

# VETERINARY MEDICINES REGULATIONS 2005

## The Law - What may change from October 2006

AMTRA SQP SEMINARS 2006



ASSURING THE SAFETY, QUALITY AND EFFICACY  
OF VETERINARY MEDICINES



## The Law - What may change from October 2006

### Why change so soon ?

- Questions from vets, pharmacists and SQPs
- Feedback from others
- Annual fee increases



ASSURING THE SAFETY, QUALITY AND EFFICACY  
OF VETERINARY MEDICINES



## The Law - What may change from October 2006

### Background

- Consult informally - SQPs
- Consult formally - published 17 March
- 12 weeks - ends 9 June



ASSURING THE SAFETY, QUALITY AND EFFICACY  
OF VETERINARY MEDICINES

## The Law - What may change from October 2006

### Fees Background

- Annual inflation increase
- Final stage of review of licensing fees
- Consult on new menu system for applications for new MAs



ASSURING THE SAFETY, QUALITY AND EFFICACY  
OF VETERINARY MEDICINES

## The Law - What may change from October 2006

### Key issues for SQPs

- How SQPs keep their qualification
- Transitional period
- What is 'present'
- How does an SQP give 'critical advice'
- Distance supply/delivery



ASSURING THE SAFETY, QUALITY AND EFFICACY OF VETERINARY MEDICINES

## The Law - What may change from October 2006

### Key issues for SQPs

How SQPs keep their qualification

- Essential that all SQPs are seen to be 'a professional person qualified to prescribe veterinary medicinal products in accordance with UK national law'
- AMTRA is responsible for raising the standards



ASSURING THE SAFETY, QUALITY AND EFFICACY OF VETERINARY MEDICINES

## The Law - What may change from October 2006

### Key issues for SQPs

Transitional periods permitted for

- SQPs to upgrade their qualification
- Marketing authorisation holders to bring their packaging into line
- Advertisers to amend their advertisements (but should all be correct by now)



ASSURING THE SAFETY, QUALITY AND EFFICACY OF VETERINARY MEDICINES

## The Law - What may change from October 2006

### Key issues

What is present?

- In 2005 Regs, requirement for SQP to be present when product was supplied
- Informal consultation responses -not practical
- In 2006 Regs, new requirements for both **prescribing** and **supplying**



ASSURING THE SAFETY, QUALITY AND EFFICACY OF VETERINARY MEDICINES

## The Law - What may change from October 2006

### SQP - Prescribing for POM-VPS

*The act of considering the specific circumstances and deciding on a recommendation*

Only an SQP can prescribe and must take the following actions:

- The SQP must be satisfied that the purchaser
  - intends to use the product for an authorised use - and
  - is competent to use it safely - and then
- The SQP must advise the purchaser of any necessary warnings in relation to the product supplied



ASSURING THE SAFETY, QUALITY AND EFFICACY OF VETERINARY MEDICINES

## The Law - What may change from October 2006

### How can an SQP do this in practice?

- For each SQP to decide - must be able to demonstrate and justify their actions to an inspector when required
- The SQP must carry out these actions in **every** case - cannot delegate



ASSURING THE SAFETY, QUALITY AND EFFICACY OF VETERINARY MEDICINES

## The Law - What may change from October 2006

### SQP actions

The SQP must engage with the customer

Possible options include:

- Orally and face to face
- Orally over a telephone
- Electronically
  - fax
  - e-mail
  - over the internet



ASSURING THE SAFETY, QUALITY AND EFFICACY OF VETERINARY MEDICINES

## The Law - What may change from October 2006

The physical presence of the prescriber on the registered premises is not required BUT the actions **MUST** always be carried out



ASSURING THE SAFETY, QUALITY AND EFFICACY OF VETERINARY MEDICINES

## The Law - What may change from October 2006

### Supply/delivery

- It is the legal responsibility of the SQP to ensure that any person carrying out a supply on their behalf is competent to do so
- Any errors that are made by that person remain the responsibility of the SQP



ASSURING THE SAFETY, QUALITY AND EFFICACY OF VETERINARY MEDICINES

## The Law - What may change from October 2006

### SQP supplying NFA-VPS

- The same actions must be carried out as for POM-VPS but there is no requirement for a prescription



ASSURING THE SAFETY, QUALITY AND EFFICACY OF VETERINARY MEDICINES

## The Law - What may change from October 2006

### Summary

The SQP is legally responsible for

- prescribing POM-VPS product
- carrying out the necessary safety actions
- ensuring the appropriate POM-VPS or NFA-VPS product is supplied and
- ensuring that others supplying the product are competent to do so



ASSURING THE SAFETY, QUALITY AND EFFICACY OF VETERINARY MEDICINES



## The Law - What may change from October 2006

### Contact details

John Millward / John FitzGerald / Heather Oliver

VMD

Woodham Lane New Haw

Addlestone

Surrey, KT15 3LS

Tel: 02476 849620 / 01932 338303 / 338316

E-mail: [j.millward@ami.gov.uk](mailto:j.millward@ami.gov.uk)

[j.fitzgerald@vmd.defra.gsi.gov.uk](mailto:j.fitzgerald@vmd.defra.gsi.gov.uk)

[h.oliver@vmd.defra.gsi.gov.uk](mailto:h.oliver@vmd.defra.gsi.gov.uk)

[www.vmd.gov.uk](http://www.vmd.gov.uk)



ASSURING THE SAFETY, QUALITY AND EFFICACY OF VETERINARY MEDICINES

