



Veterinary Medicines Directorate

Appraisal report of Information

Veterinary Medicines Directorate (VMD)

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Document History

Draft No	Date	Appraisal Stage	
1 #534210		Enters key information. Preliminary ideas expressed for the sort of material TNA wishes to select. Executive summary completed in draft. Draft sent to DRO	
2		Specific decisions for groups of records have been made and any 'review' has been recorded. It follows consideration of the file plan / shared drive. This must be done through consultation between client manager and DRO but may involve a wider client manager discussion.	
3		Final draft. This follows the conversion of broad decisions in the Appraisal Report into the selection of specified file paths entered onto the Transfer schedule.	

Approvals

Name	Role	Date
Lucy Keene	Information Management Consultant	05/01/2017
Natalie Shilling	DRO	05/01/2017
	Records Decision Panel, TNA	30/01/2017

EXECUTIVE SUMMARY

In accordance with the Records Collection Policy, most information held by the VMD and its predecessor organisations hasn't been selected for permanent preservation as it is not considered to be of public interest or historical value.

Areas that may be considered of interest and selected for permanent preservation include:

- Policy information in relation to Organophosphate Sheep Dips (OPs)
- Material relating to changes in policy or process as a result of 'Brexit'

The old VMD website (www.vmd.gov.uk) and our new presence on GOV.UK are already preserved by TNA.

Section 1: Background Information

1.1 & 1.2 Name and type of agency

The Veterinary Medicines Directorate (VMD) is an executive agency of the Department for Environment, Food and Rural Affairs.

1.3 Annual budget (if an Agency)

In 2014 / 2015 the VMD's total income was 14.42m.

The costs of the Veterinary Pharmaceutical Industry are recovered through fees and charges for authorisations and inspections work (7.25m). The costs of the Food Industry are recovered through charges levied on abattoirs and other food processors (3.93m). The cost for the government activities, enforcement, policy and other operations work, are funded by Defra (3.24m).

VMD's Annual Reports and Accounts are published every year.

1.4 Number of employees (if an Agency)

As of 31st March 2015, the VMD employed 159 permanent staff and 6 temporary staff including scientists, inspectors, finance specialists, IT specialists, and administrative staff.

1.5 & 1.6 Background, functions and activities

<https://www.gov.uk/government/organisations/veterinary-medicines-directorate/about>

The VMD was established in 1989, became a Next Steps Agency of the Ministry of Agriculture, Fisheries & Food (MAFF) in 1990, and then an Executive Agency of the Department for Environment, Food and Rural Affairs (Defra) on 7 June 2001.

We operate within an overall policy and financial framework determined by the Secretary of State for Defra, through the Parliamentary Under Secretary for farming, food and marine environment. Our day-to-day management within this framework, and our performance against our key targets, is the responsibility of our Chief Executive Officer (CEO), supported by Directors of Authorisations and Operations.

We divide our work into three main components and all records are created / managed / kept in the same way:

Veterinary Pharmaceutical Industry: the assessment of applications; issuing and maintenance of Marketing Authorisations including pharmacovigilance; the licensing of manufacturers and wholesale dealers of veterinary medicines; and inspection of manufacturers, wholesale dealers and retailers of veterinary medicines. The main customers are Marketing Authorisation holders; manufacturers and importers of veterinary medicines; manufacturers of medicated animal feedingstuffs; retailers of veterinary medicines and medicated animal feedingstuffs; the veterinary profession; other stakeholders including farmers and keepers of animals; the European Medicines Agency¹ (EMA); Department of Health² (DH); Food Standards Agency³ (FSA) and consumers.

Food Industry: the surveillance for residues of veterinary medicines and banned substances in home-produced livestock and animal products, reporting of results and co-ordinating follow-up action. The VMD has contracts with other agencies and companies who carry out work on our behalf at abattoirs and other first processing industries, and on farms. We also work with other stakeholders including consumer representative groups, the European Commission and the FSA who are responsible for food safety follow-up action.

Government: servicing, developing and implementing new policy/legislation on all aspects of veterinary medicines; providing support to Ministers through briefing and advice on replies to correspondence and Parliamentary Questions; surveillance for residues of veterinary medicines and banned substances in imported animal products; and day-to-day management of the

¹ You can find out more about the EMA via www.ema.europa.eu

² You can find out more about the DH via www.gov.uk/government/organisations/department-of-health

³ You can find out more about the work of the FSA via www.food.gov.uk

veterinary medicines Research and Development (R&D) programme on behalf of Defra. The VMD works closely with Ministers and officials of Defra and other government departments and Agencies including the FSA, the general public, industry, consumer representative groups, the European Commission, embassies and other representatives of foreign governments.

Responsibilities

The VMD's main responsibilities are:

- to lead on the UK government policy for the regulation of veterinary medicines and antimicrobial resistance in animals
- the assessment, issue and maintenance of all national Marketing Authorisations (MAs) for veterinary medicines in accordance with EC and UK legislation
- acting as Reference Member State (RMS), Rapporteur, Co-Rapporteur or Concerned Member State (CMS) for designated European applications for centralised, decentralised or mutual recognition authorisations
- controls on the manufacture and distribution of veterinary medicinal products including inspections
- enforcement of the Veterinary Medicines Regulations
- pharmacovigilance through the surveillance of Suspected Adverse Reactions (SARs)
- surveillance for residues of veterinary medicines and illegal substances in animals and animal products
- the provision and implementation of policy advice on these matters to Ministers
- the management of the Research and Development programme linked to veterinary medicine issues
- the co-ordination of Defra's work on antimicrobial resistance via the Defra Antimicrobial Resistance Co-ordination (DARC) Group

About the Department

1.7 Name of the parent or sponsoring department (if an Agency).

Department for Environment, Food and Rural Affairs (Defra)

1.8 Relationship with parent department (if an Agency)

The VMD is an executive agency of Defra.

1.9 Relationship with other organisations (agencies / NDPBs / departments / other statutory bodies)

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.

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.

The VMD collaborates with other UK Government agencies, such as the Department for Agriculture and Rural Development in Northern Ireland, the Food Standards Agency and Core Defra and its agencies.

Advisory Bodies

The **Veterinary Product Committee (VPC)** offers advice to the VMD, upon request, about applications for Marketing Authorisations (MAs) and Animal Test Certificates (ATCs). The VMD decides whether an application is to be approved, but consults the VPC where there are specific scientific issues on which it requires advice. In these cases, VPC members are external experts with the appropriate expertise to address the concerns raised by the VMD. These are identified in advance of the meeting and asked to lead the discussion.

The **Medical and Scientific Panel (MSP)** was a sub-committee of VPC comprising medical and scientific experts. It was established in 1994 as the VPC recommended a group of experts to evaluate and co-ordinate research on Organophosphate (OP) sheep dips in relation to human exposure. MSP met twice a year at the VMD.

The **Appraisal Panel (AP)** was a sub-committee of VPC comprising medical and scientific experts who met to evaluate and discuss matters in relation to pharmacovigilance issues, i.e. adverse reactions.

The **Veterinary Residues Committee (VRC)** was an independent advisory committee. Their role was to provide high quality, independent, expert advice to the VMD and the Food Standards Agency; oversee the residue surveillance programmes and surveys to ensure that they concentrated on issues of

possible concern and were well conducted; encouraging regular dialogue with stakeholders in the promotion of good practices; and taking other initiatives where relevant to attain the Committee's mandate.

Management Board

The **VMD Management Board (MB)** supports and challenges the Chief Executive. This covers, but is not limited to, the associated Accounting Officer responsibilities. The MB is collectively responsible for the agency's long term success. It provides strategic leadership for the VMD within a framework of appropriate and effective controls that enables risk to be assessed and managed. The meetings are held quarterly and representatives on the board include: VMD Chief Executive, VMD Directors, Head of Finance, Head of Business Unit, Non-Executive Directors (NEDs) and the Chief Veterinary Officer.

Section 2: Selection decisions

No material has been transferred to The National Archives.

2.1 Areas of policy work undertaken in the Agency

The VMD is involved in the development of secondary legislation governing the authorisation of veterinary medicines, medicated feedingstuffs, and residues.

The VMD provides advice on policy (e.g. PQs) relating to veterinary medicines including topics such as the development of antibiotic resistance, organophosphate sheep dips (OPs) 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', 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.

2.2 Operational work undertaken by the agency

Authorisations

The VMD assesses scientific data submitted in support of applications relating to veterinary medicines; these data are the property of the companies submitting the application. This includes applications for Marketing Authorisations as well as Animal Test Certificates that permit the trialling of veterinary medicines in the treatment of animals.

Pharmacovigilance

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.

Inspections

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.

Residues

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.

Enforcement

"Enforcement" refers to action taken by the VMD in relation to breaches of the Veterinary Medicines Regulations (VMR). The purpose of enforcement is to secure compliance with the requirements of the VMR. We therefore seek to work with businesses and individuals to assist them in complying with the legislation through the provision of advice and guidance. However, where necessary we will use more formal means of enforcement to secure compliance.

<https://www.gov.uk/government/publications/enforcement-strategy-for-animal-medicines>

2.3 Hybrid Records

The VMD implemented an electronic filing system in 2012 / 2013 (excluding financial records, which are still held in hard-copy). Prior to this, all information generated by the VMD was held in hard-copy format on a registered paper file.

Section 3: Technical Report

See from page 11 of <http://www.nationalarchives.gov.uk/documents/information-management/how-to-compile-an-appraisal-report.pdf>

3.1 Committee structure within the agency or parent department, including statutory committees directing the work of the organisation

Name of committee	Terms of reference	Select? Yes / No	Reasons for selection / non-selection, including comments on the quality of information	Selection criteria
Veterinary Products Committee (VPC)		No	<p>Minutes of the VPC meetings are published. Nowadays they are published as follows: https://www.gov.uk/government/organisations/veterinary-products-committee/about/publication-scheme</p> <p>The VPC produces and publishes an annual report every year, which provides information to the public about its activities including appointments and costs / expenses – see https://www.gov.uk/government/publications/vpc-annual-report-2013 . NB. This information was previously included in the Medicines Commission Annual Report.</p> <p>VPC related information, which has not already been in the public domain, hasn't been selected for preservation as it unlikely to be of historical interest.</p> <p>Hard-copy information up to 1 January 2013 (sub-set of 'VMD' file series) then held electronically.</p>	Non-Selection
Medical and Scientific Panel (MSP)		No	<p>The MSP was a sub-committee of the VPC formed to specially discuss and review information in relation to organophosphate (OP) sheep dips.</p> <p>The VPC produces and publishes an annual report every year, which also included information on its' sub-committees including the MSP. The annual report provides information to</p>	Non-Selection

			<p>the public about its activities including appointments and costs / expenses – see https://www.gov.uk/government/publications/vpc-annual-report-2013 . NB. This information was previously in the Medicines Commission Annual Report.</p> <p>Hard copy information up to 1 January 2013 (sub-set of 'VMD' file series) then managed electronically since.</p>	
The Appraisal Panel		No	<p>The Appraisal Panel was a sub-committee of the VPC formed to specially discuss pharmacovigilance issues (i.e. adverse events).</p> <p>The VPC produces and publishes an annual report every year, which also included information on its' sub-committees including the Appraisal Panel. The annual report provides information to the public about its activities including appointments and costs / expenses. NB. This information was previously in the Medicines Commission Annual Report.</p> <p>Hard copy information up to 1 January 2013 (sub-set of 'VMD' file series) then managed electronically since.</p>	Non-Selection
Veterinary Residues Committee	See section 1.10	No	<p>The VRC was disbanded in January 2015. It had its own presence on the old VMD website, which is still accessible via GOV.UK https://www.gov.uk/government/organisations/veterinary-residues-committee</p> <p>The VRC annual reports are also available via the above link – these reports included information on the committee's activities, appointments and costs / expenses.</p> <p>Hard copy information up to 1 January 2013 then managed electronically since.</p>	Non-Selection
Committee for Veterinary Medicinal Products (CVMP)		No	<p>This is a European committee hosted by the European Medicines Agency in London and attended by representatives from each member states' National</p>	Non-Selection

			<p>Competent Authority for the regulation of veterinary medicines. The CVMP is involved in the assessment and authorisation of veterinary medicines obtained via the centralised procedure.</p> <p>Information about CVMP, including minutes of meetings and Commission Decisions, are published by the EMA. The VMD only holds copies of papers discussed at the meetings as circulated by the EMA.</p> <p>Hard copy information up to 1 January 2013 (sub-set of 'VMD' file series) then managed electronically since.</p>	
Committee for Mutual recognition and Decentralised procedures – veterinary (CMDv); formerly the Veterinary Mutual Recognition Facilitation Group (VMRFG)			<p>This is a European committee hosted by the European Medicines Agency in London and attended by representatives from each member states' National Competent Authority for the regulation of veterinary medicines. CMDv is involved in the assessment of veterinary medicines obtained via the decentralised or mutual recognition procedures.</p> <p>Information about CMDv, including minutes of meetings, are published by the EMA. The VMD only holds copies of papers discussed at the meetings as circulated by the EMA.</p> <p>Hard copy information up to 1 January 2013 (sub-set of 'VMD' file series) then managed electronically since.</p>	Non-Selection
Other Committees			<p>VMD staff attend many different meetings held by the European Commission on various topics. The VMD files agendas, meeting papers, and minutes of these meetings.</p> <p>Hard copy information up to 1 January 2013 (sub-set of 'VMD' file series) then managed electronically since.</p>	Non-Selection

Section 4: Proposals for TNA selection

1. Policy information in relation to Organophosphate Sheep Dips (OPs)

This does not include any information in relation to the Official Group on Organophosphates (OGOP), which was an interdepartmental group involving the VMD and other government departments set up in 1997. The VMD did not lead or provide secretarial duties to this group, which were provided by the HSE.

2. Minutes of the VMD Management Board
3. Major changes to Policy as a result of 'Brexit'

Section 5: Additional information and follow up

None

Appendix: Results of folder 'review'

Not applicable