PUBLISHED MINUTES

Veterinary Products Committee

A summary of the minutes of the Veterinary Products Committee Meeting held on 6 June 2019 at the VMD, Woodham Lane, New Haw, Addlestone, Surrey.

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

Members	VMD	Officials[1]	
Mrs H Ballantyne	Ms A Seager	Others	
Dr R Bennett	Dr G Diesel	Ms K Foxall	PHE
Prof D Cavanagh	Mr J Millward		
Ms S Harmer	Dr G Clarke		
Mr M Jelley	Dr R Cooney		
Dr E Kubiak	Mr L Reynolds		
Mr S Lister	Dr P Bianciardi		
Prof J Matthews	Dr J Partridge		
Prof A Peters	Dr A Puranik		
Prof C Robertson	Mr C Abbott		
Mr J Statham			
Ms A Tarr			
Mr E Vega			
Prof J Weeks			
Mr M White			

[1] Officials may be present for all or part of the meeting or for specific agenda items.

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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 Karin Burnett, Dr Yu-Mei Ruby Chang, Mr Declan O'Rourke, Mr Peter Scott, Professor Peter Borriello and Mr Paul Green. Mr Mark Jelley and Ms Kerry Foxall took part by teleconference.

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 14 February 2019

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 5.6.2: Raising awareness of needlestick injuries**

4.1.1 The Committee were concerned about the continuing reporting of people sustaining significant needlestick injuries following use of vaccines containing mineral oil and how to raise awareness.

4.1.2 One Committee member stated that there was insufficient information on the packaging and this could be improved. Some companies produce a plastic ID style card for specific poultry products which include appropriate warnings and advice to the medical team. Needlestick injuries in the poultry sector are low and it was suggested this could be considered across other sectors.

4.1.3 A Committee member proposed that awareness of Health and Safety issues should be a dual approach from both the medical services and farmers. Farm assurance schemes could be used to raise awareness including training in the farming industry.

4.1.4 VMD stated that standard wording for user warnings for commonly used adjuvants had been agreed throughout the EU. It was agreed to discuss the proposal of a plastic card with industry and regulatory bodies.

Action 1

4.1.5 One Committee member was waiting to hear back from the NFU to see if an article could be published and proposed that awareness could be raised through training provided by NOAH as part of the vaccination module. A committee member agreed to source previously published images to support these initiatives.

Action 2

4.2. **Minute 5.7.1: FSA testing of imported products**

4.2.1 A representative from the FSA will be invited to attend the September meeting to provide an overview of imported products.

Action 3

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4.3. Minute 5.11.1: Regulatory approach to blood banks

4.3.1 VMD provided an update on the regulatory approach following discussion at the February meeting. This was a complicated area and VMD are currently in dialogue with the RCVS and the Home Office.

4.3.2 It has been further complicated by the importation (rather than UK production) of feline blood (rather than just dog blood) which was not originally considered. Agreement has been reached with the RCVS and Home Office that due to the inherent risk of importation, blood banks must be based in the UK to ensure they are within remit of the scheme.

4.3.3 Details of the criteria required for blood banks is available on gov.uk.

4.4. **Minute 8.1: VMD/VPC open meeting 2019**

4.4.1 Members were asked to consider topics for discussion and send them to the Secretariat.

Action 4

4.5. **Minute 9.1: Guidance for EU Exit**

4.5.1 This was discussed at item 7.1

4.6. **Minute 10.2.3.4: Benefit-risk assessment for vaccines**

4.6.1 A representative from VMD gave a presentation on the benefit-risk assessment for vaccines which included imported products and autogenous vaccines (AVAs).

4.6.2 The benefit-risk for imports is product dependent and more extensive for a product being imported from outside of the EU. Efficacy is not tested for but there is a requirement to report pharmacovigilance incidents for all special imports.

4.6.3 There are regulations and guidance for the authorisation of AVAs and VMD has worked with EU regulatory authorities and drafted recommended manufacturing control of AVAs within the EU. This is used as bench-mark for the manufacturing process of AVAs.

4.6.4 One Committee member asked how, with the potential world market for biologicals, the VMD would manage regulation for novel therapies, including GMOs and gene editing. The VMD anticipates setting up a Novel Therapies Group and are developing a science strategy with a view to identifying deficiencies in the regulatory approach.

4.6.5 The Committee found the presentation extremely informative and requested a further presentation on Environmental risk assessment and risk mitigation measures.

4.6.6 The presentation would be circulated to the Committee.

Action 5

4.7. **Minute 7: VPC evaluation of VMD assessments: VMD responses**

4.7.1 A member thanked VMD for responding to the comments from the Committee which they had found helpful and informative.

4.7.2 The VMD had found the Committee's comments helpful and they would be considered and reflected in future assessments.

4.8. **Minute 10.2.3.2: Use of flukicides**

4.8.1 The Committee had previously raised concerns about the volume of a flukicide being imported and the risk of anthelmintic resistance. The VMD were working with SCOPS and COWS with a view to limiting the importation of the flukicide. As part of this they would act to stop any inappropriate product advertising but emphasised they are reliant on evidence to action this. They are working with industry on improving communication and the correct use of advertising for this product.

4.8.2 A Committee member highlighted that there are alternative products and vets should be made aware of their availability.

4.9. **Update on Oral Appeal**

4.9.1 The VMD provided an update following the appeal heard by VPC at the February meeting.

5. The promotion of unrecommended anthelmintic treatment practices

5.1. A member highlighted an apparent news article about an anthelmintic product presented in a newsletter which was misleading and was promoting the product. Whilst the content was consistent with elements of the SPC the article implied that its use could improve weight gain during lambing.

5.2. SCOPS have been aware of misleading information being published and are putting pressure on SQPs to prescribe appropriately. The SQP code of practice sets out clearly the requirements of prescribing and SCOPS and COWS fully support this approach. This could be brought to AMTRA's attention if this was not being followed.

5.3. VMD stated that elements referred to in the article were consistent with the SPC and it was 'clever' advertising. However, VMD proposed to write to the producers of the newsletter with their concerns about the publication.
Action 6

5.4. A committee member suggested banning advertising of anthelmintics similar to the approach taken for antimicrobials.

5.5. A VMD representative informed the committee that the new EU regulation to come into effect in three years' time will include a restriction on advertising to be only allowed to prescribers. In light of this VMD would consider reviewing the advertising of anthelmintics.

5.6. The Committee agreed that the issue should be raised with both SQPs and vets, and one member would be writing an article for the Veterinary Times on prescribing to include dissemination to end users.
Action 7

6. The UK Pharmacovigilance report

6.1. The Committee considered and commented upon the Pharmacovigilance Report for December to March 2019, which was presented by the head of the VMD's Pharmacovigilance Unit.

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

6.2.1 VMD highlighted the reports involving spot on products and informed the Committee that the variation which introduced further warnings and the requirement for gloves to be dispensed with the product was relatively recent. Therefore, the number of these

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reports is being monitored and it has been considered that if there is no improvement in the level of reporting then the MAH may be requested to include gloves inside the packaging of the product.

6.2.2 A report was highlighted involving an accidental needlestick injury in a farmer with an oil-based vaccine which resulted in the farmer having his finger amputated.

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

6.3.1 VMD presented the animal report and highlighted several signals which had been discussed at the Alert Group meeting held in May 2019.

6.3.2 A member also commented on the high number of reports involving a range of products and questioned the reason for this. VMD confirmed that there is a very high volume of sales for this product and the nature and number of reports are being monitored carefully.

6.4. **Environmental Incidents**

6.4.1 No reports of environmental incidents had been received during the reporting period.

7. EU Exit

7.1. An update was provided to the Committee by the VMD's Director of Authorisations on the issues arising from the UK's exit from the EU and how they are being dealt with by VMD and Defra.

7.2. Information on both deal and no deal scenarios has been published and can be found on the information hub on gov.uk. This will be continually updated.

8. Items for information

8.1. The following items for information are publicly available:

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

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

8.2.1 Report to the VPC on new ATC applications.

8.2.2 Report to the VPC on applications considered by correspondence.

8.2.3 Report to the VPC on Special Import Certificates/Special Treatment Certificates.

8.2.3.1. The Committee reviewed the report and asked for further information on the volume imported for one product for use in a zoo animal and details of a number of applications for a product for use in pigeons.

Action 8

8.2.3.2. The VMD responded to questions from the Committee on the policy used for imports. VMD explained that SIC/STCs are valid for one year. If a product is authorised during that period the certificate remains valid, however a block is placed on the imported product and no repeat certificates will be issued.

8.2.3.3. The import of a product can be done by an individual or a wholesale dealer. The wholesale dealer can apply for a certificate to import the product and can only distribute on receipt of a valid SIC/STC for that product.

8.2.3.4. Applications are submitted under the prescribing cascade and there is guidance published. They are approved based on the justification submitted and STCs for exceptional use undergo further scrutiny. Where there are excessive imports of a product these are challenged and if necessary the RCVS are informed when there is possible mis-use other than availability.

8.2.3.5. VMD advised that they are considering in context the changes for imports following EU exit and would keep the Committee informed as plans evolve.

8.2.4 Report to the VPC on new MA applications granted.

8.2.5 Report from the Scientific Secretariat and the Biologicals Committee.

8.2.6 Imidacloprid distribution category change for rabbits

8.2.6.1. While the Committee understood the regulatory reasons for allowing the re-categorisation of products for rabbits containing imidacloprid to AVM-GSL, they had concerns, given discussions at previous meetings, about the potential environmental risks of increased use of products such as imidacloprid consequent to its increased availability.

8.2.7 Changes to T&S Expenses.

9. Horizon scanning: issues for consideration

9.1. The following issues were proposed for consideration at future meetings:

- Research commissioned by the VMD
- Novel therapies – in particular the regulatory approach to GMO, deletions and biologicals based on CRIPSR
- Background and ideas from SICs/STCs
- Fish farming industry (particularly salmon) and the use of parasiticides

10. Any other business

10.1. Meeting on Zoonoses

10.1.1 Details of a training workshop on Zoonoses would be circulated to the Committee.
Action 9

10.2. **Disposal of controlled drugs**

10.2.1 The report published by VMD on a survey on controlled drugs referred to difficulties in obtaining a witness on destruction of the drugs. VMD were asked to consider the eligibility of a pharmacist for this role. VMD stated that the witness must be approved by the Home Office and are considering their next steps on how to address the issues.

10.3. **Disposal of plastics**

10.3.1 A committee member raised the difficulties incurred in disposal of plastics on farms, especially drug and worm containers. Farm assurance schemes require farmers to hold the relevant disposal certificate and it would be helpful to have guidance. VMD

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were aware of the issues and are working on a solution for both plastics and unused veterinary medicines with a view to issuing guidance.

Action 10

11. Date of next meeting

11.1. The next meeting of the VPC will be held on 26 September 2019 at the VMD, Woodham Lane, New Haw, Addlestone, Surrey.

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