VETERINARY MEDICINES DIRECTORATE (VMD)
BUSINESS PLAN 2015/16
AND FORWARD LOOK TO 2018/19

1. INTRODUCTION

1.1 The VMD is a net running cost Executive Agency of the Department for Environment, Food and Rural Affairs (Defra). It receives 77% of funding from industry regulatory fees and levies and the remainder from Defra.

1.2 The VMD's primary purpose is to deliver the UK's obligations under harmonised EU legislation on 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 and animal health, the environment and to promote animal welfare by assuring the safety, quality and effectiveness 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 In order to manage the projected growth in work funded by regulatory fees we will seek to maintain staff numbers, ensuring we have the correct mix of expertise and experience to allow us to deliver the work set out below. We continue to implement Civil Service Reforms by reviewing processes to identify improvements enabling existing resource to be better deployed within the business.

2. HIGH-LEVEL SUMMARY

2.1 The key elements of VMD's Business Plan for 2015/16 are:

- delivery of core business to the satisfaction of customers
- achieve full cost recovery for the budget of £14.4m
- influence the development of revised EU legislation for veterinary medicines, medicated feeds and residues surveillance
- to continue to play leading roles in the EU on antibiotic resistance and continue implementation of the UK antimicrobial resistance strategy
- at a world level further influence the regulatory environment for veterinary medicines, and policy on antibiotic resistance issues

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

2.2 The significant challenges to the end of the current comprehensive spending round period (2016/19) are:

- to deliver the veterinary elements of the UK AMR strategy on a prioritised basis
- to implement in the UK the changes in the EU medicines legislation
- to manage the consequential effects to the ability of the VMD to deliver, resulting from external changes to the delivery landscape
- at a world level continue to influence the regulatory environment for veterinary medicines and policy on antibiotic resistance issues

2.3 Key deliverables and performance indicators (KPIs) for 2015/16

These can be summarised under 5 headings as follows:
Policy
Delivery
Customers and Interest Groups
Value for Money
Capacity and Capability

3.1 Business Priority 1 - Policy:

Policy Lead on behalf of Defra for Veterinary Medicinal Products and Antimicrobial Resistance (AMR)

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 2015/16	**KPIs for 2015/16**
1. Policy lead and provision of policy advice on veterinary medicines to Defra and others. In particular: • influence the development of the draft EU regulations for both veterinary medicines and medicated feed, • ensure the UK Veterinary Medicines Regulations remain fit for purpose.	1.1 The UK's views are agreed and incorporated into the developing EU Regulations. 1.2 Consult on Veterinary Medicines Regulations revised fees schedule by March 2016.
2. Policy lead and provision of policy advice on AMR issues to Defra and others. In particular implementation of animal health specific aspects of the cross-government 5 year AMR strategy[1], through delivery of the following key activities: monitoring sales of veterinary antibiotics in the UK; developing options for data collection on 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.	2.1 Milestones and deliverables relevant to the VMD in the UK AMR Strategy achieved (as set out in the AMR Strategy Action Plan published December 2014). 2.2 Annual report on antibiotic sales and antibacterial sensitivity data published (Q 3). 2.3 Supply sales data to the EC to meet reporting obligations. 2.4 Antibiotic use data hub live and populated with preliminary poultry data (Q4).

[1] https://www.gov.uk/government/publications/uk-5-year-antimicrobial-resistance-strategy-2013-to-2018

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 taken including, where appropriate, removal from the market.

Key Activities for 2015/16	**KPIs for 2015/16**
1. Provide scientific assessment and assurance to meet the requirements of the Veterinary Medicines Regulations and EU legislation demonstrating the benefits of authorised medicines outweigh potential risks to human, animal and environmental safety.	1-3 Quarterly reporting against Published standards which set out the timelines and performance categories for: 1.1 the main different types of marketing authorisation application work, 1.2 some inspection work and 1.3 the recording and assessment of pharmacovigilance data, and the publication of summary of product characteristics (SPC) and public assessment reports.
2. Ensure the quality of veterinary medicines and feedingstuffs containing prescribed veterinary medicines/specified feed additives by conducting risk-based inspections of manufacturers, distributors, retailers, and feed businesses. Deliver this work efficiently, including where possible through joined-up inspections, partnership agreements with other professional bodies, and through earned recognition of appropriate industry assurance schemes.	At least 90% of indicators to be at or above the effective level. Overall performance against published standards to be at or above the effective level.
3. Monitor adverse events from pharmacovigilance data, identify emerging trends or signals, and take proportionate action. Take action to encourage the reporting of adverse events.	
4. Facilitate the availability of medicines 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.	
5. Record and monitor suspected adverse events in companion animals following microchipping, with appropriate	5 Report findings at least annually in veterinary press.

communication to promote the scheme and to provide overviews of the surveillance findings. 6. Assess and accredit UK-based internet retailers that comply with the VMD's Accredited Internet Retailer Scheme. 7. Respond to Product Defect and Rapid Alert Notifications. Evaluate risk, issue advice and recommend action where appropriate.	

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 to ensure confidence in veterinary medicines, assist competitiveness, aid consumer confidence, assist with safety and help to ensure medicines, in particular antibiotics, are used responsibly to maintain effectiveness.

Key Activities for 2015/16	**KPIs for 2015/16**
1. Investigate and deal with breaches of the Veterinary Medicines Regulations.	1 Publish summary data, and outcomes of successful prosecutions.
2. Continue to engage with member states in tackling veterinary medicine crime within the EU. Strengthen our working relationship with UK Border Force in dealing with the illegal importation of veterinary medicines.	
3. Manage the VMD's medicines R&D programme in line with the new Defra R&D strategy. 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.	3 Policy decisions informed, the number and value of jointly funded projects, the number of PhD studentships supported and the number of peer-reviewed publications and authoritative reports published.
4. Deliver an efficient programme of veterinary medicines residues surveillance of UK food of animal origin to fulfil our statutory obligations.	4.1 Statutory residues plan agreed with the Commission according to the timeframe set out in Council Directive 96/23. 4.2 Publish summary results on a two-monthly basis. 4.3 Completion of the 2015

5. Investigate residue results of unauthorised substances, veterinary medicines and specified feed additives in excess of permitted limits (Maximum Residue Limits), according to risk-based standard operating procedures; deal with findings in accordance with the VMD Enforcement Strategy, including, where necessary, applying penalties proportionately to reduce the risk of further incidents.	(calendar year) statutory residues surveillance programme achieved by end February 2016 and publication of the full year results by the end of March.

C) To influence the development of new EU legislation 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 the European Commission, the European Parliament and other EU member states. To ensure as far as possible that the regulatory framework reflects the risks involved and supports growth. There are no KPIs for these activities.

Key Activities for 2015/16

1. Negotiate for the UK's position during the development of the adopted text for new EU legislation for veterinary medicines, medicated feeding stuffs and residues surveillance.

2. Collaborate with other National Competent Authorities (NCAs), the European Medicines Agency (EMA) and Directorate General for Health and Safety (DG SANTE) 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. Feed back to stakeholders and seek further involvement as the negotiations for the new legislation proceed. Use outcome of stakeholder interaction to influence position in Europe.

4. Initiate a project to consider the impacts of the legislative proposals on existing processes and charging models.

5. Seek to improve interoperability of IT systems across the EU to foster the e-Submission environment and improve efficiency within the network. Influence the development of the EU veterinary medicinal product database and associated IT systems by chairing the consultative group. 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 by the VMD are seen as effective and efficient by those we regulate and stakeholders

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 2015/16	**KPIs for 2015/16**
1. Commission, deliver and act on the findings of a survey of pharmaceutical industry customers during the latter 6 months of 2015.	1. Report by Q1 2016.
2. Compile and review the feedback from company meetings.	2. The overall median score from feedback surveys for individual VMD company meetings to be at least good for 90% or more of the meetings.

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

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.

Key Activities for 2015/16	KPIs for 2015/16
1. Carry out the annual survey of policy customers in Quarter 1.	1. The median overall score to be at least good.

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, and to enable effective feedback on our work.

Key Activities for 2015/16	KPIs for 2015/16
1. Implement the VMD communication strategy in accordance with the agreed priorities and timescales in the communications plan.	1. Communications Plan: At least 90% of actions completed within agreed timescales.
2. Respond to requests under access to information legislation in accordance with statutory guidelines.	2. Access to information 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 customers how we achieve best value for money (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 2015/16	KPIs for 2015/16
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.	1. Cost recovery to be within the range 100-102% of full cost recovery.
2. Ensure that fee levels reflect the work done and any regulatory burden reductions	2. Ensure there is at least a 5% real terms reduction in fees to

required by Government. 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 contractual objectives. 6. Consider whether business improvements can be made in response to the results from the 2014 staff survey.	the pharmaceutical industry and food industry over the period 12/13 to 15/16. 3. Delivered within the deadlines set.

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 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 2015/16	**KPIs for 2015/16**
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.	1. Positive Internal/External Audit opinion on effectiveness of financial controls to be "moderate" or better. 2.1 Delivery of targets set out in the IT strategy, but subject to changing business needs. 2.2 To achieve at least the 99%

3. Finalise the VMD digital strategy and to deliver this in accordance with the agreed plan.	uptime for VMDs IT systems
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.	4. Develop an assurance map and framework by end Q2.
5. 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.	
6. To participate in the Weybridge site reorganisation programme to enable, if necessary, a move to another office location on site with minimal business disruption.	
7. Maintain a well-trained, motivated and content workforce.	7.1 Secure re-accreditation under Investors in People (IiP) to the IIP Silver Standard. 7.2 Maintain a top quartile staff engagement score in the 2015 Civil Service People Survey. 7.3 Training days per FTE to be at least 5 days per year. 7.4 Sickness absence – to maintain in 2015/16 the low number of days lost per full-time equivalent (FTE) for short-term sickness and to perform well compared to Defra and wider public sector benchmarks for equivalent periods. (see footnote to table).

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 by searching for "VMD" on the gov.uk website.

4. RESOURCES AND DELIVERY

FINANCIAL RESOURCES

In 2014/15 23% of VMD 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.

Financial Planning Assumptions

Services funded by:		**2014/15 Forecast £m**	**2015/16 Budget £m**	**2016/17 Plan £m**	**2017/18 Plan £m**
Veterinary Pharmaceutical Industry	Income	7.2	7.4	7.5	6.6
	Expenditure	7.2	7.4	7.5	7.6
	Result	0.0	0.0	0.0	-1.0
Food industry	Income	3.9	3.9	3.9	4.0
	Expenditure	3.8	3.9	3.9	4.0
	Result	0.1	0.0	0.0	0.0
Defra Funded work	Income	3.2	3.1	3.1	3.1
	Expenditure	3.2	3.1	3.1	3.1
	Result	0.0	0.0	0.0	0.0
Total VMD	Income	14.3	14.4	14.5	13.7
	Expenditure	14.2	14.4	14.5	14.7
	Result	0.1	0.0	0.0	-1.0
Cost Recovery %		101%	100%	100%	93%
Average staff numbers (FTE):	Permanent	153	160	160	160
	Temporary	8	5	5	5
	Total	161	165	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.

From 2015/16 Defra funded work is reduced by £160k. This is the agreed VMD contribution to Defra 2015/16 savings.

The table below provides an overview of the work that the VMD plans to perform for Defra in 2015/16 under a Service Level Agreement and which is funded by Defra.

Task	Target	How	Why	Cost £m
Enforcement		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
Antimicrobial Resistance		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.	£1.2m
National and European Legislation		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.	£0.5m
Research and Development		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 ~ £1.5m held by Defra.
Expert Committees		Provide secretarial support.	To facilitate the provision of independent advice to Government on veterinary medicines and on residues of veterinary medicines in food.	£0.1m Including committee fees & expenses
Policy		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	£0.5m
TOTAL				**£3.1m**

VETERINARY MEDICINES DIRECTORATE
MAY 2015