Veterinary Medicines Directorate

GBGB Track Vet Training Day

Veterinary Medicines Regulations and Inspections

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Overview

- Introduction

- Veterinary Medicines Regulations (VMR) in relation to Veterinary Practice Premises (VPPs)

  - The Veterinary Medicines Regulations (VMR)
  - Legal Requirements under the VMR for VPPs
  - Common deficiencies found at VPP inspections

The Veterinary Medicines Directorate (VMD)

- An Executive Agency of the Department for Environment, Food and Rural Affairs (Defra)

- A “Licence to Operate” delivery body. Its primary purpose is to deliver the UK Government’s obligations under EU legislation

- UK wide responsibility (including the Devolved Administrations)

The Veterinary Medicines Regulations

- Implement EU Directive 2001/82 (amended by Directive 2004/28)
- First introduced in October 2005
- Disapplied Medicines Act 1968 to veterinary medicines
- Revoked and replaced as necessary

The VMD

Responsible for UK legislation relating to:

Authorisation of veterinary medicines:

- assessing data applications
- issuing Marketing Authorisations (MAs)

Authorisation & inspection of:

- Manufacturers (GMP and FeBOs) & Wholesale Dealers (GDP)
- Retailers - vets & SQP Retailers (pharmacies)

Monitoring:

- Residues surveillance
- Pharmacovigilance (PhV)
- Antimicrobial Resistance (AMR)

Legal Requirements under the VMR for Veterinary Practices

What do we check?

- Premises Registration
- Suitability of Premises and Storage
- (Controlled Drugs)
- Prescribing and Supply
  - Cascade
  - Labels
- Prescriptions
- Records
- Audit
- All Governed by Schedule 3 of the VMR

Premises Registration

- Premises must be Registered as a Veterinary Practice Premise (VPP) with RCVS (para 8 (1))
- Must be inspected (para 8 (4)) (Fees governed by Schedule 7)
- Each separate business must have its own Registration
- Retail supply only
- Must obtain VMPs from someone entitled to supply

Retail or Wholesale?

- Veterinary practices may only supply by retail – i.e. the final customer

- 5% allowance for wholesale supply was removed from the VMR in 2009

- Emergency supply is allowed in exceptional circumstances to alleviate animal welfare issues
- Beware of:
  - Supply to practice ‘stock’
  - Repeat supply

- If more than this, a Wholesale Dealers Authorisation is required.

Definition of a Veterinary Practice Premise

A premise

- from which the veterinary surgeons of a practice provide veterinary services; and/or,

- which is advertised or promoted as premises of a veterinary practice; and/or,

- which is open to members of the public to bring animals for veterinary treatment and care; and/or,

Definition of a Veterinary Practice Premise

- not open to the public, but which are the base from which a veterinary surgeon practises or provides veterinary services to more than one client; and/or,

- premise to which medicines are delivered wholesale, on the authority of one or more veterinary surgeons in practice

Storage and Disposal of VPPs

- **Stored appropriately**
  - all sites named
  - apart from food and drink
  - secure
  - according to marketing authorisation (MA) / SPC
  - out of reach of the general public (unless AVM-GSL)
  - effective stock control and quarantine
  - Procedures for spillages
- Backed up by temperature records
- An appropriate disposal contract must be in place including arrangements for ‘hazardous pharmaceuticals’

Controlled Drugs (CDs)

- Regulated by VMR and
- Misuse of Drugs Regulations 2001 and Misuse of Drugs (Safe Custody) Regulations 1973
- Secure Custody requirements for Schedule 2 (except secobarbitol) and some Schedule 3 CDs
- **A formal CD Register (in the prescribed format) must be kept for all Schedule 2 CDs**
- **All CDs (except Schedule 5) must be denatured before disposal**
  - **T28 exemption required**
- **Disposal of Schedule 2 CDs must be witnessed**

Supply and Administration - POMs

- Animals **must** be ‘under the care’ of the vet and clinical assessments carried out
- The vet **must** prescribe and authorise each individual treatment
- Prescriptions may be oral or in writing
- The vet may delegate supply, but remains responsible for all legal requirements

Prescribing POM medicines

- **POM-V and POM-VPS** medicines **must** be prescribed
  - "Prescribing" refers to the action of assessing the customer's requirements and deciding on the most appropriate medicine to supply
  - a prescription, which can be either oral or written, is the means by which the action of prescribing is relayed to the customer
  - where a VMP is not supplied by the person who prescribed it, the prescription must be written
  - Must be in ink or other indelible format

Supply of POM-V, POM-VPS & NFA-VPS medicines

- A person who **prescribes and supplies a POM-V or POM-VPS** medicine, or **supplies an NFA-VPS** medicine **must**:
  - be satisfied that user of the product is competent to use it safely and will use it for an authorised use
  - advise on the safe administration and on any warnings or contra-indications on the label/package leaflet
  - only prescribe/supply the minimum amount required for the treatment

Supply and Administration of all VMPs

- Administered according to their MA (part 1, 8)
  - expiry date and ‘in use’ expiry complied with
  - or under the ‘cascade’ (Schedule 4) or SAES (Schedule 6)
- Must be supplied in their authorised packaging (or other suitable container)
- Authorised product information must be visible
- ‘Other’ containers must be suitably labelled and sufficient written information supplied

Labelling

- No legal requirement to label a VMP supplied in its authorised packaging for an authorised use

- **Offence to obscure information on a VMP's authorised label (part 1, 12 (1))**

Labelling

A product supplied under the ‘cascade’ **must** be labelled with:

a) the name and address of the pharmacy or VPP supplying the product

b) the name of the prescribing vet

c) the name and address of the animal owner

d) the identification (including the species) of the animals or group of animals

e) the date of supply

f) the expiry date of the product, if applicable

Labelling

g) the name or description of the product, (at least the name and quantity of active ingredients)

h) dosage and administration instructions

i) any special storage precautions

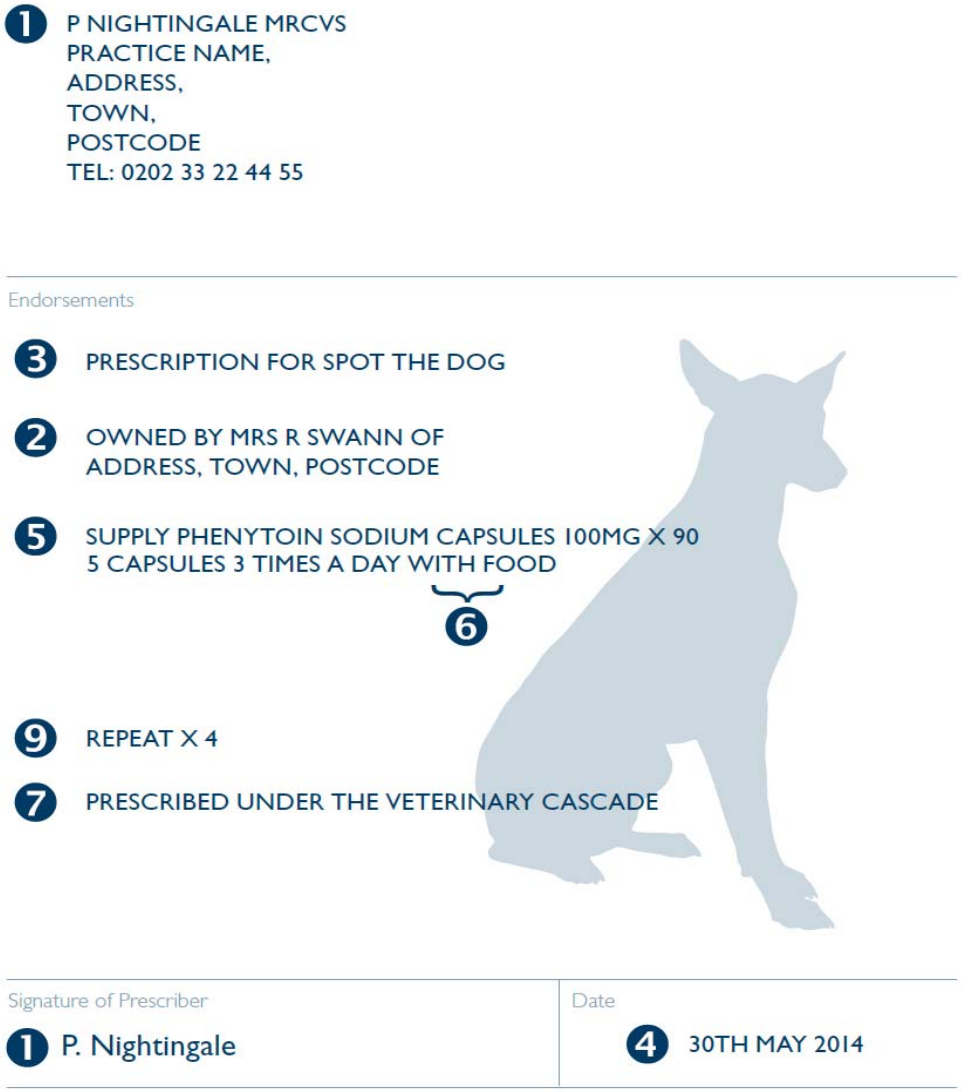
j) any necessary **warnings** for the user, target species, administration or disposal of the product

k) the withdrawal period, if relevant

l) the words “Keep out of reach of children” and “For animal treatment only”

Written Prescription requirements

1. Name, address , telephone no. & qualification of prescriber
2. Name & address of owner
3. **Address where animals kept (if different)**
4. Identification and species of animal(s)
5. Date of prescription
6. Name, quantity, dose & administration instructions
7. Any warnings, inc withdrawal period if necessary
8. If prescribed under cascade, a statement to that effect.
9. If repeatable, the number of times it can be repeated.
10. the signature or other authentication of the prescriber
11. **Validity is 6 months*** unless a shorter validity specified



Record-keeping

- A person who supplies a POM-V or POM-VPS product **must** keep records of all products received or supplied, including:
  - the date of transaction
  - the name of the VMP
  - the batch number of the VMP (although for non-food producing animals this can be on the date of receipt or when the VMP is first supplied)

Record-keeping

- the quantity received/supplied
- the name and address of the supplier or recipient
- if there is a written prescription, the prescriber's name and address and a copy of the prescription

- All documentation **must** be retained for **5 years**

Annual Audit (part 1,15)

- At least once a year, a detailed audit of incoming and outgoing VMPs **must** be reconciled with products held in stock, with any discrepancies being recorded

- Records of receipt and supply (including disposal)
- Physical stock check (at least annually)
- Running total in CD Register and regular stock check

VMD VPP Inspections Summary

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- 312 inspections conducted between Jan and June 2017
  - 1048 Recommendations
  - 1086 minor deficiencies
- 126 Major deficiencies

Rating	No.	%
Good	220	70.0
Acceptable	82	26.2
Poor	6	1.9
Unacceptable	4	1.3
NICO	2	0.6

Frequent deficiencies at VPP inspections

Deficiency	Total	Major	%
Broach dates exceeded / not recorded	253	37	82.1
No / inadequate CD records	220	25	71.4
No / inadequate temperature records	220	0	71.4
Written procedures required	202	3	65.6
Storage (including CDs)	196	13	63.4
Audit and disposal issues	178	5	59.4
Prescribing and supply issues	167	5	54.2
Labelling (including cascade)	140	9	45.4
Records of intake / supply	116	16	37.7

Summary

Contact details

- General enquiries: postmaster@vmd.defra.gsi.gov.uk
- Inspections: inspections@vmd.defra.gsi.gov.uk
- Enforcement: enforcement@vmd.defra.gsi.gov.uk
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Thank you

Any questions?