ASSURING THE SAFETY, QUALITY AND EFFICACY OF VETERINARY MEDICINES

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Our Ref: #401321

Date: 07 January 2013

Dear Sir or Madam

PUBLIC CONSULTATION ON THE VETERINARY MEDICINES REGULATIONS 2013

INTRODUCTION

1. I am writing to seek your views on the proposed changes to the Veterinary Medicines Regulations (VMR) 2011. It is intended that the revised VMR will come into force in October 2013 and will replace the current VMR 2011 (SI No 2011/2159).

2. The full consultation package is available on the VMD's website http://www.vmd.defra.gov.uk/public/vmr_consultation.aspx. Alternatively, a CD-ROM version or e-mail copy of the package can be provided on request from Lorna Shelley, telephone: 01932 338320 or e-mail: l.shelley@vmd.defra.gsi.gov.uk. Should you wish to receive only certain documents due to the size of the package, please tell Lorna and she will be pleased to help you. Due to the high costs involved with such a large volume of documents, we would prefer not to send paper copies. However, should you be unable to access an electronic version we will provide one hard copy per organisation.

3. The consultation package contains the following:
   - the Impact Assessment (IA),
   - a 'clean' copy of the draft revised VMR and a copy showing the proposed changes (highlighted by a different colour and a line in the margin, so they can easily be identified),

- the Veterinary Medicines Guidance Notes (VMGNs) that have been updated and show the proposed changes,
- a response form for you to use when submitting comments relating to these proposals.

4. A summary of the proposed changes to the VMR is listed in Annex A and each one is discussed in more detail within the IA. A list of other changes which are not included in the IA is at Annex B and a list of VMGNs that have been amended is shown in Annex C.

BACKGROUND

5. The VMR represent a 'one-stop shop' as far as possible, so that all of the legislative provisions in respect of veterinary medicines are included in a single piece of legislation.

6. The VMR are regularly revoked and remade, which provides the opportunity to make amendments and adjust our fees should the need be identified. It also avoids the accumulation of a raft of separate amending legislation and the associated difficulty for those involved in the sector to identify the provisions in force at any one time.

IMPACT ASSESSMENT (IA)

7. We have prepared an IA for this consultation. The purpose of the IA is to evaluate the possible consequences of the proposed changes for stakeholders. We invite your comments on the proposals and should be grateful to receive details of any anticipated increase or reduction in your costs, incurred as a consequence of any of the amendments to the VMR.

VETERINARY MEDICINES GUIDANCE NOTES (VMGNs)

8. In line with previous VMR consultation exercises, we are also consulting on changes to the VMGNs. The amendments are track changed in each VMGN.

9. In addition to these changes we are also trialling a proposal to highlight good practice text. This proposal is in response to feedback stating that the text showing good practice can be difficult to distinguish from legal requirements.

10. We have chosen VMGN 3 to trial this reformatting of the text, as it applies to all retailers of veterinary medicines. We welcome feedback on the trial version of VMGN 3. Following the consultation, if the highlights are considered beneficial they will be included in all of the other VMGNs.

SCOPE OF CONSULTATION

11. Copies of this letter have been sent to an extensive list of interested parties and this list is available should you wish to see it. We will be happy to forward copies of this letter to any additional interested party on request.

YOUR COMMENTS

12. The response form has been provided to help focus comments on specific areas and to help identify which groups of interested parties are affected. We welcome any comments relating to the proposals and also any comments relating to the format of the consultation.

13. **Please note that responses to this consultation will not be individually acknowledged unless specifically requested.**

14. Please send your comments to Lorna Shelley by **18 February 2013** to: Veterinary Medicines Directorate, Woodham Lane, New Haw, Addlestone, Surrey, KT15 3LS, or e-mail: l.shelley@vmd.defra.gsi.gov.uk.

THE NEW CONSULTATION PRINCIPLES

15. This consultation has been prepared in line with the Government's New Consultation Principles which state that timeframes for consultation should be proportionate and realistic to allow stakeholders sufficient time to provide a considered response. The amount of time required will depend on the nature and impact of the proposal and might typically vary between two and twelve weeks. Therefore, considering the minor nature of the changes proposed, a short six-week formal consultation will be held.

16. Defra monitors its effectiveness at consultation. Complaints or comments relating to the consultation process should be sent to Defra's Consultation Co-ordinator, Area 2D, Ergon House, Horseferry Road, 17 Smith Square, London SW1P 3JR or email to: consultation.coordinator@defra.gsi.gov.uk

MAKING COPIES OF REPLIES AVAILABLE TO THE PUBLIC

17. In line with Defra's policy of openness, at the end of the consultation period copies of the responses we receive will be made publicly available through the Defra Information Resource Centre, Lower Ground Floor, Ergon House, 17 Smith Square, London, SW1P 3JR. The information they contain will also be published in a summary of responses on the VMD's website http://www.vmd.defra.gov.uk.

18. If you do not consent to this, you must clearly request that your response be treated confidentially. Any confidentiality disclaimer generated by your IT system in e-mail responses will not be treated as such a request. You should also be aware that there may be circumstances in which Defra will be required to communicate information to third parties on request, in order to comply with its obligations under the Freedom of Information Act and the Environmental Information Regulations.

19. The Information Resource Centre will supply copies of consultation responses to personal callers or in response to telephone or e-mail requests (telephone:

0207 238 6575, e-mail: defra.library@defra.gsi.gov.uk). Wherever possible, personal callers should give the library at least 24 hours notice of their requirements. An administrative charge will be made to cover photocopying and postage costs.

OPEN MEETING TO DISCUSS THE CONSULTATION

20. I should also like to take this opportunity to invite you to a meeting at the VMD on 05 February 2013 to present an overview of the consultation responses and to provide attendees with an opportunity to raise and discuss any outstanding concerns. Coffee will be available from 1.30pm in the VMD conference room and the meeting will start at 2pm.

21. Please contact Lorna Shelley (telephone: 01932 338320 e-mail: l.shelley@vmd.defra.gsi.gov.uk) to book places. Places will be available on a first come first served basis and as the consultation group is quite large, please limit your nominations to a maximum of two from your organisation.

Yours faithfully

Dr Nick Renn
Head of Legislation Team

ANNEX A

Summary of the proposed changes to VMR are as follows:

Change 1: Amendment to the provisions relating to importation and possession of unauthorised veterinary medicines which will allow enforcement action to be taken where necessary.

Change 2: Amendment to Regulation 35 (1) (g) to permit an inspector to seize anything they believe (with reasonable grounds) to be a veterinary medicine.

Change 3: Introduction of a clause within Schedule 3 to allow the removal of a Veterinary Practice Premise (VPP) from the register if the practice is not up to the expected standards.

Change 4: Clarification of fees for applications for Marketing Authorisations relating to certain biological products.

Change 5: Introduction of a fee for the renewal of a registration of a homeopathic remedy.

Change 6: Amendment of category descriptions for extensions to Marketing Authorisations to align them with EU legislation.

Change 7: Simplification of the fees for appeals to the Veterinary Products Committee.

Change 8: Removal of the fee for additional member states on applications for a Marketing Authorisation relating to a Parallel Import.

Change 9: Reduction to fees for decentralised applications for Marketing Authorisations where the UK is the Concerned Member State or for recognition of a product authorised in another member state.

Change 10: Rebalancing of fees for manufacturers and wholesale dealers.

Change 11: Increase to the charge for inspections of veterinary practice premises (VPP) to achieve full cost recovery for this work.

Change 12: Changes to fee structure for inspections of Manufacturers and Distributors of Feedingstuffs and Suitably Qualified Persons (SQP) Premises.

Change 13: Increase for the application and subsequent annual fee for fees relating to manufacturers and distributors of feedingstuffs in Northern Ireland.

Change 14: Reduction to the fees applied by the Royal College of Veterinary Surgeons for the registration of a VPP.

ANNEX B

OTHER PROPOSED CHANGES, NOT INCLUDED IN THE IMPACT ASSESSMENT

1. Minor typographic amendments.

2. All references to offences in each of the schedules of the VMR 2013 have been combined into one overarching paragraph at the end of each schedule.

3. Changes to advertising rules described in Nick Renn's letter dated 11 October 2012 VMR 2013 (http://www.vmd.defra.gov.uk/pdf/vmr_letter1012.pdf) will be amended to prohibit the advertising of antimicrobial products to professional keepers of animals and prescription only medicines to owners or keepers of horses.

4. An amending SI to Schedule 5 of the VMR is due to come into force on 1 December 2012 and the amendments have been included in the VMR 2013.

   The amending SI:-

   - corrects a drafting error in Schedule 5 relating to applying the feed hygiene rules and principles of Regulation 183/2005 to establishments manufacturing medicated feedingstuffs. The correction has no effect on current arrangements.

   At the same time the opportunity has been taken to:-

   - correct the omission of an offence related to the supply of complementary feeds, and;

   - amend reference to the repealed Council Directive 76/371 with a reference to the current European Instrument, Commission Regulation 152/2009 which lays down the Methods of Sampling and Analysis for the Official Control of Feed.

ANNEX C

List of Amended Veterinary Medicines Guidance Notes (VMGN)

VMGN NUMBER	VMGN TITLE
1	Controls of Veterinary Medicines
3	Guidance for Retailers
4	Controls on Advertising
5	Import Certificate Schemes
8	Wholesale Dealers Authorisations for VMPs
10	Guidance on Enforcement
12	Exemptions for Small Pet Animals
15	Manufacturing Authorisations
17	Medicated Feedingstuffs and Specified Feed Additives
20	Controlled Drugs