Veterinary Products Committee

PUBLISHED MINUTES

A summary of the minutes of the Veterinary Products Committee Meeting held on 7 June 2018 at the VMD, Woodham Lane, New Haw, Addlestone, Surrey.

Chairman – Professor Malcolm Bennett BVSc, PhD, MRCVS, FRCPath, FHEA

Secretary – Sandra Russell

Members	VMD	Officials[1] Others	
Mrs H Ballantyne	Ms A Seager	Ms K Foxall	PHE
Dr R Bennett	Mr P Green		
Dr K Burnett	Ms R Manyarara		
Prof D Cavanagh	Dr G Diesel		
Dr Yu-Mei Ruby Chang	Mr S Hack		
Ms S Harmer	Ms C Stratford		
Mr M Jelley	Mr G Evans		
Prof J Matthews	Ms G Blanc		
Mr D O'Rourke	Mr K Stapleton		
Prof A Peters			
Mr P Scott			
Mr J Statham			
Ms A Tarr			
Mr E Vega			
Prof J Weeks			

[1] Officials may be present for all or part of the meeting or for specific agenda items.
[2] Attended the morning/afternoon only

Chairman's initials……..

AGENDA

Chairman's initials……..

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 Mr Bell, Dr Kubiak, Mr Lister, Professor Robertson and Mr White.

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. VMD presentation: We're going to need a bigger boat: policing internet sales

3.1. VMD's Head of Enforcement, Simon Hack, gave a presentation on the challenges his team faces ensuring that veterinary medicines are sold legally over the internet.

3.2. The Committee agreed that this information should be shared more widely amongst the BVA and sub groups.

Action point 1

4. VPC presentation: Reflections on the environmental risks of fipronil (and other parasiticides) when used as a veterinary medicinal product (VMP) for dogs

4.1. VPC Member Professor Jason Weeks gave a presentation on the environmental risks of fipronil when used as a VMP for dogs.

4.2. The Committee noted that further guidance was needed on the use of parasiticides for companion animals and agreed to provide further advice on the frequency and use of flea treatments.

Action point 2

5. Minutes of the meeting held on 01 February 2018

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

6. Matters arising from the minutes

6.1. Minute 4.3.1 & 7.3: legal distribution category changes for spot-on products

6.1.1 VMD provided an update on the products that had proposed legal category changes discussed at the last meeting. It was noted that one range of products had already been re-classified and VMD agreed to check the status of the other product.

6.1.2 Changes to legal category are published on the product information database (PID), but are not included in the monthly medicines updates published in the Veterinary Record. The Committee were concerned that information on this type of change should be included in communications about changes to medicines with the aim of informing vets, SQPs and pharmacists. VMD will consider how improvements can be made to raise awareness of changes to the legal category.

Action point 3

6.2. Minute 5.1.4: distributors and pharmacovigilance

6.2.1 One member declared a non-personal non-specific interest.
VMD officials gave a verbal update on how they are managing the requirement for marketing authorisation holders to be able to carry out audits of their distributors. One member has given a presentation on this topic to NOAH and agreed to keep the Committee updated on further work.

6.3. Minute 5.3.1: update on products previously considered by the Committee

6.3.1 One member declared a non-personal non-specific interest.
Applications to change the legal distribution categories of two products were considered by the Committee in 2016. For both products, the Committee recommended that a change from Prescription Only Medicine – Veterinarian (POM-V) to Prescription Only Medicine – Veterinarian, Pharmacist, SQP (POM-VPS) could be agreed, and the VMD granted the applications. VMD gave a verbal update on the resulting effects of the changes and confirmed that the Marketing Authorisation Holder for one of these products was obligated to submit a report including annual sales and pharmacovigilance data, and baseline efficacy data by 30 November 2018. VMD will provide feedback once these data has been received.

Action point 4

6.3.2 The Committee were interested in any advertising that had been carried out together with any feedback. It was agreed that wholesalers would be the better route to obtain this information.

6.3.3 One member was concerned about the large pack sizes being sold as these would not be appropriate to use on most farms and could contribute to anthelmintic resistance. VMD confirmed that they cannot control the pack sizes being marketed and have recently held a workshop to raise awareness of anthelmintic resistance.

6.4. Minute 8.5: review of VPC evaluation of VMD assessments

6.4.1 Members were invited to provide any suggestions on the selection and scoring of this annual exercise and submit these to the VMD. The VMD agreed to provide an example of a scoring system used for their internal audit.

Action point 5

6.5. Minute 11.1: topics for VMD & VPC open meeting

6.5.1 VPC Member Professor Jason weeks was nominated to deliver the presentation on environmental risk of fipronil when used as a VMP in dogs.

6.6. Minute 12.2.2: special imports

6.6.1 VMD provided an overview of the special imports system, and explained the assessment process which includes a benefit risk analysis of the product. One member stated that imports could be avoided if alternative authorised products were used. VMD emphasised that it was the responsibility of the veterinary surgeon to use their judgement to apply the cascade. The Committee proposed including SCOPs in the evaluation phase. VMD will consider this as part of the review of the current system following EU Exit.

Action point 6

Chairman's initials……..

7. The UK Pharmacovigilance report

7.1. The Committee considered and commented upon the Pharmacovigilance Report for December to March 2018, which was presented by the head of the VMD's Pharmacovigilance Unit.

7.2. **Suspected adverse event reports in humans**

7.2.1 VMD highlighted a recent change which was agreed at CVMP in relation to spot on products. The MAH will now provide gloves to be dispensed with the product and all the product information will be updated to include pictograms with gloved hands.

7.2.2 VMD commented on a report of a vet who suffered a miscarriage following exposure to one product. VMD will ensure the veterinary practice inspectors are aware of this issue so that this can be included in their inspection. VMD also agreed to publicise this via the Veterinary Defence Society and the Royal College of Veterinary Surgeons. Members agreed that this was an important topic to publicise and also suggested that any communication should be targeted at vet nurses as well as vets.

7.3. **Suspected adverse event reports in animals**

7.3.1 VMD highlighted a recent publication by the EMA warning vets and dog owners of the risk of eye ulceration if splashed in the eye with an ear drop product. VMD also informed members of a letter which the MAH has sent to all vets.

7.3.2 VMD commented on a high number of lack of efficacy reports involving one product. The MAH had confirmed that they are currently running a marketing campaign and this may explain the high number of reports. VMD confirmed that they had requested the MAH to record batch numbers for every report, where possible, and also note if the report of lack of efficacy was received by their marketing team or was a spontaneous report.

7.3.3 A member noted 2 signals for one product and suggested that this may be related to lack of efficacy of the product. The product can be purchased as a 50 dose bottle which should be used within 2 hours. Therefore, if practices use these size vials they may continue to use the product after this 2 hour window resulting in lack of efficacy. VMD officials agreed to take this into account when assessing these reports.

7.3.4 A member questioned if VMD carried out analyses to look for product interactions. VMD confirmed that this was not currently possible with the IT system used. However, the signal detection method assesses all product and clinical sign combinations and the assessors validate each signal. During the signal validation process the assessors would take note of any possible product interactions.

7.4. **Environmental Incidents**

7.4.1 No reports of environmental incidents had been received during the reporting period.

8. Consideration of an application: ref no. 01975/2017

8.1. The Committee examined evidence relating to an application to change the distribution category for a range of products from Prescription Only Medicine – Veterinarian (POM-V) to Non-Food Animal – Veterinarian, Pharmacist, SQP (NFA-VPS).

8.2. The Committee provided advice for consideration by the VMD.

Chairman's initials……..

8.3. VMD agreed to provide details of the criteria and guidelines used to address benefit/risk during an assessment of change of legal category.

Action point 7

9. Report from Defra Science Strategy Meeting and meeting of chairs of Defra evidence committees

9.1. The VPC Chair gave an update from two Defra meetings he had attended recently. The Defra Research Strategy Day discussed models across Government and how these could be implemented more widely.

9.2. A further meeting for Chairs of evidence groups, chaired by the Chief Scientific Advisor discussed thematic strategy topics. VPC was used as an example of a committee that should contribute to the consultation later this year on waste and the environment.

9.3. The Chief Scientific Advisor has asked committees to discuss their future roles and any evidence gaps they think might develop following EU Exit.

10. UK Exit from the EU

10.1. An update was provided to the Committee by the VMD's EU Exit Co-ordinator on the issues arising from the UK's exit from the EU and how they are being dealt with by VMD and Defra.

11. Items for information

11.1. The following items for information are publicly available:

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

11.1.2 The *Veterinary Record* (http://veterinaryrecord.bmj.com/)

11.2. The following items for information are not publicly available::

11.2.1 No new ATC applications had been received since the last meeting so there was no report.

11.2.2 Report to the VPC on Special Import Certificates/Special Treatment Certificates.

11.2.3 Report to the VPC on new MA applications granted.

11.2.4 Report from the Scientific Secretariat and the Biological Committee

12. Horizon scanning: issues for consideration

12.1. The Committee considered the administration of antibiotics via water for use in pigs. It was agreed to discuss this further at the next meeting.

Action point 8

13. Any other business

13.1. **Availability of veterinary medicinal products**

The Committee discussed the availability of two parasiticides which could impact on imports. One member will look into alternative products and provide an update at the next meeting.

Action point 9

14. Date of next meeting

14.1. The next meeting of the VPC will be on 27 September 2018 at the VMD, Woodham Lane, New Haw, Addlestone, Surrey.