

Published minutes



Veterinary Products Committee

PUBLISHED MINUTES

A summary of the minutes of the Veterinary Products Committee Meeting held on 30 September 2021 by video conference.

Chairman – Professor Malcolm Bennett BVSc, PhD, MRCVS, FRCPath, FHEA
Secretary – Chris Abbott

Members

Mrs H Ballantyne
Dr R Bennett
Prof D Cavanagh
Dr Yu-Mei Ruby Chang
Ms S Harmer
Mr M Jelley
Dr D Killick
Dr E Kubiak
Mr S Lister
Dr D Mackay
Prof J Matthews
Mr D O'Rourke
Mr R Soutar
Mr J Statham
Ms A Tarr
Mr E Vega
Prof J Weeks
Mr M White

Officials: may be present for all or part of the meeting or for specific agenda items.

VMD

Ms A Seager	Mr J Millward
Dr G Diesel	Dr M Bos
Mr G Hall	Ms C Siwicka

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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 Committee congratulated Abi Seager on her appointment to Chief Executive of VMD following Peter Borriello's retirement.
- 1.3. Apologies for absence had been received from Dr Burnett and Professor Robertson.

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. SAVSNET and Adverse Drug Reactions

- 3.1. Heather Davies, a PhD student currently working on one of the VMD's R&D projects, gave a presentation to the Committee in which she explained that she was investigating whether the Small Animal Veterinary Surveillance Network (SAVSNET) informatics system can be used to improve signal detection and reporting of adverse drug reactions (ADR). SAVSNET is embedded in practice management software and collects electronic health records in near real-time from participating first opinion veterinary practices in the UK. An ADR button was added to the system in September 2020 and since then has been used for vets and veterinary nurses to report information for onward transmission to the VMD. The project has been looking at how the information collected through electronic health records can allow an informatics approach to be taken to identifying ADRs, providing a unique source of pharmacovigilance data without relying on active reporting. By automatically scanning records for information on drug use and known side effects it has been possible to identify possible adverse reactions which may not have been reported. These reactions can be further analysed to find further data such as how long after treatment they occur. Intended future directions include improving the uptake of SAVSNET in practices and using it to monitor new drugs and identify unknown drug effects.
- 3.2. The members thanked her for an interesting presentation which emphasised the usefulness of intelligent data mining in this area. It was noted that there was an initiative to mirror its use with farm animals.

4. Minutes of the meeting held on 20 May 2021

- 4.1. 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).

5. Matters arising from the minutes

- 5.1. Minute 5.1: Working group on ectoparasiticides
 - 5.1.1 Professor Weeks had been in discussions with various organisations who were interested in joining the group looking at the environmental effects of ectoparasiticides and would be arranging a meeting with them. There was significant new academic activity in this area as well.
 - 5.1.2 A member reported that products including ectoparasiticides authorised for companion animals were commonly used on horses by their owners and this unregulated use was promoted over social media. VMD agreed to explore further and will let the committee know what action it will take before the next meeting.
- 5.2. Minute 5.2: VPC Open meeting 2021
 - 5.2.1 It was confirmed that the VMD and VPC Open Day will be held on 29 November and will again take the format of online presentations. It was agreed that VPC could

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produce videos on ectoparasiticides in the environment, the effects of climate change on veterinary medicines usage and human adverse reactions. VPC to confirm their participants to VMD by 8 October and the presentations to be completed by 3 November.

5.3. Minute 5.3: Anthelmintic resistance

5.3.1 An article written by the pharmaceutical industry had appeared in a veterinary journal recommending a treatment regime for anthelmintics which was more frequent than that described in the products' SPCs. VMD will raise with NOAH and VPC would also consider writing to them and informing BVA and BSAVA about their concerns.

5.4. Minute 6.2.2: Extemporaneous products

5.4.1 Following an action that had arisen at the May meeting, a letter had been sent on behalf of the committee to the RCVS to encourage them to remind vets of the importance of providing suitable warnings when prescribing extemporaneous products, also known as 'specials'. In their response, RCVS have committed to promote the issue in their various media.

5.4.2 VMD provided members with information about the manufacture and GMP compliance of extemporaneous products.

5.4.3 A member reported that there has been interest in off label use of a product manufactured by an authorised veterinary specials manufacturer (ManSA), although there is only anecdotal evidence of its efficacy. VMD noted that ManSAs are legally required to submit information about adverse reactions, including lack of efficacy, and a proposed amendment to the Veterinary Medicines Regulations (VMR) will allow it to request sales data for this type of product in the future.

6. The UK Pharmacovigilance report

6.1 Introduction

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

6.2 Suspected adverse event reports in humans

6.2.1. VMD highlighted a small number of hypersensitivity reactions which had been reported in people following exposure to pour-on products for sheep and cattle. VMD informed the committee that these products have been placed on alert, and the SPCs of the relevant products will be reviewed to ensure that appropriate warnings are included.

6.3 Suspected adverse event reports in animals

6.3.1. VMD informed the committee of a number of signals of concern being detected for a product for dogs. VMD confirmed that the MAH has been requested to update their SPC with further warnings and to monitor other signs where there is currently insufficient information to take immediate action. The MAH has also been requested to obtain detailed history for each adverse event to determine the use of concurrent NSAIDs.

6.4 Environmental incidents

6.4.1. No environmental reports were received during this surveillance period.

7. Evaluation of VMD assessment reports: Selection

7.1. Members were asked to select four marketing authorisation applications where the VMD has led and completed the initial assessment in the 12 months leading up to the end of August 2021 for the annual exercise to evaluate VMD assessments. The committee selected two pharmaceutical products from the list provided, both of which were indicated for use in a food-producing species, one biological product and one biopharma product.

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- 7.2. The assessment reports for the selected products would be sent to members by 12 October for them to evaluate against the specified criteria. Members were asked to submit their evaluations to the secretariat by 24 December so they could be presented to the committee for discussion at its meeting in February 2022.

8. Legislation update

- 8.1. VMD reported that it had finished the decision-making on the proposed changes to the existing VMR and was now considering the changes in the EU legislation. Consultations with the animal sector will start later this year. Divergence between the Regs was a recognised risk and mitigating actions are being considered. One such issue was the EU ban on group prophylaxis use of antimicrobials.
- 8.2. It was noted that the Scottish government was currently carrying out a review of aquaculture regulations.

9. Annual declaration of members' interests

- 9.1. Members were asked to send their declared interests to the Secretariat.

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/>).
- 10.2. The following items for information are not publicly available:
- 10.2.1 Report to the VPC on new ATC applications.
 - 10.2.2 Review of Special Import activity.
 - 10.2.2.1. A member queried the reason for the import of a product. VMD would look into and respond after the meeting.
 - 10.2.3 Report to the VPC on new MA applications granted.
 - 10.2.3.1. The name of a product was queried as it seemed to be promotional but VMD explained it met the suitability criteria.
 - 10.2.4 Report from the Scientific Secretariat and the Biological Committee.
 - 10.2.5 VPC meeting dates 2022

11. Horizon scanning: issues for consideration

- 11.1. A member had seen a roadside advert encouraging dog owners to get them treated for lungworm. As there was no product or company name mentioned it was decided it did not require further investigation.

12. Any other business

- 12.1. The following members would be leaving the Committee at the end of the year: Prof Cavanagh, Ms Harmer, Mr Lister, Prof Matthews, Mr O'Rourke and Prof Robertson. The Chairman thanked them for their valuable contributions.
- 12.2. The following members had agreed to serve a second term starting in January: Mrs Ballantyne, Dr Bennett, Dr Chang, Ms Tarr, Mr Vega and Mr White.
- 12.3. A member said that the Red Tractor veterinary reporting form requires the farmer to declare that he or she takes ultimate responsibility for the use of antibiotics on the farm, but his understanding, and that of the RCVS, is that it falls to the prescribing veterinary surgeon. He would send VMD more information to consider.

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12.4. A member questioned the extent of interaction that VMD had with CVOs in the devolved countries and VMD agreed to check what arrangements had been formalised and report back to the Committee.

13. Date of next meeting

13.1. The next meeting of the VPC will be on 3 February 2022 at the VMD, Woodham Lane, New Haw, Addlestone, Surrey.