PUBLISHED MINUTES

A summary of the minutes of the Veterinary Products Committee Meeting held on 01 February 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]	
Mrs H Ballantyne	Mr P Green	Others	
Mr R Bell	Dr N Garcia del Blanco	Ms K Foxall	PHE
Dr K Burnett	Dr R Manyarara		
Prof D Cavanagh	Dr G Diesel		
Dr Y Chang	Ms E Ursich		
Ms S Harmer	Ms S Wilson		
Mr M Jelley	Mr J Mitchell		
Dr E Kubiak	Mr M Stephens		
Mr S Lister	Dr J Pozo		
Prof J Matthews	Mr F Broadfoot		
Mr D O'Rourke	Mr C Abbott		
Prof A Peters			
Prof C Robertson			
Mr P Scott			
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.
[2] Attended the morning/afternoon only

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AGENDA

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1. Announcements and apologies for absence

1.1. The new Chairman of the Committee, Professor Malcolm Bennett, 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 Millward and Dr Bennett.

1.3. The Chairman welcomed new members Mrs Helen Ballantyne (veterinary nurse), Dr Yu-Mei Ruby Chang (epidemiology/statistics), Ms Andrea Tarr (pharmacist), Mr Enrique Vega (veterinary surgeon (public health) and food safety risk assessor) and Mr Mark White (veterinary surgeon (pigs)) to the Committee.

1.4. Professor Matthews 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 28 September 2017

3.1. The Committee had cleared the minutes of the September 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 5.1.2: update on adverse events

4.1.1 This was discussed at agenda item 5.1.2

4.2. Minute 5.2.3: availability of poisoning advice

4.2.1 This was discussed at agenda item 5.1.3

4.3. Minute 6A.6.2: AVM-GSL product advice

4.3.1 The head of the Pharmaceutical and Feed Additives Team informed the Committee that VMD had approved the change of legal category for a product that had been discussed at the September meeting. VMD agreed to provide a full update for the Committee explaining the rationale for the decision.

Action point 1

4.4. Minute 6A.6.3: reporting of adverse events by distributors

4.4.1 This was discussed at agenda item 5.1.4

5. The UK Pharmacovigilance report

5.1.1 The Committee considered and commented upon the Pharmacovigilance Report for August to November 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 is finalising a draft letter advising vets of human adverse events and warnings that are not being followed with use of various products. It is anticipated that this will be

Chairman's initials……..

submitted to the Veterinary Record for consideration for publication within the next two weeks.

5.1.3 Agenda point 4.2: VMD advised members that in situations of suspected poisoning in humans following exposure to a veterinary medicine it is anticipated that the individual would contact NHS Direct, their GP or A&E. NHS Direct staff and medical practitioners all have access to Toxbase, a database of toxicology information maintained and supported by the National Poisons Information Centre.

5.1.4 A member presented concerns relating to the reporting of adverse events for products which are distributed by a third party on behalf of the MAH. Concerns were raised that distributors do not always make it easy for individuals to report adverse events and not all reports may be passed onto the MAH. VMD explained that they do not carry out pharmacovigilance inspections for distributors but they do inspect the distributor agreements that MAHs have and in those agreements there is a requirement for MAHs to be able to carry out audits of their distributors. VMD agreed to consider this issue further.

Action point 2

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

5.2.1 VMD highlighted reports of sticky fingers following exposure to a flea and tick treatment and explained that this had been discussed at CVMP and the MAH has been requested to add further warnings to the packaging and requested to consider the inclusion of gloves with the product. A member questioned why in the recent public minutes the product was not named. Officials explained that product names are routinely removed from the public minutes for VPC.

5.2.2 A member noted a farmer who had accidentally been injected with a chlamydia vaccine and had been referred to the sexual health clinic. VMD explained that they had no further information on this referral but it appeared that it was the hospital that had referred him the clinic.

5.2.3 A member commented on needlestick injuries and noted that until recently he was unaware that these should be reported. It was suggested that further information should be put out into the public domain to encourage reporting of these adverse events. Members also noted four needle stick injury reports for an antiemetic product for dogs and cats and questioned why for most of these reports the outcome was unknown. VMD reported that additional information had been requested for these reports but no response received.

5.2.4 Members noted an adverse event involving an autogenous vaccine and questioned what kind of labelling and warnings were included with these products and what the requirements were for adverse event reporting. VMD officials explained that all necessary warnings were required to be included on the label for the product and the manufacturers are made aware of their responsibilities to pass on the warning information and to report adverse events.

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

5.3.1 VMD highlighted that four new suspected lack of efficacy reports were received during the surveillance period following the use of an anthelmintic for sheep; all of which currently had insufficient information to rule in or out the role of the product. Members questioned what the MAH responsibilities were for investigation of these reports. VMD officials explained that there is no legal requirement for the MAH to investigate all reports but they are encouraged to do so. VMD confirmed that for all

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reports received the MAH had followed up on the report and we were either awaiting further information or the MAH had not been able to get agreement from the farmer for further investigation. The VMD will provide a high level update on adverse events following a change of legal category for a product.

Action point 3

5.4. **Environmental Incidents**

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

6. Consideration of an application: ref no. 01516/2017

6.1. The Committee examined evidence relating to an application for a change of legal category from Prescription Only Medicine – Veterinarian (POM-V) to Non-Food Animal – Veterinarian, Pharmacist, SQP (NFA-VPS) for a product for use in cats.

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

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

7. Consideration of an application: ref no. 01838/2017

7.1. The Committee examined evidence relating to an application for a change of legal category from Prescription Only Medicine – Veterinarian (POM-V) to Non-Food Animal – Veterinarian, Pharmacist, SQP (NFA-VPS) for a product for use in cats and dogs.

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

7.3. Members noted that several similar product changes had been discussed by the Committee recently, and agreed to consider the criteria for appropriate legal categorisation of anti-parasitic products, particularly spot-ons, at a future meeting.

Action point 4

8. Evaluation of VMD assessment reports: results

8.1. At its meeting in September the Committee had selected five products to evaluate: three pharmaceutical products, one for use in dogs and two for horses, and two immunological products, one for use in poultry and the other for sheep and cattle.

8.2. The Committee discussed the summary of Members' evaluations and Officials responded to comments raised.

8.3. The Committee agreed that the VMD assessments of quality, efficacy and target species safety, safety to the user and consumers, environmental safety and overall benefit:risk for each product should overall be rated as performance level 1, i.e. that the VMD had identified all potentially serious risks to human and animal health or for the environment and put together a comprehensive list of relevant questions for the applicant which were clearly expressed and justified/explained.

8.4. The VPC's evaluation would be included in the overall performance assessment of the VMD, to be published in its Annual Report and Accounts 2017/2018.

8.5. The VMD would consider alternative ways to select the assessments for next year's exercise.

Action point 5

Chairman's initials……..

9. UK Exit from the EU

9.1. 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. This included information on a forthcoming stakeholder workshop to be held on 13th February 2018 which all members were invited to attend.

10. Publication of the work of the VPC

10.1. The VPC have previously published an Annual Report of its activities on GOV.UK. The majority of information held in this report is already in the public domain in the Committee's published minutes. VMD Officials put forward a proposal to replace the Annual Report and include a paragraph about the work of the VPC within the VMD's Annual Report and Accounts. Details of expenditure are already included. An additional document with details of members' biographies including declarations of interests will be published on GOV.UK. The Committee agreed and were asked to review their biographies prior to publication.

11. VMD and VPC open meetings

11.1. The joint VMD & VPC open meeting will be held on Friday 28th September 2018. Members were asked to make suggestions for topics and nominations for speakers.
Action point 6

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/).

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

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/Special Treatment Certificates. There was some discussion on the products being imported and how the system is implemented. The VMD will provide further information on the process for importing products.
Action point 7

12.2.3 Report to the VPC on new MA applications granted.

12.2.4 Report from the Scientific Secretariat and the Biological Committee.

13. Horizon scanning: issues for consideration

13.1. The VMD proposed to include topics on enforcement of internet sales and the effects of distribution category changes to products previously considered by the Committee. Suggestions by members for future topics were the environmental effects of and resistance to veterinary products other than antimicrobials (especially some of the GSL pet products), and the regulatory requirement of the VPC in regards to product categorisation changes. The regulation of GMO medicines remains a subject of interest.
Action point 8

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13.2. The VMD will circulate a letter previously sent to stakeholders on the current state of play of the review of EU legislation.
Action point 9

14. Any other business

14.1. There was no other business.

15. VPC presentation: Antimicrobial Resistance

15.1. A member of the Antimicrobial Resistance Team gave a presentation about their work. The presentation will be circulated to the Committee.
Action point 10

16. Date of next meeting

16.1. The next meeting of the VPC will be on 7 June 2018 at the VMD, Woodham Lane, New Haw, Addlestone, Surrey.

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