

EU and Beyond

The VMD works with a number of European **partners** including the regulatory agencies of the other EU member states, the European Medicines Agency (EMA), the European Directorate for the Quality of Medicines and Healthcare (EDQM) and the European Commission.



In order to obtain a Marketing Authorisation there are a number of different procedures that can be followed. Increasingly these are EU **procedures** in which one member state leads the assessment of the application and the other member states base their views on this assessment. The VMD regularly acts as the lead assessment member state and plans to remain a key player in EU procedures for veterinary medicines.

The VMD also works with countries outside the EU. For example, the VMD engages in the Veterinary International Co-Operation on Harmonisation (VICH), a process through which guidance to the pharmaceutical industry is developed at an international level. The VMD also provides training opportunities for third countries that are developing or improving their own controls relating to veterinary medicines.

Staff

The VMD employs approximately 160 people. They include almost 63 scientists (e.g. Chemists, Immunologists, Pharmacists, Toxicologists, Veterinary Surgeons), inspectors, experts in finance, IT policy and administration.

Finance

VMD's annual turnover is in the region of £14 million. Around 80% of its income is from charges and levies paid for by the relevant sectors of industry which include the pharmaceutical industry, abattoirs, veterinary surgeons and importers. This funding operates on a full cost recovery basis. Defra provide funding in the region of £3 million each year.



Location

The VMD offices are located in Woodham Lane, Addlestone, Surrey in the UK.

Further Information

The VMD's website contains information about all aspects of the VMD's work: www.vmd.defra.gov.uk.

The VMD issues a series of Veterinary Medicines Guidance Notes. These guidance notes provide further detail in connection with all aspects of the VMD's work. They are available on the VMD website (<http://www.vmd.defra.gov.uk/public/vmr.aspx>).

There are further leaflets available in this series, these are also available on the VMD website, and cover areas such as:

- Availability of veterinary medicines
- How to identify Veterinary Medicinal Products. Legal or Illegal?
- Is this Medicine Safe for my Pet?
- Adverse event reporting and follow-up
- The VMD's Accredited Internet Retailer Scheme

You can also phone the VMD on 01932 336911 for any additional assistance about veterinary medicines. Alternatively, e-mail us at postmaster@vmd.defra.gsi.gov.uk



ASSURING THE SAFETY, QUALITY & EFFICACY OF VETERINARY MEDICINES



The Work of the Veterinary Medicines Directorate (VMD)



The Veterinary Medicines Directorate is an Executive Agency of the Department for Environment, Food & Rural Affairs



The VMD is an Executive Agency of the Government's Department for Environment, Food & Rural Affairs (Defra). It has UK-wide responsibility.

Vision

The vision of the VMD is the **responsible, safe and effective** use of veterinary medicines. 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.

Responsibilities

- To **authorise** veterinary medicines and to **monitor** their safety and efficacy following authorisation.

Marketing Authorisations are issued to companies once they have demonstrated that their product is of the appropriate quality, can be used safely and will be effective when used in accordance with the label/leaflet instructions. There are just over 2000 Marketing Authorisations in the UK for veterinary medicines. The VMD website (www.vmd.defra.gov.uk) includes a list of these products and a Summary of

Product Characteristics (SPC) for each of them as well as public assessment reports for every veterinary medicine granted after 2005 and is a national or European marketing authorisation where the UK leads the assessment work.

In order to assess and act on any problems with medicines following authorisation, the VMD operates the Suspected Adverse Reaction Surveillance Scheme (SARSS) which gathers and assesses data on any reports where medicines are suspected of not being either safe or effective.

The independent UK Veterinary Products Committee (VPC) provides advice to the VMD on any aspect of veterinary medicines and a link to this can be found on the VMD website.

- To develop, update and enforce the **legislation** concerning veterinary medicines, controlling them from their point of manufacture, as they are supplied and all the way through to their moment of administration.

The **Veterinary Medicines Regulations**, bring together all of the legislation relating to veterinary medicines in the UK. A copy of the current legislation and all the associated guidance can be found on the VMD website.

- To **monitor** foodstuffs derived from animals for **residues** arising from the use of veterinary medicines and illegal substances.

Two schemes are operated by the VMD: the statutory residues programme which is paid for by the relevant UK food producers and the non-statutory programme for imported food which is paid for by the Government. The independent UK Veterinary Residues Committee (VRC) provides advice to the VMD and the Food Standards Agency (FSA) on issues about residues in foodstuffs. Links to these are available on the VMD website.

Activities

The VMD **assesses** scientific data submitted in support of applications relating to veterinary medicines. This includes applications for Marketing Authorisations as well as Animal Test Certificates (to permit the trialling of veterinary medicines in the treatment of animals). Following authorisation of products, through the monitoring of adverse reactions (side-effects) to

veterinary medicines the VMD monitors reports of suspected adverse reactions and reports of suspected lack of efficacy and examines the frequency of adverse events. The benefits of a product versus the risks are considered initially and then this analysis is re-examined at intervals to ensure it is appropriate for the product to remain available in its current form.

The VMD **inspects** premises in the UK at and from which medicines are manufactured, stored and supplied. The premises inspected include: sites manufacturing veterinary vaccines, feed mills and farms manufacturing medicated feeds, agricultural merchants (also referred to as Suitably Qualified Person (SQP) premises) and sites exclusively manufacturing veterinary pharmaceutical products, sites exclusively wholesaling veterinary medicines and veterinary practices. The VMD accredits reputable companies selling medicines on the internet through its Accredited Internet Retailer Scheme to reduce the risk of people buying medicines that are not safe or effective.

The VMD co-ordinates the collection of samples of foodstuffs such as meat, milk and eggs from both UK produce and imported produce and arranges their **analysis** for residues derived from the use of veterinary medicines or from the use of illegal substances. The VMD is responsible for the reporting of results and for any enforcement action concerning the illegal use of a medicine that results in the detection of residues above the 'maximum residue limit' or arising from the detection of illegal substances.

The VMD provides advice on **policy** relating to veterinary medicines. This includes answering Parliamentary Questions and providing advice to Ministers. Recent areas covered include topics such as the development of antibiotic resistance, and the development of UK and EU legislation.

The VMD provides **advice** to veterinary surgeons and the public on the use of veterinary medicines in relation to the 'cascade' (the cascade permits UK veterinary medicines or other types of medicines to be used other than in accordance with the SPC where there is a justified clinical need to do so), legal distribution categories and availability of medicines. It does not provide advice on individual clinical cases.

The VMD co-ordinates Defra funded **research** relating to veterinary medicines.