PUBLISHED MINUTES

Veterinary Products Committee

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A summary of the minutes of the Veterinary Products Committee Meeting held on 14 February 2019 at the VMD, Woodham Lane, New Haw, Addlestone, Surrey.

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

Members
Mr R Bell
Dr R Bennett
Dr K Burnett
Prof D Cavanagh
Dr Yu-Mei Ruby Chang
Ms S Harmer
Mr M Jelley
Dr E Kubiak
Mr S Lister
Prof J Matthews
Mr D O'Rourke
Prof A Peters
Prof C Robertson
Mr J Statham
Ms A Tarr
Mr E Vega
Prof J Weeks
Mr M White

Officials

VMD
Ms A Seager
Mr P Green
Dr G Clarke
Ms G Blanc
Dr G Diesel
Ms S Brown
Ms C Stratford
Dr R Cooney

Chairman's initials……..

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AGENDA

Chairman's initials……..

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 Mrs Ballantyne. Dr Burnett and Professor Matthews 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. Oral appeal for an application: ref no. 00355/2018

3.1. The Committee heard an appeal from a Marketing Authorisation Holder relating to a suspension of a product.

3.2. The Committee provided advice to the VMD for consideration.

4. Minutes of the meeting held on 27 September 2018

4.1. The Committee had cleared the minutes of the September 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 6.3.1 (June 2018): Legal category change

5.1.1 The VMD provided feedback on data provided by the Marketing Authorisation Holder (MAH) for a product following the change of its legal category. The MAH was asked to submit annual data returns and providing information about the volume of product sales, proportion of sales through different prescriber groups, the number of SQPs provided with product-specific training and lack of efficacy reports. The MAH committed to do a surveillance study to see if there has been a significant change of efficacy since the change. The results of the baseline efficacy surveillance study were presented. The VMD and VPC considered that the MAH had addressed all the requirements satisfactorily and no concerns were raised.

5.1.2 One Committee member congratulated the VMD for working with the company to achieve this and said that the information received from prescribing and efficacy surveillance was useful.

5.2. Minute 3.5 (September 2018): Benefit-risk assessment for vaccines

5.2.1 This item will be discussed at the next meeting.

5.3. Minute 3.6: Environmental incident reporting

5.3.1 The VMD stated that they receive a number of reports from various sources and welcome any further information that is available.

5.4. Minute 5.1.1: Raising awareness of enforcement issues

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5.4.1 VMD gave a presentation at AHDA in January about preventing illegal internet sales and are working with a VPC member to place an article in the veterinary nursing journals. The BVA have also been approached.

5.5. Minute 5.3.1 Raising awareness of legal category changes

5.5.1 The VMD confirmed that changes to legal categories are now published in the Veterinary Record.

5.6. Minute 6.2.2: Needle stick injuries

5.6.1 VMD produced a summary of the number of human adverse reaction reports involving needlestick injuries for the past 10 years. The committee commented that there is likely to be a lack of correlation between the number of reports received and the number of actual needlestick injuries as it is suspected that a large number are not reported. It was noted that the number had decreased in human medicine due to the use of re-sheathing needles but this was unlikely to be a factor in the veterinary field due to cost. VMD were requested to produce the same summary every year so that trends in numbers could be monitored.

Action point 1

5.6.2 The committee suggested a number of routes to increase awareness of this issue including training modules for farmers and SQPs. The committee agreed that a slide should be produced which could be sent to training providers to include in their courses.

Action point 2

5.7. Minute 8.1: FSA testing of imported products

5.7.1 VMD will arrange for a representative from the FSA to talk about the testing of imported products at a future meeting.

Action point 3

5.8. Minute 8.2: Residues testing reports

5.8.1 The VPC considered the paper setting out the VPC's role in the analysis of results of residues testing reports. One member asked for the presentation information on this item from the last meeting.

5.9. Minute 11.2.2 and 11.2.3: Special imports

5.9.1 This was discussed under item 10.2.

5.10. Minute 13.1: High Court ruling on human products

5.10.1 The Committee noted a high court ruling against a pharmaceutical company which tried to prevent routine NHS prescription of a cheaper medicine in favour of products that were authorised to treat the condition. The VMD stated that this high court judgement has no impact on the veterinary sector and the prescribing cascade.

5.11. Minute 13.2: Blood Banks

5.11.1 VMD are currently in discussions with Home Office and RCVS to agree a regulatory approach for blood banks. The VMD stated that the Committee will be informed once a decision has been reached.

Action point 4

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6. The UK Pharmacovigilance report

6.1.1 The Committee considered and commented upon the Pharmacovigilance Report for August to November 2018 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 three reports involving eye injuries and ulceration in people after one product was splashed into their eyes. VMD confirmed that this issue was noted last year. At that time EMA had published a news article warning vets and owner of this risk and the MAH sent a letter to all veterinary practices alerting vets to this risk. The MAH has also been requested to update their product information accordingly.

6.2.2 A Committee member commented on a report involving a product for pigs where a horse vet had accidentally self-injected the product. The member confirmed that this is an oral vaccine used in pigs however it is known to be used rectally in horses under the cascade.

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

6.3.1 The committee noted a signal for one product. VMD confirmed that a follow up had been received for this particular report and the number of affected dogs was confirmed to be 5, instead of 1000.

6.3.2 The committee also noted a signal for eye disorders following the use of a vaccine but noted that all the cats involved had been concurrently administered other vaccines and raised concerns that these cats may have been immunosuppressed resulting in the signs observed.

7. Evaluation of VMD assessment reports: results

7.1. The Committee discussed the summary of Members' evaluations of five products selected at the last meeting and Officials responded to comments raised.

7.2. The Committee agreed that the VMD assessments of quality, efficacy and target species safety, safety to the user and consumers, environmental safety and overall benefit:risk for each product were of a very high standard. One member commended the VMD for the excellent quality and level of detail of these reports.

7.3. Members agreed to continue with the current scoring system for this year's exercise which they had found to be useful.

7.4. The VPC's evaluation would be included in the overall performance assessment of the VMD, to be published in its Annual Report and Accounts 2018/2019.

8. VMD and VPC open meetings 2018

8.1. The feedback from the meetings had been very positive. The Committee agreed to discuss topics for this year's open meeting at the next meeting in June.

Action point 5

9. EU Exit

9.1. 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

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Defra. They are managing the risk for deal or no deal and guidance on both scenarios will be published during February. The Committee will be sent details once this is published.

Action point 6

9.2. The VMD provided an overview of the Special Import Scheme and explained how this should be applied in accordance with the requirements of the cascade. As from April for import purposes, the EU will be treated as a third country and all imports will be classified as Special Treatment Certificates (STC). Applications for new products will be assessed and a decision made based on the overall risk profile. There will be no changes to the published standards and further information will be published on Gov.uk during February.

9.3. A VPC member asked how VMD will deal with the certificates that have already been issued and the VMD confirmed they would remain valid for one year from issue. VMD also explained that justification for imports and specific user warnings are recorded in the database which will be reviewed as part of the current exercise.

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

10.2.1.1. No new ATC applications had been received since the last meeting.

10.2.2 Report to the VPC on Special Import Certificates

10.2.3 Report to the VPC on Special Treatment Certificates.

10.2.3.1. The VPC reviewed the reports on Special Import and Treatment Certificates and the justification for the import of two flukicide products when there are other flukicides (containing different active substances) authorised in the UK. VMD stated that the justification for the original import was for use on farms where there is evidence of anthelmintic resistance to authorised products. The VMD confirmed that use of products imported under the SIS was at the clinical jurisdiction of the individual prescribing vet.

10.2.3.2. VMD recognised the concerns about resistance and are talking to industry groups (SCOPS and COWS) and will use their opinions to inform its decision on future imports of these products. One Committee member agreed to work with the VMD to communicate the different types of flukicides and how these are prescribed.

Action point 7

10.2.3.3. VMD stated that two BCG vaccines are being imported due to a shortage in the UK. One of these is from Bulgaria and has been approved by Defra and is authorised on a named group basis so traceability can be maintained.

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10.2.3.4. One committee member emphasised the risk of serious exotic diseased in Eastern European countries and the need for assurance that this risk had been mitigated. VMD will include information on quality controls of these products in their presentation on benefit/risk of vaccines at the next meeting.

Action point 8

10.2.3.5. The Committee noted that there had been shortages of Immobilon and VMD stated that this was out of their control.

10.2.3.6. The Committee also noted the supply issue with Isoflurane and this was a concern to vets. The VMD had permitted the import of alternative products to help deal with the situation but noted that there had been a critical shortage and will apply the lessons learned should a similar issue arise in the future.

10.2.4 Report to the VPC on new MA applications granted.

10.2.5 Report from the Scientific Secretariat and the Biological Committee.

11. Horizon scanning: issues for consideration

11.1. This item will be discussed at the June meeting.

12. Any other business

12.1. **Product labelling correction**

12.1.1 One Committee member stated that a product which contained paracetamol and codeine was referred to within the SPC as an NSAID. This is incorrect and is not consistent with products with the same active ingredients which are not referred to as NSAIDs.

12.1.2 VMD stated that the product is currently being reviewed and any errors in the SPC and labelling will be changed as part of this exercise.

12.2. **Alert Group membership**

12.2.1 The Chairman reported that the member who sat on the VMD's Alert Group which evaluates all reported suspected adverse events and environmental incidents involving veterinary medicines had recently stepped down and asked if any other members were interested in taking his place. Dr Bennett and Ms Tarr volunteered.

13. Date of next meeting

13.1. The next meeting of the VPC will be held on 6 June 2019 at the VMD, Woodham Lane, New Haw, Addlestone, Surrey.

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