Veterinary Products Committee

# PUBLISHED MINUTES

**A summary of the minutes of the Veterinary Products Committee Meeting held on 28 September 2017 at the VMD, Woodham Lane, New Haw, Addlestone, Surrey.**

Chairman – Professor Bill Reilly BVMS BSc DVSM HonFRCVS
Secretary – Sandra Russell

| Members | | Officials[1] | |
|---|---|---|---|
| | VMD | | Others |
| Prof M Bennett | Mr P Green | | Ms K Foxall (PHE) |
| Prof C Bryant | Dr G Diesel | | |
| Prof F Burke | Ms R Manyarara | | |
| Dr K Burnett | Dr N Garcia del Blanco | | |
| Prof D Cavanagh | Mrs A Seager | | |
| Mrs M Chambers | Mr G Evans | | |
| Ms S Harmer | Ms N Anderson | | |
| Dr E Kubiak | Mr C Abbott | | |
| Mr S Lister | | | |
| Prof J Matthews | | | |
| Mr R Morris | | | |
| Mr D O'Rourke | | | |
| Prof A Peters | | | |
| Prof C Robertson | | | |
| Mr J Sherington | | | |
| Mr J Statham | | | |
| Prof J Weeks | | | |

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



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## AGENDA

1. Announcements and apologies for absence

2. Declaration of interests

3. Minutes of the meeting held on 18 May 2017

4. Matters arising from the minutes:
   4.1. Adverse events caused by tilmicosin
   4.2. User warnings for tick and flea collars
   4.3. VPC Open meeting

5. UK Pharmacovigilance Report for April to July 2017

6. Consideration of an application: ref no. 000540/2017

7. UK Exit from the EU

8. Evaluation of VMD assessment reports

9. Antimicrobial Sales Data Report

10. Annual return of Members' interests

11. Items for information

12. Horizon scanning: issues for consideration

13. Any other business

14. VMD presentation

15. Date of next meeting



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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 Professor Borriello, Mrs Ackerman, Mr Bell, Professor Collins, Mr Jelley and Mr Scott.

1.3. Mrs Chambers, Professors Bryant, Matthews and Robertson and Ms Foxall took part by 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 18 May 2017

3.1. The Committee had cleared the minutes of the May 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 5.2.2: adverse events caused by tilmicosin, and Minute 5.2.5: user warnings for flea and tick collars

4.1.1 Updates on these issues were provided under item 5.

4.2. Minutes 6.1: VPC Open meeting

4.2.1 The Committee noted that Mr O'Rourke and Professor Matthews would be giving talks on the benefits of pharmacovigilance reporting and availability of anthelmintics at the VPC Open meeting on 29 September.

## 5. The UK Pharmacovigilance report

5.1.1 The Committee considered and commented upon the Pharmacovigilance Report for April to July 2017, which was presented by the head of the VMD's Pharmacovigilance Unit.

5.1.2 VMD provided an update on the action points from the last meeting. VMD confirmed that there had been five human deaths reported involving tilmicosin in the UK, since the products were first authorised in 1991. All five reports involved suicide and the last one occurred in 2014. VMD also informed the committee of a recent safety alert released by the FDA which mentioned 25 human deaths involving a product containing tilmicosin. A committee member commented that this product is available for use by farmers in the US compared to only vets in the UK, which may explain their higher figures. VMD also informed the committee that they were in the process of drafting a short communication discussing several product issues, including tilmicosin and flea and tick collars; and the importance of following the SPC warnings and advice. A committee member suggested using RCVS to distribute any messages to the veterinary community.

**Action Point 1**



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

5.2.1 VMD provided an update to the committee regarding the human reports of sticky fingers after spillage of a tick and flea treatment. The Marketing Authorisation Holder (MAH) has distributed demonstration pipettes to veterinary practices enabling vets to demonstrate the application to owners and also leaflets which could be passed on to owners. Officials also confirmed that a similar issue had been noted in other EU member states and the rapporteur for the product was reviewing the SPC warnings.

5.2.2 A member noted three further reports involving isoflurane, after bottles had been dropped and broken. The committee questioned whether glass bottles were required for this product. VMD officials confirmed that due to quality issues with the product, glass bottles were necessary.

5.2.3 A report was noted which involved an owner who accidentally ingested two tablets prescribed for her dog and subsequently called the NHS advice line. The committee questioned what sort of advice is given by the NHS advice lines and if there is a poison information service which medical professionals can contact. VMD officials agreed to look into this.
**Action Point 2**

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

5.3.1 VMD officials highlighted a signal noted from case assessments of rabbit deaths following use of a biological product for rabbits. All these reports lacked detail and no diagnostics were carried out making it impossible to completely rule out the product. However, VMD officials also noted a high number of reports of deaths in rabbits following use of other products which makes this more difficult to assess. The committee commented that rabbits are very sensitive to stress and this should be taken into account.

5.3.2 VMD also highlighted two signals for neurological signs for a product containing sarolaner, which is the same group as fluralaner, the active ingredient of Bravecto for which convulsions have recently been requested to be added to the SPC. VMD officials confirmed that the MAH for the product containing sarolaner had recently submitted a variation application to add neurological signs to section 4.6 of the SPC.

5.3.3 The committee questioned whether or not investigations and post mortems were required and were there any pathology labs which specialised in this area. VMD officials stated that they were unaware of any specialist pathology labs and there was no obligation on MAHs to carry out investigation or post mortems on affected animals. However, many MAHs do this to try to gain more information about their own products.

5.4. **Environmental Incidents**

5.4.1 One environmental incident had been received during the reporting period.

## 6. Consideration of an application: ref no. 00540/2017

6.1. The Committee examined evidence relating to an application for a change of legal category from NFA-VPS (Non-Food Animal – Veterinarian, Pharmacist, SQP) to AVM-GSL (Authorised Veterinary Medicine – General Sales List) for products for use in dogs.

6.2. One Member declared a non-personal non-specific interest.

6.3. The Committee provided advice for consideration by the VMD.
**Action Point 3**

## 7. UK Exit from the EU

7.1. 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. Delivery plans are being put together which include critical points requiring decisions within certain timeframes and workshops have been set up for different stakeholder groups.

## 8. Evaluation of VMD assessment reports

8.1. 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 2017, 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.

8.2. The Committee selected two immunological products, one for use in chickens and one for use in sheep and cattle. Also, three pharmaceutical products, two for use in horses and one for use in dogs.

8.3. The Secretariat will forward copies of the initial assessment reports of the selected products to members by 13 October 2017 for them to evaluate against the specified criteria. Members were asked to submit their comments to the Secretariat by 15 December 2017 so that they can be collated and presented to the Committee for discussion at its meeting in February 2018.
**Action Point 4**

## 9. Annual return of Members' interests

9.1. Members were asked to let the Secretariat have their updated declarations of interest by 31 October 2017 so they can be included in the Committee's annual report for 2017.

## 10. Items for information

10.1. The following items for information are publicly available:

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

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

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

10.2.1 Report to the VPC on new ATC applications.

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



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10.2.2.1 Although the product was not included on the report, a member expressed their thanks to the VMD for their prompt response in processing the import of a badger vaccine.

10.2.3 Report to the VPC on new MA applications granted.

10.2.4 Report from the Scientific Secretariat and the Biological Committee.

10.2.5 VPC meeting and distribution dates for 2018

**11. Horizon scanning: issues for consideration**

11.1. The VMD proposed to include topics on antimicrobial resistance matters and the effects of distribution category changes to products previously considered by the Committee. Suggestions by members for future topics were examining the effects of GMO medicines on the environment and adverse event reporting for the benefit of new members.
**Action Point 5**

**12. Any other business**
**VPC appointments**

12.1. The Cabinet Office has decided that the VPC no longer needs to be regulated by the Office for the Commission of Public Appointments (OCPA). As a result, the VMD now controls the recruitment process for new members and existing members are no longer required to provide annual performance appraisals.

12.2. The following members have served two terms and will be retiring from the Committee at the end of the year: Mrs Ackerman, Professor Bryant, Professor Burke, Mrs Chambers, Professor Collins, Mr Morris and Mr Sherington. The Chairman thanked them for their contributions.

12.3. Professor Reilly would also be retiring after serving on the Committee for 12 years including 6 years as Chairman, and members and VMD officials thanked him for his considerable contribution to the work of the Committee.

12.4. The following members have agreed to be re-appointed for a further 4 year term starting from January: Professor Cavanagh, Mrs Harmer, Mr Lister, Professor Matthews, Mr O'Rourke and Professor Robertson.

12.5. A recruitment process is being carried out to appoint 10 new members to start in January, including new positions with specialisms in epidemiology, novel therapies and pigs.

**13. Date of next meeting**

13.1. The next meeting of the VPC will be on 01 February 2018 at the VMD, Woodham Lane, New Haw, Addlestone, Surrey.



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