



Presentation at BVA Congress

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Better Regulation on Medicines

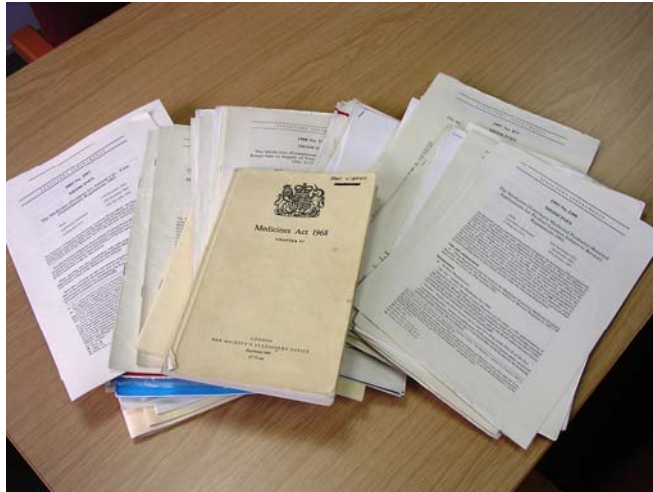
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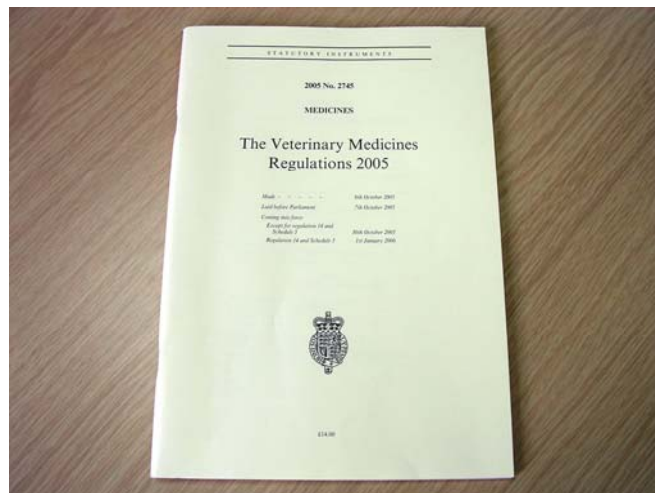
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Simplification of the legislation

- Clarity through a single text written in plain English
- Guidance Notes used to provide detailed advice
- Annual update to take account of practical issues ('tracked changes' document)
- Retain single legislative text throughout



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Why do we need regulation?

- To control risks to human health; animal health; and the environment through safe use of veterinary medicines.
 - Professional advice where needed
 - Controlled supply proportionate to risk
 - Controlled manufacture to ensure consistency of the products
 - Surveillance to assure risk mitigation is effective
- Provide assurance on efficacy
- Provide reliable information to users (“the Ronseal ethic”)





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Why is a cascade needed?

- Very good reasons to use authorised veterinary medicines
- Recognition of availability problem
- Cascade permits a controlled freedom of clinical judgement
- Cascade is a risk-based model for using unauthorised medicines



Legal use of an unauthorised VMP

- Cascade use
 - Off label use of UK product
 - Use for unauthorised species
 - Unauthorised for veterinary use in the UK
- Special Import Certificate
 - Use of product from another member state
- Special Treatment Certificate
 - Use of product from non-EU country



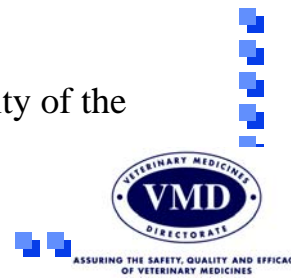
What is the cascade?

- If there is **no authorised veterinary medicinal product in a Member State** for a condition affecting a (food/non food) species, **by way of exception**, the veterinarian responsible may, **under his/her direct personal responsibility** and in particular **to avoid causing unacceptable suffering** treat the animal concerned



Responsibilities under the cascade

- For food animals
 - Only use products approved for use in food animals
 - Apply minimum withdrawal periods
 - 7 days for eggs and milk;
 - 28 days for meat from poultry and mammals;
 - 500 degree days for meat from fish
- Record use and retain for five years
- Cascade use is under the responsibility of the veterinary surgeon



Why follow the Cascade?

- **Criminal offence not to follow cascade**
- **But scientific reasons for following this include**
 - Veterinary medicines have been tested in animals and the correct dose etc. established
 - Veterinary medicines are appropriately labelled
 - Veterinary companies marketing these products are equipped to deal with reports of suspected adverse reactions
 - Just because products contain the same active and amount does not mean they will behave identically in the animal; factors that influence behaviour include:
 - Other ingredients
 - Method of manufacture
 - Veterinary generics have been compared with veterinary pioneer (leading) products
 - Human generics have not been compared with veterinary pioneer products



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It is important to realise the cascade is a derogation for the veterinary surgeon from the legal requirement to treat animals with authorised veterinary medicines.

It should be valued and used with thought, diligence and professionalism and always in the best interests of the animal

At all times ask yourself if your peers would support your judgement, in court if necessary.



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Veterinary Practice registration



- Legislative requirement from April 2009
- RCVS will maintain the register
- Applications from October 2008
- Registration fee
- Any veterinary surgeon directly supplying medicines to a fee paying client must work from a registered premises.



Practice Inspections

- Commence April 2009
- Will use the register of premises as a basis for inspection
- Practices registered with PSS covered by RCVS inspection
- Non-PSS practices inspected by Animal Medicines Inspectorate (fee of £250)
- Inspection is required by law.



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