Veterinary Products Committee

PUBLISHED MINUTES

A summary of the minutes of the Veterinary Products Committee Meeting held on 23 May 2024 at the VMD, Woodham Lane, New Haw, Addlestone, Surrey.

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

Members
Dr D Bartley
Dr M Bowen
Mr B Buckle
Dr Y Chang
Prof M Clark
Prof K Ganapathy
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 M Bos
Dr B Berrocal-Gonzalez
Ms J Perrett
Mr B Corbett
Mr L Reynolds

Apologies
Dr R Bennett
Mr M Jelley

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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 and Mr Jelley.

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 by David Morton of the Association of Veterinary Ethics Committees**

3.1. Mr Morton had been invited to talk to the Committee about the work of the Association of Veterinary Ethics Committees (AVEC). He helped set up AVEC over a year ago in order to raise and harmonise standards of ethics in relation to clinical veterinary research (CVR) and clinical practices. The RCVS oversees non-experimental research projects carried out under exemption from ASPA home office licence and not requiring ATC approval from the VMD. It decides what are exceptional and what are recognised and routine veterinary practices and assesses and approves project applications. All projects must be subjected to an ethics review and AVEC works with the RCVS to try to harmonise decisions, raise standards and provide education and training. The key criteria for ethics review include checking project design and integrity and avoiding and minimising harm to the animals being used. The risks and alternatives must be clearly set out and compliance with legal requirements confirmed. The 3Rs are built into the process. In this way animals are protected, good science promoted, and vets given legal security. AVEC now comprises the ethics review bodies of all vet schools and major pharmaceutical companies and charities that carry out CVR with the view of supporting them, e.g. by providing resources for their activities to achieve common (high) standards.

3.2. The Chair thanked Mr Morton for talking to the Committee about his work. He was asked if project outcomes are published, and he explained that reviews are completed but there is no official publishing scheme in place. He noted that RCVS can only control what its members do, and some non-experimental agricultural husbandry and practices are not covered. VMD explained that it takes an ethical approach when assessing ATC applications for animal tests to develop medicinal products and takes into account VICH GL9 on good clinical practice. Vets must comply with the Veterinary Surgeons Act and have professional responsibility to report substandard practices. Members noted that vet schools take care to check that research abides by an ethical approach and this can be labour intensive, and any efficiencies would be welcomed. Mr Morton said that AVEC's work currently receives no funding, but it may be needed going forward. There are great variations in research projects and a more flexible approach is needed.

4. **Presentation by Dr PJ Noble (University of Liverpool) on use of Artificial Intelligence in veterinary clinical practice**

4.1. Dr Noble joined the meeting to explain how Artificial Intelligence (AI) is being used to help veterinary practices and the animals they treat. He is involved in applying AI to data in SAVSNET which is used by veterinary practices to record and manage their client records. AI is used to create a useful dataset from clinical notes. Different types of AI programmes are being employed including generative models, large language models and bidirectional encoder representations. These can be fine-tuned using specialised veterinary language to create rich, focused tabulated output from millions of records. 10 year's worth of data in SAVSNET is being interrogated to create new adverse event reports for individual animals as

well as information on topics of specific interest such as the use of licensed drugs. The AI programmes need to be trained to recognise valuable data and this is an ongoing process in order to keep up-to-date with veterinary developments.

4.2. Members were impressed by what Dr Noble and his colleagues are achieving with the careful application of AI and asked whether its use can be widened through training. He noted that the work is specialised and there is no one model which can do everything and there are currently no guidelines for its use in the veterinary setting. The aim is to provide AI tools so that any veterinary practice can provide reports to owners from their practice management systems.

5. Minutes of the meeting held on 8 February 2024

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

6. Matters arising from the minutes

6.1. Item 7.1: VMD response to VPC evaluation of assessments

6.1.1 VMD assessors had provided responses to members' comments on their assessments during the annual evaluation exercise.

6.2. Item 10.2: Topics for future meetings

6.2.1 A speaker will attend the committee in October to talk about sustainability in veterinary medicine prescribing and use.

6.2.2 VMD will ask the Defra Exotics Group to attend the next meeting to explain how new diseases to the UK are being tackled.

7. The UK Pharmacovigilance report

7.1. Introduction

7.1.1 The Committee considered the Pharmacovigilance report for December to March and did not have any comments to raise for the head of the VMD's Pharmacovigilance Team.

7.2. Suspected adverse event reports in humans

7.2.1 There were no adverse events in humans reported.

7.3. Suspected adverse event reports in animals

7.3.1 VMD highlighted that it has a product for cats under alert after analysing the results in the report for the term paresis. It will continue to monitor this product for this and other known/unknown signals and is in the process of assessing the Periodic Safety Urgent Report (PSUR) the Pharmacovigilance team has just received from the Marketing Authorisation Holder (MAH). This could contain further data to validate this signal and allow VMD to request that is added to the product information through the variation procedure.

7.3.2 VMD confirmed that the assessment of the PSUR for a product resulted in the request to the MAH to include in the product information for several following adverse events: VMD is waiting for the MAH variation submission to implement this request.

7.4. Environmental incidents

7.4.1 No environmental incidents had been reported.

8. Review of equine anthelmintic SPCs

8.1. VMD have identified that several currently UK authorised equine anthelmintic products contain statements on their SPCs regarding interval dosing programmes that are no longer recommended due to the increased risk of anthelmintic resistance selection and associated health and welfare concerns.

8.2. The Committee was asked to review and agree the following text to replace the outdated statements regarding interval dosing for affected products: *"Inappropriate use of anthelmintics may increase resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on professional advice and take into account current best practice recommendations for parasite control."*

8.3. The Committee was also asked to review and agree the necessary changes to bring the text in affected SPCs in line with current best practice for sustainable parasite control in equines.

8.4. The Committee agreed the changes. VMD would now ask the MA holders for the products to change the wording on their SPCs accordingly. Awareness of the changes would be raised through the Vet Record and equine press and members of the CANTER group. SQP training will be important for controlling the prescribing and use of these products in the horse community.

9. Special Imports

9.1. The Special Import reports were reviewed. VMD would check the justification for importing Ketoprofen for chickens.

10. Availability of Vaccines

10.1. Brian Corbett, VMD's Head of Borders and Resilience, explained that demand for vaccines is increasing and outstripping supply which has led to issues with availability. Industry is facing a number of issues arising from EU exit, trade changes and the impact of Covid which have affected the production of existing vaccines. The recent rise of exotic diseases such as Avian Influenza and Bluetongue require the production of new vaccines which also stretches resources. Government has offered support and funding and VMD is meeting with companies to identify the issues and come up with an action plan but it is proving challenging to join up all the bodies involved.

10.2. Members noted the threats posed by exotic diseases in different species and that a major livestock disease campaign has been launched. There are a number of initiatives and opportunities for innovation to develop new types of products but a lack of framework in place. A shift in attitude from Industry is needed towards aiming to eradicate diseases globally. VMD confirmed that it is considering approving the emergency use of vaccines to tackle exotic diseases before making its recommendation to Ministers.

10.3. VMD said that it was open to assessing innovative vaccines and there were no blocks to any technologies under the new UK veterinary medicines legislation. However, EU regulations are different and it needs to be made clearer to companies how to manage the requirements. More vaccines are needed now and long-term capability needs to be established using a business model which is less reactive and more proactive. It was agreed to provide regular updates on progress to the Committee.

11. Legislation update

11.1. The SI to amend the Veterinary Medicines Regulations 2013 has passed parliamentary scrutiny and been signed off by the Minister and the new legislation came into force on 17 May. The numerous changes have been well received. VMD has published accompanying guidance to help stakeholders understand the new requirements.

12. **Items for information**

12.1. The following items for information are publicly available:

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

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

12.2.1 Report to the VPC on new MA applications granted.

12.2.2 Report from the Scientific Secretariat and the Biological Committee.

12.2.3 Report to the VPC on new ATC applications.

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

13.1. VMD has been contacted by a company with a proposal for a new technology for regulating online prescribing. It was agreed to invite them to a committee meeting to discuss it.

13.2. A member raised a question about residues in imported food products of anaesthetics used on animals. VMD would check if this falls under Defra's food policy.

13.3. Post meeting note: Controls on residues in imported foods is the responsibility of Defra's UK Office for SPS & Trade Assurance. This Office was established after EU-exit and ensures that the countries that we trade with have SPS controls in place which ensure the quality and safety of their foodstuffs. In practice, this includes controls on residues of veterinary medicines – a subject area which the VMD's Residues Team provides technical expertise to the UK SPS Office. To obtain Defra approval to export produce to the UK, assurances on residues are sought via routine audit and assessment of trading partners, looking at their veterinary medicines legislation, testing programmes, and the follow-up measures taken in instances of non-compliance.

14. **Any other business**

14.1. **Advertising the benefits of veterinary medicines**

14.1.1 Ms Tarr brought to the Committee's attention a research paper in the Vet Record (White et al) that has highlighted that qualitative information about the benefits of a treatment is deficient in the SPCs. The research project examined a year's worth of adverts published in the Vet Record and Vet Times and the main purpose of the research was to describe the nature of the adverts. The researchers also made an observation about the availability of supplementary information to help vets make therapeutic decisions. They noted that the product leaflet accompanying medicines authorised by the US FDA routinely includes qualitative information on the benefits *and* adverse effects of the product. In contrast, SPCs for products authorised in the UK do not routinely include such data on benefits (although they do include categorical information on adverse effects frequency). She was asked to write a commentary to accompany this research in the Vet Record.

14.1.2 VMD noted that SPC headings are mandated in the UK and there isn't much scope for adding information. It is up to the prescriber to check the suitability of products. VMD does include more clinical information for products in their UK public assessment reports which are available on the Public Information Database (PID). VMD is reviewing their format and presentation on PID to see whether the information can be made clearer and more accessible. A member noted that the US employs a system of standardised reports to cover every eventuality while the UK prefers to synthesise relevant information into the SPC.

14.2. **Use of the Cascade**

14.2.1 The Committee discussed the scope of the cascade and how it should be applied.

15. **Date of next meeting**

15.1. The next meeting of the VPC will be on 24 October 2024 at the VMD, Woodham Lane, New Haw, Addlestone, Surrey.