Veterinary Products Committee

Published minutes

A summary of the minutes of the Veterinary Products Committee Meeting held on 9 February 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
Mr M Clark
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
Mr M White

Officials: may be present for all or part of the meeting or for specific agenda items.

VMD

Mr G Hall
Ms B Berrocal-Gonzalez
Dr R Cooney
Dr C Stratford
Mr J Millward
Ms A Burrows

Apologies

Dr Y Chang
Prof J Weeks

Chairman's initials……..

1. Announcements and apologies for absence

2. Declaration of interests

3. Minutes of the meeting held on 6 October 2022

4. Matters arising from the minutes
   4.1. Vet Record article on product labelling for endectocide products containing moxidectin
   4.2. Bacteriophages

5. UK Pharmacovigilance Report for August to November 2022

6. VPC Strategy

7. Evaluation of VMD assessment reports: Results

8. Special Imports

9. Horizon scanning

10. Legislation update

11. Items for information

12. Any other business

13. 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 members Dr Chang and Professor Weeks and Ms Seager and Dr Clarke of the VMD.

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 6 October 2022**

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 12.1.3: Vet Record article on product labelling for endectocide products containing moxidectin**

4.1.1 In October the committee had considered an article in the Vet Record which had suggested clearer product labelling was needed for endectocide products containing moxidectin to prevent them being misused by farmers. VMD have since reviewed the points raised and reported back to the committee that it has a published product literature standard for a voluntary labelling scheme for the inclusion of chemical group symbols on sheep anthelmintics. The EMA have recently updated their guidance on warnings to be included for anthelmintic products to emphasise the risks of under/overdosing for development of anthelmintic resistance and the UK have also adopted these changes. SCOPS have also published an article in Over The Counter entitled 'Reducing Anthelmintic use in ewes at Lambing' which includes specific information on the importance of correct use of moxidectin 2% wormers in ewes and links to specific advice on use of this product available on the SCOPS website.

4.1.2 Members commented that product labelling and leaflets are often unclear due to the small lettering and technical wording used. VMD noted that for products also authorised in the EU, there is specific EU guidance regarding packaging requirements, and any diversion from these would prevent co-authorisation in the two jurisdictions. The terms used for adverse events are limited to those provided by VeDDRA (Veterinary Dictionary for Drug Regulatory Activities). The VMD's product literature standard also sets out the minimum font sizes which can be used. The potential introduction of e-leaflets is proposed under the consultation on changes to the Veterinary Medicines Regulations (VMR) and this would help make information easier to read.

4.1.3 It was noted that there is information available to farmers on using anthelmintics and agreed that prescribers (i.e. vets, pharmacists and SQPs) play an important role in providing advice at point of sale and having meaningful discussions with buyers. At a recent AHDA conference it was discussed how SQPs and vets can work better together. It is unavoidable that veterinary prescription only medicines use complex language and it is up to the prescriber to make their proper use clear to the user.

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Veterinary medical premixes for feed are highly regulated and need to be properly prescribed. A VMR consultation proposal is for a requirement for prescribers of prescription-only medicines to record the rationale for their prescribing decisions when an oral prescription is made.

4.2. **Minute 3: Bacteriophages**

4.2.1 Members noted that the therapeutic use of bacteriophages in animals continues to be a hot topic of interest in the veterinary sector and a parliamentary select committee is looking into their potential. They could reduce reliance on antibiotics and studies are ongoing in the UK on treating salmonella infections in poultry and reducing lameness in cattle. VMD noted that most countries, including the UK, regard them as veterinary medicines and therefore needing a marketing authorisation. An EMA guideline on phage therapies is out for public consultation and the VMD is working on a common set of guidelines with the MHRA. VMD is open to having meetings with companies to discuss potential applications but they need to understand the challenges in producing application dossiers and complying with the quality chapter of the pharmacopeial guide. VMD is flexible about receiving limited market applications where appropriate which can reduce the need for expensive studies.

5. **VPC Strategy**

5.1. The Committee reviewed the draft VPC strategy which aims to set out what activities it would carry out over the next few years and how it would approach them. It was agreed that subgroups could be formed to look at specific issues and external experts co-opted to provide advice when needed. Some members felt they would not be able to make significant additional time commitments and it was agreed to continue with the current frequency of meetings with scope to hold more if required. This will depend on what issues arise out of leaving the EU which VMD will want to seek the committee's advice on, such as the need to consider product referrals. It was agreed the committee should contribute to the VMD's regulatory science strategy and R&D strategy. VMD will determine what budget is available for the committee in the next financial year.

5.2. VMD accepted the need to tighten up meeting procedures and to keep a better record of the committee's external communications and a record of when it asks individual members for advice outside the committee. It would also produce standard operating procedures for how the committee deals with appeals and referrals.

5.3. It was agreed that the committee needs to develop a communication plan and VMD's Information Co-ordination and Engagement team would come to the next meeting to discuss how it could help deliver this.

6. **The UK Pharmacovigilance report**

6.1. **Introduction**

6.1.1 The committee considered and commented upon the pharmacovigilance report for August to November, which was presented by the head of the VMD's Pharmacovigilance Team.

6.1.2 After consideration of the questions received before the meeting and the discussion with the members of VPC, the need to update and review the report and instructions was identified.

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6.1.3 The Pharmacovigilance Team will prepare a presentation of all the activities the team performs, including changes due to the revised Veterinary Medicines Regulations. The VPC report and instructions will be reviewed as well.

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

6.2.1 The accidental needle-stick injuries are still reported in high number by veterinary professionals.

6.2.2 The VPC was sent the link to the new VMD communication website. There is an article in the Pharmacovigilance section raising awareness

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

6.3.1 There were no questions re: signals validated for companion animals during this period.

6.3.2 There were no questions regarding signals validated for production animals during this period. There was a brief discussion regarding causes for underreporting in this sector and the need to educate farmers and professionals that the main goal of collating Pharmacovigilance information is to have a better understanding of the product safety profile, not to take the products from the market.

6.3.3 There was an update on a product for horses (Suspected Lack of Efficacy reports increased above average during 2021 but were now back to normal. A member reported that the increase during 2021 was likely due to a campaign at vet level to promote reporting of lack of efficacy of the product). A product for companion animals was highlighted as VMD's post PSUR recommendations on Pharmacovigilance grounds were under discussion with the company.

6.4. **Environmental incidents**

6.4.1 There had been a report of high mortality in a beehive reported by FERA. VMD had requested further details and was still waiting to receive confirmation if further information is available.

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. They were impressed by the high standard of assessments carried out by the VMD's assessors but noted the poor quality of some of the application dossiers. VMD will respond in writing to comments raised by members so that final ratings can be agreed at the May VPC meeting.

7.2. It was agreed that it was difficult for members to review all the selected products and the next time the exercise is run it will be considered how to allocate the products amongst the members in accordance with their areas of interest.

8. **Special Imports**

8.1. VMD will respond in writing to comments on the special import reports sent to it by members.

9. **Horizon Scanning**

9.1. This was discussed under item 5.

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10. **Legislation Update**

10.1. VMD has started the public consultation on revisions to the Veterinary Medicines Regulations which will run until 31 March. There is no firm timeline yet in place for when the new regulations will come into force. The next revision will take place within two or three years.

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.

11.2.3.1. Members questioned the justification for an ATC application and VMD will explain the issues it considers when assessing ATCs at a future meeting.

12. **Any other business**

12.1. **Zinc oxide study**

12.1.1 A member questioned the way VMD queries regarding use of zinc oxide on pig farms had ended in an inconclusive manner and VMD would look into and report back to him.

13. **Date of next meeting**

13.1. The next meeting of the VPC will be on 25 May 2023 at the VMD, Woodham Lane, New Haw, Addlestone, Surrey.

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