



# Availability of Veterinary Medicines

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ASSURING THE SAFETY, QUALITY AND EFFICACY  
OF VETERINARY MEDICINES



# Topics

- Who we are/what we do
- Overview of legislation
- Availability of medicines:
  - Cascade
  - Import certificates
  - Schedule 6 products



# Who we are

- Executive agency of Defra
- Three main areas: Authorisations, Residues, Operations
  - Authorisation of VMPs
  - Inspection of manufacturers, wholesalers and retailers of VMPs (only)
  - Pharmacovigilance
  - Surveillance for residues of VMPs and illegal substances in animals and animal products
  - Provision and implementation of policy advice on VMPs
  - Management of the Research & Development programme linked to VMPs
  - Co-ordination of Defra's work on antimicrobial resistance via the Defra Antimicrobial Resistance Coordination (DARC) Group



# Legislation in the EU/UK

## EU Directive 2001/82 as amended on veterinary medicines

- Sets out the controls on the manufacture, authorisation, marketing, distribution and post-authorisation surveillance of veterinary medicines applicable in all Member States
- The Directive provides the basis for the UK controls on veterinary medicines, which are set out nationally in the Veterinary Medicines Regulations



# Legislation in the EU

- Directive 2001/82 is undergoing revision

Key points:

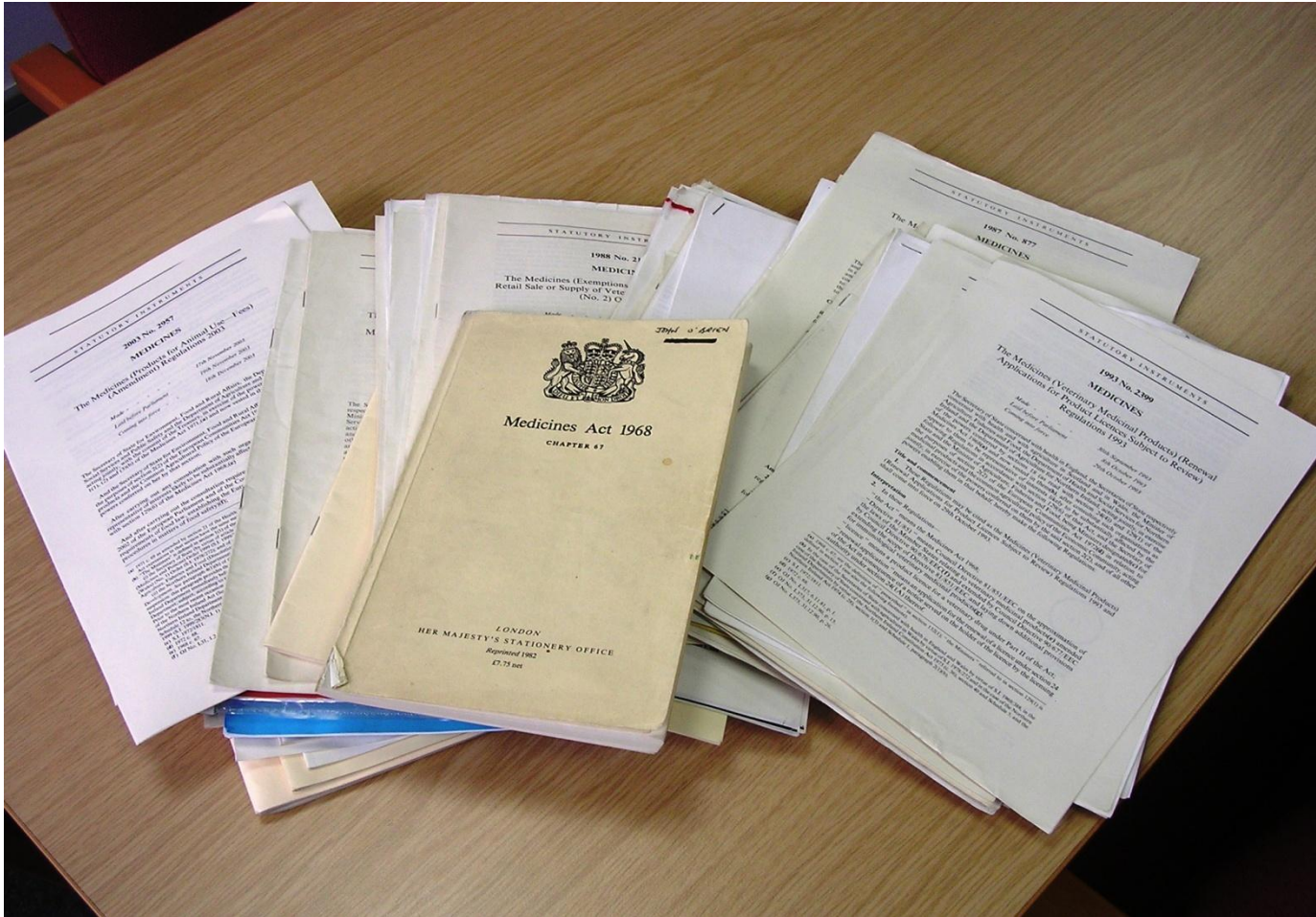
- Availability of veterinary medicines
- New needs/new challenges
- Prescribing cascade
- Authorisation procedures



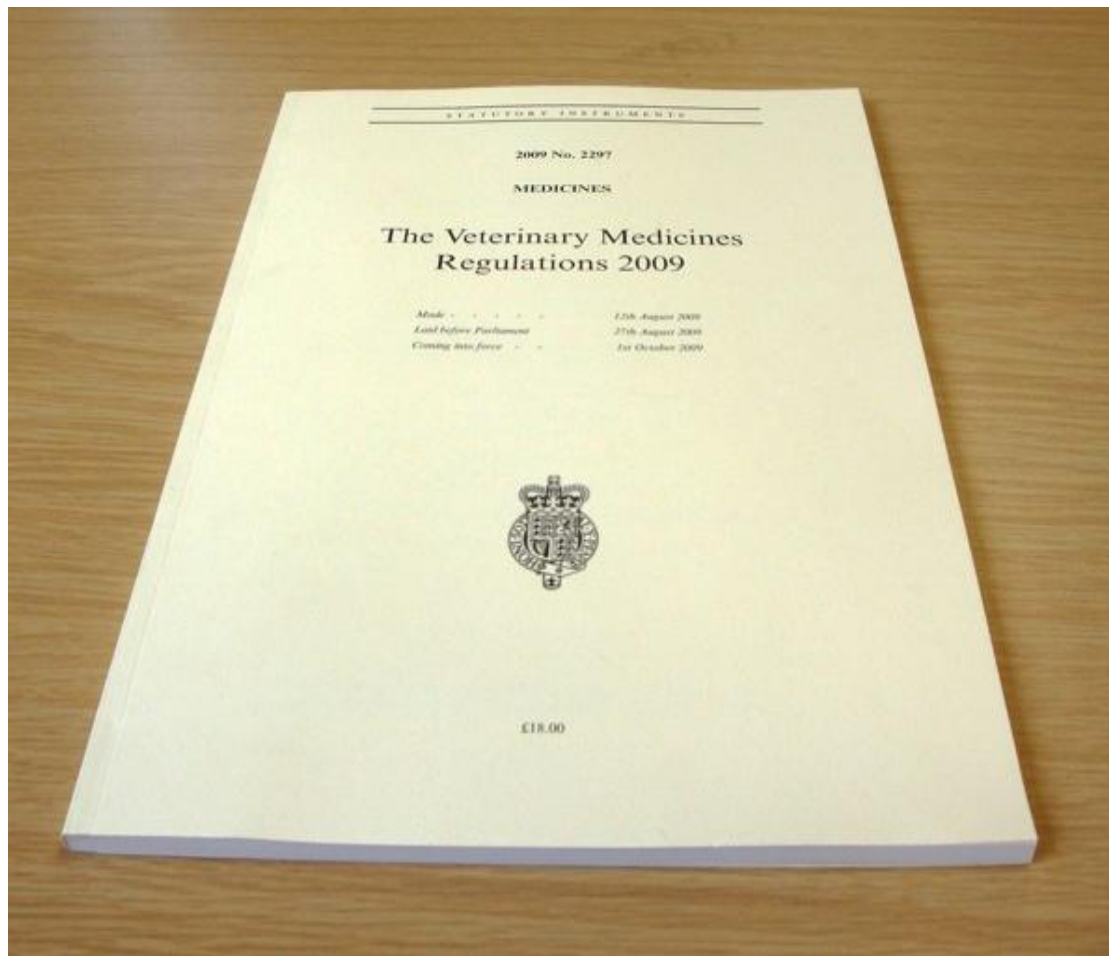
# Legislation in the UK

- Revoked and remade annually since 2005  
– but skipped 2010
- Public consultation and impact assessment on proposed changes carried out before policy changes are made
- Accompanied by guidance notes (under revision)





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2009 No. 2297

MEDICINES

# The Veterinary Medicines Regulations 2009

Made . . . . .	13th August 2009
Laid before Parliament . . . . .	27th August 2009
Coming into force . . . . .	1st October 2009



€18.00



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# Cascade

- There are some animal diseases/conditions for which no VMP is authorised within the UK as a result of the much smaller market for veterinary pharmaceuticals
- Lack of availability for minor use/minor species recognised by European Commission
- The 'Cascade' is a legal framework for veterinary surgeons to use when selecting a different medicine



# Cascade

- VMR – Schedule 4 (1):

Level 1	VMP authorised in the UK for another species, or another condition in the same species
Level 2	Human medicine authorised in the UK VMP authorised in another member state
Level 3	Extemporaneous preparations by veterinary surgeon, pharmacist or specials' manufacturer

- After cascade options are exhausted, a vet can consider importation of medicines from outside EU





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# Importation of veterinary medicines

- Only a veterinary surgeon registered with the RCVS can apply to an import certificate to treat animals under his/her care
- The veterinary surgeon has the responsibility for making the clinical decision to import a suitable medicine
- Strong recommendation to report adverse reactions



# SIC Scheme

- Special Import Certificate (SIC):
  - To import a suitable veterinary medicinal product authorised in another EU member state
- Responsibility of the vet to justify use according to the 'cascade'
- No SIC certificate granted if there is a suitable UK product available (veterinary or human)



# STC Scheme

- Special Treatment Certificate (STC):
  - To import a suitable veterinary medicinal product authorised outside the EU or an EU authorised human product
  - In exceptional cases, importation of a product from within Europe or a Third Country that does not have a full Marketing Authorisation
- Again, responsibility of the vet to justify use according to the 'cascade'
- No STC certificate granted if there is a suitable UK or EU veterinary product available



# WDICs

- Wholesale Dealers Import Certificate (WDIC):
  - Allows importer to hold and supply a product to the holder of a valid SIC or STC
- Must have a Wholesale Dealers Authorisation or be a registered pharmacist
- Need a supporting SIC/STC before approval of an initial WDIC



# Application

- Can apply on-line via our website or by post
- Products only made available on-line after assessment of an initial SIC/STC
- Products may be removed from online application:
  - If a UK authorised product has become available
  - If the VMD wishes to monitor the justifications for importation
  - New data becomes available that indicates that the product is no longer suitable for online application



# Processing

- Assessment of SIC/STCs usually involves:
  - Check that there is no suitable alternative products available in the UK (or other EU Member State)
  - Assessment of reasons for not using alternative products
  - Check that the product is suitable for importation
  - For STCs, confirmation of TSE compliance
  - For immunological STCs, assessment of inactivation data, extraneous agents testing, batch release results / protocol
  - For live / notifiable immunologicals, further consultation (e.g. with core Defra) to ensure that there will be no interference with existing surveillance schemes



# Facts and Figures

- In 2010:
  - Approx. 11000 applications granted
  - Approx. 6270 SICs, 4620 STCs, 110 WDICs
  - Approx. 7060 (64%) were online applications
- Most 'popular' applications:
  - Allergen products
  - ACP injectable products
  - Vitamin K1
  - Botulism vaccine
  - Founderguard





# Small Animal Exemption Scheme (SAES)

## Schedule 6

- Exemption from the requirement to hold a Marketing Authorisation (MA)

Must only be indicated for:

- Cage birds
- Homing pigeons
- Aquarium animals
- Terrarium animals
- Rabbits
- Ferrets
- Small rodents



Not for main companion or food producing animals



# Small Animal Exemption Scheme (SAES)

- Limitations: Pack size – single course of treatment
- Labels: “This veterinary medicine is marketed in accordance with the Small Animal Exemption Scheme.” Extra warnings as specified by VMD
- Exclusions: Injections, ophthalmics, aural medicines, antibiotics, psychotropics, treatment of disease requiring vet diagnosis



# SAES

## Active substances

- Products may only contain active substances approved by the VMD for use under the scheme
- List of active substances in the website
- Information checked by VMD's vets – active permitted under the scheme? Any specific safety warnings?



# SAES Products

- It must not be intended for treatment of conditions that require a precise diagnosis or the use of which may cause effects that impede or interfere with subsequent diagnostic or therapeutic measures
- Full details in the guidance



# Our website

- Some links:

Product information database

<http://www.vmd.defra.gov.uk/ProductInformationDatabase/>

Adverse reactions reporting

<http://www.vmd.defra.gov.uk/adversereactionreporting/>

Information for veterinary professionals

<http://www.vmd.defra.gov.uk/vet.aspx>

Information leaflets

<http://www.vmd.defra.gov.uk/public/leaflets.aspx>

Guidance notes

[http://www.vmd.defra.gov.uk/public/vmr\\_vmgn.aspx](http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx)



# Contact Details

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

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