ASSURING THE SAFETY, QUALITY AND EFFICACY
OF VETERINARY MEDICINES

Summary of Responses to the Consultation on the Amendments to the Veterinary Medicines Regulations 2011 SI 2159 and 10 Veterinary Medicines Guidance Notes

Contents

May 2013

1. Introduction

This document contains a summary of responses to the consultation on the amendments to the Veterinary Medicines Regulations (VMR) 2011 SI 2159 which came into force on 1 October 2011 and 10 Veterinary Medicines Guidance Notes (VMGN). The formal public consultation commenced for 6 weeks between 7 January 2013 and 18 February 2013. An Open Meeting was held at the VMD on 5 February for interested parties to discuss the proposals. The consultation package and a summary of the Open Meeting are available on the VMD website at the following link: http://www.vmd.defra.gov.uk/public/consultations_previous.aspx

2. Copies of Consultation Responses

Responses to the consultation are available from the Defra Information Resource Centre, Lower Ground Floor, Ergon House, 17 Smith Square, London, SW1P 3JR.

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.

3. Background

Directive 2001/82/EC as amended by 2004/28/EC on the community code relating to veterinary medicinal products sets out the controls on the manufacture, authorisation, marketing, distribution and post-authorisation surveillance of veterinary medicines applicable in all European Member States. The Directive provides the basis for the UK controls on veterinary medicines, which are set out nationally in the VMR. The VMR is revoked and replaced on a regular basis after consultation with interested groups to ensure that they are up-to-date and fit for purpose.

The VMR first came into force in October 2005 to implement Directive 2001/82 and consolidate all the controls on veterinary medicines that were previously part of the Medicines Act 1968 and over 50 amending Statutory Instruments. The VMR also implement EU legislation relating to medicated feeds, and some specified feed additives used in feedingstuffs.

4. Summary of Responses

The VMD is thankful to all those who participated in this consultation and is grateful for all the responses received. The VMD welcomes the additional information and constructive suggestions provided by respondents. 33 written responses were received. A list of those who responded is given in Annex A.

5. Next Steps

Full consideration has been given to the results of the consultation and views incorporated into the Impact Assessment.

A high proportion of the respondents commented on the proposed increases to fees. In response to consultation comments, the VMD has withdrawn, or reduced the proposed fee increases included in changes set out in Proposal 10 and 12 (below).

A number of comments were also received on the fee increases set out in Proposal 11. However, after further consideration of the cost involved in this activity, and in order for the VMD to achieve full cost recovery, it was decided that this proposal will remain.

In response to all comments received on fee changes we have decided to revisit our position on fee charged for certain activities. This investigation may reveal that further changes are required to ensure that the VMD's costs are met. If this is the case we will again consult with any new proposals at a later date.

The changes to the VMR 2011 are planned to come into force on 1 October 2013.

6. Results of the Consultation

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

Fourteen comments were received regarding this proposal. All supported this change.

Way Forward

This proposal was accepted.

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

Fourteen comments were received regarding this proposal. All supported this change.

One respondent stated that the phrase "with reasonable ground" could be subjective and therefore requested clarity. It was also suggested that, if following a successful appeal, the seizure was overturned, then it may be appropriate to consider compensation if the product is not longer in date.

Way Forward

This proposal will be included in the Veterinary Medicines Regulations 2013. VMGN 10 Guidance on Enforcement will be also be amended to clarify the circumstances when seizure would be appropriate. We will review the suggestion of appropriate compensation as part of the next round of amendments to the VMR

Proposal 3: Introduction of a clause within Schedule 3 to allow the removal of a veterinary practice premise from the register if the practice is not up to the required standards.

Sixteen comments received with 13 supporting this change and 3 asked for clarity on how this change would be put into practice and guidance for the veterinary practices.

Way Forward

This proposal was accepted and comments have been noted.

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

Of 11 comments 6 were supportive of the change and 5 no comments.

Feedback from a stakeholder, who was in support of measures to increase the availability of medicines, questioned whether increasing fees for biosimilar products may have the effect of reducing availability of generic vaccines.

Way Forward

This proposal was accepted and comments have been noted.

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

Of 12 comments, 7 supported the change of which 3 agreed that homeopathic medicines should be subject to the same fees and registration procedures as other medicines and 5 no comments.

Way Forward

This proposal was accepted.

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

Of 11 comments, 6 supported the change and 5 no comments.

One respondent also stated that some manufacturers may pass on this fee increase, indirectly, by increasing their cost price and this would lead to retailers also reviewing their prices.

Way Forward

This proposal was accepted.

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

Of 12 comments, 7 supported the change, 4 no comments and 1 stated that while simplification of fee structure is beneficial, the fee increase was high.

Way Forward

This proposal was accepted.

Proposal 8: Removal of the fee for additional member States on application for a Marketing Authorisation relating to a Parallel Import.

Of 11 comments, 4 supported the change and 7 no comments.

Way Forward

This proposal was accepted.

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

Of 11 comments, 7 supported the change and 4 no comments.

Way Forward

This proposal was accepted.

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

Of 11 comments, 1 supported the change, 6 no comments and the following feedback from 4 respondents:

- Disappointment over the 17% fee increase for Manufacturers
- Concern over the 74% increase in fees for wholesale dealers.
- Suggestion that the fees should remain unchanged and the surplus income from the manufacturer should be used to off-set the deficit in the wholesale inspections income.
- Concern that the fee increase could be passed on, resulting in an increase in the running costs of a charity. It was further explained that as charities are unable to pass on fee increases to their clients, additional funding through donations would be required or a reduction in the charitable service.
- The change would have small impact on wholesalers as increased costs would be passed on to the consumers.

Way Forward

This proposal was accepted in part. We have responded to feedback by withdrawing the fee increases for Schedule 6 (Exemption for small pet animals) wholesalers as the impact may have been disproportionate given the small size of the trade. Other comments have been noted.

Proposal 11: Fee increase for inspections of veterinary practice premises to achieve full cost recovery for this work.

Of 17 comments, 3 supported the change, 4 no comments and 10 opposed.

The 10 opposing comments stated that a 40% rise in fees is a significant increase. All respondents recommended a graded fee system that would take into account the size of the practice. The following suggestions were also received:

- Reduced fees for multi premise practices as the management system is the same in every premise.
- Charging per practice rather than premise.
- Inspections of multi premise practices to be carried out on the same inspection visit where possible. This would reduce the travel costs of the inspector and in turn the inspection fee.

- Separate fee for charities that are unable to pass on the charges to clients and will either need to find additional funding through donations or reduce charitable service in order to offset rising costs.
- Request for a freeze on inspection fees for charities.

Way Forward

The above comments were considered, however in view of the costs involved in this activity and in order for the VMD to make cost recovery, it was decided that this proposal would remain. However, in response to comments the VMD intends to consider the future of the fees structure and level in more detail.

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

Of 15 comments, 2 supported the change, of which 1 stated their support providing the charges are proportionate, 8 no comments, 1 expressed concerns about over regulating medicated feedingstuff as it may result in compounders withdrawing from this facility and 4 expressed concerns over the fee increase and felt it was disproportionate.

Way Forward

After considering the consultation responses we intend to partially implement Proposal 12 in the following way:

- The new fees structure for the manufacturers and distributors of feedingstuffs will be introduced. This will include a reduction in the amount charged for the annual fee and the introduction of a separate fee for the inspection. However the inspection fee will be reduced moving to a more or less cost-neutral position for compliant businesses when compared with the 2011 fees.
- The proposed restructuring and fee increases for SQPs have been withdrawn and the 2011 fees for these establishments will remain in place.

Please note that the fees for these 2 types of establishments will be included in the VMD's review of its fees structures and charges. We are obliged to fully recover our costs and anticipate that we will need to introduce revised increases at some point in the short to medium term. When the outcome of this review is known, we plan to consult on any re-proposed fee charges.

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

Of 11 comments, 1 supported the change providing the fee increases were proportionate and 10 no comments.

Way Forward

This proposal was accepted.

Proposal 14: Reduction to the fees applied by the Royal College of Veterinary Surgeons for the registration veterinary practice premises.

Of 16 comments, 7 supported the change of which 3 commented that this reduction does not offset the impact of the inspection fee increase in proposal 11, 7 no

comments, 1 request for this fee to be waived and another for a greater fee reduction for charities.

Way Forward

This proposal will be included in the final Impact Assessment. The VMD plans to address the remaining comments as part of its fees review.

All proposals

Two respondents gave general and positive feedback to all the proposals.

*****

General Comments – not proposal specific

Advertising of Prescription Only Medicines – Veterinarian (POM-V) to farmers

Mixed comments were received on the change to prohibit advertising of antimicrobial to farmers. Some in support, others understood the rationale behind this change and some opposed the change. Stakeholders claimed that this change would not alter antimicrobial resistance levels within the UK and others stated that information on these products should come from people who understand how they work and when to use them to best effect. Requests were made to the European Commission and the VMD to consider how companies can communicate about POM-V products to farmers for educational purposes.

Advertising of Prescription Only Medicines – Veterinary, Pharmacist, SQP (POM-VPS) products to horse owners

Stakeholders objected and opposed the proposal to ban the advertising of POM-VPS products to keepers of horses. Some argued that educational advertising is an appropriate means to raise awareness of diseases and various treatment options available.

Way Forward

All comments have been noted.

Written Prescriptions

Two comments were received on the legislation regarding written prescriptions. One highlighted the need for raising the awareness of the requirements of the VMR regarding written prescriptions. Another stated the need for specific wording requirements of written prescriptions to be legislated.

Way Forward

Comments have been noted. Further information on the legal requirements of written prescriptions and the process of reporting prescription misuse can be found on the VMD's website at the following link:

http://www.vmd.defra.gov.uk/public/vmr_misuse.aspx

Cascade

Collective comments and concerns received from the veterinary industry on the legislation and use of cascade on small animals. A request was made to the VMD to review and change the small animal cascade.

Way Forward

All comments have been noted.

Falsified Medicines Directive 2011/62/EU

One comment received suggesting that the Falsified Medicines Directive 2011/62/EU should be incorporated into these proposals.

Way Forward

The Falsified Medicines Directive 2011/62/EU amends European Directive 2001/83 which sets out the restrictions on the supply, manufacture and marketing of human medicines within the EU and does not have any provisions for veterinary medicinal products. The Veterinary Medicines Directive 2001/82 as amended, is currently under review. Should a similar proposal for veterinary medicines be adopted as a result of this review this will be implemented into UK law.

Veterinary Medicines Guidance Notes (VMGNs)

We consulted on 10 of our guidance notes these are as follows:

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

We are grateful for the five responses on the amendments to the VMGNs. These will be considered when the guidance is amended.

Annex A

Consultation Respondents	
1	AAS Vets Ltd
2	Agricultural Industries Confederation (AIC)
3	Animal Health Distributors Association (AHDA) (UK) Ltd
4	Animal Medicines Training Regulatory Authority (AMTRA)
5	British Small Animal Veterinary Association (BSAVA)
6	British Veterinary Association (BVA)
7	Camelid Veterinary Services
8	Cats Protection
9	Clynderwen & Cardiganshire Farmers (CCF) Ltd
10	David Beattie
11	Department of Agriculture & Rural Development Northern Ireland (DARDNI)
12	Dogs Trust
13	Farmers' Union of Wales
14	General Pharmaceutical Council (GPhC)
15	Gina Desai
16	Kim Hamer
17	Lanes Vet Group
18	Manor Drug Company (Nttm) Ltd t/a Vet-Medic
19	National Farmers Union (NFU)
20	National Office of Animal Health (NOAH)
21	People's Dispensary for Sick Animals (PDSA)
22	Pharmaceutical Society, Northern Ireland
23	Queen Mother Hospital for Animals
24	Rita Alves
25	Royal Association of British Dairy Farmers
26	Royal College of Veterinary Surgeons (RCVS)
27	Royal Pharmaceutical Society
28	Scottish Environment Protection Agency
29	Steffan Veterinary Services Ltd
30	Trilanco Ltd
31	VETCEL LTD
32	Welton Vet Ltd
33	Zoetis UK Limited (formerly Pfizer Animal Health)