Veterinary Products Committee

# PUBLISHED MINUTES

**A summary of the minutes of the Veterinary Products Committee Meeting held on 19 October 2023 at the VMD, Woodham Lane, New Haw, Addlestone, Surrey.**

Chair – Helen Ballantyne PGDip BSc (Hons) RN RVN
Secretary – Chris Abbott

Members
Dr R Bennett
Dr M Bowen
Dr Y Chang
Dr K Ganapathy
Mr M Jelley
Mrs F Kidd
Prof D Killick
Dr E Kubiak
Dr D Mackay
Mr R Soutar
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 A Kennedy
Dr G Clarke
Dr R Cooney
Dr G Withanage
Ms S Brown
Dr M Bos
Ms M Tejero

Others
Ms G Hollis
Mr B Buckle
Dr D Bartley

**Published minutes**

1. Announcements and apologies for absence

2. Declaration of interests

3. Presentation: Setting standards for Vet Tech - is it about time?

4. Minutes of the meeting held on 25 May 2023

5. Matters arising from the minutes
   5.1. VPC Communications strategy
   5.2. Advice for needlestick injuries
   5.3. Zinc Oxide study in pigs

6. UK Pharmacovigilance Report for April to July 2023

7. Consideration of an application: ref no. 03092/2021

8. Pharmaceuticals in the Environment

9. Evaluation of VMD assessment reports: Selection

10. Special Imports

11. Horizon scanning

12. Legislation update

13. Annual declaration of members' interests

14. Items for information

15. Any other business

16. Date of next meeting

1. **Announcements and apologies for absence**

1.1. The committee were informed that Professor Malcolm Bennett had sent apologies and was unable to attend this meeting which was to be his last as Chair. Members and VMD officials expressed their gratitude for the engaging way he had chaired meetings over the past six years which has encouraged open and useful debate. Mrs Helen Ballantyne has been appointed to officially take over as Chair in January and chaired this meeting in his absence.

1.2. This was the last meeting for Dr Elizabeth Kubiak and the committee thanked her for the valuable contributions she has made over the past twelve years as a member.

1.3. The Chair welcomed newly appointed members Benjamin Buckle, a toxicologist, and Dr Dave Bartley, a parasitologist, to the meeting as observers. Their official terms start in January.

1.4. Apologies were received from Professors Clark and Statham.

1.5. 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.

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. **Presentation: Setting standards for Vet Tech - is it about time?**

3.1. The Chair welcomed Georgie Hollis, creator of the Veterinary Wound Library, to the meeting to speak about veterinary technology and how these products exist in an unregulated marketplace. Veterinary technology covers a wide range of items intended for clinical and therapeutic use ranging from wound dressings to diagnostic equipment and software. Human medical devices are authorised by the MHRA but there is no legislation which applies to veterinary devices within the UK or within the EU. Georgie Hollis stated that there is no legal framework to enforce standards or body dedicated to overseeing their manufacture and sale and regulation is reliant upon current consumer law via trading standards and Advertising Standards (ASA). Furthermore, she stated that due to the lack of regulatory control, products can be substandard or advertised using unsubstantiated claims about their effectiveness which poses significant risks to animal welfare. There is a lack of legal protection for end users such as veterinary practices and liability lies with them, not the manufacturer. Ms Hollis has been researching these issues for some time and is keen to find solutions which have the support of stakeholders and regulators. Her proposals include the formation of a system which can provide oversight and control such as an ombudsman scheme for product providers. She also aims to create a Veterinary Technology Registry for classifying and rating products in order to provide assurance of their safety and reliability. The next step will be setting up a steering group to overlook the project and help identify courses of action and source funding for research.

3.2. Members thanked Ms Hollis for providing an insight into these issues and recommended the RCVS as a primary interested party and noted they have a practice standards scheme which covers the maintenance of veterinary products. The BVA, BEVA and Association of Anaesthetists are other bodies with scope for involvement. VMD reported that there are no immediate plans to establish veterinary legislation to cover medical devices within the UK. Any regulation would need to clarify the scope of veterinary devices, the need to invest in expertise to assess and also come with a requirement for inspections; the work involved would be substantial. In order to advance her project, members recommended that Ms Hollis start small by looking at a limited range of products. Several members were interested in

discussing further with her outside the meeting and the committee asked her to return to provide an update when some progress has been made.

4. **Minutes of the meeting held on 25 May 2023**

4.1. The committee had cleared the minutes of the May meeting by correspondence and the Summary minutes were available on the VPC website (Veterinary Products Committee - GOV.UK (www.gov.uk)).

5. **Matters arising from the minutes**

5.1. **4.1.2/5.4.1 VPC Communications strategy and advice for Needlestick injuries**

5.1.1 It was noted that articles from members on needlestick injuries have been published on the VPC page of VMD Connect and members were asked to consider providing pieces on other items of interest. Two issues arising from the latest pharmacovigilance reports were thought to be suitable. It was agreed to ask Georgie Hollis to provide a summary of veterinary technology issues.

5.2. **4.5.1 Zinc Oxide study in pigs**

5.2.1 VMD reported that the findings of the Zinc Oxide study had been taken to the Pharmaceuticals in the Environment group. A member noted that supplies of the product for use on farms were nearly exhausted.

6. **The UK Pharmacovigilance report**

6.1. **Introduction**

6.1.1 The committee considered and commented upon the Pharmacovigilance Report for April to July 2023, which was presented by Dr Anne-Sophie Kennedy, Senior Pharmacovigilance Assessor in the VMD's Pharmacovigilance Team.

6.1.2 VPC were informed of a recent GOV.UK pharmacovigilance publication on anaphylaxis following intravenous co-amoxiclav use (a human product used under the prescribing cascade), including the subsequent updated warning for end users of two potential batches that had increased reports of anaphylaxis in animals, although there were no issues in humans. The human product Marketing Authorisation Holder (MAH) had been very helpful in providing information on a voluntary basis regarding this issue, although human product MAHs and the MHRA do not have a legal obligation to investigate or report on animal adverse events. Changes to prescribing practices were discussed.

6.1.3 VPC were informed of a recent GOV.UK pharmacovigilance publication on human adverse events following accidental oral exposure to pergolide (due to it being hidden in food items prior to administration to horses).

6.1.4 VPC were informed of some recent reports of adverse events in animals following accidental exposure to topical human hormone replacement creams. VMD's pharmacovigilance database will accept adverse event reports for animals following exposure to human medicines.

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

6.2.1 There were reports of adverse reactions in humans following exposure to pour-on/ spray-on production animal products. In most of the cases adequate PPE was not worn and, in some cases, the adverse reactions seen were very severe. Summary of Product Characteristics (SPC) warnings are comprehensive therefore VMD

wishes to increase the awareness of warnings and would like advice from VPC on how best to achieve this.

6.2.1.1. There had been a pre-meeting question from a member on whether importance of PPE during use of cypermethrin, especially in warm weather, could be highlighted on VMD Connect. It was agreed this could be a good topic.

6.2.1.2. There was discussion on how best to ensure this message is received by the correct individuals, and agreement that liaising with Suitably Qualified Persons (SQPs) who would be prescribing the products would be a useful starting point. Any communications to end users, for example seasonal farm workers, need to carefully consider literacy levels, English as second language readers, and text size.

6.2.2 A member commented on a number of human needle stick injuries for a product. This may be due to increasing use and also due to the increased awareness and promotion on social media regarding the reporting of adverse events for this product.

6.2.3 A member had submitted a pre-meeting question on whether a VMD Connect publication could be useful to highlight the risk of humans cutting their fingers on the foil of containers for a product, but also flagged the potential concerns over endorsement as only one MAH's product. It was agreed that a publication on VMD Connect could be considered. Previous publications had been drafted for this issue, however as there is only one product these were not published and a more general notice on care when opening product packaging could be more appropriate.

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

6.3.1 There were reports of injection site reactions from a vaccine not matching the current SPC description. During the meeting there were discussions on the difference between use on a limited number of naïve animals during clinical trials versus field use. Differences in adverse events may be anticipated as a result of this. The current proposal is to continue liaising with the MAH and review the Periodic Safety Update Report (PSUR) data when available.

6.3.2 The committee noted an increased number of reports and adverse events for a product that are not noted on the SPC and significant social media attention regarding this topic. VMD is currently assessing the PSUR to decide how to address the pharmacovigilance data.

6.4. **Environmental incidents**

6.4.1 There were no comments on the environmental incidents reported.

6.5. **Other**

6.5.1 VMD would circulate the EU guideline on the definition of a potential serious risk to human or animal health or for the environment to members for their information.

7. **Consideration of an application: ref no. 03092/2021**

7.1. The committee examined evidence relating to an application for a new marketing authorisation.

7.2. No members declared an interest.

7.3. The committee provided advice for consideration by the VMD.

8. **Pharmaceuticals in the Environment**

8.1. Professor Weeks gave an update on the work of the Pharmaceuticals in the Environment group which he chairs. This cross government group is currently looking at potential adverse effects which pharmaceutical products may have on waterways. Regulatory changes are not yet an option and the group is focusing on mapping sources and pathways and finding evidence of effects. Once gaps have been identified, the group will discuss finding solutions with Industry and then develop a road map for tracking progress towards them. It has been found that concentrations of the substances being considered are higher in urban areas which suggests a correlation with their use on companion animals. The group has talked to veterinary practices and the retail sector to find out what checks are done at the time of sale of products. Some of these require prescription and others are on the general sales list.

9. **Evaluation of VMD assessment reports: Selection**

9.1. For the VPC's annual exercise to evaluate VMD assessments, 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 2023. They selected three pharmaceutical products from the list provided and one biological product.

9.2. The assessment reports for the selected products would be sent to members by 27 October for them to evaluate against the specified criteria. Members were asked to submit their evaluations to the secretariat by 15 January 2024 so they could be presented to the committee for discussion at its meeting in February.

10. **Special Imports**

10.1. The reports on special import certificates (SICs) granted since the last meeting were reviewed. It was noted that certificates for Furazone can only be issued on a named case basis due to its higher risk profile. The increase in the number of SICs granted for products containing sulphonamide were due to a current shortage in the UK. Members queried the authorisation of Amikacin for animal groups when it is an aminoglycoside of last resort in human medicine and VMD would consider how it has been categorised further.

10.2. VMD was aware of issues with vaccine availability and is seeing alternative vaccines imported under SIC to fill supply gaps. VMD will be hosting a roundtable discussion on 7 November with stakeholders and interested parties to raise awareness of the issues, better understand the problem statement and to see where efforts can be focussed on long term supply chain resilience.

11. **Horizon Scanning**

11.1. The committee agreed to invite a speaker on sustainability in veterinary medicines to the next meeting.

12. **Legislation update**

12.1. VMD reported that the formal government response to the consultation on the Veterinary Medicines Regulations will be published soon. The SI will then be laid before parliament for scrutiny and approval in the first quarter of 2024.

13. **Annual declaration of members' interests**

13.1. Members were asked to send their annual declarations of interests to the secretariat.

14. **Items for information**

14.1. The following items for information are publicly available:

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

14.2. The following items for information are not publicly available:

14.2.1 Report to the VPC on new MA applications granted.

14.2.2 Report from the Scientific Secretariat and the Biologicals Committee.

14.2.3 Report to the VPC on new ATC applications.

14.2.4 VPC meeting dates for 2024

15. **Any other business**

15.1. **Bacteriophages**

15.2 Members asked for an update on the regulation of bacteriophages and VMD reported it is reviewing gap analyses for a potential new application to see if it is suitable for Limited Marketing Authorisation.

16. **Date of next meeting**

16.1. The next meeting of the VPC will be on 8 February 2024 at the VMD, Woodham Lane, New Haw, Addlestone, Surrey.