

SUMMARY MINUTES



PUBLISHED MINUTES

A summary of the minutes of the Veterinary Products Committee Meeting held on 15 September 2016 at the VMD, Woodham Lane, New Haw, Addlestone, Surrey.

Chairman – Professor Bill Reilly BVMS BSc DVSM HonFRCVS
Secretary – Lea Stott

Members

Mrs N Ackerman
Mr R Bell
Prof M Bennett
Dr K Burnett
Prof F Burke
Mrs M Chambers
Prof C Collins²
Ms S Harmer
Mr M Jelley
Mr S Lister
Prof J Matthews
Mr R Morris
Mr D O'Rourke
Prof A Peters
Prof C Robertson
Mr P Scott
Mr J Sherington
Mr J Statham
Prof J Weeks

Officials¹

VMD

Dr M-O Hendrickx
Mr J Millward
Mrs A Seager
Dr S Eckford
Mrs K Gray
Ms C Stratford
Dr N Garcia del Blanco
Mrs N Dorian
Ms K Grace
Mrs H Reeves

Others

Ms Kerry Foxall PHE

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

² Attended the morning/afternoon only

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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 Bleiker, Professor Bryant, Professor Cavanagh, Dr Kubiak, Professor Borriello and Mr Green.
- 1.3. Mr O'Rourke, Professor Peters and Ms 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. Presentation: Risk ranking pharmaceuticals and other chemicals found in UK rivers

- 3.1. Professor Andrew Johnson of the Centre for Ecology and Hydrology gave a presentation to the Committee about some of the environmental effects of medicines.

4. Minutes of the meeting held on 26 May 2016

- 4.1. The Committee had cleared the minutes of the May 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 4.1.1: Needlesticks and best practice article publication (*Veterinary Record*)
 - 5.1.1 The Chair informed the Committee the article for the *Veterinary Record* has been completed and submitted for publication.
- 5.2. Minute 4.4.1: Overdosing report
 - 5.2.1 VMD Officials provide an update; they have requested more information from the Marketing Authorisation Holder (MAH). This item will return to the Committee once the new data has been assessed.
- 5.3. Minute 4.7.1: VPC Open meeting 2016
 - 5.3.1 There will be no formal attendance at the VMD Open meeting by the VPC.
- 5.4. Minute 4.7.2: Antimicrobial resistance presentation
 - 5.4.1 The Committee requested a presentation on antimicrobial resistance which will be provided for the January 2017 meeting.
- 5.5. Minute 4.7.3: Role of VPC in antimicrobial resistance
 - 5.5.1 This will be covered during the January 2017 meeting.
- 5.6. Minute 4.10.1: Access to and assessment of prescription records
 - 5.6.1 This was discussed under item 8.

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- 5.7. Minute 5.2: Signal detection work outcomes.
5.7.1 The Annual Report will be presented at the May 2017 meeting.
- 5.8. Minute 5.4.4: Warnings on an imported product
5.8.1 At a previous meeting the Committee raised a concern over the lack of suitable warnings on product information for an imported product containing mineral oil which was involved in a human adverse event. VMD Officials have investigated and agreed that additional warnings should be added to the special treatment certificates issued for this product.
- 5.9. Minute 7.2.2.1: SIC/STC paper
5.9.1 A request had been made to add information about the reasons for importing products to the regular SIC/STC report paper provided for each meeting. The Head of the General Assessment Team provided an update and it was agreed by the Committee that if they required more information on an individual product they were to inform the VMD.
- 5.10. Minute 7.2.2.2: Import of a product under SIC
5.10.1 At a previous meeting the Committee discussed the usage of particular products and their withdrawal periods highlighted in the report. The Head of the General Assessment Team confirmed this issue had been investigated and shorter withdrawal periods were not considered sufficient justification to import in place of a UK product.
- 5.11. Minute 8.1: Horizon scanning
5.11.1 There were no issues noted for consideration at the meeting. Members were asked to consider topics for future meetings.
- 5.12. Minute 9.1: BSAVA Show publicity survey
5.12.1 The VMD provided the results of the survey completed at the BSAVA event in April.
- 6. The UK Pharmacovigilance report**
- 6.1. **Introduction**
6.1.1 The Committee considered and commented upon the Pharmacovigilance Report for April to July, which was presented by the Head of the VMD's Pharmacovigilance Unit.
- 6.2. **Suspected adverse event reports in humans**
6.2.1 VMD officials highlighted a cluster of human adverse reactions following the use of a specific dog collar. It was noted that in the majority of cases owners had not followed the user warnings in the SPC.
- 6.3. **Suspected adverse event reports in animals**
6.3.1 A member noted new signals for an emulsion for injection for pregnant cows. VMD officials explained that these related to new cases of bovine neonatal pancytopenia in calves born to dams which had been vaccinated using this product before its withdrawal from the market in 2011.
6.3.2 A member questioned if a specific pattern of adverse events had been noted with regard to an injectable product for dogs. VMD officials explained that a wide range

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of adverse event reports had been received with no specific pattern apart from autoimmune disorders, which were recently added to the SPC.

7. Written Appeal for an application: ref no. 00093/2015

- 7.1. The Committee considered an appeal against the VMD's decision to refuse an application to register a homeopathic product for cattle.
- 7.2. No interests were declared.
- 7.3. The Committee upheld the VMD's decision to refuse the application.

8. Consideration of an application: ref no. 01587/2015

- 8.1. The Committee examined evidence relating to an application for a change of legal distribution category from Prescription Only Medicine – Veterinarian (POM-V) to Prescription Only Medicine – Veterinarian, Pharmacist, SQP (POM-VPS) for a product for use in sheep.
- 8.2. Four members declared personal, non-specific interests and took no part in the discussion except, at the Chairman's discretion, to answer questions.
- 8.3. The Committee provided advice for consideration by the VMD.

9. Consideration of an application: ref no. 00833/2015

- 9.1. The Committee examined evidence relating to an application for a change of legal distribution category from POM-V to POM-VPS for a product for use in sheep.
- 9.2. Two members declared personal, non-specific interests which had lapsed.
- 9.3. Two members declared non-personal, non-specific interests.
- 9.4. The Committee provided advice for consideration by the VMD.

10. Evaluation of VMD assessment reports

- 10.1. This is the annual exercise for the VPC to select assessment reports of Marketing Authorisation applications where the VMD has led and completed the initial assessment in the 12 months leading up to end August 2016, for evaluation. The Committee was asked to select five products from the list provided, at least one of which must be a pharmaceutical and one an immunological. At least one of the products should be indicated for use in a food-producing species.
- 10.2. The Committee selected one immunological product for use in sheep and four pharmaceutical products, two for use in sheep, one for use in chickens and the other for use in cattle.
- 10.3. The Secretariat will forward copies of the initial assessment reports of the selected products to members by 07 October 2016 for them to evaluate against the specified criteria. Members were asked to submit their comments to the Secretariat by 02 December 2016 so that they can be collated and presented to the Committee for discussion at its meeting in January 2017.

Action Point 1

SEPTEMBER 2016 MEETING
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11. Antimicrobial Sales Data Report

11.1. The Committee considered and commented upon the UK Veterinary Antibiotic Resistance and Sales Surveillance (UK-VARSS) Report for 2015.

12. Annual return of Members' interests

12.1. Members were asked to let the Secretariat have their updated declarations of interest by 14 October 2016 so they can be included in the Committee's annual report for 2016.

Action Point 2

13. Members' annual performance appraisal

13.1. Members were asked to complete the self-assessment section of the 2016 annual assessment form and return it to the Secretariat by close of play on 14 October 2016.

Action Point 3

14. Items for information

14.1. The following items for information are publicly available:

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

14.1.2 The *Veterinary Record* (<http://veterinaryrecord.bmj.com/>)

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

14.2.1 Report to the VPC on new ATC applications.

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

14.2.3 Report to the VPC on new MA applications granted.

14.2.4 Report from the Scientific Secretariat and the Biological Committee.

14.2.5 VPC meeting and distribution dates for 2017

15. Horizon scanning: issues for consideration

15.1. There were no issues for consideration.

16. Any other business

16.1. The UK's Exit from the EU

16.1.1 Officials informed the Committee that the implications to the VMD of the UK's exit from the EU are currently being examined. This will feature as a regular agenda item at future meetings.

Action Point 4

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17. Date of next meeting

17.1. The next meeting of the VPC will be on 26 January 2017 at the VMD, Woodham Lane, New Haw, Addlestone, Surrey.