

SUMMARY MINUTES



Veterinary Products Committee

PUBLISHED MINUTES

A summary of the minutes of the Veterinary Products Committee Meeting held on 1 October 2015 at the VMD, Woodham Lane, New Haw, Addlestone, Surrey.

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

Members

VMD

Officials¹

Others

Mr R Bell	Dr M-O Hendrickx	Dr M Jacobs	PHE ¹
Prof M Bennett	Ms J Blenkinsop	Jennifer Bonnah	GFDA ²
Dr T Bleiker	Mr G Davis	Asare Yeboah	GFDA ²
Prof F Burke	Dr G Diesel		
Prof D Cavanagh	Ms Suzanne Eckford		
Mrs M Chambers	Dr N Garcia del Blanco		
Prof C Collins	Ms Katherine Grace		
Ms S Harmer	Mrs R Pearson		
Dr E Kubiak	Dr R Woodland		
Mr S Lister			
Prof J Matthews			
Mr R Morris			
Mr D O'Rourke			
Prof A Peters			
Mr A Prail			
Mr P Scott			
Mr J Sherington			
Mr K Siddorn			

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

² Ghanaian Visitors to the VMD

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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. Dr Jacobs and Professor Matthews took part via teleconference link.
- 1.3. Apologies for absence had been received from Prof P Borriello, Prof C Bryant, Dr R Jefferson, Prof C Robertson, Mrs N Ackerman and Dr T Marrs.
- 1.4. The Chairman welcomed Lea Stott who assumed the Secretary role in July 2015.

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 21 May 2015

- 3.1. 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).

4. Matters arising from the minutes

- 4.1. Minute 4.1.1: Needlesticks and best practice publication (*European Journal of Emergency Medicine*)
 - 4.1.1 The article has not yet been published and remains in the 'Published ahead of print' section on the Journal's website (<http://journals.lww.com/euro-emergencymed/pages/default.aspx>) as reported at the last meeting.
- 4.2. Minute 4.2.1: Needlesticks and best practice publication (*Veterinary Record*)
 - 4.2.1 The Committee was informed that the editor of the *Veterinary Record* is keen to produce an article to be considered, which the Chairman agreed to progress.
- 4.3. Minute 4.5.1: Pour-on products and dosing systems
 - 4.3.1 The issue of leaking packs and poor compatibility between the immediate product packaging and administration guns was raised at the NOAH/VMD Liaison meeting in June where it was noted that the issue had been previously investigated in 2010. As the situation had not changed since that time, with a very low number of reports in relation to the sales figures, it was agreed that no further action was necessary. Several VPC members considered that there is significant under reporting of this issue and the Committee requested the VMD consider how they can encourage farmers to report the issues they encounter to provide a better picture of what really occurs in the field.
- 4.4. Minute 4.7.1: Evaluation criterion for the 2015 review of VMD assessment reports
 - 4.4.1 The updated level 1 evaluation criteria for the review of the VMD's assessment reports was circulated in the May meeting minutes and this was accepted.

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- 4.5. Minute 4.8.1: Publication of the VPC annual report 2014
- 4.5.1 Members have been informed that the Minister agreed to the publication of the VPC annual report on 6 June 2015 and wrote to the Chairman thanking the Committee for its work. Publication of the report was announced by the Minister on 13 July 2015 and it is available on the VPC pages on the GOV.UK website.
- 4.6. Minute 4.9.1: VPC Open meeting
- 4.6.1 Members were informed after the May meeting that it was decided not to go ahead with the VPC Open meeting this year due to a lack of topic suggestions. A report of the VMD Open meeting to be held on 2 October 2015 will be included in the February 2016 VPC meeting papers.
- 4.7. Minute 5.2.1: Warnings on a Dog Flea Shampoo
- 4.7.1 The VMD's human safety assessors have investigated the warnings on a Dog Flea Shampoo regarding asthma and as the SPC states "Persons who are hypersensitive (allergic) to pyrethrum extract should handle the product with care" this warning is considered to be sufficient. The Committee agreed it is sufficient and need not be strengthened.
- 4.8. Minute 5.2.2: A Pour-on for Cattle Solution
- 4.8.1 A further request for information was made to the marketing authorisation holder but despite several attempts no medical records have been provided and in view of the patient suffering from depression it was not considered appropriate to pursue further. The Committee accepted the dosing equipment used was found to be functioning properly and with regards to the volume of product which leaked into his boots, it was not possible to quantify the amount but there was "enough to wet his socks". The Committee commented no further action to be taken.
- 4.9. Minute 5.2.3: Pharmacovigilance reports for Fipronil products
- 4.9.1 Officials have contacted the Committee member who raised this issue to highlight that this had been considered in the paper published in the Vet Record on 3 January 2015. It was agreed that no further action was required.
- 4.10. Minute 5.2.5: An Inhalation Vapour, Liquid for Dogs
- 4.10.1 Following internal discussions it was agreed that no further action was required as the warnings on the SPC are sufficient and a representative of the marketing authorisation holder had visited the practice to provide further education.
- 4.11. Minute 7.1: VPC appointments' exercise
- 4.11.1 Ministers have approved the re-appointment of seven members for a further four years: Professor Reilly, Mr Bell, Professor Bennett, Dr Bleiker, Dr Kubiak, Professor Peters and Mr Scott. The Chairman thanked the re-appointed members for their willingness to continue on the Committee. The advert for the recruitment of five new members was posted on GOV.UK on 27 August 2015 and the closing date for applications is 9 October 2015. Interviews of suitable candidates will be held in November 2015.
- 5. The UK Pharmacovigilance report**
- 5.1.1 The Committee considered and commented upon the Pharmacovigilance Report for April to July 2015, which was presented by the head of the VMD's Pharmacovigilance Unit.

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5.2. Suspected adverse event reports in humans

5.2.1 Officials highlighted reports relating to a pour-on product for cattle and two flea and tick products for dogs and cats. Many of these reports involved situations where the individuals involved had not followed the user warnings stated in the SPC.

5.2.2 Members questioned whether the VMD could put articles in the farming press or magazines for the pet-owning public to highlight the importance of following the warnings in SPCs and reporting any adverse events. One member recommended pictorial representations of this in order to simplify the guidance where appropriate. VMD officials confirmed that this is part of their communications strategy and there were some articles being prepared for these different audiences but there were limited resources to do this. VPC members requested to see some of these articles.

5.3. Suspected adverse event reports in animals

5.3.1 Officials highlighted a few products for which new signals were found. These included two centrally authorised products, one human product and one imported product.

5.3.2 A member questioned what SPC changes had been made for a specific rabbit vaccine and what the findings of the recent post-authorisation safety study were. Officials confirmed that the warning was added to the SPC before the study was completed and advised users that dwarf breeds of rabbits were at higher risk of adverse events. The study did not find any significant difference in safety between this product and another product currently authorised in another member state.

5.3.3 Members noted that a large number of reports related to off-label use of products and questioned what follow up actions VMD proposed to deal with this issue. Officials confirmed that this was part of the communication strategy and publicity project of the VMD.

5.4. Environmental Incidents

5.4.1 Two reports of environmental incidents had been received during the period but neither of them were considered to represent an adverse effect on the environment.

6. Consideration of an application: ref no. 01386/2013

6.1. The Committee examined evidence relating to an application for a Marketing Authorisation.

6.2. One member declared a personal, non-specific interest which had lapsed.

6.3. Three members declared a non-personal specific interest and took no part in the discussion except, at the Chairman's discretion, to answer questions.

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

7. Selection of VMD assessment reports for evaluation

7.1. 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 2015, for evaluation. The Committee was asked to

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select five products from the list provided, at least one of which must be a pharmaceutical and one an immunological. One of the products should be indicated for use in a food-producing species.

- 7.2. The Committee selected three immunological products, one for use in salmon and two for use in chickens, and two pharmaceutical products, one for use in fish and the other for use in dogs.
- 7.3. The Secretariat will forward copies of the initial assessment reports of the selected products to members by 23 October 2015 for them to evaluate against the criteria specified in VPC(15)036. Members are asked to submit their comments to the Secretariat by 18 December 2015 so that they can be collated and presented to the Committee for discussion at its meeting in February 2016.

8. Antimicrobial Sales Data Report

- 8.1. The Committee considered and commented upon the UK Veterinary Antibiotic Resistance and Sales Surveillance (UK-VARSS) Report.
- 8.2. As the draft report, which is due to be finalised and submitted to Ministers for approval to publish by 18 November 2015, will be circulated to DARC (Defra Antimicrobial Resistance Co-ordination Group) for comments, VPC members will also be asked to comment and will be advised of the deadline for this.

9. Annual return of Members' interests

- 9.1. Members were asked to let the Secretariat have their updated declarations of interest by 30 October 2015 so they can be included in the Committee's annual report for 2015.

10. Members' annual performance appraisal

- 10.1. Members were asked to complete the self-assessment section of the 2015 annual assessment form and return it to the Secretariat by close of play on 30 October 2015.

11. Items for information

- 11.1. The following items for information are publicly available:
 - 11.1.1 The Veterinary Medicines Directorate Product Information Database (<http://www.vmd.defra.gov.uk/ProductInformationDatabase/>).
 - 11.1.2 The *Veterinary Record* (<http://veterinaryrecord.bmj.com/>)
 - 11.1.2.1. The Committee discussed the relevance of receiving the first page of the *Veterinary Record* within the distribution. It was agreed the link on the agenda would be maintained.
 - 11.1.3 VPC meeting and distribution dates for 2016 have been agreed.
- 11.2. The following items for information are not publicly available:
 - 11.2.1 Report to the VPC on new ATC applications.
 - 11.2.2 Report to the VPC on applications considered by correspondence.

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- 11.2.3 Report to the VPC on Special Import Certificates/Special Treatment Certificates.
 - 11.2.3.1. The Committee noted the STC for a GMO vaccine had been imported. Officials re-iterated that all applications received to import a veterinary medicine are subject to rigorous benefit: risk assessment before the STC is accepted.
- 11.2.4 Report to the VPC on new MA applications granted.
- 11.2.5 Report from the Scientific Secretariat and the Biologicals Committee.

12. Horizon scanning: issues for consideration

- 12.1. The Committee asked the VMD for information regarding our involvement in international activities and bodies. A short paper with such information will be included in the February 2016 VPC meeting papers.
- 12.2. Veterinary Medicines should also be considered for wider environmental impacts; reference was made to the REACH evaluations. It was noted that VMD and VPC have been exploring this and will update the VPC in the future.
- 12.3. The Committee asked whether given the recent reorganisation within Defra there would be any impact to the VPC. Officials confirmed that they were not aware of any changes that would affect the Committee.

13. Any other business

- 13.1. The Chairman thanked the retiring members for their contributions.

14. VPC presentation

- 14.1. EC proposals for changes to veterinary medicines and medicated feed legislation
 - 14.1.1 The Committee considered a presentation on changes to veterinary medicines and medicated feed legislation.

15. Date of next meeting

- 15.1. The next meeting of the VPC will be on Wednesday, 3 February 2016 at the VMD, Woodham Lane, New Haw, Addlestone, Surrey.