Veterinary Medicines Directorate
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Overview of the past year and a forward look

Nick Renn
Head of Legislation
Veterinary Medicines Regulations
Revision of EU law
Red Tape Challenge
Cascade
Prescription tampering
Poster campaign
Veterinary Medicines Regulations: Changes introduced in 2013

Public Consultation in January 2013 for 6 weeks

Asked for views on:
- some minor changes to law
- changes in fees

Held an open meeting on 5th February:
- Presented the proposed changes
- listened to concerns of stakeholders
Veterinary Medicines Regulations Changes introduced in 2013 (ii)

Post consultation:

1. Amended the provisions relating to importation and possession of unauthorised veterinary medicines (Regulations 25(1) and 26(2)).

2. Permit an inspector to seize anything they believe (with reasonable grounds) to be a veterinary medicine (Regulation 25(2)).

3. Allow the removal of a veterinary practice premise from the register if the practice is not compliant (Schedule 3, paragraph 8(3)5).
Veterinary Medicines Regulations
Changes introduced in 2013 (iii)

Not part of the consultation:

Advertising:

1. No person may advertise antimicrobials to professional keepers of animals (Regulation 11 (4)).

2. POM-VPS medicines can no longer be advertised to keepers of horses (Regulation 11 (5)).
Veterinary Medicines Regulations
Changes introduced in 2013 (iv)

Fees for SQP premises:

Proposed increases and restructure to annual fee plus an inspection fee
Objections during consultation
Left 2011 fees in place

Into force on 1 October 2013:
Track-change version of 2011 to compare Revised Guidance Notes and old versions with t/c
Veterinary Medicines Regulations
The next steps

Now reviewing all inspection fees

Changes will be introduced once concluded via an Amending Statutory Instrument relating only to Schedule 7

For the medium term:

Fees will be kept under review
No immediate plans to consider other changes
Review of EU law on veterinary medicines

Revision of Directive 2001/82 on veterinary medicinal products

VMD held an open meeting in January 2010, where Commission presented

General objectives

- To increase availability of veterinary medicinal products
- To improve functioning of the internal market
- To decrease administrative burden
...while not compromising public and animal health
Review of EU law on veterinary medicines (ii)

The Commission started the process in 2010

Public Consultation – we responded to after listening to views of stakeholders

Published on Europa November 2011:
http://ec.europa.eu/health/veterinary-use/rev_frame_index_en.htm

Current information is that the proposal for the revised law will be available in April 2014
Review of EU law on veterinary medicines (iii)

October meeting with DG SANCO

CAVEAT: CONTENTS MAY CHANGE FOLLOWING INTER-SERVICE REVIEW

To improve availability of veterinary medicines, many of the changes relate to authorisation processes:

- Access to European central authorisations easier
- National, mutual and de-centralised retained
- Minor species and bees to have separate provisions

Data protection extended – specific provisions for bees
Clinical trials: Harmonisation of data requirements
Review of EU law on veterinary medicines (iv)

Product labelling: pictograms on packaging

Sunset clause will be removed

Measures to ban antibiotics if supported by evidence

Cascade prescribing rules – bee products from outside EU
- restrictions on some antibiotics

Competent Authority must operate a “help-desk”
Review of EU law on veterinary medicines (v)

Member States must allow internet sales, but under own rules

Publicly accessible list of internet retailers

No decoupling of prescribing and supply
  – “never the Commission’s intention”

Others in scope:
Advertising may change: definition of general public?
Horse medicines – non-food status?
Red Tape Challenge

Part of the Government’s deregulation agenda

Agriculture theme ran over the summer months

13 comments on VMD issues

Changing policy on clinical trials to speed up the process

Use to strengthen negotiating position for new EU law

Cabinet Office and Defra to publicise outcome
Prescribing: cascade questionnaire

To inform our negotiating position for the review of EU law
On-line survey from May to 12 July 2013
230 responses

Viewed cascade as being essential for animal welfare
Obtaining owner’s consent viewed as onerous
Call for specific guidance; eg domestic chickens

We are currently completing the draft report

Publication due during the summer.
Prescribing: Misuse of prescriptions

Complaints: suppliers receiving altered prescriptions
March 2012 asked all vets in UK for evidence on the types of misuse and the extent.
23 responded: changing quantities/dates
   forging vets signatures
   forging whole prescriptions

Summary report on VMD website
As a result: On-line reporting form
   Changed our guidance
So far 351 cases, with 34 referred for investigation as fraud
Is Your Veterinary Medicine Legal?

Veterinary medicines purchased and used in the UK must be authorised by the Veterinary Medicines Directorate (VMD).

Buying veterinary medicines on the internet?

There are restrictions on the importation of some medicines.

**BE CAUTIOUS:**
- the seller must be based in the UK;
- the products must be UK authorised medicines;
- if not an [AVM-GSL*] product, the person selling the medicines must be a vet, pharmacist or SQP**;
- the seller must ask for a prescription if the medicine requires one.

*It is an offence to alter a written prescription unless authorised to do so by the person who signed it*

To help identify where to buy legal medicines the VMD has set up an Accredited Internet Retailers Scheme (AIRS). Accredited sites will have this logo displayed on their website:

For further information, or to see a list of UK authorised medicines and Accredited Internet Retailers, contact the VMD or visit our website [www.vmd.defra.gov.uk](http://www.vmd.defra.gov.uk)

*AVM-GSL* – a category of veterinary medicine that anyone can sell

**Suitably Qualified Person – a person who is trained and qualified to sell POM-VPS and NFA-VPS medicines
Thank you