EXPLANATORY MEMORANDUM TO

THE VETERINARY MEDICINES REGULATIONS 2033

2013 No. 2033

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 Veterinary Medicines Regulations (VMR) 2013 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 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:

- 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;
- Regulation (EC) 767/2009 placing on the market and the use of feed.

4.2 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. The Directive was considered by the EU Scrutiny Committee in 2004. We have updated the VMR regularly since 2005. A transposition note is at Annex 1.

4.3 The regular 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.

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 There are 15 proposed changes to the VMR 2013, full details of which are provided in the Impact Assessment. A summary of the changes are as follows:

- Reductions to existing fees for certain types of applications and inspections to avoid over recovery of costs;
- Increases to existing fees arising from additional responsibilities required by European legislation or in order to ensure full cost recovery;
- Three minor adjustments to inspectors' enforcement powers.

7.2 The Veterinary Medicines Directorate is the UK Regulatory Authority for veterinary medicines and as such is required to recover the costs of its authorisation and related activities through fees charged to the industry. The amendments to the fees ensure full cost recovery is achieved with no cross-subsidy.

7.3 The VMR sets out the controls on the manufacture, distribution, possession, prescription, dispensing, administration and use of veterinary medicinal products. Its aim is to ensure that veterinary medicines for both food producing and companion animals are safe for the consumer, the human administering the medicines, the treated animal and the environment.

7.4 Through an Enforcement Strategy the Veterinary Medicines Directorate seeks to work with businesses and assist them in complying with the VMR through the provision of sound advice and guidance. However it is imperative that the VMR provide a range of enforcement tools that can be used to secure compliance. The three minor adjustments to inspectors' enforcement powers clarify existing powers.

7.5 The proposed changes have not attracted particular public or media attention but have been of interest to those directly involved; primarily the companies producing and marketing the products, veterinary practices, pharmacies, agricultural merchants, veterinary wholesalers, farmers and owners of companion animals.

- Consolidation

7.6 Not applicable.

8. Consultation outcome

8.1 Proposed changes to the VMR were submitted to a full public consultation from 7 January to 18 February 2013. A formal consultation package was published on the Veterinary Medicines Directorate's website and letters were sent to over 800 interested organisations and individuals. This public consultation aimed to seek stakeholders' views on the costs and benefits that the proposed

changes would impose on businesses. In addition, an open meeting was held in February to offer further opportunity for stakeholders to discuss the proposed changes.

8.2 33 written responses were received to the consultation. The respondents generally supported the proposals but also provided comments on particular issues many of which commented on the proposed increases to fees. The Government took on board the consultees' comments and in response decided to withdraw or reduce the increase to fees for some types of premises. In particular, we have:

- Withdrawn the fees increase for "Schedule 6" wholesalers;
- Withdrawn the proposed restructure and increase of fees for Suitably Qualify Persons premises;
- Reduced the proposed inspection fees for manufacturers and distributors of medicated feedingstuffs.

9. Guidance

9.1 The Veterinary Medicines Directorate publishes guidance on the regulation of the manufacture, distribution and use of veterinary medicines. The guidance which has required updating due to changes made at this revision of the VMR has been made and included within the consultation package.

10. Impact

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

10.2 The impact on the public sector is negligible.

10.3 An Impact Assessment will be published alongside the Explanatory Memorandum on www.legislation.gov.uk.

11. Regulating small business

11.1 The legislation applies to small business. EU law applies to all veterinary medicinal products as the risks of illegal use are the same irrespective of the size of the company dealing with the product and for this reason the Government cannot make specific exemptions for small firms.

11.2 To minimise the impact of the requirements on firms employing up to 20 people, the approach taken by the Veterinary Medicines Directorate is to carry out a continual process of informal consultation with stakeholders on proposed legislative developments. In response to stakeholders' comments during the consultation period, two proposals have been withdrawn and one proposed fee reduced, all of which would have had a direct impact on small businesses.

11.3 The basis for the final decision on what action to take to assist small business was formed from feedback received during the consultation period. As part of the consultation of these new regulations, the Veterinary Medicines Directorate invited (along with other stakeholders) small businesses to an open meeting to discuss the proposed amendments to the VMR. In response to feedback received during this meeting and written consultation responses it was decided that the three proposals would be withdrawn or amended.

12. Monitoring & review

12.1 The outcome of the VMR 2013 will be subject to an internal review after 12 months and the legislation may be amended accordingly.

13. Contact

13.1 Paul Green at the Veterinary Medicines Directorate of the Department for Environment, Food and Rural Affairs, tel: 01932 338303 or e-mail: p.green@vmd.defra.gsi.gov.uk.

Annex 1 - Transposition Table

Transposition note setting out how Directive 2001/82 as amended is implemented in the Veterinary Medicines Regulations 2013

Provisions of Directive 2001/82 as amended	**Implementation in the Veterinary Medicines Regulations 2011**
Article 1	Regulation 2 and in the body of the Regulations.
Article 2	Nothing to implement.
Article 2(2)	Regulation 2(5)
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. Articles 8, 15 and 17 of Regulation (EC) No 767/2009 of the European Parliament and of the Council on the placing on the market and use of feed in relation to feedingstuffs containing specified feed additives are implemented in the VMR Schedule 5 paragraphs 6, 14 and 17. The rest of this Regulation is implemented by the Animal Feed (England) Regulation SI 2010/2503.
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 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. This provision also implements the amendments to directive 2001/82/EC made by Regulation 470/2009, Art 30, on list of essential substances for horses and on withdrawal periods).
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 Regulation 2377/90 was replaced by Regulation 470/2009 and Regulation 37/2010 - Schedule 1 paragraphs 2, 23 and 24
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 paragraph 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(8) 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	Schedule 1 part 4 – Variations to marketing authorisations are regulated by Commission Regulation (EC) 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products.
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 homeopathics 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 21(1)(c)
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 1
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 to 36
Article 80(1) second paragraph	Regulation 34(9)
Article 80(1) third paragraph	Regulation 34(10)
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 80(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 8(5)
Article 81(2)	Schedule 1 paragraph 30
Article 81(2) second paragraph	Schedule1 paragraph 27 and Schedule 2 paragraph 8(5)
Article 82(1)	Schedule 1 paragraph 27 and Schedule 2 paragraph 8(5); 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, e.g. 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 homeopathics.
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 homeopathics.
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 ab	Administrative measure; nothing to implement.
Article 2 of Directive 2001/28	Schedule 1 paragraphs 11(3) and 12(2)