

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 21 May 2015 at the VMD, Woodham Lane, New Haw, Addlestone, Surrey.

Chairman – Professor Bill Reilly BVMS BSc DVSM HonFRCVS
Secretary – Mrs Nina Dorian

Members

Mrs N Ackerman
Mr R Bell
Prof M Bennett
Dr T Bleiker
Prof C Bryant
Prof F Burke
Prof D Cavanagh
Mrs M Chambers
Ms S Harmer
Dr R Jefferson
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
Prof C Robertson
Mr P Scott
Mr J Sherington
Mr K Siddorn

Officials¹

VMD

Dr M-O Hendrickx
Mr P Green
Ms J Blenkinsop
Dr G Diesel
Dr N Garcia del Blanco
Dr R Woodland

Others

Ms L Evans HSE
Dr M Jacobs PHE

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

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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. Professor Bryant, Dr Jacobs, Professor Matthews and Mr O'Rourke took part via teleconference link.
- 1.3. Apologies for absence had been received from Dr Jefferson.
- 1.4. The Chairman welcomed Dr Marie-Odile Hendrickx who has been appointed Director of Authorisations, replacing Dr Jackie Atkinson who resigned in September 2014, and Nina Dorian who is currently occupying the Secretary role on a temporary basis.
- 1.5. The Chairman also welcomed Dr Jacobs, from Public Health England (PHE), and Ms Evans, from the Health and Safety Executive (HSE), to their first VPC meeting.

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 29 January 2015

- 3.1. The Committee had cleared the minutes of the January meeting by correspondence and the Summary minutes have been published on [GOV.UK](http://gov.uk).

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 paper by members which has been accepted for publication by the European Journal of Emergency Medicine has not yet been published, although an electronic version is available on the journal's website in the 'Published Ahead-of-Print' section (<http://journals.lww.com/euro-emergencymed/pages/default.aspx>). The Secretariat will advise the Committee when it has been published and in the meantime will circulate a PDF proof version to members.

Action Point 1

- 4.2. Minute 4.1.2: Needlesticks and best practice publication (*Veterinary Record*)
 - 4.2.1 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

- 4.3. Minute 4.8.1: Presentation on the proposals for changes to veterinary medicines and medicated feed legislation
 - 4.3.1 This presentation will be given at the October VPC meeting.
- 4.4. Minute 5.1.3: VMD's pharmacovigilance industry information day
 - 4.4.1 A link to the presentations given at the pharmacovigilance industry information day in 2014 has been sent to Members ([Pharmacovigilance Industry Information Day](#)).

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4.5. Minute 5.2.1.4: Pour-on products and dosing systems

- 4.5.1 The issue of leaking packs and poor compatibility between the immediate product packaging and administration guns will be raised with NOAH at the June Liaison meeting and the HSE will be contacted once the outcome of these discussions is known.

Action Point 3

4.6. Minute 5.2.3.2: Reporting environmental incidents

- 4.6.1 The VMD's environmental safety assessor has contacted the relevant agencies to clarify which environmental incidents should be reported.

4.7. Minute 7.3: Annual evaluation of VMD assessments

- 4.7.1 The criteria for the annual evaluation against which the VPC assess the VMD against Performance Level 1 is to be adapted to read "The VMD identified all potentially serious risks to human and animal health or for the environment within the context of the existing regulatory framework and put together a comprehensive list of relevant questions for the applicant which were clearly expressed, justified/explained and pivotal to the benefit:risk assessment."

Action Point 4

4.8. Minute 8.3: VPC annual report 2014

- 4.8.1 The publishing of the final annual report for 2014 has been delayed by the General Election. It is likely it will not be published until June or July.

Action Point 5

4.9. Minute 9.2: VPC open meeting

- 4.9.1 Members were asked to consider possible topics for the VPC presentation to be given at the VMD and VPC Open meeting on 2 October and send suggestions to the Secretariat.

Action Point 6

5. The UK Pharmacovigilance report

- 5.1. The Committee considered and commented upon the Pharmacovigilance Report for December 2014 to March 2015, which was presented by Gillian Diesel from the VMD's Pharmacovigilance Unit.

5.2. Suspected adverse event reports in humans

- 5.2.1 A member commented on a report where an owner suffered an asthma attack after using a bathing product on their dog. It was noted that the product contained pyrethrins which are known to cause paraesthesia but are not known to be sensitizers. However, a literature search had shown a similar report of an asthma attack following use of a product containing pyrethrins. The committee questioned whether there were any warnings on the product regarding asthma and VMD officials committed to look into this.

Action Point 7

- 5.2.2 A member commented on a report involving a farmer that developed neurological signs after using a pour-on solution for cattle. The product had leaked from the pack into his boots and the farmer had not washed the product off. VMD officials stated that additional information had been sought from the reporting MAH but no further information could be obtained from the patient. Members questioned what volume of product had spilled into the farmer's boots and if the leak was due to human error or

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a fault with the product packaging or dosing gun. VMD officials stated that it was unlikely to be able to obtain further information on this case but agreed to contact the MAH again to seek further information.

Action Point 8

- 5.2.3 A member commented on the number of reports involving the same identified product. VMD officials stated that the number was low when compared to the overall sales for these products but agreed to review the number of reports.

Action Point 9

- 5.2.4 A member commented on the two reports relating to accidental Needlestick injuries whilst using a product; both involved fish vaccinators which required surgical intervention. VMD confirmed that this product is not currently authorised in the UK but was imported. A member noted that it is likely that the import of this product will increase due to the recent withdrawal of two other fish vaccines from the market.
- 5.2.5 A member noted the two reports concerning an inhalation vapour for dogs; one involving a vet who gave birth prematurely and the other involving three miscarriages. VMD officials confirmed that these reports both related to the same veterinary practice and that the MAH had visited the practice to investigate further. No leaks in the anaesthetic system were found but the practice did not have a scavenging system in place. The VMD confirmed that there are extensive warnings in the SPC regarding scavenging systems and advising that pregnant ladies should not have any contact with the product. Members suggested that this issue should be raised with the Royal College of Veterinary Surgeons Standards Committee. VMD agreed to consider these issues and decide whether any further action is needed.

Action Point 10

5.3. Suspected adverse event reports in animals

- 5.3.1 A member questioned whether there had been any further follow-up or information on a signal noted at the previous meeting involving a flea collar. VMD officials responded explaining that this signal was detected using Proportional Reporting Ratio (PRR) due to the fact that only four reports had been received for this product, all of which involved death. On reviewing the data further and comparing these cases to the sale volumes it was found that the incidence was very rare and there were no concerns to be addressed at this time. VMD have committed to continue to monitor for any further reports for this product.
- 5.3.2 A member noted the large number of signals for an injectable product for dogs. VMD officials confirmed that this is a centrally authorised product and due to the number and variety of signals detected, the MAH was requested to look into this in further detail and compare the adverse events received for this product versus a sister product. However, their response was limited and the VMD will ask the Rapporteur to request further analysis from the MAH. VMD also confirmed that there had been a large number of queries from veterinary professionals regarding this vaccine.
- 5.3.3 VMD officials informed the committee that due to the large number of reports and signals for neurological signs following use of a product for cats that the MAH had been requested to add additional warnings to the SPC.

5.4. Environmental Incidents

- 5.4.1 One report was received during the reporting period and was noted by a member.

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6. Consideration of an application: ref no. AN:01544/2013

- 6.1. The Committee examined evidence relating to an application for the authorisation of a viral autogenous vaccine.
- 6.2. There were no declarations of interest.
- 6.3. The Committee provided advice for consideration by the VMD.

7. VPC Appointments' exercise

- 7.1. Progression of the VPC Appointments' exercise has been delayed by the General Election. Twelve posts, including a new post for an Environmental Scientist, need to be filled. Subject to Ministers' approval seven members will hopefully be straightforward reappointments. Provisional sift and interview dates have been set in October and November.

8. Items for information

- 8.1. The following items for information are publicly available:
 - 8.1.1 The Veterinary Medicines Directorate Product Information Database (<http://www.vmd.defra.gov.uk/ProductInformationDatabase/>).
 - 8.1.2 The *Veterinary Record* (<http://veterinaryrecord.bmj.com/>)
- 8.2. The following items for information are not publicly available:
 - 8.2.1 Report to the VPC on new ATC applications.
 - 8.2.2 Report to the VPC on applications considered by correspondence.
 - 8.2.3 Report to the VPC on Special Import Certificates/Special Treatment Certificates.
 - 8.2.3.1. The committee noted the List of SIC/STCs issued. A member queried why an STC for a potential GMO vaccine had been granted and asked what was the legal status of the vaccine in Europe; the VMD explained that this wasn't a GMO vaccine, but a DNA vaccine. This vaccine had been through a centralised procedure in Europe but was withdrawn by the applicant due to efficacy concerns and therefore it is not authorised in Europe. The VMD reassured the committee that all applications received to import veterinary medicinal products including vaccines are subject to a thorough benefit:risk assessment before the authorisation is granted.
 - 8.2.4 Report to the VPC on new MA applications granted.
 - 8.2.5 Report from the Scientific Secretariat and the Biological Committee.
 - 8.2.6 Freedom of Information requests.

9. Horizon scanning: issues for consideration

- 9.1. There were no issues noted for consideration at the meeting. Members were asked to identify possible areas of interest for future meetings.

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10. Any other business

10.1. Autumn Conference Season – Needlestick Presentation

- 10.1.1 Professors Robertson and Burke offered to make slides on sharps injuries and high pressure injuries available for those members that may wish to use them for educational or teaching purposes. These can be obtained from the Secretariat.

11. Date of next meeting

- 11.1. The next meeting of the VPC will be on 1 October 2015 at the VMD, Woodham Lane, New Haw, Addlestone, Surrey.