

### **Published Minutes**

A summary of the minutes of the Veterinary Products Committee Meeting held on 26 May 2022 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 M Bowen

Dr K Burnett

Dr Y Chang

Dr K Ganapathy

Mr M Jelley

Mrs F Kidd

Dr D Killick

Dr E Kubiak

Dr D Mackay

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:

Mr G Hall

Dr M Bos

Mr M Escribano

Dr G Clarke

Dr R Cooney

Ms R Appleyard

Ms L Biffar

Ms R Mitchell

### Other:

Ms K Foxall (UKHSA)

# **Apologies:**

Dr R Bennett Mr M Clark

Ms A Seager

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# **Agenda**

- 1. Announcements and apologies for absence
- 2. Declaration of interests
- 3. Minutes of the meeting held on 3 February 2022
- 4. Matters arising from the minutes
  - 4.1. Ectoparasiticides in waterways
  - 4.2. Anthelmintic resistance
  - 4.3. Withdrawal periods for fish products
- 5. UK Pharmacovigilance Report for December to March 2022
- 6. Role of VPC: planning session
- 7. Legislation update
- 8. Items for information
- 9. Horizon scanning
- 10. Any other business
- 11. Date of next meeting

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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. Apologies for absence had been received from Dr Bennett, Mr Clark and Ms Seager.
- 1.3. New VMD employees Lucia Biffar, Rowena Mitchell and Roxanne Appleyard attended as observers.

### 2. Declaration of interests

2.1. The Chairman reminded Members of the procedure for declaring interests at VPC meetings. No interests were declared.

# 3. Minutes of the meeting held on 3 February 2022

3.1. The Committee had cleared the minutes of the February meeting by correspondence and the Summary minutes were available on the VPC website (www.gov.uk/government/organisations/veterinary-products-committee/about/membership).

### 4. Matters arising from the minutes

- 4.1. Minute 4.1.1: Ectoparasiticides in waterways
  - 4.1.1 VMD are due to hold a progress meeting soon with University of Sussex about their research project and continue to liaise with Environment Agency about concentration levels of fipronil and imidacloprid in waterways.
- 4.2. Minute 4.3.1: Anthelmintic resistance
  - 4.2.1 The Chairman had written to NOAH to raise the committee's concerns about an article which seemed to encourage a frequency of use of anthelmintics on pets which it was felt was unnecessary or even excessive and which had been used in other literature.
  - 4.2.2 Members emphasised the need to educate veterinary practitioners, retailers and owners about how to use anthelmintics properly and that it was important to get the message across in advertising using clear language. VMD noted that this was outside its remit but that it was aware that other countries are also considering how to manage these products more effectively. It was noted that SQP registration bodies are useful contacts for spreading the message about good practice.
- 4.3. Minute 7.2: Withdrawal periods for fish products
  - 4.3.1 VMD stated that it was not looking to change the withdrawal periods set for products used under the cascade for fish at this time.

# 5. The UK Pharmacovigilance report

### 5.1 Introduction

- 5.1.1 No particular comments were received from the Committee upon the Pharmacovigilance Report for December to March, which was presented by the head of the VMD's Pharmacovigilance Unit, Miguel Escribano.
- 5.1.2 He apologised for not having yet addressed the suggestions to improve these reports which were made at the last VPC meeting. The VMD's pharmacovigilance database has recently changed, and the pharmacovigilance team still needs time to understand how these reports will be produced, and how they can be presented in a useful format to the Committee.

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## 5.2 Suspected adverse event reports in animals

5.2.1 Mr Escribano highlighted some specific signals that have been detected in animals during the last 4 months. These included a possible cardiac issue, hypersensitivity reactions and neurological signs related to a product indicated for pain relief for companion animals. There had also been an increase in cases of acute mastitis and associated death related to a teat sealant which may have been caused by intramammary antibiotic shortage in 2021 and potential off label use or change of use on farm. A member of the Committee highlighted the importance of being mindful of the farming community and try to include languages other than English in the publications. The Committee also mentioned that there could be disproportionality of these adverse events amongst similar products based on the differences of the brands involved.

## 5.3 Suspected adverse event reports in humans

- 5.3.1 Mr Escribano highlighted some specific signals that have been detected in humans during the last 4 months. These included neurological symptoms reported (headache, nausea, feeling tired) for a sheep product containing cypermethrin. The addition of a warning on the SPC to advise of possible neurological symptoms after exposure is being considered. It was noted that an educational approach and pharmacovigilance publication for cypermethrin would be of benefit as most of the cases are following exposure without recommended PPE. It was highlighted by the Committee that VMD should try to make these publications available online so that they can be advertised in forums to reach a larger audience.
- 5.3.2 There had been an isolated but severe case of vision affected in a dog after exposure to an endectocide. VMD will look into the formulation to see if it can be related to the excipients in the composition and will look to propose changes to SPC on next PSUR assessment, possibly to the whole range of products.
- 5.3.3 The Committee provided comments on the possibility to run signal detection analysis based on chemical structure similarity rather than individual actives, as this way it would probably be easier to detect signals for products with very low number of reports. It was agreed to discuss this possibility outside of VPC.

## 5.4 **PSUR activity**

- 5.4.1 Mr Escribano highlighted several items related with PSUR activity including a proposal to review and update the SPCs for products containing cloxacillin and ampicillin.
- 5.5 The Chairman reminded the members to provide comments on the adverse event reports prior to the meeting so these can be addressed properly by the Pharmacovigilance team.

### 6. Role of the VPC

- 6.1 Members and VMD officials discussed how the role of the VPC could change and develop following the UK's exit from the EU and the way it could best contribute to the agency's aims. It was agreed that there is a continued need for a committee which is independent from the VMD and is seen to be acting independently when it provides advice. Its work was seen as falling into two main areas reactive and proactive:
  - Reactive activities could include discussions on product advice, including novel and innovative products, company representations to the VPC where there may be disagreement with the VMD decision and providing advice on class referral / reviews

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- Proactive activities could be around intelligence gathering, agreeing educational
  material and messaging to share with networks in helping to affect change, for example
  prescribing habits etc; also having a programme of information sharing between VPC /
  VMD on issues of the day. To also provide proposals for the VMD R&D programme.
- 6.2 It was recognised that there was also a need to raise the VPC profile in order to
  - Maximise membership networks and join up with them to promote agreed VPC messaging
  - Become more joined up with cross government groups to ensure the practicalities and real-world experience relating to veterinary medicines gains wider traction
  - Improve education what role does VPC play in promoting best practice, liaising with networks, joint messaging with VMD? VPC can target and use messaging opportunities that are not open to the regulator.
  - Promote intelligence and early warning opportunities and use networks and personal expertise to flag up issues that might be coming down the line. These could range from novel therapies or treatments to publications in veterinary press to the use of imports. To have the discussions and then to agree any VPC messaging and who to target for example in the area of imports or prescribing habits. Essentially to flag a potential issue, consider the impacts and then agree the priority and targeting of any messaging.
- 6.3 Given the above and that the VMD is now responsible for assessing products that in the EU are eligible for submission under the centralised procedure, consideration also needs to be given to whether the composition of the VPC need enhancing, and members would consider whether there are any expertise gaps on the committee.
- 6.4 Professor Bennett and Dr Mackay offered to prepare a draft strategy for the VPC while the VMD agreed to look at reworking the agenda format.
- 6.5 Professor Bennett would liaise with members collate a list of VPC member networks.
- 6.6 VMD will provide its R&D strategy or similar document to the committee.
- 6.7 VMD and members would provide a list of topics that might be suitable for topical presentations.

# 7. Legislation

7.1. VMD confirmed that it continues to hold informal workshops with stakeholders and the public consultation on proposed changes to the VMR is likely to start before the end of the year.

### 8. Items for information

- 8.1. The following items for information are publicly available:
- 8.2. The Veterinary Medicines Directorate Product Information Database (http://www.vmd.defra.gov.uk/ProductInformationDatabase/).
- 8.3. The following items for information are not publicly available:
  - 8.3.1 Report to the VPC on new ATC applications.
  - 8.3.2 Review of Special Imports
    - 8.3.2.1. A member raised the issue of import certificates being granted due to wholesalers reporting temporary product outages and VMD confirmed it was aware of this.
    - 8.3.2.2. It was questioned why the import of injectable gentamicin was allowed when it is available in the UK.
  - 8.3.3 Report to the VPC on new MA applications granted.

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Chairman's	initials

- 8.3.4 Report from the Scientific Secretariat and the Biological Committee.
- 9. Horizon scanning: issues for consideration
- 9.1. See item 6.7.
- 10. Any other business
- 10.1. There was no other business.
- 11. Date of next meeting
- 11.1. The next meeting of the VPC will be on 6 October 2022 at the VMD, Woodham Lane, New Haw, Addlestone, Surrey.

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