EXPLANATORY MEMORANDUM TO

THE VETERINARY MEDICINES REGULATIONS 2006

2006 No. 2407

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

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

2. Description

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

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

Background

3.1 These Regulations provide a single comprehensive set of controls on all aspects of veterinary medicines, other than residues. They revoke and replace the Veterinary Medicines Regulations 2005(hereon referred to as the 2005 Regulations), which consolidated legislative provisions previously contained in the Medicines Act 1968 and approximately 45 statutory instruments.

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

3.3 The reason for the revocation and replacement of the 2005 Regulations follows a period of post-implementation review, both with stakeholders and within the Department, which has included attendance by officials at numerous meetings of interested industry groups and continued informal consultation on specific issues since the 2005 Regulations came into force. The review period highlighted a number of areas where the new legislation required further amendment to remain fit for purpose. As proposed at the time the 2005 Regulations came into force, it was considered that to maintain the simplified format, and thereby to reduce administrative burdens, they should be revoked and replaced rather than amended with an additional piece of secondary legislation.

3.4 The principal changes to the 2005 Regulations are as follows.
They change the way that fees are charged for new marketing authorisations to reflect more accurately the work involved in any individual application (Schedule 6).

They extend the requirement to hold a Certificate of Competence from those purchasing a product to those who are engaged in dipping sheep (Part 3 of Schedule 3).

They clarify the existing regulations in respect of retail supply by veterinary surgeons, pharmacists and suitably qualified persons (Part 1 of Schedule 3)
They re-introduce requirements for recording specific batches of veterinary medicinal products administered to food-producing animals (regulations 18 and 19).

They re-introduce requirements in respect of labelling veterinary medicinal products at the time of retail supply to avoid essential safety warnings and other information being obscured (Schedule 3 paragraph 11).

They introduce provisions for the approval of a manufacturer of an veterinary medicine for administration under the cascade (Part 4 of Schedule 2).

They introduce a provision that the incorporation of veterinary medicinal products into feed for animals for domestic consumption or non-food animals no longer requires approval (Schedule 5 paragraph 6).

Medicines Act

3.5 Although the 2005 Regulations disapplied the provisions of the Medicines Act relating to veterinary medicines, there were insufficient resources available at the time to amend the Medicines Act to remove from it all references to veterinary medicines. This work has now been undertaken, with the cooperation on the Department of Health, and consequential amendments to this effect are incorporated into Schedule 8 of the Regulations.

Other Legislation

3.6 We are aware that there is a need to review a number of other pieces of legislation that may make reference to veterinary medicines. Consequential amendments are incorporated into Schedule 9 for those that have been identified. Subject to available resources, we intend to continue the review of other legislation so that further amendments can be included in future if necessary.

Fees

3.7 The VMD is required by Ministers to recover the full cost of the authorisation of veterinary medicines, medicated feeds and feed additives from its customers, principally the veterinary pharmaceutical industry. To continue to achieve this it is necessary to increase the existing fees to recover inflation.

3.8 The Regulations also implement the final stage of a three-year project, previously agreed with industry, to restructure fees. The final stage affects the balance of fees for variations by increasing the fee for minor variations and reducing the fee for major ones so that the fees better relate to the amount of work involved. In addition, a new menu-based system for the fees charged in relation to applications for new marketing authorisations is being introduced. It is intended that by providing a greater number of options the new menu-based system will more closely align the VMD's cost recovery for different types of application to the amount of work required to process and assess them. These changes will substitute existing procedures and should therefore broadly be cost neutral.

3.9 The additional revenue raised against industry by the inflationary increases introduced by these Regulations is estimated to be in the order of £135,000 for fees related to the authorisation of veterinary medicines, and £23,000 for fees related to medicated feeds and feed additives. This is equivalent to approximately 2.5% and 5% respectively of the total take from industry in 2005/06. These changes will have a significant impact on some individual companies. However there are decisive arguments on fairness, transparency and predictability underpinning the changes. The impact on business will depend on the number of applications made in a year and business turnover.

3.10 Fees were last increased in 2005, resulting in an estimated 9.7% increase in total VMD income from industry. A table comparing the old and new fees is attached at Annex 1.

4. Legislative Background

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

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

(a) coccidiostats;

(b) histomonostats;

(c) all other zootechnical additives except —

(i) digestibility enhancers;
(ii) gut flora stabilisers; and
(iii) substances incorporated with the intention of favourably affecting the environment.

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

5. Extent

5.1 This instrument applies to all of the United Kingdom.

6. European Convention on Human Rights

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

7. Policy background

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

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

7.3 While the proposals were being developed a series of informal consultations and presentations were held with a wide range of interested organisations and individuals. A formal consultation package was published on the Veterinary Medicines Directorate (VMD) website and letters were sent to over 800 interested organisations and individuals. 12 weeks were allowed for comment and the 41 respondents generally supported the proposals but provided comments on particular issues, many of which sought clarification or raised points of detail. The majority of comments covered the clarification of Schedule 3 in relation to retail supply. The accompanying Regulatory Impact Assessment (RIA) covers the main issues raised by consultees.

7.4 In addition, a separate consultation was held on a revised proposal outlining the provisions for the administration of homoeopathic veterinary remedies. This was to address a legislative gap that was identified after the initial consultation had been issued. 67 consultees responded, but of these only 3 made specific comments about the proposed amendment – full details are provided in the RIA as mentioned above.

7.5 The VMD is the UK Regulatory Authority for veterinary medicines. It is required to recover the costs of its authorisation and related activities through fees charged to the industry. The fees are provided in the 2005 Regulations, rather than in separate fees legislation. The proposed changes for the fees elements contained within the 2006 Regulations include changes to the structure of the fees regime and to the amounts charged. The most significant issues raised are summarised below:

7.6 Consultees were invited to indicate their preference between retaining the current system, which has been in operation for many years, and adopting the new menu-based system for the fees charged in relation to applications for new marketing authorisations. Comments were received from one consultee. The National Office of Animal Health (NOAH), representing the manufacturers of UK animal medicines,

reported that the “view on balance” was that they favoured the new menu-based approach. No consultees expressed a preference for retaining the current system.

7.7 Comments were received from one consultee, suggesting that the fee categories of feed manufacturers could be simplified, in particular in relation to manufacturers of premixtures. These fee categories did not correspond with the three broad categories of manufacturers referred to in Schedule 5 of the Regulations, which lists premixture manufacturers as a category on its own.

7.8 The 2006 Regulations now separate out both premixture activities into a separate "premixture" fee category. This will result in some premixture manufacturers paying a lower fee and will make charging by activity more transparent as categories will be better distinguished.

8. Impact

8.1 A Regulatory Impact Assessment is attached to this memorandum.

8.2 No significant impact on the public sector is anticipated.

9. Contact

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

	Old Fee £	Change %	New Fee £	Schedule 7 Para
Note: fees in shaded boxes are replaced by the "Fees Menu".				
National Marketing Authorisation Applications				
Standard	6,390	N/A	Menu	
New active substance	25,500	N/A	Menu	
Complex	14,795	N/A	Menu	
Identical data	1,785	N/A	Menu	
Provisional - New active substance	14,795	N/A	Menu	
Conversion from Provisional - New Active Substance - within 2 years[1]	10,705	N/A	Menu	
Provisional - Complex	6,390	N/A	Menu	
Conversion from Provisional - Complex - within 2 years[1]	8,405	N/A	Menu	
[1]Conversion after more than 2 years attracts the full application fee.				
Pharmacologically Equivalent Marketing Authorisations:				
Reference product authorised within the UK	4,995	N/A	Menu	
Reference product authorised outside the UK[2]	6,390	N/A	Menu	
[2]Translation costs will also be charged where applicable.				5
Parallel Imports				
Application[2]	2,000	2.50%	2,050	12(1)
Reference product authorised outside the UK - one member State	1,650	2.50%	1,690	12(1)
Additional member States	330	2.50%	340	12(1)
National Marketing Authorisation Variations				
Type IA (per Directive 1084/2003)	330	33.0%	440	13(3)
Type IB (per Directive 1084/2003)	770	8.40%	835	13(4)
Type IB: Identical changes to a number of products - each subsequent product	330	33.0%	440	13(4)
Type II (per Directive 1084/2003)	2,540	-12.6%	2,220	13(5)
Type II: Identical changes to a number of products - each subsequent product	330	33.0%	440	13(5)
Type II reduced fees[3]	770	8.40%	835	13(5)
Type II multiple updates[4]	n/a	new	4,440	13(2)
[3]The Regulations Para 13(5) set out 9 conditions under which reduced Type II fees are payable.				
[4]More than one variation to the quality data in a MA on the same application form, other than where one or more of the variations refers to a new active substance and the applicant does not submit a Certificate of Suitability issued by the European Pharmacopeia relating to the new source, or if a significant formulation change is applied that requires a new assessment of the safety or efficacy of the product.				
National Marketing Authorisation Renewals				
1st Renewal of MA granted on or after 30 October 2005	1,275	2.50%	1,305	18(1)
1st Renewal of MA granted before 30 October 2005	1,275	2.50%	1,305	18(2)(a)
Subsequent renewal of MA granted before 30 October 2005	290	2.50%	295	18(2)(a)
Renewal where further assessment of post authorisation commitments is required	1,275	2.50%	1,305	18(2)(b)
Provisional MA - 1st reassessment	290	2.50%	295	18(3)
Provisional MA - subsequent reassessment	1,275	2.50%	1,305	18(3)
Homoeopathic Registration				
Application - repeat stocks and formulations:				
- not more than 5 stocks	150	2.50%	155	20(1)
- more than 5 stocks	350	2.50%	360	20(1)
Application - repeat stocks or formulations:				
- not more than 5 stocks	430	2.50%	440	20(1)
- more than 5 stocks	625	2.50%	640	20(1)
Application - other:				
- not more than 5 stocks	710	2.50%	730	20(1)
- more than 5 stocks	920	2.50%	945	20(1)
Application - pre-existing Human UK or Human/Veterinary other member State:				
- not more than 5 stocks	150	2.50%	155	20(1)
- more than 5 stocks	350	2.50%	360	20(1)

	Old Fee £	Change %	New Fee £	Schedule 7 Para

Note: fees in shaded boxes are replaced by the "Fees Menu".

Mutual Recognition

The Mutual Recognition of UK Marketing Authorisations (UK is RMS):

Where the application is received within six months of the grant of the Marketing Authorisation, or for a further application for an additional member State within six months of the first member State application
- mutual recognition by one member State

	One member state:		One member state:	
Pharmaceutical - Food Producing	2,290	2.50%	2,345	17(2)
Pharmaceutical - Non-Food Producing	1,775	2.50%	1,820	17(2)
Immunologicals	2,000	2.50%	2,050	17(2)

Where the application is received within six months of the grant of the Marketing Authorisation
- assistance towards mutual recognition by the second and each successive member State

	2nd and each successive:		2nd and each successive:	
Pharmaceutical - Food Producing	500	2.00%	510	17(2)
Pharmaceutical - Non-Food Producing	500	2.00%	510	17(2)
Immunologicals	500	2.00%	510	17(2)
Simultaneous application	n/a	new	110	17(4)

Where the application is received more than six months after the grant of the Marketing Authorisation
- mutual recognition by one member State

	One member state:		One member state:	
Pharmaceutical - Food Producing	9,860	2.50%	10,105	17(3)
Pharmaceutical - Non-Food Producing	6,905	2.50%	7,080	17(3)
Immunologicals	8,385	2.50%	8,595	17(3)

Where the application is received more than six months after the grant of the Marketing Authorisation
- assistance towards mutual recognition by the second and each successive member State

	2nd and each successive:		2nd and each successive:	
Pharmaceutical - Food Producing	500	2.00%	510	17(3)
Pharmaceutical - Non-Food Producing	500	2.00%	510	17(3)
Immunologicals	500	2.00%	510	17(3)
Simultaneous application	n/a	new	110	17(4)

Recognition by the UK of other member States' Marketing Authorisations (UK is CMS):

Standard	4,225	N/A	Menu
New active substance	14,070	N/A	Menu
Complex	8,445	N/A	Menu
Identical data	1,120	N/A	Menu
Pharmacologically equivalent - reference product authorised in the UK	3,305	N/A	Menu
Pharmacologically equivalent - reference product not authorised in the UK[5]	4,225	N/A	Menu

[5]Translation costs will also be charged if applicable.

Decentralised Procedures:

Where applications are submitted simultaneously across a number of member States for a product that does not yet have an MA granted within the EU:

Where UK is Reference Member State (RMS):

- recognition by one member State:

Standard	10,400	N/A	Menu
New active substance	29,510	N/A	Menu
Complex	18,800	N/A	Menu
Additional applications submitted at the same time for different strengths of the same active substance in the same dosage form - for each additional strength	n/a	N/A	Menu
Identical data	4,075	N/A	Menu
Pharmacologically equivalent - reference product authorised in the UK	9,000	N/A	Menu
Pharmacologically equivalent - reference product not authorised in the UK[5]	10,400	N/A	Menu

[5]Translation costs will also be charged if applicable.

	Old Fee £	Change %	New Fee £	Schedule 7 Para
Note: fees in shaded boxes are replaced by the "Fees Menu".				
- recognition by the second and each successive member state:				
All above categories except "different strengths of the same active substance in the same dosage form"	500	N/A	Menu	
Additional applications submitted at the same time for different strengths of the same active substance in the same dosage form - for each additional strength per member State	n/a	N/A	Menu	
Where UK is CMS (i.e. not the reference member State):				
Standard	4,225	N/A	Menu	
New active substance	14,070	N/A	Menu	
Complex	8,445	N/A	Menu	
Additional applications submitted at the same time for different strengths of the same active substance in the same dosage form - for each additional strength per member State	n/a	N/A	Menu	
Identical data	1,680	N/A	Menu	
Pharmacologically equivalent - reference product authorised in the UK	3,305	N/A	Menu	
Pharmacologically equivalent - reference product not authorised in the UK[5]	4,225	N/A	Menu	
Mutual Recognition Variations:				
Extension of a Marketing Authorisation				
The fee for an application for an extension of an MA as specified in Annex II to Directive 1084/2003 is: - if applying for a UK MA, the national MA application fee plus fees for any mutual recognition procedure; or - if using decentralised procedure, the fee for an MA using the decentralised procedure.				
Where UK is CMS:				
Type IA (per Directive 1084/2003)	330	33.00%	440	14(3)
Type IB (per Directive 1084/2003)	355	33.50%	475	14(3)
Type IB - identical data, identical changes and submitted at the same time:				
- first variation	355	33.50%	475	14(3)
- each subsequent variation	330	33.00%	440	14(3)
Type II (per Directive 1084/2003)	2,540	-12.60%	2,220	14(3)
Type II - identical data, identical changes and submitted at the same time:				
- first variation	2,540	-12.60%	2,220	14(3)
- each subsequent variation	330	33.00%	440	14(3)
Type II - to correct SPC or product literature, or simple text layout changes, not resulting from safety concerns, no new studies, no change to aspects of dossier	355	33.50%	475	14(3)
Where UK is RMS:				
Type IA (per Directive 1084/2003)	1,675	-7.20%	1,555	14(3)
Type IB (per Directive 1084/2003)	2,705	-9.30%	2,455	14(3)
Type IB - identical data, identical changes and submitted at the same time:				
- first variation	2,705	-9.30%	2,455	14(3)
- each subsequent variation	1,675	-7.20%	1,555	14(3)
Type II (per Directive 1084/2003)	10,125	-11.20%	8,990	14(3)
Type II - identical data, identical changes and submitted at the same time:				
- first variation	10,125	-11.20%	8,990	14(3)
- each subsequent variation	1,675	-7.20%	1,555	14(3)
Type II - to correct SPC or product literature, or simple text layout changes, not resulting from safety concerns, no new studies, no change to aspects of dossier	2,705	-9.30%	2,455	14(3)
Renewals for Mutual Recognition and Decentralised Procedure:				
Where UK is RMS:				
Renewal after 5 years of granting of MA	1,720	2.50%	1,765	19(a)
Where UK is CMS:				
Renewal after 5 years of granting of MA	1,145	2.50%	1,175	19(b)

[5]Translation costs will also be charged if applicable.

	Old Fee £	Change %	New Fee £	Schedule 7 Para
Note: fees in shaded boxes are replaced by the "Fees Menu".				
Manufacturer's Authorisation				
Application	2,595	2.50%	2,660	24
Variation requiring scientific or pharmaceutical assessment	465	2.50%	475	25
Variation not requiring scientific or pharmaceutical assessment	160	2.50%	165	25
Autogenous vaccine - standard authorisation for each manufacturing site	2,960	2.50%	3,035	26(1)
Autogenous vaccine - single batch	1,480	2.50%	1,515	26(2)
Autogenous vaccine - variation requiring inspection	2,960	2.50%	3,035	26(1)
Autogenous vaccine - variation not requiring inspection	280	2.50%	285	26(3)
Annual Fee - other than autogenous vaccines	240	2.50%	245	27(1)
Annual Fee - autogenous vaccines - % of turnover in previous calendar year	0.67%	0.00%	0.67%	27(2)
Authorisation to manufacture a veterinary medicinal product prepared extemporaneously (i.e. for administration under the cascade):				
Standard authorisation for each manufacturing site	n/a	new	3,035	26(1)
Single batch	n/a	new	1,515	26(2)
Variation requiring inspection	n/a	new	3,035	26(1)
Variation not requiring inspection	n/a	new	285	26(3)
Annual Fee for standard authorisation - % of turnover in previous calendar year	n/a	new	0.67 %	27(2)
Inspection fees				
Note: In addition to inspection fees, the travel and subsistence costs of inspectors and any additional costs reasonably incurred by them (including interpreters' fees) are payable.				35
Immunological GMP inspections:				
Super site	24,015	2.50%	24,615	29(1)
Major site	16,900	2.50%	17,325	29(1)
Standard site	5,435	2.50%	5,570	29(1)
Minor site	4,745	2.50%	4,865	29(1)
GMP Inspections other than Immunological inspections:				
Super site - Sterile	17,685	2.50%	18,125	30
Major site - Sterile	9,775	2.50%	10,020	30
Standard site - Sterile	4,805	2.50%	4,925	30
Minor site - Sterile	3,215	2.50%	3,295	30
Super site - non-sterile	10,660	2.50%	10,925	31
Major site - non-sterile	5,610	2.50%	5,750	31
Standard site - non-sterile	4,025	2.50%	4,125	31
Minor site - non-sterile	2,170	2.50%	2,225	31
Super site - Assembly of products only	7,750	2.50%	7,945	32
Major site - Assembly of products only	5,235	2.50%	5,365	32
Standard site - Assembly of products only	2,570	2.50%	2,635	32
Minor site - Assembly of products only	1,325	2.50%	1,360	32
Test sites				
Inspection of a test site	2,665	2.50%	2,730	33
Small Animal Blood Bank Certificate:				
Authorisation to operate a small animal blood bank	2,960	2.50%	3,035	34(1)
Subsequent inspection	2,960	2.50%	3,035	34(1)
Variation	280	2.50%	285	34(2)
Wholesale Dealer's Authorisation				
Application - first year's turnover estimate more than or equal to £40,000	1,510	2.50%	1,550	36(1)(a)
Application - first year's turnover estimate less than £40,000	620	2.50%	635	36(1)(b)
Variation requiring scientific or pharmaceutical assessment	465	2.50%	475	37(1)(a)
Variation not requiring scientific or pharmaceutical assessment	160	2.50%	165	37(1)(b)
Annual Fee - turnover more than or equal to £40,000	485	2.50%	495	38(a)
Annual Fee - turnover less than £40,000	240	2.50%	245	38(b)

Fees relating to feeding stuffs

Note: different fees apply in Great Britain (GB) and Northern Ireland (NI).
(Figures in brackets apply if the annual fee is not paid within 60 days of the demand).

	Old Fee £	Change %	New Fee £	Schedule 7 Para
Note: fees in shaded boxes are replaced by the "Fees Menu".				
Application and inspection:				
Application for the approval of an establishment to manufacture a specified feed additive or a premixture using a specified feed additive and the subsequent annual fee (in the case of premises that only manufacture specified feed additives and already have a manufacturing authorization relating to veterinary medicinal products for incorporating into feeding stuffs, no fee is payable).	GB: 866 NI: 466	N/A	N/A	39(1)
Application for the approval of an establishment to manufacture feeding stuffs using specified feed additives directly, premixtures using veterinary medicinal product or feeding stuff at any concentration, and the subsequent annual fee.	GB: 546 NI: 368	N/A	N/A	39(1)
Application for the approval of an establishment to manufacture a specified feed additive and the subsequent annual fee (in the case of premises that only manufacture specified feed additives and already have a manufacturing uthorization relating to veterinary medicinal products for incorporating into feeding stuffs, no fee is payable).	N/A	New	GB: 910 (1,090) NI: 489 (587)	39(1)
Application for the approval of an establishment to manufacture feeding stuffs, using specified feed additives or veterinary medicinal products, at any concentration, and the subsequent annual fee.	N/A	New	GB: 575 (690) NI: 386 (463)	39(1)
Application for the approval of an establishment to manufacture premixtures and the subsequent annual fee.	N/A	New	GB: 575 (690) NI: 386 (463)	39(1)
Application for the approval of an establishment to manufacture feeding stuffs using veterinary medicinal product only at a rate of 2kg per tonne or more when the feeding stuffs are to be placed on the market, and the subsequent annual fee.	GB: 365 NI: 271	5.00%	GB: 385 (460) NI: 285 (342)	39(1)
Application for the approval of an establishment to manufacture feeding stuffs using premixtures from specified feed additives when the feeding stuffs are to be placed on the market, and the subsequent annual fee.	GB: 188 NI: 145	5.00%	GB: 195 (235) NI: 152 (182)	39(1)
Application for the approval of an establishment to manufacture feeding stuffs using veterinary medicinal product only at a rate of 2kg per tonne or more when the feeding stuffs are to be used by the person manufacturing the feeding stuffs, and the subsequent annual fee.	GB: 135 NI: 111	5.00%	GB: 140 (170) NI: 117 (140)	39(1)
Application for the approval of an establishment to manufacture feeding stuffs using premixtures from specified feed additives when the feeding stuffs are to be used by the person manufacturing the feeding stuffs, and the subsequent annual fee.	GB: 115 NI: 93	5.00%	GB: 120 (145) NI: 98 (118)	39(1)
Note: Where more than one of the above activities is carried out at one premises, only one fee (the highest) is payable.				39(2)
Distributors:				
Application to be a distributor of specified feed additives, premixtures or feeding stuffs containing specified feed additives, or premixtures or specified feed additives containing veterinary medicinal products, and the subsequent annual fee.	GB: 128 NI: 59	5.00%	GB: 135 (160) NI: 62 (74)	40(1)
Approval of premises for supply by Suitably Qualified Persons				
Approval of premises	232	5.00%	245	48(1)(a)
Subsequent annual fee	165	5.00%	175	48(2)(a)
Subsequent annual fee - if not paid within 60 days	197	5.00%	205	48(2)(a)
Approval of premises - horses and companion animals only	127	5.00%	135	48(1)(b)
Subsequent annual fee - horses and companion animals only	88	5.00%	90	48(2)(b)
Subsequent annual fee - horses and companion animals only - not paid within 60 days	107	5.00%	110	48(2)(b)

	Old Fee £	Change %	New Fee £	Schedule 7 Para
Note: fees in shaded boxes are replaced by the "Fees Menu".				
Annual Fees for Marketing Authorisations				
Graded - % on turnover	0.67%	0.00%	0.67%	21(2)&(3)
Fixed - per Marketing Authorisation				
Turnover of all authorised products equal to or greater than £220,000	215	2.50%	220	21(2)
Turnover of all authorised products less than £220,000	55	100%	110	21(3)
Authorisation holder who fails to provide audit certificate within 30 days of demand				
Additional fee to above:				
Basic fee	10,500	2.50%	10,765	22(1)
Additional fee per MA held	2,100	2.50%	2,155	22(1)
Late payment of annual fees:				
Additional fee as percentage of annual fee due:				
Paid 31 to 60 days after due date	1%	0.00%	1%	23(1)(a)
Paid 61 to 90 days after due date	2%	0.00%	2%	23(1)(b)
Over 90 days after due date	5%	0.00%	5%	23(1)(c)
Testing of samples				
The fee for testing a sample required to be submitted by the Secretary of State is the full economic cost of the test				41(1)
Animal Test Certificates				
Application - Type A (as set out in para 42(1)(a),(b) and (c)	320	2.50%	330	42(1)
Application - in any other case	765	2.50%	785	42(2)
Variation (for each change)	250	2.50%	255	42(3)
Renewal	120	2.50%	125	42(4)
Import Certificates				
Special Import Certificate (treatment under the cascade)	15	2.50%	15	43
Special Treatment Certificate (treatment in exceptional circumstances)	30	2.50%	30	44(1)
Renewal of STC - online application via VMD website	15	2.50%	15	44(1)
Renewal of STC - postal application	30	2.50%	30	44(1)
Note: STC fees are per animal, except for some exception circumstances (“discrete groups”) agreed in writing.				
Specific Batch Control				
Authorisation to release a product under specific batch control	520	2.50%	535	45
Submission of the results of tests carried out on a batch of immunological products prior to release	75	5.00%	80	46
Export Certificates				
Each Certificate	30	2.50%	30	47
Certified copy of each original	15	2.50%	15	47
Application to Veterinary Products Committee (VPC)				
Standard	485	2.50%	495	49(1)
New active substance	1,820	2.50%	1,865	49(1)
Complex	1,050	2.50%	1,075	49(1)
Pharmacologically equivalent	485	2.50%	495	49(1)
Identical data	190	2.50%	195	49(1)
Variation - Type 1A	n/a	new	195	49(2)
Variation - Type 1B	n/a	new	195	49(2)
Variation - Type II	n/a	new	260	49(2)
Animal Test Certificate	635	2.50%	650	49(1)

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 2006

PROVISION OF AMENDED DIRECTIVE	IMPLEMENTATION
Article 1	Regulation 2 and in the body of the Regulations
Article 2	Nothing to implement
Article 2(2)	Regulation 2(4)
Article 2(3)	Largely nothing to implement, but inspectors have powers to inspect starting materials
Article 3(1)(a)	Excluded from the Directive but included in Schedule 5 of the Regulations
Article 3(1)(b)	These are excluded under regulation 15(2) except for vaccines administered to other animals, which are regulated under Part 2 of Schedule 2
Article 3(1)(c)	Regulation 3(1)
Article 3(1)(d)	Although not covered by this Directive, these are regulated by other Community legislation and are dealt with in Schedule 5
Article 3(1)(e)	This contradicts Article 9. Trials are controlled under animal test certificate under Regulation 8(2)
Article 3(2)	Schedule 3 paragraph 12 (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 3
Article 8 second paragraph	Community competence
Article 8 third paragraph	Schedule 4 paragraph 4
Article 9	Regulation 8
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 62, 65 and 66
Article 16(3) and 16(4)	This is already permitted under the cascade in Schedule 4
Article 17	Schedule 1 paragraph 62
Article 18	Schedule 1 paragraph 63
Article 19	Schedule 1 paragraph 62

Article 20	Schedule 1 paragraph 62
Article 21.1	Schedule 1 paragraphs 17 and 43
Article 21.2	Schedule 1 paragraph 43
Article 22	Schedule 1 paragraph 20
Article 23 (1), (2) and (3)	Administrative measure; nothing to implement
Article 23(4)	Regulation 31
Article 24	Schedule 2 paragraph 12
Article 25(1)	Schedule 1 paragraph 22
Article 25(2)	Regulation 6
Article 25(3) and 25(4)	Schedule 1 paragraph 25
Article 26(1)	This is the general provision on labelling, which is dealt with in more detail in Title V of the Directive. Labelling is dealt with in Schedule 1 Part 7.
Article 26(3)	Schedule 1 paragraph 26
Article 27(1)	Schedule 1 paragraph 36
Article 27(2)	Schedule 1 paragraph 27
Article 27(3)	Schedule 1 paragraph 28
Article 27(5)	This is achieved by Regulation 6
Article 27(a) first paragraph	Schedule 1 paragraph 31 (1)
Article 27(a) second paragraph	Schedule 1 paragraph 31(2)
Article 27(a) third paragraph	Schedule 1 paragraph 31(3)
Article 28(1)	Schedule 1 paragraph 32(1)
Article 28(2) first paragraph	Schedule 1 paragraph 32(2)
Article 28(2) second paragraph	Schedule 1 paragraph 32(4) and (5)
Article 28(3)	Schedule 1 paragraph 32(6) and (7)
Article 28(4)	Schedule 1 paragraph 32(8)

Article 28(5)	Schedule 1 para 32(9)
Article 28(6)	Schedule 1 paragraph 32(10)
Article 29	The Department considers that Article 29 adds nothing to the general law and that there is nothing to implement
Article 30 first paragraph	Schedule 1 paragraph 24(1)
Article 30 second paragraph	Schedule 1 paragraph 24(2)
Article 30 third paragraph	Schedule 1 paragraph 24(3)(a)
Article 30 fourth paragraph	Regulation 4(2)
Article 31	Administrative measure; nothing to implement
Article 32(1) first paragraph	Schedule1 paragraph 41(2) and (4)
Article 32(1) second paragraph	Schedule 1 paragraph 41(3) and (5) and paragraph 42(1)
Article 32(1) third paragraph	Schedule 1 paragraph 41(5)
Article 32(2)	Schedule 1 paragraph 41(1) and (5) and paragraph 42(1)
Article 32(3)	Schedule 1 paragraph 43(2)
Article 32(4)	Schedule 1 paragraphs 41(6), 42(2) and 43(3) and
Article 32(5)	Schedule 1 paragraph 41(9) and 43(7)
Article 33(1) first paragraph	Schedule 1 paragraph 41(6) and 43(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 41(10) and 43(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 41(10), 42(4) and 43(8)
Article 39	Variations where a product is authorised in more than one member State are dealt with by Regulation (EC) No. 1084/2003, which is enforced in Schedule 1 paragraph 33. The rest of the paragraph is administrative measure; nothing to implement
Article 40	Schedule 1 paragraph 39
Article 41	Administrative measure; nothing to implement
Article 42	Administrative measure; nothing to implement
Article 43	Administrative measure; nothing to implement
Article 44(1)	Regulation 5
Article 44(2)	Regulation 5
Article 44(3)	Schedule 2 paragraph 12
Article 44(4)	Administrative measure; nothing to implement
Article 45	Schedule 2 paragraph 3
Article 46	Administrative, but covered by Schedule 2 paragraph 7(1)
Article 47	Schedule 2 paragraph 2(1)
Article 48	Schedule 2 paragraph 2(2)
Article 49	Regulation 31(2)

Article 50(a)	Schedule 2 paragraph 9(2)
Article 50(b)	This refers to other domestic legislation; there is nothing to implement
Article 50(c)	A holder can only manufacture in accordance with his authorisation.
Article 50(d)	Regulations 33 and 34
Article 50(e)	This is a necessary implication of Schedule2 paragraph 12
Article 50(f)	Schedule 2 paragraph 9(3)
Article 50(g)	Regulation 21
Article 50 (a)(1)	Achieved by the power of entry in regulation 33(7)
Article 50(a)(2)	Administrative measure; nothing to implement
Article 51	Administrative measure; nothing to implement
Article 52	Schedule 2 paragraph 9(2)
Article 53 and 54	Schedule 2 paragraph 10; the Directive requirement is unworkable and the Department has tried to come up with a sensible interpretation, which also reflects current practice
Article 55(1)(a)	Schedule 2 paragraph 12(1)
Article 55(1)(b) first paragraph	Schedule 2 paragraph 12(2)
Article 55(2)	Schedule2 paragraph 12(3)
Article 55(3)	Schedule 2 paragraph 12(4)
Article 56	Schedule 2 paragraph 11(1)
Article 57	The provisions relating to homoeopathics in Part 9 of Schedule 1 do not disapply the requirement for a manufacturing authorisation; Schedule 1 paragraph 63(1)(c)
Article 58(1) to (3)	Schedule 1 paragraph 44 and 47

Article 58(4)	Schedule 1 paragraph 46(1)
Article 58(5)	This refers to authorisations granted by the European Medicines Agency and so is administrative.
Article 59(1)	Schedule 1 paragraph 50
Article 59(2)	Schedule 1 paragraph 51
Article 59(3)	Schedule 1 paragraph 46(1)
Article 60	Schedule1 paragraph 47(2)
Article 61	Schedule 1 paragraph 47 and 49
Article 62	Schedule 1 paragraph 38
Article 63	Administrative measure; nothing to implement
Article 64	Schedule 1 paragraph 52
Article 65(1)	Regulation 13 and Schedule 3 paragraph 2 and paragraph 16.
Article 65(2)	Schedule 3 paragraph 17(4)
Article 65(3) first and third paragraph	Regulation 22
Article 65(3) second paragraph	Schedule 3 paragraph 21(3)
Article 65(3)(a)	Schedule 3 paragraph 17(4)(b)
Article 65(4)	Schedule 3 paragraph 2
Article 65(5)	Regulation 9(4)(c) 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 14
Article 66 third paragraph	Regulation 23(4)
Article 66(3)	Schedule 3 paragraph 13
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 5
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 54
Article 74 second paragraph	Schedule 1 paragraphs 54 and 55
Article 75(1) to 75(4)	Schedule 1 paragraphs 56 and 57
Article 75(5)	Schedule 1 paragraph 58
Article 75(6)	Administrative measure; nothing to implement
Article 75(7)	Schedule 1 paragraph 58(4)
Article 75(8)	Schedule 1 paragraph 59
Article 76(1)	Administrative measure; nothing to implement
Article 76(2) and (3)	Schedule 1 paragraph 57(3)

Article 77(1) first and third paragraphs	Administrative measure; nothing to implement
Article 77(1) second paragraph	Schedule1 paragraph 56(4)
Article 77(2)	Administrative measure; nothing to implement
Article 78	Schedule 1 paragraph 60
Article 79	Administrative measure; nothing to implement
Article 80(1) first paragraph	Regulations 32 to 35
Article 80(1) second paragraph	Regulation 33(7)
Article 80(1) third paragraph	Regulation 33(8)
Article 80(1) fourth paragraph	Nothing to implement; this is a voluntary inspection
Article 80(1) fifth paragraph	Regulation 34
Article 80(2)	Schedule 1 paragraph 2(5)
Article 80(3)	Schedule 2 paragraph 8
Article 89(4)	If a third country manufacturer refuses to be inspected he is not accepted as a manufacturer for the purposes of a marketing authorisation
Article 80(5), (6) and (7)	Schedule 2 paragraph 7
Article 81(1)	Schedule 1 paragraph 30 and Schedule 2 paragraph 9(5)
Article 81(2)	Schedule 1 paragraph 29
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 40(3)
Article 82(3) to (5)	Administrative measure; nothing to implement
Article 83(1) and (2)	Schedule 1 paragraph 38. 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 38(4) and 40
Article 85(1) and (2)	Schedule 2 paragraph 5
Article 85(3)	Regulation 11
Article 86	This is not disapplied by Schedule1 Part 9 and accordingly applies to homoeopathics
Article 87	This is "encouragement" and will be achieved by circulars
Article 88 to 90	Administrative measure; nothing to implement
Article 91(1)	Schedule 1 paragraph 60
Article 91(2)	Schedule 1 paragraph 28
Article 91(3)	Administrative measure; nothing to implement
Article 92	This is not disapplied by Schedule1 Part 9 and accordingly applies to homoeopathics
Article 93	Regulation 30
Article 94 first paragraph	Administrative measure; nothing to implement
Article 94 second paragraph	Schedule1 paragraph 25
Article 95	Regulation 3(2)

Article 95a()	Disposal is covered by the marketing authorisation
Article 95 (a) and (b)	Administrative measure; nothing to implement
Article 2 of Directive 2001/28	Schedule 1 paragraphs 11(3) and 12(2)

Regulatory Impact Assessment

Title: The Veterinary Medicines Regulations 2006

INTRODUCTION

1. Controls on veterinary medicines are required to ensure their safe, effective and responsible use, in particular to protect the safety of treated animals, people handling medicines and consumers of produce from treated animals and the environment. It is also important that sufficient medicines are available to treat and prevent disease in the wide variety of different species present in the UK and that new medicines are developed to counter new and evolving disease patterns.

Following a complete review of the previous regulatory regime for veterinary medicines in the UK, the Veterinary Medicines Regulations 2005 came into force on 30 October 2005. These Regulations implemented new European legislative provisions and took forward the recommendations from two reports on aspects of the supply of prescription-only veterinary medicines in the UK. Significant simplification of the legislation was achieved as a result. The Department indicated that it would review, revoke and re-make the Regulations annually to keep them and any fees up to date and to maintain transparency and simplification by avoiding a raft of amending Statutory Instruments. This review, with key stakeholders, has identified the need for minor amendments, to provide increased clarity and to ensure that the Regulations remain fit for purpose.

Fees

The VMD charges fees for its licensing and feed additive registration services to meet its full cost recovery target. In addition to a number of individual fee changes, there are four key proposals on fees:

a) To increase fee levels in line with inflation i.e. by 2.5%.

b) To introduce a new menu-based system for the fees charged in relation to applications for new Marketing Authorisations. Consultees were invited to indicate their preference between retaining the current system, which has been in operation for many years, and adopting the new system. It is intended that by providing a greater number of options the new menu-based system will more closely align the Veterinary Medicines Directorate's cost recovery for different types of application to the amount of work required to process and assess them. During the process of drawing up the fees menu there has been frequent informal consultation with industry representatives and they are well aware of the proposals. The proposed fees menu for new pharmaceutical applications has been available to Marketing Authorisation holders for more than nine months to allow them to

compare the fees for new applications using the fees menu to those using the current system. In addition, a number of Industry workshops were held at the VMD. Action has been taken on suggestions for minor changes to the system. No major concerns have been expressed during this period.

c) To change the balance of the fees for variations by increasing the fee for minor variations and reducing the fee for major ones so that the fees relate better to the amount of work.

d) To increase the Animal Medicines Inspectorate (AMI) fees by 5% to take account of inflation in 2005/06 and 2006/07, i.e. 2.5 % for each year. AMI fees were not increased for inflation in the previous year's Regulations and the proposed 5% increase will therefore restore the appropriate fee levels.

To implement the necessary changes whilst maintaining the simplified structure of the Regulations within a single piece of legislation, it is proposed that they should be revoked and replaced with new Regulations, to come into force on 1 October 2006.

PURPOSE AND INTENDED EFFECT

(i) Objective

2. To revoke and replace the Veterinary Medicines Regulations 2005 (SI 2005/2745) with updated Regulations that achieve the intended outcomes described above.

This measure is required to:

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

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

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

iv. Introduce revised licensing fee scales to take account of inflation and other unrecovered costs.

v. Recover the projected annual costs of assessing applications for veterinary medicinal product marketing authorisations (MAs) and associated services, including inspections of premises and pharmacovigilance.

vi. Introduce revised fee scales for the Animal Medicines Inspectorate work (registration of medicated feed, feedingstuffs and premises for supply by suitably qualified persons) to take account of inflation.

vii. Introduce an alternative system for calculating fees for new Marketing Authorisations.

3. Groups and Sectors Affected

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

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

The majority of changes are minor modifications of current procedures that, although necessary to address legislative gaps, or better clarify existing provisions, would have only a small impact on current practice. The changes in respect of the fee increases and the fees structure are set out separately and in detail in Annex 1.

Racial Equality
This proposal has been considered against the Race Relations Act, 1976 (as amended by the Race Relations (Amendment) Act 2000) and there is no evidence to show that this proposal has a differential impact on different racial groups.

Devolution

4. The Regulations would apply to the UK as control of medicines is reserved to Westminster. However, enforcement of the controls is not reserved, so the devolved administrations would make provisions to cover this aspect.

(ii) Background and Rationale for Government intervention

5. No medicinal product can be considered completely risk free and many are potentially harmful if not used responsibly. In view of this, there is a need to

maintain a robust system to regulate the safety, quality and efficacy of veterinary medicinal products placed on the market, as well as their distribution, supply and use, in order to safeguard the public, including consumers of animal produce, the environment, and the health and welfare of animals.

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

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

It is therefore proposed to implement a number of amendments to the legislation at the same time as the necessary adjustments to the fee structures are made, to ensure that the Regulations remain up to date and that they reflect the minimum level of regulation that is required. It is not believed that these amendments would add any significant additional administrative requirements on businesses and overall they are expected to be cost neutral.

6. In addition to the proposed changes in respect of fees, which are outlined separately in Annex 1, the following issues are proposed for inclusion in the Veterinary Medicines Regulations 2006:

i. Extend the requirement to hold a Certificate of Competence from those purchasing a sheep dip product to those who are engaged in dipping sheep.

ii. Clarify the existing regulations in respect of retail supply by Registered Qualified Persons (RQPs) - veterinary surgeons, pharmacists and suitably qualified persons (SQPs).

iii. Re-introduce requirements for recording specific batches of veterinary medicinal products administered to food-producing animals. These requirements were inadvertently omitted from the 2005 Regulations.

iv. Re-introduce requirements in respect of labelling of veterinary medicinal products at the time of retail supply to avoid essential safety warnings and other information being obscured. These requirements were inadvertently omitted from the 2005 Regulations.

v. Introduce the optional inclusion of the statement 'UK authorised veterinary medicinal product' (or other wording specifying that the product is authorised for use in the UK, if it is in accordance with the Marketing Authorisation) on the packaging of authorised veterinary medicinal products.

vi. Introduce provisions for the approval of a manufacturer of an extemporaneous veterinary medicine, for administration under the prescribing cascade.

vii. Introduce a provision clarifying the controls on administration of Veterinary Homoeopathic Remedies

Consultation

7. The formal consultation package included the draft 2006 Regulations, two alternative proposals for Schedule 7 (fees): an update of the current Schedule and a separate one incorporating the fees menu, a partial Regulatory Impact Assessment and revised Guidance Notes to accompany the Regulations. All the associated documents were available electronically on the VMD website (www.vmd.gov.uk) and were sent to consultees by email, CD Rom or in hard copy when requested.

The consultation period ran for 12 weeks, from 17 March 2006. Following the end of the consultation period, two public meetings were held, during which consultees were able to discuss the key issues raised.

In addition a separate formal consultation exercise was carried out between 26 May and 7 July on a provision relating to the administration of homoeopathic veterinary remedies. A consultation letter outlining the proposed amendment was sent to interested organisations and individuals and the consultation package was published on the VMD website. The following groups were consulted:

(i) Within Government

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

(ii) Public consultation

A wide range of interested parties were consulted, including all of the VMD's pharmaceutical industry customers, stakeholders from the veterinary and pharmacy professions, farming organisations, veterinary charities, pet owners, owners and keepers of horses, feed merchants, saddlers and consumer organisations. The consultation encompassed small and independent business interests as well as larger concerns and representative bodies, to ensure a wide spectrum of views were invited.

OPTIONS

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

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

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

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

The options for the changes in respect of fees are outlined in Annex 1. The options for all other proposed regulatory changes are outlined below:

i. Extend the requirement to hold a Certificate of Competence to those engaged in dipping sheep.

It is proposed to extend the requirement to hold a Certificate of Competence (CoC) in the safe use of sheep dip to those who carry out the dipping (currently only purchasers must hold the CoC). During the past three years

the Environment Agency (EA) has reported a number of pollution incidents of watercourses that have involved sheep dip products. The pollution has caused considerable loss of aquatic life in the affected rivers with a resulting depletion of fish stocks. The Veterinary Medicines Directorate (VMD) and the EA have identified a number of actions to address the pollution from sheep dips. One of the steps we propose is to strengthen the requirement for the CoC in the new Veterinary Medicines Regulations.

This action underpins three of Defra's high-level objectives:

Objective 1: To promote and improve the rural, urban, marine and global environment.
Objective 4: To promote sustainable, diverse, modern and adaptive farming through domestic and international actions.
Objective 6: To protect the public interest in relation to environmental impacts and health and ensure high standards of animal health and welfare.

OPTION 1 - Do Nothing
If nothing is done, the sheep farmers would still be able to dip sheep to control scab and other ectoparasites without receiving the training required for a CoC. The risk of pollution to watercourses would remain the same and it is quite possible that invertebrate and fish life would be lost from affected river catchments. This protects neither the public interest nor the environment and is contrary to the three Departmental objectives listed above. **This option is not considered viable therefore.**

OPTION 2 - Industry Self Regulation
It is unclear whether industry self-regulation would be effective. Farm assurance schemes certainly work for other farmed animal rearing practices. However, the VMD is of the opinion that without the emphasis provided by a change in the law, farmers may not adjust their working practices when dipping. As a consequence this is a high-risk strategy and is not preferred. **This option is not considered viable therefore.**

OPTION 3 - Introduce the requirement
The presence of a qualified person at every sheep dipping should optimise the likelihood that the dip products would be used and disposed of in ways that minimise the risk to the environment. Thus river pollution incidents would be reduced to a minimum and river ecology conserved.

Consultation Comments

Comments were received from 2 respondents, both of which related to clarification of detail and one of which also suggested that additional guidance should be provided to sheep dippers to minimise pollution of watercourses. It was considered that this issue could be effectively incorporated within existing systems of industry self-regulation. No other significant issues were raised.

ii. Clarify the existing regulations in respect of retail supply by Registered Qualified Persons (RQPs) - veterinary surgeons, pharmacists and suitably qualified persons (SQPs).

In the current Regulations, the responsibilities of the RQP (that is, a veterinary surgeon, a pharmacist or a registered Suitably Qualified Person) are set out clearly, however there remains some confusion over the RQP's authority to legally delegate tasks arising from the retail supply of veterinary medicines.
In response to feedback from stakeholders from within the supply chain, it is proposed to strengthen the existing wording within the legislation so that, when prescribing, the Responsible Qualified Person must provide the required advice to the purchaser in every case, be able to intervene in each sale if the RQP is a Suitably Qualified Person and, if necessary, to refuse the transaction. It is not considered necessary to specify by which media the advice must be supplied, but the legislation would reflect more clearly the fact that an offence is committed if the advice is not supplied. It is also proposed that a provision is added in respect of the supply by an RQP who has already prescribed a product. In every case the responsibility for the supply remains with the person prescribing, unless a written prescription is given and another RQP carries out the supply. The provisions in respect of written prescriptions have also been strengthened to clarify that the RQP is responsible for ensuring that any prescription he supplies against is genuine.

OPTION 1 - Do Nothing
If nothing is done there will be continued confusion over how the legislation should be interpreted, in particular in relation to supply by SQPs. This could result in an uneven playing field within the industry, with some suppliers applying a lower level of control on supply than others. **This option is not considered viable therefore.**

OPTION 2 - Industry Self Regulation
There are existing codes of practice providing guidance for each type of RQP:

a. veterinary surgeons have the Royal College of Veterinary Surgeons 'Guide to Professional Conduct'
b. pharmacists have the Royal Pharmaceutical Society of Great Britain 'Code of Ethics and Standards'
c. SQPs have the Code of Practice for the Registration of Retail Premises and Suitably Qualified Persons.

Implementing the required amendments using this option would not provide the clarity in the legislation that has been requested by RQP representative groups. **This option is not considered viable therefore.**

OPTION 3 - Introduce the requirement
The inclusion of a clearer provision within the Regulations would ensure that retail supply can be effectively controlled, which would benefit the supply industry and consumers alike. The proposed re-draft of Schedule 3 of the Regulations is intended to clarify the legislative position for those authorised

to supply veterinary medicinal products, whilst remaining in line with the requirements of the European legislation.

Consultation Comments

Comments were received from 23 consultees on various sections of the proposed amendments to Schedule 3, with many consultees suggesting further amendments to the legislation.

The proposed change to allow an RQP to supply a medicine without having to be being present at the time of supply was supported by 2 consultees and opposed by 8. Those opposing the amendment felt that the new wording represented a 'watering down' of the regulatory requirement, particularly as it applied to SQPs, and that it would encourage abuse of the regulatory system by unscrupulous suppliers. This issue was also raised by a number of attendees who opposed it at the post-consultation public meeting.
In light of consultee responses, the proposed wording for Schedule 3 has been amended to set out more clearly the responsibilities of both veterinary surgeons and SQPs in relation to retail supply. The revised draft has been seen by the main consultees affected by the amendment and the majority have approved the changes.
Other comments raised by consultees included a request that the telephone number of the prescriber be included on all written prescriptions and that prescriptions should clearly state when medicines have been prescribed using the cascade.

iii. Re-introduce requirements for retailers to record specific batches of veterinary medicinal products administered to food-producing animals.

The requirement for records to be kept of specific batch numbers of veterinary medicinal products administered to food-producing animals throughout the supply chain was included in previous legislation that was revoked on 30 October 2005, but it was inadvertently omitted from the 2005 Regulations. Retailers and keepers of food-producing animals in the UK have been accustomed to recording this information within their existing animal medicines records for many years and it is a necessary measure in respect of food safety. The provision is also a requirement of EU legislation.

OPTION 1 - Do Nothing
In the current Regulations there is a requirement for retailers to record batch numbers of all prescription medicines that have been supplied during a given time period, but these records do not have to relate to specific animals. Therefore a new provision is necessary to ensure that the records kept for food-producing animals reflect the information that is needed and required by EU legislation. **This option is not considered viable therefore.**

OPTION 2 - Industry Self Regulation

It is considered that industry self-regulation would not be effective in this case and that by implementing this requirement within, for example, a farm assurance scheme, there would not be sufficient incentive or coverage for farmers to comply with the requirement. **This option is not considered viable therefore.**

OPTION 3 - Introduce the requirement

The requirements for record keeping in relation to medicines administered to food-producing animals are already set out in the current Regulations and to maintain the clear legislative position it is proposed that the additional provision in respect of batch number recording should be included in the 2006 Regulations.

Consultation Comments

3 consultees responded, 2 requested further clarification and one submitted a response outlining the financial implications of the batch-recording requirement for veterinary surgeons. This information is outlined in more detail in section 9, Analysis of Costs and Benefits, however the response related specifically to the costs associated with the requirement for batch numbers of all prescription medicines supplied to be recorded (including non-food animal medicines).

iv. Re-introduce requirements in respect of labelling of veterinary medicinal products at the time of retail supply to avoid essential safety warnings and other information being obscured.

Prior to 30 October 2005, The Medicines (Labelling) Regulations 1976 applied to veterinary medicines. In the current Regulations there are no specific requirements in respect of the labelling of medicines by RQPs at the time of retail supply. There are clear provisions in respect of the information that must be provided on product labelling by manufacturers and this information is part of the terms and conditions of each authorisation that permits a product to be placed on the market. During the previous simplification exercise this requirement was overlooked and the RQP is therefore able to decide how much additional information was required if an additional label was added at the time of retail supply.

In response to feedback from the veterinary profession and pharmacists, this position has been reviewed and it is accepted there is a regulatory gap resulting from the revocation of the 1976 Regulations. It is proposed that if a veterinary medicinal product is supplied in its authorised container, the information on the container must not be obscured in any way. In addition, when a product is being supplied in an unauthorised container (such as when a small number of tablets are dispensed from a large container into a separate bottle) the RQP must ensure that sufficient written information is provided on the label to enable the product to be used safely – such as warnings and contra-indications, the dosage instructions, the batch number and the expiry

date of the product, the name and address of the person supplying and the date. Copies of the package leaflet can be used to provide this information easily.

OPTION 1 - Do Nothing

This option is not considered to be viable because there is a gap in the existing legislation that has been the subject of a number of requests from the retail supply industry to remedy. If no action is taken then there is a risk that medicines dispensed into unauthorised containers will not be supplied with the necessary information to ensure the safe handling and use of the product. This creates increased risk to human and animal health. **This option is not considered viable therefore.**

OPTION 2 - Industry Self Regulation

There are existing codes of practice providing guidance for each type of RQP:

a. veterinary surgeons have the Royal College of Veterinary Surgeons 'Guide to Professional Conduct'
b. pharmacists have the Royal Pharmaceutical Society of Great Britain 'Code of Ethics and Standards'
c. SQPs have the Code of Practice for the Registration of Retail Premises and Suitably Qualified Persons.

The difficulty with implementing the required amendments using this option is that each body will have different procedures and timescales for the update of their respective codes of practice. The VMD would provide recommended wording but there is a risk that the guidance will not be promulgated as effectively, as meaningfully, or as consistently as a regulatory requirement affecting all RQPs. As the issue centres on promoting the safe handling and use of veterinary medicines, and the risks associated with unsafe use could be high, it is considered that the new provision could not be adequately enforced through means of Codes of Practice. **This option is not considered viable therefore.**

OPTION 3 - Introduce the requirement

It is proposed that a new provision is included in the 2006 Regulations to ensure that the existing regulatory gap is closed and that human and animal safety is better maintained.

Consultation Comments

2 consultees responded, they did not oppose the amendment, but both raised questions in relation to the provision of additional copies of product-related information with medicines, if necessary, at the time of dispensing. Advice on this aspect has been included in the related guidance.

v. Introduce a provision for the inclusion of a tailored statement for use in Marketing Authorisations authorised through the mutual recognition and

decentralised procedures, or where dual labelling or harmonisation of the SPC has been agreed, as an alternative to the phrase used on national only authorisations "UK Authorised Veterinary Medicinal Product". It is also needed for small packs where the full wording of the current phrase is too long.

The requirement for the statement 'UK Authorised Veterinary Medicinal Product' to be included on all UK authorised veterinary medicinal products was introduced in the 2005 Regulations to improve recognition of UK authorised products and to enable counterfeit and illegally imported products to be more easily identified. This change was accepted by the pharmaceutical industry, however a new issue has arisen which needs to be addressed: some veterinary medicinal products that are authorised for use within the UK are also authorised for use in other European Member states and have dual labelling, or a harmonised Summary of Product Characteristics (SPC) as part of their marketing authorisations to enable the product to be sold in more than one country with identical packaging. To address this issue we propose that an additional option for the statement required on the labelling should be included in the Regulations that a different tailored phrase can be used provided it has been specified in the Marketing Authorisation.

OPTION 1 - Do Nothing

The current situation would prohibit the legal trade of dual-labelled veterinary products within the EU. In such cases the 'UK authorised' statement could be considered to be misleading on packaging also used in another Member State. The manufacturers of these products have raised the issue with VMD and it is considered that a change is needed to the current regulation to address the problem. **This option is not considered viable therefore.**

OPTION 2 - Industry Self Regulation

This option is not considered to be viable because the requirements for labelling information on product packaging are currently set out in both UK and EU legislation. **This option is not considered viable therefore.**

OPTION 3 - Introduce the requirement

It is proposed that the wording of the existing regulation is changed. This was considered to be the simplest and most effective method of introducing the required result. However, in light of consultation comments received (see below), an alternative option has been introduced.

Consultation comments

3 consultees (including one speaking 1 at a public meeting) commented on this proposal. 2 raised the point that the tailored statement was not a requirement of EU legislation but specific to the UK, and as such was unnecessarily burdensome on an industry that produces products for use throughout the EU. Another consultee gave the viewpoint that the use of the statement on product labels had significantly improved recognition of the authorised status of their own products and that there was strong support for

the amendment from their customers. In the light of these views the use of such statements on the label has been made permissive and Option 4 is proposed:

OPTION 4
Introduce the optional inclusion of the statement 'UK authorised veterinary medicinal product' (or other wording specifying that the product is authorised for use in the UK, if it is in accordance with the Marketing Authorisation) on the packaging of authorised veterinary medicinal products.

vi. Introduce provisions for the approval of a manufacturer of an extemporaneous veterinary medicine, for administration under the prescribing cascade.

The prescribing cascade is a system whereby, if no authorised veterinary medicine is available, a veterinary surgeon can prescribe a medicine for use in a different animal species, or a human medicine or a veterinary medicine authorised in another member state, or as the last option, a medicine extemporaneously prepared by the veterinary surgeon himself, a pharmacist, or an authorised manufacturer. The current Regulations do not make provision for a manufacturer to be authorised specifically to make up such an extemporaneous medicine. All types of manufacture for veterinary medicines in the UK have to be authorised. Prior to 30 October 2005 this type of activity could be carried out using a manufacturer's 'Specials Licence', which was authorised for human or veterinary medicines under the Medicines Act. This issue was not raised by consultees prior to the change in legislation, but since the new Regulations came in to force the VMD has recognised that there is a need for provision to be added to enable this type of manufacture to continue.

OPTION 1 - Do Nothing
Because the current regulatory system does not provide a means to authorise a manufacturer of an extemporaneous veterinary medicine, **this option is not considered viable.**

OPTION 2 - Industry Self Regulation
The legislative requirement for manufacturers to be authorised is set down in EU legislation and so it is not possible to implement a special ability for a manufacturer outside a legislative provision. **This option is not considered viable therefore.**

OPTION 3 - Introduce the requirement
By including provisions within the 2006 Regulations for a manufacturer to apply for an authorisation specifically for extemporaneous medicines the existing regulatory gap will be closed.

Consultation Comments

No consultation comments were received on this proposed amendment.

vii. Introduce a provision clarifying the controls on the administration of Veterinary Homoeopathic Remedies

The purpose of the proposed amendment was to address a legislative gap, which has been identified in the 2005 Regulations, in relation to the administration of homoeopathic veterinary medicinal products.

The UK is required by EU legislation to have in place a means of regulating the use of homoeopathic remedies in animals, encompassing a Registration Scheme, the provision of 'grandfather rights' for remedies existing before the introduction of the Scheme, and the ability of a veterinary surgeon to prescribe unregistered homoeopathic remedies under the prescribing cascade. Remedies registered under the simplified scheme, and those with grandfather rights, should be able to be administered by anyone.

The 2005 Regulations only allow a homoeopathic medicine to be administered to an animal under the responsibility of a veterinary surgeon; therefore any other administration is illegal under the current Regulations. This was identified as a legislative gap and is not in accordance with the EU Directive.

OPTIONS 1 & 2 – Do nothing & Industry Self Regulation
Because the current situation represents a legislative gap, **these options are not considered viable.**

OPTION 3 – Introduce the Requirement
By adding provisions within the 2006 Regulations that stipulate who can administer homoeopathic veterinary remedies, the missing legislative control, as required by the Directive will be addressed.

Consultation Comments

Comments were received from 67 consultees but many did not address the substance of the consultation commenting rather on the status of homoeopathic remedies in general. This reflected two very different stances, neither of which took into account the fact that there is a requirement for all EU Member states to have legislative provisions in respect of homoeopathic remedies. 37 responses were opposed to any amendment because the consultees felt that its inclusion promoted the use of homoeopathic remedies in animals. 30 responses were also opposed to any amendment because the consultees felt that it would prevent the continued use of all homoeopathic remedies in animals without any regulation. However there were 3 responses focused on the proposal and of these 1 supported and 2 opposed the proposal.

ANALYSIS OF COSTS AND BENEFITS

9. An analysis of the anticipated costs, benefits and impacts in respect of sustainable development for the Regulations as a whole and each of the

proposed changes to the legislation are outlined below. Please refer to Annex 1 for the proposed changes to fees.

Benefit of Regulatory Simplification
By keeping all the requirements in a single legislative instrument it is much easier for those concerned, both within Government and industry, to find the relevant legal requirements. This is also further enhanced by the structure of the Regulations, which consist of a main body with a number of Schedules, each covering particular aspects.

Although difficult to quantify, the simple format and structure of the legislation should make it easier for interested parties to locate and understand the provisions, to check what is and is not permitted and, where appropriate, to ensure that they comply with any relevant provisions. Furthermore, this structure should make it easier for interested parties to satisfy themselves that the Regulatory Authority complies with the law and to challenge it if they consider it appropriate to do so. Although detailed guidance has been prepared on the main areas of the controls, this will inevitably not cover all the provisions. Clear and easily understood legal provisions should help those involved in the manufacture, marketing, supply and use of veterinary medicines to have increased confidence in the legality of their business activities. This should also help to reduce the administrative burden on industry and reduce the time and cost of obtaining legal advice.

i. Extend the requirement to hold a Certificate of Competence to those engaged in dipping sheep.

a) Sectors and groups affected by the change.
Sheep farmers will be required to ensure that a person holding a certificate of competence is present when dipping is carried out. The current requirement is that only a holder of a Certificate of Competence or a person acting on their behalf is able to buy sheep dip products.

The concerns of angling associations and environmental groups will also be met in part since the incidents of watercourse pollution following sheep dipping should be considerably reduced.

b) Analysis of costs and benefits.
Currently there are over 18,000 people involved in sheep farming who hold a National Proficiency Test Council (NPTC) certificate of competence in the safe use of sheep dips (CoC). The NPTC believes therefore, that the great majority of sheep dippers have the CoC qualification and so the introduction of this requirement should not require large numbers of sheep farmers to register and pay for the qualification. If some farms currently dip sheep without a CoC holder being present, then the costs of the extra staff time will be incurred unless one of the current dippers obtains a CoC. During the consultation process no comments were received that related to possible increased costs resulting from this requirement.

Enquiries made by the Department indicate the following costs:

- The cost for registration with NPTC is £24.00
- The actual assessment may only be carried out by approved NPTC assessors and the cost of a training course can vary from £90.00 - £200.00, depending on the fee charged by the training provider.
- If any of the two compulsory units for the qualification needs to be re-sat then this would incur a £17.00 fee per unit.

It is anticipated that the cost of enforcing the requirement could be met through service level agreements with the EA and SVS, who are in contact with farmers routinely. Costs via this route should be minimal.

The reduction in the incidents of polluted watercourses will be the primary benefit. However, we anticipate that the change will help to diffuse calls to ban the sale of sheep dip products, which are the most effective way of treating sheep ectoparasites.

c) Compliance and administrative costs for the Department and for business

This information is given in the analysis of costs and benefits and also applies here. Compliance is likely to be high and the administrative costs low.

d) Sustainable development, impacts

i. Social – recognition of needs of everyone

The strengthening of the training requirements for sheep dipping would ensure that operators are aware that sheep dip chemicals are highly toxic to invertebrate life and that the products must be used in a way which does not pollute the environment. Fish stocks would be unaffected and the angling community would then be able to continue to fish rivers.

ii. Environmental

The provision would help to ensure that the rivers previously polluted by sheep dip can return to their full ecological diversity. Future pollution of rivers with sheep dip should then be reduced to a minimum.

iii. Economic

The resulting reduction in the pollution of rivers may lead to a corresponding reduction in the calls for sheep dip products to be banned. In turn the continued marketing authorisation for sheep dip products would ensure the sheep ectoparasites can be controlled effectively, which would not place the sheep industry at a financial disadvantage. Minimising the risk of pollution would allow the angling industry to function with less interruption to services.

Consultation comment

A suggestion was made during the consultation that further guidance could be issued to sheep dippers to prevent the likelihood of watercourses being polluted. This action is being taken forward separately in conjunction with farming groups and the Environment Agency and SEPA.

ii) Clarify the existing regulation in respect of retail supply by Registered Qualified Persons (RQPs).

a) Sectors and groups affected by the change.
Veterinary surgeons and Suitably Qualified Persons (SQPs) selling prescription only medicines would be affected by the proposed change, which would clarify the regulatory controls relating to the responsible supply of these medicines. The Regulations would apply equally to Pharmacists supplying veterinary medicines, but they may not be as affected by the change because they already operate to similar requirements in The Pharmacy Act.

Customers of these businesses would be positively affected by the change in terms of the advice that they are entitled to receive from their supplier.

b) Analysis of costs and benefits, including compliance and administrative costs for the Department and business.
The change has been proposed to address a perceived lack of clarity in the current Regulations, a view put forward by retailers themselves. It is intended that the legislative change would enable retailers of prescription medicines to have a clearer idea of which elements of supply can be delegated and which must remain the full responsibility of the RQP.

SQPs were the main group of retailers that informed the Department that they had encountered additional financial burden as a result of the introduction of the 2005 Regulations, and from whom the majority of requests for more clarity arose. Prior to the formal consultation for the 2006 Regulations the Department wrote informally to all SQPs, asking for feedback on the type of clarification that would be supported by industry, as well as any other issues of importance The feedback received was used to develop the proposed amendment in the 2006 Regulations that was included in the formal consultation. However the responses from the formal consultation did not follow the same line so that the provisions have been redrafted to take account of the concerns expressed.

There are already existing requirements relating to SQPs and it is not anticipated that the groups affected will have any increased compliance or administrative costs resulting from this proposal.

It is anticipated that enforcement of this requirement could be done through existing inspection regimes. Therefore, additional costs to the Department via this route should be minimal.

c) Sustainable development, impacts

i. Social – recognition of needs of everyone
The Social benefits of the proposed change centre on improved clarity in terms of the advice retailers are required to provide to their customers and this will further enhance the safe and responsible use of veterinary medicines.

ii. Environmental

Some veterinary medicinal products can have a detrimental effect on the environment if they are used incorrectly or disposed of in the wrong way. By ensuring that correct and timely advice and information is given to all purchasers of prescription veterinary medicines, the Regulations provide a mechanism for protecting our environment. Good animal health and welfare also plays a significant role in preserving our environment and this legislative change will safeguard the supply of veterinary medicines, which in turn would contribute to the health and welfare of animals.

iii. Economic

Many veterinary surgeons have existing systems in place whereby they delegate responsibility to other members of their staff who carry out the actual handing over of the veterinary medicinal product to customers after the veterinary surgeon has prescribed the product. The legality of this procedure is confirmed by the regulations.

Consultation Comments

No new details of costs were provided during the consultation period. However, as a result of consultee comments the original amendment was re-drafted to ensure that SQPs in particular must be able to intervene during supply of veterinary medicines, or check the product after it has been allocated for supply to a customer and satisfy himself that the person handing over or dispatching is competent to do so.

iii) Introduce requirements for recording specific batches of veterinary medicinal products administered to food-producing animals.

a) Sectors and groups affected by the change.

Large animal veterinary surgeons and livestock farmers will be affected by the proposed change.

b) Analysis of costs and benefits

The proposed change is to re-introduce a requirement that was inadvertently omitted during the simplification exercise that replaced the previous legislation. The practice of recording batch numbers of veterinary products administered to food-producing animals has been in existence for a number of years and the majority of those groups affected will have continued to keep these records in the meantime.

The benefit of the change will be that all batches of veterinary medicines administered to food-producing animals will be traceable, ensuring that animal health as well as food safety for humans is maintained and monitored.

c) Compliance and administrative costs for the Department and business.

There will be no new costs to the Department of enforcing this requirement, which will continue to be done through routine on-farm and veterinary records inspections carried out by the State Veterinary Service.

There are already existing requirements for records to be kept relating to medicines administered to food-producing animals and it is not anticipated that the groups affected will have any increased compliance or administrative costs resulting from this proposal.

Consultation Comments

3 consultees responded, 2 seeking further clarification of the proposal and 1 providing 2 sets of estimated costings for the provision of new or updated IT systems in veterinary practices for the recording of batch numbers of medicines supplied via barcode scanners. The total estimated compliance costs to the industry as a whole, as provided by one consultee, ranged from £4.3 million up to £23.22 million.

This represents a maximum cost of circa £10,500 per veterinary practice, depending on the standard of IT equipment currently in use and also the number of scanners required by each business.

It should be noted that these figures relate to the projected compliance costs for installing an electronic system of maintaining records of the batch numbers of all prescription medicines supplied by veterinary surgeons and do not reflect the ongoing 'business as usual' compliance costs of the proposed amendment. EU legislation requires that these records are maintained by all suppliers of prescription medicines and this provision was brought in with the 2005 Regulations. The amendment proposed in the 2006 Regulations relates only to a re-instatement of the specific need to record each batch of veterinary medicine administered to a food-producing animal.

However, the estimated costs provided above have been taken into account by the Department and it is recognised that the batch recording provisions in the legislation are potentially burdensome. The pharmaceutical industry is working to introduce standardised barcodes, including batch details, onto all product labels to reduce suppliers' administrative time spent on keeping records. This change is anticipated to take up to three years to implement.

d) Sustainable development, impacts

i. Social – recognition of needs of everyone

The social benefits of the proposed change will be the increased traceability of medicines used in food-producing animals, which will enable swift action to be taken to remove animals from the food-chain should a batch of medicine they have received prove to be unsafe to humans. It will also enable manufacturers to recall specific batches of medicines that have not yet been used. It should be noted that, whilst

the need for regulation is apparent, the incidence of batch recalls for veterinary medicines is very low.

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

iii. Economic
The specific cost information provided is discussed above. It is not considered that there will be a significant economic impact as a result of the required addition to the records that are already kept. The change is intended to bolster the existing safeguards to enable food-producing animals to continue to be treated with safe and effective veterinary medicines.

iv) Introduce additional requirements in respect of labelling of veterinary medicinal products at the time of retail supply.

a) Sectors and groups affected by the change.
Veterinary surgeons and pharmacists supplying veterinary medicines would be affected by this change. These are the groups who have requested that a requirement be put into the Regulations. Customers of these groups would also be affected in terms of how the products they purchase are labelled.

b) Analysis of costs and benefits
The proposed legislative change clarifies how veterinary surgeons and pharmacists should implement current practice. It is not anticipated that there would be any increased costs to industry.

c) Compliance and administrative costs for the Department and business

There would be no additional costs to the Department of enforcing this requirement which would continue to be done through routine retailer's records inspections.

If there were any increased cost for business, this would result from additional administrative time spent on the labelling of unauthorised containers. During informal consultation with stakeholders the Department was advised that this practice is already common.

Consultation Comments

Of the 2 consultees who commented on the proposed amendment, neither gave examples of any additional costs. It was suggested that the need to provide specific product information with medicines dispensed into unauthorised containers by way of copied package inserts could be burdensome but this was not quantified.

d) Sustainable development, impacts
i. Social – recognition of needs of everyone

The social impact of the proposed change is not considered to be significant, although consumers would potentially have renewed confidence in terms of the information they are entitled to receive on medicine labels.

ii. Environmental

There is a positive environmental impact associated with the change in that essential information on the safe disposal of veterinary medicines would not be obscured by over-labelling or omitted from labelling of unauthorised containers.

iii. Economic

The economic impact is not considered to be significant, although, as mentioned above, the extra safety aspects provided by the additional labelling requirements would reinforce existing consumer confidence in the veterinary medicines market.

v) Introduce the optional inclusion of the statement 'UK authorised veterinary medicinal product' (or other wording specifying that the product is authorised for use in the UK, if it is in accordance with the Marketing Authorisation) on the packaging of authorised veterinary medicinal products.

a) Sectors and groups affected by the change.

Veterinary pharmaceutical manufacturers would primarily be affected by this change, as would veterinary retailers and customers using the veterinary medicinal products.

b) Analysis of costs and benefits

The proposed change is not what was originally consulted on, which was to increase the flexibility of the existing mandatory requirement to include the phrase 'UK authorised veterinary medicinal product' on labels and packaging. It was initially proposed that a variation on this phrase should be introduced for products authorised in additional Member States and with dual labelling.

Consultation comments

2 consultees raised the point that the additional flexibility of the tailored statement for UK veterinary medicinal products was unnecessarily burdensome on an industry that produces products with similar labelling for use throughout the EU because there could be many versions of labels for the same product. No estimated costs were provided in relation to the production of labels and therefore it has not been possible to quantify any such burden.

A revised amendment has been proposed as a result of feedback from stakeholders on the unnecessary administrative burdens that the enforced use of the phrase created. However this view was not unanimous and it was decided that, by making the use of the phrase permissive, those who wish to continue to use it as means of identifying the authorised status of their products could do so.

c) Compliance and administrative costs for the Department and business

The costs to the Department of this change are minimal and would be fully recovered through the fees charged as part of the authorisation process. There would be no significant increases in administrative or compliance costs for industry associated with the change and a reduction in costs as a result of the change has not been quantified.

d) Sustainable development, impacts

i. Social – recognition of needs of everyone

The social impact of this change is likely to be minimal, although consumers would continue to be able to recognise that they are using an authorised veterinary product if the phrase is used on product labels.

Consultation Comments

A consultee in support of the proposed amendment suggested that increased recognition of their products' authorised status was beneficial to consumers.

ii. Environmental

The environmental impact of this change would be minimal.

iii. Economic

It is considered that the economic impact of the change, whilst not high, would be most significant for holders of marketing authorisations because they would be able to meet the UK labelling requirements without compromising recognition of a product's authorised status in more than one country.

vi) Introduce provisions for the approval of a manufacturer of an extemporaneous veterinary medicine, for administration under the prescribing cascade.

a) Sectors and groups affected by the change.

Manufacturers of veterinary pharmaceutical medicines will primarily be affected by the change, as will veterinary surgeons requiring extemporaneous medicines to be made up according to a prescription.

b) Analysis of costs and benefits

An application for an authorisation to manufacture a veterinary medicinal product for administration under the cascade is £3,035 for each manufacturing site, with the same fee for each subsequent inspection, which will be carried out at intervals of two years. An annual fee of £245 is payable in respect of each manufacturing authorisation. These costs have been calculated to enable full cost recovery to be accomplished in respect of the administrative work required by the Department to process and assess the application and to undertake the necessary inspection work.

It is anticipated that the size of the manufacturing sector that will wish to gain such an authorisation is not great:
There are currently 288 manufacturers who hold authorisations to manufacture veterinary medicines, and of these there are 87 manufacturers who also hold an authorisation to manufacture a human 'Special', which is the equivalent of a veterinary extemporaneous medicine.

c) Compliance and administrative costs for the Department and business

The cost to the Department of enforcing the requirement will be recovered through the inspection fees.

No estimates of additional compliance or administrative costs were provided during the consultation. The Department is committed to combining inspections where more than one activity is being undertaken (e.g. human and veterinary medicines manufacturing) and there is flexibility within the fees system to accommodate this where appropriate.

d) Sustainable development, impacts

i. Social – recognition of needs of everyone

The social impact of this change is likely to be minimal, although the benefit will be that small enterprises that wish to work within this area will be able to do so. Also, extemporaneous veterinary products being manufactured by these small businesses will be produced in facilities which have been inspected to ensure they meet the required standards for the manufacture of these types of product. This will ensure that the resulting products are safe to use.

ii. Environmental

The environmental impact of this change is likely to be minimal, although the site inspections, as mentioned above, will ensure that the environmental impacts in respect of manufacture of medicines are properly considered.

iii. Economic

It is considered that the economic impact of the change, whilst not high, will be most significant for these specific manufacturers, as it will facilitate those wishing to provide a service to make up extemporaneous medicines for veterinary surgeons.

vii. Introduce a provision clarifying the controls on the administration of Veterinary Homoeopathic Remedies

a) Sectors and groups affected by the change

Veterinary surgeons, pet owners, farmers and homoeopathic practitioners will be primarily affected by the change, although registered pharmacists, manufacturers of homoeopathic remedies and retailers of pet and agricultural products will also be affected in terms of supply of remedies.

b) Analysis of costs and benefits

The proposed amendment is intended to clarify the types of homoeopathic remedy that can be legally administered to animals and by whom. The current situation with regard to homoeopathic remedies used in animals is largely unregulated, with many over the counter human remedies being purchased by pet owners to use on their own pets and relatively few veterinary surgeons prescribing extemporaneous homoeopathic remedies for use on specific animals under their care. The size of the veterinary homeopathic sector is considered to be small in comparison to the homoeopathic industry as a whole and it is difficult to quantify if there are potential costs associated with this change.

c) Compliance and administrative costs for the Department and business

The introduction of the amendment would enable the Department to take action against those who are using homoeopathic remedies outside the terms of the legislation and it is anticipated that the additional costs associated with any such action would be incorporated within the VMD's existing inspection and enforcement regime.

As discussed above, no estimated costs to business are available in respect of the proposed amendment due to the diverse nature of the homoeopathic remedies sector. It is anticipated that some homoeopathic remedy manufacturers will need to register new products under the Simplified Registration Scheme. Such fees range from £155 up to £945 per registration and there is currently only one such registered product.

Consultees did not provide any information relating to anticipated costs or savings resulting from the proposed amendment.

d) Sustainable development, impacts

i. Social – recognition of needs of everyone

The social impact of the proposed amendment will be of significance only to those who wish to use homoeopathic remedies in the treatment of animals and it is anticipated that the majority of remedies being used currently would continue to be used at they are now. Therefore the impact would not be great.

ii. Environmental

The Environmental affects of the amendment are considered to be insignificant.

iii. Economic

As discussed earlier, the veterinary homoeopathic sector is not considered to be a large industry and therefore the economic impact of the proposed amendment is expected to be minimal.

10. OTHER REGULATORY ISSUES RAISED DURING CONSULTATION

I. Veterinary surgeon's premises

6 consultees raised the need to address the regulatory imbalance caused by veterinary surgeons not being required to supply medicines from registered premises. As a result the inspection regime for veterinary surgeons is considered by stakeholders to be less rigorous than that applicable to other retailers.

The VMD is well aware of this issue. There is currently no legal requirement for a veterinary surgeon to provide any of his/her services from registered premises and this may fall under the auspices of the Veterinary Surgeon's Act when it is amended in future.

II. Advertising of POM-V medicines to Veterinary Nurses

This issue was highlighted by a number of consultees who felt that Veterinary Nurses did not receive satisfactory information on new products as a result of the restrictions on advertising. The Department plans to consult informally with interested groups to consider possible proposals for change in the 2007 Regulations.

III. Audit – Financial implications

The financial burden imposed by the requirement to hold an annual audit for prescription medicines was raised, although no estimated costs were provided. This provision is a requirement of EU legislation and therefore must be implemented in the UK. The Government considers this can be achieved through the routine stock control audits carried out by most businesses.

IV. Charity use of unauthorised medicines - exemption under cascade

Veterinary charities providing free veterinary care to pet owners in receipt of benefits requested an exemption, specific to their sector, from the requirement to use authorised veterinary medicines when cheaper human equivalent medicines were available. It was suggested that such an exemption could be incorporated into the cascade system and was necessary to enable such organisations to continue to provide free veterinary care to as many clients as possible. This exemption was not considered viable or ethical.

V. Amendments to Feed Additives provisions

A number of amendments to the legislation were put forward by consultees all of which related to improved clarity of the provisions and did not significantly change the proposed legislative position.

Specialist Input – lawyers, economists etc

The Veterinary Medicines Regulations 2006 have been drafted by a dedicated Defra lawyer. Departmental economists have scrutinised the proposals and any resulting feedback has been taken on board.

10. SMALL FIRMS IMPACT TEST

At the time of the introduction of the new Regulations a series of presentations were held, attended by a range of interested organisations and individuals,

including those representing small businesses such as veterinary surgeons' industry groups, veterinary wholesalers and SQPs. At these meetings feedback was sought and the key issues that have continued to be raised in correspondence to the VMD have been incorporated in the 2006 Regulations.

Articles outlining the main questions and answers about the Regulations have appeared in the VMD news publication, *MAVIS*, as well as in many other veterinary periodicals. The main issues relating to small firms that were raised were in respect of supply by SQPs. Following informal consultations with relevant groups and a further re-draft after the conclusion of the formal consultation, these issues have been addressed by clarifying the legislative requirements in respect of retail supply.

No other significant issues relating to small firms were raised as a result of the informal and formal methods of consultation held and no related details of costs were provided, other than those mentioned in respect of implementation batch recording IT equipment in section 9iii b) of this RIA.

11. COMPETITION ASSESSMENT

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

A – the veterinary pharmaceutical industry;
B – veterinary practices;
C – agricultural merchants;
D – veterinary wholesale dealers.

A. Veterinary Pharmaceutical Industry

The veterinary pharmaceutical industry comprises approximately 150 companies who between them currently hold marketing authorisations (MAs) for some 2000 veterinary medicinal products authorised in the UK. In some cases two or more of these may be owned by a "parent" company. The companies range from large multinationals to small businesses. Approximately 90% of sales in the £450 million animal medicines market are attributable to approximately 25% of the 150 current MA holders. A period of 10 years is accepted as an illustrative norm for the time taken to develop and bring to the market a new product. The provisions of the Regulations that impact upon the veterinary pharmaceutical industry will apply across the board and are not considered to affect some companies substantially more than others. The provisions are not considered likely to affect the market structure or to impose higher costs for new companies than for existing ones. The changes to the Regulations will not affect the current position in respect of companies' ability to choose price, quality, range or location of their products.

B. Veterinary Practices

The Royal College of Veterinary Surgeons (RCVS) Annual Report 2005 indicates that there are some 3,686 veterinary practices and branches in the UK. The British Veterinary Association has estimated that there are approximately 2,200 separate practices. The RCVS Report indicates that 49% of practices focus mainly on small (i.e. non-food) animals, 1% on farm animals, 47% on mixed animals (i.e. small animals and food animals), and 1% on equines (horses and ponies). The Competition Commission Report on the Supply within the UK of prescription-only veterinary medicines, published in April 2003, suggests that approximately 40% of practices operate from 1 site, 30% from 2 sites, 16% from 3 sites and a smaller proportion from more than 3 sites (Table 6.2 on p.142 of the Report). The Competition Commission Report also suggests that the average main veterinary practice is staffed by approximately 9 people - in round terms 3 veterinary surgeons, 3 veterinary nurses and 3 other staff. The Report indicates that practice branches average approximately 4 staff and that a small number of veterinary hospitals average 20 staff. The Report also notes as major trends that numbers of large animal practices are in decline while small animal practices have increased in recent years. The Report also indicates 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.

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 companies' ability to choose price, quality, range or location of their products.

C. Agricultural Merchants

Approximately 1300 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 not characterised by rapid technological change.

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

D. Veterinary Wholesale Dealers

Approximately 160 wholesalers are authorised to deal in veterinary medicines. These include enterprises dealing solely in veterinary medicines as well as others that wholesale deal both human and veterinary medicines. Licence 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 licenses specify the categories of product (i.e. POM-V, POM-VPS, NFA-VPS, AVM-GSL) and types of product (e.g. ointments, tablets, sterile liquids etc) that they relate to as well as listing all sites at which the relevant activities may be carried out. The sector is not characterised by rapid technological change. The changes to the Regulations are not considered likely to affect the market structure or to impose higher costs for new companies than for existing ones, or to significantly affect the current position in respect of companies' ability to choose price, quality, range or location of their products.

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

12. ENFORCEMENT AND SANCTIONS

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

13. IMPLEMENTATION AND DELIVERY PLAN

In line with Better Regulation best practice, revised guidance documents have been produced to take into account the changes to the legislation. To assist consultees in considering the implications of the changes within the new Regulations, and to ensure that the guidance is finalised in time for publication three months before the Regulations come into force, these documents were issued as part of the consultation package. Additional changes to the guidance requested during the consultation period have been issued in revised drafts, and will be finalised when the Regulations come into force.

It is proposed that the Veterinary Medicines Regulations 2006 would come into force on 1 October 2006, in accordance with the Government-wide adoption of Common Commencement dates.

14. POST-IMPLEMENTATION REVIEW

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

15. SUMMARY AND RECOMMENDATION

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

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

16. DECLARATION

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

Signed.....Ben Bradshaw.....

Date.....16 August 2006.....

..Parliamentary Under-Secretary of State.....
Department for Environment, Food and Rural Affairs

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ANNEX 1

REGULATORY IMPACT ASSESSMENT - FEES

1. Title

The Veterinary Medicines Regulations 2006 – fees relating to veterinary medicines.

2. Purpose and intended effect

(i) Objective

This measure is required to:

- introduce revised licensing fee scales to take account of inflation and other unrecovered costs;

- recover the projected annual costs of assessing applications for veterinary medicinal product marketing authorisations (MAs) and associated services, including inspections of premises and pharmacovigilance;

- introduce revised fee scales for the Animal Medicines Inspectorate work (registration of medicated feed, feedingstuffs and premises for supply by suitably qualified persons) to take account of inflation.

- introduce a new menu-based system for the fees charged in relation to applications for new Marketing Authorisations. It is intended that by providing a greater number of options the new menu-based system will more closely align our cost recovery for different types of application to the amount of work required to process and assess them.

The charges under this legislation apply in the UK.

(ii) Background

These Regulations will amend the fees currently charged in accordance with the Veterinary Medicines Regulations 2005, which established the fees for applications and inspections relating to authorisations and certificates issued under those Regulations. With effect from 1 October 2006 the Veterinary Medicines Regulations 2006 will come into force and the Veterinary Medicines Regulations 2005 will be revoked.

The fees proposed within the updated Schedule 7 takes account of the need to revise the current levels in respect of inflation and adds fees for areas of work that have not previously been carried out. The proposals are intended to achieve full cost recovery.

The fees structure proposed within the menu based option for Schedule 7 does not change much of the VMD's income from Industry significantly. However, fees for new applications for marketing authorisations would be set on a different basis than at present. The new structure provides greater transparency and flexibility, enabling fees to reflect the amount of assessment work needed as closely as possible. This structure follows an extensive review of marketing authorisation fees, including a detailed examination of the way in which new and revised data requirements embodied in the Regulations over the past years have affected the VMD's operations.

(iii) Risk assessment

If the revised fee scales are not introduced, full cost recovery would not be achieved. Both proposals for Schedule 7 will meet this requirement.

3. Options

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

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

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

4. Benefits

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

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

5. Costs

(i) Compliance costs

The additional revenue raised against industry by the inflationary increases introduced by these Regulations is estimated to be in the order of £135,000 for fees related to the authorisation of veterinary medicines, and £23,000 for

fees related to medicated feeds and feed additives. This is equivalent to approximately 2.5% and 5% respectively of the total take from industry in 2005/06. The overall impact on business resulting from the fee changes will depend on the number of applications made in a year and business turnover.

The new system for assessing fees for new marketing authorisations is designed to be cost neutral overall when compared to the old fees structure. However, within the overall cost to industry, there would be significant differences between individual application fees. This is because the basis for determining the fees depends upon a much wider set of criteria than the current system. For example, the new system recognises that assessment of an application for a product designed for a food producing species is necessarily more extensive than for a product designed for a non-food producing species.

The results of comparing all new application fees under both the new and the old systems showed that 50% of the applications tested would be charged a higher fee under the new system and 50% would be charged a lower fee. The percentage differences ranged from 1.6% to over 100%, depending on individual aspects of the applications. The impact of implementing the new system for this group of applications depends on the number and type of new applications made by companies.

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

(ii) Other Costs
As these Regulations increase fees for work done, there are no other costs.

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

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

There should be no non-recurring costs.

6. Equity and fairness

The proposed fee increase and other listed charges will apply evenly to all types of customer, except that companies with turnover of less than £220,000 will pay a reduced fixed annual fee.

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

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

8. Competition assessment

This has been assessed against the competition filter and it is concluded that these changes would have no impact on competition between existing or new members of the market.

9. Enforcement and sanctions

It is not anticipated that these proposals would change existing arrangements for enforcement and sanctions. The VMD retains, as a last resort, the right to suspend Marketing Authorisations.

10. Monitoring and review

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

11. Consultation

(i) Within government

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

(ii) Public consultation

A wide range of interested parties were consulted, including all of the VMD's pharmaceutical industry customers, stakeholders from the veterinary and pharmacy professions, farming organisations, veterinary

charities, pet owners, owners and keepers of horses, feed merchants, saddlers and consumer organisations. The consultation encompassed small and independent business interests as well as larger concerns and representative bodies, to ensure a wide spectrum of views were invited.

(iii) Menu-based fee system

Consultees were invited to indicate their preference between retaining the current system, which has been in operation for many years, and adopting the new menu-based system for the fees charged in relation to applications for new Marketing Authorisations.

Comments were received from one consultee. The National Office of Animal Health (NOAH), representing the manufacturers of UK animal medicines, reported that the “view on balance” was that they favoured the new menu-based approach. NOAH pointed out that this was not a strong view and suggested that the new system has scope to develop over time.

No consultees expressed a preference for retaining the current system.

(iv) Animal Medicines Inspectorate fees

Comments were received from one consultee, suggesting that the fee categories of feed manufacturers could be simplified, in particular in relation to manufacturers of premixtures.

The current Regulations fee schedule shows the highest fee category as a "manufacturer of Specified Feed Additives (SFAs) or premixtures containing SFAs", whilst the second highest fee category is for "manufacturers of feedingstuffs using SFAs directly, VMPs at any level and manufacturers of premixtures containing VMPs". These fee categories do not correspond with the three broad categories of manufacturers referred to in Schedule 5 of the Regulations, which lists premixture manufacturers as a category on its own.

The VMD therefore intends to separate out both premixture activities into a separate "premixture" fee category. This will result in some premixture manufacturers paying a lower fee and will make charging by activity easier as categories will be better distinguished.

ANNEX 2

Summary of Additional Costs as a result of the Veterinary Medicines Regulations 2006

Description of Additional Cost	Group Affected	Cost	Rationale
Fees related to applications for the authorization of veterinary medicines	Pharmaceutical Industry – including Manufacturers and Marketing Authorisation holders	£135,000 (2.5% increase)	Inflationary increase to cover increased Departmental costs
Fees related to the Animal Medicines Inspectorate	Merchants, Saddlers and on farm Feed Compounders	£23,000 (5% increase)	Inflationary increase to cover Animal Medicines Inspectorate Departmental costs – 2.5% for 2005/6 2.5% for 2006/7
Extension of requirement to gain a Certificate of Competence in the use of sheep kp from purchasers to include users	Farmers and farm workers	£224 per person	Training and registration to gain a Certificate of Competence in the use of sheep dip
New provision for approval of manufacturer of an extemporaneous veterinary medicine	Manufacturers of products for individual animals (extemporaneous veterinary medicine)	£3,280 per manufacturer	For authorization and inspection, additional provision requested by manufacturers

Departmental costs continue to be covered by the fees charged.

Changes to the balance of specific fees (fees menu system) are to bring the fee in line with the work and therefore may change in respect of an individual application. This will not make any overall impact on any one sector of the Industry. These changes will substitute existing procedures and should therefore broadly be cost neutral.