Veterinary Products Committee

PUBLISHED MINUTES

A summary of the minutes of the Veterinary Products Committee Meeting held on 27 September 2018 at the VMD, Woodham Lane, New Haw, Addlestone, Surrey.

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

Secretary – Sandra Russell

Members		Officials[1]	
Mrs H Ballantyne	VMD	Others	
Mr R Bell	Mrs A Seager	Ms K Foxall	PHE
Dr R Bennett	Dr G Clarke		
Dr K Burnett	Dr G Diesel		
Dr Yu-Mei Ruby Chang	Mr S Archer		
Ms S Harmer	Mr E Crutcher		
Mr M Jelley	Dr E Ursich		
Dr E Kubiak	Mr D Bradbury		
Prof J Matthews			
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			

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

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 Professor Borriello, Mr Green, Professor Cavanagh, Mr Lister, Mr Millward and Mr Scott.

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. Benefit-risk decision making in the authorisation of veterinary medicines

3.1. One member declared a non-personal non-specific interest.

3.2. VMD veterinary assessor Simon Archer gave a presentation on the benefit-risk process used in the authorisation of veterinary medicines.

3.3. The Committee discussed how the prospective risks are taken into account and required further clarification about how benefits were quantified. There was further discussion on whether financial implications on sectors were considered. Members were also given an explanation on how the equivalent process works in the EU.

3.4. A member asked if data on the number of animals to be treated were used as part of the process. The VMD confirmed that they were and are obtained from the studies submitted as part of the application and are monitored through pharmacovigilance.

3.5. A member asked how the benefit-risk assessment is carried out for autogenous vaccines and vaccines in general. It was agreed to discuss this at the next meeting.

Action point 1

3.6. There was discussion about the level of benefit-risk assessment carried out for environmental risk. A member highlighted that there are other reporting schemes in addition to the VMD that report environmental incidents. Members proposed that information on environmental incidents could be sourced using the appropriate channels and this should be considered.

Action point 2

4. Minutes of the meeting held on 7 June 2018

4.1. 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).

5. Matters arising from the minutes

5.1. Minute 3.1: Presentation to the BVA on enforcement

5.1.1 VMD to raise awareness of enforcement with BVA. Members were also asked to raise this with stakeholder groups using their communication channels.

Action point 3

Chairman's initials……..

5.2. Minute 4.2: Advice on use of flea products in small animals

5.2.1 A committee member will be providing a presentation at the VMD/VPC open meeting on 28th September to raise awareness.

5.3. Minute 6.1.2: Raising awareness of changes to the legal category

5.3.1 Currently, VMD do not publicise changes to downgrade a legal category as this could be deemed to be promotional. Changes to upgrade a legal category would be publicised using relevant communication channels.

5.3.2 Members discussed the importance of making key stakeholders aware and proposed various communication channels and publications that could be used to raise awareness.

5.3.3 It was acknowledged that more open communication was required and it was crucial that up to date information was available. VMD will look into the options available and emphasised that Committee Members could also use their channels to raise awareness.

Action point 4

5.4 Minute 12.1: Administration of antibiotics via water for use in pigs.

5.4.1 An article is due to be published by the Pig Health and Welfare council anti-microbial sub-group.

5.5 Minute 13.1: Availability of anthelmintics for horses

5.5.1 Guidelines have been published on alternative products due to the unavailability of products containing praziquantel. The choice of products is limited, and alternative products include those with a combined active ingredient.

6. The UK Pharmacovigilance report

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

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

6.2.1 The VMD highlighted reports relating to human skin reactions following exposure to spot on products and a number of eye and respiratory reactions in owners and vets who had accidentally been exposed to a product.

6.2.2 Members commented on the large number of reports of needle stick injuries in the report despite the VPC's previous awareness campaign. Members noted several stakeholder groups, which would benefit from further information on this topic, and requested the continuing promotion of awareness. Members also requested VMD to produce a summary of the last 10 years of data; thereby to show whether the numbers of needle stick injuries are increasing or decreasing and split by the category of individual affected – farmer / vet / SQP.

Action point 5

6.2.3 A member commented on a report where a worker at an equestrian centre was not instructed in the safe use of a product and had not used any protective equipment when handling the product; leading to hospitalisation. The member queried whether or not VMD would contact this reporter and perhaps involve the HSE. VMD confirmed that their policy has been to not take any enforcement action based on

pharmacovigilance reports in order to ensure that further reporting of such cases is not discouraged.

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

6.3.1 The VMD updated the committee on changes, which have been agreed for the SPC of a product, to provide warnings about the risk of eye ulcers and to ensure the product is administered safely. The VMD also highlighted a number of lack of efficacy reports for fipronil products and explained that at this stage it is unclear if this is due to a genuine increase in cases, or due to a change in reporting requirements. VMD also highlighted two new signals for neurological signs following use of a product; the MAH has been asked to comment on these in their next PSUR.

6.4. **Environmental Incidents**

6.4.1 One environmental report was received during the surveillance period and was noted by the committee.

7. Evaluation of VMD assessment reports

7.1. This is the annual exercise for the VPC to select assessment reports of Marketing Authorisation applications where the VMD has led and completed the initial assessment in the 12 months leading up to the end of August 2018, for evaluation. The Committee was asked to select five products from the list provided, at least one of which must be a pharmaceutical and one an immunological. At least one of the products should be indicated for use in a food-producing species.

7.2. The Committee selected one immunological product, for use in sheep. Also, four pharmaceutical products, one for use in chickens, one for use in horses, one for use in cows and one for use in cats.

7.3. The Secretariat will forward copies of the initial assessment reports of the selected products to members by 12 October 2018 for them to evaluate against the specified criteria. Members were asked to submit their comments to the Secretariat by 21 December 2018 so that they can be collated and presented to the Committee for discussion at its meeting in February 2019.

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

Action point 6

8. Residues surveillance in the UK

8.1. Mr Crutcher from the VMD's Residues team gave a presentation on the statutory programme and proposed programme in the future. He explained the process for testing of imported goods carried out by border inspection posts on behalf of the Food Standards Agency (FSA). The Committee requested a representative from the FSA to attend a future meeting to explain the process.

Action point 7

8.2. The Committee discussed the possibility of having regular reports of residues results for future meetings. Two members volunteered to set up a sub-group to review the results and report to the Committee.

Action point 8

Chairman's initials……..

9. UK exit from EU

An update was provided to the Committee by the VMD on the issues arising from the UK's exit from the EU and how they are being dealt with by VMD and Defra. VMD will update the Committee with further details at the next meeting.

Action point 9

10. Annual return of Members' interests

10.1. Members were asked to complete and submit their updated declarations of interest by 31 October 2018.

Action point 10

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 Report to the VPC on new ATC applications.

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

11.2.2.1. The Committee identified two authorised products that were being imported and asked for justification for the imports.

Action point 11

11.2.2.2. The Committee proposed that the volume of the product imported should also be added to the table for future meetings.

Action point 12

11.2.3 Report to the VPC on new MA applications granted.

11.2.4 Report from the Scientific Secretariat and the Biological Committee.

11.2.5 VPC meeting dates in 2019

12. Horizon scanning: issues for consideration

12.1. No items were proposed.

13. Any other business

13.1. **NHS Ruling for use of off-label product**

13.1.1 A Committee member referred to the recent High Court ruling against a pharmaceutical company to stop routine NHS prescription of a cheaper medicine in favour of products that were actually authorised to treat the condition. The cheaper authorised medicines were not for treatment of the condition. The Committee asked if this would also apply to veterinary products. VMD officials agreed to investigate further and report back to the Committee.

Action point 13

Chairman's initials……..

13.2. **Import of blood for cats**

13.2.1 A Committee member highlighted an issue with the import of blood for use in cats, as there is no information to indicate that the blood components are screened on import. There was concern this could result in the potential introduction of exotic diseases into the UK. Further information was needed on how this is regulated and VMD agreed to investigate and report back to the Committee.

Action point 14

14. Date of next meeting

14.1. The next meeting of the VPC will be held on 14 February 2019 at the VMD, Woodham Lane, New Haw, Addlestone, Surrey.

Chairman's initials……..