

PUBLISHED MINUTES
VETERINARY MEDICINES REGULATIONS
VETERINARY PRODUCTS COMMITTEE

SUMMARY MINUTES



PUBLISHED MINUTES

A summary of the minutes of the Veterinary Products Committee Meeting held on 2 October 2014 at the VMD, Woodham Lane, New Haw, Addlestone, Surrey.

Chairman – Professor Bill Reilly BVMS BSc DVSM HonFRCVS
Secretary – Colin Bennett

Members

Mrs N Ackerman
Mr R Bell
Prof M Bennett
Prof C Bryant
Prof F Burke
Prof D Cavanagh
Mrs M Chambers
Ms S Harmer
Dr T Marrs
Prof J Matthews
Mr R Morris
Mr D O'Rourke
Prof A Peters
Prof C Robertson
Mr P Scott
Mr J Sherington
Mr K Siddorn

VMD

Dr N Garcia del Blanco
Dr A-M Brady
Mr G Davis
Dr G Diesel
Miss K Grace
Mr P Green
Dr K Healey
Miss L Johnson
Mrs R Pearson
Mrs H Reeves
Mrs A Seager
Mr J-P Schmidt
Dr A Tait
Miss N Vasan

Officials¹

Others

Dr M Jacobs PHE

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

PUBLISHED MINUTES
VETERINARY MEDICINES REGULATIONS
VETERINARY PRODUCTS COMMITTEE

SUMMARY MINUTES

AGENDA

1.	Announcements and apologies for absence	3
2.	Declaration of interests	3
3.	Draft minutes of the meeting held on 22 May 2014	3
4.	Matters arising from the minutes:	
4.1.	Needlesticks and best practice publication	3
4.2.	Selection of VMD assessment reports for evaluation	4
4.3.	Comparison between the incidence of adverse event reports of GSL and other legal categories.	4
4.4.	Reporting environmental incidents involving veterinary medicines	4
4.5.	Product literature: packaging and labels	4
4.6.	COT review of OP (Organophosphate) literature	4
4.7.	Future of the MSP	4
4.8.	VMD and VPC open meetings	4
5.	UK Pharmacovigilance Report for April to July 2014	4
6.	Consideration of an application: ref no. 00140/2014	6
7.	Evaluation of VMD assessment reports	6
8.	VMD assessment reports: proposals for changes to the evaluation procedure	7
9.	UK Veterinary Antibiotic Resistance and Sales Surveillance Report	7
10.	Annual return of Members' interests	7
11.	Members' annual performance appraisal	7
12.	Items for information	7
13.	Horizon scanning: issues for consideration	8
14.	Any other business	8
15.	VPC presentation: Product literature	8
16.	Date of next meeting	9

PUBLISHED MINUTES
SUMMARY MINUTES

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. The Chairman informed the Committee that Jackie Atkinson, Director of Authorisations had resigned from the VMD at the end of September to take up a position with a pharmaceutical company.
 - 1.2.1 He passed on her thanks to the Members for everything the Committee has done to help her and the VMD to further the common goals around the availability of safe and effective medicines for animals and, in particular her appreciation for Members' commitment to attending VPC meetings, especially when they have so many other competing priorities.
 - 1.2.2 In response the Committee asked for its best wishes for her success in her new role to be recorded.
 - 1.2.3 The Chairman welcomed Dr Anna-Maria Brady, who has been appointed interim Director of Authorisations.
- 1.3. Professor Matthews and Professor Peters took part via teleconference link.
- 1.4. Dr Jacobs (PHE) also took part via teleconference link.
- 1.5. Apologies for absence had been received from Dr Bleiker, Dr Jefferson, Dr Kubiak, Mr Lister and Mr Prail.

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 22 May 2014

- 3.1. The Committee had cleared the minutes of the May meeting by correspondence. However, there was one amendment to the list of attendees: 'Dr C Bryant' was amended to read 'Prof C Bryant'.
- 3.2. The Summary minutes were available on the VPC website (<https://www.gov.uk/government/organisations/veterinary-products-committee/about/membership#minutes>).

4. Matters arising from the minutes

4.1. Minute 4.1.3: Needlesticks and best practice publication

- 4.1.1 The paper on which three members had collaborated had been accepted for publication. The Secretariat would advise the Committee when it had been published.

Acton Point 1

- 4.1.2 A Member agreed to prepare a synopsis of the paper and submit it to professional journals for publication.

PUBLISHED MINUTES
SUMMARY MINUTES

- 4.2. **Minute 4.6.1: Selection of VMD assessment reports for evaluation**
4.2.1 See Item 8, below.
- 4.3. **Minute 7.2.3: Comparison between the incidence of adverse event reports of GSL and other legal categories**
4.3.1 See Item 5, below.
- 4.4. **Minute 9.2.1: Reporting environmental incidents involving veterinary medicines**
4.4.1 See Item 5, below.
- 4.5. **Minute 9.3.2: Product literature: packaging and labels**
4.5.1 See Item 15, below.
- 4.6. **Minute 5: COT review of OP (Organophosphate) literature**
4.6.1 Copies of correspondence between the author of a report considered by the COT (Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment) and the COT Chair were noted by the Committee.
- 4.7. **Minute 6: Future of the Medical and Scientific Panel**
4.7.1 The Committee was advised that Ministers had been informed that the VMD had accepted its advice that, in the light of the COT's conclusions in its ['Statement on long-term neurological, neuropsychological and psychiatric effects of low-level exposure to organophosphates in adults'](#), there was no longer a need for the Medical and Scientific Panel (MSP).
4.7.2 Thus, the MSP had been formally wound up on 31 July and the MSP Chair and members had received valedictory letters from Professor Borriello, CEO, VMD, thanking them for their service to the MSP.
4.7.3 The Chairman thanked Dr Jefferson (MSP Chair), Dr Kennett, Dr Marrs and Dr Pugh for their contribution to the work of the Panel.
- 4.8. **VMD and VPC open meetings**
4.8.1 The Committee was reminded that the VMD and VPC open meetings would be held on 8 October in the Weybourne building of the Animal and Plant Health Agency (formerly the AHVLA).
4.8.2 A Member would be giving a presentation entitled '*Pharmacovigilance – a new approach?*'.
4.8.3 Members who had not already done so were asked to advise the Secretariat as soon as possible if they intended to attend.
- 5. The UK Pharmacovigilance report**
5.1. The Committee considered and commented upon the Pharmacovigilance Report for April to July 2014, which was presented by the head of the VMD's Pharmacovigilance Unit.
5.2. **Action Point 3 from May 2014 (Minute 7.2.3)**
5.2.1 Officials presented two graphs displaying the number of human and animal adverse event reports for each year (1995 – 2014), subdivided by distribution category for animal anti-parasitic spot-on and spray products. They showed that the majority of

PUBLISHED MINUTES
SUMMARY MINUTES

reports were received for products from the POM-V (Prescription Only Medicine–Veterinarian) category and although the potential for reporting bias was acknowledged, the Committee agreed that they demonstrated the safety of products distributed through the AVM-GSL (Authorised Veterinary Medicine–General Sales List) distribution category. The increase in the number of animal reports over the years was noted and was attributed to better publicity of pharmacovigilance and the engagement of the veterinary industry. However, it was noted that there were still very few reports received from Suitably Qualified Persons (SQPs) who are authorised under UK legislation to prescribe and supply certain lower risk veterinary medicines, for example some wormers and other antiparasitic treatments. Two Members stated they were interested in discussing this further with the Pharmacovigilance team and developing ways of increasing awareness and reporting from SQPs and the general public.

5.3. Action Point 4 from May 2014 (Minute 9.2.1)

5.3.1 Officials presented a summary of the environmental monitoring of veterinary medicines, highlighting those organisations from which information is most often received, and a graph showing the number of reports received per year (1987 – 2014).

5.3.2 It was noted that the VMD is the only veterinary medicines regulatory authority in Europe with a dedicated reporting form for environmental incidents. A Member questioned whether there should be active surveillance for environmental issues, especially with regard to antimicrobial resistance. However, Officials explained that the VMD was represented at other meetings and this was more of an overarching policy issue and not limited to pharmacovigilance.

5.4. Suspected adverse event reports in humans

5.4.1 Members commented on a report of a man who was found to have low testosterone levels after breaking open capsules of a product authorised for use in dogs.

5.4.1.1. Two Members declared non-personal non-specific interests in the product.

5.4.1.2. The Committee questioned whether the warnings in the Summary of Product Characteristics (SPC) were sufficient and Officials explained that the SPC did contain some warnings advising users not to break open capsules but they would look into this further.

Action point 2

5.4.2 A Member noted three reports involving a product authorised for use in sheep.

5.4.2.1. These reports all involved non-specific signs, very similar to some of those reported with organophosphate dips. Officials stated that the product would be monitored for further reports.

5.4.2.2. One of the reports received related to a quality issue with the container and Officials agreed to check whether the other reports also related to this.

Action point 3

5.4.3 A Member commented on a report of a needlestick injury relating to a vaccine for use in sheep.

5.4.3.1. A Member declared a non-personal non-specific interest in the product.

PUBLISHED MINUTES
SUMMARY MINUTES

5.4.3.2. The severity of the injury, which required two surgical procedures to treat, was noted.

5.5. Suspected adverse event reports in animals

5.5.1 An Official presented the results of the Proportional Reporting Ratio (PRR) analysis and highlighted those products which had been recommended for further monitoring. A recent letter in the *Veterinary Record*, relating to lack of efficacy reports for Pexion (imepitoin) Tablets for Dogs, was also brought to the attention of members.

5.5.2 In response to a question, Officials confirmed that known adverse events were considered in light of those already listed in the SPC of the product in question and other similar products when assessing any signals detected through the PRR analysis.

5.5.3 In response to a question about a signal for an injectable product authorised for use in a number of species, Officials stated that only four reports had been received to date; two involved horses and two involved cattle. All four reports appeared to be typical cases of anaphylaxis.

5.6. Environmental Incidents

5.6.1 Although no environmental incidents had been reported during this period, there would be a number of reports for the Committee to consider at its January meeting.

6. Consideration of an application: ref no. 00140/2014

6.1. The Committee examined evidence relating to an application for a change of legal category from POM-V (Prescription Only Medicine – Veterinarian) to NFA-VPS (Non-Food Animal – Veterinarian, Pharmacist, Suitably Qualified Person) for a product authorised for use in dogs and cats.

6.2. There were no declarations of interest.

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

7. Selection of VMD assessment reports for evaluation

7.1. In line with the agreed procedure, the Committee was asked to select five products from a list of new marketing authorisation applications where the VMD had led and completed the initial assessment in the 12 months leading up to the end of August 2014. At least one of the products had to be a pharmaceutical product, one a biological product and one a product indicated for use in food-producing species.

7.2. The Committee selected three immunological products, one for use in salmon, one for use in horses and one for use in pigs, and two pharmaceutical products, one for use in poultry, and the other for use in dogs, cats, horses and sub-human primates.

7.3. The Secretariat would forward copies of the initial assessment reports of the selected products to Members by 23 October for them to evaluate against the specified criteria. Members were asked to submit their comments by 19 December so that they could be collated and presented to the Committee for discussion at the January meeting.

Acton Point 4

OCTOBER 2014 MEETING
Revised 19/11/2014
#718727
VMD/L4/COST/016/C

Page 6 of 9

Chairman's initials... 

PUBLISHED MINUTES
SUMMARY MINUTES

8. VMD assessment reports: proposals for changes to the evaluation procedure

- 8.1. The Committee considered the proposals for a change to the procedure for evaluating the VMD's assessment reports.
- 8.2. The purpose of the evaluation was to provide a critique of the assessment report, to examine whether the basis for the questions/conclusions was sound and transparent, rather than to re-assess the application.
- 8.3. The Committee recognised that a high score was to be expected if the assessments were completed properly and concluded that the current procedures were appropriate and should not be changed.

9. UK Veterinary Antibiotic Resistance and Sales Surveillance Report

- 9.1. The Committee considered and commented upon the UK Veterinary Antibiotic Resistance and Sales Surveillance (UK-VARSS) Report.
- 9.2. Officials updated the Committee on the changes and new format, which were mostly cosmetic, the data having been collected and analysed as per previous reports.
- 9.3. Following an overview of the headline trends in sales data for 2013 a Member commented that the intramammary sales figures presented in the report could misrepresent usage in the dairy industry. Officials explained that readers of the report needed to be aware that the data presented are sales data and not consumption data, and therefore a comment would be inserted into the report to re-iterate this and avoid misinterpretation.
- 9.4. Members who wished to submit comments were asked to forward them, by email, to the Secretariat before 10 October 2014.

10. Annual return of Members' interests

- 10.1. Members were reminded to let the Secretariat have their updated declarations of interest for inclusion in the Committee's annual report for 2014, by close of play on 30 October 2014.

11. Members' annual performance appraisal

- 11.1. Members who had not returned their 2013 appraisals to the Secretariat were asked to do so as soon as possible.
- 11.2. All members were asked to complete the self-assessment section of their 2014 annual assessment form VPC(14)036 and return it to the Secretariat by close of play on 30 October 2014.

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

PUBLISHED MINUTES
SUMMARY MINUTES

- 12.1.3 Freedom of Information requests received
(http://www.vmd.defra.gov.uk/business/ati_disclosure.aspx)
- 12.1.4 The Food Standards Agency's Annual Science Report 2013/14
(<http://www.food.gov.uk/about-us/publications/busreps/csreps>).

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

- 12.2.1 Report to the VPC on new Animal Test Certificate applications
- 12.2.2 Report to the VPC on applications considered by correspondence
- 12.2.3 Report to the VPC on Special Import Certificates/Special Treatment Certificates
- 12.2.4 Report to the VPC on new MA applications granted
- 12.2.5 Report from the Scientific Secretariat and the Biological Committee.

13. Horizon scanning: issues for consideration

- 13.1. A member suggested that the potential effects of the EC's recently announced proposals for veterinary medicines and medicated feed legislation would be a useful issue on which to receive updates.
- 13.2. Officials explained that the essential framework would remain but the proposals for revised European Regulations will be discussed at public open meetings to be held later in 2014. The Committee would be given a presentation on developments at a future meeting.

Action point 5

- 13.3. The veterinary medicines and the medicated feed proposals were available respectively at http://ec.europa.eu/health/veterinary-use/rev_frame_index_en.htm and http://ec.europa.eu/food/food/animalnutrition/labelling/medicated_feed_en.htm.

14. Any other business

14.1. Extraordinary meeting 2015

- 14.1.1 The Committee had been advised that it might be necessary to hold an additional meeting in February or March and Members were asked to make every effort to attend.

15. VPC presentation: Product literature

- 15.1. Following the suggestion at the May meeting (under 'Horizon scanning') that the VMD might undertake a review of product labelling because of concerns raised by some Members about the similarity in product packaging for product ranges and the possibility of the wrong product being taken from the shelf, the VMD concluded that a short presentation to clarify the requirements and restrictions that apply to product labelling, would be more appropriate.
- 15.2. The Head of the VMD's General Assessment Team (GAT) gave an interesting and informative presentation entitled '*Assessment of Product Literature*' after which she, and the Head of the VMD's Pharmacovigilance team, responded to questions.

PUBLISHED MINUTES
SUMMARY MINUTES

- 15.3. Marketing authorisation holders have to ensure that their packaging and labels comply with specific standards, and the VMD's GAT conducts thorough assessments of all packaging etc. before a product can be marketed.
- 15.4. Members continued to express concerns about similarities in packaging which could result in the administration of the wrong product but Officials explained that prescribing errors should be reported to the marketing authorisation holders, who are required to include them in the Periodic Safety Update reports sent to the VMD. If significant reports were received, the VMD could ask for appropriate changes to be made. However, in the absence of any such evidence, if the packaging and labels complied with the regulations the VMD could not impose further, undue burdens on the authorisation holder.
- 15.5. A Member undertook to raise the reporting of 'near misses' (where the wrong product had been selected but not administered) with the British Small Animal Veterinary Association and the Chair asked the VMD to consider asking other representative organisations whether this information was available or could be obtained.

Action point 6

- 15.6. The presentation would be available to members on the VPC members' forum.

16. Date of next meeting

- 16.1. The next meeting of the VPC will be on 29 January 2015 at the VMD, Woodham Lane, New Haw, Addlestone, Surrey.