

VETERINARY MEDICINES DIRECTORATE BUSINESS PLAN 2012/13 to 2014/15

(Please note that a full glossary of acronyms can be found at annex A to this Plan)

INTRODUCTION

1. The Veterinary Medicines Directorate (VMD) is an Executive Agency of the Department for Environment, Food and Rural Affairs (Defra). The VMD is a net running cost Agency, receiving nearly 80% of funding from industry fees and levies and the remainder from Defra (FFG).
2. Although a Defra Agency, the VMD has UK-wide responsibility for veterinary medicines regulation. In regulating veterinary medicines it works closely with Defra and with the Devolved Administrations to help and advise them on the delivery of their animal health objectives where veterinary medicines have a role. The VMD also works with other Government Departments (OGDs) who have responsibilities for areas of work that are included in the VMD's regulatory remit (e.g. FSA on food safety, Home Office on controlled drugs).
3. Medicines regulation is harmonised across the EU (including the EEA countries) and the VMD operates as part of the European Medicines Regulatory Network (EMRN) to deliver the processes leading to the authorisation of veterinary medicines.
4. This business plan covers the remaining three years of the Comprehensive Spending Review (CSR) period 2012/13 to 2014/15. It identifies Business Priorities, Activities and performance indicators for the first year and likely key issues for the subsequent years. It is expected that the next business plan (due for publication in March/April 2013) will cover the remaining two years of the CSR.

HIGH-LEVEL SUMMARY

5. The key elements of VMD's Business Plan for 2012/13 are:
 - achieve full cost recovery for the budget of £14.4m.
 - develop and start to implement a new Business Improvement Delivery Plan for the VMD.
 - influence the development of revised legislation in the areas of veterinary medicines, medicated feeds and residues surveillance.

- take steps to improve the surveillance for antimicrobial resistance in the UK and EU
- continue to play a leading role in HMA including chairing its veterinary AMR Task Force.

VMD'S PURPOSE AND WAYS OF WORKING

6. 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.
7. It will meet this aim through proportionate regulation, providing high quality services to relevant interest groups and utilising clear agreements with service providers.
8. The VMD **vision** is the responsible, safe and effective use of veterinary medicinal products.
9. The VMD is a "Licence to Operate" delivery body. Its primary purpose is to deliver the UK's obligations under EU legislation related to the use of veterinary medicines. In May 2011 the Defra Business Plan for 2011 to 2015 was published. This sets out the Department's Vision, Coalition Priorities, Structural Reform Plan, Departmental Expenditure and Transparency information in a common format required across all Departments. The VMD contributes to Defra's Structural Reform Priority: 'to support and develop British farming and encourage sustainable food production' and to its major responsibility: 'to prepare for and manage risk from animal disease'. This is done by:
 - a) ensuring that appropriate quality standards and timelines are applied throughout the approvals process to ensure that authorised veterinary medicines are assessed for:
 - quality, safety and efficacy - to provide reassurance that they are produced in a way that ensures a consistent product at a suitable premises, to provide reassurance that they will not harm the environment, public (consumer/user) or target species and that they will deliver their label claims if used in accordance with the marketing authority holders' instructions.
 - residues - to provide reassurance that residues found in meat, milk or other foodstuffs derived from livestock treated with veterinary medicines in accordance with the manufacturer's instructions will not harm the consumer, thus **ensuring** food remains safe. The VMD commissions residues monitoring work to give further assurance regarding food safety.

- b) working with colleagues in Defra to understand their approach to endemic, new and emerging diseases in the UK, providing advice on medicines availability and, where necessary, applying rapid and proportionate approval processes for companies developing new veterinary medicines to tackle such diseases.
 - c) acknowledging that farm livestock are a key national asset and authorised veterinary medicines (including vaccines), which prevent or treat disease, are integral to maintaining the health, welfare and efficiency of farmed livestock and contribute to the sustainability of UK farming.
 - d) the VMD also has responsibilities for the assessment and authorisation of companion animal veterinary medicines. Zoonotic diseases affecting human health are a significant factor and this will include wildlife veterinary medicines such as vaccines against rabies and TB in badgers. Although companion animals are not a key factor in the Defra Business plan they are, nevertheless, part of the UK responsibilities to be fulfilled under the Veterinary Medicines Directive. There are in the region of 2,300 UK authorised veterinary medicines and of these approximately half of them include an indication for use in a non-food producing species.
10. The VMD has UK-wide responsibility for the regulation of veterinary medicinal products and its work assists the Devolved Administrations to deliver their priorities and responsibilities. We work with the Devolved Administrations to take account of their needs when delivering against the business priorities in this plan.
 11. The VMD will keep the Defra CVO, relevant Defra groups and the Devolved Administrations updated on the authorisation of veterinary medicines and related issues that are relevant to their objectives to the extent that this is possible without breaching commercial confidentiality.
 12. The VMD will contribute to the Civil Service's and Defra's work to reduce costs and input to relevant central initiatives aimed at reducing the national deficit. Our aim will be to maintain and, where possible, improve the quality of service and value for money to all our customers.
 13. In accordance with the Government's transparency agenda, financial information relating to the VMD and a staff Organogram can be found at **www.vmd.defra.gov.uk**.
 14. The VMD will continue to identify and introduce changes to improve VFM across the VMD. As part of every project, including IT projects, we will identify and capture anticipated VFM metrics. A number of projects completed during 2011/12 have increased efficiency, in particular, the ability to securely handle dossiers submitted electronically rather than on paper and to convert those submitted on paper to electronic format. The rationalisation of two former

systems into a single inspection management database system, that supports the VMD wide inspection needs, has simplified the management of this work. The implementation of an updated pharmacovigilance database will improve the methods for data capture and data analysis, so improving efficiency. Work is continuing under the “Efficiency and Partnership Programme” which aims to look at the organisation of work and allocated resources within the VMD, and to look for opportunities for savings through partnerships with others. Within the first two years of this plan work to make an on-line export certificate site available will continue and is also expected to bring efficiency savings.

15. The VMD will continue to make improvements to its service delivery through seeking the opinions of customers. We will again use the results of the surveys to adapt the services we provide to ensure that they remain customer focused and reflect the respective interest group needs whilst achieving our vision of responsible, safe and effective use of veterinary medicinal products. We will continue to consult our customers and interest groups at the earliest stage during development of policy and strategy and invite them to put forward proposals for the development of effective regulatory mechanisms.
16. Over a number of years the VMD’s Business Improvement Delivery Plan (BIDP) has been a key driver for VFM changes across the Agency. The actions arising from the 2009 and 2010 Civil Service wide staff surveys and the 2009 IIP reassessment have been completed and during 2012/13 a new BIDP will be developed to allow us to act on opportunities identified through the 2011 Civil Service wide staff survey, work being carried out in response to the Judge review of the VMD and the EFQM benchmarking carried out in winter 2012. Benchmarking allows the VMD to identify best practice and review its procedures and performance enabling the VMD to introduce changes which will bring VFM benefits.
17. An area of focus for 2012/13 will be introducing an e-filing system across the whole of the VMD and the roll out of a new correspondence management database to support this. In addition by the end of the first year of this plan we expect to have completed the process of scanning data so that it can be held in electronic format, for data submitted to VMD in support of historical applications relating to authorised products. By the end of March 2013 we expect to make estimated savings in the region of £50,000 per annum at today’s costs from the reduction of storage charges.
18. The VMD has a wide range of customers and interest groups - from the general public, the food and pharmaceutical industries, to Ministers and the European Commission. These include specific sectors such as the veterinary pharmaceutical industry, the veterinary profession, suppliers of Veterinary Medicinal Products, primary processors of animal products, farmers, companion animal owners, various professional and consumer representative organisations and specific interest groups.

19. The VMD has thousands of customers who pay for the services provided. These include for example pharmaceutical companies, abattoirs, vets, animal health retailers and animal feed mills. Indirect fee-paying customers, such as pet owners and farmers are equally important to the VMD. We include as our customers (both fee paying and non-paying) the following groups:

Those we **directly regulate are**: the pharmaceutical industry, retailers, wholesale dealers and manufacturers of veterinary medicines, vet practice premises, Suitably Qualified Persons supplying certain veterinary medicines, feed mills producing medicated feed for animals, farmers recording medicines use, importers of medicines for animals and illegal operations (through enforcement).

Those who **benefit** from our work include animal keepers (including farmers and pet owners), the general public through healthier animals and safe food production, and the animals themselves.

Those **other interested parties** who liaise with the VMD include Government departments and agencies (Defra and its Agencies, Food Standards Agency, MHRA, DH, HPA, HSE, Scottish Government, the Welsh Assembly and the Northern Ireland Executive), other medicines regulatory bodies (EMA, EU national competent authorities and third country competent authorities). Trade and professional organisations such as NOAH, IFAH, AHDA RCVS, GPhC, BVA AIC NFU etc. Technical Advisory committees including VPC/VRC RUMA/SCOPS/ etc. Food business operators, supermarkets etc. Farmers and bodies such as the researchers and academia involved in medicines research and training.

Please note that this list is necessarily incomplete.

20. The VMD operates to a published Communications Strategy and uses a variety of means to provide information to its audiences and will improve accessibility to all interested parties by ensuring that the information on its website (www.vmd.defra.gov.uk) is both up-to-date and expressed in language appropriate to the intended audience. To facilitate this a new VMD website was launched in January 2011 and arrangements introduced to keep it up to date. Results from surveys will be used to make further improvements to the website.
21. The VMD will continue to work to the requirements of the Freedom of Information Act and the Environmental Information Regulations. A summary of the requests we have dealt with under the access to information legislation will be published in our Annual Report and Accounts. In addition, details of all requests to the VMD and our responses under this legislation will continue to be published on our web site at http://www.vmd.gov.uk/business/ati_disclosure.aspx.

KEY STRATEGIC PRIORITIES FOR THE VMD

2012/13

AUTHORISATIONS WORK

22. Increasingly over the past decade, as the nature of the work in the Authorisations Division has moved from primarily national only applications towards European applications, we have had to adjust the skill base of our resources to address this change which has been matched by a change in the pattern of our income sources. This trend is expected to continue over the period of this business plan with national application volumes forecast to decrease by 2% (£0.02m) and European application volumes forecast to increase by 12% (£0.3m) by 2014/15.
23. In addition to the change in balance between EU and national authorisations work, the nature of the application types continues to shift with the proportion of generic applications continuing to grow in EU and national procedures. The pharmaceutical industry itself continues to fragment, with company mergers leading to a small number of large multi-national companies, whilst a number of small companies, often in specialist areas, continue to operate usually at a national level. There are however signs that some of these smaller companies are now exploring opportunities in the EU marketplace, which will lead to further Mutual Recognition and Decentralised procedures and the UK will hope to continue to attract a significant proportion of the lead assessment work.

WORKING AS PART OF THE EU NETWORK

24. Veterinary medicines regulation is governed by EU Legislation. Our EU strategy is intended to ensure that the VMD assumes a leading role in developing policies, legislation and guidelines on issues that are likely to have a significant impact on veterinary medicines safety and/or availability or significantly affect the way the VMD regulates medicines in the UK. Priority issues are antimicrobial resistance, revision of EU legislation and the challenges posed by older, non-harmonised national Marketing Authorisations. We will continue to place significant emphasis on working with EU colleagues for the strategic development of the EU Veterinary Medicines Systems.
25. As a result:
- the VMD will lead and actively contribute to the work of the HMA taskforce responsible for delivering the HMA Strategy and action plan on antimicrobial issues. Through this work and in collaboration with other organisations such as the RCVS, BVA and NOAH, the VMD hopes to achieve a better understanding of the risk factors encouraging the development of antimicrobial resistance and to put in place appropriate education and training programmes to help ensure the continued

availability of a wide range of effective antimicrobials for use in all animal species.

- the Commission is expected to propose major changes to the EU legislation related to the regulation of veterinary medicines and their use, as well as introducing a new Animal Health Law. In all cases the VMD will work to influence the legislation to ensure that safe and effective veterinary medicines remain available for use in animals and regulatory burdens are kept to the minimum. The UK will continue to Chair the CMDv Legislation Working Group as a means to promote and influence proposed legislation across the EMRN.
 - the EU network has seen an increasing number of referrals which are ultimately aimed at minimising potential risks associated with the use of veterinary medicines and, where appropriate, achieving harmonised Summary of Product Characteristics (SPCs). One of the major issues to be tackled over the period covered by this plan is how to deal with the legacy of nationally authorised veterinary medicines which have very divergent SPCs across the EU, some of which may have implications for safety and efficacy. The early phase of this plan will involve looking at ways to avoid such SPCs becoming further divergent from each other. In this regard the VMD will build on its partnership initiative with Ireland, Belgium and The Netherlands. The CMDv and CVMP is dealing with formal harmonisation under the current EU legal framework and the development of new proposals to deal with harmonisation under the revised EU legislation.
26. In order to ensure the VMD's EU activities are prioritised appropriately its EU Steering Committee will continue to provide oversight of this area, ensuring all the VMD's EU activities are co-ordinated and appropriately resourced.
27. The VMD will continue to maintain an active role in the CVMP and CMDv meetings by assessing MRL applications, centralised and de-centralised product applications and referring issues of concern for consideration. We will also contribute to the development of new proposals from these meetings that are aimed at prioritising resources, introducing efficiencies and harmonisation of approaches, in order to manage better the increasing volume of work for these groups. The VMD will continue its involvement with the CVMP's working parties, providing expertise to assist with the development of advice and guidance for industry.
28. A risk based approach will be used when deciding on the level of assessment given to applications involving a number of member states. Applications where the VMD takes a leading role (i.e. RMS/Rapporteur/Co-Rapporteur) will be subject to full scrutiny. For other applications the VMD will seek to use the assessment of the other member state as the basis for its decision. In the case of high risk products an appropriate level of scrutiny will still be applied.

29. The UK plays a leading role at the HMA (veterinary) meetings and is active in several areas in the HMA joint meeting with the heads of human agencies. The CEO and/or the Director of Authorisations attend meetings of the HMA (four per year). During the period of this plan the VMD will contribute to the work of the HMA group dealing with planned improvements to the EU legislation relating to veterinary medicines as well as leading the group dealing with antimicrobial resistance. The VMD will continue to contribute to the wider corporate issues, including telematics.
30. The **European Technology Platform for Global Animal Health (ETPGAH)** seeks to use available technology more effectively in the control of animal diseases in the EU. The CEO currently represents HMA on the Platform's *Executive* Board and the Steering Council. In addition, the VMD provides the secretariat to the UK mirror group aimed at delivering the Technology Platform initiative in the UK. ETPGAH aims to facilitate better co-ordination of R&D in the veterinary field and to increase the availability of technical tools (medicines and diagnostics) aimed at animal health.
31. The VMD is already engaged in the VICH process, which develops guidelines and pharmacopoeial monographs which are applicable in three regions of the world (EU, Japan and USA). The VMD will continue to contribute to this process and will cultivate its existing bilateral relationships with third countries such as Australia, Canada, New Zealand and USA. The VMD will continue to contribute to the work of the OIE, for example in the area of rabies vaccines.
32. **EU Legislative Reviews:** The EC is working on the revision of the Veterinary Medicines Directive (2001/82), the Residues Surveillance Directive (96/23) and the Medicated Feedingstuffs Directive (90/167). The VMD is leading on providing the UK's input during negotiations and will work closely with Ireland who hold the presidency during a critical phase.
33. **Antimicrobial Resistance:** Defra transferred responsibility for antimicrobial resistance policy to the VMD on 1 April 2011. This complements the AMR work already done by the VMD and is a work area of increasing significance. The VMD has an important role in both co-ordinating R&D in this field and in working to educate manufacturers, distributors, prescribers and users regarding responsible use. In November 2011 the Commission launched its' Action Plan for antimicrobial resistance and is now expected to develop specific proposals which VMD will seek to influence. Effective engagement in the EU approach to antimicrobial resistance is essential and the VMD will take a key role in 12/13 to seek to improve the co-ordination of surveillance for antimicrobial resistance, particular for target animal pathogens in the UK and the EU.

34. **VMD Enforcement Strategy:** The VMD Enforcement Strategy was published in March 2010 and will continue to be used to address the issue of unauthorised products claiming medicinal properties such as nosodes and nutritional therapies.
35. **Telematics:** The VMD is highly reliant upon efficient, tailored IT systems some of which are required to be integrated with increasingly important EU telematic (IT) systems which underpin the European network of medicine agencies. The VMD will continue to participate in work to develop a common EU portal for the submission of applications and data for Marketing Authorisation applications and will continue to provide adverse event data to the EudraVigilance database and to regularly update the information on UK authorised veterinary medicines included in the publicly accessible database EudraPharm. Through HMA, the VMD will seek to influence the development and population by all NCAs of an enhanced version of this product database or a replacement database. The ESVAC database is an additional area requiring input of data on the sales of antimicrobials for use in animals.
36. **Quality System:** The establishment of a quality standard within the EMRN is increasingly becoming an emerging requirement for NCAs. This is considered to be a likely business requirement for continued involvement with EU assessment work. In anticipation of this developing requirement in 2008/09 the VMD introduced a quality system in the GMP inspection team and the first audit against agreed standards took place during 2009/10. The experience of that work has been used as the basis for developing an Agency wide quality system which is now fully implemented. The quality system will be refined to improve its operation and in 2012/13 a gap analysis will be performed to establish what would be required to gain formal accreditation to ISO9001. According to the findings, the cost and the likelihood of any EU legal requirement for accreditation, this may be sought and obtained before the end of the period of the plan for whole of the VMD.
37. **Communications:** The VMD has enhanced its public profile considerably in recent years. A Communications Strategy and Plan, for internal and external communication, has been published and will be updated as necessary. We will continue to seek to raise awareness amongst the wider professional and public audiences of the importance and benefits of the regulatory system and control measures that are in place for veterinary medicines. As part of the delivery of this plan in 2011/12 the VMD participated in a number of events targeting the veterinary profession, animal keepers and the public in order to raise awareness about the work of the VMD and the Veterinary Medicines Regulations. This has proved to be very successful and a similar programme is planned for coming years. We will continue to build our contacts with consumer organisations and other stakeholders to facilitate better two-way communications with them.

38. **Effect of CSR:** The Comprehensive Spending Review settlement has inevitably increased the funding pressures across Government and will have a considerable impact across the life of this business plan. The VMD will work with the expenditure controls on public sector pay and recruitment to minimise the risk of loss of expertise and to ensure it can respond quickly to fluctuations in workload. The VMD will implement changes arising from the VMD's analysis of the recommendations made through the Judge review (see para 16) in order to improve efficiency and to optimise the use of partnerships. The uncertain economic climate may also impact on industry activity, which could influence the demand for VMD work and therefore its costs and income from fees and charges. The VMD will continue to use information from the industry to predict future trends and workloads.

We will also explore the extent to which the current operating business model is the most appropriate.

39. **Replacement Head of Financial Services:** The Head of Financial Services left the VMD at the end of March 2012, Recruitment of a replacement is in progress. An Interim Head of Financial Services has been appointed whilst recruitment is completed.

2013/14-2014/15

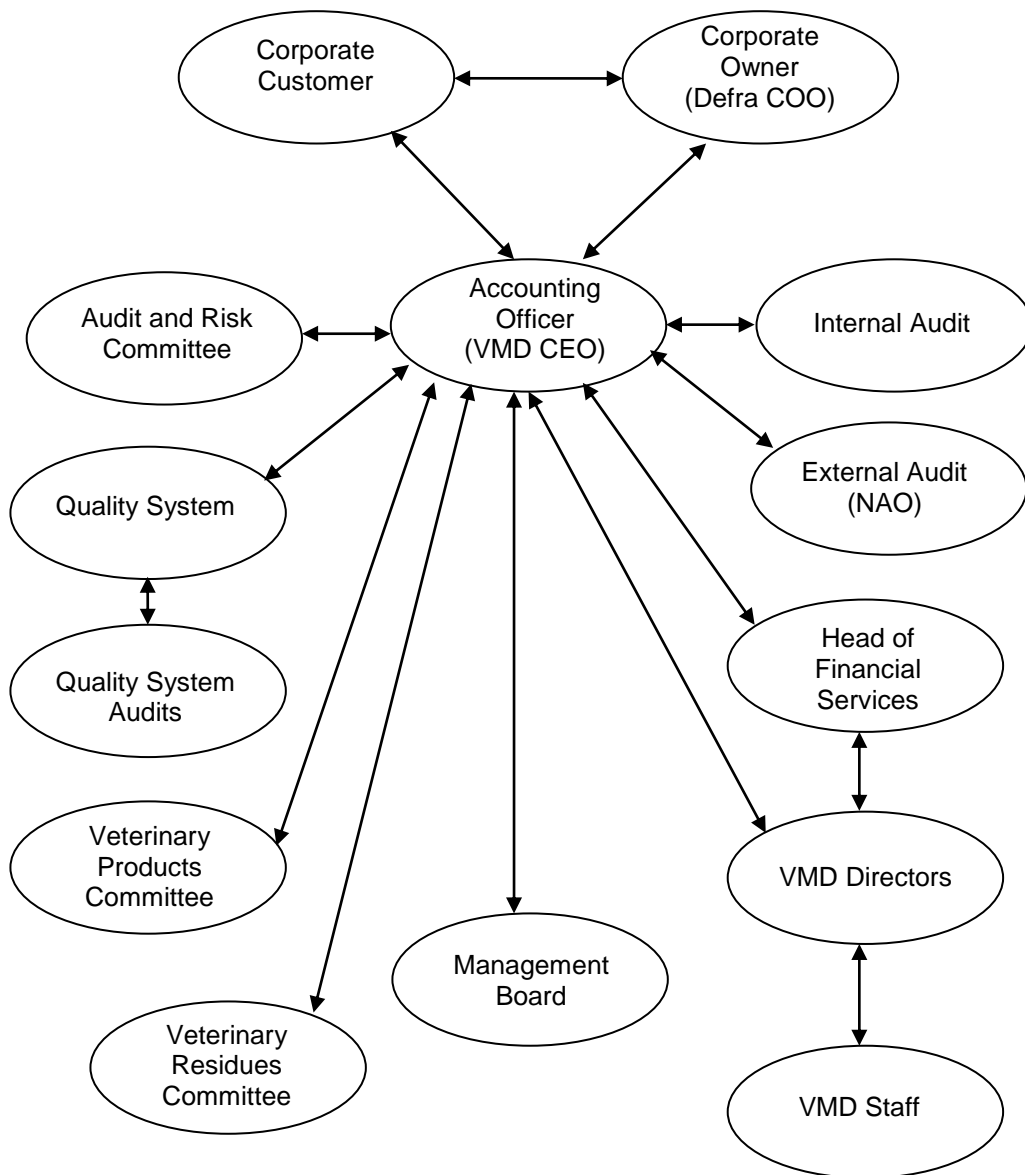
40. Implement the changes agreed in the EU legislation reviews on the Veterinary Medicines, Medicated Feed and Residues Directives.
41. Implement any changes required as a result of the Commission's antimicrobial resistance strategy.
42. Consider with Defra the future of the non-statutory residues scheme following the proposed implementation of the revised Vet Checks Directive.

GOVERNANCE AND RISK MANAGEMENT

43. The Secretary of State for Defra determines the overall policy and financial framework within which the VMD operates. The VMD is a net running cost agency with the Defra Deputy CVO as Corporate Customer and the Defra Chief Operating Officer as Corporate Owner who receives advice on the Agency's strategic direction and performance from the VMD Owner Advisory Board. In 2011/12 23% of funding came from Defra and 77% from fees and charges to industry and this split is expected to continue. The VMD will continue to review its fees and charges to ensure that costs are recovered as accurately as possible without the risk of cross-subsidy. The CEO is accountable to the Secretary of State for Defra for the performance and operation of the VMD in accordance with its framework document.

44. Day-to-day management within this framework is the responsibility of the CEO who, as Agency Accounting Officer, is individually and personally accountable to the Minister for achieving good value for money, regularity and propriety in the administration and operation of the VMD. The CEO is entitled to direct contact with HM Treasury with regard to the proper conduct of the VMD's finances. As Accounting Officer, the CEO has responsibility for maintaining a sound system of internal control that supports the achievement of the VMD's policies, aims and objectives, whilst safeguarding the funds and departmental assets for which the CEO is personally responsible, in accordance with the responsibilities assigned to the CEO in "Managing Public Money". The CEO is supported by Directors of Authorisations and Operations and a Management Board. This support structure provides an advisory and challenge function and is designed to give the CEO adequate insight into the business of the organisation and its use of resources to allow informed decisions about progress against business plans. There is no legal or statutory corporate structure to senior management within the VMD, unlike the private sector in which Directors are individually and severally accountable and liable for the decisions of the Board. Although responsibilities are delegated by the CEO to other senior managers, the formal accountability cannot be delegated or shared.

45. The Accounting Officer relies upon assurance from many sources, these can be summarised diagrammatically as follows:



46. The VMD has a comprehensive risk-management process reaching every level of the business under the leadership of the CEO and taking advice from the independent Audit & Risk Committee. As Chairman of the VMD's Management Board, the CEO has responsibility for providing the strategic leadership necessary to endorse the VMD's risk management procedures and to ensure that they are being implemented appropriately throughout the Agency. As Accounting Officer, the CEO has responsibility for maintaining a sound system of internal control that supports the achievement of the VMD's policies, aims and objectives, whilst safeguarding the public funds and departmental assets for which the CEO remains personally responsible, in accordance with the responsibilities assigned in Managing Public Money.
47. Establishing the levels of operational, scientific and financial risk and putting in place proportionate and effective measures to manage such risks is intrinsic to the VMD's work. The VMD's Internal Audit strategy will ensure that the adequacy and effectiveness of internal controls is reviewed on an annual basis.
48. The staff, their experience and expertise are the key asset of the VMD. Considerable effort is put into ensuring that expertise is kept current, however we accept that travel to CPD events around the world is expensive in money, time and environmental terms and we continue to seek novel solutions to minimise the cost of this work whilst ensuring the learning remains effective. The VMD will provide local support to managers to ensure that Defra HR policies are implemented consistently and effectively throughout the Agency. Our performance will be benchmarked against the IIP standard in 12/13 but we will review the benefits of this standard, for future years.

IT

49. The IT team deliver a full range of services, including maintaining and upgrading hardware, software and bespoke databases and developing in-house IT systems to underpin the efficient operation of the VMD. We are working to deliver the Government's vision for full electronic service delivery. Our IT Strategy, which defines the work programme for our IT staff, has been developed with this vision in mind.
50. We will also continue to integrate and align where appropriate our systems and databases as part of the European programme to allow for the exchange, storage and retrieval of information on veterinary medicines authorised in the EU and on the pharmacovigilance information for such products.

BETTER REGULATION

51. The VMD is working in a number of areas to ensure better regulation by reducing or removing regulatory burdens where appropriate. In particular we are working within the EU to ensure that legislation changes do not result in unnecessary burdens. Within the UK the 2011 revision of the Veterinary Medicines Regulations was subject to scrutiny to ensure that regulatory

burden was appropriate. Where possible, inspections have been delegated to others to reduce burdens. Examples would be the GMP inspection of joint human and animal manufacturing sites by the MHRA on behalf of the VMD and the Veterinary Practice Premises inspections being carried out on behalf of the VMD by the RCVS. In addition the VMD provides clear guidance and downloadable notes and leaflets to ensure that customers fully understand the regulatory framework.

JOINT WORKING

52. In January 2012 we initiated a project within the VMD to identify additional opportunities where partnerships would facilitate better delivery and offer greater value for money. This work builds on a number of existing partnership agreements some of which are mentioned above. Joint working underpins the EU NCA network to deliver all EU authorisation procedures

SUSTAINABILITY

53. The VMD is working to establish appropriate baseline data for its operation which has been complicated as previously the VMD building has been considered as part of the larger site and not in isolation. Waste is already 100% recycled and efforts have been made in past years to reduce water electricity and gas usage. Further opportunities for savings will be investigated over the period of this plan, however initial work indicates that this will require capital works and a cost:benefit analysis will guide further actions.

OBJECTIVES

KEY DELIVERABLES FOR THE VMD 2012/13-2014/15 AND KPIs FOR 2012/13 Business Priority 1 - Delivery:

- A) The VMD's role, as regulator, is to authorise veterinary medicines, inspect premises at which they are manufactured, distributed and supplied and monitor their impact. This will be achieved by ensuring that veterinary medicines are **authorised** according to legislative requirements and based on sound science. The VMD will ensure that the ongoing benefit:risk assessment of veterinary medicines remains positive by **monitoring** the effect of their use, and **responding** to adverse reactions by taking proportionate action on quality, safety and efficacy as necessary.

Key Activities for 2012/13

1. Provision of scientific assessment and assurance to meet the requirements of the VMR demonstrating the benefits of authorised medicines outweigh potential risks to human, animal and environmental safety.
2. Provide internet access to public assessment reports and SPCs for nationally authorised products, and EU authorised products, where VMD led the assessment.
3. Ensure the quality of veterinary medicines by risk-based inspection of manufacturers, distributors and retailers, including veterinary practice premises. Ensure the quality and safe supply of feedingstuffs containing prescribed veterinary medicinal products and/or specified feed additives through the approval and risk-based inspection of relevant businesses.
4. Monitor adverse reactions from pharmacovigilance data and identify emerging trends or signals. Take proportionate action when necessary. Present a summary performance report periodically to VPC meeting for independent consideration and advice. Take action to encourage the reporting of suspected adverse reactions (SARs), especially through the online portal.
5. Provide a fast and efficient service to veterinary surgeons for issuing Import Certificates, in accordance with the VMR.
6. Facilitate the importation of medicines when needed to prevent disease outbreaks, provide advice on the use and availability of veterinary medicines for controlling or preventing national disease outbreaks, including endemic, new and emerging diseases (including bees).

KPIs for 2012/13

- a) Quarterly reporting against Published standards which set out the timelines and performance categories for: the main different types of marketing authorisation application work, the recording of pharmacovigilance data and the publication of SPCs and public assessment reports. At least 90% of indicators to at least be at the effective level.
- b) Annual overall reporting against Published standards which set out the criteria and performance categories for the standard of VMD's assessment work as judged by the independent Veterinary Products Committee. Performance to be at least judged as effective.
- c) Quarterly reporting against published standards which set out the timelines and performance categories for the inspection of manufacturers and wholesalers. All inspection indicators to be at least at the effective level.
- d) Overall performance against published standards, as calculated according to the equation set out in the published standards, to at least be at the effective level.
- e) The VMD website will be available for the provision of information on veterinary medicines and to apply for import certificates and report adverse reactions on-line for at least 99% of the year.

Other Indicators for 2012/13

- a) The VMD will encourage electronic reporting of adverse reactions through attendance at shows, through press articles and in talks and meetings. As an indicator of our success we will report the percentage increase in the proportion of spontaneous adverse reactions reported on-line over the year from a baseline as at 2011 Q4 of 31.5%.

- B) Evidence of actions that influence the responsible, safe and effective use of veterinary medicines according to the legislative requirements through proportionate surveillance and inspection activities. Where necessary, use enforcement action to detect and deter illegal manufacture, distribution, advertising or use of products. Introduction and revision of current policies to carry out proportionate regulation of medicines in the veterinary sector.

Key Activities for 2012/13

1. Progress a project to revise or revoke and remake the Veterinary Medicines Regulations and update all VMGNs as necessary. Review and modify if appropriate the policy on advertising.
2. Investigate unlawful distribution in accordance with VMD's published Enforcement Strategy. Investigate and follow-up breaches of the VMR in accordance with the VMD Enforcement Strategy. Publish on a quarterly basis a high level anonymised summary of enforcement activities and issued improvement and seizure notices
3. Monitor sales of veterinary antimicrobials in the UK by collecting and publishing the antimicrobial sales data on an annual basis. Report results of monitoring to the EU ESVAC database. Work across Government with manufacturers, distributors and users to promote responsible use of antimicrobial products. Seek to promote and co-ordinate appropriate R&D and surveillance into antimicrobial resistance in the UK and EU. Support the Defra Antimicrobial Resistance Co-ordination (DARC) group meetings arranged quarterly.
4. Manage the VMD's medicines R&D programme in line with the decisions of VMD's R&D Steering Committee.
5. To develop and deliver for 2012/13 an efficient programme of residues surveillance which fulfils the UK statutory obligations and which within the constraints of the available funding examines on a risk basis the presence of residues in foodstuffs from third countries. Publish summary residue surveillance results on a quarterly basis.
6. Investigate positive residue results in excess of appropriate legal limit (MRL) according to risk-based standard operating procedures, and apply penalties proportionately to reduce the risk of further incidents.

KPIs for 2012/13

- a) Statutory residues plan agreed with the Commission according to the timeframe set out in Council Directive 96/23.
- b) Report on antimicrobials sales data to be published by 31 October each year. Supply sales data to the ESVAC project to meet its deadline (September as of 2011).
- c) Completion of the July 2011 to February 2012 non-statutory residues surveillance programmes achieved by end April 2012. Completion of the 2012 (calendar year) statutory residues surveillance programme achieved by end February 2013 and publication of the figures for both the 2011 statutory programme and the 2011/12 non statutory programme in the VRC annual report by end September 2012.

- C) Work to ensure as far as possible that UK policy principles influence EU legislative change, further the principles of market harmonisation and the development of efficient and effective procedures and guidance within the European Medicines Regulatory Network (EMRN).

Key Activities for 2012/13

1. Contribute to the development of the revised EC legislation for veterinary medicines, medicated feeding stuffs and residues surveillance.
2. Collaborate with other National Competent Authorities (NCAs), the EMA and DG Sanco particularly through effective attendance at meetings of HMA, CVMP and CMDv and related working groups to influence EU strategy development.
3. Engage with UK interested parties, other Member States and the European Commission to take forward the Cabinet Office initiative on proportionate regulation and the reduction of administrative burdens to industry.
4. Publish the outcome of consultations with interested parties on our website; holding a workshop for interested parties to discuss the Commission's impact assessment on the Directive 2001/82; ensuring the page on the VMD's website re the review of the directive is kept up to date.
5. Seek to improve interoperability of IT systems across the EU to foster the eSubmission environment and improve efficiency within the network.
6. Engage with the EMA, Codex Alimentarius, OIE and other international bodies to influence the harmonisation of guidance and standards applied to the regulation of medicines and the development of policy on risk management of key issues such as antimicrobial resistance, residue analysis and surveillance.

KPIs for 2012/13

- a) Report the number of EU Working Parties, Taskforces, Sub-Groups, Guideline revisions etc. led by the VMD to Agency Ownership Board meetings.

Other Indicators for 2012/13

- b) Report the number of EU IT system developments, including those relating to e-submissions, influenced by the VMD to Agency Ownership Board meetings.

Business Priority 2 – Customers and Interest Groups:

- A) Ensure that the veterinary pharmaceutical industry consider the level of service provided by the VMD to be good or excellent and that the VMD act on areas identified requiring improvement within the confines of the available resources.

Key Activities for 2012/13

1. Summary of results from 2011 customer survey and summary action plan to be produced. Complete actions in accordance with agreed action plan.
2. Compile and review the feedback from company meetings.

KPIs for 2012/13

- a) Report on customer survey to be published by 31 July 2012.
- b) All HIGH importance actions identified from the Customer Survey completed within agreed timescales.
- c) The overall median score from feedback surveys for individual VMD company meetings to be not less than 4 (scale 1-5 with 4 good and 5 excellent) for at least 90% of the meetings.

- B) Policy customers in Defra and OGDs considering the level of service provided by the VMD to be satisfactory.

Key Activities for 2012/13

1. ART to carry out the annual survey of VMD's policy customers.

KPIs for 2012/13

- a) The median overall score to be at least 4.0 (out of 5.0).

- C) Communications to customers and interest groups

Key Activities for 2012/13

1. Implement the VMD communication strategy in accordance with agreed priorities and timescales in the communications plan.
2. Respond to requests under access to information legislation in accordance with statutory deadlines.

KPIs for 2012/13

- a) Communications Plan: At least 90% of high importance actions completed within agreed timescales.
- b) ATI Requests: at least 95% cases responded to on time.

Business Priority 3 – Value For Money:

Achieve cost recovery and demonstrate progress in the three elements of Value for Money (Economy, Efficiency and Effectiveness) whilst maintaining appropriate work and delivery standards.

Key Activities for 2012/13

1. Achieve full cost recovery for the VMD, in line with Treasury Guidance on fees and charging demonstrated through an NAO audited Annual Report and Accounts.
2. Ensure that fee levels generally reflect the work done and do not increase by more than inflation unless justified.
3. Engage as appropriate in central initiatives intended to provide VFM, ensuring VMD's business needs are understood and solutions are fit for purpose. Monitor the performance of new systems to ensure they deliver the promised VFM.
4. Manage the research, analytical, sampling and surveillance contracts to ensure they meet their objectives.
5. Reduce consumables and data storage costs by scanning archived marketing authorisation data and introducing electronic filing in the authorisations area. Continue to develop electronic capability for submission of other application types and internal storage.
6. Develop a Business Improvement Plan to include work on reviewing the efficiency of the VMD and the benefits that enhanced partnerships could offer, the results from the 2011 annual staff surveys and the winter 2012 EFQM assessment.
7. Continue to embed the VMD Quality Management System (QMS) including the carrying out of internal audits in accordance with the annual plan and implementing the agreed changes to ensure the system is robust, proportionate and meets business needs. Evaluate the benefits and costs of seeking formal accreditation.

KPIs for 2012/13

- a) Cost recovery to be within the range 100-102% of full cost recovery.
- b) Research, analytical, sampling and surveillance contracts: percentage of programme delivered in year, and the percentage increase/decrease in costs year on year reported to Agency Ownership Board meetings.
- c) E-Working: reduction in paper based storage costs (£ savings).
- d) Business improvement: launch new Plan to VMD staff by end July 2012 and start implementation of all high priority and 50% of the medium priority actions which arise by 31 March 2013.

Other Indicators for 2012/13

- e) Quality Management: Percentage of compliant procedures and percentage of procedures/processes audited, reporting of steps to achieve formal accreditation if applicable.
- f) Percentage average fee changes in year.

Business Priority 4 - Capacity and Capability: Ensuring the VMD utilises its funding streams efficiently to maintain capability and capacity to deliver its business objectives and is fit for purpose.

Key Activities for 2012/13

1. Deliver financial controls, VMD's Training and Liaison services, Quality and Design Services and Business Support to agreed timelines and/or internally published standards.
2. Implement the VMD's IT Strategy according to priorities set by VMD's IT Strategy Committee.
3. Ensure that risks are actively identified and managed and that actions are recorded in the VMD's Risk Register and reviewed on a quarterly basis by the VMD's Audit and Risk Committee.
4. Provide timely and accurate secretariat services to the Veterinary Products Committee, the Veterinary Residues Committee, DARC and other committees/meetings as necessary.

KPIs for 2012/13

- a) Internal/External Audit opinion on effectiveness of financial controls and more generally systems to be "Substantial".
- b) Sickness absence – days lost per FTE. (see footnote to table)
- c) Training budget spend as training days per FTE.

Other Indicators for 2012/13

- d) Percentage delivery of targets set out in the IT strategy, but subject to changing business needs.
- e) Percentage of VMD IT systems downtime.
- f) Through good management practice and the implementation of business improvements identified through the work identified above the VMD will seek to maintain the staff engagement score in the 2012 Civil Service People Survey, and will report outcomes from that survey to the VMD Agency Ownership Board.

Footnote: We are working to reduce the days lost through absences where the causes can be managed by the individual or through reasonable adjustments in line with the Defra Sickness Absence Management Policy. For this indicator we will differentiate the progress made on incidental absences from those resulting from serious long term diagnosed illnesses and injuries.

RESOURCES AND DELIVERY

FINANCIAL RESOURCES

Financial Planning Assumptions

Services funded by:		2011/12	2012/13	2013/14	2014/15
		Forecast £m	Budget £m	Plan £m	Plan £m
Veterinary Pharmaceutical Industry	Income	7.5	7.3	7.5	7.6
	Expenditure	7.4	7.3	7.5	7.6
	Result	0.1	0.0	0.0	0.0
Food industry	Income	3.7	4.0	3.9	3.9
	Expenditure	3.7	4.0	3.9	3.9
	Result	0.0	0.0	0.0	0.0
Defra Funded work	Income	3.5	3.2	3.2	3.2
	Expenditure	3.4	3.2	3.2	3.2
	Result	0.1	0.0	0.0	0.0
Total VMD	Income	14.7	14.5	14.6	14.7
	Expenditure	14.5	14.5	14.6	14.7
	Result	0.2	0.0	0.0	0.0
Cost Recovery %		101%	100%	100%	100%
Average staff numbers (FTE):	Permanent	149	153	157	159
	Temporary	6	6	2	0
	Total	155	159	159	159

Income sources - note:

54. Income from the “Veterinary Pharmaceutical Industry” is derived from fees in the Veterinary Medicines Regulations. Income from the “Food Industry” is derived from charges in the Charges for Residues Surveillance Regulations 2006 (Amended). All income from industry is dependent on the volume of industry activity. Income for “Defra-funded work” is confirmed by an annual funding allocation from the Department.

How VMD's resources are used

a) Services funded by the Veterinary Pharmaceutical Industry

Authorisation Work

55. A key function of the VMD is to authorise new veterinary medicinal products and maintain marketing authorisations for those products in the UK that continue to have a positive benefit/risk assessment. This involves the assessment of new applications for marketing authorisations, and any applications for variation and renewal of the data packages for existing authorised products.
56. This work is the subject of published standards (available on our website www.vmd.defra.gov.uk) that set out the timelines and quality which the VMD strives to achieve. These standards cover application related work as well as pharmacovigilance and some inspection activities. The extent to which the VMD meets these standards will continue to be monitored and published at least quarterly. In this way we will sustain our high level of performance whilst also taking forward initiatives for the future aimed at improving efficiency for both the VMD and the pharmaceutical industry.

Post Authorisation Work

57. The VMD will support the EudraVigilance Veterinary (EV Vet) system for the electronic exchange of pharmacovigilance information with MA holders. During 2010/11 the VMD introduced an on-line reporting form for suspected adverse reactions for use by veterinarians and the general public. Throughout the period of this plan we will continue to publicise this system in order to maximise the proportion of suspected adverse reactions reported in this way and increase the overall number of reactions reported. The updated national database of suspected adverse reactions to veterinary medicines facilitates improved statistical analysis of the data. The VMD will make use of this analytical tool and report possible serious suspected adverse reactions to the VPC.
58. To ensure the continued quality, safety and efficacy of veterinary medicines on the UK market, manufacturers of both pharmaceutical and biological veterinary medicines in the UK and third countries are subject to risk-based inspections in accordance with the principles of EU Good Manufacturing Practice (GMP). The supply of veterinary medicines through the distribution chain is similarly monitored on a risk-based approach in accordance with the principles of Good Distribution Practice (GDP).
59. The review of inspection fees to enable the move to full risk based inspections will be completed and a consultation held on the options. During 2011/12 the risk based inspection policy for veterinary practice premises and SQP Retailers was published in the revised VMGN 3; similarly the feed business risk based inspection policy was published in VMGN 17.

60. Our inspections team will continue to ensure that feedingstuffs containing veterinary medicinal products and/or specified feed additives are manufactured to required standards and that the retail supply of veterinary medicines is carried out in accordance with the Veterinary Medicines Regulations. Discussions will continue with other government organisations and trade association groups, including farm assurance schemes, to see if they are able to undertake feed inspection for the VMD as part of their routine inspections.
61. Our inspections team also carries out inspections of veterinary-only wholesale dealers and those veterinary practice premises that are not part of the Royal College of Veterinary Surgeons' Practice Standard Scheme.
62. Inspection and accreditation of internet retailers will be introduced over the course of this plan to provide animal owners with the assurance that they are buying authorised veterinary medicines from websites accredited by the VMD.
- b) Services funded by the Food Industry (surveillance for residues of veterinary medicines)**
63. Statutory Residues Surveillance is required by EU legislation to provide assurances that the controls on the use of medicines in food producing animals are working and there is no risk to consumers. This surveillance uses samples of meat, milk, eggs, fish and honey from UK producers and is mostly funded by levies charged to first processors of food from animals e.g. abattoirs and egg packers industry, with the testing of honey being funded by Defra. The costs come from sub-contracted sampling and analysis work, administered by a VMD residues team. Analytical services for this work have been provided by FERA (a Defra Executive Agency) since January 2011. Proposals to amend the EU legislation that governs the scheme are expected to be announced by the European Commission and negotiations are expected to begin over the course of this plan. We will negotiate for greater legislative flexibility so that sampling and charging can take account of developing national issues.
- c) Services funded by Defra (advice to Ministers and the EU, supplementary residues surveillance)**
64. We will continue to lead on veterinary medicines policy development and regulatory enforcement and to run the non-statutory residues surveillance scheme, testing imported food of animal origin from outside of the EU. This work funded by Defra is set out in the table below.
65. Over the period of the plan Defra funding for the non-stat residues scheme is expected to reduce as the scheme's role is overtaken by surveillance under the new Veterinary Checks Directive.

66. The VMD took over responsibility for all antimicrobial resistance policy, surveillance and R&D work from core Defra on 1 April 2011.
67. The table on the following page provides an overview of the work that the VMD plans to perform for Defra in 2012/13 under a Service Level Agreement and which is funded by Defra.

Task	Target	How	Why	Cost
OP sheep dips - develop policy following COT review of R&D results	3b	Provide papers for COT in collaboration with the Official Group on OPs.	To determine if historical low dose long term use of OP sheep dips has caused chronic health problems suffered by some sheep farmers.	<£0.1m
Veterinary Medicines Regulations	3b	Implement agreed changes for 2011 and consult on changes to VMR for 2012. Prepare for Commission proposals to amend EU legislation.	Keep national legislation up to date taking into account requests for change made by interested parties.	£0.5m
Enforcement	3b	Act on intelligence to identify cases and liaise with investigators and lawyers to take proportionate action.	To ensure that authorised veterinary medicinal products are supplied with the right professional support and that unauthorised products are not available to unsuspecting animal owners.	£0.9m
Antimicrobial Resistance	3b	Provide Defra policy advice including surveillance and R&D. Run the Defra Antimicrobial Resistance Co-ordination Group and compile the annual sales data report.	Develop policy on the use of antimicrobials in animals to reduce the risks of both developing antimicrobial resistance in animals and the possible consequences to humans from the food chain.	£0.7m
Medicated feedingstuffs and feed additives.	3b	Negotiate on EC legislation and advise on product applications. Lead on the revision of the Medicated Feedingstuffs Directive.	To ensure that the UK's view on the regulation of medicated feeds is, as far as possible, reflected in the revised Directive. To ensure EC legislation is proportionately implemented in UK.	£0.3m
Research and Development	3b	Identify issues and call for proposals to address them. Manage Defra's veterinary medicines and antimicrobial resistance R&D budget.	Provide evidence to underpin veterinary medicines and antimicrobial resistance policy and residues surveillance.	£0.1m NB this does not include the R&D budget £2.2m of which is retained by CSA.
Disease control issues	3b	Provide advice on the use and availability of veterinary medicines for controlling disease outbreaks, including exotic diseases and diseases of bees.	To help FFG develop disease control strategies that comply with veterinary medicines legislation.	<£0.1m

Task	Target	How	Why	Cost
Non-statutory Residues Scheme	3b	Develop and implement annual surveillance plan using sub-contractors for sampling and analysis.	Provide evidence of residues in imported and retail produce not included in the Directive specifying the coverage of the Statutory Scheme.	£0.2m staff and overhead £0.2m sub-contracted £0.4m Total
Statutory Residues Testing - Honey	3b	Develop and implement annual surveillance plan using sub-contractors for sampling and analysis.	Provide evidence of residues in home-produced honey.	<£0.1m
Veterinary Residues Expert Committee	3a	Provide secretarial support.	Provision of independent advice for the VMD and FSA Chief Executives.	<£0.1m including committee fees & expenses
Veterinary Products Committee	3a	Provide secretarial support.	Provision of independent advice for Ministers.	£0.1m including committee fees & expenses (50% is Defra-funded)
EU and international negotiation and representation	3c	Attend EU e.g. Standing Committees, Council Working Groups, and other international meetings e.g. Codex.	Ensure UK influences the development of veterinary medicines policy and procedures in the EU and worldwide and, in particular, the re-negotiation of the veterinary medicines, residues surveillance and medicated feed Directives.	<£0.1m
Freedom of Information requests	All	Implement Access to Information legislation in consultation with core-Defra.	Release as much requested information as possible while respecting commercial confidentiality and personal data.	£0.1m
TOTAL				£3.2m

**VETERINARY MEDICINES DIRECTORATE
MARCH 2012**

ACRONYMS AND DEFINITIONS

AIC	Agricultural Industries Confederation
AHDA	The Animal Health Distributors Association
AMR	Antimicrobial resistance
ARC	Audit and Risk Committee
BEMA	Benchmarking of European Medicines Agencies
BIDP	VMD's Business Improvement Development Plan
BVA	British Veterinary Association
CEO	Chief Executive Officer
CPD	Continuing Professional Development
CVMP	Committee for Veterinary Medicinal Products
CMDv	Co-ordination Group for Mutual Recognition and Decentralised Procedures – Veterinary
COT	Committee on Toxicity of Chemicals in Food
CSA	Defra's Chief Scientific Advisor
CSR	Comprehensive spending review
CVO	Chief Veterinary Officer
DARC	Defra Antimicrobial Resistance Co-ordination group
DECC	Department of Energy and Climate Change
Defra	Department for Environment Food and Rural Affairs
DG Sanco	Directorate General for Health and Consumer Affairs
DH	Department for Health
DSOs	Defra's Departmental Strategic Objectives
EC	European Commission
EEA	European Economic Area
EU	European Union
EFQM	European Foundation for Quality Management
EMA	The European Agency for the Evaluation of Medicinal Products
EMRN	European Medicines Regulatory Network
ESVAC	European Surveillance of Veterinary Antimicrobial Consumption
ETPGAH	European Technology Platform for Global Animal Health (EU European Union)
EV Vet	EudraVigilance Veterinary system for the electronic exchange of pharmacovigilance information
FERA	The Food and Environment Research Agency
FFG	Food and Farming Group - part of core Defra
FSA	Food Standards Agency
GDP	Good Distribution Practice
GMP	Good Manufacturing Practice
GPhC	General Pharmaceutical Council
HMA	Heads of Medicines Agencies
HMA(v)	Heads of Medicines Agencies (Veterinary)
HMA(j)	Heads of Medicines Agencies (Joint human and veterinary)

HPA	Health Protection Agency
HSE	Health and Safety Executive
IFAH	International Federation for Animal Health
IIP	Investors in People
KPI	Key performance Indicator
MAH	Marketing Authorisation Holder
MHRA	Medicines and Healthcare products Regulatory Agency
MRL	Maximum Residue Limit
MS	Member State
NAO	National Audit Office
NCA	National Competent Authority
NFA-VPS	Non-Food Animal - Veterinarian, Pharmacist, SQP
NFU	National Farmers Union
NOAH	National Office of Animal Health
OGD	Other Government Department
OIE	World Organisation for Animal Health
OP	Organophosphorus
POM-VPS	Prescription Only Medicine - Veterinarian, Pharmacist, SQP
PSUR	Periodic Safety Update Report
R&D	Research and Development
RCVS	Royal College of Veterinary Surgeons
RMS	Reference Member State
RQP	Registered Qualified Person
RUMA	Responsible Use of Medicines In Agriculture Alliance
SAR	Suspected adverse reaction
SCOPS	Sustainable control of parasites in sheep
SP	Synthetic Pyrethroid
SPC	Summary of product characteristics
SQP	Suitably Qualified Person
TB	Tuberculosis
UK	United Kingdom
UKPAR	UK Public Assessment Report
VFM	Value for Money
VICH	Veterinary International Co-operation on Harmonisation
VMD	Veterinary Medicines Directorate
VMGN	Veterinary medicines guidance note
VMP	Veterinary Medicinal Product
VMR	Veterinary Medicines Regulations
VPC	Veterinary Products Committee
VRC	Veterinary Residues Committee

Net Running Cost Agency: An Agency where the CEO has responsibility and flexibility to manage the business within a financial target set annually by Ministers. (In the case of the VMD, full cost recovery to be within the range 100-102%).

Licence to Operate Delivery Body: An Agency responsible for carrying out statutory obligations placed on the UK Government.

IIP: IIP assessment is carried out by independent assessors and provides a benchmark against “best practice”, and operates throughout the UK. The benchmarking process is open to both government and non-government businesses.