

PUBLISHED MINUTES
VETERINARY MEDICINES REGULATIONS
VETERINARY PRODUCTS COMMITTEE



PUBLISHED MINUTES

A summary of the minutes of the Veterinary Products Committee Meeting held on 26 May 2016 at the VMD, Woodham Lane, New Haw, Addlestone, Surrey.

Chairman – Professor Bill Reilly BVMS BSc DVSM HonFRCVS
Secretary – Lea Stott

Members

Mrs N Ackerman
Mr R Bell
Prof M Bennett
Dr T Bleiker
Dr K Burnett
Prof F Burke
Prof D Cavanagh
Mrs M Chambers
Prof C Collins
Ms S Harmer
Mr M Jelley
Dr E Kubiak
Mr S Lister
Prof J Matthews
Mr R Morris
Mr D O'Rourke
Prof A Peters
Prof C Robertson
Mr P Scott
Mr J Sherington
Mr J Statham
Prof J Weeks

Officials¹

VMD

Mr P Green
Dr M Hendrickx
Dr N Garcia del Blanco
Dr G Diesel
Mrs V Warnock
Dr S Spencer
Mr K Stapleton
Mrs F Fernandez

Others

Dr M Jacobs 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 Professor Bryant, Professor Borriello and Mr Millward.
- 1.3. Professor Matthews, Professor Peters, Mr Sherington, Mrs Chambers and Dr Jacobs (PHE) 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 3 February 2016

- 3.1. 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).

4. Matters arising from the minutes

- 4.1 Minute 4.1.1. Needlesticks and best practice article publication (*Veterinary Record*)
 - 4.1.1 The article was published in the February edition of the European Journal of Emergency Medicine. The Chair informed the Committee that the Veterinary Record article is being progressed.
- 4.2. Minute 5.2.2 Horse vaccine needle stick injury
 - 4.2.1 The VMD informed members that the case had originally been reported to the VMD by the vet involved in 2006. The case report was published in the British Medical Journal Case Reports journal in 2010. When the MAH carried out a literature search for the purposes of their PSUR the article was not picked up as the search engine they were using did not index that journal. This was noted by the EMA, and since then the MAH has requested for this journal to be indexed. The MAH could not provide a reason for the delay between them becoming aware of the report and providing an update to the original case. However, VMD recently carried out an inspection of the MAH concerned, and noted that they have good SOPs in place to ensure this would not happen again in the future.
- 4.3. Minute 5.3.2 Signal detection outcomes log
 - 4.3.1 This was discussed under agenda item 5.
- 4.4. Minute 5.4.1 Report of overdosing for a product
 - 4.4.1 No issues arising from VPC(16)024 paper provided by the Officials.
- 4.5. Minute 6.5 An application for change of category
 - 4.5.1 At its February meeting the Committee considered the proposed legal distribution category change. Further questions have been asked and the responses are expected in June 2016 and will be considered at the September meeting.

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- 4.6. Minute 9.1 VPC annual report 2015
- 4.6.1 The VPC annual report has been published on GOV.UK and sent to the Minister for information.
- 4.7. Minute 9.1 VPC Open meeting 2016: suggestions for topics
- 4.7.1 Members were asked to consider topics for the VPC presentation to be given at the VMD and VPC Open meeting on 16 September 2016.
- 4.7.2 During the discussions in 4.7.1 the Committee stated they would be very interested in a presentation from the Antimicrobial Resistance Team (AMR) and asked the VMD to consider if this could be possible at a future meeting.
- 4.7.3 The Committee asked the VMD to consider if the VPC have a role in AMR.
- 4.8. Minute 10.1.4 Enforcement Newsletter
- 4.8.1 As requested, Members have been added to the distribution list for the quarterly Enforcement newsletter.
- 4.9. Minute 11.2 Horizon scanning: suggestions for topics
- 4.9.1 This was discussed under agenda item 8.
- 4.10. Minute 6A.6.8.13 Access to and assessment of prescription records
- 4.10.1 Further discussions are taking place, and a full update will be provided for the next VPC meeting in September.

5. The UK Pharmacovigilance report

- 5.1. The Committee considered and commented upon the Pharmacovigilance Report for December to March 2016, which was presented by the Head of the VMD's Pharmacovigilance Unit.
- 5.2. The Committee considered the outcomes achieved through the signal detection work provided by the Pharmacovigilance Team and recommended that this be presented to the Committee on an annual basis going forwards. A member agreed that the recent changes to an SPC were in line with expectations. The Committee considered how best to communicate the activities of the Pharmacovigilance Team. The Head of the Pharmacovigilance Team explained that it can take a long time for actions to be completed due to various processes. The Committee suggested they review the outcomes achieved through signal detection on an annual basis.
- 5.3. The Committee advised that there has been a general improvement in the quality of information provided to the Committee by the Pharmacovigilance Team.
- 5.4. **Suspected adverse event reports in humans**
- 5.4.1 The Committee discussed an adverse event involving accidental exposure of a Postman to a veterinary medicine due to leaking packaging. Members communicated that there are limited requirements (except those set out by Royal Mail) regarding sending veterinary medicines.
- 5.4.2 The Head of the Pharmacovigilance Team communicated concerns regarding the number of human adverse events occurring relating to specials. It was also highlighted that the responsibility for labelling these products falls to the prescribing vet.

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- 5.4.3 A member raised the possibility of discussing Pharmacovigilance at the open meeting, including the need to be careful with veterinary medicines. It was highlighted that a presentation on needle stick injuries had been delivered two years previously.
- 5.4.4 A member raised concerns over the lack of suitable warnings on product information for an imported product containing mineral oil which was involved in a human adverse event. The Head of the Pharmacovigilance Team highlighted that the VMD have no jurisdiction over the labelling of products authorised outside of the UK. The VMD do add warnings to the import certificate if deemed necessary; the concerns over this product will be raised internally.
- 5.4.5 A member questioned how use of an intranasal vaccine resulted in an accidental injection. The Committee agreed that this was likely to have taken place when drawing up the vaccine from the vial.

5.5. Suspected adverse event reports in animals

- 5.5.1 The Head of the Pharmacovigilance Team communicated concerns raised during Alert Group and at Pharmacovigilance Working Party regarding adverse event relating to a product. The MAH was asked to provide comparisons between two products but the data received in response was limited. Questions will be posed to the MAH expressing the UK's concern. The Committee discussed the reasoning behind the use of the vaccine. A member pointed out that there was limited evidence to suggest the serovars covered were significant in the UK and that the need to develop such a vaccine had been based on studies in the US and Germany. The possible reasons for the apparent increase in adverse events were discussed including the vaccination of older populations. One member highlighted that there has been a significant reduction in clinical Leptospirosis in cattle over the last 10 years. The Head of the Pharmacovigilance Team communicated that at least one other member state shares the UK's concerns and discussed the numbers of serious reports (for all products) received by other member states.
- 5.5.2 A member raised concerns over the quality of data received in some adverse event reports. Another member pointed out that these were likely reports received directly from reporters rather than via the MAHs.

5.6. Environmental Incidents

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

6. Importation of Vaccine from the US

- 6.1. This product is a vaccine intended for use in dogs. It is authorised in US and imported under STC to be used in individual animals in UK. The Committee had raised some questions in relation to this product, mainly aimed to clarify if the safety had been evaluated by the VMD before allowing the importation of this product.
- 6.2. The VMD provided some responses to the questions raised, which clarified that this product went through a Centralised application for a Marketing Authorisation, which was subsequently withdrawn by the company. The principle point was conflicting data on the efficacy of the product between the study and the findings published in a peer reviewed journal.

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- 6.3. The Committee were satisfied with the responses provided by the VMD, but there was some additional discussion regarding the procedure followed to evaluate the user risk and other potential risks in general for this specific type of product. A VMD official from the Biologicals team explained that the assessment is done based on data provided to address these aspects of safety of the product, which usually encompass studies and also relevant published literature, as well as risk assessment.
- 6.4. A question was also raised regarding the use of a product for which the efficacy has not been adequately proven. The VMD Officials explained that the importation scheme ensures that the products being imported are at the adequate quality and safety standard, but the efficacy is not considered and the vet's judgement for using specific products is not questioned if an authorised alternative is not available in UK. More detailed explanation of the context of the use of this product by vets in practice was provided by a VPC Member, based on published literature and lack of alternative products.

7. Items for information

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

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

7.1.2 The *Veterinary Record* (<http://veterinaryrecord.bmj.com/>)

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

7.2.1 Report to the VPC on new ATC applications.

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

7.2.2.1. The Committee requested an additional column be added to the document provided.

7.2.2.2 The Committee discussed the usage of particular products and their withdrawal periods highlighted in the report; they requested the VMD investigate this and update the Committee at the next meeting.

7.2.3 Report to the VPC on new MA applications granted.

7.2.4 Report from the Scientific Secretariat and the Biological Committee.

8. Horizon scanning: issues for consideration

- 8.1. The Committee was asked to consider suggestions for future meetings.

9. Any other business

9.1. Publicity Survey: A VPC member who attended the BSAVA Show commented on the VMD's stand and the survey they were conducting and asked if the VPC could see the results from this survey.

9.2. VPC Open Meeting: The Committee suggested the Open Meeting was put on line and made public.

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10. VPC presentation: Environmental impacts of veterinary medicines

10.1. Following a request by Members, VMD Officials gave a presentation on the environmental impact of veterinary medicines.

11. Date of next meeting

11.1. The next meeting of the VPC will be on 15 September 2016 at the VMD, Woodham Lane, New Haw, Addlestone, Surrey.