



Department
for Environment
Food & Rural Affairs

www.defra.gov.uk

Veterinary Medicines and Antimicrobial Resistance Evidence Plan

**Policy portfolio: Animal Health Scanning and
Trade Policy**

**Policy area within portfolio: Global trade and
aquaculture health**

Timeframe covered by Evidence Plan: 2013/14 - 2017/18

Date of Evidence Plan: March 2013

This evidence plan was correct at the time of publication (March 2013). However, Defra is currently undertaking a review of its policy priorities and in some areas the policy, and therefore evidence needs, will continue to develop and may change quite rapidly. If you have any queries about the evidence priorities covered in this plan, please contact StrategicEvidence@defra.gsi.gov.uk.

© Crown copyright 2013

You may re-use this information (not including logos) free of charge in any format or medium, under the terms of the Open Government Licence. To view this licence, visit www.nationalarchives.gov.uk/doc/open-government-licence/ or write to the Information Policy Team, The National Archives, Kew, London TW9 4DU, or e-mail: psi@nationalarchives.gsi.gov.uk

PB 13931

Contents

1. Policy context.....	1
2. Current and near-term evidence objectives	2
3. Future evidence needs	3
4. Meeting evidence needs	5
5. Evaluating value for money and impact	6

1. Policy context

What are the key policy outcomes for the policy programme/area?

United Kingdom (UK) and European Union (EU) legislation to ensure that veterinary medicines can be used safely and effectively is administered in the UK by the Veterinary Medicines Directorate (VMD). Two Defra Departmental objectives are relevant to the policy work of the VMD. These are to:-

- Support and develop British farming and encourage sustainable food production and
- Prepare for and manage risk from animal and plant disease.

Specifically, the aim of the VMD is to protect public health, animal health, the environment and promote animal welfare by assuring the safety, quality and efficacy of veterinary medicines.

Evidence from both Research and Development (R&D) and non-R&D (e.g. antimicrobial resistance monitoring, pharmacovigilance and veterinary drug residue surveillance) is used to underpin an effective system for the authorisation and control of veterinary medicines in order to achieve these aims.

An effective system will:

- protect those consuming the produce of animals that have been treated with them or coming into contact with veterinary medicines through handling them;
- ensure continued availability of safe and effective veterinary medicinal products in order to protect animal welfare and ensure sustainable livestock production;
- minimise the potential impact of treatment on the aquatic and terrestrial environments; and
- minimise the threat to animal and public health by limiting the development of resistance to medicines.

The budget for R&D evidence is held by Defra on behalf of the VMD and overseen by the Chief Scientific Advisor. The VMD, on behalf of Defra and the administrations in England, Scotland and Wales manages a portfolio of research in support of veterinary medicines related policies across Great Britain.

The budget for non-R&D evidence is held by Defra (for antimicrobial resistance and non-statutory veterinary drug residue surveillance) and VMD (for statutory veterinary drug residue surveillance and monitoring adverse reactions to veterinary medicines). Statutory veterinary drug residue surveillance is required to meet EU legislation and is completely funded by a levy on industry.

Official Defra figures show the total value of the UK livestock output in 2011 was £12.6bn. The veterinary expenses for food production were £414m and the National Office of Animal Health estimates the sales of veterinary medicines for food producing species at approximately £220m, which is included in the veterinary expenses.

The potential economic impacts relating to policy areas of interest to the VMD are discussed in more detail in Section 3, below.

2. Current and near-term evidence objectives

What are the current and near-term objectives for evidence and how do they align to policy outcomes?

The objectives for evidence collection to meet the key policy objectives identified above are delivered by a combination of research, monitoring, discussions with experts within Defra, other government Departments and externally, and collation of data covering veterinary medicines quality, prescribing and usage, disease patterns and trade in animal products for human food from a range of sources. All areas are kept under review and action taken as required on specific topics. A number of objectives are statutorily required whilst others are required to inform and develop policy. These are listed separately below, with those which are not statutorily based placed in a descending order of priority.

Objectives required to inform and develop policy

- Investigations into the usage of antibiotics in companion and livestock animals and possible linkage with carriage of antibiotic resistant bacteria of significance to public health to provide evidence relevant to the European “Action plan against the rising threats from antimicrobial resistance” (http://ec.europa.eu/dgs/health_consumer/docs/communication_amr_2011_748_en.pdf).
- Studies to help develop strategies to limit the development of anthelmintic resistance in sheep, cattle and horses.
- Pilot studies into potential alternative treatment for bees and how Maximum Residue Limits might be set for veterinary medicines in honey.
- Assessment of potential impact of veterinary medicines on terrestrial and aquatic environments and ecosystems to minimise the impact of treatments on the environment and biodiversity.
- Development of alternative methods to replace or reduce animal testing in the development and production of biological products for animals to meet government commitment to the 3Rs – i.e. Replacement, Refinement and Reduction, a widely accepted ethical framework for conducting scientific experiments using animals humanely, a government priority.

Objectives required to meet statutory policy requirements

- Commission monitoring of veterinary drug residues in food of animal origin, with analytical services currently provided by the Food and Environment Research Agency (Fera), to meet EU requirements;
- Monitoring of specified antibiotic resistant bacteria, particularly food-borne pathogens, in animals farmed for food production in the UK, with analytical services currently provided by the Animal Health Veterinary Laboratories Agency (AHVLA), to meet EU requirements;
- Collation of sales data for antimicrobials in the UK on an annual basis to meet EU requirements;
- Monitoring and assessment of health effects on humans, animals and the environment from use of veterinary medicines to ensure the potential for adverse effects is minimised.

3. Future evidence needs

What are the longer-term evidence needs for the policy area/ programme?

There are several policy areas which can be expected to be of importance in the medium to long term and the evidence needs for them are presented below in a descending order of priority. In each case, evidence may be sourced from a range of disciplines including veterinary and human health, analytical chemistry and social scientists to comprehensively address any needs identified.

Resistance to veterinary medicines, principally but not exclusively to antibiotics and anthelmintics, can be expected to continue to grow in importance and concern if the threat to animal and public health is to be minimised. The development of resistance to these medicines could have serious implications for the continuing availability of effective veterinary medicines. Furthermore, where classes of active ingredients are used in both veterinary and human medicine, resistance evolving from veterinary prescribing may impact on human health either through the food chain or contact with animals.

To set the antimicrobial resistance (AMR) issue in context, a recently published EU report (http://www.ema.europa.eu/docs/en_GB/document_library/Report/2009/11/WC500008770.pdf) records that the European Centre for Disease Prevention and Control estimates that AMR results each year in 25,000 deaths in the EU and related costs of over €1.5 billion in healthcare expenses and productivity losses. Evidence is needed to quantify the risk to public health from AMR resulting from the patterns of use of antimicrobials in both companion animals and livestock.

Furthermore, the development of resistance in gastrointestinal nematodes to several classes of anthelmintic is a current and major threat to the sustainability of sheep farming in the UK and an emerging threat in cattle and other livestock species. The VMD collects data on adverse reactions to veterinary medicine treatments and reports of treatment failures can give a valuable indication of the development of resistance to the medicines being used.

Continued availability of effective Veterinary Medicinal Products is dependent upon their responsible use, and evidence is therefore needed regarding the factors that encourage development of resistance, drivers for the prescription of veterinary medicines involving input as required from social scientists and to support best practice protocols for their use. (http://ec.europa.eu/dgs/health_consumer/docs/communication_amr_2011_748_en.pdf).

The Government takes seriously the suggestion that the use of veterinary drugs presents a potential risk to operators and the environment and the VMD requires evidence to ensure the protection of those coming into contact with veterinary medicines whether by direct physical contact, contact with animals or consuming animal products after treatment with the medicines. It also accepts that there is little scientific evidence to link chronic health effects in humans and impact on the environment with low doses of these substances. However, a number of related issues are currently being considered by independent advisory committees and if advised accordingly further evidence may need to be sought to answer questions raised by these committees. For example, the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment is currently considering the results of studies on the possible long-term impact of organophosphates used in sheep dips. In addition, advanced therapies that rely on biotechnology processes, e.g. genetically modified organisms (GMOs), are increasingly being developed for veterinary use and it is important that evidence is available as reassurance of their wider safety.

It is important for the VMD to ensure the continued availability of safe and effective veterinary medicinal products to protect animal welfare and ensure sustainable livestock production. However, the availability of veterinary medicines for the treatment of diseases where there is no economic incentive for pharmaceutical companies to develop them can result in compromised animal welfare and indirect impacts on rural industries and food safety. For example, the economic value of honey bees and bumble bees as pollinators of commercially grown insect pollinated crops in the UK is estimated at over £200m per year. Concern is growing over the health and loss of bee colonies over recent years. It is likely that evidence will need to be collected to understand the causes of this and set in place strategies to maintain and restore bee colonies and the VMD will collaborate as appropriate with Defra colleagues responsible for bee health and welfare.

Globalisation and climate change are bringing about changes to the pattern of animal diseases found in the UK and there is a significant risk that diseases previously considered exotic may enter the UK, as recent disease outbreaks have demonstrated. There have been over 14 exotic disease outbreaks in the last 10 years including foot and mouth disease, bird flu and bluetongue. The costs of disease outbreaks range from £2 million

(minor) to over £3 billion (major outbreak). Disease outbreaks can have a massive impact on the national economy and human and animal health. Evidence is required to identify and prioritise actions necessary to tackle potential disease outbreaks in conjunction with Defra colleagues responsible for animal health and welfare.

Veterinary drug residues in foods for human consumption will continue to be an area of consumer interest and the VMD will collect and take action where necessary on the results of veterinary drug residue monitoring to protect consumers and ensure that the authorisation and control of veterinary medicines is effective. These residues in food of animal origin can also give rise to international trade issues. For example, the EU banned the use of growth promoting hormones in food producing animals and the World Trade Organisation found against the EU in an international trade dispute. The international community recently agreed to standards for ractopamine, a beta agonist growth promoter for use in cattle and pigs, which the EU does not accept. It is likely that the UK will be expected to assist the EU in providing evidence to fight this case. The international community is now considering a number of other veterinary drugs which the UK and EU oppose and each will require further evidence to be provided to support our claims.

The European Commission is paying close attention to the potential effects of veterinary medicines on the environment and ecosystems and this fits well with the VMD policy aim to minimise the potential impact of treatments on the aquatic and terrestrial environments. A number of current surveys within the EU might lead to increasing demands on veterinary medicines in the longer term, for example on veterinary medicines which might reach drinking water supplies and the implications this might bring. Evidence will be needed to inform discussions on this topic as it develops.

4. Meeting evidence needs

What approach(es) will be taken to meeting evidence needs?

The VMD maintains a number of independent advisory and expert committees, such as the Veterinary Products Committee, the Defra Antimicrobial Resistance Co-ordination Group and the Veterinary Residues Committee, all of which contribute to the evidence pool available to the VMD and the assessment of specific topic areas as required. Advice from these groups helps to identify external evidence which must be sought, or an internal investigation of existing evidence within VMD/Defra if this is more appropriate. Members of VMD staff also serve on a wide range of committees both nationally and internationally and this provides feedback on important topic areas such as the potential human health impacts of antimicrobial resistance and the authorisation of veterinary medicines in the EU and internationally. In addition, the VMD has an extensive network of informal and formal contacts both nationally and internationally which provides constant information updates on current and emerging issues which might impact on policy areas for which the VMD is responsible or in which the VMD might have a shared interest. Examples include colleagues in Defra and other government departments in the UK and abroad, e.g. veterinarians, chemists, statisticians, social researchers, and economists, together with

experts in academia. This ensures a multi-disciplinary approach to identifying evidence needs and assessing the relative priorities of these needs and any approaches to providing the evidence.

Internal resources such as data collated by the VMD on annual sales of antimicrobials, adverse reactions to veterinary medicines, external sources of data e.g. DISCONTTOOLS (<http://www.discontools.eu/Diseases>) and results of veterinary medicine residue monitoring will also be considered to inform and prioritise evidence needs.

As a commissioner of research the VMD has a dedicated R&D manager supported by a research and development committee with membership drawn from across all expertise areas within the VMD together with representatives from Defra, Devolved Administrations, and other government Departments. The remit of this group extends from suggesting, discussing and prioritising by consensus the evidence needs and the best way to provide this evidence to assessing ongoing evidence collection (from commissioned studies and from internal reviews) and ultimately providing comment on the quality of the evidence produced and the impact it has on policy development. By involving other Departments with specific responsibilities for areas where there may be commonality of interest e.g. animal health and welfare, pesticides (where the VMD is represented on the Analytical Sub-Group of the Pesticides Residues in Food committee), bee health or food safety, overlap in evidence collection and divergence of policy can be avoided and the options for collaborative working with other government and non-government funding bodies is optimised.

5. Evaluating value for money and impact

What approach(es) will be taken to maximise and evaluate value for money and impact from evidence?

The VMD maintains a dedicated research and development group (see above) specifically to identify and prioritise evidence needs and the optimum means of delivering the necessary advice. Where evidence is to be commissioned from an external source either by open competition or by internal commissioning within Defra, all proposals received on the topic will be subjected to independent peer review for both quality and value for money prior to a successful proposal being accepted. Evidence providers will be expected to comply with Defra guidance on quality standards and any ethical considerations. Members of this group with specific expertise assist the VMD R&D manager to assess progress as the study is conducted.

On conclusion of external studies, the R&D manager in consultation with the group will consider the overall cost of the study and the potential for controversial findings and if necessary seek independent peer review of the final study report prior to accepting it. All final reports from studies supported by the VMD are published unless there are exceptional reasons. Publication may be delayed for a short period to allow contractors to

prepare scientific papers where previous publication of data might otherwise prejudice acceptance by peer reviewed journals.

The group and colleagues responsible for policy in the areas of study will be kept informed of studies as they progress and will consider the impact studies will have on policy development and the need for further evidence. The group will periodically review the influence of evidence collection on policy development and use this to inform identifying future evidence needs.

Evidence collection programmes and the impact they have had on policy will be subjected to external review at approximately five yearly intervals. The output of these reviews will inform future evidence needs.