EXPLANATORY MEMORANDUM TO THE

MEDICINES (PRODUCTS FOR ANIMAL USE – FEES) (AMENDMENT) REGULATIONS 2004

2004 No. 3081

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 Parliament by Command of Her Majesty.

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

2. **Description**

2.1 The Medicines (Products for Animal Use – Fees) Regulations 2004 ("*the principal Regulations"*) come into force on the 17 November 2004. They revoke and re-enact the fees for applications and inspections relating to (i) licences and certificates issued under the Medicines Act 1968 and (ii)marketing authorisations granted under the Marketing Authorisations for Veterinary Medicines Products Regulations 1994 set by the Medicines (Products for Animal Use – Fees) Regulations 1998 ('the 1998 Regulations). The fees ensure that the Veterinary Medicines Directorate continues to meet its Ministerial target of full cost recovery.

2.2 The Medicines (Products for Animal Use – Fees) (Amendment) Regulations 2004 make three changes to the principal Regulations as follows:

2.2.1 A paragraph originally present in the 1998 Regulations concerning fees for homeopathic products that the principal Regulations inadvertently excluded is restored.

2.2.2 Two sub-paragraphs concerning applications for assistance for mutual recognition were found to inadvertently exclude reference to an additional fee payable. The wording of the sub-paragraph is clarified by the amending Regulations in order for the additional fees to apply as intended.

2.2.3 A paragraph concerning fees for site inspections was found to disapply wrongly a previous paragraph. The error is corrected by the amending Regulations in order for the fees to apply as intended.

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

3.1 Regulation 2(2) corrects an error introduced by the principal Regulations, concerning the fees for applications for assistance in connection with mutual recognition applications: the principal Regulations provided that the first such application made in each six-month cycle after grant would incur only a basic fee. These Regulations provide that an additional charge for the sixth and each additional Member State covered by such applications is also payable.

3.2 Regulation 2(3) corrects an error introduced by the principal Regulations relating to the inspection fees for biological products. The principal Regulations provided that the

only inspection fees payable for such products were those set out in paragraph 3 of Schedule 2 where the circumstances described in that paragraph applied. The effect of these Regulations is that the fees for inspections of biological products are those set out in paragraph 2 of that Schedule, unless paragraph 3 applies.

3.3 Regulation 2(4) corrects an omission from the principal Regulations relating to application fees for registration of homoeopathic veterinary medicinal products. This regulation reduces the fees payable in the circumstances described from £620 and £800, depending on the number of homoeopathic stocks contained, as taken from the 'any other application' row of the table in paragraph 2 of Schedule 4 of the principal Regulations, to £130 and £305 respectively.

3.4 Since the amendments restore the fee structure to that consulted upon prior to the making of the principal Regulations, no new consultation has bee carried out. Thus the reference in the preamble to consultation is a reference to the original consultation.

3.5 This S.I. will be sent out free of charge to all known recipients of the principal Regulations.

4. Legislative Background

4.1 These Regulations amend the Medicines (Products for Animal Use – Fees) Regulations 2004, which establish the fees for applications and inspections relating to (i) licences and certificates issued under the Medicines Act 1968 and (ii) 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 A consultation letter was sent to all marketing authorisation holders and to other interested parties including consumer organisations before the introduction of the principal Regulations. The amending Regulations merely introduce the fees at the level anticipated in that consultation.

8. Impact

8.1 A full Regulatory Impact Assessment was prepared for the principal Regulations that come into force on 17 November. Since the amending Regulations merely introduce the fees at the level anticipated in that Regulatory Impact Assessment, no new RIA has been undertaken. The reference in the explanatory note to the RIA is thus a reference to the original RIA.

9. Contact

9.1 Michael Addison at the Veterinary Medicines Directorate can answer any queries regarding the instrument.

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