

PUBLISHED MINUTES
VETERINARY MEDICINES REGULATIONS
VETERINARY PRODUCTS COMMITTEE



Veterinary
Products
Committee

PUBLISHED MINUTES

A summary of the minutes of the Veterinary Products Committee Meeting held on 26 September 2019 at the VMD, Woodham Lane, New Haw, Addlestone, Surrey.

Chairman – Professor Malcolm Bennett BVSc, PhD, MRCVS, FRCPath, FHEA
Secretary – Sandra Russell

Members

Mr R Bell
Dr R Bennett
Dr K Burnett
Prof D Cavanagh
Dr Yu-Mei Ruby Chang
Ms S Harmer
Mr M Jelley
Mr S Lister
Mr D O'Rourke
Prof A Peters
Prof C Robertson
Mr J Statham
Ms A Tarr
Mr E Vega
Prof J Weeks
Mr M White

VMD

Mr P Green
Dr G Diesel
Mr J Millward
Dr G Clarke
Mr J Mitchell
Ms H Swift
Mr M Stephens
Mrs S Paterson
Mr C Abbott

Officials¹

Others

Ms K Foxall PHE

¹ Officials may be present for all or part of the meeting or for specific agenda items.

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1. Announcements and apologies for absence

- 1.1. The Chairman reminded Members and Officials that all papers, unless otherwise indicated, and discussions of the Committee are confidential. No information relating to the proceedings of the Committee or papers presented to the Committee may be divulged to any third party.
- 1.2. Apologies for absence had been received from Mrs Ballantyne, Dr Kubiak, Professor Matthews, Mr Scott, Professor Borriello and Mrs Seager.
- 1.3. Mr Jelley and Ms Foxall joined via teleconference.

2. Declaration of interests

- 2.1. The Chairman reminded Members of the procedure for declaring interests at VPC meetings. Interests declared were minuted under the individual items.

3. Minutes of the meeting held on 6 June 2019

- 3.1. The Committee had cleared the minutes of the June meeting by correspondence and the Summary minutes were available on the VPC website (www.gov.uk/government/organisations/veterinary-products-committee/about/membership).

4. Matters arising from the minutes

- 4.1. Minute 4.1: Raising awareness of needlestick injuries
 - 4.1.1 A committee member highlighted that people with needlestick injuries who attend a minor injuries unit are treated by nurse practitioners who may not be aware of the information available. It was important to raise awareness and increase knowledge in this sector and various networks and journals had been identified to do this. Previous articles that had been published would be used as a basis for a new one on the subject and permission had been given by former member Professor Frank Burke for the use of photographs.
 - 4.1.2 The Committee agreed that an article should also be placed in SQP and NFU publications to raise awareness in these sectors.

Action 1

- 4.1.3 A committee member raised the possibility of the production of cards containing information on needlestick injuries for relevant vaccines. VMD would discuss with NOAH to encourage this approach with industry.

Action 2

- 4.2. Minute 4.2.1: FSA testing of imported products
 - 4.2.1 The Committee are keen to have a presentation on this topic and this will be followed up with the FSA.

Action 3

- 4.3. Minute 4.4.1: VMD and VPC Open meeting

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4.3.1 The Chair had given a presentation at the meeting and thanked all Committee members who had provided contributions. The VMD also thanked the Chair for the informative presentation. There had been a wide range of questions which would be shared with the attendees. Stands on various topics that had been set up in VMD were well received. It was proposed that if this event was repeated next year it would be good to include a VPC stand.

4.4. Minute 5: Advertising of anthelmintics

4.4.1 VMD have held formal meetings with vets and acknowledge the concerns with this issue. The Committee were concerned that misrepresentation of products is still going on and veterinary societies and Health & Welfare groups are also concerned by this practice. The VMD's Enforcement Team have been dealing with some cases; in one case, which is still ongoing, an article was taken down following intervention from the VMD.

4.4.2 VMD stated that they are in the process of revising the Veterinary Medicines Regulations which will go to consultation and this would be an opportunity to raise these concerns. One member stated that it is possible to refer a case to NOAH.

4.5. Minute 10.2: Special Imports

4.5.1 This was discussed under item 12.2.

4.6. Minute 10.2: Disposal of plastics on farms

4.6.1 This currently falls under the remit of the Environment Agency who are responsible for driving any change to the current policy. Farm assurance schemes require waste and recycling management plans to be in place.

4.6.2 There were two issues where further guidance was needed. One was the disposal of containers with the unused product and the second was farm plastic waste disposal. One member stated that the poultry sector have skips on farms and use a commercial company to dispose of plastics and a clinical waste carrier for out of date medicines. It was noted that most farms in other sectors do not carry out this practice. One member stated that vets are licensed to transport waste materials, however there is an associated cost to be licensed for commercial waste disposal.

4.6.3 Resources and waste strategy was a topic discussed at a recent Defra leadership event and VMD agreed to use these links to find out more information.

Action 4

5. The UK Pharmacovigilance Report for April to July 2019

5.1. Introduction

5.1.1 The Committee considered and commented upon the Pharmacovigilance Report for April to July 2019, which was presented by the head of the VMD's Pharmacovigilance Unit.

5.2. Suspected adverse event reports in humans

5.2.1 VMD highlighted the reports involving a spot on product. Members discussed whether or not gloves were provided with these products. VMD officials explained that a

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variation was approved which required the marketing authorisation holder to supply gloves with the product; however, it is unknown if vets are routinely providing owners with these gloves. VMD officials informed the committee that the MAH sent a letter to all vet practices advising that gloves should be worn when applying the product. Further comments were raised regarding whether or not an article should be written to advise vets of this requirement and whether the MAH should be required to question reporters whether or not gloves were worn or were provided. Members also questioned whether gloves had been made a requirement with the product in the USA. VMD officials explained that there were ongoing discussions at PhVWP and CVMP.

Post-meeting note: gloves are not required with use of the product in the USA.

- 5.2.2 A member questioned a report of hypersensitivity in a dog owner following application of a spot on product on her dog. The report had stated that the owner was on asthma medication. The assessor had commented that as the individual was on asthma medication, this would suggest that she was more sensitive to these types of reactions. The member questioned whether the assessor meant that the asthma medication made the owner more prone to these adverse events; or whether, as an asthma sufferer, she was more prone to these events.

Post-meeting note: the assessor confirmed that it was suspected that being an asthma sufferer made the owner more prone to suffer hypersensitivity reactions.

5.3. Suspected adverse event reports in animals

- 5.3.1 A member noted a signal for hyperglycaemia associated with use of medetomidine and questioned why we had received reports of this given that it is a known adverse event. VMD officials explained that they encourage reporting of all adverse events; even known adverse effects. In this particular product, hyperglycaemia is not specifically listed as a known adverse event in the SPC.

5.4. Environmental incidents

- 5.4.1 VMD officials commented on two environmental reports received during this surveillance period. One report involved deliberate poisoning and the other involved poisoning of ravens following the death of a recently treated sheep.

6. Consideration of an application: ref no. 00253/2019

- 6.1. The Committee examined evidence relating to an application for a variation to change the legal distribution category for a range of products.
- 6.2. The Committee provided advice for consideration by the VMD.

7. Written Appeal for an application

- 7.1. The Committee reviewed written evidence following the VMD's refusal of an application to add a new substance to the list of approved active substances that may be used in products marketed under Schedule 6 of the Veterinary Medicines Regulations (VMR) 2013.
- 7.2. The Committee gave its advice to the VMD.

8. EU Exit

- 8.1. An update was provided to the Committee by the VMD's Director of Operations on the issues arising from the UK's exit from the EU and how they are being dealt with by VMD and Defra.

9. Research commissioned by the VMD

- 9.1. Members reviewed a list of recent research commissioned by the VMD. Members found this interesting and further updates would be given when available.

Action 5

10. Evaluation of VMD assessment reports: selection

- 10.1. This is the annual exercise for the VPC to select assessment reports for Marketing Authorisation applications where the VMD has led and completed the initial assessment in the 12 months leading up to the end of August 2019, for evaluation. The Committee was asked to select four products from the list provided, at least one of which was indicated for use in a food-producing species.

10.2. The Committee selected two products for use in dogs, one for cattle and one for horses.

10.3. The Secretariat will forward copies of the initial assessment reports of the selected products to members by 11 October 2019 for them to evaluate against the specified criteria. Members were asked to submit their comments to the Secretariat by 20 December 2019 so that they can be collated and presented to the Committee for discussion at its meeting in February 2020.

10.4. Members were asked to use the two sets of criteria agreed for the evaluation exercise.

Action 6

11. Annual return of Members' interests

- 11.1. Members were asked to let the Secretariat have their updated declarations of interest by 31 October 2019.

Action 7

12. Items for information

- 12.1. The following items for information are publicly available:

12.1.1 The Veterinary Medicines Directorate Product Information Database (<http://www.vmd.defra.gov.uk/ProductInformationDatabase/>).

- 12.2. The following items for information are not publicly available:

12.2.1 Report to the VPC on new ATC applications.

12.2.2 Report to the VPC on Special Import Certificates

12.2.2.1. VMD provided clarification sought by the Committee on two imported products discussed at the June meeting.

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12.2.2.2. The Committee asked for further information on the volume for one product imported for use in sheep.

Action 8

12.2.2.3. VMD would also look into the reports they currently produce and see any of these would be preferential to the report produced for VPC.

Action 9

12.2.3 Report to the VPC on Special Treatment Certificates.

12.2.4 Report to the VPC on new MA applications granted.

12.2.5 Report from the Scientific Secretariat and the Biological Committee.

12.2.6 VPC meeting dates for 2020

13. Horizon scanning: issues for consideration

13.1. The following topics have been proposed for consideration at a future meeting:

- Novel therapies – in particular the regulatory approach to GMO
- Background and ideas from SICs/STCs
- Environmental risk assessment

14. Any other business

14.1. The following members would be leaving the Committee at the end of the year: Mr Bell, Dr Kubiak, Professor Peters and Mr Scott. The Chairman thanked them for their important contributions.

15. Date of next meeting

15.1. The next meeting of the VPC will be held on 13 February 2020 at the VMD, Woodham Lane, New Haw, Addlestone, Surrey.