#447719

Summary of the Open Meeting for the Veterinary Medicines Regulations Public consultation

Held on 5 February 2013 at the Veterinary Medicines Directorate

Present:	VMD	Paul Green – Director of Operations Nick Renn – Head of Legislation John Millward – Head of Inspections and Investigations Gavin Hall – Head of Licensing Administration Branch Jo Cawthorne – Legislation Team Ravinder Sagoo – Legislation Team Denise Burge – Legislation Team Lee Grist – Quality Management and Design
External attendees:		See attached list

Paul Green welcomed the attendees and outlined the purpose of the meeting. Nick Renn then gave a presentation highlighting the proposed changes to the Veterinary Medicines Regulations (VMR) and reminded the meeting that the consultation will close on 18 February 2013. A copy of the presentation is available at:

http://www.vmd.defra.gov.uk/pdf/vmr13/OpenMeetingPresentation.pdf

After the presentation everybody present was invited to ask questions and make comments. These are summarised below under each proposed change it relates to.

Amend the provisions relating to importation and possession of unauthorised veterinary medicines (Change 1).

Q: Clarification was sought on the meaning of the amendment to Regulation 25(1) from “to import” to “being concerned in the importation of”.

A: If an inspector finds evidence that shows someone has been involved in the importation of unauthorised veterinary medicines, the proposed change to Regulations 25(1) and 26(1) will allow the VMD to take action.

Q: Are the inspectors relying on people providing such evidence? It was felt unlikely that people would willingly supply such evidence.

A: This is dealt with by the offence of ‘possessing’ an unauthorised veterinary medicine. A person may be in possession of an unauthorised medicine but not have any recorded evidence of being concerned with the importation. The VMD will act on evidence it receives and encourages anyone with information on illegal activity to come forward.

Amend Regulation 35 (1) (g) to permit an inspector to seize anything they believe (with reasonable grounds to be a veterinary medicine (Change 2).

No comments discussed during the meeting.

Introduce a clause within Schedule 3 to allow the removal of a VPP from the register if the practice is not up to the required standards (Change 3).

Q: Clarification was sought on whether it is the VMD's intention to close down a practice if necessary?

A: The VMD's published enforcement strategy sets out that the VMD will first enter into correspondence and then would only consider whether enforcement action was appropriate if the correspondence did not achieve any improvement. In the case of any inspected premises, the owner would be given verbal feedback during the inspection and this would be followed with a written inspection report. Only as a last resort would the VMD seek to remove a veterinary practice should it continue to be non-compliant.

Q: Does the RCVS also inspect veterinary practices and do they have the powers to shut them down?

A: The VMD and the RCVS have an agreement whereby the RCVS informs the VMD of any critical deficiencies which we will then investigate. The VMD and the RCVS routinely share information.

Clarification of fees for applications for Marketing Authorisations relating to "bio-similar" products (Change 4).

No comments discussed during the meeting.

Introduce a fee for the renewal of a registration of a homeopathic remedy (Change 5).

No comments discussed during the meeting.

Amendment of category descriptions for extensions to Marketing Authorisations (MA) (Change 6).

No comments discussed during the meeting.

Simplify the fees for appeals to the Veterinary Products Committee (VPC) (Change 7).

No comments discussed during the meeting.

Removal of the fee for additional member states on application for a MA relating to a Parallel Import (Change 8).

No comments discussed during the meeting.

Reduction to fees for Decentralised applications for MAs where the UK is Concerned Member State or for recognition of a product authorised in another member state (Change 9).

No comments discussed during the meeting.

Rebalancing of fees for manufacturers and wholesale dealers (Change 10).

No comments discussed during the meeting.

Fee increase for inspections of veterinary practice premises (Change 11).

Q: Clarification was sought on whether the VMD is aiming to recover 100% of costs incurred by the Inspections and Investigations Team.

A: It was confirmed that 100% of costs need to be recovered for the Inspections and Investigations Team.

Q: How had a 40% increase for veterinary practice inspections been worked out?

A: When the VMD started inspecting veterinary practice premises in 2009 the fee set was based on an estimate of how long each inspection would take. Following the first round of inspections it became apparent through work recording figures that the preparation for the inspection, the actual inspection, preparing the report and travel to and from the premises was rather more costly on the VMD's time than was being charged.

Changes to the fee structure for inspections of Manufacturers and Distributors of Feedingstuffs and Suitably Qualified Person (SQP) Premises (Change 12).

Q: There was support of the move to risk-based inspections but concern about the associated £70,000 increase in fees to industry.

A: Again the VMD's work recording data indicated that the fees being charged did not cover the costs of the inspections and so an increase is required. Nevertheless, the move to risk-based inspections will have an immediate impact on industry due to the increase of fees but over time the compliant organisations will be charged less than non-compliant organisations which will be inspected more frequently.

Q: Is the inspection of an SQP premises more detailed than the inspection of a veterinary practice premises as the proposed fee for an SQP premise is £272 more than the proposed fee for a veterinary practice?

A: The VMD asked for this to be added to the formal consultation response so that it can be investigated and addressed.

Increase for the application and subsequent annual fee for fees relating to manufacturers and distributors of feedingstuffs in Northern Ireland (Change 13).

No comments discussed during the meeting.

Changes to the fees applied by the RCVS for the registration of VPPs (Change 14).

No comments discussed during the meeting.

General questions

Q: How does the VMD fund advice given on non-authorised products? Are there any risks involved in providing short answers to such requests?

A: If the request for advice is straight forward we will answer and no fee is charged. If the request requires a more detailed answer and involves a number of teams and expertise then a fee will be charged of £885.

If non-authorised products appear on the market that should have full marketing authorisations, these are dealt with by the VMD Enforcement Team. Again if anybody knows of unauthorised veterinary medicines being sold then the evidence should be provided to the VMD.

Q: Surprise was expressed at the ban on advertising including horse anthelmintics (POM-VPS medicines) to owners and keepers of horses.

A: This relates to the definition of 'general public' which is used in the VMP Directive 2001/82, but not defined. The VMR refers to "professional keepers of animals" rather than "general public". The EU Commission was not in agreement with the VMD's interpretation. On considering the rules in the VMR 2011, it was apparent that people who keep horses for their own pleasure are not professional keepers of horses and so it will no longer be permissible to advertise horse worming medicines to owners and keepers of horses.

Q: Who checks the VMD to ensure costs are accurate?

A: The VMD undergoes internal and external audits. The Annual Report and Accounts are signed off by the NAO and laid before parliament each year and are then published for anybody to read. The VMD is not benchmarked against similar agencies in the UK, but is benchmarked against other agencies in the EU.

Q: A point was raised on Animal Test Certificates (ATCs). This was discussed at the VMD Open Meeting in 2012 and there it was said there would be more discussion during the consultation of the regulations, however there is nothing regarding ATCs in this consultation.

Directive 2010/63/EU on the protection of animals used for scientific purposes is currently being transposed by the Home Office into new Regulations which are due to replace the Animal Scientific Procedures Act (ASPA). We are aware that following

a public consultation the Home Office was due to lay the new Regulations before Parliament during January 2013 but we understand that this has been delayed. The VMD is in regular contact with the Home Office.

There was some discussion on MRLs set by the dairy industry and those set by VMD. It was agreed that the issue needs to be discussed but this was not the forum.

Q: Information on the unsupportive comments received so far to the consultation was requested

A: These will be published with all comments received at the end of the consultation exercise.

Q: Details of the time lines of when the regulations will come into force was requested.

A: When the consultation has ended and all comments have been considered, the Impact Assessment will need to be amended to reflect any changes. The IA then needs to be signed off by the Defra Chief Economist and two Defra committees plus two other government gateways. There is no definite date but it is planned that the new regulations will come into force in October 2013.

Concluding remarks and close of the meeting.

Nick Renn thanked everyone for attending and for providing a useful debate and discussion on the issues proposed for consultation. He invited further comments by 18 February 2013.

Veterinary Medicines Directorate
February 2013

External attendees

Jim Bell	MSD
Mary Passmore	MSD
Phil Sketchley	NOAH
Donal Murphy	NOAH
Louise Lacey	Bayer
Caroline Griffin	Vetoquinol UK Limited
Stephen Dawson	AMTRA
Sandra Nicoll	Abbott Animal Health
Jane Parry	Merial Animal Health Ltd
Paul Cooper	Assentra Limited
Ian Scott	AHDA (UK) Ltd
Victoria Marshall	Boehringer Ingelheim Ltd
Anna Paonne	MedicAnimal Ltd
Frederic Altenbourger	MedicAnimal Ltd
Andrew Bucher	MedicAnimal Ltd
Anthony Roberts	RCVS
Peter Jinman	RCVS
Edward Wood	Sinclair Animal & Household Care (Beaphar)
Sally Everitt	BSAVA
Rebecca Hubbard	Veterinary Times
John Alborough	JCA Media Group Ltd
David Tibbles	Pfizer
Scott Price	Pfizer
Edward Ferguson	Pfizer
Den Leonard	Lambert Leonard and May
Tara Elliott	Summit Veterinary Pharmaceuticals Ltd
Owain Hughes	Summit Veterinary Pharmaceuticals Ltd
Zuber Mitchla	Allen & Overy LLP