

# VETERINARY MEDICINES REGULATIONS 2005

## The Law - What has changed and why ?

AMTRA SQP SEMINARS 2006



ASSURING THE SAFETY, QUALITY AND EFFICACY  
OF VETERINARY MEDICINES



## The Law - What has changed and why ?

Background	why new legislation
Key Changes	impact on SQPs
Timing	future plans
Other Issues	distribution category review



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## The Law - What has changed and why ?

### Background

- Medicines Act 1968
- + 50 amending SIs
- Marsh Report
- Competition Commission Report
- 2001/82 reviewed
- 2004/28



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## The Law - What has changed and why ?

### Background

- Start again
- Consult informally - meetings, concept notes
- Consult formally - twice!
- Still listening (and consulting)



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## The Law - What has changed and why ?

### Key changes

- Disapply Medicines Act 1968
- One piece of legislation
  - Written in plain English
  - Updated annually
  - Opportunity to keep legislation relevant
  - Fees included



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## The Law - What has changed and why ?

### Key changes

#### EU Directive requirements

- All food producing animal medicines POM
- Veterinary prescription “any prescription for a veterinary medicinal product issued by a professional person qualified to do so in accordance with applicable national law”
  - Prescribing not restricted to veterinary surgeons
  - No prior diagnosis required



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## The Law - What has changed and why ?

### Key changes

#### Distribution categories

- Allowed UK to maintain distribution system by implementing Marsh and CC recommended tiered POM system
- POM = POM-V
- P – deleted: products become POM-V, POM-VPS or NFA-VPS
- PML = POM-VPS or NFA-VPS
- GSL = AVM-GSL



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## The Law - What has changed and why ?

### Key changes

#### Distribution

#### SQPs

- Must pass exam
- Must register with recognised body
- May sell POM-VPS and NFA-VPS products for which trained, from registered premises
- May receive advertisements about POM-VPS
  - anyone can for NFA-VPS products



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## The Law - What has changed and why ?

### SQP - Prescriptions

- May be oral or written (unlikely)
- If written must include following information
  - (a) the name and address of the person prescribing the product;
  - (b) the qualifications enabling the person to prescribe the product;
  - (c) the name and address of the owner or keeper;
  - (d) the species of animal, identification and number of the animals;
  - (e) the premises at which the animals are kept if this is different from the address of the owner or keeper;
  - (f) the date of the prescription;
  - (g) the signature or other authentication of the person prescribing the product;
  - (h) the name and amount of the product prescribed;
  - (i) the dosage and administration instructions;
  - (j) any necessary warnings;
  - (k) the withdrawal period if relevant.



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## The Law - What has changed and why ?

### SQP Registration Bodies

SoS approval only if the body

- Has an adequate training programme
- Has adequate standards in deciding whether or not to register someone as an SQP
- Requires SQPs to follow Code of Practice
- Maintains a programme of CPD for persons registered with it
- Operates an appeal system against non-registration or removal



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## The Law - What has changed and why ?

### Key changes

#### Distribution

- Vet may dispense against another vet's prescription
- Vet may supply to animals not under his care, except POM-V products



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## The Law - What has changed and why ?

### Key changes

#### Distribution

- Breaking bulk
  - Vet - any product to any level
  - Pharmacist - any product to any level, except injectables
  - Wholesale Dealer and SQP - only outer packing to facilitate supply if instructions on use readily available



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## The Law - What has changed and why ?

### Key changes

#### Distribution

- Internet/Postal supply allowed provided permitted supplier applies statutory controls i.e.
  - prescription available where necessary (e.g. POM-V products)
  - provides advice on safe administration
  - advises as necessary on warnings or contra-indications
  - is satisfied that person is competent to use product safely and intends to use it for which it is authorised



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## The Law - What has changed and why ?

### Key changes

#### Horse Medicines

- Medicines can be authorised for non-food producing horses
- Horses not for human consumption (in horse passport) can be regarded as pets under the cascade



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## The Law - What has changed and why ?

### Key changes

#### Advertising POMs

- POM-V to vets, pharmacists and professional keepers of animals
- POM-VPS to vets, pharmacists, SQPs, other veterinary healthcare professionals, professional keepers of animals, owners or keepers of horses

Price lists are exempted from the advertising ban



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## The Law - What has changed and why ?

### What is a price list?

A list of product names and prices that may also include -

- Images of the products
- A summary of the use of the products e.g. "Palatable wormer for dogs"
- Links to electronic SPCs

**BUT**

**All products must be treated in the same way so that no product is promoted above another e.g. same size image, use of colour**



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## The Law - What has changed and why ?

### Key changes

Wholesale dealers may only advertise human medicines to vets, including in a price list, if -

- List is sent on request
- Vet has specified type of human medicine
- List states product does not have a veterinary MA and can be used only under cascade
- List contains only human medicines that can be used legally under the cascade



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## The Law - What has changed and why ?

### Key changes

Available information

- Summary of Product Characteristics on VMD website
  - up to date
  - NOAH compendium still available
- UKPARs
  - summary product assessment reports
  - for products authorised after 30 October 2005
  - on VMD website
- SQPs
  - list of registered persons and premises



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## The Law - What has changed and why ?

### Key changes

#### Enforcement

- Possession of unauthorised medicine becomes a criminal offence
- Abuse of the cascade becomes a criminal offence
- Improvement Notices
- Seizure Notices
  - notices will be published
- Checks



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## The Law - What has changed and why ?

### Key changes

#### Record Keeping

- Batch recording for companion animal medicines
  - use already available records
  - note batch number and date first used



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## The Law - What has changed and why ?

### Timing

- Regulations came into force 30 October 2005
- Transitional periods
  - labelling changes
  - SQP training
- Annually revoke and re-make
  - new fees
  - consider other changes



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## The Law - What has changed and why ?

### Other Issues

#### Distribution Category Review

- Make case for change
- VMD/VPC consider
- 3 month consultation on proposed changes



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## The Law - What has changed and why ?

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