The Annual Report 2013
of the
Veterinary Products Committee
and its sub-committee, the
Medical and Scientific Panel

Contacts

Committee and Office Support Team

The Committee and Office Support Team (COST) at the Veterinary Medicines Directorate (VMD) provides administrative support to the Veterinary Products Committee (VPC) and its sub-committee, the Medical and Scientific Panel (MSP). Contact details are:

COST, VMD, Woodham Lane, New Haw, Addlestone, Surrey, KT15 3LS
tel: 01932 336911
email: vpc@vmd.defra.gsi.gov.uk
fax: 01932 336618

or

Colin Bennett (VPC Secretary)
Direct line: 01932 338490
email: c.bennett@vmd.defra.gsi.gov.uk

Pharmacovigilance

If you would like to report a suspected adverse event involving a veterinary medicinal product, an interactive adverse event reporting form for completion and submission online is available on the VMD website. Adverse event and environmental report forms can be downloaded from the same website. If you want further information please contact:

Pharmacovigilance Unit, VMD, Woodham Lane, New Haw, Addlestone, Surrey, KT15 3LS
tel: 01932 336911
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The Veterinary Products Committee

Background

The VPC was established in 1970 by an Order made under section 4 of the Medicines Act 1968 (the Act). On 30 October 2005 the Order was revoked by regulation 44(4) of, and Part 1 of Schedule 8 to, the Veterinary Medicines Regulations 2005 (SI 2005/2745) (the Regulations). However, regulation 28 of the Regulations provided that there should continue to be a VPC. The Regulations are revoked and replaced regularly. The current provision providing for the continued existence of the VPC is regulation 28 of the Veterinary Medicines Regulations 2013 (SI 2013/2033), which are available on the VMD website.

The Role of the VPC

The VPC is consulted by the Veterinary Medicines Directorate (VMD) where it requires advice on specific scientific issues relating to marketing authorisations (MAs), exceptional MAs, or animal test certificates (ATCs). Having considered that advice it is the VMD, not the VPC, that makes the decision whether to grant or refuse a MA or an ATC, grant one that is different from that which was applied for, vary it other than on the application of the holder, suspend or revoke it, or refuse to grant a variation applied for by the holder. Further information on the work of the VMD and the authorisation process is available on the VMD website.

The VPC also considers reports of suspected adverse events relating to veterinary medicines and provides advice to the VMD.

The VPC also considers appeals when the VMD intends to suspend a MA on the grounds of safety, quality or efficacy, or to refuse to grant a MA or an ATC, grant one that is different from that which was applied for, vary it other than on the application of the holder, refuse to grant a variation applied for by the holder, or revoke it. The Veterinary Medicines Regulations make provision for a fee to be charged for an appeal to the VPC.

Further information on our role and terms of reference is available on our website.

The annual report of the Veterinary Products Committee and its sub-committee 2013

Introduction by the Chairmen

Professor Bill Reilly
Chairman,
VPC

Welcome to the 2013 Annual Report of the Veterinary Products Committee.

The reduction in the number of applications for marketing authorisations on which we are asked for advice prompted our decision, in 2012, to reduce the number of our meetings from six to three. Also during 2012 we received a presentation on 'Pharmacovigilance and Signal Detection' which led, this year, to a revision to the way in which suspected adverse events in animals are reported to us. The 'animal' part of the pharmacovigilance report is now based on a Proportional Reporting Ratio system which has significantly reduced the number of reports for us to consider.

During the year, and in anticipation of the retirement of a number of members at the end of December, VMD Officials and I reviewed the expertise represented on the VPC and concluded that there was no longer a need for more than one member in any specialism. We also agreed that while there was no longer a need for a residues analyst, the Committee would benefit from the appointment of a practising suitably qualified person (SQP) with qualifications and experience in the supply of veterinary medicines for large animals. Our proposals were accepted by ministers and an appointments' exercise was completed in time to allow the successful applicants an opportunity to observe at our September meeting.

I am most grateful to all the members of the VPC and the Medical and Scientific Panel for their continued commitment and support. I would also like to express my thanks to officials at the VMD for their advice and, in particular, to the members of the Committee and Office Support Team for their support and assistance.

Dr Robert Jefferson
Chairman,
MSP

We agreed in 2012 not to meet again until the COT (Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment) had published its final report on its Review of Epidemiological Literature on Organophosphates and Health Outcomes Relating to the Nervous System. As a consequence, the MSP has held no meetings in 2013.

However, I too would like to thank the members of the Medical and Scientific Panel for their continued commitment and support, and for their willingness to continue as members of the Panel even though its future appears uncertain.

The annual report of the Veterinary Products Committee

Meetings

We held regular meetings in February and September. Summary minutes of our meetings are available on our website.

Our open meeting was held in September at the Animal Health and Veterinary Laboratories Agency (AHVLA), New Haw, Addlestone, Surrey, KT15 3NB and followed the VMD open meeting. Following an introduction by the Chairman, Professor Matthews gave an extremely interesting and informative presentation entitled *'Anthelmintic Resistance'*, which is available on our website.

A report of the 2013 open meetings has not been produced as a recording is available on the VMD website.

Applications considered by the VPC

During 2013 we examined evidence relating to an application for a marketing authorisation for a vaccine for use in cattle and we gave our advice to the VMD.

Evaluation of the VMD's assessments of applications for Marketing Authorisations

As part of the VMD's published standards, each year we carry out an evaluation of the VMD's assessment of new applications for marketing authorisations (MAs) made under the national and European procedures. Rather than considering final assessment reports, we consider the initial assessment reports which reflect the assessment of the VMD. We undertake our evaluation using the assessment report but, if necessary, we are able to examine particular studies in the supporting data.

The aim of the relevant published standard is to provide a measure of the quality of the science based decisions reached by the VMD assessors. Our assessment does not provide information on either the readability or presentation of assessment reports, which are assessed internally.

At our November 2012 meeting we had selected five products, one for use in sheep and goats, two for use in pigs, one for use in bees, and one for use in dogs. After discussing the individual assessments at our February meeting we agreed that our overall assessment of 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 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.

Our evaluation was included in the overall performance assessment of the VMD, published in its Annual Report and Accounts 2012/2013 and available on the VMD website.

At our September meeting we again selected five products, of which two were for use in cattle, one was for use in cattle and sheep, one was for use in pigs and one was for use in dogs. We agreed to provide the VMD with our individual assessments before the end of the year and discuss them at our first meeting in 2014.

Pharmacovigilance

We continued to monitor veterinary pharmacovigilance activities through the reports compiled by the VMD's Pharmacovigilance Unit, of:

- adverse events reports in animals involving veterinary medicines provisionally classified as serious
- adverse events reports in humans (defined as a reaction which is noxious and unintended and which occurs in a human being following exposure to a veterinary medicine), and
- environmental incidents associated with the use or administration of authorised veterinary medicines.

The VMD presented the Alert Group's conclusions following signal detection analysis of the 3438 animal reports received between November 2012 and July 2013. Details were also presented of the 118 reports concerning adverse events in humans received during this period. No environmental incidents were reported. Reports received from August to November 2013 will be considered at our meeting in January 2014.

Further information on the reports considered is available in the minutes of our meetings, available on our website.

Further information on pharmacovigilance is available on the VMD website.

Each year, the VMD publishes, in the *Vet Record,* a report of the suspected adverse events it has received. The most recent report, for 2012, was published in 2013 in Volume 173, Issue 23.

Reports from the Medical and Scientific Panel

We received a report from the Medical and Scientific Panel at our February meeting and noted its decision not to meet again until the COT (Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment) had published its final report on its Review of Epidemiological Literature on Organophosphates and Health Outcomes Relating to the Nervous System.

Sales of antimicrobial products used as veterinary medicines in the UK in 2012

We commented upon the VMD's draft Antimicrobial Sales Data Report for 2013, which detailed UK sales of antibiotic, antiprotozoal and antifungal products used as veterinary medicinal products in 2012. We raised a number of issues to which the VMD responded and we concluded that the report was a positive initiative and we supported its publication.

The report, which is available on the VMD website, is the 15th in a series initiated in response to recommendations made by the Advisory Committee on the Microbiological Safety of Food (ACMSF) and is an important part of the Defra (Department for Environment, Food and Rural Affairs) antimicrobial resistance strategy.

Access to information

The Freedom of Information Act 2000 requires all Non-Departmental Government Bodies to have an approved publication scheme in place. The VPC's publication scheme is available, free of charge, from the Committee and Office Support Team at vpc@vmd.defra.gsi.gov.uk and on the VPC website.

We received one Freedom of Information request in 2013 (ATI0273, concerning the sourcing of meat/meat products). The response is available on the VMD website.

All VPC reports, summary minutes of VPC and sub-committee meetings held since 2009, and all papers not subject to commercial confidentiality are available on the VPC website and free of charge from the Committee and Office Support Team. Copies of summary minutes of earlier VPC meetings are available from the Committee Support Team.

Membership

In April ministers agreed that Mrs Nicola Ackerman, Professor Clare Bryant, Professor Francis Burke, Professor David Cavanagh, Mrs Margaret Chambers, Dr Christopher Collins, Professor Jacqueline Matthews, Mr Robert Morris, Mr Andrew Praill, Mr Declan O'Rourke, Professor Colin Robertson and Mr John Sherington should be reappointed for a further four years from 1 January 2014.

On 16 July, following a recruitment exercise, Defra published an information bulletin announcing the appointment of Ms Sally Harmer, a practising suitably qualified person (SQP) with qualifications and experience in the supply of veterinary medicines for large animals (SQPs are authorised under UK legislation to prescribe and supply certain lower risk veterinary medicines, for example some wormers and other antiparasitic treatments) and Mr Stephen Lister, a veterinary surgeon specialising in poultry medicine, for a period of four years from 1 January 2014.

On 31 December Professor Diana Anderson, Dr Susan Bews, Mr Peter Cargill, Dr Ed Houghton and Dr Steven Kayne retired from the Committee.

A full list of members is available on the VPC website.

The next round of appointments will be held during 2015 and further information will be available on the VPC and Cabinet Office, Public Appointments, websites in due course.

Declarations of interest in the pharmaceutical industry

To avoid any public concern that commercial interests might affect our advice, the arrangements which govern relationships between members and the pharmaceutical industry and information on significant and relevant interests are on public record at the request of ministers. The circumstances in which we should declare an interest in the pharmaceutical industry are provided in the Code of Practice for Members of the VPC and its Sub-Committees. The Code, and a summary of our interests for 2013, is available on our website.

Cost

The cost of the VPC and its sub-committees in 2013 was £41,509. A summary of the 2013 costs and the costs 2009 - 2013 are given in Annex A.

The annual report of the Medical and Scientific Panel

Introduction

In 1994 the VPC recommended that a sub-committee, comprising medical and scientific experts, should be established to evaluate and co-ordinate research on organophosphate (OP) sheep dips in relation to possible human exposure. Further information is available on our website.

Meetings

At our meeting in November 2012 we agreed that we would not meet again until the final report of the COT (Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment's) Review of Epidemiological Literature on Organophosphates and Health Outcomes Relating to the Nervous System had been published. As the report was not published, no meetings were held in 2013.

Summary minutes of previous meetings are available on our website.

Membership

In April ministers agreed that, from 1 January 2014, Dr Robert Jefferson should be re-appointed as Chairman for a further two years and Dr Robin Kennett and Dr William (John) Pugh should be reappointed for a further four years.

On 31 December Professor Len Levy OBE retired from the MSP.

A full list of members is available on our website.

Declarations of interest in the pharmaceutical industry

To avoid any public concern that commercial interests might affect our advice, the arrangements which govern relationships between members and the pharmaceutical industry and information on significant and relevant interests are on public record at the request of ministers. The circumstances in which we should declare an interest in the pharmaceutical industry are provided in the Code of Practice for Members of the VPC and its Sub-Committees. The Code, and a summary of our interests for 2013, is available on our website.

Cost

The cost of the MSP in 2013 is included in the summary of the costs of the VPC and its sub-committees at Annex A.

Annex A: Summary of costs of the VPC and its sub-committees 2013

For each meeting they attend, members are entitled to claim a preparation fee of £76 and an attendance fee of £148 (the Chairman's fees are £94 and £185 respectively). In addition, members can claim an extra preparation fee of £76 for each additional item on which they are asked to lead at any one meeting. Travel and subsistence is also payable within the Defra guidelines.

The cost of the VPC and its sub-committees in 2013 was £41,509. A summary of the 2013 costs and a comparison of costs 2009 - 2013 is shown below.

	Meetings held		Travel & subsistence		Preparation & attendance		Other costs		TOTAL	
	2012	**2013**	2012 £	**2013 £**	2012 £	**2013 £**	2012 £	**2013 £**	2012 £	**2013 £**
VPC[1]	6	**2**	34,550	**24,685**	26,322	**15,048**	4,438	**1,776**	65,310	**41,509**
Appraisal Panel[2]	0	**0**	662	**0**	0	**0**	0	**0**	662	**0**
MSP[3]	2	**0**	3,265	**0**	1,902	**0**	75	**0**	5,241	**0**
TOTAL	8	**2**	38,477	**24,685**	28,224	**15,048**	4,512	**1,776**	71,213	**41,509**

[1] including the cost of the open meeting
[2] the Appraisal Panel was wound up after its meeting in October 2011
[3] the Medical and Scientific Panel has not met since November 2012