**EXPLANATORY MEMORANDUM TO THE**

**THE MEDICINES (PRODUCTS FOR ANIMAL USE – FEES) REGULATIONS 2004**

**2004 No.2750**

**1.** This explanatory memorandum has been prepared by the Veterinary Medicines Directorate, an Executive Agency of the Department for Environment, Food and Rural Affairs and is laid before the House of Commons by Command of Her Majesty.

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

**2. Description**

2.1 Under the provisions of EC and UK legislation, no veterinary medicinal product may be marketed without a marketing authorisation, which is granted only after a detailed scientific assessment of the data relating to safety, quality and efficacy. These Regulations increase and restructure the existing fees charged to the veterinary pharmaceutical industry to recover the full cost of the authorisation of veterinary medicines. It also increases fees charged to the industry for the cost of granting product licences for those veterinary medicinal products that do not require a marketing authorisation under Community law but which are required to be licensed under domestic law.

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

3.1 The VMD is required by Ministers to recover the full cost of the authorisation or licensing of veterinary medicines from the veterinary pharmaceutical industry. To continue to achieve this it is necessary to increase the existing fees to recover inflation and pay assimilation costs, a shortfall in income suffered in the current year resulting from lower than anticipated industry turnover growth, and the costs of preparing for the introduction of an extended Pharmacovigilance programme in accordance with EC legislative requirements.

3.2 The Regulations also implement the first stage of a three-year project to restructure licence fees. Where annual fees are charged, the current differentiation between companies with turnovers in sales of veterinary medicinal products of under or over £2.8m will be abolished and uniform rates of annual fees will be applied.

3.3 Overall the fee changes result in an 8.7% increase in total VMD income from industry. Although this seems high, just over a fifth of the increase is because the industry overstated its turnover in the consultation undertaken in respect of the 2003 fee increases, which led to VMD not increasing annual fees as much as planned. This shortfall was met by Defra. In addition there

were historical anomalies built into the fee structure. The correction of these will affect some individual companies in material ways. 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 company turnover.

3.4 Fees were last increased in 2004 by an average of 3%.

## 4. Legislative Background

4.1 These Regulations revoke, and re-enact the fees charged in accordance with the Medicines (Products for Animal Use – Fees) Regulations 1998 (SI 1998/2428), 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.

## 5. Extent

5.1 This instrument applies to all of the United Kingdom.

## 6. European Convention on Human Rights

6.1 Not applicable.

## 7. Policy background

7.1 The VMD carries out the assessment of applications; issuing and maintenance of Marketing Authorisations; pharmacovigilance for veterinary medicines; and the licensing and inspection of manufacturers and wholesale dealers of veterinary medicines.

7.2 The main customers are marketing authorisation holders; manufacturers and importers of veterinary medicines and medicated animal feedingstuffs; retailers of veterinary medicines and medicated animal feedingstuffs; the veterinary profession; and farmers and keepers of animals.

7.3 The VMD is required by Ministers to recover the full cost of its licensing activities, thus the aim of these fee amendments is to ensure full cost recovery. The fee restructuring is the first stage of a three-year project to establish a fee structure that is transparent, flexible and reflects more accurately the actual costs incurred by VMD.

7.4 There has been extensive consultation with the pharmaceutical industry customers. The numbers are as follows:

| **Sector** | **No of companies** |
|---|---|

| | |
|---|---|
| Marketing Authorisation Holders | 116 |
| Manufacturers | 46 |
| Wholesale Dealers | 136 |
| Exporters | 29 |

7.5 Eight responses to the consultation were received. Three companies with low turnovers and the National Office for Animal Health expressed concern that the proposal would significantly increase their costs. The VMD accept the argument put forward that low turnover companies would be adversely affected in the short-term although the proposals would be cost neutral over a five-year period. To overcome the short-term effect the fixed annual fee element has been reduced to 12.5% of the proposed figure for companies with a turnover in sales of veterinary medicinal products of less than £208,000. The intention will be for the amount of this 'transitional relief' to be reduced over a five year period after which companies with low-turnover will pay the same fixed annual fee as those above the threshold figure of £208,000.

## 8. Impact

8.1 A Regulatory Impact Assessment is attached to this memorandum.

## 9. Contact

9.1 Michael Addison at the Veterinary Medicines Directorate Tel: 01932 338370 or e-mail: m.addison@vmd.defra.gsi.gov.uk can answer any queries regarding the instrument.

**REGULATORY IMPACT ASSESSMENT**

**1. Title**

The Medicines (Products for Animal Use – Fees) Regulations 2004

**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;

- restructure annual fees so as to apply them fairly across the customer base, and to recover additional costs.

The charges under this legislation apply in the UK.

***(ii) Background***

These Regulations revoke, and re-enact the fees charged in accordance with, the Medicines (Products for Animal Use – Fees) Regulations 1998 (SI 1998 No 2428), 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.

***(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 & 2 above.

***4. Benefits:***

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

***Business Sectors Affected***

*Within the pharmaceutical industry*:

| | |
|---|---|
| Marketing Authorisation Holders | 116 |
| Manufacturers | 46 |
| Wholesale Dealers | 136 |
| Exporters | 29 |

No records are available on the absolute size of these firms, only information on sales of veterinary medicinal products.

***Issues of equity and fairness:***

The proposed fee increase and other listed charges will apply evenly to all types of customer. The current differentiation between companies with a turnover in sales of veterinary medicinal products of under or over £2.8m will be abolished and uniform rates of fixed and graded annual fees will in future be applied to all companies. This will provide a fairer and more transparent basis for charging.

***5. Costs:***

***(i) Compliance costs:***
The additional revenue raised against industry by this Regulation is estimated to be in the order of £400,000, equivalent to approximately £220 per extant Marketing Authorisation. The amount does however depend on the pattern of applications made by companies. To put this in context, the costs of licensing a veterinary medicinal product represent a small proportion of the total costs of developing a product and bringing it to the market, which can run to up to £10 million.

***(ii) Other Costs:***
As this is a regulation to increase fees for work done, there are no other costs.

***(iii) Costs for a "typical" business:***

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

Additional **recurring costs** for a typical business in the above sectors are difficult to assess because of the disparity in size, complexity, geographical spread of sites and numbers of products handled by the companies in question. All of these factors can affect the level of fees charged and hence the costs likely to be incurred by individual businesses. There were significant historical anomalies built into the existing annual fee structure, which had to be addressed sooner or later. The necessary restructuring, based on fairness and transparency, may affect some individual companies in material ways. However companies should be able to absorb the overall impact of the measure without it creating an unacceptable trading disadvantage.

There should be no **non-recurring costs.**

***6. Consultation with small business: Small Firms' Impact Test***

Most Marketing Authorisations are held by the large veterinary pharmaceutical companies 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 affect on large companies whilst increases in Graded Annual Fees tend to protect new products which have not yet reached the peak of the product sales cycle. Fixed Annual Fees have to date only been paid by larger companies with an annual turnover in veterinary medicinal products of more than £2.8 million. It is intended to apply a new lower Fixed Annual Fee to all companies in future. In return for this, small companies (measured by turnover in veterinary medicinal products) will obtain a lower percentage rate levied on turnover.

***7. Competition assessment***

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

***8. 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.

***9. Monitoring and review***

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

## *10. Consultation*

### *(i) Within government*

The following governmental bodies have been consulted:

Department of Health
Medicines and Healthcare products Regulatory Authority
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. |

## *11. Summary and recommendations*

It is recommended that the fees are increased by an overall 8.7% of licensing income to maintain the effectiveness of the operations of the VMD and in order to maintain the UK's competitive position in veterinary medicines within the European Union.

***12. Declaration***

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

*Signed* Ben Bradshaw

*Date* 15th October 2004

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

***Contact Point***

Enquiries and comments on this regulatory impact assessment should be addressed to:

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