EXPLANATORY MEMORANDUM TO

THE VETERINARY MEDICINES (AMENDMENT) REGULATIONS

2014 No. 599

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

2. Purpose of the instrument

2.1 The Veterinary Medicines Regulations (VMR) 2013 came into force on 1 October 2013 and laid down controls and procedures concerning the authorisation, manufacture, supply and use of veterinary medicines in the UK to ensure that the legislation remains up to date. They include provisions on medicated feeds and feed additives and a revised fee structure. The Veterinary Medicines (Amendment) Regulation 2014 is necessary to correct six minor errors in the 1 October 2013 Regulations.

3. Matters of special interest to the [Joint Committee on Statutory Instruments *or* the Select Committee on Statutory Instruments]

3.1 None

4. Legislative Context

4.1 The VMR implement the requirements of Directive 2001/82/EC, as amended by Directive 2004/28/EC. This Directive outlines the rules and requirements for the regulation of medicines for animal use. The VMR also implement Directives and Regulations relating to medicated feeds.

4.2 The VMR 2013 came into force on 1 October 2013 and contained six typographical type errors. The purpose of this instrument is to rectify those errors.

5. Territorial Extent and Application

5.1 This instrument applies to all of the United Kingdom.

6. European Convention on Human Rights

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

7. Policy background

- What is being done and why

7.1 The purpose is to correct six errors in the VMR 2013. This SI was laid in the house on 20 August and included a full Impact Assessment, Explanatory Memorandum and Transposition Note. The errors are as follows:

i) ambiguity in a paragraph relating to the prescribing of medicated feedingstuffs. This correction returns the law to the situation we understood was in the VMR 2011. On discussing the error with Lawyers, they advised a change to the drafting to address an ambiguity.

ii) incorrect references for offences regarding importing/re-exporting of premixes or feedingstuffs. This is to address wrong references to offences in Regulation 43 in VMR 2013. The correction ensures the offences remain as they were in the VMR 2011.

iii) inadvertent removal of an offence relating to the requirement that for medicated feedingstuffs, a vet may only prescribe a veterinary medicinal product which is authorised for incorporation into feedingstuffs. This corrects the offence for the ambiguity addressed by point i) above.

iv) the word "non" is omitted before "food-producing" in a table of fees. This is to correct the omission.

v) an incorrect fee for a wholesale dealer's import certificate which needs correcting.

vi) the method of calculation for the fee for specific batch control applications is expressed incorrectly and needs to be addressed.

- Consolidation

7.2 Not applicable.

8. Consultation outcome

8.1 A full consultation was carried out on the VMR (2013) from 7 January to 18 February 2013. None of the six errors were commented on.

8.2 A consultation is not necessary for the Veterinary Medicines (Amendment) Regulation 2014 as changes i)-iii) do not change the law. Amendments iv) and v) bring the wording back into line with the previous version of the VMR and do not alter the effect that anyone who had read the consultation version would have understood. Amendment vi) achieves the end set out in the consultation, namely to ensure that the fees charged for particular applications to reflect VMD's actual cost of handling the application and to reduce the fee for this type of application.

9. Guidance

9.1 The Veterinary Medicines Directorate publishes guidance on the regulation of the manufacture, distribution and use of veterinary medicines.

10. Impact

10.1 The impact on business, charities or voluntary bodies is negligible.

10.2 The impact on the public sector is negligible.

10.3 An Impact Assessment has not been prepared for this instrument.

10.4 The amending instrument will correct six errors to ensure that the VMR has the intended impact.

11. Regulating small business

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

11.2 To minimise the impact of the requirements on firms employing up to 20 people, the approach taken by the Veterinary Medicines Directorate is to carry out a continual process of informal consultation with stakeholders on proposed legislative developments.

11.3 The impact on small business of the VMR 2013 was considered in the impact assessment and as part of the consultation process. As part of the consultation on these new regulations, the Veterinary Medicines Directorate invited (along with other stakeholders) small businesses to an open meeting to discuss the proposed amendments to the VMR. In response to feedback received during this meeting and in written consultation responses Ministers decided that three proposals would be withdrawn or amended.

12. Monitoring & review

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

13. Contact

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