Veterinary Products Committee

PUBLISHED MINUTES

A summary of the minutes of the Veterinary Products Committee Meeting held on 8 February at the VMD, Woodham Lane, New Haw, Addlestone, Surrey.

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

Members
Dr M Bowen
Mr B Buckle
Dr Y Chang
Prof M Clark
Dr D Bartley
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.

VMD
Mr G Hall
Dr R Cooney
Dr G Clarke
Dr B Berrocal-Gonzalez
Dr M Bos
Ms S Brown
Ms K Gray
Ms A Baker

Apologies
Dr R Bennett
Prof K Ganapathy
Mr M Jelley

Chairman's initials

1. Announcements and apologies for absence

2. Declaration of interests

3. Minutes of the meeting held on 19 October 2023

4. Matters arising from the minutes
   4.1. Communication
   4.2. Pharmaceuticals in the Environment

5. UK Pharmacovigilance Report for August to November 2023

6. Consideration of an application: ref no. 02287/2023

7. Evaluation of VMD assessment reports: Results

8. Special Imports

9. Legislation

10. Horizon scanning

11. Items for information

12. Any other business

13. 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 Dr Bennett, Mr Jelley and Professor Ganapathy.

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 19 October 2023**

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

4. **Matters arising from the minutes**

4.1. **Minute 5.1: Communication**

4.1.1 VMD gave an update on the Avian Influenza situation. The Defra vaccination task force is gathering evidence for its recommendation to the Secretary of State and EFSA is due to give its opinion by the end of March. Recorded cases have been lower than expected in recent months but ongoing mild weather could cause an increase. The French authorities have taken a national policy to vaccinate ducks which has resulted in the US and Japan temporarily suspending imports of poultry products. There has been a call to vaccinate endangered and breeding raptors. VMD is in touch with manufacturers and assessing an application for a vaccine and more applications are expected. The emergency use of unauthorised products is also being considered as an option. A member noted that some areas of the poultry sector are not enthusiastic about vaccinating and the costs involved.

4.1.2 VMD will ask the APHA if a representative from the vaccination task force can attend the May meeting to give an update.

4.2. **Minute 8: Pharmaceuticals in the Environment**

4.2.1 VMD met with the Pesticides Action Network (PAN) to discuss their proposal that certain veterinary pesticides are banned. VMD stressed that these are veterinary medicinal products where approval is only granted where the benefits of use outweigh the risks. The VMD continues to take a balanced approach where a number of other factors are considered including the positive impacts on animal health and human health. It is that message the VMD need to consistently promote. Professor Weeks gave an update on the activities of the cross-government Pharmaceuticals in the Environment group which met on 24th January when it looked at presentations from interested parties on pathways that harmful substances can take to the environment. Further evidence gaps were noted by the group including the need to better understand the actual impacts that imidacloprid and fipronil have on aquatic eco-systems and the consequences to human and animal health of a potential change in parasiticide use in companion animals. It is not just an issue for companies to solve and public messaging will be important. The next step is for the cross-government Pharmaceuticals in the Environment group to share further information with the VPC, and in time post workshop outputs.

4.2.2 A member commended the VMD on its activity in supporting evaluation of the extent and relevance of veterinary pharmaceuticals in the environment. This is an area that is also likely to come increasingly into public discussion. Therefore in order to avoid reputational risk, the VMD was encouraged to ensure any public statements around environmental risk and veterinary pharmaceuticals are: 1. not reassuring beyond the level of evidence required by the regulatory assessment, 2. reflect the limited nature of environmental assessments made during regulatory assessments of small animal products and 3. highlight the VMD's support for work aimed at improving our understanding in this area.

5. The UK Pharmacovigilance report

5.1. Introduction

5.1.1 The Committee confirmed receipt of the Pharmacovigilance Report for August to November, which was presented by the head of the VMD's Pharmacovigilance Team.

5.1.2 No comments had been received by the Pharmacovigilance Team from VPC members.

5.2. Suspected adverse event reports in humans

5.2.1 This report contained a high percentage of needlestick incidents (not significantly different compared to previous reports).

5.3. Suspected adverse event reports in animals

5.3.1 Signals detected were not new and were already under active alert (monitoring) and/or undergoing a variation process to change the product information.

5.3.2 There was an update regarding a human product containing Amoxicillin/Clavulanic Acid used under the cascade in dogs and a surge in adverse events reported.

5.3.3 Two publications in Gov.uk informed end users of the increase in adverse events after administration of Amoxicillin/ Clavulanic, including information on specific batch numbers related to the adverse events. Unfortunately, the Pharmacovigilance Team are still receiving reports and are working with the VMD Comms Team to review and improve our communications to make sure we effectively reach our target audience.

5.4. Environmental incidents

5.4.1 There were no questions from VPC members on this report.

6. Consideration of an application: ref no. 02287/2023

6.1. The Committee examined evidence relating to an application for a variation to change the legal distribution category for a range of products.

6.2. The Committee provided advice for consideration by the VMD.

7. Evaluation of VMD assessment reports: Results

7.1. The Committee reviewed the summary of members' evaluation of four products selected at the last meeting for its annual quality exercise. Members agreed to give the VMD's assessments an overall substantial rating, finding them to be comprehensive and that all relevant issues had been identified. VMD will respond in writing to comments and questions raised by members.

7.2. Members identified two potential areas for improvement: a better and more thorough validation process would help prevent inadequate product applications going forward for assessment. VMD commented that its validation procedure is an administrative function that

simply checks that the appropriate documentation has been provided. It was noted that other regulatory bodies do undertake a more comprehensive review at the validation stage and there may be benefits in following this approach.

7.3. The second issue was a potential lack of understanding by VMD assessors of systems involved in veterinary practices in the field and the issues they raise. VMD commented that a number of its assessors have veterinary experience but would welcome any offers from members to provide specialist training as the sessions they have provided in the past were very educational.

8. **Special Imports Review**

8.1. A member provided an update on a lack of availability of products in the fish sector and difficulties finding suitable alternatives to import and how they can be less favourable to use. VMD welcomed the information provided and would make the AMR team aware of issues around imported antimicrobials. Availability of medicines, particularly vaccines, is a problem being felt across different veterinary sectors and VMD had arranged a workshop with representatives at the end of last year to discuss. An action plan is now being drawn up, including high level strategies that may be available to incentivise manufacturers; and the opportunity to submit a joint review of products to increase the size of available markets. Regular liaison with regulatory bodies in other countries takes place in order to get a better understanding of the global issues. This is a long-term project which will take several years to complete.

8.2. Members were reminded that the VMD has a dedicated mailbox at supply@vmd.gov.uk should anyone wish to report supply issues. They were also encouraged to use their networks to increase awareness of prescribing concerns they may have with using imported products. Members welcomed changes in the revised Veterinary Medicines Regulations (VMR) which will include an increased obligation on marketing authorisation holders to report product shortages. VMD will publicise shortages but must do this must be balanced against the drive to panic buy. The aim is to provide companies with information which will help them maintain adequate and not excessive stockpiles.

8.3. A member noted that vets deal with wholesalers as intermediaries who can provide a barrier to timely communication about how long shortages will last. VMD confirmed it does ask for resolution dates when shortages arise and follows these up with companies but also acknowledged improvements can be made to how this information is advertised. It is looking into procedures for human products which use an alert system.

8.4. The VMD's revised and improved Special Imports Service and is in public beta testing. Users will need to register for the service first.

9. **Legislation**

9.1. The government's response to the consultation on the VMR has been published and notes the substantial support to the original proposals made, the majority of which will be implemented. The GB VMRs will introduce closer alignment with the regulatory framework in place in Northern Ireland. All feedback was considered, and the consultation response will highlight where policy proposals were supported, where some concerns were raised and whether the proposal was retained or revised accordingly. Of interest to the fish sector are withdrawal periods for products used under the cascade and these will be kept in line with the EU. The requirement for the use of prescription products to be under the care of vets has been clarified. It has been made clear that medicated feeds can be ordered when needed and manufactured by feed mills but can only be supplied with a veterinary prescription. The next step will be for the changes SI to be laid in parliament and the details approved with the final aim being for the new VMR to come into force before the summer. There were a number

of new proposals received which won't be included in the current revision to the VMR but will come out in other guises or be considered with future changes to the legislation.

10. **Horizon scanning: issues for consideration**

10.1. A speaker has agreed to attend the committee in October to talk about sustainability in veterinary medicine prescribing and use.

10.2. New proposals suggested were:

- how innovations in vaccine production and incentives for manufacturers can be co-ordinated by the organisations involved and VMD's role in this.
- emerging diseases: VMD would look into whether the Defra Exotics group could speak to the committee.
- the effects of certain products on the gut microbiome and on ADI figures used for calculating MRLs. VMD would ask their Safety assessment team to contact the member who raised this issue.
- looking at ways of joining up the landscape for Home Office licences and ATCs and reducing barriers.
- improving the UK as an environment for clinical veterinary pharmaceutical research. A member who serves on the Association of Veterinary Ethics Committees would provide the secretariat with contact details.
- applications of Artificial Intelligence in veterinary medicine. Members were asked to consider how it can be used in their areas and report suggestions to the VMD.

11. **Items for information**

11.1. The following items for information are publicly available:

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

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

11.2.1 Report to the VPC on new MA applications granted.

11.2.2 Report from the Scientific Secretariat and the Biological Committee.

11.2.3 Report to the VPC on new ATC applications.

12. **Any other business**

12.1. There were no matters arising.

12.1.1 VMD would circulate members' biographies for checking and update their information on Gov.uk and VMD Connect accordingly.

13. **Date of next meeting**

13.1. The next meeting of the VPC will be on 23 May 2024 at the VMD, Woodham Lane, New Haw, Addlestone, Surrey.