VMD Practice Premise Inspections

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Inspections & Investigations Team
Veterinary Medicines Directorate

ASSURING THE SAFETY, QUALITY AND EFFICACY OF VETERINARY MEDICINES

The VMD

- VMD is an executive agency of DEFRA
- Based at Addlestone, Surrey
- Competent authority for veterinary medicines in the UK
- Veterinary Medicines Regulations 2013
- DARD for feed / Schedule 5
- DHSSPS for VMPs / Schedule 3

ASSURING THE SAFETY, QUALITY AND EFFICACY OF VETERINARY MEDICINES

Veterinary Medicines Legislation

- Purpose: to control risks to human health; animal health; and the environment through safe use of effective veterinary medicines
- Delivered through the VMR by:
  - Authorisation of VMPs
  - Controlled manufacture
  - Controlled distribution/supply with professional advice
  - Post-authorisation surveillance

The Veterinary Medicines Regulations

- Implements EU Directive 2001/82 (amended by Directive 2004/28)
- First introduced in October 2005
- Disapplied Medicines Act 1968 to veterinary medicines
- Consolidated veterinary medicines legislation
- Normally reviewed and replaced every 18 - 24 months
- Includes 7 Schedules

Classification of VMPs

Set out in part 2 and Schedule 3 of the VMR

- Prescription Only Medicine – Veterinarian [**POM–V**]
- Prescription Only Medicine – Veterinarian, Pharmacist, Suitably Qualified Person (SQP) [**POM–VPS**]
- Non–Food Animal – Veterinarian, Pharmacist, SQP [**NFA–VPS**]
- Authorised Veterinary Medicine – General Sales List [**AVM–GSL**]

Other VMPs referred to in the VMR

- Exemptions for small pet animals (Schedule 6 products)
- Homeopathic Remedies
- Unauthorised Products (SIC, STC, Extemporaneous products)

Controlled Drugs regulated by the VMR & the Misuse of Drugs Regulations 2001 (MDR)

Supply of VMPs by Veterinary Surgeons

Veterinary surgeons can supply:

- POM-V medicines for administration to an animal under his/her care (registered clients) following a clinical assessment of the animal
- POM-V*, POM-VPS & NFA-VPS to non-registered clients *(*in accordance with a written prescription from another vet)*
- Can only supply from premises registered with the RCVS as a veterinary practice premises (VPPs)
- and AVM-GSL medicines

Supply of VMPs by Veterinary Surgeons

Premises likely to be considered as 'veterinary practice premises' (VPP) by the RCVS and the VMD are those:

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

Supply of VMPs by Veterinary Surgeons

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

- premises 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,

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

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
  - Person competent to use the product safely
  - Intends to use it for its prescribed use
  - Provide advice on safe administration and any warnings
- 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

Prescribing POM medicines

- A veterinary surgeon supplying a VMP (other than one classified as AVM-GSL) must be present when it is handed over unless the veterinary surgeon—
  - authorises each transaction individually **before** the product is supplied; and
  - is satisfied that the person handing it over is competent to do so.
- A veterinary surgeon or a person acting under a veterinary surgeon's responsibility may open any package containing a veterinary medicinal product.

Veterinary Practice Premise Inspections

ASSURING THE SAFETY, QUALITY AND EFFICACY OF VETERINARY MEDICINES

Veterinary Practice Premises

- As of 1st April 2009 all VMPs supplied by a veterinary surgeon must be from a registered premise
- Register held by RCVS
- Just over 5,100 premises in the UK
- Practices can join the RCVS Practice Standards Scheme (PSS)
- Approx 50:50 between VMD and PSS over UK
- Approx 80:20 VMD/PSS in Northern Ireland
- 4 year inspection interval if compliant
  - Reduced pro-rata for non-compliances

Reception / waiting Area

- Any VMPs on self service
- Shop area
- Check for VMPs / products with medicinal claims
- VMPs behind reception
- Storage suitability
- Advertising / posters
- Looking for human products, products being promoted for cascade use

Consultation Room(s)/Dispensary

- VMP storage
  - Suitability (out of reach of clients, ideally in cupboards)
  - Temperature (risk of being stored outside optimum)
- Broach dates
  - Do they start a couple of days after the letter arrived
  - Out of Date bottles with a recent opened date on them
- Human VMPs
  - Large stocks
  - Generics when veterinary versions exist
  - Braille on most packs (easy way to spot human products)


Loxicom
profender
Lectade Small Animal

Fridges

- Domestic fridges often used
  - No fan to keep temperature constant
  - Can be easily overloaded
  - More likely to have warm spots
- Pharmacy fridges
  - Fans installed to keep constant temperature
  - Max/min thermometer built in
- Staff fridge
  - Must be separate from the VMP fridge
  - Not used as an overflow store!

Wall Chillers

- Rarely have temperature monitoring
- Green light – all OK?? But is it??...
- No temperature ranges set/given for green/amber/red lights
- Hatch can easily be left open, compromising the lower vaccines

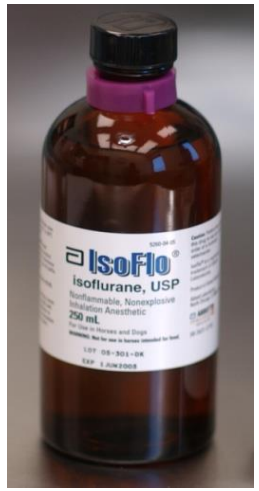
Thermometers vs Dataloggers

- Mostly see basic thermometers
- Current temperature recorded (+time on some)
- New max/min thermometers seen but no one has any idea how to read it or why.
  - Max/min rarely reset
- Recommend thermal brake on sensor
  - Readings more consistent of the product (and not the warm air that rushes into the fridge every time the fridge is opened)

Thermometers vs Dataloggers

- Not the magic bullet everyone thinks they are!
- Rarely downloaded
- No one knows what the flashing lights mean
- Occasionally put in the fridge without being set up properly (so not even recording!)
- Limits of tolerance not set properly
- Set up to record immediately (so out of tolerance before it makes it into the fridge).

Prep / Operating areas



- Prep tray
  - Broach dates / out of dates
- Crash box
  - Out of dates
  - Easily accessible
- Isoflo / Sevoflo (inhalation anaesthetics)
  - Sevoflo only licensed for dogs!
  - Cascade issues on Cats/small furries

Controlled Drugs Storage

- Cabinet with authorised access
- Secured to fabric of building
  - If I can move it then its not secured!
- Out of dates
  - Segregated and labelled appropriately
- Schedule 2 disposals are witnessed
- Broach dates
- All disposed of CD are rendered unusable
- Requisition orders on file

CD Disposal

- Render product **unusable**
- Denaturing kits
  - Ideal, but only one use
  - Cat litter & soap - The “Blue Peter” version
  - Use for clumping cat litter!
- Record batch details and volumes in the register and witness to sign
- Dispose into Out of Date VMP bin

CD Registers

- Fully bound book
- Book for each separate stock (cars)
- Bottles
  - Stock in mls
- Broach dates
- Vials
  - Full unused vials must have witnessed destruction
  - Keep stocks in number of vials
  - Once opened and used, remainder is waste
- Ketamine register
  - Section 4.35 of the RCVS Code of Professional Conduct
  - Being re-classified, probably will be upgraded to Schedule 2
- "The Angels Share"
  - Dispensing errors
  - My working is upto 0.1ml error per draw
  - Bottle stock amended at the end of each bottle

Labelling

- Two “rules” for labelling, one for VMPs and one for product prescribed under the Cascade
- Recommend putting cascade info on all labels
  - Ensures that cascade products are correctly labelled
  - Initials OK for prescriber
- ‘Farm’ as species... Not helpful!
- Labels don’t obscure product info
  - Farm products often pre-labelled
- Handwritten labels from farm visits
  - Do they exist? Are they used? ……REALLY?

Labelling

- If a veterinary medicinal product is supplied in a container specified in the marketing authorisation, it must not be supplied if any information on the outer packaging (or, if there is no outer packaging, the immediate packaging) is not clearly visible at the time of supply or has been changed in any way.
- If a veterinary medicinal product is supplied in a container other than that specified in the marketing authorisation, the person supplying the veterinary medicinal product must ensure that the container is suitably labelled and must supply sufficient written information (which may include a copy of the summary of product characteristics or the package leaflet) to enable the product to be used safely.

Cascade Labelling

Unless the veterinary surgeon who prescribed the veterinary medicinal product both supplies the product and administers it to the animal in person, the person supplying it must label it (or ensure that it is labelled) with at least the following information—

- the name and address of the pharmacy, veterinary surgery or approved premises supplying the veterinary medicinal product;
- **the name of the veterinary surgeon who has prescribed the product;**
- the name and address of the animal owner;
- the identification (**including the species)** of the animal or group of animals;
- the date of supply;
- the expiry date of the product, if applicable;
- the name or description of the product, which should include at least the name and quantity of active ingredients;
- dosage and administration instructions;
- any special storage precautions;
- any necessary warnings for the user, target species, administration or disposal of the product;
- **the withdrawal period, if relevant; and**
- the words "Keep out of reach of children" and "For animal treatment only".

Records – The Legislation

Any person permitted under these Regulations to supply a VMP classified as POM-V or POM-VPS who **receives or supplies** any such veterinary medicinal product must keep all documents relating to the transaction that show—

- the date;
- the name of the veterinary medicinal product;
- the batch number *(except that, in the case of a product for a non-food-producing animal, this need only be recorded either on the date of receipt of the batch or the date a veterinary medicinal product from the batch is first supplied*);
- the quantity;
- the name and address of the supplier or recipient; and
- if there is a written prescription, the name and address of the person who wrote the prescription and a copy of the prescription.

If the documents do not include this information that person must make a record of the missing information as soon as is reasonably practicable following the transaction.

Client Records – Small Animal

- Treated as individuals
- Histories usually detailed
- Recommend batch details, especially for vaccines, but not a legal requirement
- But often don't record VMPs used during procedures, and record "GA-Spay" instead
  - Could be recorded on anaesthesia form

Client Records – Farm / Equine

- Rarely more than a list of VMPs supplied and a sentence for a call out.
  - Eg Visit + drugs - £80 !!!!
- Some practices provide health plans, which are more detailed
- Identification of the animal(s) usually missing
- Cascade usage is rarely recorded properly
  - Reason for cascade usage
  - Identification of animal
  - Product details and batch number
  - Withdrawal period given
  - Details of dosage(s) given

Administration to Food producing

A veterinary surgeon who administers a veterinary medicinal product to a food-producing animal **must either enter the following information personally in the keeper's records or give it to the keeper in writing** (in which case the keeper must enter the following into those records)—

- the name of the veterinary surgeon;
- the name of the product and the batch number;
- the date of administration of the product;
- the amount of product administered;
- the identification of the animals treated; and
- the withdrawal period.

On Farm Records

- Regulation 18 states:
  - A veterinary surgeon who administers a VMP to a food-producing animal must either enter the information personally in the keeper's records or give it to the keeper in writing
- The industry standard is to provide this information on the end of month invoice
- *Some* practices will also provide batch numbers at this point, *very few* give withdrawal periods.
- This is a **SERIOUS** food safety risk as farmers often have no idea what has been used till weeks afterwards

Food Producing Animals

Batch numbers

- Rarely given out at time of supply/administration
- Records and actual often differ, especially on supplies from vehicles
- Staff can try to help by making their 'best guess' at what was supplied - ☹
- Happens more at practices with a choice of batch numbers to assign to supplies

Horses

- Recommend recording that passport has been signed off on the client record

Sheep dips

- Only to clients with a valid certificate of competence for dipping.
- If in doubt then DON'T SUPPLY!

Written Prescriptions

Must be in ink or other indelible format and include:

- the prescriber's name, address and telephone number
- the prescriber's qualification
- the name and address of the animal owner or keeper
- the identification (including the species) of the animal or group of animals to be treated

Written Prescriptions cont'd

- the premises where the animals are kept (if different to that of the owner or keeper)
- the date of the prescription
- the signature or other authentication of the prescriber
- the name and amount of the product prescribed
- the dosage and administration instructions
- any necessary warnings

Written Prescriptions cont'd

- the withdrawal period, if relevant
- if it's prescribed under the 'cascade', a statement to that effect
- A written prescription is valid for 6 months unless the prescriber states a shorter period
- A written prescription may only be used once, unless the prescriber states it is repeatable – and the number of repeat supplies that may be made

Supply of POM-V against a written prescription

The vet or pharmacist must:

- only supply the product detailed in the prescription
- take all reasonable steps to satisfy him/herself that the prescription has been issued by a vet
- ensure that it is supplied to the person named in the prescription

Prescriptions

- All required info included
- Copy kept (recommended)
- Treat like a cheque
  - Volumes in words and numbers
  - Sign any amendments
- Can be valid for upto 6 months
- Controlled drug prescriptions only valid for 28 days
- Prescription tampering is fraud, report online at http://www.vmd.defra.gov.uk/mswd/vmr_misuse.aspx

Feed Prescriptions – WDA/MFS

- 3 copies must written
  - Prescriber
  - Supplier
  - Owner/keeper
- A copy actually makes it to the farm
- Possession of a medicated feedingstuff is an offence without a valid written prescription
- In feed VMPs to approved premises only
  - DARD register online at http://www.dardni.gov.uk/animal-feed
- NO TOPDRESSING!

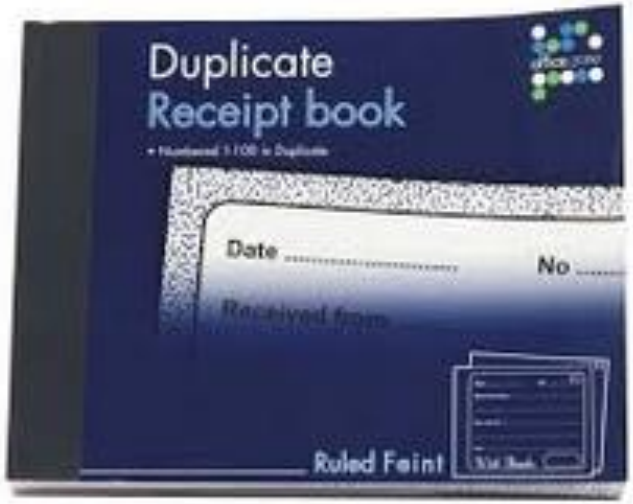
Procedures / SOPs

What are the practice procedures/ policies for...

- Supply when no vet is present
- Supply of VPS products to non-clients
- Pre-authorisation of products
  - Flea/worm treatments (preventatives)
  - Farm health plans
- Stock control / disposal records
- Controlled drugs
- Returns procedure
- Spill kit

Vehicles

- A veritable treasure trove!
  - Most practices have no idea what is in the vehicles
  - No broach dates
  - Out of date products
  - No provisions to reduce temperature extremes
  - No temperature monitoring
  - No cool box/bag
  - CD storage & register issues
  - Disposal issues
- Records should be for-
  - Both administered to animal and supplied to keeper
  - All required info recorded and given to animal keeper



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ASSURING THE SAFETY, QUALITY AND EFFICACY OF VETERINARY MEDICINES

Wholesale Dealing

- A wholesale dealer authorisation (WDA) is required to wholesale all VMPs (inc AVM-GSL, Schedule 6 & homeopathic products)
- WDAs for vet-only sites granted and inspected by the VMD
- WDAs for human/veterinary sites granted and inspected by the Medicines and Healthcare Products Regulatory Agency (MHRA)
- Retailers may wholesale *in* ***exceptional circumstances*** to alleviate an animal welfare issue.

..and some of the rest...

- Disposal facilities
- Spill kit
- Health plans / schemes
- Audits / stock takes
- SARSS
- SIC/STC's kept and usage records
- Extemps (nostrums)
- Homeopathics
- Project licence held?
- SQPs

The Veterinary Cascade

- Schedule 4 in the VMR
- a veterinary medicinal product authorised in the United Kingdom for use with another animal species, or for another condition in the same species; or
- if there is no such product that is suitable, **either**—
  - (i)a human medicinal product authorised in the United Kingdom; or
  - (ii)a veterinary medicinal product not authorised in the United Kingdom but authorised in another member State for use with any animal species (in the case of a food-producing animal, it must be a food-producing species); or
- if there is no such product that is suitable, a veterinary medicinal product prepared extemporaneously by a pharmacist, a veterinary surgeon or a person holding a manufacturing authorisation authorising the manufacture of that type of product.

The Veterinary Cascade

- For food producing animals then any product used under the cascade must be listed in Table 1 in the Annex to Commission Regulation (EU) No 37/2010.
- Withdrawal is the statutory minimum or the longest on the product (whichever is greater)
- Statutory minimum withdrawal periods:
  - 28 days for meat
  - 7 days for milk and eggs
  - 500 degree days for fish

VETERINARY MEDICINES VMD DIRECTORATE

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Veterinary Specials

- Veterinary Specials are bespoke extemporaneous preparations that are manufactured for a specific animal under the clinical direction of a veterinary surgeon.
- These prescription medicines do not hold a marketing authorisation from the VMD, but can legally be used under the prescribing cascade.
- Extemporaneous preparations such as veterinary specials can be prepared by:
  - A veterinary surgeon registered with the RCVS;
  - A pharmacist registered with the General Pharmaceutical Council or the Pharmaceutical Society of Northern Ireland in accordance with a prescription from a veterinary surgeon;
  - A manufacturer who has been authorised to do so.
- Can not be wholesaled / placed on the market
- Must be labelled as a cascade VMP

Residues

- VMD collects over 30,000 samples per year for statutory surveillance
- Also sample imported foods
- Tested for residues of:
  - Illegal medicines
  - Authorised medicines
  - Some environmental contaminants
- Where residues of concern are detected a follow-up investigation is undertaken
- Results are published quarterly in MAVIS

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Advertising VMPs

It is an offence to advertise:

- a VMP if the advert is misleading or makes a claim that is not in the product's SPC
- psychotropic drugs or narcotics to anyone other than a veterinary surgeon or pharmacist
- a human medicine for administration to animals
- an unauthorised product inc SICs/STCs & 'specials'

Advertising VMPs

- POM-V products may only be advertised to veterinary surgeons, veterinary nurses, pharmacists or professional keepers of animals*

*(*except antimicrobials [antibiotics])*

- POM-VPS products may only be advertised to veterinary surgeons, veterinary nurses, pharmacists, SQPs, other veterinary health care professionals, professional keepers of animals or professional keepers of animals*

*(*excludes general horse owners)*

Price Lists

- Price lists are not advertising
- A price list is a list of products together with the price that is being charged for them
- No single product may be promoted above any other
- Photographs of the products are acceptable provided that all the images are consistent in terms of size and type.

Accredited Internet Retailer Scheme (AIRS)

- VMD launched the Accredited Internet Retailer Scheme (AIRS) on 25 May 2012
- Specified criteria covering supply procedures, information for customers and advertising VMPs
- AIRS is voluntary ... and free
- Currently 28 websites owned by 25 retailers

AIRS

Aims to help on-line buyers of veterinary medicines

- Shows that the retailer is accredited by the VMD
- Confirms that the website has been assessed and complies with the Scheme's requirements and the VMR
- Reduces the risk of buying unauthorised products
- Reduces the risk of buying inappropriate or ineffective products

The VMD Website

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Subscribe to What's New

What's New

(06/03/14)

The Home Office has concluded its consultation on the scheduling of tramadol and exemptions for tamazepam prescriptions.

(06/03/14)

VMD Pharmaceutical Industry Information Event - Provisional Agenda

(11/02/14)

Advertising FAQ document amended January 2014

(05/02/14)

VMD Pharmaceutical Industry Information Event - 12th June 2014

(29/01/14)

Version 89 of MAVIS has been published

(27/01/14)

Welcome to the Veterinary Medicines Directorate

The vision of the VMD is the responsible, safe and effective use of veterinary medicinal products. In working towards achieving this vision the VMD aims to protect public health, animal health, the environment and promote animal welfare by assuring the safety, quality and efficacy of veterinary medicines.

This website is divided into a number of sections reflecting the needs of our customers and stakeholders. Please select the area that closely reflects your area of interest. Please note that some of the information may be found in more than one section.

Quick Links

- Report an Adverse Event (yellow form)
- Product Information Database
- Special Import Site
- Information Leaflets
- Guidance Notes (VMGNs)
- Veterinary Medicines Regulations
- Online Export Certificates

Events & Meetings

VMD events and events VMD will be attending as an exhibitor in 2014:

3-6th April

British Small Animal Veterinary Association(BSAVA) NIA, Birmingham

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Product Information Database

Can search for all UK authorised veterinary medicines

- suspended and expired products
- specified feed additives (SFAs)

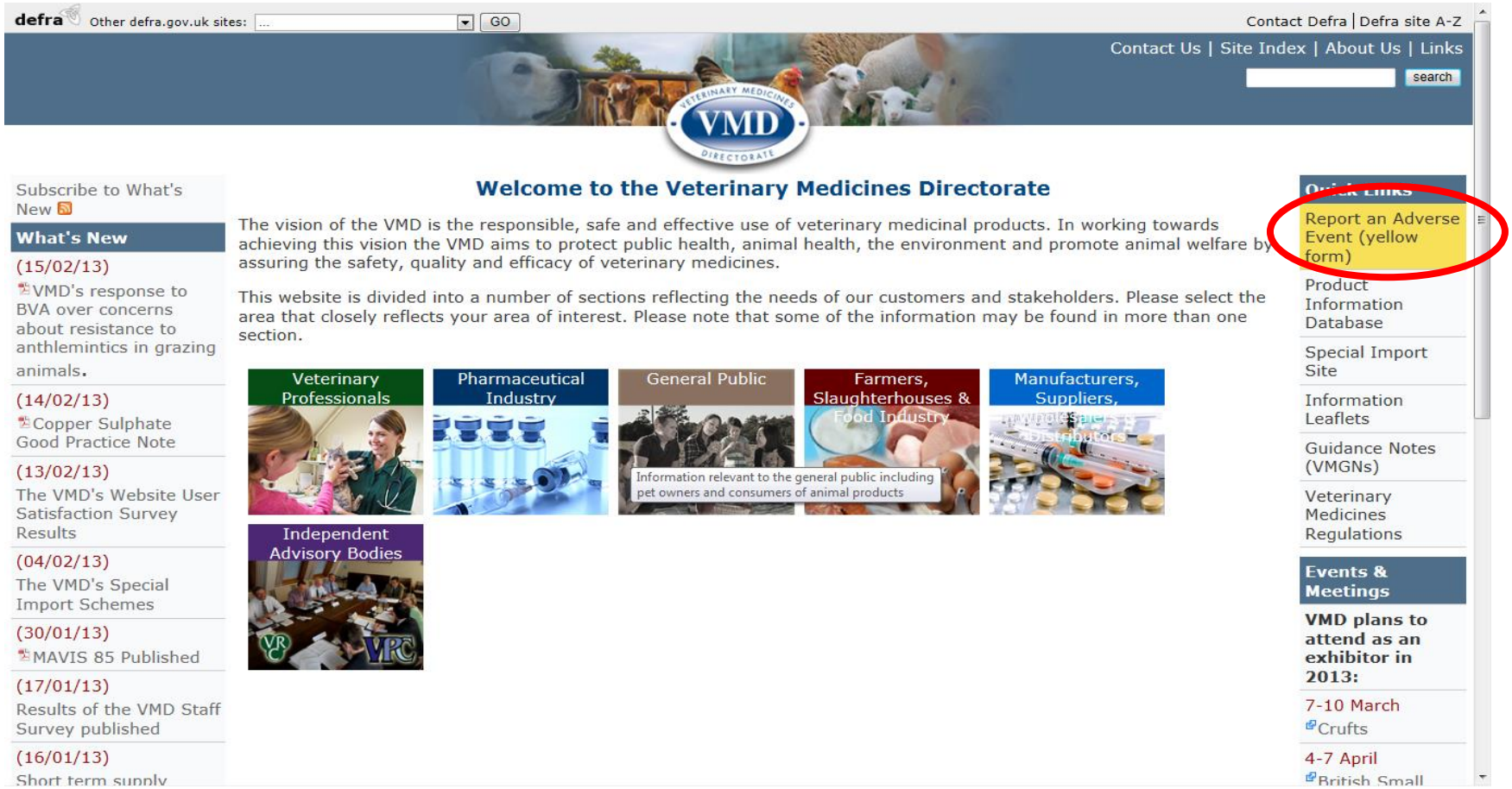
Search criteria include:

- product name
- active substance
- distribution category
- Species

Reporting Adverse Events (AEs)

- Anyone *can* report an AE
- Vets & SQPS *should* report AEs
- Simple online form
- Includes suspected lack of expected efficacy (SLEE)
- Includes known reactions
- Includes environmental issues

Reporting Adverse Events



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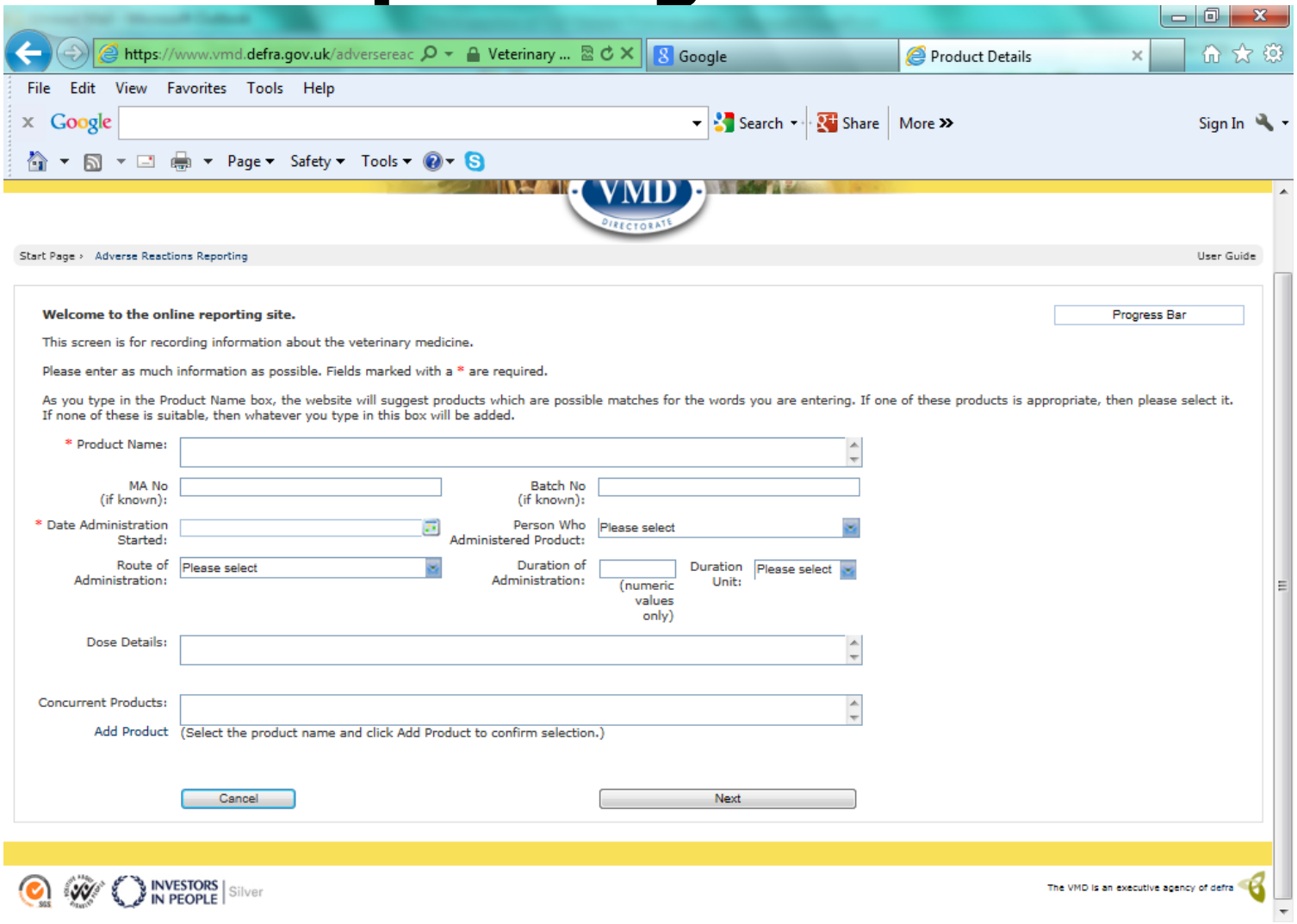
Reporting AEs online



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ASSURING THE SAFETY, QUALITY AND EFFICACY OF VETERINARY MEDICINES

Special Import Site

- Site for vets to apply to import a non-UK authorised veterinary or human medicine under the 'prescribing cascade'

- Lists veterinary medicines supply problems and alternatives available (where they exist)

Further Information

Veterinary Medicines Directorate (VMD)
www.vmd.defra.gov.uk
Tel: 01932 336911

- Veterinary Medicines Guidance Notes (VMGNs)

VMGN 1 - *Controls of veterinary medicines*
VMGN 3 - *Guidance for retailers*
VMGN 4 - *Controls on advertising*
VMGN 13 - *Guidance on the use of the cascade*
VMGN 14 - *Record-keeping requirements for VMPs*
VMGN 20 - *Controlled Drugs*

- Information Leaflets

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