

PUBLISHED MINUTES

A summary of the minutes of the Veterinary Products Committee Meeting held on 13 February 2025 at the VMD, Woodham Lane, New Haw, Addlestone, Surrey.

Chair – Helen Ballantyne Secretary – Chris Abbott

Members

Dr D Bartley

Dr R Bennett

Dr M Bowen

Dr Y Chang

Prof M Clark

Mr M Jelley

Mrs F Kidd

Prof D Killick

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.

<u>VMD</u>

Other officials

Mr G Hall

Dr H Dowlman, Defra

Dr B Berrocal-Gonzalez

Dr R Cooney

Dr G Clarke

Mrs L Felstead

Mr M Stephens

Mr L Reynolds

Ms N Graves

Apologies

Mr B Buckle

Prof K Ganapathy

PUBLISHED MINUTES

- 1. Announcements and apologies for absence
- 2. Declaration of interests
- 3. Minutes of the meeting held on 24 October 2024
- 4. Matters arising from the minutes
 - 4.1. Discussion topics
 - 4.2. ATC applications
 - 4.3. Acronyms
 - 4.4. Amendment to minutes
- 5. Consideration of an application: ref no. 01548/2024
- 6. Presentation: online prescribing
- 7. Pharmacovigilance Report for October to December 2024
- 8. Evaluation of VMD assessments: Results
- 9. Product update
- 10. Special Imports
- 11. Aquaculture therapies
- 12. Defra Exotic Disease
- 13. Availability of vaccines
- 14. Legislation update
- 15. Horizon scanning
- 16. Items for information
- 17. Any other business
- 18. Date of next meeting

1. Announcements and apologies for absence

- 1.1. The Chair 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 Buckle and Dr Ganapathy.

2. **Declaration of interests**

2.1. The Chair 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 24 October 2024

3.1. The Committee had cleared the minutes of the October meeting by correspondence and the Summary minutes were available on the VPC website (<u>Veterinary Products Committee - GOV.UK (www.gov.uk)</u>).

4. Matters arising from the minutes

4.1. Minute 4.1: Discussion topics

- 4.1.1 A Member of the Defra Exotic diseases team will join the meeting later to give an update on their work.
- 4.1.2 A guest speaker will attend the June meeting to talk about sustainability in veterinary medicines.
- 4.1.3 Residues surveillance programmes and technology will be considered at the June meeting.

4.2. Minute 13.2 ATC applications

4.2.1 VMD officials explained that it values Members' views on ATC applications and a paper is provide at each meeting for this purpose.

4.3. Minute 13.3 List of acronyms

4.3.1 A list of acronyms was provided for Members' information.

4.4. Amendment to minutes

- 4.4.1 It was agreed to amend the minutes of the February 2024 meeting to make it clear that the VMD is leading on the pharmaceuticals in the environment review through the PIE group. Professor Weeks chairs the group and gave an update on its recent activities and how the slow progress made delivering results has led to some criticism. However, new data published indicates that areas of rivers downstream of water used by companion animals conclusively show a large increase in pesticides and it seems clear that veterinary medicines are the source. This is despite all the correct environmental assessments and regulatory measures being carried out for the products. Dialogue is ongoing with industry representatives and a workshop will be held in June to discuss all the components and find ways of resolving problems while being mindful of benefit:risk arguments. Subjects will include disposal advice. SQP checks and use of QR codes on packaging. Actions being considered are voluntary at the moment but this could change. The UK has links with the European Medicines Agency who are also dealing with this issue; VICH is also evaluating its guideline on environmental risks. Updates from the PIE group are published on VMD Connect.
- 4.4.2 Members noted the severity and complexity of the challenges being faced. There is a need for assistance from the veterinary sector including better education for vets

to reduce the over prescription of, and use of ectoparasiticides, which are used much more than endoparasiticides. There is great resistance to losing these very useful products.

5. Consideration of an application: ref no. 01548/2024

5.1. The Committee examined evidence relating to an application for a change of legal category for a marketing authorisation and provided advice to the VMD.

6. Presentation by Rahkesh Thakkar – online prescribing

- Mr Rahkesh Thakkar had been invited to talk to the Committee about the online prescribing system he has been developing. Mr Thakkar owns an independent online pharmacy, Vets4u, which dispenses veterinary medicines and has been considering how to move the prescribing process entirely online in order to increase efficiency, reduce the incidences of prescription fraud and reduce burden. The system he has designed is called Veterinary Prescribing Services (VPS) and operates on the cloud. It works by assigning client requests for medicines made in person or to an online retailer a unique digital code. These are sent to a veterinary surgeon for screening and processing using their Electronic Practice Management System (EPMS) which generates a prescription token which is sent to a pharmacy for obtaining and dispensing the products. The system is secure and access rights restricted to authorised users. It reduces human error and fraud and provides supply chain traceability as well as enabling better post market surveillance of product use. It also reduces prices by allowing more generic products to be dispensed and loosening manufacturer and wholesaler bias towards branded products with big mark ups. Challenges he is facing include producing software to link up the different systems involved and he wants to work with government to achieve this and realise the advantages the system would provide.
- 6.2. Members appreciated the benefit of the aims of Mr Thakkar's proposals but also recognised the significant challenges involved. These include assuring the privacy of personal data held in different systems and regulating data ownership. VMD has concerns around the obligation for dispensers to report information on wholesale dealing. Mr Thakkar said that he wants to split dispensing and prescribing which will separate out the commercial imperative and give dispensers more confidence. The system has a lot of potential for creating prescription data and recording patient follow up information. He would like the VMD to lead on taking this forward in order to realise his designs. The Committee thanked him for presenting some interesting proposals.

7. The UK Pharmacovigilance report

- 7.1. The Head of the VMD's Pharmacovigilance team gave a verbal update on adverse events they have been dealing with in recent months.
- 7.2. A list of pharmacovigilance updates can be found on VMD's new web page https://www.gov.uk/guidance/urgent-safety-updates-for-veterinary-medicines. This also includes any updates involving non-veterinary medicinal products used in animals. Anyone can receive updates on this page via email by clicking on the 'Get emails about this page' button. A full list of SPC changes for veterinary medicinal products can be found on the monthly medicines update page on VMD Connect, and further information on veterinary medicines can be found at the VMD's Gov.uk page.

8. Evaluation of VMD assessment reports: Results

8.1. Members had provided ratings and comments on the four products selected at the last meeting for the VPC's annual exercise to evaluate VMD's assessments. The results were reviewed and the Committee agreed to give VMD's assessments an overall substantial rating, finding them to be comprehensive and that all relevant issues had been identified.

VMD officials thanked them for the time and effort spent on completing this demanding task and will respond in writing to the comments and questions raised by Members.

9. **Product update**

9.1. VMD assessors gave an update on a product application for which the Committee had previously provided advice. The application had then been approved subject to the condition that the marketing authorisation holder provide further data on post authorisation use. That had now been received and the results were presented to the Committee. Members were satisfied that the information provided was satisfactory and agreed that the condition had been met.

10. Special Imports

10.1. There were no comments on the reports.

11. Aquaculture Therapies

- 11.1. A Member raised the issue of "what is a medicine" when it relates to various therapies (current and proposed) used in aquaculture, specifically salmon farming, as there seem to be some inconsistencies compared to therapeutic use in other species. These include unauthorised products or substances being used to prevent and treat conditions and diseases in fish and therefore appearing to fall within the definition of medicinal use. Examples include:
 - freshwater being used to treat ectoparasites of fish in the marine phase of production and common salt, similarly, being used to treat ectoparasites of fish in freshwater
 - bacteriophage products regarded as "water treatments" in Norway (e.g. Custus YRS) but yet to have an appropriate status determined in the UK
 - a variety of chemical and herbal products aimed at reducing pathogen levels in water and being promoted for use in aquaculture globally (eg. Supratect in Canada and API Stress Coat)
 - Products aimed at altering (increasing, decreasing or changing the consistency of) the mucus layer of skin and gills, either by inclusion in food, water or by direct application, are now on the market (e.g. Vidalife)
- 11.2 There were also examples of products requiring authorisation as medicines when used in fish but not for other species, such as formaldehyde, which is defined as a medicine when used to treat fish (e.g. Aquacen in Spain) but not, apparently, when used in footbaths to control pododermatitis in land-based livestock.
- 11.3 The pragmatic approach currently taken to the use of various products is appreciated, however, it does seem that more consistency is needed and that the definitions currently used were largely drawn up when treatment of farmed fish was not a significant concern, so a review seems appropriate.
- 11.4 Members were concerned about the common use of some unauthorised products which have no proof of efficacy. VMD reported that it has a subgroup which is looking at the very challenging subject of bacteriophages. It was agreed that the use of therapies in aquaculture is a developing area which could usefully be revisited.

12. Defra Exotic Disease

12.1. Dr Heather Dowlman of the Defra Exotic Disease team explained how they deal with unusual diseases which affect the UK. The approach taken is to detect incidents, apply controls to stop their spread using animal and food movement restrictions and eradicate them through vaccination and culling if necessary. Particularly dangerous animal diseases are notifiable

and animal keepers are legally required to report incidents to Defra. The team are currently dealing with outbreaks of Avian Influenza, Bluetongue, Classical Swine Fever and Epizootic Haemorrhagic Disease. VMD contributes by assessing and authorising vaccines and has recently authorised several BTV-3 Bluetongue and H5 avian influenza vaccines. Lumpy Skin Disease and African Swine Fever are not endemic in the UK but are being monitored and measures are being taken to prevent them spreading here.

13. Availability of vaccines

13.1. There was no discussion of this item.

14. Legislation update

14.1. The Legislation Office has been renamed the Policy Development and Delivery team.

15. Horizon scanning: issues for consideration

15.1. No discussion.

16. **Items for information**

- 17. The following items for information are publicly available:
- 17.1. The Veterinary Medicines Directorate Product Information Database (http://www.vmd.defra.gov.uk/ProductInformationDatabase/).
- 17.2. The following items for information are not publicly available:
 - 17.2.1 Report to the VPC on new MA applications granted.
 - 17.2.2 Report from the Scientific Secretariat and the Biological Committee.
 - 17.2.3 Report to the VPC on new ATC applications.
 - 17.2.4 List of acronyms.

18. Any other business

18.1. The VMD would like the Committee's advice on an application for an Autogenous Vaccine Authorisation. Due to the short timetable, this will be dealt with by correspondence and appropriate Members will be contacted outside the meeting.

19. Date of next meeting

19.1. The next meeting of the VPC will be on 12 June 2025 at the VMD, Woodham Lane, New Haw, Addlestone, Surrey.