EXPLANATORY MEMORANDUM TO

THE VETERINARY MEDICINES REGULATIONS 2005

2005 No.2745

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. 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 replace the Medicines Act and approximately 45 statutory instruments that previously covered individual aspects of the production and placing on the market of veterinary medicines. Residues are not included because the European Commission is about to make proposals to revise the EC legislation. These changes will be incorporated into the Regulations when they are agreed so that there will be a single instrument Industry has indicated their very strong support for this approach.

Medicines Act

3.2 The Medicines Act 1968 has proved cumbersome, and the procedures in the Act no longer fit the modern system for the control of medicine as set out in the new Directive.

3.3 The licensing regime in the Medicines Act was disapplied in 1995 by the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994. These regulations go further and cover such aspects as manufacture, distribution, classification, administration to the animal, possession, post-authorisation surveillance and enforcement. The Department decided that it would be very much easier for the user to have all this in one document rather than making the user refer to the Medicines Act for some aspects. Consequently the regulations disapply the Medicines Act. We have not revoked the Act as it continues to apply to some aspects of human medicines.

3.4 Ideally, the Medicines Act should be amended to remove from it all references to veterinary medicines. However, the Department has decided that such an exercise

is not currently possible with the resources available. A decision was taken that the most important requirement was the simplification of the legislation in a way that implements the new Directive as transparently as possible.

Labelling

3.5 The labelling provisions are in Title V of the Directive. They are confused and insufficient, and in some places contradictory. The Department decided that, rather than follow the provisions slavishly, the new regulations should include all the provisions of the Directive, but in a clearer and more logical way. The new system reflects current practice for labelling as specified in the marketing authorisations currently being issued. These were discussed at length with industry, and there was consensus that the requirements in the regulations provide maximum clarity and are also as user-friendly as possible. This is clearly of the utmost importance in dealing with veterinary medicines where there are serious consumer safety implications in respect of food-producing animals.

Encouragement

3.6 Some parts of the Directive (for example, Article 72) require a member State to "encourage" certain actions. This is clearly not suitable for legislation that attracts a criminal penalty. The Department implements these through a programme of communication and publications.

Record keeping

3.7 The Directive requires retailers of prescription-only medicines to record certain information (Article 66 of the Directive as implemented in regulation 23 of the Regulations). Formerly this requirement was only for products for food-producing animals, and the new provision has extended the requirement to products for all animals. The Regulations give a retailer (such as a pharmacist or a veterinary surgeon) a choice of how he complies. He can do this by keeping copies of existing documentation (such as invoices and patient records) or keeping a separate record. This is to meet the requirements of the Directive while at the same time minimising the burden on the industry. In the case of a batch number (requirement of the Directive) this is achieved by requiring the retailer to record the date that he starts to use a particular batch. This achieves the necessary traceability without placing an unnecessary additional burden on the retailer.

Feedingstuffs

3.8 The Directive does not deal with feedingstuffs. However, the Department is responsible for feedingstuffs containing veterinary medicinal products, and feedingstuffs containing certain other non-medicated feed additives. As these are part of the enforcement of veterinary medicines, it was decided to include them in these Regulations. The regime is based on EU Regulations, and these are enforced in Schedule 5. As the main EU Regulation (Regulation 183/2004) does not come into force until 1 January 2005, the Department decided that the simplest approach was to delay the coming into force of Schedule 5 until then. The two alternatives to this approach would have been to set out the existing regime in the Regulations and then disapply them after two months, bringing in the new regime at that time, or to amend the Regulations immediately after they had been made, so as to introduce the new

provisions on 1 January 2006. The Department decided that the approach of delaying bringing the Schedule into force until 1 January 2006 was the clearest approach.

Fees

3.9 The VMD is required by Ministers to recover the full cost of the authorisation or licensing of veterinary medicines from its customers, principally the veterinary pharmaceutical industry. To continue to achieve this it is necessary to increase the existing fees to recover inflation, non-recoverable VAT costs, the cost of developing, preparing and maintaining UK Public Assessment Reports (UKPARs) to the standard required by the new EC legislation and the costs associated with the introduction of an extended pharmacovigilance programme (monitoring of suspected adverse reactions) in accordance with EC legislative requirements.

3.10 The Regulations also implement the second stage of a three-year project to restructure licence fees that has previously been agreed with industry. In addition, new fees for varying the conditions specified in a marketing authorisation are being introduced in line with the UK variations procedures set out in the Regulations. These charges will substitute existing procedures and should therefore broadly be cost neutral.

3.11 Overall the additional revenue raised against industry by these Regulations is estimated to be in the order of £500,000, equivalent to approximately 9.7% of the total take from industry in 2004/05. Of this, approximately 3.5% is necessary to cover the UKPAR costs and 2.5% to cover the extended pharmacovigilance programme. 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.

3.12 Fees were last increased in 2004, resulting in an 8.7% 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 an amending EU Directive (2004/28/EC - a transposition note is attached at Annex 2). The amending Directive was published on 30 April 2004 following negotiations between the European Commission, Member States and the European Parliament. The negotiations formed part of an extensive review of EU legislation on both human and veterinary medicines on which the Department of Health led for the UK. The Department of Health and the Department for Environment, Food and Rural Affairs (Defra) jointly submitted Explanatory Memorandum (EM) 1459/01 on 17 January 2002. The House of Commons Scrutiny Committee cleared the EM on 26 June 2002 following a debate in European Standing Committee C. The House of Lords Scrutiny Committee subsequently cleared the EM in January 2003. Further EMs were submitted at key stages as negotiations developed, and additional information was provided by letter to the Committee Chairmen. In transposing the Directive's provisions consideration has been given to incorporating requirements in Codes of Practice or guidance notes rather than including the detail in legislation, where appropriate. However, in general there has been limited scope for flexibility in order to fulfil the UK's obligations of membership of the EU.

4.2 The Regulations also take forward the principles of the Government's Better Regulation initiative. In this context they replace voluminous UK legislation, including numerous amendments, based on the Medicines Act 1968, much of which is outdated, cumbersome and difficult to understand. They will contain all the UK legislation directly applicable to veterinary medicines in a single set of Regulations, apart from the DTI legislation at 4.3 below. Their structure is based on a main body with separate schedules for different aspects and they are drafted as far as possible in plain English. This is intended to make them transparent and easy to navigate and understand. Furthermore, it is proposed that the Regulations will not be amended in future. It is intended that when any changes are required they will be revoked and replaced by a new set of Regulations incorporating the changes. In this way a single piece of legislation containing all the current provisions will be maintained.

4.3 In addition, the Regulations take forward certain recommendations in recent reports of the Independent Review of Dispensing by Veterinary Surgeons of Prescription Only Medicines (the "Marsh Report") and of the Competition Commission on the supply within the United Kingdom of prescription-only veterinary medicines. Other recommendations of the Competition Commission Report are being taken forward in separate legislation made by the Department for Trade and Industry.

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 In 1995 two EU authorisation procedures were established. One is a centralised procedure, applicable to certain high technology and other innovative products, under which marketing authorisations are issued by the European Commission and are valid in all Member States. The other is a decentralised procedure under which the holder

of a marketing authorisation issued in one Member State may apply to one or more other Member States to issue identical authorisations based on mutual recognition. In considering applications both procedures permit Member States to take account of differences such as local disease patterns, species, husbandry techniques and environmental factors that may affect the safe and effective use of a product in a particular Member State.

7.3 The EU legislation establishing these procedures required the European Commission to undertake a review of their operation within 10 years. On the basis of this review the Commission proposed amendments to the legislation on both human and veterinary medicines, which were considered by the Member States and the European Parliament. This led to the publication of Directive 2004/28/EC, which amends Directive 2001/82/EC on veterinary medicines. The Veterinary Medicines Regulations implement these provisions as amended.

7.4 In addition to implementing the amended EU provisions, the opportunity has been taken to undertake a complete review of the UK legislation and to simplify, streamline and update it, replacing numerous instruments with a single set of Regulations containing all the provisions. The Regulations also take account of relevant recommendations in the recent Marsh and Competition Commission Reports on the supply of veterinary prescription only medicines.

7.5 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. One issue, that of requiring all medicines for use in food-producing animals to be available only on prescription - prescription only medicines (POMs) - attracted some public attention but this was largely because it was misrepresented in some parts of the media as applying to medicines for non-food animals kept as pets. In addition, beekeepers expressed concerns about the potential effects if medicines for bees had to be obtained through veterinary surgeons. However, the Regulations include provisions for medicines currently available without prescription to be supplied by suitably qualified persons other than veterinary surgeons. In addition, separate negotiations are continuing in Europe to exempt bee medicines from the prescription requirement. A proposal to prohibit the distance selling of veterinary medicines supplied by post or courier also attracted some interest from pet owners as well as retail suppliers. In the light of comments received the Regulations were amended to allow such sales to continue.

7.6 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 300 interested organisations and individuals. Four months were allowed for comment and some 300 responses were received. 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 focussed on four main issues including those referred to above on prescription only status for food animal medicines and the proposals on distance selling. The other two issues concerned restrictions on the

advertising of prescription only medicines and record-keeping requirements for suppliers of POMs.

7.7 The advertising issue concerns a provision in the Regulations implementing one in the amended Directive prohibiting advertising to the general public of veterinary POMs. Provisions are included in the Regulations to permit such advertising to relevant healthcare professionals. Following comments received the exemptions have been extended to also permit advertising to professional owners/keepers of animals.

7.8 The record-keeping issue relates to the implementation of a provision in the amended Directive extending record-keeping requirements that currently apply to most medicines for food-producing animals to apply also to medicines for companion (i.e. pet) animals. A number of comments were received, particularly from companion animal veterinary practices expressing concern about the potential costs of complying with the requirements. However, we intend to take a pragmatic approach to the requirements that will allow flexibility in the way they are met, making full use of information already recorded. We consider that this will avoid any significant costs being incurred.

7.9 The Regulations also include provisions to apply a derogation in the Directive providing an exemption from marketing authorisation requirements for certain medicines intended solely for use in specified species kept as pets. This was the subject of separate consultation with companies marketing such products and was supported by those concerned.

7.10 In addition, separate consultations were held on revised proposals for medicated feeds and feed additives and on proposals for revised fees charged by the Veterinary Medicines Directorate (VMD) for regulatory activities concerning the authorisation of veterinary medicines and related work.

7.11 The provisions on medicated feeds and feed additives were revised to take account of a new EU Regulation, which required some consequential amendments to the relevant schedule to the Veterinary Medicines Regulations. Consultation respondents provided comments on particular issues, many of which sought clarification or raised points of detail. The main issues raised related to:

- apparent inconsistencies with separate legislation being developed by the Food Safety Authority (FSA) to implement some parts of the new EU Regulations;

- clarification of provisions for the approval of distributors of medicated feeds;

- inclusion of provisions for suspension and revocation of approvals as an alternative to prosecution where certain requirements are not met; and

- applying the provisions of the prescribing cascade (which, in the absence of a product authorised for the condition and species being treated permit a veterinary surgeon to prescribe or administer certain alternatives) to apply to in-feed veterinary medicinal products.

These issues were taken into account and the draft Regulations were amended as appropriate.

7.12 The VMD is the UK Regulatory Authority for veterinary medicines. It is required to recover the costs of its licensing and related activities through fees charged to the industry. It was decided to include the fees provisions in the new regulations, rather than retaining separate fees legislation. The provisions include changes to the structure of the fees regime and to the amounts charged. Although these changes were widely consulted upon, only four responses were received as set out in the attached RIA. The two most significant issues raised are summarised below.

7.13 Comments were received from one respondent relating to the cost of producing UK Public Assessment Reports (UKPARS). The additional resources needed to develop, prepare and maintain the UKPARs require an increase of 11% on the capital fees for assessment work. The National Office of Animal Health (NOAH), the trade association representing the veterinary pharmaceutical industry, believes that the charge should come from the public purse and not be levied as a further charge on MA holders. However, the VMD is required by Ministers to recover the full cost of the authorisation of veterinary medicines from the veterinary pharmaceutical industry. Government funding is not available to cover the cost of this activity and the only option available is to apply the 11% increase in capital fees.

7.14 Comments were received from one respondent relating to the Graded Annual Fee rate. The Graded Annual Fee is charged as a percentage of industry turnover in the preceding calendar year. NOAH expressed concern that the VMD had not revealed the turnover growth assumption made in deciding the necessary fee rate. NOAH believes that the industry turnover growth for 2004 was 4%. The VMD's planning assumptions included a 2% industry turnover growth. NOAH's assertion that industry turnover growth has been 4% for the preceding calendar year means that VMD could receive up to 2% more than predicted in pricing calculations. In response to NOAH, the VMD has therefore reduced the increase in Graded Annual Fee from 11.5% to approximately 9.5%. (Figure roundings to two decimal places in fact mean that the reduction will actually be 1.7%).

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.

ANNEX 1

	Existing Fee £	New Fee £
National Marketing Authorisation Applications		
New active substance (formerly "Major")	22,270	25,500
Complex	12,920	14,795
Standard	5,580	6,390
Identical data (formerly "Simple (Copycat)")	1,555	1,785
Provisional - New active substance	12,920	14,795
Conversion from Provisional - New Active Substance - within 2 years[1]	9,350	10,705
Provisional - Complex	5,580	6,390
Conversion from Provisional - Complex - within 2 years[1]	7,340	8,405
[1]Conversion after more than 2 years attracts the full application fee.		
Pharmacologically Equivalent (previously "Abridged Standard") Marketing Authorisations:		
Reference product authorised within the UK	4,360	4,995
Reference product authorised outside the UK[2]	n/a	6,390
[2]Translation costs will also be charged if applicable.		
Parallel Imports		
Application[2]	1,745	2,000
Reference product authorised outside the UK - one member State	n/a	1,650
Additional member States	n/a	330
National Marketing Authorisation Variations		
Complex	2,460	n/a
Standard	620	n/a
Administrative/new company name	240	n/a
Type I - Change of Address	240	n/a
Consequential scientific	240	n/a
Scientific	620	n/a
Type II - Simultaneous change	240	n/a
- Change of distributor	240	n/a
- Change of MA holder	240	n/a
- Simple dosage changes	620	n/a
- Additional safety warnings	620	n/a
- Minor corrections/changes	620	n/a
- Full Type II	2,460	n/a
Type IA (per Directive 1084/2003)	n/a	330
Type IB (per Directive 1084/2003)	n/a	770
Type IB: Identical changes to a number of products - each subsequent product	n/a	330
Type II	n/a	2,540
Type II: Identical changes to a number of products - each subsequent product	n/a	330
Type II reduced fees[3]	n/a	770
Autogenous (formerly "Emergency") Vaccine	40	n/a
[3]The Regulations set out 9 Type II categories that attract the Type II reduced fee		
National Marketing Authorisation Renewals		
1st Renewal after 5 years of granting of MA issued on or after 1 November 2005	1,110	1,275
1st Renewal of MA issued before 1 November 2005	n/a	1,275
Subsequent renewal of MA issued before 1 November 2005	n/a	290
Subsequent renewal where further assessment required to satisfy post authorisation commitments	n/a	1,275
Second or successive renewal	1,110	n/a
Provisional MA - 1st reassessment	n/a	290
Provisional MA - subsequent reassessment	n/a	1,275
Provisional MA - second or successive renewal	1,110	n/a
Change of Ownership	1,110	n/a
Autogenous (formerly "Emergency") Vaccine	40	n/a

Homoeopathic Registration

Application - repeat stocks and formulations		
- not more than 5 stocks	130	150
- more than 5 stocks	305	350
Application - repeat stocks or formulations		
- not more than 5 stocks	375	430
- more than 5 stocks	545	625
Application - other		
- not more than 5 stocks	620	710
- more than 5 stocks	800	920
Application - pre-existing Human/EEA State		
- not more than 5 stocks	130	150
- more than 5 stocks	305	350
Renewal	90	n/a
Variation	105	n/a

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 - mutual recognition by one member State (previously up to five member states):

	Up to five member states:	One member state:
Major	3,995	n/a
Complex	2,670	n/a
Standard	1,150	n/a
Simple (Copycat)	390	n/a
Pharmaceutical - Food Producing	n/a	2,290
Pharmaceutical - Non-Food Producing	n/a	1,775
Immunologicals	n/a	2,000

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 (previously sixth and each succesive member State):

	6th and each successive:	2nd and each successive:
Major	865	n/a
Complex	420	n/a
Standard	215	n/a
Simple (Copycat)	70	n/a
Pharmaceutical - Food Producing	n/a	500
Pharmaceutical - Non-Food Producing	n/a	500
Immunologicals	n/a	500

Where the application is received more than six months after the grant of the Marketing Authorisation - mutual recognition by one member State (previously up to five member states):

	Up to five member states:	One member state:
Pharmaceutical - Food Producing	9,795	9,860
Pharmaceutical - Non-Food Producing	6,540	6,905
Immunologicals	5,230	8,385

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 (previously sixth and each succesive member State):

	6th and each successive:	2nd and each successive:
Pharmaceutical - Food Producing	1,230	500
Pharmaceutical - Non-Food Producing	820	500
Immunologicals	655	500

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

New active substance (formerly "Major")	12,285	14,070
Complex	7,375	8,445
Standard	3,690	4,225
Identical data (formerly "Simple (Copycat)")	975	1,120
Pharmacologically equivalent - reference product authorised in the UK	n/a	3,305
Pharmacologically equivalent - reference product not authorised in the UK[5]	n/a	4,225

[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:

New active substance (formerly "Major")	n/a	29,510
Complex	n/a	18,800
Standard	n/a	10,400
Identical data (formerly "Simple (Copycat)")	n/a	4,075
Pharmacologically equivalent - reference product authorised in the UK	n/a	9,000
Pharmacologically equivalent - reference product not authorised in the UK[5]	n/a	10,400

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

- recognition by the second and each successive member state:

All above categories	n/a	500

Where UK is CMS (ie not the reference member State):

New active substance (formerly "Major")	n/a	14,070
Complex	n/a	8,445
Standard	n/a	4,225
Identical data (formerly "Simple (Copycat)")	n/a	1,680
Pharmacologically equivalent - reference product authorised in the UK	n/a	3,305
Pharmacologically equivalent - reference product not authorised in the UK[5]	n/a	4,225

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

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	240	n/a
Type IB	240	n/a
Type II	2,460	n/a
Variation with extras	4,375	n/a
Connected variation	240	n/a
Type IA (per Directive 1084/2003)	240	330
Type IB (per Directive 1084/2003)	240	355
Type IB - identical data, identical changes and submitted at the same time:		
- first variation	n/a	355
- each subsequent variation	n/a	330
Type II	2,460	2,540
Type II - identical data, identical changes and submitted at the same time:		
- first variation	n/a	2,540
- each subsequent variation	n/a	330
Type II - to correct SPC or product literature, or simple text layout changes	n/a	355

Where UK is RMS:

Type IA	1,590	n/a
Type IB	2,615	n/a
Type II	9,145	n/a
Variation with extras	10,460	n/a
Connected variation	1,590	n/a
Type IA (per Directive 1084/2003)	240	1,675
Type IB (per Directive 1084/2003)	240	2,705
Type IB - identical data, identical changes and submitted at the same time:		
- first variation	n/a	2,705
- each subsequent variation	n/a	1,675
Type II	2,460	10,125
Type II - identical data, identical changes and submitted at the same time:		
- first variation	n/a	10,125
- each subsequent variation	n/a	1,675
Type II - to correct SPC or product literature, or simple text layout changes	n/a	2,705

Renewals for Mutual Recognition and Decentralised Procedure:

Where UK is RMS:

Renewal after 5 years of granting of MA	n/a	1,720

Where UK is CMS:

Renewal after 5 years of granting of MA	n/a	1,145

Manufacturer's Authorisation

Application	2,505	2,595
Variation requiring scientific or pharmaceutical assessment	445	465
Variation not requiring scientific or pharmaceutical assessment	150	160
Autogenous (formerly "emergency") vaccines:		
Standard authorisation for each manufacturing site		2,960
Single Batch		1,480
Variation requiring inspection		2,960
Variation not requiring inspection		280
Annual Fee - other than autogenous vaccines	230	240
Annual Fee - autogenous vaccines - % of turnover in previous calenday year	0.71%	0.67%
Emergency vaccines	110	-
"Special & Transitional cases"	110	-
Variation emergency vaccines	110	-
Variation - "Special & Transitional cases"	110	-

Note: If an inspection is necessary, an inspection fee is charged in addition to the application fee.

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.

Immunological GMP inspections:

Supersite	17,085	24,015
Major site	9,440	16,900
Standard site	6,160	5,435
Minor site	3,105	4,745
Test site	n/a	2,665
Biological product - Quality Control only	1,480	n/a
Biological product - Quality Control only - Identical Data	65	n/a

Note: Follow-up inspections attract the above fee only if conducted more than 6 months after the original inspection.

GMP Inspections other than Immunological inspections:

Supersite - Sterile	17,085	17,685
Major site - Sterile	9,440	9,775
Standard site - Sterile	4,640	4,805
Minor site - Sterile	3,105	3,215
Supersite - non-sterile	10,300	10,660
Major site - non-sterile	5,420	5,610
Standard site - non-sterile	3,885	4,025
Minor site - non-sterile	2,095	2,170
Supersite - Assembly of products only	7,485	7,750
Major site - Assembly of products only	5,055	5,235
Standard site - Assembly of products only	2,480	2,570
Minor site - Assembly of products only	1,280	1,325
Emergency vaccines	115	-

Test sites

Inspection of a test site	n/a	2,665

Small Animal Blood Bank Certificate:

Authorisation to operate a small animal blood bank	n/a	2,960
Subsequent inspection	n/a	2,960
Variation	n/a	280

Wholesale Dealer's Authorisation

Application - first year's turnover estimate more than or equal to £40,000	1,455	1,510
Application - first year's turnover estimate less than £40,000	595	620
Variation requiring scientific or pharmaceutical assessment	445	465
Variation not requiring scientific or pharmaceutical assessment	150	160
Annual Fee - turnover more than or equal to £40,000	465	485
Annual Fee - turnover less than £40,000	230	240

Fees relating to feedingstuffs

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 products for incorporating into feedingstuffs, no fee is payable).	GB: 866 NI: 466	UK: 866 NI: 466
Application for the approval of an establishment to manufacture feedingstuffs using specified feed additives directly, premixtures using veterinary medicinal product or feedingstuff at any concentration, and the subsequent annual fee	GB: 546 NI: 368	GB: 546 NI: 368
Application for the approval of an establishment to manufacture feedingstuffs using veterinary medicinal product only at a rate of 2kg per tonne or more when the feedingstuffs are to be placed on the market, and the subsequent annual fee	GB: 365 NI: 271	GB: 365 NI: 271
Application for the approval of an establishment to manufacture feedingstuffs using premixtures from specified feed additives when the feedingstuffs are to be placed on the market, and the subsequent annual fee	GB: 188 NI: 145	GB: 188 NI: 145
Application for the approval of an establishment to manufacture feedingstuffs using veterinary medicinal product only at a rate of 2kg per tonne or more when the feedingstuffs are to be used by the person manufacturing the feedingstuffs, and the subsequent annual fee.	GB: 135 NI: 111	GB: 135 NI: 111
Application for the approval of an establishment to manufacture feedingstuffs using premixtures from specified feed additives when the feedingstuffs are to be used by the person manufacturing the feedingstuffs, and the subsequent annual fee	GB: 115 NI: 93	GB: 115 NI: 93

Note: Where more than one of the above activities is carried out at one premises, only one fee (the highest) is payable.

Distributers:

Application to be a distributor of specified feed additives, veterinary medicinal products for incorporating into feedingstuffs, premixtures or feedingstuffs containing them	GB: 128 NI: 59	GB: 128 NI: 59
Renewal	GB: 128 NI: 59	GB: 128 NI: 59

Annual Fees for Marketing Authorisations

Graded - % on turnover	0.61%	0.67%
Fixed - per Marketing Authorisation		
Turnover of all authorised products equal to or greater than £215,000	208	215
Turnover of all authorised products less than £215,000	26	55
Authorisation holders who fails to provide audit certificate within 30 days		
Additional fee to above:		
Basic fee	10,000	10,500
Additional fee per MA held	2,000	2,100
Late payment of annual fees:		
Additional fee as percentage of annual fee due:		
Paid 31 to 60 days after due date	1%	1%
Paid 61 to 90 days after due date	2%	2%
Over 90 days after due date	5%	5%

Submission 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.

Animal Test Certificates

Application - Type A	305	320
Application - Type B	735	765
Variation	240	250
Renewal	115	120

Import Certificates:

Special Import Certificate - from inside the EU	n/a	15
Special Import Certificate - from outside the EU	n/a	30
Speciat Treatment Authorisation	n/a	15
Renewal of SIC/STA - online application via VMD website	n/a	15
Renewal of SIC/STA - postal application	n/a	30

Note: Import certificate fees are per animal, except for some exceptional circumstances ("discrete groups") agreed in writing.

Specific Batch Control

Certificate to release a product under specific batch control	500	520
Submission of the results of tests carried out on a batch prior to release[6]	n/a	75

[6]As a transitional measure, no fee is payable in relation to results submitted before 1 April 2006.

Export Certificates

Each Certificate	25	30
Certified copy of each original	10	15

Approval of premises for supply by Suitably Qualified Persons

Approval of premises	232	232
Approval of premises - horses and companion animals only	127	127
Subsequent annual fee	165	165
Subsequent annual fee - horses and companion animals only	88	88
Subsequent annual fee - if not paid within 60 days	197	197
Subsequent annual fee - horses and companion animals only - not paid within 60 days	107	107

Application to Veterinary Products Committee (VPC)

New active substance (formerly "Major")	1,755	1,820
Complex	1,010	1,050
Standard	465	485
Pharmacologically equivalent	n/a	485
Identical data (formerly "Simple (Copycat)")	180	190
Animal Test Certificate	610	635

ANNEX 2

TRANSPOSITION NOTE 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 2005

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(3)
Article 3(2)	Dealt with under the "cascade" provisions in Schedule 3 paragraph 8 and Schedule 4 paragraph 2
Article 4(1)	This derogation is not being exercised
Article 4(2)	Schedule 6
Article 5	Regulations 4 and 6
Article 6(1)	Schedule 1 paragraph 23
Article 6(2)	Action by Member State
Article 6(3)	Schedule 1 paragraph 23
Article 7	Schedule 1 paragraph 16
Article 8 first paragraph	Schedule 4 paragraph 4
Article 8 second paragraph	Community competence
Article 8 third paragraph	Schedule 4 paragraph 5
Article 9	Regulation 8

Articles 10 and 11	The cascade under Schedule 4 paragraphs 2 and 3
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(7)
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 13.
Article 65(2)	Schedule 3 paragraph 14(4)
Article 65(3) first and third paragraph	Regulation 22
Article 65(3) second paragraph	Schedule 3 paragraph 18(3)
Article 65(3)(a)	Schedule 3 paragraph 14(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 10
Article 66 third paragraph	Regulation 23(5)
Article 66(3)	Schedule 3 paragraph 9
Article 67 first and third paragraph	Schedule 3 paragraph 1
Article 67 second paragraph	Schedule 3 paragraph 5(2)
Article 68(1)	This is achieved though the classification of the veterinary medicinal products
Article 68(2) and (3)	The lists are published by the Department and the appropriate professional bodies. The records are in the record-keeping requirements at Regulations 17 to 24.
Article 68(3)	Administrative measure; nothing to implement
Article 69	Regulation 17, 19 and 20
Article 70	Schedule 4 paragraph 6
Article 71	The Department has not exercised this derogation
Article 72(1)	This "encouragement" is done by means of circulars and does not appear in legislation
Article 72(2)	The Department has not exercised this power
Article 73	Administrative measure; nothing to implement
Article 73(a)	Administrative measure; nothing to implement
Article 74 first paragraph	Schedule 1 paragraph 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)

FULL REGULATORY IMPACT ASSESSMENT

TITLE: THE VETERINARY MEDICINES REGULATIONS 2005

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 the medicine 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. There is a large amount of UK legislation regulating veterinary medicines. Much is based on the 1968 Medicines Act and some has been amended many times. Some changes are necessary following a review and consequential amendment of European legislative provisions and to take forward recommendations in two reports on aspects of the supply of prescription-only veterinary medicines in the UK. It is considered that the time is right for a complete review and overhaul of the UK legislation. Significant compensatory simplification will be achieved as a result because the Veterinary Medicines Regulations 2005 are intended to replace the existing UK legislation on veterinary medicines.

PURPOSE AND INTENDED EFFECT

(i) Objective

2. The objective of the Regulations is to:

(a) implement amendments to EU legislation on veterinary medicines;

(b) increase the transparency of the legislative provisions by replacing the Medicines Act and numerous statutory instruments (SIs) with a single set of Regulations containing where possible simplified and streamlined provisions that are clearer and more easily understood;

(c) take forward relevant recommendations of the Marsh and Competition Commission reports on the supply of prescription-only medicines.

And in doing so to produce a regulatory regime that:

(i) maintains and strengthens necessary safeguards and promotes the safe, effective and responsible use of veterinary medicines;

(ii) minimises burdens on industry as far as possible;

(iii) encourages the development and availability of veterinary medicines and makes the UK an attractive base for the research and development of new products;

(iv) helps to facilitate competition in the supply of veterinary medicines so as to increase consumer choice and foster competitive pricing of veterinary medicines;

(v) retains the position of the UK as a leading regulatory authority in respect of European authorisation procedures.

3. The changes will primarily affect the veterinary pharmaceutical industry, which includes the companies marketing, and manufacturing 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;
registered agricultural merchants and saddlers;
owners and keepers of food animals (including farmers and beekeepers);
owners and keepers of companion and other non-food 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.

However, the control regime for veterinary medicines is well established and, while some changes are substantial, the majority are minor modifications of current procedures that will have only a small impact on current practice.

Devolution

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

(ii) Background

5. The Medicines Act 1968 introduced the requirement for veterinary medicines to be authorised before they may be placed on the market in the UK. Marketing authorisations (MAs) are only granted following scientific assessment of data generated by the applicant against

statutory criteria of safety, quality and efficacy. The 1968 Act, and secondary legislation made under it, set out controls on the manufacture, distribution, sale, supply and administration of veterinary medicines. Since 1981 many aspects of these controls, including the procedures and requirements for authorisation, have increasingly been harmonised across the European Community and have consequently been set out in EU legislation. In the UK, parts of the Medicines Act and related statutory instruments (SIs) have been disapplied and replaced by Regulations directly implementing provisions of EU directives.

6. In accordance with a requirement in EU legislation, a major review of the operation of the European procedures and controls (known as Review 2001) was carried out during 2000 and 2001. Before this work was started the European Commission codified the previous legislation into a single Directive (2001/82/EC). The Review 2001 considered the provisions in this Directive, a Directive on human medicines and an EU Regulation which set out procedures for EU centralised authorisations for veterinary and human medicines and established a European Medicines Agency. The European Commission proposed amendments to each. After negotiations among the Member States and the European Parliament, an amending Directive (2004/28/EC) and a replacement Regulation (No. 726/2004) were adopted on 31 March 2004. As EU Regulations are directly binding on Member States, transposition of the new Regulation into EU law is not required. However, there is a need to change UK legislation to reflect the codification and implement the provisions of the amending EU Directive.

7. In addition, the Report of the Independent Review of Dispensing by Veterinary Surgeons of Prescription Only Medicines (the Marsh Report of May 2001 – available on www.vmd.gov.uk under "Independent Review of Dispensing") included recommendations, accepted by the Government, that have been deferred until the outcome of the EU review became known. These, and relevant recommendations of the Competition Commission Report on the supply within the United Kingdom of prescription-only veterinary medicines (CM 5781 of 11 April 2003 – available on www.competition-commission.org.uk) will be incorporated within the new legislation.

8. It was also decided to use this opportunity to carry out a Better Regulation Review of all the UK legislation on veterinary medicinal products. Rather than further amending the existing legislation (the 1968 Act and some 50 SIs and a further 50 amending SIs), it is intended that the new SI will revoke or disapply the existing legislation and replace it with a single set of Regulations containing all the required provisions. It is also intended that the new Regulations will remove provisions no longer considered necessary and simplify and streamline others wherever possible. For some aspects, the new Regulations will apply changes to the procedures and practices

currently followed, for others they will merely present the requirements in a clearer and more transparent way, making it easier for relevant requirements to be identified and understood. The Regulations will also include the UK legislative provisions governing medicated feedingstuffs and zootechnical feed additives so that it will be possible to access all these provisions in one document. In addition, the Regulations will include the provisions governing the fees charged by the VMD for licensing and associated work on veterinary medicines that were previously contained in separate legislation. A separate RIA was prepared in respect of the fees proposals and is attached as an Annex to this RIA.

(iii) Risk Assessment

9. 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.

10. The regulatory system, which, in essence, 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.

11. The annual turnover of the UK veterinary pharmaceutical industry was approximately £420 million in 2004. However, the veterinary pharmaceutical industry is a global one and the enlarged European Union's Single Market of 450 million people and many million animals represents a significant market for the industry. A fragmented regulatory system would be a significant barrier to trade and would impose unnecessary financial and regulatory burdens on the industry, which, in turn would militate against the development and availability of veterinary medicines, particularly for minor species and conditions. For this reason, since 1981, the Community has been working to remove these barriers so that a veterinary medicinal product authorised in one Member State can be marketed in another, (by developing authorisation procedures based on mutual recognition) and, for certain products, by developing a centralised authorisation procedure under which marketing authorisations are valid throughout the EU. The steps towards the creation of a Single Market in veterinary pharmaceuticals have gone hand in hand with robust public and animal health and environmental protection.

12. It is an obligation of membership of the EU to fully implement the amendments contained in Directive 2004/28/EC. Failure to do so would leave the UK at risk of infraction proceedings. In addition, the

Government has accepted recommendations made in the Marsh and Competition Commission Reports and some changes to legislation are required to take these forward.

13. The current UK legislation is voluminous, provisions are often difficult to locate and their meaning is frequently unclear. This makes it difficult for industry and others to identify the requirements they should follow and difficult for the regulatory authority to ensure that the provisions are applied consistently and fairly. The new Regulations seek to re-order the provisions within a single SI and to present them in a clearer and more transparent way. In addition, the new Regulations seek to remove existing provisions that are not required by EU law and are no longer considered necessary for the safe and effective use of veterinary medicines in the UK.

Benefits of the Proposals to the UK

14. The proposed Regulations include a number of provisions, resulting both from the amendments to EU legislation and from the Better Regulation Review of the UK legislation, that are considered beneficial to the UK. These include the following:

i. Provision to authorise generic products based on reference products authorised in another Member State rather than the reference product having to be authorised in the Member State in which the generic application is made.

ii. Provision to allow generic applications to include data from tests and/or trials to address issues that are not adequately covered by reference to the “parent” product.

iii. Data protection period harmonised at 10 years across the EU (in line with current UK provisions) plus extensions of up to 3 years for medicines for fish and bees and in certain circumstances where additional food-producing species are added to an authorisation.

iv. Prescribing cascade options extended to permit veterinarians to use medicines authorised in another Member State where no suitable medicine is available in the UK.

v. Prescribing cascade modified to allow horses declared non food-producing under the horse passport requirements to be treated with medicines whose active ingredients do not have maximum residue limits (MRLs) established.

vi. Provision to permit authorisation for use in horses declared non food-producing under the horse passport provisions of medicines whose active ingredients do not have established MRLs (this allows the UK to retain a number of medicines for use in such horses that would otherwise be prohibited).

vii Provision to permit the use in food-producing horses of medicines whose active ingredients do not have MRLs but that are on a list of substances considered essential for the treatment of horses to be produced by the Commission subject to the application of a minimum 6-month withdrawal period.

viii. Abolition of the regular 5-yearly renewal requirement for marketing authorisations and replacement with a single renewal with provision for a second renewal exceptionally where justified by monitoring of adverse reactions.

ix. Renewal applicants need only provide a list of documents submitted rather than a full revised data dossier.

x. Increased frequency of periodic safety update reports (PSURs) which will strengthen post-authorisation monitoring of adverse reactions to authorised products.

xi. Provision for simultaneous applications in two or more Member States under the decentralised authorisation procedure rather than having to obtain an initial authorisation before applying to other Member States.

xii. Formalisation of the veterinary mutual recognition facilitation group (VMRFG). This was established informally by the UK to facilitate mutual recognition procedures. It is being given formal status, which will give increased weight to its opinions and recommendations.

xiii. Provision for all medicines for food-producing animals to be prescription only medicines (POMs), in line with EU requirements, while essentially maintaining the current UK distribution arrangements for most products that are currently available without veterinary intervention.

xiv. Provision for the issue of certificates of good manufacturing practice (GMP) and for the publication of holders of GMP certificates.

xv. Provision for the publication of summaries of product characteristics (SPCs) and UK public assessment reports (UKPARs).

These provisions will help to make it easier for companies to market their products and, by increasing the availability of medicines, will help veterinarians and animal owners/keepers to obtain safe and effective medicines. The main thrust of the Regulations is to maintain and enhance animal welfare. The maintenance of good animal health and welfare will result in significant social benefits, as will strengthening the monitoring of adverse reactions to authorised products and increasing transparency by making more information publicly available.

Significant Compensatory Simplification

15. In addition to the above, the Regulations will also be beneficial in terms of simplifying the structure and format of the legislation on veterinary medicines. They replace the Medicines Act and some 50 statutory instruments (SIs) with a single set of Regulations containing all the provisions on veterinary medicines. They also contain the provisions on medicated feeds and zootechnic feed additives, which are subject to different EU legislation, and provisions on fees, all of which were previously contained in several separate SIs. By putting all the requirements in a single legislative instrument it will make it much easier for those concerned 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. In addition, the aim has been to draft the Regulations, as far as possible, in language that can be readily understood by non-lawyers. This should make them much easier to understand than the previous legislation, much of which was written in outdated and largely incomprehensible language and which contained numerous references to other sections or pieces of legislation. Furthermore, a policy decision has been taken that the Regulations will not be amended in the future. Where changes are required, the Regulations will be revoked and replaced with new Regulations incorporating the necessary changes. In this way, it is intended that current Regulations will provide a comprehensive consolidated piece of legislation and will avoid the need to locate and consider additional amending SIs.

16. Although difficult to quantify, the simplification of the 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, the new 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. Clearer and more 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. They should also help to reduce the administrative burden on industry and reduce the time and cost of obtaining legal advice.

OPTIONS

17. 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 provisions in the amending Directive permit flexible interpretation of the requirements, alternative interpretations have been considered. Where legislative provisions are considered to be required, two basic options were considered:

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

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

It was considered that option (a), while being administratively simpler, would further add to the already voluminous legislation on veterinary medicines and would do little, if anything, to improve the transparency of the regulatory regime. It was therefore decided to proceed with option (b) and to combine this with a full review of all the existing UK legislation against the principles of the Better Regulation initiative.

18. Specific options relating to significant issues considered as having potential for economic, social or environmental implications are identified below. As indicated below, some of these relate to specific provisions in the Directive for which there is little or no flexibility in the way that they are implemented.

Options for Specific Issues

I. Authorisation of medicines without MRLs for use in non food-producing horses.

EU law prohibits the authorisation of a veterinary medicine for food-producing animals unless a maximum residue limit (MRL) has been established for the pharmacologically active substance(s) it contains. This is necessary to ensure consumers of produce from treated animals are not exposed to potentially harmful residues of the medicine. In the UK the majority of horses are traditionally regarded as non-food producing and are used for social and leisure activities. However, under EU law horses are classified as a food-producing species. The cost of generating the necessary data and of compiling and submitting an application for the establishment of an MRL is such that it is not considered economically attractive by companies marketing veterinary medicines for use in horses. There is, therefore, a risk that medicines necessary for the health and welfare of horses could be lost.

The amended Directive provides a derogation from the MRL requirement allowing, subject to certain restrictions, veterinary medicines without an MRL to be authorised for horses declared non-food producing in accordance with the horse passport scheme rules. Although the UK currently permits such products, with a contra-indication that they should not be used in food producing horses, the Commission has challenged the legality of this in the absence of a

robust mechanism for distinguishing horses that may be slaughtered for human consumption. Horse passport schemes will provide an appropriate mechanism for applying the derogation in the amended Directive across the UK, which will allow many of the current products to be retained. However, the derogation excludes products containing substances in Annex IV of Regulation (EEC) No 2377/90 (the EU MRL Regulation). Currently one such product is authorised in the UK and it will not be able to remain on the market when the amended directive takes effect. The EU horse passport legislation also permits the use of certain medicines without MRLs in food-producing horses provided a minimum 6-month withdrawal period is observed.

Option 1: Continue to allow authorised products with contra-indications as now. This would leave currently authorised products in a legally uncertain position. It is highly likely that the Commission would take infraction proceedings against the UK and, ultimately the medicines concerned may be lost. **It is not considered viable therefore.**

Option 2: Include a provision in the Royal College of Veterinary Surgeons (RCVS) Code of Practice requiring veterinary surgeons to be responsible for verifying that particular horses will not enter the food chain and restrict all such medicines to use by veterinary surgeons only. This would not satisfy the Commission that a robust system was in place to distinguish between food-producing and non food-producing horses and would be likely to incur infraction proceedings and potential loss of products as in option 1. Also, veterinary surgeons would not know for certain whether individual horses would enter the food chain and would, therefore, be unable to provide verification. **It is not considered viable therefore.**

Option 3: Incorporate the derogation into the new legislation and vary the relevant existing MAs so that product labels refer to the horse passport requirements. This option would utilise the established horse passport provisions and would fully implement the EU provisions thereby removing the risk of infraction proceedings.

Option 4: Revoke all the marketing authorisations for veterinary medicines for horses unless a relevant MRL and residues depletion data package exists for each. This option would not take advantage of the derogation provided in the Directive. It would not contravene EU provisions and, would not, therefore, attract infraction proceedings. However, it would result in the loss of some medicines, which would adversely affect the health and welfare of UK horses and would offer no benefits. **It is not considered viable therefore.**

Consultation Comments

Comments were received from 8 respondents, most of which related to clarification of detail and concern that essential medicines should not be lost. No significant issues were raised.

II. Provision for veterinary surgeons to use products authorised in another Member State under the cascade options.

Under existing provisions, veterinary surgeons treating a condition in an animal for which no veterinary medicine is authorised may use, in descending order of preference, a medicine authorised for a different species or condition, a medicine authorised for human use or a medicine specially prepared at the time to the veterinary surgeon's specifications. The amended Directive includes provision for veterinary surgeons, in accordance with national measures, to import and use a veterinary medicine authorised in another Member State as an alternative to a UK authorised human medicine.

Option 1: Retain the current cascade options and not implement the amendment. This would not effectively implement the provision in the amending Directive, which is not permissive, but is a requirement placed on Member States. **It is not considered viable therefore.**

Option 2: Implement the amendment via the RCVS Code of Practice. The authorisation, import and use of veterinary medicines are controlled by legislation. A provision is therefore required in law to implement the amendment and **implementation via a code of practice is not considered appropriate**.

Option 3: Include a provision in the new legislation to permit veterinary surgeons to import and use veterinary products authorised in other Member States without restriction. To ensure the safe use of veterinary medicines it is important that the regulatory authority is aware of the products being used and of any relevant pharmacovigilance (suspected adverse reactions) information. In addition, the use of some products may not be desirable even though they are authorised in another Member State. For example, some immunological products, such as live vaccines, may risk introducing a disease organism or may interfere with a disease control strategy. Other products may carry risks related to particular husbandry techniques, environmental factors or disease patterns applicable in the UK. Furthermore, in the case of food-producing animals, the amending Directive requires Member States to take all necessary measures concerning the import, distribution, dispensing of and information on products permitted under this provision. Failure to control the import and use of these products would therefore pose unacceptable safety risks and would not adequately implement the amending Directive's requirements. **This option is not considered viable therefore.**

Option 4: Include a provision in the new legislation to permit veterinary surgeons to import and use veterinary products authorised in other Member States subject to prior notification. This option would go some way towards addressing the concerns identified in option 3 but would not provide adequate safeguards in terms of ensuring that medicines

carrying unacceptable risks were excluded, or that the use of the product was justified – i.e. that no suitable alternative was authorised within the UK. **This option is not considered viable therefore.**

Option 5: Include a provision in the new legislation to permit veterinary surgeons to import and use veterinary medicines authorised in other Member States subject to prior approval of the UK regulatory authority. Requiring prior approval would address the concerns identified in options 3 and 4 and would provide a basis for ensuring the Directive's requirements were fulfilled. There is a risk that requiring an evaluation and approval may cause unacceptable delays in the required medicines becoming available. This could be addressed in part by the development of an interactive computerised system that would allow veterinary surgeons to enter required details over the Internet. Where the answers to standard questions demonstrated that use of the requested product was justified and did not pose unacceptable risks, the system could provide the veterinary surgeon with an authorisation number that would allow immediate import and use of the product. Where concerns remained, the request could be automatically referred to an appropriate regulatory scientist for further evaluation. The system would require a substantial database on which automatic approvals or referrals would be based and would need to be operable when the new legislation took effect. In anticipation of this option being taken forward the VMD began work to develop such a system to ensure its availability within the required timescale.

Consultation Comments

Comments were received from 11 respondents, 7 comments supported the proposal, two raised respective concerns about potential abuse and that the provision was slow and bureaucratic and two sought clarification.

III. Changes to data protection periods and increased flexibility for generic applications.

Current legislation permits an applicant for a MA for a generic product (ie a product that the applicant can demonstrate is "essentially similar" to one already authorised in the UK) to omit from the application the results of certain tests and trials and to refer instead to the relevant data provided in support of the "parent" authorisation. This option is only available with the agreement of the holder of the parent authorisation unless the parent product has been authorised for at least 10 years. The current Directive permits Member States to adopt either a 6 or 10-year period of data protection. When this provision was introduced in 1995, the UK opted to apply the maximum 10-year period. The amending Directive harmonizes the protection period at 10 years throughout the EU and permits generic applications based on "parent" authorisations in Member States other than that in which the generic application is made. It also extends the 10-year period to 13

years for products for fish or bees and up to 13 years where additional food producing species are added. In addition, it permits application for and grant of an authorisation 2 years before expiry of the data protection period, but does not allow such products to be marketed until the protection period has expired.

Option 1: Retain the current provisions. This option would not benefit anyone, as it would deny both innovator and generics companies the enhanced incentives provided in the Directive. It would not implement the Directive's provisions effectively and would carry a high risk of infraction proceedings from the Commission and/or legal challenge from both innovator and generics companies. **This option is not considered viable therefore.**

Option 2: Implement the changes via a Code of Practice. The nature of the provisions makes them unsuitable for implementation other than in legislation. **This option is not considered viable therefore.**

Option 3: Include provisions implementing the changes in the new legislation. There is little room for flexibility in implementing these provisions, particularly as they operate in a European context. Transposing them fully into the new legislation would therefore represent the most effective way of achieving their purpose and realising their potential benefits.

Consultation Comments

Comments were received from 3 respondents. All supported the proposal, and one suggested it would be better if the additional years for additional species were restricted to mutual recognition authorisations. The Directive does not permit this.

IV. Record-keeping requirements for retail suppliers of veterinary medicines.

Current legislation requires retail suppliers to keep specified records of transactions relating to veterinary medicines for use in food-producing animals, other than general sales list (GSL) products, and to retain these for 3 years. There is also a requirement to conduct, at least annually, an audit of records and stock held. The provision concerns prescription only medicine (POM), pharmacy (P) and pharmacy and merchants list (PML) products and therefore affects veterinary surgeons, pharmacists and registered agricultural merchants. This provision takes advantage of a derogation in the current Directive that permits Member States to limit the scope of the requirement. When the current provisions were implemented in the UK, Ministers agreed to limit their scope in line with the derogation in the Directive but, nevertheless, said that retailers were encouraged to voluntarily apply the provisions to companion animal products.

The amending Directive removes the derogation and modifies the scope of this provision, requiring the records to be kept in respect of all POMs. It also extends the period of retention from 3 to 5 years. This may apply the requirements to some food producing products that are currently GSL if they become POM under point VII. However, more significantly, the modified scope will include POMs for companion animals that are currently excluded from the requirement.

Option 1: Retain the current provisions. As with other issues, the "do nothing" option would not meet the UK's obligations of EU membership to fully implement Community legislation and would invite infraction proceedings. **This option is not considered viable therefore.**

Option 2: Implement the new provisions via relevant Codes of Practice. While this may be possible, it is necessary that an appropriate deterrent is in place, in the form of effective legal sanctions, to ensure compliance and to comply with the obligations of Membership of the EU. Since lack of adequate records could have potentially serious safety implications in some circumstances, it is considered that compliance should continue to be supported by the force of law. **This option is not considered viable therefore.**

Option 3: Include the amended provisions in the new legislation. This is considered the only option that would comply with the Directive's provisions and meet the UK's EU obligations. Including the provision in legislation (as is the case with the current record-keeping provisions) with the related sanctions is more likely to achieve universal compliance and, therefore, fair and consistent application of the requirement.

Consultation Comments

Comments were received from 78 respondents, almost all veterinary surgeons, making this one of the three main issues raised during the formal consultation. All except one response opposed the proposed requirements. Most considered them to be excessive, costly and unworkable, particularly the requirement to record batch numbers. Three comments raised concerns about the perceived financial burden on animal charities and animal training hospitals. Two respondents expressed similar concerns in relation to wholesale dealers. One respondent supported the proposal but suggested a transitional period for implementation to allow the introduction of a two – dimensional bar coding system that is being developed by manufacturers.

V. Increased flexibility in mutual recognition procedures.

Under current provisions, in order to obtain a MA in two or more Member States under the mutual recognition procedure, an applicant must first obtain a marketing authorisation from a single Member State. Having done so the marketing authorisation holder may then apply to

one or more other Member States to grant marketing authorisations identical to the one issued, on the basis of mutual recognition. In this case the marketing authorisation already issued is used as the reference authorisation and the Member State that issued it becomes the reference Member State (RMS) in the mutual recognition process. The amending Directive also changes the provision allowing an applicant to simultaneously submit applications to two or more Member States such that the RMS would be the Member State in which the first authorisation was granted. The amended provision permits the applicant to choose a RMS without the need to obtain a MA before so doing and then to progress the application in multiple Member States concurrently. This will speed the process considerably.

Option 1: Retain current provisions. This would not encourage increased availability of veterinary medicines. Also, as this relates to an EU procedure, this option would attract infraction proceedings and legal challenge from marketing authorisation holders. **This option is not considered viable therefore.**

Option 2: Implement the new provisions in published guidance. It is not appropriate to regulate the grant or refusal of marketing authorisations via guidance or other non-statutory means. **This option is not considered viable therefore.**

Option 3: Include the provisions, together with details of the procedure and detailed timetable to be followed, in new legislation. It is likely that this detailed timetable will be revised from time to time to enable the procedures to be followed most effectively. It is therefore not considered appropriate to include all the details in the legislation especially as EU wide guidance will be published centrally. **This option is not considered viable therefore.**

Option 4: Include the framework provisions in the new legislation and set out the detail, including a detailed timetable that accords with the timescales set out in the Directive, in published guidance. This would allow flexibility to agree the detail EU wide thereby maximising the benefits and would provide transparent provisions in line with the policy objective. It is essential that these procedures are agreed and guidance provided by all the Member States acting together. This is being carried forward by the EU Coordination Group which considers applications for the authorisation of veterinary medicines and a timetable will be adopted and published in due course.

Consultation Comments

Comments were received from 5 respondents. All supported the proposal but one pointed out that the lack of a detailed timetable should not be used to hinder or block applications.

VI. Extension of good manufacturing practice (GMP) to starting materials.

Current legislation requires veterinary medicines to be manufactured in accordance with the principles and guidelines of good manufacturing practice (GMP). This is necessary to obtain a manufacturing authorisation which is required for all manufacturers of veterinary medicines within the EU, including those manufacturing veterinary medicines for export, and for veterinary medicines manufactured in third countries and imported into the EU. GMP provisions are set out in Directive 91/412/EEC. While starting materials used as ingredients in veterinary medicines are currently subject to controls set out in Annex I to the veterinary medicines Directive, they are not currently subject to GMP requirements. The Amending Directive on veterinary medicines extends the GMP compliance requirement to active substances used as starting materials for veterinary medicinal products.

Option 1: Continue to rely on manufacturers to control the quality of starting materials they produce or buy in. This would not remove the current theoretical risk to users and consumers nor would it comply with the Directive's requirements. **This option is not considered viable therefore.**

Option 2: Institute a full inspection and GMP certification of all manufacturers of starting materials worldwide. This would address the theoretical risk but is considered disproportionate and too costly. **This option is not considered viable therefore.**

Option 3: Require full inspection and GMP certification of starting material manufacturers in the EU but not for those outside the EU where the controls of the importer would be relied upon. This would not entirely address the theoretical risk and would create an anomalous situation in which EU manufacturers would be disadvantaged as those in third countries would be able to supply more cheaply. **This option is not considered viable therefore.**

Option 4: Use a risk-based approach to consider inspection and GMP certification of the manufacture of starting materials where the ingredients, processes or previous history demonstrate that a risk may arise. A risk-based approach, harmonised across the EU, is considered proportionate. It would benefit users and consumers by addressing the theoretical risk while keeping costs down. The European Agency is currently considering the details of such an approach and we are inputting into the development of this and intend to adopt the agreed procedure.

Consultation Comments

1 comment was received, supporting the proposal.

VII. Extension of scope of veterinary prescription only medicine (POM) requirements.

The current Directive sets out criteria which, if met, require the veterinary medicine concerned to be available only in accordance with a prescription – a veterinary prescription only medicine (POM). This provision is without prejudice to stricter Community or national rules. Broadly, it applies to products subject to official restrictions or where particular precautions or a veterinary diagnosis is required to ensure the safe use of the product. In the UK the retail supply of veterinary POMs is restricted to veterinarians or pharmacists dispensing in accordance with a veterinary prescription. Veterinary medicines for which it is considered that veterinary involvement is not necessary for their safe use but that some control over retail supply is required (eg advice at the point of sale) are classified pharmacy (P) or pharmacy and merchants list (PML) products. P products may be supplied by registered pharmacists and PML products by registered pharmacists or by registered agricultural merchants by, or under the direction of, a suitably qualified person. Veterinary medicines that are considered suitable for supply without controls are classified as general sale list (GSL) products and may be supplied from any retail outlet. In addition, premixes for incorporation into medicated feedingstuffs, which are subject to different controls, are currently classified as MSF (a medicated premix which requires a prescription) or MSFX (a medicated premix which does not require a prescription), which broadly equate to POM and PML.

The amending Directive includes a provision requiring all medicines for administration to food producing animals to be POMs. There is also a provision allowing exemptions for categories of products on a list to be proposed by the Commission and voted on by the Member States. At the time of preparing this RIA it is not known what will be included on this list but it is hoped that it may include many of the current GSL products and medicines for bees, for which veterinary intervention is not considered appropriate. Currently in the UK there are approximately 300 PML and 170 GSL products for food animals, many of which, such as wormers, are routinely and safely used by farmers and stockmen without the need for veterinary involvement. If a prescription from a veterinary surgeon were required for these products it would significantly increase costs and inconvenience to farmers and other owners of food animals with no resulting benefit in respect of the safe use of the products. However, the amending Directive adds a definition of “veterinary prescription” which allows issue by “a professional person qualified to do so in accordance with applicable national law”.

Option 1: Retain the current POM provisions. This would under-implement the Directive and would carry a very high risk of infraction proceedings being taken by the Commission. **This option is not considered viable therefore.**

Option 2: Add products for use in food producing animals to the list of criteria for POMs included in the new legislation and require a prescription from a veterinary surgeon for all such products. This option would have significant adverse affects on farmers and agricultural merchants and animal health and welfare as described above and would offer no benefits in terms of safety or availability of veterinary medicines. **This option is not considered viable therefore.**

Option 3: Introduce a tiered system of POMs that includes subcategories for which suitably qualified persons, other than veterinary surgeons may issue prescriptions. This option would take advantage of the Directive's definition of "veterinary prescription" and would also accord with recommendations of the Marsh and Competition Commission Reports on the supply of veterinary POMs.

Option 4: As option 2 above, requiring a prescription written by a veterinary surgeon for all products in the proposed POM-V and POM-VPS categories (broadly equating to the current POM and PML categories respectively) but linked to the withdrawal of the right of veterinary surgeons to dispense such products except for small amounts when required for emergency needs or to meet animal welfare needs until a prescription can be dispensed by a pharmacist or suitably qualified person (SQP). This option was suggested during consultation. It would force veterinarians to supply written prescriptions and would encourage animal owners to "shop around" to find a suitable supplier/dispenser of the medicine. In this way it would encourage competition among suppliers. However, it would also limit that competition by removing veterinary surgeons from the potential suppliers. It would also tend to maximise the costs and inconvenience to farmers and animal owners/keepers by requiring them, in every case where a POM or PML medicine was required, to obtain a prescription from a veterinary surgeon and pay associated consultation fees and then present the prescription to a pharmacist or SQP for dispensing. We consider that option 3, together with provisions being taken forward by the DTI requiring veterinarians to offer prescriptions, offers the greatest range of consumer choice. **This option is not considered viable therefore.**

Consultation Comments

Comments were received from 19 respondents. 14 were from beekeepers and beekeeping organisations (from whom a significant amount of correspondence on the same issue was also received outside of the formal consultation). These expressed concerns about the potential increased costs and inconvenience to beekeepers if all bee medicines had to be obtained via a veterinary surgeon. One comment raised similar concerns in relation to other routinely used products currently classified PML. One response queried whether

supply via a veterinary surgeon would add cost or inconvenience. One response suggested that the proposed tiered POM system would be detrimental to the long-term health of livestock and did not accord with the harmonisation objectives of the Directive. One response supported the proposal. One response stressed that any solution to maintain bee health should not be at the expense of food safety.

VIII. Restrictions on Advertising POM products

Current UK legislation prohibits advertising of veterinary medicines that is false or misleading. This is carried forward into the new Regulations. The amended Directive also adds a requirement for Member States to prohibit the advertising to the general public of veterinary medicines that contain psychotropic drugs or narcotics (i.e. substances capable of affecting mental perception or activity) and those that are classified as POM. There is, therefore, an obligation to take this provision into the new Regulations.

Option 1: Include in the Regulations a provision simply prohibiting advertising products that are POM, or that contain psychotropic drugs or narcotics. This would prevent anyone, including veterinary surgeons and pharmacists being informed about new medicines. It may also have significant implications for magazines and other publications that carry such advertisements. **This option is not considered viable therefore.**

Option 2: Include a prohibition as in option 1, but provide an exemption for products in the proposed POM-V (currently POMs) and POM-VPS categories (currently PMLs) in respect of advertising material sent to veterinary surgeons or pharmacists or in publications directed at either profession. This would fulfil the requirement in the Directive and would permit veterinarians and pharmacists to be informed of new products. However, it would prevent the advertising of products that are currently PML to the suitably qualified persons (such as agricultural merchants) legally allowed to sell them. It would also prevent advertisements of such products to farmers and other professional animal owners/keepers. PML products are currently advertised in farming and other specialist magazines as well as at agricultural shows and similar events and in agricultural merchants' premises. Such advertising is considered necessary to inform farmers and other professionals of the range and types of product available to them. **This option is not considered viable therefore.**

Option 3: As option 2 but provide additional exemptions to allow advertising of PML products for food producing animals (proposed POM-VPS) to professional animal owners/keepers via specialist magazines, agricultural shows and agricultural merchants.

Consultation Comments – Option 4

Comments were received from 94 respondents. This was one of the three main issues raised during the formal consultation exercise. Most comments pointed out that while option 3 permits advertising of POM-VPS products to relevant healthcare professionals and animal owners/keepers and of POM-V products to relevant healthcare professionals, it does not allow POM-V products to be advertised to professional animal owners/keepers. Comments were also received suggesting that the exemptions should include veterinary nurses, beekeepers and horse owners, and seeking clarification of advertising. We therefore reconsidered this provision, taking account of the importance of raising the awareness of disease control measures among professional owners/keepers. It is also considered relevant to the Defra Animal Health and Welfare Strategy and the importance placed on good practice in animal husbandry and preventative medicines to help keep the use of therapeutic medicines to the minimum necessary for good health and welfare, particularly antibiotics. Consequently, an **option 4** was developed to permit advertising of an informative and educational nature to professional animal owners/keepers provided there is no specific promotion of a product other than the linkage permitted by an advertising strap line. This would create a link to a specific company as the providers of the information and to a product indicated for the condition described in the advertisement. Thus it would be possible to provide information about a disease, its symptoms and how to prevent it, along with a strapline indicating that the information had been provided by the particular company, which was the manufacturer of the product referred to. This revised option was published as an Informal Reaction Note during the consultation period.

The revised proposal was generally well received. 3 comments were received opposing option 4 and supporting the original proposal.

In addition, two comments suggested including a statutory defence and 5 comments suggested that limiting the content of advertising to medicinal claims contained in the authorised summary of the product characteristics (SPC) would be too restrictive. One comment supported this restriction.

IX. Restrictions on Distance Retail Selling of POM Products

Under current legislation veterinary medicines may be supplied by post. In the case of POM products a prescription would be required to authorise the dispensing of the medicine unless it was dispensed by the prescriber. Once in possession of an appropriate prescription the product may be supplied by the supplier as he or she sees fit.

To ensure the safe and effective use of POM products it is considered that it is necessary for advice to be given to the user (or his/her representative) in person at the point of sale/supply. Therefore, it was

considered that such sale or supply should be conducted in person rather than through the post.

Option 1: To achieve this, a provision was included in the draft Regulations requiring POM-V and POM-VPS products to be supplied in person to the person named on the prescription or his representative and prohibiting supply by post. This was initially considered to be the only option for achieving the desired outcome.

Consultation Comments – Option 2

Comments were received from 108 respondents making this one of the three main issues raised during the formal consultation exercise. 89 comments opposed the proposal. These indicated that the provision as drafted was unworkable and would put at risk a number of businesses that operate within the other relevant legal provisions and would inconvenience animal owners/keepers and, in some cases, could increase the amount they paid for medicines. Two comments expressed concerns about the enforcement of provisions governing postal supply. We therefore reconsidered the provision and developed **option 2** to permit postal supply by persons legally permitted to supply POMs (Registered Qualified Persons – RQPs) provided the RQP fulfils his/her professional duties and responsibilities under the legislation, including the provision of relevant advice and information. In this context "postal supply" would include supply by Royal Mail, courier or any other competent delivery service. This revised option was published as an Informal Reaction Note during the consultation period.

The revised option received general support and 7 further comments supporting it were received. 10 further comments, mostly from veterinary surgeons, opposed the revised option, supporting the original proposal. However, 3 of these suggested certain exemptions, eg for veterinary surgeons. It was not considered justified or appropriate to exempt veterinarians while prohibiting postal supply by pharmacists and other RQPs.

X. Abolition of 5-yearly renewal of MAs.

Current legislation requires marketing authorisations to be renewed at 5-yearly intervals. This requires submission of an application for renewal supported by a dossier updating information previously submitted, taking account of scientific and technical progress and of pharmacovigilance (suspected adverse reactions and environmental safety incidents) information received. The amending Directive requires a single renewal 5 years after authorisation, based on a re-evaluation of the risk/benefit balance. After this the authorisation remains valid indefinitely unless the regulatory authority considers there are justified pharmacovigilance grounds for one additional renewal after a further 5 years. Where a product is not marketed for 3 consecutive years the authorisation becomes invalid unless an

exemption can be justified (e.g. for veterinary medicines used against sporadically occurring diseases such as Foot and Mouth Disease). There is also an overarching provision which permits the authorities to re-evaluate the risk / benefit balance of a product at any time for justified reasons.

Option 1: Retain the current 5-yearly renewal requirements. This option would almost certainly incur infraction proceedings for failure to properly implement the amended Directive and would, equally certainly, attract legal challenge from marketing authorisation holders, neither of which could be defended. **This option is not considered viable therefore.**

Option 2: Implement the new provisions via a Code of Practice. As option 2 for point III above, the nature of the provision makes it unsuitable for implementation by anything other than legislative change. **This option is not considered viable therefore.**

Option 3: Include provisions implementing the changes in the new legislation. As with option 3 for point III above, there is little room for flexibility in implementing these provisions, particularly as they operate in a European context. Transposing them fully into the new legislation would therefore represent the most effective way of achieving their purpose and realising their potential benefits.

Consultation Comments

Comments were received from 4 respondents. 3 supported the proposal. One expressed some concern at the abolition of renewals but expressed hope that the increased frequency of pharmacovigilance PSUR reports would ensure effective post marketing surveillance.

XI. Increased frequency of pharmacovigilance periodic safety update reports (PSURs).

Marketing authorisation holders (MAHs) are currently required to report any suspected serious adverse reactions and human adverse reactions related to the use of their product within a maximum of 15 days. Other suspected adverse reactions are included in periodic safety update reports (PSURs), which MAHs are required to provide immediately on request or routinely at set intervals. The current periods for PSURs are 6-monthly for the first 2 years following authorisation, annually for the subsequent 2 years and at the first renewal and 5-yearly thereafter. The amended Directive increases the frequency of PSURs to 6-monthly following authorisation and for 2 years after initial placing on the market, annually for the following 2 years and at 3-yearly intervals thereafter. The frequency has been increased because of the replacement of regular 5-yearly renewal of marketing authorisations with a single (and possible second) renewal only.

Option 1: Retain current requirements. Apart from not implementing the Directive's requirements and the consequential risk of infraction proceedings, this option would reduce the effectiveness of the pharmacovigilance systems which, in the light of discontinuance of regular MA renewals, would weaken the systems for monitoring the ongoing safety and efficacy of authorised products. **This option is not considered viable therefore.**

Option 2: Incorporate the amended provisions in the new legislation. This option would achieve the objective of fully implementing the Directive's provisions and would strengthen the systems for monitoring the ongoing safety and efficacy of authorised products.

Consultation Comments

Comments were received from 2 respondents, both supported the proposal.

BENEFITS - ECONOMIC, ENVIRONMENTAL AND SOCIAL

I. Authorisation of medicines without MRLs for use in non food-producing horses.

This provision primarily benefits horses and horse owners in the UK. It will also benefit veterinary surgeons treating horses by helping to maintain the availability of medicines, and the veterinary pharmaceutical industry, which produces and markets the products. There will be a social benefit from maintaining the range of veterinary medicines available to treat horses used for leisure activities.

Option 3: Incorporate the derogation into the new legislation and include in the relevant existing MAs a reference to the horse passport requirements with a 6-month withdrawal period. This option would allow the continued availability of essential medicines for horses and would, therefore, contribute to the health and welfare of horses in the UK while ensuring effective consumer protection.

This is considered the only viable option for implementing this provision as discussed in section 3 above. Option 4 remains possible but would lead to the loss of the relevant medicines for use in horses and would appear to provide no benefit.

No significant issues were raised during the consultation.

II. Provision for veterinary surgeons to use products authorised in another Member State under the cascade options.

This provision primarily benefits animal owners, including farmers and commercial producers, veterinary surgeons and animal health and

welfare, by allowing access to additional medicines where no suitable product is available in the UK.

Option 5: Include a provision in the new the legislation to permit veterinary surgeons to import and use veterinary medicines authorised in other Member States subject to prior approval of the UK regulatory authority.

We consider this to be the only viable option for implementing this provision in a way that allows veterinary surgeons access to medicines from other Member States, where no product is available in the UK while retaining control of imported medicines. The provision is intended to be exceptional and, as such, any impact will be limited overall but may have significant health and welfare benefits in individual cases.

No significant issues were raised during consultation.

III. Changes to data protection periods and increased flexibility for generic applications.

Developing and bringing to market a new veterinary medicine is a costly process and may take up to 10 years and cost around £10 million. To stimulate development of new veterinary medicines it is necessary to ensure that innovator companies are able to recover their development costs and generate sufficient profits to make reinvestment in further research and development economically attractive. At the same time there is a need to encourage the availability of cheaper, generic versions of authorised products to stimulate competition and reduce prices. The data protection and generic application provisions attempt to balance these aspects so that animals and animal owners (including farmers and commercial keepers) benefit from both the availability of essential new medicines and from the cheaper prices stimulated by generic competition. In an EU context the amended provisions seek to increase the incentives for innovator companies by harmonising the data protection period at 10 years (increased to 13 for certain minor species and additional food-producing species). These are balanced by provisions allowing generics companies to obtain authorisations so that they can market products as soon as the protection periods expire and to apply for generic authorisations in Member States other than those in which the parent product is authorised.

Option 3: Include provisions implementing the changes in the new legislation.

As set out in section 3 above, we consider that there is little scope for flexibility in the implementation of this provision and that option 3 is the only viable way forward. No significant issues were raised during

consultation and no details of anticipated costs or benefits were provided.

IV. Record-keeping requirements for retail suppliers of veterinary medicines.

This provision will affect retail suppliers of POM veterinary medicines. These are currently veterinary surgeons and pharmacists and may, in the future, include agricultural merchants and possibly other establishments employing the services of an SQP following the adoption of option 3 in VII above. As the provisions are already applied to products for food-producing animals, other than GSL products, the extension of scope of POMs to include all products for food animals (point VII) will only affect this in respect of any products for food animals that are currently GSL and that become POM. Currently, any retail outlet may supply GSL products but, in practice, veterinary medicines for food-producing animals are only stocked by veterinary practices, agricultural merchants and some pharmacies catering for agricultural clients. This aspect will therefore have minimal effect. More significant will be the application of the requirements to sales of POMs for companion (ie non food-producing) animals.

The provision is designed to increase the traceability of, and accountability for, those veterinary medicines which it is considered should be supplied under the control of a responsible qualified person. Manufacturers and wholesale dealers are required to maintain similar records for all veterinary medicines received and/or supplied. Together with retailer's records (and, in the case of food-producing animals, on-farm records) an audit trail of products and specific batches is provided. This is particularly important should a batch or batches need to be recalled and/or treated animals identified for any reason (eg if a manufacturing defect or contamination incident raises urgent safety issues). An effective audit trail also helps to prevent the use of illegal medicines and the diversion of medicines to illegal "street abuse". Extending the provisions to companion animal POMs will strengthen these aspects and will therefore help to promote the safe, effective and responsible use of authorised products which will benefit animal health and welfare, pet owners, veterinary surgeons and, ultimately, the veterinary pharmaceutical and related industries.

Option 3: Include the amended provisions in the new legislation.

There is little scope for flexibility in implementing this provision and we consider the proposed legislation is the minimum required to comply with EU requirements. The record-keeping requirements are already applied to medicines for food-producing animals other than GSL products so the extension of scope mainly affects the supply of POM products for use in companion animals. Consultation comments received indicate that, while the value of the requirements in respect of food-animal products is generally accepted, they are considered to be

of less value in respect of companion animal products. Nevertheless, we consider that there is a need to ensure effective traceability and batch recall of companion animal POMs should this become necessary.

V. Increased flexibility in mutual recognition procedures.

This increased flexibility will primarily benefit companies wishing to market a veterinary medicinal product in two or more Member States. However, by speeding up the process it will help to increase the availability of veterinary medicines and also benefit animal owners/keepers, including farmers and other commercial enterprises, and veterinary surgeons.

Option 4: include general provisions in legislation with details in guidance.

As explained in section 3, as this relates to EU procedures, there is little flexibility in its implementation. No significant issues were raised during consultation.

VI. Extension of good manufacturing practice (GMP) to starting materials.

GMP requires that manufacturers operate consistently in a clean and properly controlled environment. This is controlled by means of regular inspection and the issuing of GMP certificates to those that demonstrate that they are satisfactory. Many starting materials are produced in third countries, which may have their own parallel requirements that are recognised centrally by the EU. Others may have control mechanisms that have not been recognised but would not welcome frequent costly visits from inspectors from the EU Member States. At the same time, the costs of the inspections would be passed on to the owner or keeper of treated animals by increases in the prices of individual products. This could lead to significant increases in the costs of veterinary medicines and worsen the overall availability of medicines with the consequent risks in respect of disease control and animal welfare. It is essential that an appropriate balance between control and costs is achieved so that availability is not adversely affected.

This will primarily affect manufacturers of veterinary medicines but could also have implications for users of the products and consumers of animal produce.

Option 4: Use a risk-based approach to consider inspection and GMP certification of the manufacture of starting materials where the ingredients, processes or previous history demonstrate that a risk may arise.

We consider this to be the only viable option. No significant issues were raised during consultation.

VII. Extension of scope of veterinary prescription only medicine (POM) requirements.

This will primarily affect farmers and other owners of food-producing animals and those supplying current POM and PML medicines, i.e. veterinary surgeons, pharmacists and agricultural merchants. It could potentially incur significant additional costs and inconvenience for farmers by requiring veterinary intervention, and the associated consultation fees etc for all medicines required for food-producing animals, including those that are routinely used and for which veterinary intervention is not considered necessary for their safe and effective use. In addition, it could have very serious economic implications for agricultural merchants who currently supply the majority of PML products. It could also impact adversely on the availability of treatment for animals and therefore disease control and animal welfare.

Option 3: Introduce a tiered system of POMs that includes subcategories for which suitably qualified persons, other than veterinary surgeons may issue prescriptions.

We do not consider the requirement for all medicines for food-producing animals to be POM to have any significant benefit. However, we consider the proposed option 3 to be the most effective way of complying with the EU requirements while maintaining the supply of the majority of current non-POM medicines without the need for the intervention of a veterinary surgeon. The proposed option for implementation was generally supported, although some veterinary surgeons raised concerns about the principle of non veterinary surgeons issuing prescriptions. However, comments received during formal consultation mainly focussed on the potential for negative impact if all food animal medicines had to be obtained via veterinary surgeons.

VIII. Restrictions on Advertising of POM Products

These provisions are required by the Directive. Their purpose is to prevent the advertising to the general public of POM veterinary medicines, for which decisions on the appropriate, safe and responsible use require some specialist knowledge.

Option 4: This was developed in response to consultation comments received. It is as option 3 but with a further exemption. It prohibits advertising of POMs but includes exemptions in respect of veterinary surgeons, pharmacists and other relevant healthcare professionals and professional animal owners/keepers.

This would achieve compliance with the Directive while permitting the continued advertising of current POM and PML products to relevant professionals with appropriate knowledge to ensure their safe and responsible use. It would thus allow transmission of information necessary to raise the awareness of relevant professionals of disease control measures including the importance of good practice in animal husbandry and preventative medicines.

IX. Restrictions on Distance Retail Selling of POM Products

Option 2: to permit postal supply by persons legally permitted to supply POMs (Registered Qualified Persons – RQPs) provided the RQP fulfils his/her professional duties and responsibilities under the legislation, including the provision of relevant advice and information.

This option was developed in response to comments received during consultation. It will ensure that suppliers of POM products provide any necessary advice required for the safe storage, use and disposal of the medicine at the time it is supplied and to satisfy themselves that the person to whom the product is supplied appears to have sufficient knowledge and ability to use the product safely. It is considered that this provision will contribute to the safe and effective use of veterinary POM products while allowing businesses and users of veterinary medicines that depend on postal or similar supply to continue to operate.

X. Abolition of 5-yearly renewal of marketing authorisations (MAs).

This provision will primarily benefit companies marketing veterinary medicines by removing the costs of having to apply for regular renewal of MAs. It is intended that the continued safety of veterinary medicines will be assured by a single renewal after 5 years (with a possible second renewal if considered necessary on the basis of suspected adverse reaction reports (SARs) received) and the strengthening of the SAR procedures. A provision invalidating MAs where products are not marketed for 3 consecutive years will prevent unused MAs remaining. There is also provision for the regulatory authority to review the risk/benefit ratio of a product at any time.

Option 3: Include provisions implementing the changes in the new legislation.

The amending Directive's provisions are specific and there is little scope for flexibility in implementation.

This provision will result in savings for the veterinary pharmaceutical industry but no details have been provided and we have been unable to quantify the savings. No significant issues were raised during consultation.

XI. Increased frequency of pharmacovigilance periodic safety update reports (PSURs).

In essence this provision increases the frequency of PSURs following renewal of the MA after 5 years from 5-yearly to 3-yearly. This reflects increased emphasis on pharmacovigilance (monitoring of suspected adverse reactions), which is considered necessary to ensure continued safety following the discontinuation of the current 5-yearly renewal requirement. It will benefit animal health and welfare and consequently owners/keepers of animals and veterinary surgeons by helping to ensure the continued safety and efficacy of authorised products. It will also benefit companies marketing the products by contributing to a strengthened pharmacovigilance system that permits the discontinuance of regular renewal of authorisations.

Marketing authorisation holders (MAHs) are currently required to report any suspected serious adverse reactions and human adverse reactions related to the use of their product within a maximum of 15 days. Other suspected adverse reactions are included in periodic safety update reports (PSURs), which MAHs are required to provide immediately on request or routinely at set intervals. The current periods for PSURs are 6-monthly for the first 2 years following authorisation, annually for the subsequent 2 years and at the first renewal and 5-yearly thereafter. The amended Directive increases the frequency of PSURs to 6-monthly following authorisation and for 2 years after initial placing on the market, annually for the following 2 years and at 3-yearly intervals thereafter.

Option 2: Incorporate the amended provisions in the new legislation.

As with point X above, this is an aspect where the amending Directive's provisions are specific with consequently little scope for flexibility in implementation. The provision will strengthen the monitoring of safety of products in the light of the abolition of regular renewal of MAs. In essence, the two provisions may be seen as parts of the same issue. No significant issues were raised during consultation.

COSTS - ECONOMIC, ENVIRONMENTAL AND SOCIAL

I. Authorisation of medicines without MRLs for use in non food-producing horses.

Option 3: Incorporate the derogation into the new legislation and include in the relevant existing MAs a reference to the horse passport requirements with a 6-month withdrawal period.

This would incur the costs of the required variations and label reprints for marketing authorisation holders (MAHs). These costs are likely to be minimal because the changes will mainly be made at the same time

as other amendments requested by the MAH. This action would avoid the costs associated with the medicines being lost as in option 1.

No significant issues were raised during consultation and no details of additional costs were provided.

II. Provision for veterinary surgeons to use products authorised in another Member State under the cascade options.

Option 5: Include a provision in the new legislation to permit veterinary surgeons to import and use veterinary products authorised in other Member States subject to prior approval of the UK regulatory authority.

Under Option 5, veterinary surgeons would incur the cost of importing products – possibly via a wholesaler. These would probably be passed on to the animal owner. It should, however, avoid the potential costs associated with options 3 or 4 that could be incurred in the event of an imported product resulting in a safety issue – consumer, human/animal health, or environmental. Costs of an outbreak of a disease that is not currently present in the UK could be very high. Option 5 Would also incur costs for the regulatory authority in evaluating applications/developing an interactive computer system but these should be partially offset by a reduced number of applications under the current special treatment authorisation (STA) system. There may be some additional costs for veterinary practices that do not currently have access to the Internet but the number of these is steadily diminishing. In addition we intend to charge a fee for issuing certificates (see separate RIA on fees attached).

Because this provision is intended to be used exceptionally, overall costs are considered unlikely to be very significant. No significant issues were raised during consultation and no details of additional costs were provided.

III. Changes to data protection periods and increased flexibility for generic applications.

Option 3: Include provisions implementing the changes in the new legislation.

As the UK already applies a 10-year data protection period this will generally not change but the additional periods for products for fish and bees and additional food-producing species on individual authorisations, represent potential increased income for innovator companies that develop these products. Also, in a European context, the companies will benefit from those Member States that currently have data protection periods of less than 10 years (although that is outside the scope of these Regulations). Similarly, allowing generics companies to develop products and to apply for and obtain MAs before

the expiry of the data protection period allows them to bring the products to market earlier, which represents increased sales.

No significant issues were raised during consultation and no details of costs or savings were provided.

IV. Record-keeping requirements for retail suppliers of veterinary medicines.

This provision will extend record-keeping and stock audit requirements to retail sales of POMs for non food-producing animals. This will affect veterinary practices, pharmacies and agricultural merchants retailing such products.

Option 3: Include the amended provisions in the new legislation.

This could potentially incur some compliance costs in the 3 sectors affected. However, those currently supplying non-GSL products for food-producing animals will already comply with the requirements in relation to those products and will need only to extend their systems to include companion animal POMs, where they are not already doing so. This is likely to apply to all agricultural merchants (because the medicines they sell are mainly for food animals) and many veterinary practices as well as some rural pharmacies. However, companion animal veterinary practices and pharmacies that currently supply veterinary medicines only for companion animals may not keep such records or conduct the required stock audits and may need to set up appropriate systems to do so.

A number of concerns were raised during consultation, mainly by veterinary practices, about the potential impact of these provisions, particularly the recording of manufacturers' batch numbers. Estimates of additional costs involved across the approximately 2200 veterinary practices in the UK ranged from £4.3 million to £23 million. One response estimated an additional £450 per practitioner per day for time taken to record batch numbers each time a product was supplied or administered. However, the estimates provided did not take into account that the requirements are not new for products for food producing animals and that the extension of scope only applies to POMs for companion animals, it will not apply to NFA-VPS or AVM-GSL products. These are medicines for which it is considered that a prescription from an appropriate qualified person is necessary to ensure their safe and effective use.

In the light of comments received the VMD published a clarification note. This set out a pragmatic approach which would allow the requirements to be met using any records already kept (eg client consultation and stock records) provided that, taken together, they enable effective product recall and guard against abuse/misuse of the products concerned. In this way, we consider the requirements can be

met with no significant cost implications. The clarification note also recognised that some practices would need some time to adapt their current record keeping systems and may not fully meet the provisions initially. We also recognise that manufacturers are developing a bar coding system that will hold all the required information and may be used throughout the supply chain, but this is unlikely to be available for some time. Whether or not veterinary practices and others decide to take advantage of this system when available will be for them to decide at some future time.

V. Increased flexibility in mutual recognition procedures.

Option 4: include general provisions in legislation with details in guidance.

No additional costs arising from this provision were anticipated. No significant issues were raised during consultation and no details of costs or savings were provided.

VI. Extension of good manufacturing practice (GMP) to starting materials.

Option 4: Use a risk-based approach to consider inspection and GMP certification of the manufacture of starting materials where the ingredients, processes or previous history demonstrate that a risk may arise.

A risk-based approach, harmonised across the EU, is considered proportionate. It would benefit users and consumers by addressing the theoretical risk while keeping costs down.

No additional costs arising from this provision were anticipated. No significant issues were raised during consultation and no details of costs or savings were provided.

VII. Extension of scope of veterinary prescription only medicine (POM) requirements.

This will primarily affect farmers and other owners of food-producing animals and agricultural merchants. It could potentially incur significant additional costs and inconvenience for farmers by requiring veterinary intervention, and the associated consultation fees etc for all medicines required for food-producing animals, including those that are routinely used and for which veterinary intervention is not considered necessary for their safe and effective use. In addition, it could have very serious economic implications for agricultural merchants who currently supply the majority of PML products.

We consider that the proposed option 3 will avoid most of the potential increases in costs referred to above and associated with option 2.

Option 3: Introduce a tiered system of POMs that includes subcategories for which suitably qualified persons, other than veterinary surgeons may issue prescriptions.

In essence, this would largely maintain the status quo. Products that are currently classified PML would be reclassified as a category of POM but would still be supplied, as now, by veterinary surgeons, pharmacies or agricultural merchants (or other establishments employing an SQP) without the need for a prescription to be issued by a veterinary surgeon. There may be small costs incurred by supplying pharmacists or agricultural merchants being required to issue prescriptions but these are likely to be minimal as only very basic information is likely to be required for these products. It is likely that companies marketing the products will have to change product labels to reflect the new categories but if these can be accommodated with routine reprints or included with other changes, these costs may also be minimal. Although these products may already be supplied by pharmacists and suitably qualified persons employed by agricultural merchants under the current P and PML arrangements, some additional training input is likely to be required under this option.

There is a particular issue in relation to products for bees. There are currently only four products authorised in the UK for use in bees. These are currently classified as GSL and may be supplied by any retail outlet, including specialist beekeeping suppliers. Under the amended Directive they may need to be reclassified as POM. If included in the less restrictive POM category as above, impact on beekeeping enterprises would be minimised as the products could still be available from beekeeping suppliers if they employed a suitably qualified person. There is, however, a provision in the amended Directive allowing certain types of products, on a list to be prepared by the European Commission, to be exempted from the POM requirement. The UK is strongly supporting the inclusion of products for use in bees on this list. If this is achieved the products concerned will be unaffected by the extension of scope of the POM requirements.

Consultation responses were mostly from beekeeping interests stressing concerns about the negative impact that would result if bee medicines had to be obtained from a veterinary surgeon. However, no details of anticipated costs or benefits were provided.

VIII. Restrictions on Advertising POM Products

A blanket prohibition on advertising of POMs (including current PML products) to the public, as well as preventing information on the products reaching those that need it, would be likely to have a negative impact on those sectors that are dependant upon advertising and sponsorship revenue such as publications and agricultural shows.

Option 4: This was developed in response to consultation comments received. It is as option 3 but with a further exemption. It prohibits advertising of POMs but includes exemptions in respect of veterinary surgeons, pharmacists and other relevant healthcare professionals and professional animal owners/keepers.

Option 4 is considered to achieve the Directive's purpose while avoiding any significant impact on costs or advertising revenue.

IX. Restrictions on Distance Retail Selling of POM Products

Option 2: to permit postal supply by persons legally permitted to supply POMs (Registered Qualified Persons – RQPs) provided the RQP fulfils his/her professional duties and responsibilities under the legislation, including the provision of relevant advice and information.

This option was developed in response to comments received during consultation. It received general support. No details of any anticipated costs were provided.

X. Abolition of 5-yearly renewal of marketing authorisations (MAs).

Option 3: Include provisions implementing the changes in the new legislation.

This would save MA holders the cost of producing renewal applications and supporting data dossiers every 5 years. The savings may be partially offset by the regulatory authority requiring more frequent PSURs (see IX below) and additional information to support a review of the product risk/benefit ratio but the latter is only likely to occur if triggered by pharmacovigilance or other safety concerns.

No additional costs were anticipated as this provision will result in savings. No significant issues were raised during consultation and no details of costs or savings were provided.

XI. Increased frequency of pharmacovigilance periodic safety update reports (PSURs).

This will affect all marketing authorisation holders (MAHs).

In essence this provision increases the frequency of PSURs following renewal of the MA after 5 years from 5-yearly to 3-yearly. This reflects increased emphasis on pharmacovigilance (monitoring of suspected adverse reactions), which is considered necessary to ensure continued safety while allowing the current 5-yearly renewal requirement to be discontinued. It will benefit animal health and welfare and consequently owners/keepers of animals and veterinary surgeons by helping to ensure the continued safety and efficacy of authorised

products. It will also benefit companies marketing the products by contributing to a strengthened pharmacovigilance system that permits the discontinuance of regular renewal of authorisations.

Option 2: Incorporate the amended provisions in the new legislation.

MAHs are currently required to supply the required information; the only significant change is an increase in frequency of reports from 5 to 3-yearly. It is not considered that this would significantly impact on costs, particularly as any increased costs would be set against the savings following the abolition of 5-yearly renewals.

No significant issues were raised during consultation and no details of costs or savings were provided.

Other Issues Raised During Formal Consultation

i. Data Sheets

Comments were received from 6 respondents concerned that the Regulations did not require marketing authorisation holders (MAHs) to produce a data sheet for each of their products. The Medicines Act prohibits promotional material for a veterinary medicine being sent to a veterinary practice unless a related data sheet has been sent within the preceding 15 months. The majority of companies have utilised the data sheet compendium produced and distributed annually by NOAH to meet this requirement. The purpose of the provision was to prevent veterinary surgeons being unduly influenced by advertising material when selecting a medicine for a particular case. Since 1995 MAHs have been required by EU law to produce a summary of the product characteristics (SPC) for each of their products. The information required on an SPC is virtually identical to that required in a data sheet. Since 2000 the legislation has allowed MAHs to use SPCs to fulfil the data sheet requirements if they so choose. In addition, the amended Directive requires the VMD to publish SPCs and these will, in future, be available on the VMD website. The Veterinary Medicines Regulations do not carry forward the Medicines Act requirement to send data sheets to veterinary practices before sending promotional material because this provision is no longer considered necessary. There is, however, nothing in the Regulations to prevent this if companies choose to do so. We consider that it is for NOAH and their member companies to consider whether or not to continue to produce the compendium.

ii. Enforcement and Inspection Issues

Comments were received from 11 respondents relating to the detail of enforcement and inspection provisions and seeking clarification. The Regulations broadly carry forward current provisions for inspection and enforcement except for the introduction of improvement notices and the

creation of a new offence of possession, which are discussed in section 9 below. No significant issues were raised.

iii. Veterinary Surgeons Dispensing Prescriptions issued by Another Veterinary Surgeon

Comments were received from 14 respondents concerning veterinarians issuing and dispensing prescriptions. Under the Medicines Act a veterinarian may only dispense medicines for administration to an animal under his or her care. The Regulations take forward a recommendation of the Competition Commission by permitting a veterinary surgeon to dispense a prescription issued by another veterinary surgeon. This is intended to facilitate greater competition in the supply of prescription medicines. Some comments sought clarification of the respective responsibilities of the prescribing and dispensing veterinarian. Other comments concerned the requirement not to charge for issuing prescriptions and related issues. The issue of veterinary surgeons offering but not charging for prescriptions is outside the scope of these Regulations as it relates to Competition Commission remedies being taken forward in Regulations being developed by the Department of Trade and Industry.

iv. Suitably Qualified Persons (SQPs) for Prescribing

Comments were received from 18 respondents concerning the SQP in relation to the supply of POM-VPS medicines. The comments mainly concerned clarification of details of the role of the SQP in relation to the sale of products, the need to ensure satisfactory training and the provision of “grandfather” rights and transitional periods in respect of SQPs currently employed by agricultural merchants.

Further Provisions in the Regulations

In addition to the provisions discussed above, the Regulations also contain provisions covering exemptions for certain veterinary medicines, medicated feeds and feed additives and fees charged by the Veterinary Medicines Directorate for work related to the authorisation of veterinary medicines. An additional provision to prohibit the advertising to veterinary practices of human medicines that cannot legitimately be used in animals has been included in response to concerns raised by the veterinary pharmaceutical industry.

A. Exemption Provisions

Article 4 of Directive 2001/82/EC as amended by Directive 2004/28/EC permits Member States to exempt from the marketing authorisation requirements specified veterinary medicinal products provided certain conditions are met. Eligible products are those intended solely for use in aquarium fish, cage birds, homing pigeons, terrarium animals, small rodents, ferrets and rabbits kept exclusively as pets.

It is known that a number of such products are currently being marketed illegally, particularly for use in pet fish. It is considered that introducing an exemption scheme will remove from the "illegal" category those products that meet the requirements and therefore pose little risk. Establishing formal exemption provisions and procedures will thus allow enforcement activity to be focussed on products that present the greatest risk to pet owners and consumers, thereby increasing its effectiveness.

Consultation on the proposed exemption provisions was carried out separately to that on the main Regulations. The proposed exemption scheme received widespread and positive support from industry. Representatives from both smaller and larger companies worked closely with the VMD to overcome a number of difficulties in the detail required to implement the scheme satisfactorily.

B. Medicated Feeds and Feed Additives

The Regulations include a schedule setting out controls on medicated feeds and feed additives. This was revised to take account of the coming into force of EU Regulation (EC) No. 183/2005 of 12 January 2005, laying down requirements for feed hygiene. Although the EU Regulation is directly binding on all Member States, some consequential amendments to the relevant schedule to the Veterinary Medicines Regulations were required. Separate legislation is also being developed by the Food Standards Agency (FSA) reflecting aspects of the EU Regulations on feeds.

In respect of the Veterinary Medicines Regulations, the main changes relate to the duties on manufacturers and distributors of relevant products. These include new requirements for hazard analysis and critical control points (HACCP).

A separate formal consultation was carried out on both the revised feeds and fees provisions, together with 5 guidance notes additional to the 18 included in the earlier consultation on the main regulations. In respect of feeds, the provisions were revised to reflect the new EU Regulation after the first consultation had been issued. Therefore Consultees were given the opportunity to comment on the revised provisions in the separate consultation. Responses from both consultations were reviewed together. Comments were received from 13 respondents. They covered a range of issues including points of detail and clarification and drafting changes have been made where appropriate. The main issues arising from the consultation are set out below.

Food Standards Agency legislation

The Food Standards Agency is currently consulting on separate feed legislation implementing aspects of the same EC Regulations as those reflected in the VM Regulations.

Consultation comments

One respondent pointed out some discrepancies between the Veterinary Medicines Regulations and the draft FSA legislation. Drafting changes have been made to the Regulations where appropriate.

Non-compliance

The Regulations include offences for non-compliance with some provisions by feedingstuffs manufacturers and distributors.

Consultation comments

Two respondents highlighted the lack of provisions for suspension and revocation of approval of establishments as an alternative to prosecution where appropriate. The Regulations have been amended to include such provisions.

Application of prescribing cascade provisions

In the absence of a veterinary medicine authorised for the species and condition being treated, the prescribing cascade provisions permit veterinary surgeons to prescribe or administer certain alternatives. The draft Regulations did not apply the cascade provisions to veterinary medicines for incorporation into feedingstuffs.

Consultation comments

Two respondents pointed out that the Regulations did not apply these provisions to feeds, one of whom also raised consequential concerns about animal health and welfare problems that were considered likely to result. The Regulations were consequently amended to apply the provisions to in-feed medication.

Approval of distributors

Establishments that manufacture and distribute medicated feedingstuffs are subject to approval.

Consultation comments

Three responses were received raising concerns about the lack of clearly defined provisions for approval of distributors. Two respondents commented that, in particular, it was unclear whether the requirements applied to veterinary surgeons who wished to distribute premixtures

and feedingstuffs. The Regulations were consequently amended to clarify the provisions and, in particular, to make clear that the requirements continue to apply to veterinary surgeons.

C. Fees Provisions

The VMD is required to recover the full costs of assessing applications for veterinary medicinal product marketing authorisations and associated services, including inspections of premises and pharmacovigilance (surveillance of adverse reactions to veterinary medicines) by charging fees to industry for the work carried out. It was decided to incorporate the provisions for fees into the Veterinary Medicines Regulations, rather than retaining separate legislation. The provisions include changes to the structure of the fees regime and to the amounts charged. The changes reflect EU requirements for the regulatory authority to publish information on the assessment of applications and strengthened pharmacovigilance procedures, as well as modified UK procedures for varying the terms of authorisations. In addition the Regulations implement the second stage of a three-year project to restructure licensing fees based on a menu approach previously agreed with industry.

As well as being subject to a separate formal consultation, a separate Regulatory Impact Assessment has been prepared in respect of the fees proposals and is attached as Annex A to this RIA.

D. Prohibition of Advertising Certain Human Medicines to Veterinary Practices

In response to concerns expressed by the pharmaceutical industry a provision has been added prohibiting the advertising, including the sending of price details, to veterinary surgeons of medicines authorised for human use that may not legally be administered to animals.

Under the “prescribing cascade” veterinarians may prescribe or administer to animals medicines authorised for human use where no medicine is authorised for the species and condition being treated and where no suitable alternative authorised veterinary medicine exists. However, human medicines will not have been assessed for use in animals and such use may involve potential risks, which the authorisation process seeks to minimise. Furthermore, excessive use of human medicines also impacts upon the sales of authorised veterinary products and is a disincentive to the development of authorised veterinary products, which, in the longer term would reduce the availability of safe and effective veterinary medicines.

A number of human medicines contain active ingredients that are also found in veterinary products (although differences in formulation etc may affect their safe and effective use in animals). In such cases, differences in the structure and size of the veterinary and human

medicines markets mean that the human products are often significantly cheaper than the veterinary ones. There is growing concern that the cascade options are being abused and that cheaper generic human medicines are being used where authorised veterinary medicines are available. The National Office of Animal Health (NOAH) claim that, in a randomly chosen category of medicines where both human and veterinary products exist, more than 25% of the value of the medicines used in animals over a period related to human products.

Veterinary wholesale dealers routinely distribute to veterinary practices information relating to the products they can supply, including price details. We recognise that this is necessary for the effective supply of products. However, we consider that there is no justification for distributing to veterinary practices advertising or promotional material that relates to human medicines where equivalent authorised veterinary products exist, i.e. human medicines that may not be legally administered to animals. Indeed, we are concerned that the distribution of such material may encourage veterinary surgeons to use human medicines illegally. We therefore proposed inclusion in the new Regulations of a provision prohibiting the distribution of such material.

We consulted separately on this proposal by letter to all authorised veterinary wholesale dealers (approximately 160), the Royal College of Veterinary Surgeons, the British Veterinary Association and the National Office of Animal Health. We received 14 responses of which 2 opposed the proposal, 3 gave qualified support, 1 listed 7 points in support and 3 against and 8 gave full support.

EQUITY AND FAIRNESS

16. The proposed changes to the requirements are wide-ranging and affect controls on the manufacture, authorisation, marketing, distribution, supply and use of veterinary medicines. However, most of the changes amount to “fine tuning” of procedures and provisions that are already well established and, consequently, are not considered to introduce inequality or unfairness. Those aspects that have been identified as having potential cost implications primarily affect companies marketing veterinary medicines, veterinary practices, pharmacies and agricultural merchants, many of which are small businesses. However, the changes will impact on those concerned equitably with no specific area being disadvantaged. Informal consultation with these and other interests affected did not raise any issues of equity or fairness. No significant relevant issues were raised during formal consultation.

CONSULTATION WITH SMALL BUSINESS: THE SMALL FIRMS IMPACT TEST

17. In addition to the formal consultation, a series of presentations were held which a range of interested organisations and individuals, including those representing small businesses, attended. These highlighted the main issues and organisations were asked to provide information on any cost implications they identified. In addition, information on the proposals, including copies of the overhead slides used in the presentations, a consolidated version of the Directive highlighting all the changes, and notes setting out detailed proposals for new distribution categories, and revised proposals for controls on advertising and distance selling were placed on the VMD website, as were the consultation documents. Related articles detailing progress have appeared in the VMD news publication *MAVIS*. A letter was also sent to interested organisations asking for details of any cost implications for them. No significant issues relating to small firms were raised and no related details of costs were provided.

    In respect of the proposed introduction of the small animals exemption scheme, several businesses were visited as part of the small business litmus test. The likely impacts of the scheme were discussed, including the possible financial affects on business. The scheme received unanimous support, with significant advantages expected for those companies marketing products in accordance with the provisions.

COMPETITION ASSESSMENT

18. In 2002 the Competition Commission investigated the supply of veterinary prescription only medicines (POMs) in the UK. It published a report in 2003 that contained a number of recommendations intended to increase competition in the supply of these medicines. Some of these are being addressed in legislation made under the Fair Trading Act 1973 by the Department of Trade and Industry (DTI). Other Competition Commission recommendations that have been accepted by Government are being taken forward in the Veterinary Medicines Regulations. However, these primarily support or facilitate changes being taken forward in the DTI legislation and, in themselves, are unlikely to have significant impact. The most significant is the provision allowing a veterinary surgeon to dispense a prescription issued by another veterinary surgeon. Current legislation only permits a veterinarian to dispense medicines that he or she has prescribed for animals under his or her care. Historically, veterinarians have tended to operate as a “one-stop shop”, supplying most medicines that they prescribe even though prescriptions may also be dispensed by any registered pharmacy. By allowing other veterinary surgeons to dispense the prescription consumer choice will be increased. However, the significant underlying change will be an obligation for veterinary surgeons to offer clients a written prescription that they can

take elsewhere to be dispensed. This is being taken forward in the DTI legislation and is thus outside the scope of these Regulations.

Overall, the proposed regulations are likely to affect a number of markets related to veterinary medicines. However, as explained in paragraph 16 above, it is considered that most of the proposed changes are unlikely to have any significant impact. The competition filter test was completed in respect of 4 markets considered to be most affected –

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

A. Veterinary Pharmaceutical Industry

The veterinary pharmaceutical industry comprises approximately 140 companies who between them currently hold marketing authorisations (MAs) for some 2000 veterinary medicinal products authorised in the UK. In some cases two or more of these may be owned by a "parent" company. The companies range from large multinationals to small businesses. Approximately 90% of sales in the £389 million animal medicines market are attributable to approximately 25% of the 120 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 sector is not, therefore, characterised by rapid technological change. 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 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 (ie non-food) animals, 1% on farm animals, 47% on mixed animals (ie 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. The record-keeping requirements may have a greater impact on companion animal practices, as those dealing with food animals are already required to keep the relevant records.

C. Agricultural Merchants

Approximately 800 premises in the UK are registered for the supply of veterinary medicines classified as PML by some 500 agricultural merchant businesses. 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 PML veterinary medicines, merchants need to register with the Royal Pharmaceutical Society of Great Britain (RPSGB) (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 suitably qualified person (SQP) to authorise each sale of PML 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 main provisions of the Regulations that impact on merchants are those relating to the new distribution categories, primarily triggered by the amended EU requirement that all medicines for use in food-producing animals should be prescription only. The VMD has worked closely with agricultural merchants and their representative trade

organisation the Animal Health Distributors' Association (AHDA) to develop provisions that will comply with the EU Directive while retaining the essential elements of the PML supply system. There are also provisions to strengthen the training of SQPs but these include transitional provisions to allow existing SQPs to upgrade. The Regulations 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 significantly 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 licensed 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 wholesale dealer licences are held by companies who hold marketing authorisations. Individuals, partnerships, limited companies and corporate bodies are all eligible to hold wholesale dealer licences 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 licences specify the categories of product (ie POM, PML, GSL) and classes of product (eg 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 Regulations 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 significantly affect the current position in respect of companies' ability to choose price, quality, range or location of their products.

19. The competition filter test indicated that a simple competition assessment, rather than a detailed assessment was required. On this basis no significant competition issues were identified. No significant competition issues were raised during consultation.

ENFORCEMENT AND SANCTIONS

20. 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. It is envisaged that enforcement responsibilities will remain as under existing legislation. There will, however, be some changes in practice in the carrying out of some enforcement activities, such as inspections currently undertaken in England on behalf of the enforcement authority by the Royal

Pharmaceutical Society of Great Britain and the State Veterinary Service, in order to ensure a more cost-effective and appropriate service.

21. A range of penalties and sanctions exist under current legislation and it is envisaged that these will be broadly retained. However, the proposals include some changes to offences. Where changes or modifications are proposed the Home Office has been consulted. The most significant change is the creation of a new offence of possessing an illegal medicine. Under the Medicines Act and related legislation it is an offence to place on the market, or to administer an unauthorised medicine, or to import it for either of those purposes. Successful prosecution requires proof of placing on the market or of administration and in some cases this has proven difficult to establish. Since there can be no valid reason for possessing an illegal medicine other than for the purpose of supplying or administering it, this defect has been remedied in the new Regulations by the creation of the offence of possession.

22. A significant change in the approach to enforcement is the creation of improvement notices. It is envisaged that these may be issued by inspectors to individuals failing to comply with the provisions of the Regulations where no immediate safety risk exists. The improvement notice will detail what constitutes the failure to comply, what measures need to be taken in order to comply and sets a time limit of not less than 14 days for the individual concerned to take those measures. Non-compliance with an improvement notice is an offence under the Regulations. This procedure formally establishes a period during which relatively minor breaches to the requirements may be rectified without the need for further legal action. By offering an opportunity to remedy failings without further penalty it is considered that this measure will encourage compliance without the cost and resource implications of prosecution.

MONITORING AND REVIEW

22. The operation of the procedures and requirements set out in the legislation will be subject to ongoing monitoring and any issues arising or raised will be considered to determine whether any changes are required. Article 86 of Regulation (EC) No 726/2004 requires the European Commission to publish a general report on the operation of the EU medicines regime under both the Regulation and the two Directives (on human and veterinary medicines respectively) at least every ten years. This will provide a useful basis for carrying out a more detailed review of the UK legislation, although evaluation of the effectiveness of the new Regulations will be monitored and reviewed within the ongoing VMD customer satisfaction surveys and feedback from stakeholders. It has been decided that the Regulations will not be amended but, when changes are required, will instead be revoked and replaced so that they remain as a single comprehensive and current

piece of legislation. The inclusion of fees provisions means that these will need reviewing annually to take account of inflation and any other relevant changes. This will provide a regular annual basis for reviewing the operation of all the provisions of the Regulations and making any changes necessary.

CONSULTATION

(i) Within Government

23. Interested Government Departments, including the devolved administrations, were kept informed of progress as the EU proposals and negotiations developed and as the UK Regulations were developed. Presentations on the UK proposals were made to the Devolved administrations, Defra Animal Health and Welfare Directorate and the Food Standards Agency and relevant aspects were discussed with the Medicines and Healthcare Products Regulatory Agency of the Department of Health and with the Department for Trade and Industry.

(ii) Public Consultation

24. Interested organisations have been kept informed of progress of the EU proposals for amending the Directive throughout the negotiations both by letter and attendance at update meetings. Progress reports were also published in *MAVIS*, the VMD's periodic news publication, and on the VMD website. Informal consultations and presentations have been held with interested groups and individuals during the period when the UK policy proposals were developed and further consultations have been held on particular issues where appropriate. All parties that have expressed interest were included in the informal consultations.

25. A formal consultation exercise on the main Regulations and 18 associated draft guidance notes was conducted between 4 January 2005 and 3 May. In view of the complexity and breadth of the proposed legislation, 16 weeks was allowed for responses. Over 300 responses were received. In addition a separate formal consultation exercise was carried out between 17 May and 8 August on provisions for fees, revised provisions for medicated feeds and feed additives and 5 additional draft guidance notes. In both cases letters were sent to interested organisations and individuals and the consultation package was published on the VMD website and announced in *MAVIS*. The consultation packages were also made available in paper or CD-Rom versions on request.

Implementation of EU Provisions/ Gold Plating

26. The Regulations have been scrutinised to identify any provisions that are considered either to under implement or to gold plate the

Directive's provisions. We are advised by our legal advisors that there are none.

SUMMARY AND RECOMMENDATION

27. As well as implementing an amended EU Directive, the Veterinary Medicines Regulations also replace voluminous UK legislation on veterinary medicines that is outdated and difficult to understand. In line with the Government's Better Regulation principles, they will provide a single set of Regulations that contain all the provisions, including those on medicated feeds and feed additives and on fees charged for licensing and related work, in a format that makes them easier to find and to understand.

28. The content of the Regulations is wide-ranging and affects all aspects of controls on veterinary medicines from authorisation and manufacture through to supply and use. However, in the main, the changes contained in the Regulations amount to fine tuning of well established systems and procedures. The Regulations will continue to ensure the availability of safe and effective veterinary medicines and to safeguard consumers of produce from treated animals. As well as the benefits of clearer more accessible legislation, the changes will lead to some reductions in costs, eg for companies marketing the products by removing the requirement for ongoing 5-yearly renewal. These will, however, largely be offset, eg by enhanced pharmacovigilance (monitoring of suspected adverse reactions) requirements and requirements for increased public availability of information. On balance, the Regulations are not considered to have a significant impact in terms of costs or savings. Where potential significant costs were identified during consultation, such as with the proposals to prohibit distance selling, the provisions have been amended to remove these. Concerns were also expressed about the potential costs of meeting the extended record-keeping requirements, but we consider that these provisions may be met by making full use of information already recorded without incurring significant additional costs.

29. The fees provisions, which are explained more fully in the attached Annex A, are expected to increase the amount paid in fees across the veterinary pharmaceutical industry by some £500,000. However, 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 be in excess of £10 million.

30. It is recommended that the options indicated in sections 3 to 5 above, as incorporated in the Veterinary Medicines Regulations 2005, are taken forward and that the Regulations come into force on 30 October 2005 to meet the EU deadline for transposition of the amended Directive.

DECLARATION

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

Signed.....Ben Bradshaw.

Date..... 17th September 2005.

Ben Bradshaw, Parliamentary Under Secretary of State, Department for Environment, Food and Rural Affairs

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ANNEX A

FULL REGULATORY IMPACT ASSESSMENT – FEES PROVISIONS

1. Title

The Veterinary Medicines Regulations 2005 (provisions on fees relating to veterinary medicines).

2. Purpose and intended effect

(i) Objective

This measure is required to:

- introduce a revised licensing fee scale 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;

- recover the additional resources to develop, prepare and maintain UK Public Assessment Reports (UKPARs) to the standard required by Directive 2004/28/EC;

- introduce a revised fees structure to accommodate operational changes required under the Veterinary Medicines Regulations.

The charges under this legislation apply in the UK.

(ii) Background

These Regulations will amend the fees currently charged in accordance with the Medicines (Products for Animal Use – Fees) Regulations 2004, which established the fees for applications and inspections relating to licences and certificates issued under the Medicines Act 1968 and marketing authorisations granted under the Marketing Authorisations for Veterinary Medicines Products Regulations 1994. With effect from 30 October 2005 the Veterinary Medicines Regulations 2005 will come into force. From this date the Medicines Act 1968 will no longer apply to Veterinary Medicines and the Marketing Authorisations for Veterinary Medicines Products Regulations 1994 and the Medicines (Products for Animal Use – Fees) Regulations 2004 will be revoked.

From 1st November 2005, all EU regulatory agencies will have to prepare a public assessment report (PAR – in the UK an UKPAR) on new marketing authorisations, and update those reports when any changes to the underlying

marketing authorisation are made. This requirement was introduced under EU Directive 2004/28/EC. The additional resources required to develop, prepare and maintain the UKPARs to the standard required by the Directive will require an increase of 11% on the capital fees for assessment work.

In addition a number of changes are introduced by the Veterinary Medicines Regulations 2005, which affect work required in relation to various aspects of the processing of applications for, and maintenance of, marketing authorisations and certificates. Changes have also been introduced to requirements related to pharmacovigilance and inspections. In some cases new fees have been introduced to cover this work. However, for some aspects, such as renewal of MAs, new procedures replace current requirements and the related new fees are to some extent offset by reductions in other areas.

(iii) Risk assessment

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

3. Options

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

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

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

There have been no changes made to the above options as a result of the public consultation.

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 professional reputation within the worldwide 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 annual revenue raised against industry by these Regulations is estimated to be in the order of £500,000, equivalent to approximately 9.7% of the total income from industry in 2004/05. The amount does however depend on the pattern of applications made by companies. To put this 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 be in excess of £10 million.

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

(iii) Costs for a "typical" business
There is no such thing as a typical company in this sector. The effect of this proposal will depend on how often a company makes an application to the VMD, how many marketing authorisations they 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 £215,000 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.

The VMD met with company representatives in May to set out its proposals for changes to good manufacturing practice (GMP) inspections and batch release arrangements for immunological veterinary medicinal products. We

gave each company representative a copy of the presentation made on the day, a Q&A brief covering the essential issues, and (in confidence) a spreadsheet setting out the consequences of the fee changes to their company based on previous and planned activity.

8. Competition assessment

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

9. Enforcement and sanctions

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

10. Monitoring and review

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

11. Consultation

(i) Within government

The following governmental bodies have been consulted:

Department of Health
Medicines and Healthcare products Regulatory Agency
Scottish Executive Environment and Rural Affairs Department
Dept of Agriculture & Rural Development for Northern Ireland
National Assembly for Wales Agriculture Department
Department of Health & Social Security Northern Ireland
UKREP.

(ii) Public consultation

All of the VMD's pharmaceutical industry customers have been consulted on these proposals. The numbers are as follows:

Sector	No of companies
Marketing Authorisation Holders	116
Manufacturers	46
Wholesale Dealers	136
Exporters	29

In addition, all organisations and individuals on the VMD's consultation list for the Veterinary Medicines Regulations 2005 have been consulted. In total approximately 900 organisations and individuals have been consulted.

12. Issues Raised During Formal Consultation

(i) UK Public Assessment Reports

Comments were received from one respondent relating to the cost of producing UK Public Assessment Reports (UKPARS). The additional resources needed to develop, prepare and maintain the UKPARs require an increase of 11% on the capital fees for assessment work. NOAH, the trade association representing the veterinary pharmaceutical industry, believes that the charge should come from the public purse and not be levied as a further charge on MA holders.

The VMD is required by Ministers to recover the full cost of the authorisation of veterinary medicines from the veterinary pharmaceutical industry. Government funding is not available to cover the cost of this activity and the only option available is to introduce the proposed increase in capital fees.

(ii) Annual fees

Comments were received from one respondent relating to the Graded Annual Fee rate. The Graded Annual Fee is charged as a percentage of industry turnover in the preceding calendar year. NOAH expressed concern that the VMD had not revealed the turnover growth assumption made in deciding the necessary fee rate. NOAH believes that the industry turnover growth for 2004 was 4%.

The VMD's planning assumptions included a 2% industry turnover growth. NOAH's assertion that industry turnover growth has been 4% for the preceding calendar year means that VMD could receive up to 2% more than predicted in pricing calculations. In response to NOAH, the VMD has therefore reduced the increase in Graded Annual Fee from 11.5% to approximately 9.5%. (Figure roundings to two decimal places in fact mean that the reduction will actually be 1.7%).

(iii) GMP and Batch Release for Immunological Veterinary Medicinal Products

Comments were received from two respondents relating to the proposed increase in fees for Immunological GMP inspections and batch release. NOAH was supportive of the proposed changes, which more closely align costs with fees. The other respondent was concerned about the resulting increase in fees to its company.

The concerned company is a relatively small company, the economics of which are hit relatively hard by this necessary re-alignment of fees with costs. The Regulations provide powers for the Secretary of State to waive or reduce fees on request where this is required in the interests of human or animal health or to protect the environment. Rather than breach the principle of full

cost recovery in setting fees, it is thought better to address this individual problem through these powers should a request be made.

(iv) Inspection of contract test sites

Comments were received from two respondents relating to the introduction of a fee for the inspection of contract test sites. These were previously covered by the QA/QC batch release scheme. Both respondents expressed concern that the proposal would introduce an unnecessary duplication of testing where one site could possibly be both a contract test site and an autogenous vaccine-manufacturing site.

In response to this concern, the regulations have been amended to avoid duplication of fees in such circumstances.

13. Summary and recommendation

It is recommended that the fees are increased by an overall 9.7% of licensing income in order to maintain the effectiveness of the operations of the VMD, encompass additional EU requirements and maintain the UK's competitive position in veterinary medicines within the European Union.