VETERINARY MEDICINES DIRECTORATE
BUSINESS PLAN 2014/15
AND FORWARD LOOK TO 2018/19

1. INTRODUCTION

1.1 The Veterinary Medicines Directorate (VMD) is a net running cost Executive Agency of the Department for Environment, Food and Rural Affairs (Defra). It receives nearly 80% of funding from industry regulatory fees and levies and the remainder from Defra.

1.2 The VMD's primary purpose is to deliver as part of the European Medicines Regulatory Network the UK's obligations under harmonised EU legislation related to the use of veterinary medicines.

1.3 The VMD **vision** is the responsible, safe and effective use of veterinary medicinal products.

1.4 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. It will meet this aim through proportionate risk based regulation, providing high quality services to relevant interest groups and utilising clear agreements with service providers.

1.5 The VMD has UK-wide responsibility for veterinary medicines regulation, working closely with Defra and with the Devolved Administrations to help and advise them on the delivery of their medicines related animal health objectives. 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. the Food Standards Agency (FSA) on food safety and the Home Office (HO) on controlled drugs.

1.6 The government priorities to tackle the deficit and create a business environment that supports economic growth will help shape the VMD's future activities. The VMD will continue to work as 'one business' with colleagues in Defra and the wider network, to bring together structures, systems and processes to deliver a better customer experience at a lower cost or improved value for money; and to implement the outcomes of the Civil Service Reform programme. This business plan identifies Business Priorities for the final year of the current Comprehensive Spending Review (CSR) period and looks ahead to the important issues likely to arise during the next spending review period.

1.7 The VMD is a risk management organisation whose primary role is to weigh up the benefits of veterinary medicines against their risks. It seeks to manage the risks associated with its operating environment to ensure business continuity and excellence in delivery. In particular industry turnover can significantly affect income: this is managed with the help of market forecasts informed by industry and modelling of historic trends. Uncertainties about

changes to the regulatory environment are managed by close involvement with and the influencing of European processes. The Chief Executive as Accounting Officer is supported by the VMD Management Board and two Directors. The Management Board includes; three Non-Executive Directors [all of whom sit on the Audit and Risk Assurance Committee] and a Defra Director level board member.

1.8 Over the coming year, despite the expected continuing constraints on funding from Government, in order to manage the projected growth in work funded by regulatory fees we will seek to recruit 4 additional staff, ensuring we have the correct mix of expertise and experience to allow us to deliver the work set out below. We are implementing Civil Service Reforms and seeking improvement in business practices to enable existing resource to be redeployed within the business.

HIGH-LEVEL SUMMARY

2.1 The key elements of VMD's Business Plan for 2014/15 are:

- delivery of core business to the satisfaction of customers.
- achieve full cost recovery for the budget of £14.5m.
- influence the development of revised legislation for veterinary medicines, medicated feeds and residues surveillance.
- to continue to play leading roles in the EU on antibiotic resistance
- to continue to develop plans for the implementation of the UK antimicrobial resistance strategy

In addition we will:

- continue to respond to issues that could have serious economic impact, for example by dealing promptly with applications for emergency vaccines for livestock.
- complete the work to identify the most appropriate business model for the VMD
- bring the non-statutory residues surveillance scheme to closure in March 2015
- seek to maintain staffing levels to ensure adequate delivery capacity and capability
- continue to provide value for money.

2.2 The significant challenges for the next comprehensive spending round period 2015/19 are currently considered to be:

- to deliver the veterinary elements of the UK AMR strategy on a prioritised basis
- to implement in UK changes in the EU medicines legislation
- to implement the outcomes of the consideration of business models for the VMD
- to implement the outcomes of the consideration of site rationalisation

KEY DELIVERABLES AND PERFORMANCE INDICATORS (KPIs) FOR 2014/15

These can be summarised under 4 headings as follows:

Business Priority 1 - Policy:

Policy Lead on behalf of Defra for Veterinary Medicinal Products and Antimicrobial resistance

Business Priority 2 - Delivery:

A) Facilitate wider availability of veterinary medicines

B) Surveillance and enforcement activities that influence the responsible, safe and effective use of veterinary medicines.

C) To influence EU legislative change and the development of appropriate procedures and guidance within the European Medicines Regulatory Network (EMRN).

Business Priority 3 – Customers and Interest Groups:

A) To ensure that the regulatory services provided meet the needs of the veterinary pharmaceutical industry.

B) Provision of appropriate services to policy customers in Defra and other government departments (OGDs).

C) Communications to, and engagement with, customers and interest groups

Business Priority 4 – Value For Money:

Achieve cost recovery and delivery of Value for Money.

Business Priority 5 – Capacity and Capability:

To ensure funding streams are used efficiently to maintain capability and capacity to deliver business objectives.

3.1 Business Priority 1 - Policy:

Policy Lead on behalf of Defra for Veterinary Medicinal Products and Antimicrobial resistance

Why are we doing this? The VMD has overall responsibility in the UK for veterinary medicines policy and animal health aspects of antimicrobial resistance in England in the broader context of Defra's Animal Health and welfare responsibilities and the contribution this makes to safeguarding public health.

Key Activities for 2014/15	**KPIs for 2014/15**
1. Policy lead and provision of policy advice on veterinary medicines to Defra and others. In particular: revision of the animal test certificate (ATC) scheme such that all aspects relating to clinical trials, including animal welfare, are regulated by the VMD; respond to the Committee on Toxicity of Food, Consumer Products and the Environment (CoT) conclusions on long-term neurological, neuropsychological and psychiatric effects in adults of low-level exposure to organophosphates used as animal medicines; influence the development and application of the EU legislative framework.	a) Consult on a revised Veterinary Medicines Guidance Note 6 on ATCs by 31 March 2015. b) Government response to the CoT statement finalised by 31 March 2015. c) Milestones and deliverables relevant to the VMD in the UK AMR Strategy achieved. (as set out in the AMR Strategy Action Plan due for publication November 2014)
2. Policy lead and provision of policy advice on antimicrobial resistance issues to Defra and others. In particular implementation of animal health specific aspects of the cross-government 5 year AMR strategy, through delivery of the following key activities: monitoring sales of veterinary antibiotics in the UK by collecting and publishing sales data on an annual basis; developing options for an alternative data collection programme that permits analysis of antibiotic consumption by animal species; liaison across Government and with manufacturers, prescribers and users to promote responsible use of antibiotics; delivery of an effective antibacterial susceptibility surveillance programme; promotion and co-ordination of appropriate research and development (R&D) into antibiotic resistance in the UK and EU.	d) Annual report on antibiotic sales and antibacterial sensitivity data published. Supply sales data to the ESVAC project to meet its deadline.

3.2 Business Priority 2 - Delivery:

A) Facilitate wider availability of veterinary medicines

Why are we doing this? We authorise veterinary medicines. Our work creates an environment that provides confidence and investment within the medicines industry and enables exports. It protects the food chain, human and animal health as well as the environment. It also ensures that unsafe medicines can be identified and appropriate corrective action or, where appropriate, removal from the market.

Key Activities for 2014/15	**KPIs for 2014/15**
1. Provision of scientific assessment and assurance to meet the requirements of the Veterinary Medicines Regulations (VMR) and EU legislation demonstrating the benefits of authorised medicines outweigh potential risks to human, animal and environmental safety. 2. Ensure the quality of veterinary medicines and feedingstuffs containing prescribed veterinary medicines by risk-based inspection of manufacturers, distributors and retailers, including as appropriate veterinary practice premises. Deliver this work through partners where possible e.g. RCVS re PSS inspections and Cefas re fish farmer inspections in England & Wales. 3. Monitor adverse events from pharmacovigilance data and identify emerging trends or signals. Take proportionate action when necessary. Where potentially significant issues are identified share the findings with the Veterinary Products Committee (VPC) for independent consideration and advice. Take action to encourage the reporting of adverse events especially through the online portal. 4. Facilitate the availability of medicines when needed to treat animals or 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.	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, some inspection work and the publication of summary of product characteristics (SPC) and public assessment reports. At least 90% of indicators to at least be at the effective level. 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. b) The VMD's product information database and online services will be available for at least 99% of the year.

5. Record and monitor suspected adverse reactions to companion animal microchips, with appropriate communication to promote the scheme and to provide overviews of the surveillance findings.	

B) Surveillance, research and enforcement activities that influence the responsible, safe and effective use of veterinary medicines.

Why are we doing this?: To detect unsafe products or activities and to take corrective action so ensuring confidence in veterinary medicines, assisting competitiveness, aiding consumer confidence, assisting with safety and helping to ensure medicines, in particular, antibiotics are used responsibly so they continue to be effective to treat animals and humans.

Key Activities for 2014/15	**KPIs for 2014/15**
1. Investigate unlawful distribution and investigate and follow-up breaches of the VMR in accordance with the VMD Enforcement Strategy. Issue improvement and seizure notices.	a) Statutory residues plan agreed with the Commission according to the timeframe set out in Council Directive 96/23.
2. Manage the VMD's medicines R&D programme in line with the VMD R&D strategy and the decisions of VMD's Research Programme Steering Group. In particular, to explore opportunities to use research funds in conjunction with universities to co-fund [with at least 50% from the university] PhD studentships, the first to commence during 2014/15.	b) In line with the monitoring of success markers of achievement in the VMD's R&D strategy document, we will report year on year the number of policy decisions informed, the number and value of jointly funded projects and the number of PhD studentships supported.
3. Deliver an efficient programme of veterinary medicines 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.	c) Completion of the 2013 non-statutory residues surveillance programmes achieved by end April 2014. Completion of the 2014 (calendar year) statutory residues surveillance programme achieved by end February 2015 and publication of the figures for both the 2013 statutory and non-statutory programmes in the Veterinary Residues Committee (VRC) annual report by end September 2014.
4. Investigate positive residue results of unauthorised substances and VMPs in excess of appropriate legal limits (MRLs) according to risk-based standard operating procedures, and apply penalties proportionately to reduce the risk of further incidents.	

C) To influence EU legislative change and the development of appropriate procedures and guidance within the European Medicines Regulatory Network (EMRN).

Why are we doing this?: To seek, as far as possible, to ensure that EU changes do not discriminate against UK businesses and to ensure UK citizens animals and the environment are suitably protected by influencing the position of other EU member states. To ensure as far as possible that the regulatory framework reflects the risks involved and supports growth.

Key Activities for 2014/15	**KPIs for 2014/15**
1. Contribute to the development of the revised European Commission (EC) legislation for veterinary medicines, medicated feeding stuffs and residues surveillance.	None.
2. Collaborate with other National Competent Authorities (NCAs), the European Medicines Agency (EMA) and Directorate General for Health and Consumer Affairs (DG Sanco) particularly through effective attendance at meetings of the Heads of Medicines Agencies (HMA), Committee for Medicinal Products for Veterinary Use (CVMP) and the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Veterinary (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. Hold a workshop for interested parties to discuss the Commission's proposals on the replacement to Directive 2001/82; ensuring the VMD's online information on the review of the directive is up to date. The timescale is subject to the Commission releasing the proposal for the new European law.	
5. Seek to improve interoperability of IT systems across the EU to foster the e-Submission environment and improve	

efficiency within the network. 6. Engage with national and 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 antibiotic resistance, residue analysis and surveillance. 7. Chair the HMA veterinary antimicrobial resistance (AMR) Task Force. Chair the Committee for Veterinary Medicinal Products' (CVMP's) Antimicrobials Working Party.	

3.3 Business Priority 3 – Customers and Interest Groups:

A) To ensure that the regulatory services provided meet the needs of the veterinary pharmaceutical industry.

Why are we doing this?: To remain competitive within the EU and to inform continual business improvement. This is important as it allows us to retain a critical mass of specialists and helps the sustainability of the operation offering opportunities for better value for money whilst at the same time providing the ability to identify additional services that may be desired. It also supports earning of foreign income.

Key Activities for 2014/15	**KPIs for 2014/15**
1. Develop and implement an action plan arising from the outcomes of the 2013 customer survey by end July 2014. 2. Compile and review the feedback from company meetings.	a) Action plan produced by agreed dates. Implementation carried out in accordance with timescales set out in plan. b) 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. 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) Provision of appropriate services to policy customers in Defra and other government departments (OGDs).

Why are we doing this?: To ensure the services provided meet policy customer needs in a cost efficient way to support animal, public and wider environmental health, and economic growth, in the context of animal medicines.

Key Activities for 2014/15	**KPIs for 2014/15**
1. The VMD to carry out the annual survey of policy customers in Quarter 1.	a) The median overall score to be at least 4.0 (scale 1-5 with 4 good and 5 excellent).

C) Communications to customers and interest groups

Why are we doing this? To raise awareness of the work of the VMD and why it is important that veterinary medicines are properly regulated and used. To enable effective feedback on our work.

Key Activities for 2014/15	**KPIs for 2014/15**
1. Implement the VMD communication strategy in accordance with the agreed priorities and timescales in the communications plan. 2. Respond to requests under access to information legislation in accordance with statutory deadlines.	a) Communications Plan: At least 90% of actions completed within agreed timescales. b) ATI Requests: at least 95% cases responded to on time.

3.4 Business Priority 4 – Value For Money:

Achieve cost recovery and delivery of Value for Money.

Why are we doing this? To ensure that we can demonstrate to all our customers how we achieve best value for money (VFM), whilst understanding that cost saving is only one element of VFM. To ensure an appropriate regulatory framework is in place that supports growth whilst providing appropriate safeguards to protect the food chain, human and animal health and the environment.

Key Activities for 2014/15	**KPIs for 2014/15**
1. Achieve full cost recovery for the VMD, in line with Treasury Guidance on fees and charging demonstrated through an National Audit Office (NAO) audited Annual Report and Accounts. 2. Ensure that fee levels generally reflect the work done and reflect any regulatory burden reductions required by Government through "better regulation" or other initiatives. In particular ensure there is at least a 5% real terms reduction in fees to the pharmaceutical industry and food industry over the period 12/13 to 15/16. 3. Develop a fees variation Statutory Instrument (SI) to the Veterinary Medicines Regulations. 4. Engage as appropriate in central initiatives intended to provide VFM (including Economy, Efficiency and Effectiveness), ensuring the VMD's business needs are understood and solutions are fit for purpose. Monitor the performance of new systems to ensure they deliver the intended VFM. 5. Manage the research, analytical, sampling and surveillance contracts to ensure they meet their objectives. 6. Consider whether business improvements can be made in response to the results from the 2013 staff survey. 7. Following whole business certification to ISO 9001:2008 in 2013, continue to develop the VMD's Quality Management System (QMS) in accordance with the principles of continuous improvement.	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 Management Board meetings.

3.5 Business Priority 5 – Capacity and Capability:

To ensure funding streams are used efficiently to maintain capability and capacity to deliver business objectives.

Why are we doing this?: To enable the VMD to deliver its other business objectives by maintaining staffing and other support structures at a level that ensures the business is fit for purpose. Through risk management we aim to identify and respond to issues that could adversely affect the business. We seek continuous improvement to enable us to meet current and future business needs and to ensure we remain competitive alongside other National Competent Authorities.

Key Activities for 2014/15	**KPIs for 2014/15**
1. Business support functions to agreed timelines and/or internally published standards. 2. Implement the VMD's ICT strategy according to priorities set by the VMD's IT Steering Committee. 3. To develop a VMD digital strategy and to deliver this in accordance with the agreed plan. 4. 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, and key risks at Management Board meetings. 5. Provide timely and accurate secretariat services to the Veterinary Products Committee, the Veterinary Residues Committee, DARC and other committees/meetings as necessary. 6. To input to the Weybridge site reorganisation to enable, if necessary, a move to another office location on site with minimal business disruption. 7. To explore alternative business models for the VMD and if appropriate submit proposals to Defra for approval.	a) Internal/External Audit opinion on effectiveness of financial controls to be "Substantial". b) Sickness absence – to work towards a further reduction in the number of days lost per full-time equivalent (FTE) in 2014/15 compared to the VMD's figures for 2012/13 and 2013/14 and to perform well compared to Defra and wider public sector benchmarks for equivalent periods. (see footnote to table) **Other Indicators for 2014/15** a) Learning and Development spend as training days per FTE seeking to ensure that staff receive their "5 days per year". b) Percentage delivery of targets set out in the IT strategy, but subject to changing business needs. c) To achieve at least the 99% uptime for VMDs IT systems

	achieved in 13/14. d) Through good management practice and the implementation of business improvements identified through the work identified above the VMD will seek to maintain the top quartile staff engagement score of 66% achieved in the 2013 Civil Service People Survey. We will report outcomes from that survey to the VMD Management 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 and report on the progress made on both incidental absences and those resulting from serious long term diagnosed illnesses and injuries.

More information on the work of the VMD can be found at www.vmd.defra.gov.uk .

(The VMD website is expected to move to within the GOV.UK site during the Summer of 2014)

4. RESOURCES AND DELIVERY

FINANCIAL RESOURCES

In 2013/14 22% of VMD funding came from Defra and 78% from regulatory 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.

Funding from Defra is drawn down on an equal amounts per quarter basis.

Financial Planning Assumptions

Services funded by:		**2013/14 Forecast £m**	**2014/15 Budget £m**	**2015/16 Plan £m**	**2016/17 Plan £m**
Veterinary Pharmaceutical Industry	Income	7.5	7.4	7.6	7.7
	Expenditure	7.5	7.4	7.6	7.7
	Result	0.0	0.0	0.0	0.0
Food industry	Income	3.6	3.9	3.9	3.9
	Expenditure	3.6	3.9	3.9	3.9
	Result	0.0	0.0	0.0	0.0
Defra Funded work	Income	3.1	3.2	3.2	3.2
	Expenditure	3.0	3.2	3.2	3.2
	Result	0.1	0.0	0.0	0.0
Total VMD	Income	14.2	14.5	14.7	14.8
	Expenditure	14.1	14.5	14.7	14.8
	Result	0.1	0.0	0.0	0.0
Cost Recovery %		101%	100%	100%	100%
Average staff numbers (FTE):	Permanent	154	161	161	161
	Temporary	7	5	4	4
	Total	161	166	165	165

Income sources - note:

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.

The table below provides an overview of the work that the VMD plans to perform for Defra in 2014/15 under a Service Level Agreement and which is funded by Defra.

Task	Target	How	Why	Cost £m
Enforcement	3b	Act on intelligence and increased surveillance of internet sites for unauthorised products/claims 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.	£0.7m
Non-statutory Residues Scheme	3b	Develop and implement annual surveillance plan using sub-contractors for sampling and analysis.	To provide evidence of residues in imported and retail produce not included in the Directive specifying the coverage of the Statutory Scheme.	£0.4m
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.	To support development of 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.	£1.0m
National and European Legislation	3b	Implement agreed changes for 2013. Prepare for Commission proposals to amend EU legislation.	To keep national legislation up to date and fee levels appropriate for the work involved.	£0.4m
Research and Development	3b	Identify issues and call for proposals to address them; manage Defra's veterinary medicines and antimicrobial resistance R&D budget	To provide evidence to underpin veterinary medicines and antimicrobial resistance policy and residues surveillance.	£0.1m NB this does not include the R&D budget of ~ £1.6m held by Defra.
Expert Committees	3a	Provide secretarial support.	To facilitate the provision of independent advice to Government on veterinary medicines and on residues of veterinary medicines in food.	£0.2m Including committee fees & expenses
Policy	All	Draft correspondence, advice and briefing for Ministers and colleagues in Defra, OGDs and DAs; provide advice to customers and stakeholders on interpretation veterinary medicines legislation; communications activity; prepare for the transfer to .GOV.UK; respond to access to information requests; surveillance for residues in UK honey.	To support development of policy on veterinary medicines and to support the delivery of VMD's regulatory functions	£0.4m
TOTAL				**£3.2m**

VETERINARY MEDICINES DIRECTORATE
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