

PUBLISHED MINUTES
VETERINARY MEDICINES REGULATIONS
VETERINARY PRODUCTS COMMITTEE

SUMMARY MINUTES



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A summary of the minutes of the Veterinary Products Committee Meeting held on 18 May 2017 at the VMD, Woodham Lane, New Haw, Addlestone, Surrey.

Chairman – Professor Bill Reilly BVMS BSc DVSM HonFRCVS
Secretary – Chris Abbott

Members

Mrs N Ackerman
Prof M Bennett
Prof D Cavanagh
Mrs M Chambers
Ms S Harmer
Mr M Jelley
Dr E Kubiak
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

VMD

Mr P Green
Dr M-O Hendrickx
Dr G Diesel
Ms E Ursich
Ms R Manyarara
Mrs A Seager

Officials¹

Others

Ms K Foxall

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. Apologies for absence had been received from Dr Bleiker, Professor Borriello, Professor Bryant, Dr Burnett, Professor Collins, Mr Lister, Mr Millward and Mrs Stott.
- 1.3. Mrs Chambers, Professors Matthews and Peters and Ms Foxall (PHE) 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. Minutes of the meeting held on 15 September 2016

- 3.1. The Committee had cleared the minutes of the September 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 5.1: Needlesticks and best practice article publication
 - 4.1.1 The Committee was informed that the article by Professors Burke, Reilly and Robertson and Mrs Ackerman entitled 'Needlestick and inoculation injuries in veterinary and animal workers' had been published in the March edition of *In Practice* journal ([Volume 39, issue 3](#)).
- 4.2. Minute 5.4: Antimicrobial resistance presentation
 - 4.2.1 This presentation would now be given at the September Committee meeting.
- 4.3. Minute 10.3: Evaluation of VMD assessment reports
 - 4.3.1 At its meeting in September the Committee had selected five products to evaluate: 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.
 - 4.3.2 The Committee had agreed earlier via correspondence 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.
- 4.4. Minute 16.1.1: UK exit from the EU
 - 4.4.1 An update was provided under item 7.

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5. The UK Pharmacovigilance report

5.1. Introduction

5.1.1 The Committee considered and commented upon the Pharmacovigilance Reports for August 2016 to March 2017, which were presented by the head of the VMD's Pharmacovigilance Unit.

5.1.2 VMD officials presented the team's Outcomes Log to the committee following the agreement last year to provide this report once per year. This document details all the changes to product labelling and information, made based on pharmacovigilance data. Officials explained that for non-urgent changes, MAHs were given 6 months to submit a variation.

5.2 Suspected adverse event reports in humans

5.2.1 The Committee noted a suicide report involving a prescription only product (insulin) and questioned how the individual involved had obtained the product. Officials explained that a dog owner, whose dog had recently died, wanted to donate the remaining product to an animal charity, and she knew that the individual in this case volunteered at a local dog charity and so passed the product on to her. Officials explained that the offences committed had been recorded and dealt with appropriately.

5.2.2 Committee members raised concerns about a report involving a farmer who suffered a needle stick injury with an empty syringe of a product containing tilmicosin. Members questioned if the warnings on the packaging are sufficient. Officials stated that the product has extensive warnings. A member questioned how many deaths have been reported in relation to this product, officials agreed to confirm this at the next meeting. A member noted that this product had been discussed by CVMP several years ago, at which point additional safeguards had been put in place. Members suggested that it would be beneficial for VMD to send a reminder to vets that the product is by veterinary administration only, automatic injection systems which use needles should not be used, the administration of the product by a farmer is illegal and all needles and syringes used to administer the product should not be left on the farm, but disposed of appropriately.

Action Point 1

5.2.3 A member who noted a number of reports following exposure to inhalation (fluranes) anaesthetic products, questioned whether or not scavenging systems were mandatory in veterinary practices and whether or not pregnant women are allowed to work with these products. Another member stated that the use of a scavenging system was mandatory but there are different standards of systems used. The member also stated that it was common for pregnant veterinary staff members to have contact with the product despite user warnings on the products advising against this. Officials explained that the spike in these reports during this period was likely to be due to the batch recall which was carried out for one of these products which reminded users of these warnings.

5.2.4 Members noted a high number of reports involving a tick and flea treatment causing sticky fingers. Officials explained that due to the nature of the product it is very difficult to wash off. They stated that the cases reported were non-serious and the product has extensive labelling advising owners on how to open the product and to apply using gloves. A member also reported that the MAH has provided

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practices with empty practice tubes so that vets can demonstrate the application of the product to owners.

- 5.2.5 Officials commented on the number of reports received involving tick and flea collars. In most cases the owners involved had not followed user warnings. Members suggested that VMD should send a reminder to vets to make sure they explain to owners all the user warnings.

Action Point 2

- 5.2.6 A member noted a report of suspected infection following exposure to a live bacterial and viral vaccine. Officials explained that these cases are rare but similar reports had been received previously. Officials also explained that Public Health England were reviewing these reports.

5.3 **Suspected adverse event reports in animals**

- 5.3.1 Members questioned the reason for the high reporting level for a specific tick and flea treatment. Officials explained that due to a recent social media campaign, owners were reporting more cases and also pointed out, that as the product is administered once every 3 months, owners are more likely to report any clinical signs occurring during that 3 month period, regardless of other possible causes. Officials explained the impact of social media is an emerging issue and is being discussed at an EU level.

5.4 **Environmental incidents**

- 5.4.1 Two environmental reports were received during this period. These reports were not discussed during the meeting.

6. VMD and VPC Open meetings

- 6.1. The Committee was provided with a report of the 2016 VMD Open meeting and asked for suggestions for presentations for the 2017 VPC Open meeting, to be held in conjunction with the VMD's Open meeting on Friday 29 September. Two members offered to speak about pharmacovigilance and a recent project to change prescribing categories for some medicines. The Chairman thanked them for their suggestions.

Action Point 3

7. UK exit from the EU

- 7.1. The Committee considered a presentation by the VMD's EU Exit Co-ordinator on issues arising from the UK's exit from the EU and how they are being dealt with by the VMD and Defra. The VMD would welcome views from members on any specific issues they would like to raise and suggestions for opportunities, and it was agreed that the topic would remain a regular item on the agenda.

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/>)

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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 Special Import Certificates/Special Treatment Certificates.

8.2.2.1. Following a question from a member, officials explained that import of a product under SIC/STC would not usually be permitted if a suitable alternative product became authorised in the UK and this is monitored by the VMD. However, there can be a delay before the authorised product is available on the market.

8.2.3 Report to the VPC on new MA applications granted.

8.2.4 Report from the Scientific Secretariat and the Biologicals Committee.

9. Horizon scanning: issues for consideration

9.1. Suggestions from members for future topics included the environmental impact of exit from the EU and GMO products, and an update on the effects of changes to distribution categories for products considered by the Committee in 2016.

Action Point 4

10. Any other business

10.1. A member informed the Committee that the Federation of Infection Societies Conference 2017 which will be meeting from 30 November to 2 December in Birmingham.

11. Date of next meeting

11.1. The next meeting of the VPC will be on 28 September 2017 at the VMD, Woodham Lane, New Haw, Addlestone, Surrey.