irregularities or unusual features discovered as the result of such inspection and monitoring.	**We agree.** Partners in local networks will agree protocols for sharing of intelligence and for access to information needed for investigations.
11. The special form should show the GMC registration number of the medical practitioner to whom the pad of forms has been issued.	**We agree in principle.** Future systems will use a special 12-digit code which will uniquely identify all prescibers, their practice and PCT. However, absence of the identifier (for handwritten prescriptions) should not make the prescription invalid.
No other practitioner should be permitted to use it.	**We agree.** Controls on computer systems will normally prevent this.
The form should require the prescriber to indicate whether the prescription has been issued under the NHS or privately.	**We agree.** Private prescribers will be required to use a similar but distinct form. Each prescription would have its own unique identification number.
Each prescription would have its own unique identification number.	**We agree in principle.** Prescription forms already have distinct numbers, but capturing this information will depend on introducing scanning technology at PPA. Further work is need and to determine if existing prescription numbers would be

	suitable or if new systems for generating prescription identifiers would be required. The same identification numbers could be used for PDRCs for injectable Schedule 2 drugs to enhance the audit trail. In the longer term, ETP will generate a unique prescription number for each prescription.
14. The amount of a controlled drug that can be dispensed on a single prescription should be limited to a supply sufficient to last 28 days. This restriction would not apply to drugs in	**We agree in principle**, though in exceptional circumstances a supply of more than 28 days may be justified. The Government will work with professional bodies to develop good practice guidance.
31. Consideration should be given to changing the law so that all controlled drugs would become the property of the Crown on the death of the patient for whom they were prescribed.	**We disagree.** The Government is not persuaded that this change in the law is either necessary or would (as the Inquiry intended) make it easier for healthcare professionals to remove unwanted controlled drugs after the death of a patient. Under current legislation, no patient or carer is entitled to possess a controlled drug once there is no longer a clinical need. It would seem easier to rely on this argument than to attempt to persuade a grieving relative that they no longer "owned" the medicines in question – this might be particularly difficult in the case of a privately dispensed controlled drug.