

Published minutes



Veterinary Products Committee

Published minutes

A summary of the minutes of the Veterinary Products Committee Meeting held on 25 May 2023 at the VMD, Woodham Lane, New Haw, Addlestone, Surrey.

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

Members

Mrs H Ballantyne
Dr R Bennett
Dr M Bowen
Dr Y Chang
Dr K Ganapathy
Prof D Killick
Dr E Kubiak
Dr D Mackay
Mr R Soutar
Prof 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

Mr G Hall
Dr R Cooney
Dr G Clarke
Dr C Stratford
Mr M Stephens
Ms B Berrocal-Gonzalez
Ms A Kennedy
Dr M Bos
Ms S Brown
Ms N Chinneck (observer)
Mr J Evans (observer)

Apologies

Mr M Clark
Mr M Jelley
Mrs F Kidd

Published minutes

1. Announcements and apologies for absence
2. Declaration of interests
3. Minutes of the meeting held on 9 February 2023
4. Matters arising from the minutes
 - 4.1. VPC strategy and communications plan
 - 4.2. Appeals and Referrals procedures
 - 4.3. Evaluation of VMD assessments
 - 4.4. ATC procedures
5. UK Pharmacovigilance Report for December to March 2023
6. Special Imports
7. Horizon scanning
8. Items for information
9. Any other business
10. Date of next meeting

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 Mr Clark, Mr Jelley and Mrs Kidd.

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 9 February 2023

- 3.1. The committee had cleared the minutes of the February meeting by correspondence and the Summary minutes were available on the VPC website ([Veterinary Products Committee - GOV.UK \(www.gov.uk\)](http://www.gov.uk)).

4. Matters arising from the minutes

4.1. Minute 5.1: VPC Strategy and Communications Plan

- 4.1.1 VMD's head of Information Coordination and Engagement, Carol Siwicka, explained how the VMD engages with stakeholders and the public through various media channels in a targeted way so that its messages have a wide reach and maximum impact. It has a blog and a large social media presence across several platforms including LinkedIn, Twitter and Facebook. The VMD Connect website has been launched recently and will be used to inform interested parties about regulatory issues of current interest in a timely manner. It can also be used as an accessible gateway to the large amount of information and guidance VMD publishes on Gov.uk. VMD also disseminates messages through networks and amplification partners, such as the RCVS, to achieve the widest possible reach.
- 4.1.2 The VPC has a presence on VMD Connect and it was agreed that would be a good starting place for posting articles on topics which have been considered at meetings. It can then consider expanding into social media and how to manage this in a way that promotes good messaging while minimising negative feedback. VMD offered to help build VPC's communications strategy as it develops and can provide analytics data on use of its online pages.

4.2. Minute 5.2: Appeals and Referrals procedure

- 4.2.1 The procedure for hearing appeals from applicants was provided for members' information. It was agreed to add that individual members are to be appointed to review documentation and provide advice to the committee before appeals are heard. VMD will develop its referral procedure before the committee's role in them is decided.

4.3. Minute 7.1: Evaluation of VMD assessments

- 4.3.1 VMD assessors had responded in writing to comments raised by members on the four products looked at during the VPC's annual evaluation exercise. The committee agreed to give the assessments a substantial rating while noting additional wording to include within the Summary of Product Characteristics for one of the products.

4.4. Minute 11.2.3: ATC applications

- 4.4.1 VMD's Head of Efficacy assessment for pharmaceutical products, Michael Stephens, explained how the VMD assesses ATC applications submitted by applicants seeking approval to carry out field trials for novel products or existing

products outside the scope of their marketing authorisation. A benefit:risk assessment is carried out and assurance of safeguards sought. Submitted data must support target species safety and provide a reasonable expectation of efficacy.

4.4.2 Members found the information presented on ATC procedures interesting and reassuring and suggested it is made available on VMD's Connect site.

4.5. **Minute 11.2.3: zinc oxide study**

4.5.1 In response to a question from a member raised at an earlier meeting, VMD reported that a zinc oxide study on farms had been undertaken to test a model. It will check whether any follow up is planned and report back.

5. **The UK Pharmacovigilance report**

5.1. The committee considered and commented upon the pharmacovigilance report for December to March, which was presented by Anne-Sophie Kennedy, Senior Pharmacovigilance Assessor in the VMD's Pharmacovigilance Team. Two new pharmacovigilance assessors, Nicole Chinneck and James Evans, attended as observers.

5.2. The latest format of the report was presented, including how it can be filtered and searched, what data is present, how signals are assessed, and examples of what might be considered a validated or non-validated signal. It was noted that there is no species column, which is currently not feasible due to how information is transferred between databases, however this will continue to be reviewed. Any further feedback on the report can be sent to the pharmacovigilance team.

5.3. It was explained what an 'alert' is from a pharmacovigilance perspective, including how a product is placed on alert, what this means, and what this information is used for.

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

5.4.1 No specific concerns were raised. Members noted that a number of reports of needlestick injuries were still being raised and proposed that this could be publicised as a safety message by VPC on the Connect site.

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

5.5.1 No specific concerns were raised.

5.6. **Environmental incidents**

5.6.1 Reports involving phenobarbitone had been raised and Dr Kennedy commented that this could be due to carrion birds having access to carcasses. She is liaising with VMD's environmental assessors as to whether a publication is required to advise on correct disposal of carcasses.

5.6.2 Following a question on how environmental reports are received, it was explained that the Pharmacovigilance Team has a list of organisations that usually submit environmental incidents, and if none are received in a specific time period then this is chased up with the organisations.

5.6.3 VMD reported that it had established the new Pharmaceuticals In the Environment (PIE) group. This will provide a UK cross-government platform to enable discussion and knowledge exchange relating to pharmaceuticals in the environment from human, veterinary, and where there is cross over, agricultural and non-agricultural sources. The group aims to develop a co-ordinated strategy to reduce the impacts of pharmaceuticals on the environment (biodiversity) and human health. It has identified its first priority area, which is to gain a better understanding of the potential sources of fipronil and imidacloprid levels detected in UK surface waters and to work towards reducing these levels. Membership currently includes the VMD,

Environment Agency, HSE, Defra, MHRA and Professor Weeks as the VPC representative. The inaugural meeting was held in April to agree the group's terms of reference and initial priorities. There will be a public announcement of the group's formation in June. An update will be provided at the October VPC meeting.

6. Special Imports

- 6.1. The Head of VMD's Supply Team, Stacey Brown, reported on special import activity over the last four months and highlighted several issues. Members were asked to use their networks to dispel the view that shortages of veterinary vaccines in sheep are a result of Brexit and/or increased administrative burdens but are in fact usually a consequence of manufacturing issues. Members were also asked to promote to their networks the responsible use of imported antimicrobials such as Gamaret for cattle and that use of Intra Dysovinol under the cascade should be for exceptional use only. VMD noted that the statutory minimum withdrawal periods apply for products imported under cascade use, although a different withdrawal period may be set which is detailed on the import certificate. It was agreed that it would be useful for VMD/VPC to provide guidance on cascade use and statutory withdrawal periods to expert species groups and to remind the importing vet to read the import certificate which provides information on conditions of use.
- 6.2. A revised online special import service will be launched into private beta testing soon. Further information about how to sign-up to participate in testing are available on [VMD Connect](#).

7. Horizon Scanning

- 7.1. It was agreed to invite speakers to talk on two topics at the October meeting: sustainability in veterinary medicine prescribing and use and veterinary wound care.

8. Legislation Update

- 8.1. Engagement on the consultation on the Veterinary Medicines Regulations (VMR) had been very good and VMD were now assessing the responses received. The approach under the Retained EU Law bill has changed from revoking all EU legislation to keeping it unless it is actively revoked so there is now less risk of losing important legislation.
- 8.2. A member questioned the legality of online retailers offering subscription schemes and special deals to customers which encourage them to buy more prescription products and antiparasitics in particular. VMD noted this was primarily a pricing issue which falls outside its remit but the revised VMR will introduce some new advertising rules which will give it more enforcement powers to prevent the improper advertising of medicines. In addition, all online retailers will be required to be registered with the VMD. A stakeholder workshop will be held later this year to discuss how to better optimise prescribing/sale of veterinary medicines (particularly considering online sales). The committee will consider drafting an article regarding inappropriate advertising/overuse/over prescribing of certain types of product.

9. Items for information

- 9.1. The following items for information are publicly available:
 - 9.1.1 The Veterinary Medicines Directorate Product Information Database (<http://www.vmd.defra.gov.uk/ProductInformationDatabase/>).
- 9.2. The following items for information are not publicly available:
 - 9.2.1 Report to the VPC on new MA applications granted.
 - 9.2.2 Report from the Scientific Secretariat and the Biological Committee.
- 9.3. Report to the VPC on new ATC applications

10. **Any other business**

10.1. **Membership appointments**

10.1.1 Mr Jelley, Dr Killick, Dr Mackay, Mr Soutar, Prof Statham and Prof Weeks have been reappointed to serve a further term on the committee from January 2024.

10.1.2 A recruitment exercise is being run to recruit five new members. They include a new Chair, toxicologist, microbiologist and parasitologist.

11. **Date of next meeting**

11.1. The next meeting of the VPC will be on 19 October 2023 at the VMD, Woodham Lane, New Haw, Addlestone, Surrey.