

PUBLISHED MINUTES
VETERINARY MEDICINES REGULATIONS
VETERINARY PRODUCTS COMMITTEE

SUMMARY MINUTES



**Veterinary
Products
Committee**



PUBLISHED MINUTES

**A summary of the minutes of the Veterinary Products Committee Meeting held on
29 January 2015 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
Dr T Bleiker
Prof F Burke
Prof D Cavanagh
Mrs M Chambers
Prof C Collins
Ms S Harmer
Dr E Kubiak
Mr S Lister
Dr T Marrs
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

VMD

Miss J Blenkinsop
Prof P Borriello
Mr G Davis
Dr G Diesel
Ms S Eckford
Dr N Garcia del Blanco
Mr P Green
Dr K Healey
Miss L Johnson
Mr K Stapleton
Ms C Stratford

Officials¹

Others

Mr M Hawes

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

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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 Marrs and Professor Matthews took part via teleconference link.
- 1.3. Apologies for absence had been received from Professor Bryant, Dr Jefferson and Professor Robertson.
- 1.4. The Chairman welcomed Suzanne Eckford who has been appointed Head of the Pharmaceuticals and Feed Additives Team, replacing Dr Alex Tait who retired in December, and Jennifer Blenkinsop who has joined the VMD's Pharmacovigilance team.
- 1.5. The Chairman also welcomed Martin Hawes, a mature student at the Royal Veterinary College on a two-week placement with the VMD, who attended as an observer.

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 2 October 2014

- 3.1. The Committee had cleared the minutes of the October meeting by correspondence and the Summary minutes have been published on GOV.UK.

4. Matters arising from the minutes

- 4.1. Minute 4.1.1: Needlesticks and best practice publication
 - 4.1.1 The Committee was informed that the paper was still awaiting publication. The Secretariat would advise the Committee when it had been published.

Action Point 1

- 4.1.2 The Committee was also informed that the *Veterinary Record* had shown an interest in publishing an article, which the Chair agreed to progress.

Action Point 2

- 4.2. Minute 5.4.1.2: SPC warnings for a product authorised for use in dogs
 - 4.2.1 Officials had examined the warnings currently found on the SPC and product literature, noting that 'Do not divide or open capsules' is on the carton. The Committee agreed that no additional information was required to ensure user safety.
- 4.3. Minute 5.4.2.2: Containers of a product for use in sheep
 - 4.3.1 Officials confirmed that the quality defect mentioned in one human report was not responsible for the exposure to the product.
- 4.4. Minute 7.3: Evaluation of VMD assessments
 - 4.4.1 This was discussed at agenda item 7.
- 4.5. Minute 9: UK Veterinary Antibiotic Resistance and Sales Surveillance Report 2013
 - 4.5.1 The Committee had been notified that the report was published on 18 November and was available at:

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<https://www.gov.uk/government/publications/veterinary-antimicrobial-resistance-and-sales-surveillance-2013>.

- 4.6. Minute 10 1: Annual return of Members' interests
4.6.1 Those Members who have yet to submit their declarations of interest were asked to complete and forward them to the Secretary as soon as possible.
- 4.7. Minute 11.2: Members' annual performance appraisal
4.7.1 Those Members who have yet to submit their annual performance assessments were asked to forward them to the Secretary as soon as possible.
- 4.8. Minute 13.2: Proposals for changes to veterinary medicines and medicated feed legislation
4.8.1 The Committee was informed that a presentation has been scheduled for the May meeting.

Action Point 3

- 4.9. Minute 15.5: Similarity of product packaging: canvassing veterinary organisations
4.9.1 The Committee was informed that the letter to the veterinary associations had not yet been written as it had been decided that it would be better to first write a short article based on reports already held, in order to stimulate interest in the topic. Work on this was in progress and, in the meantime, the VMD had been canvassing the opinion of delegates at the veterinary conferences they attend, in the form of an additional question in the educational quiz competitions that vets and nurses enter on the stand.

5. The UK Pharmacovigilance report for August to November 2014

- 5.1. The Committee was informed that the VMD's Pharmacovigilance Unit had held its first Industry Information Day on 26 November 2014. Over 50 industry representatives from across Europe attended in person and more than a dozen watched the live webcast.
- 5.1.1 A total of eight presentations were delivered on various aspects of pharmacovigilance by both scientific and administrative staff, taking into account questions that delegates had submitted in advance.
- 5.1.2 Over 80% of those attending in person completed feedback forms, scoring all presentations highly for both content and delivery. Although there had been some technical difficulties with the webcast, the day was rated as a great success by those attending in person with an average score (out of 5) of 4.3 for usefulness and 4.4 for organisation.
- 5.1.3 Recordings of all the presentations and copies of the slides are now available on GOV.UK using the search term "phv industry info day" or via the following link www.gov.uk/government/news/pharmacovigilance-industry-information-day-26-november-2014.
- 5.1.3.1. Officials agreed to forward the link, above, to Members after the meeting.

Action Point 4

- 5.2. The Committee considered and commented upon the Pharmacovigilance Report for August to November 2014, which was presented by the Head of the Pharmacovigilance team.
- 5.2.1 **Suspected adverse event reports in humans**

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- 5.2.1.1. A Member commented on a report of a woman who developed Parkinson's disease more than 30 years after exposure to a product authorised for use in cats and dogs.
- 5.2.1.2. A Member noted a reported suicide following suspected use of a product authorised for use in cattle and sheep. Investigation had shown that the product had not been prescribed or used on the farm in the past three to four years and therefore its source was uncertain.
- 5.2.1.3. Members also noted another report relating to an attempted suicide using a product authorised for use in small animals and cattle and questioned whether further regulation, for example, requiring them to be stored in controlled drugs cabinets, could reduce such incidents. Officials felt that this was unlikely to have an impact.
- 5.2.1.4. A Member commented on the reports relating to a pour-on product authorised for use in sheep and suggested that some of them could be related to leaking packs and poor compatibility between the immediate product packaging and administration guns. It was suggested that these products should be supplied in sealed systems. Officials explained that administration guns did not fall within the remit of the VMD if not sold within the same packaging as the product but suggested that the issue could be raised with HSE and NOAH for further investigation.

Action Point 5

- 5.2.1.5. Members suspected that there had been an increase in the number of reports of needlestick injuries and questioned why the VMD action was generally noted as 'no further action'. Officials explained that the vast majority of these cases were asymptomatic and that as the role of pharmacovigilance is to look for trends, took no action on individual reports, unless a particularly serious and unexpected reaction was observed.

5.2.2 Suspected adverse event reports in animals

- 5.2.2.1. A VMD Official presented the results of the Proportional Reporting Ratio (PRR) analysis and highlighted those products which had been put on alert and recommended for further monitoring. Officials highlighted three products for which concerns had already been raised in Europe at the Pharmacovigilance Working Party.
- 5.2.2.2. Officials highlighted a signal for death for a product authorised for use in cats. It was noted that four reports involving death had been received. These would be looked at in more detail following the receipt of the next PSUR which is due by the end of January 2015.
- 5.2.2.3. The Alert Group Member noted that the PRR analysis system has been refined further and is now robust, adding value to the pharmacovigilance system. In response to questions from Members, Officials explained that both the VMD and the European systems use the Proportional Reporting Ratio (PRR) but the European system runs the analysis on selected products based on a schedule, whilst the VMD system runs the analysis on all of the data in the database.

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5.2.3 Environmental Incidents

5.2.3.1. Twenty-five environmental incident reports had been received during this period, after the VMD had contacted the environmental agencies, reminding them of the necessity to report such events. Of these reports, 24 were historical and most involved an active substance which was no longer available as an authorised veterinary medicinal product. One spontaneous report had been received for which further information had been requested. Officials postulated that in this case lambs which had been tail docked had also been dipped. The kite had then ingested the tails of the lambs leading to death. However, a Member suggested that it would be unlikely for lambs to be tail docked at an age when they would also be exposed to dipping, and therefore this was unlikely to have been the cause.

5.2.3.2. Officials stated that they intended to contact the relevant agencies in order to educate and encourage correct reporting of environmental incidents.

Action Point 6

6. Consideration of an application: ref no. 00616/2014

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, SQP) for a product for use in dogs.

6.2. There were no declarations of interest.

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

7. Evaluation of VMD assessment reports

7.1. At its meeting in October the Committee had selected five products to evaluate: 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.

7.2. The Committee discussed the summary of Members' evaluations and Officials addressed specific comments, explaining that the Committee had reviewed initial assessment reports and that in some cases applicants for marketing authorisations were required to use, for example, standard warning statements to comply with European Legislation.

7.3. The Committee accepted Officials' explanations but agreed that the 'Level 1' evaluation criterion did not reflect this and should be amended for the 2015 review.

Action Point 7

7.4. 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 should overall be rated as performance level 1, i.e. that the VMD had identified all potentially serious risks to human and animal health or for the environment and put together a comprehensive list of relevant questions for the applicant which were clearly expressed and justified/explained.

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7.5. The VPC's evaluation would be included in the overall performance assessment of the VMD, to be published in its Annual Report and Accounts 2014/2015.

8. VPC annual report 2014: first draft

8.1. The first draft of the Committee's 2014 annual report was presented for consideration.

8.2. Members noted the revised format and agreed to submit comments to the Secretary by 19 February.

8.3. The final report, to be agreed by the Chairman, would be submitted to Ministers for approval to publish on GOV.UK. and the Committee would be informed when it has been published.

9. VMD and VPC open meetings 2014 and 2015

9.1. The Committee noted the analysis of attendance and summary of the feedback from the 2014 open meeting.

9.2. The Committee was asked for suggestions for presentations for the 2015 open meeting, to be held on Friday September 25, as nothing had been suggested in the feedback.

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/>).

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

10.1.3 Freedom of Information requests.

10.1.4 GOV.UK.

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

10.2.1 Report to the VPC on new ATC applications.

10.2.2 Report to the VPC on applications considered by correspondence.

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

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. Pharmaceutical pollution of the environment

11.1.1 A Member had asked for this document which was published in *The Guardian* on 13/10/2014 (www.theguardian.com/environment/2014/oct/13/drugs-flushed-into-the-environment-could-be-cause-of-wildlife-decline) to be seen by the Committee.

11.1.2 Officials gave a brief summary of the article concerning the potential environmental effects of residues of pharmaceuticals from release via animal and human sewage.

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In particular, the article reported classes of pharmaceuticals of concern including endocrine disruptors, antiparasitocides and antibiotics. In addition, specific cases were described such as the diclofenac usage in cattle in India and Pakistan which led to a large decline in populations of old world vultures. Similar articles had been published, most recently, from *The Times* in December 2014 entitled "Painkillers put otters at risk".

- 11.1.3 Officials explained that the effects on the environment of pharmaceuticals are unclear as it is a complex issue and further information is required. The VMD is represented on the Committee for Veterinary Medicinal Product's Environmental Risk Assessment Working Party and DEFRA's Pharmaceuticals in the Environment work group and is aware of various initiatives and work being done to address the issue of the impact of pharmaceuticals on the environment, in particular
- new guidance on how to conduct risk assessments for persistent, bioaccumulative and toxic substances is being developed
 - as the European Commission is developing a strategic approach to the pollution of the environment by pharmaceuticals, a recent Commission workshop on pharmaceuticals (human and veterinary) in the environment took place at which the "Lifecycle stages of Pharmaceuticals" (i.e. product development, authorisation, production, consumption/use and disposal) were considered in terms of impact on the environment
 - the EU Water Framework Directive which aims to achieve good qualitative and quantitative statuses of water bodies throughout Europe was mentioned. As part of this, monitoring for chemicals considered of concern is conducted and further chemicals are assessed for concern and whether they should be added to the list of chemicals monitored. Zinc and cypermethrin were given as examples in terms of active substances in veterinary medicines monitored for

11.1.4 Officials would provide the Committee with regular updates.

12. Any other business

12.1. The Chair informed the Committee that the Secretary would be retiring before the next meeting and, on behalf of the Committee, thanked him for his service to the Committee.

13. Date of next meeting

13.1. The next meeting of the VPC will be on 21 May 2015 at the VMD, Woodham Lane, New Haw, Addlestone, Surrey.