

PUBLISHED MINUTES
VETERINARY MEDICINES REGULATIONS
VETERINARY PRODUCTS COMMITTEE

SUMMARY MINUTES



PUBLISHED MINUTES

A summary of the minutes of the Veterinary Products Committee Meeting held on 3 February 2016 at the VMD, Woodham Lane, New Haw, Addlestone, Surrey.

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

Members

Mr R Bell
Prof M Bennett
Prof F Burke
Dr K Burnett
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 J Sherington
Mr J Statham
Prof J Weeks

Officials¹

VMD

Mr P Green
Dr M-O Hendrickx
Mr J Millward
Mr G Davis
Dr G Diesel
Mrs V Warnock
Mr G Evans
Dr S Eckford
Mrs C Stratford
Mrs K Gray
Dr N Garcia del Blanco

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. The Chairman formally welcomed four new members, Dr Karin Burnett (toxicologist), Mr Mark Jelley (working farmer), Mr Jonathan Statham (large animal veterinary surgeon) and Professor Jason Weeks (environmental scientist), to their first meeting.
- 1.3. Apologies for absence had been received from Mrs Ackerman, Dr Bleiker, Professor Borriello, Professor Bryant and Mr Scott.
- 1.4. Professor Matthews 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 1 October 2015

- 3.1. The Committee had cleared the minutes of the October 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 4.2.1: Needlesticks and best practice publication (*Veterinary Record*)
 - 4.1.1 The Chairman informed the Committee that he has arranged a meeting with the editor to discuss the publication of this article.
- 4.2. Minute 4.3.1: Adverse event reporting by farmers
 - 4.2.1 VMD Officials reported that encouraging reporting of adverse events, especially for food producing species has been one of the VMD's communications priorities for several years. As such the VMD would be attending the Royal Three Counties Show in June and the Pharmacovigilance Annual Review had been made more accessible and relevant to all stakeholders. This had been published on Gov.uk, and separate notifications to veterinary professionals and animal owners were being written.
- 4.3. Minute 5.2.2: Information articles for farmers and the public
 - 4.3.1 VMD Officials presented the six articles and letters that had been published in the Vet Record and Veterinary Journal during 2015. Although none of these were aimed at farmers, officials explained that more targeted articles were planned and this work had begun with this year's review which was much more comprehensive than those published in previous years. It groups events by species and veterinary medicine type, summarising the most commonly reported symptoms. It also points readers towards relevant guidance and publications, as well as providing advice on avoiding adverse events, and what to do when they happen.

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4.4. Minute 7.3: Evaluation of VMD assessment reports

4.4.1 This was discussed at agenda item 7.

4.5. Minute 12.1: VMD involvement in international activities

4.5.1 The VMD Officials presented to the Committee their involvement in both International and European activities.

4.6. Minute 12.1: Wider environmental impacts of veterinary medicines

4.6.1 A presentation to the Committee will be made by the VMD at the May meeting.

5. The UK Pharmacovigilance report

5.1.1 The Committee considered and commented upon the Pharmacovigilance Report for August to November 2015, which was presented by the head of the VMD's Pharmacovigilance Unit.

5.2. Suspected adverse event reports in humans

5.2.1 The head of VMD's Pharmacovigilance Unit pointed out the new format of the report on human adverse reactions. The Committee welcomed the detail in the paper from the VMD detailing the views of safety assessors to the reports along with the current user safety information in relevant SPCs for pharmaceutical products.

5.2.2 A member noted a report detailing a published paper describing a needle stick injury involving a horse vaccine. The member questioned why it had taken so long for this report to be submitted to the VMD given that this paper was published in 2010.

5.2.3 A member noted a report involving off-label administration by spraying instead of being administered in drinking water as recommended. The member questioned whether VMD would go back to reporters of these sorts of reports to advise against off-label use. VMD explained that this was not VMD's policy, so as not to discourage further reporting, but stated that if a consistent trend was identified then they would contact the MAH concerned or highlight the issue in publications.

5.3. Suspected adverse event reports in animals

5.3.1 The head of VMD's Pharmacovigilance Unit highlighted the high number of signals detected for antiparasitic products. VMD stated that they had requested that additional adverse reaction signs, in particular, neurological signs, were added to the SPC. VMD also highlighted the number of reports of lack of efficacy for a particular product. A member noted that this was widely known in practice particularly in those cases involving moribund animals.

5.3.2 A member questioned whether any outcomes had been achieved through the signal detection work. VMD provided examples where changes to the SPC had been requested based on signal detection. VMD explained that many changes were based following PSUR assessments due to the already formalised procedure available for making changes but stated that signal detection and PSURs complemented each other. VMD agreed to provide the VPC with a copy of their outcomes log.

5.4. Environmental Incidents

5.4.1 The head of VMD's Pharmacovigilance Unit presented the one environmental report received during the period and its apparent effect on benthic fauna surrounding fish farms. It was noted that the report had mentioned that overdoses of the product had

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been used on occasions. A member stated that due to increasing levels of lack of efficacy that overdosing was common practice. The VMD explained that the MAH had been asked to comment on this report.

6. Consideration of an application: ref no. 00833/2015

- 6.1. The Committee examined evidence relating to an application for a change of legal category from POM-V (Prescription Only Medicine – Veterinarian) to POM-VPS (Prescription Only Medicine – Veterinarian, Pharmacist, SQP) for a product for use in sheep.
- 6.2. Two Members declared personal, non-specific interests which had lapsed.
- 6.3. One Member declared a personal, non-specific interest and took no part in the discussion except, at the Chairman's discretion, to provide comments and answer questions.
- 6.4. One Member declared a non-personal, non-specific interest.
- 6.5. The Committee provided advice for consideration by the VMD and endorsed the list of questions to be sent to the applicant. It also requested that the applicant's response be presented and discussed at a future VPC meeting.

7. Evaluation of VMD assessment reports

- 7.1. At its meeting in October the Committee had selected five products to evaluate: three immunological products, one for use in salmon and two for use in chickens, and two pharmaceutical products, one for use in fish, and the other for use in dogs.
- 7.2. 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. VPC annual report 2015: first draft

- 8.1. The first draft of the Committee's 2014 annual report was presented for consideration.
- 8.2. Members agreed to submit comments to the Secretary by 26 February.
- 8.3. The final report, to be agreed by the Chairman, would be submitted to Ministers for approval to publish on GOV.UK. and the Committee would be informed when it has been published.

9. VMD Open Meeting 2015

- 9.1. The Committee was asked for suggestions for presentations for the 2016 open meeting, to be held on Friday September 16.

10. Items for information

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

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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/>)

10.1.3 Freedom of Information requests

10.1.4 VMD Enforcement newsletter Issue 4

The Committee welcomed sight of the newsletter and it was agreed they would like to receive the newsletter in the normal distribution from the Enforcement team via email.

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 applications considered by correspondence.

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

10.2.4 Report to the VPC on new MA applications granted.

10.2.5 Report from the Scientific Secretariat and the Biological Committee.

10.2.6 Review of the VPC

11. Horizon scanning: issues for consideration

11.1. The Committee was asked to consider suggestions for future meetings.

12. Any other business

12.1. There were no matters arising.

13. Date of next meeting

13.1. The next meeting of the VPC will be on 26 May 2015 at the VMD, Woodham Lane, New Haw, Addlestone, Surrey.