

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 22 May 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
Dr T Bleiker
Dr C Bryant
Prof F Burke
Prof D Cavanagh
Mrs M Chambers
Dr C Collins
Ms S Harmer
Dr E Kubiak
Dr T Marrs
Prof J Matthews
Mr R Morris
Mr D O'Rourke
Mr A Prail
Prof C Robertson
Mr P Scott
Mr J Sherington
Mr K Siddorn

Officials*

VMD

Dr N Garcia del Blanco
Mr G Davis
Dr G Diesel
Mr S Fletcher
Mr P Green
Dr J Kay
Dr N Renn

Others

Mr M Al-Arifi SFDA
Mr S Al-Shahrani SFDA

* 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 23 January 2014	3
4.	Matters arising from the minutes:	
4.1.	COT review of OP (Organophosphate) literature	3
4.2.	Needlesticks and best practice publication	3
4.3.	Declarations of interest	3
4.4.	Self-assessments	3
4.5.	Application for a variation: an update on progress	3
4.6.	VPC evaluation of VMD assessments	3
4.7.	VPC Annual Report	4
4.8.	VPC Triennial review	4
5.	COT review of OP (Organophosphate) literature	4
6.	Report from the Medical and Scientific Panel	4
7.	UK Pharmacovigilance Report for December 2013 to March 2014	5
8.	Items for information	6
9.	Any other business	6
10.	Horizon scanning	6
11.	Date of next meeting	7

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 welcomed Professor David Coggon, Chair, COT (Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment) and Saeed Al-Shahrani and Mohammed Al-Arifi, who work for the Saudi Food and Drug Authority.
- 1.3. Apologies for absence had been received from Dr Jefferson, Mr Lister and Professor Peters.
- 1.4. Professor Matthews and Mr O'Rourke took part via teleconference link.

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. Draft minutes of the meeting held on 23 January 2014

- 3.1. The draft minutes of the meeting held in January were agreed subject to the correction of a typographical error.

4. Matters arising from the minutes

4.1. Minute 4.1.3: COT review of OP (Organophosphate) literature

- 4.1.1 See agenda item 5, below.

4.2. Minute 4.3.3: Needlesticks and best practice publication

- 4.2.1 The paper 'Penetrating Injuries in Veterinary Practice' on which three Members have collaborated, has been submitted for publication. The Secretariat would advise the Committee when it was published.

Action Point 1

4.3. Minute 4.8.1: Declarations of interest

- 4.3.1 All Members had completed and returned their declarations of interest and the [website](#) had been updated.

4.4. Minute 4.9.1: Self-assessments

- 4.4.1 All members had completed and returned their self-assessments and the Chair would contact members.

4.5. Minute 6.3: Application for a variation ref no. 01452/2011: progress report

- 4.5.1 The Committee was informed that the applicant, having been advised of the points that needed to be addressed before the variation could be authorised, had withdrawn the application.

4.6. Minute 7.5: VPC evaluation of VMD assessments

- 4.6.1 A member was reviewing the procedure and would report back at a future meeting.

Action Point 2

PUBLISHED MINUTES
SUMMARY MINUTES

4.7. Minute 8.3: VPC Annual Report 2013

- 4.7.1 On 18 March the Minister agreed to the publication of the VPC annual report and wrote to the Chairman thanking him for the Committee's valuable work. Publication was announced by the Minister on 24 March.
- 4.7.2 The annual report was published on the [VPC website](#) and copies had been sent, for information, to the VMD's non-executive directors.

4.8. Minute 4.2: VPC Triennial review

- 4.8.1 The Committee was informed that, to address one of the recommendations in the report of the triennial review of the VPC, a report of the Committee's work during 2013 was presented for information to the VMD's Management Board on 6 March.
- 4.8.2 The Board had noted the report.

5. COT review of OP (Organophosphate) literature

- 5.1. Professor Coggon, Chair, COT (Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment) gave an interesting and informative presentation on the recently published [Statement on long-term neurological, neuropsychological and psychiatric effects of low-level exposure to organophosphates in adults](#) following the completion of its review of OP literature.
- 5.2. Professor Coggon responded to a number of questions covering, for example, the scope and funding of the research projects reviewed.
- 5.3. The Chairman thanked Professor Coggon for attending the VPC.

6. Report from the Medical and Scientific Panel

- 6.1. The report of the MSP's meeting on 23 April had been distributed to the Committee.
- 6.2. The MSP had considered the COT's 'Statement on long-term neurological, neuropsychological and psychiatric effects of low-level exposure to organophosphates in adults' and the accompanying [lay summary](#).
- 6.3. In the light of the COT's conclusions the MSP had considered its future. It had noted that since the introduction of improved delivery systems for OP sheep dips, the VMD had received very few suspected adverse event reports relating to OP sheep dips and those that had been received were historical.
- 6.4. The Panel had been in complete agreement that there would be little value in its retention, and it should recommend to the VPC that the MSP should be wound up.
- 6.5. Following its meeting the Chairman had asked the National Poisons Information Services for information on reports received by the NPIS of diazinon poisoning. The response had included the research paper 'National toxicovigilance for pesticide exposures resulting in health care contact – An example from the UK's National Poisons Information Service'. The Panel had considered these additional papers and agreed that there was nothing therein that would cause it to reconsider its recommendation.
- 6.6. The VPC endorsed the MSP's recommendation and advised the VMD accordingly.

PUBLISHED MINUTES
SUMMARY MINUTES

7. The UK Pharmacovigilance report

7.1. Introduction

7.1.1 The Committee considered and commented upon the Pharmacovigilance Report for December 2013 to March 2014, which was presented by the Head of the VMD's Pharmacovigilance Unit.

7.2. Suspected adverse event reports in humans

7.2.1 A large proportion of reports related to accidental self-injection and accidental exposure, via dermal, oral or ocular routes to ectoparasiticide products applied topically, but there had been no reports of any major concern.

7.2.2 Members questioned whether a report of a euthanasia product, used deliberately for the purposes of suicide, should have been recorded as an adverse event, and expressed concern that this report could potentially affect any statistical analysis conducted on the data. VMD Officials stressed that it was important to be aware of all reports relating to use of a product, including misuse or abuse, so that action could be taken if the VMD became aware of a trend or series of similar reports, and confirmed that such reports would not be allowed to affect future analyses.

7.2.3 A Member had questioned the number of reports relating to topically applied products and expressed concern that point of sale advice was not influencing pet owner behaviour to prevent such reactions. VMD Officials commented that in the latest surveillance period there were no severe reactions, or reactions with long lasting effects relating to these products and, based on the data available, the incidence of reactions to these products in relation to sales data was very low (<1 in 100 000 doses sold). Members expressed some concern that the legal category of some of these products may be GSL (General Sales List) and therefore there would be no point of sale advice. VMD Officials explained that products would be categorised as GSL only if the benefit-risk balance was appropriate. When a product's legal category was changed it was subject to closer monitoring as the frequency at which Periodic Safety Update Reports were requested was increased to match that of newly authorised products. VMD Officials agreed to look at the incidence figures for those products in the GSL category in comparison to the other categories.

Action Point 3

7.3. Suspected adverse event reports in animals

7.3.1 A Member commented on the high number of reports received for two vaccines authorised for use in dogs, both of which were frequently used in combination.

7.3.2 VMD Officials referred the Committee to a paper they had prepared summarising the high number of reports received for two recently authorised products for use in dogs.

7.3.2.1. A Member declared a personal, non-specific interest and took no part in the discussion except, at the Chairman's discretion, to answer questions. A member declared a non-personal non-specific interest.

7.3.2.2. VMD Officials stated that they had already taken action with the marketing authorisation holder over the way in which the product had been advertised. A Member commented that the high number of lack of efficacy

PUBLISHED MINUTES
SUMMARY MINUTES

reports could possibly be related to the use of the product in dogs which had not responded to treatment with other authorised products.

7.4. Environmental Incidents

7.4.1 No reports of environmental incidents had been received during the reporting period.

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/>)

8.1.3 2014 VMD and VPC Open meeting arrangements

8.1.4 VPC meeting and distribution dates for 2015

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

8.2.3 Report to the VPC on new MA applications granted

8.2.4 Report from the Scientific Secretariat and the Biological Committee

9. Horizon scanning: issues for consideration

9.1. Needlesticks

9.1.1 As the reports of needlestick incidents formed the majority of human suspected adverse events, the Committee asked whether there was any more that could be done to bring the issue more into the public domain.

9.1.2 It was recognised that publication of the paper 'Penetrating Injuries in Veterinary Practice' (see item 4.2, above) would help and it was suggested that, after publication, it could be publicised with a letter in the *Vet Record* and *BVN Journal*.

9.2. Environmental incidents

9.2.1 The Committee was concerned that there appeared to be no reporting of environmental incidents and asked for a summary of current environmental monitoring involving veterinary medicines.

Action Point 4

9.3. Product labelling

9.3.1 Members expressed concern about the legibility of product labels and the similarity of packaging for product ranges.

9.3.2 Officials agreed to consider a review of product packaging/labels, addressing 'Similarity and Clarity' and would report back at a future meeting.

Action Point 5

10. Any other business

10.1. Middle East Respiratory Syndrome (MERS)

10.1.1 A Member asked whether there had been any incidence of MERS in the UK and whether any products were under development.

PUBLISHED MINUTES
SUMMARY MINUTES

10.1.2 The incidence of the disease in people involved with camels was thought to be quite low and the VMD was unaware of any cases in the UK or any UK product development.

11. Date of next meeting

11.1. The next meeting of the VPC would be on 2 October 2014 at the VMD, Woodham Lane, New Haw, Addlestone, Surrey.