Veterinary Products Committee

PUBLISHED MINUTES

A summary of the minutes of the Veterinary Products Committee Meeting held on 20 May 2021 by video conference.

Chairman – Professor Malcolm Bennett BVSc, PhD, MRCVS, FRCPath, FHEA
Secretary – Sandra Russell

Members

Mrs H Ballantyne
Dr R Bennett
Dr K Burnett
Prof D Cavanagh
Dr Yu-Mei Ruby Chang
Ms S Harmer
Mr M Jelley
Dr D Killick
Dr E Kubiak
Mr S Lister
Dr D Mackay
Prof J Matthews
Mr D O'Rourke
Prof C Robertson
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

Ms A Seager	Dr M Bos	Ms A Kennedy
Dr G Diesel	Ms S Brown	Ms N Anderson
Dr G Clarke	Ms K Gray	Mr C Abbott
Mr G Hall	Mr N O'Brien	

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PUBLISHED MINUTES

FINAL MINUTES

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. There were no apologies for absence.

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. Impact of climate change on diseases and use of veterinary medicines

3.1 Professor Weeks and Mr Statham gave a presentation on the effects on animal health of climate change, including how it has led to an increase in vector-borne and zoonotic animal diseases resulting to greater livestock mortality, particularly in developing countries, with harmful consequences for human health and economic wellbeing. Warmer climates have allowed diseases to spread more easily, and new medicines have been developed to combat conditions which have become endemic in the UK. Poor animal health caused by changing weather patterns has led to an increase in use of antibiotics and anthelmintics around the world and concerns about resistance developing.

3.2 Proposed ways forward include developing a greater understanding of the implications of climate change on animal health, promoting better use of medicines and improving cattle health to reduce their production of greenhouse gas emissions. VMD is involved in looking at new technologies in this area.

4. Minutes of the meeting held on 4 February 2021

4.1. 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).

5. Matters arising from the minutes

5.1. Minute 5.4.2: Working group on ectoparasiticides

5.1.1 The Chairman reported that several bodies had indicated they would like to contribute to the VPC's group looking into the effect of ectoparasiticides on the environment and he will consult with Professor Weeks about the way forward.

5.2. Minute 5.5.1: VPC Open meeting 2021

5.2.1 Members proposed the following topics for the 2021 Open meeting: the effect of ectoparasiticides on the environment, the effect of climate change on use of veterinary medicines and human adverse event reporting. To be decided closer to time after a date for the meeting is decided.

5.3. Minute 7.2: Evaluation of VMD assessments: scoring system

5.3.1 It was agreed to replace the points scoring system for the VPC's annual evaluation exercise with a more qualitative one. The guidance will need to be amended to make it clear what is expected from members.

5.4. Minute 9.2.2: Special Import activity reports

5.4.1 Ingredients information had been added to the Special Import activity reports to be considered under item 10.2.

5.5. Minute 10.2: Commitment study

5.5.1 VMD reported that the results of an efficacy study for a product following a change to its legal distribution category would not be available until 2023 when it will be presented to the committee.

5.6. Minute 10.3: Anthelmintic resistance

5.6.1 The Chairman will write to the Animal Health and Welfare Board about the committee's concerns regarding increasing anthelmintic resistance.

6. The UK Pharmacovigilance report

6.1. Introduction

6.1.1 The Committee considered and commented upon the Pharmacovigilance Report for December to March 2021, which was presented by the head of the VMD's Pharmacovigilance Unit.

6.1.2 VMD officials had circulated a paper responding to questions submitted in advance of the meeting which included the progress on an article to remind vets of the importance of taking all SPC warnings into consideration when prescribing products.

6.2. Suspected adverse event reports in humans

6.2.1 The committee commented on a human adverse event report where an owner developed hair loss, vomiting, diarrhoea and headaches after starting treatment of her dog with a compounded anti-cancer drug. The owner was reported to have used appropriate PPE. Members questioned what warnings were provided with this product. VMD stated that according to the regulations, the prescribing, use of and warnings given with these products is the responsibility of the prescribing vet. However, the extemporaneous product manufacturer has committed to providing further warnings on the packaging in future. VMD agreed to also review if other manufacturers produce this product, and if so, the warnings are also provided to them to include on their packaging.

6.2.2 Members questioned if VMD monitored the volumes of extemporaneous products manufactured and what the prescribing cascade is. One member provided an example of the use of a product when there is an authorised product available in New Zealand which could be imported. VMD agreed to provide the committee with information on the prescribing cascade*. They informed the committee that VMD is currently reviewing the legislation and one of the topics under review is extemporaneous products and their oversight. Members requested information on the GMP oversight of extemporaneous products. VMD committed to providing further information but also reminded the committee that these products are not assessed by the VMD. It was agreed that VPC should write a letter to RCVS to encourage them to remind vets of the importance of providing suitable warnings with these products.

*Post meeting note: Information is available at The cascade: prescribing unauthorised medicines – GOV.UK (www.gov.uk).

6.2.3 A member raised concerns about the presentation of one adverse event in the report involving a vaccine for pigs and how little information was available. VMD confirmed that many adverse event reports are submitted by marketing authorisation holders. These often result from telephone enquiries from vets or owners who contact the MAH to ask for their advice after accidental self-injection. In these circumstances, the MAH often provides prompt advice and tells the individual to seek medical advice. They then re-contact the reporter to obtain further information for the purposes of adverse event reporting and are then often unable to obtain that information as the reporter no longer wants to engage and respond to the queries. The member questioned if there is any way of ensuring that adverse events reported

to an MAH sales representative or technical advisor are reported to VMD. VMD confirmed that this is a legal obligation on the MAH to report these cases and during the pharmacovigilance inspections that VMD conducts, one of the aspects reviewed is the reporting of adverse events and the ability of MAH staff to recognise adverse events.

6.2.4 A member noted four human adverse event reports involving accidental injection for two related products. The member questioned why the report stated that there are no SPC warnings relating to accidental injection. VMD committed to review this and report back.

6.2.5 A member commented that they had seen a TV advert for a flea spot-on treatment where an owner was seen applying the product without using gloves. They were concerned that lay public might generalise such an application method to all spot-on products. VMD confirmed that there is only one spot-on product for dogs which requires the use of gloves, and therefore it is acceptable if the video related to a different product.

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

6.3.1 No questions were discussed in the meeting.

6.4. **Environmental incidents**

6.4.1 No environmental reports were received during this surveillance period.

7. Consideration of an application: ref no. 01807/2020

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

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

8. Illegal supply of antibiotics in Northern Ireland

8.1. There had been recent media reports of instances of veterinary surgeons supplying antibiotics (POM-V) from veterinary practice premises (VPPs) in Northern Ireland (NI) without appropriately prescribing them, in breach of the Veterinary Medicines Regulations 2013. VPC members had also been approached directly by a journalist for their comments.

8.2. VMD explained that it had responsibility for inspecting VPPs in NI and taking limited enforcement actions but in practice works closely with the NI regulatory authorities, the Department of Health (DoH) and DAERA. In this case, the DoH is leading on enforcement action and the VMD is being kept abreast through its regular meetings with DoH and DAERA during which information and intelligence is shared.

8.3. Members commented that it was a widespread issue that had been going on for a long time and felt the response from the authorities had been slow. VMD noted that they can only take action based on evidence and welcomed feedback on how to make improvements. It was noted that it was difficult for whistleblowers to report their own suppliers and it was good that this issue had come to light and action is being taken.

8.4. It was agreed that in future any members receiving requests from journalists should avoid giving opinions on behalf of the committee and refer the matter to the chairman and VMD. The guidance for new members will be revised accordingly.

9. Legislation update

9.1. VMD reported that it the Medicines and Medical Devices Act 2021 had been passed which now gave it primary powers to amend legislation. The Veterinary Medicines Regulations 2013 are being updated to reflect changes to the medicines landscape and cover any gaps, as well as making the UK an attractive place for industry and organisations to deal with post

EU membership. NI has the additional challenge of adopting EU legislation and VMD is monitoring and looking to mitigate areas of divergence which may arise, such as the use of the cascade, pharmacovigilance reporting and the small animal exemption scheme. New UK legislation needs to be in place by the end of the year and VMD will provide a high level summary on progress at the next meeting.

10. Items for information

10.1. The following items for information are publicly available:

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

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

10.2.1 Report to the VPC on new ATC applications.

10.2.2 Report to the VPC on Special Import Certificates.

10.2.2.1. Members queried the quantity of products being imported for use in pigeons and the import of an antibiotic. VMD will investigate and respond to the members after the meeting.

10.2.3 Report to the VPC on new MA applications granted.

10.2.4 Report from the Scientific Secretariat and the Biological Committee.

11. Horizon scanning: issues for consideration

11.1. There were no new issues proposed.

12. Any other business

12.1. The chairman would contact members after the meeting for their views on participation at future meetings once they are held again at the VMD.

13. Date of next meeting

13.1. The next meeting of the VPC will be on 30 September 2021 at the VMD, Woodham Lane, New Haw, Addlestone, Surrey.