VETERINARY MEDICINES DIRECTORATE (VMD)
Deliverables and KPIs for 2017/18

1. Business Priority 1 - Policy:

A) Policy Lead on behalf of Defra for Veterinary Medicines 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 2017/18	**KPIs for 2017/18**
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, particularly for the aims of reducing regulatory burden and combating antimicrobial resistance (AMR) • ensure the UK Veterinary Medicines Regulations remain fit for purpose.	1. Veterinary Medicines Regulations revised fees schedule completed and laid by end 2017/18
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] and the government's response to the independent review on AMR[2], through delivery of the following key	2.1 Milestones and deliverables relevant to the VMD in the UK 5yr AMR Strategy achieved 2.2 Annual report on antibiotic sales and antibacterial susceptibility data published (Q3).

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

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.	2.3 Supply sales and resistance data to the EC to meet reporting obligations. 2.4 One health report published (jointly with PHE) Q4 2.5 Broader cross-Defra engagement and governance achieved by Q3

Preparing for EU Exit

B) **Why are we doing this?** The UK is preparing to leave the EU. As a consequence we need to ensure that animal medicines availability in the UK is not compromised and that the UK remains attractive to the pharmaceutical industry for marketing authorisations application and complying with all post authorisation regulations.

Key Activities for 2017/18	**KPIs for 2017/18**
1. Identify day 1 issues	1. All identified by Q2
2. Identify all current veterinary medicines regulations that could impact on trade with the EU and others	2. All identified by Q2
3. Identify and be in a position to influence (or attain membership) of non-EU international bodies and committees relevant to medicines regulations	3. Detailed report by Q3
4. Develop all-option contingency plans for continuation of VMD services post EU Exit	4. Detailed options planned by Q3
5. Identify necessary transitional arrangements	5. All identified by Q3

2 Business Priority 2 - Delivery:

A) Facilitate optimal availability and safe use 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 2017/18	**KPIs for 2017/18**
1. Fully support TOM in general and the FFAPH system group in particular to identify and realise improvements in service delivery quality and efficiency.	
2. Provide scientific assessment and assurance to meet the requirements of the Veterinary Medicines Regulations and EU legislation to ensure the benefits of authorised medicines outweigh potential risks to human, animal and environmental safety.	2-4 Quarterly reporting against 45 **Published standards** which set out the timelines and performance indicators for a range of key functions[3] Overall performance against published standards to be at or above the effective level (≥90% of performance indicators met).
3. 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.	

[3] Performance indicators for the main types of marketing authorisation application work,some inspection work, the recording and assessment of pharmacovigilance data, and the publication of summary of product characteristics (SPC) and public assessment reports.

4. Monitor adverse events from pharmacovigilance (PhV) data, identify emerging trends or signals, and take proportionate action. Encourage the reporting of adverse events.	4. Report PhV findings to the Veterinary Products Committee and publish findings.
5. 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.	
6. Record and monitor suspected adverse events in companion animals following microchipping, with appropriate communication to promote the scheme and to provide overviews of the surveillance findings. [Dependent on Defra securing industry funding for the scheme]	6 Report findings at least annually in veterinary press.
7. Respond to Product Defect and Rapid Alert Notifications. Evaluate risk, issue advice and recommend action where appropriate.	7. All responded to appropriately within five working days.

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 2017/18	**KPIs for 2017/18**
1. Deliver an efficient programme of veterinary medicines residues surveillance of UK food of animal origin to fulfil our	1.1 Statutory residues plan agreed with the Commission according to the timeframe set out in Council Directive 96/23.

statutory obligations and start preparations for implementing a national programme of surveillance once the UK leaves the EU.	1.2 Publish summary results on a two-monthly basis. 1.3 Completion of the 2016 (calendar year) statutory residues surveillance programme achieved and published by end of Q1 2017.
2. Investigate residue results of veterinary medicines and specified feed additives in excess of permitted limits (Maximum Residue Limits) and unauthorised substances, 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.	
3. Investigate and deal with breaches of the Veterinary Medicines Regulations. 4. Strengthen our working relationship with UK Border Force in dealing with the illegal importation of veterinary medicines.	3-4 Publish summary data including cases handled, internet listings removed, enforcement notices served, and outcomes of successful prosecutions on a quarterly basis in the Enforcement Newsletter and MAVIS (newsletter for industry)
5. Continue to strengthen our working relationships with internet sales platforms to enable us to robustly tackle the illegal marketing and sales of veterinary medicines.	5. All major internet platforms to be aware of the complexities of the Veterinary Medicines Regulations and work with us with a view to tackling illegal sales

C) **To support and influence the development of the regulation of veterinary medicines outside of the EU in low and middle income countries and the international convergence of regulation processes.**

Why are we doing this?: There is increasing international recognition of the importance of regulation of veterinary medicines driven by a combination of interest in stewardship and appropriate use of antibiotics and development of livestock business for

low and middle-income countries. UK international action is expected for both antimicrobial resistance (AMR) and Sustainable Development Goals. The VMD capability to support these initiatives is increasingly recognised at the global level, non-government funding is available to be accessed, and increasing influence outside of the borders of the EU supports EU-exit objectives.

Key Activities for 2017/18	**KPIs for 2017/18**
1. Market VMD's capabilities amongst third sectors funders eg World Bank, Galvmed and Bill & Melinda Gates Foundation; and Dfid	1.1 To secure at least one externally funded capacity building project 1.2 To provide at least one on-site training event to a third country with full cost-recovery
2. Advise on the development of 'one-health' AMR action plans in non-EU countries in support of the AMR Global Action Plan, United Nations General Assembly Declaration, and international actions of the UK 5yr AMR strategy.	2. Official participation in development of AMR action plans for at least one third country.

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, to prepare for the UK's exit from the EU and to inform continual business improvement. This helps retain a critical mass of specialists and helps the sustainability of the operation, and offers opportunities for better value for money, whilst at the same time providing the ability to identify additional services. It also supports earning of foreign income.

Key Activities for 2017/18	KPIs for 2017/18
1. Commission, deliver and share the findings of the biennial survey of pharmaceutical industry customers during second half of 2017/18.	1. Report by end 2017/ 2018
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 other government departments and the Devolved Administrations.

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 2017/18	KPIs for 2017/18
1. Carry out the annual survey of policy customers in Q 1	1. The median overall score to be at least good.
2. To maintain close liaison, particularly for current revision of medicines legislation and for AMR.	

C) Communications and data provision 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. To enable maximum utilisation of VMD datasets.

Key Activities for 2017/18	**KPIs for 2017/18**
1. Communicate effectively and pro-actively with main stakeholder groups (industry, vets, farmers and pet owners) in line with the VMD's annual Communications priorities and overarching Communications strategy	1. Attend nine shows/events representing the range of VMD's stakeholders.
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. Make VMD datasets publicly available unless commercial in confidence or risk of breach of data protection.	3. Maintain and review datasets published on data.gov.uk. Continue to publish VMD datasets.

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 2017/18	KPIs for 2017/18
1. Achieve full cost recovery for the VMD, in line with Treasury Guidance on fees and charging demonstrated through National Audit Office (NAO) audited Annual Report and Accounts. 2. Ensure that fee levels reflect the work done and any regulatory burden reductions required by Government.	1. Cost recovery for charged for regulatory services to be within the range 100-102% of full cost recovery. 2. Positive contribution to Defra's overall target of a £470m reduction in regulatory burden

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 as it enters the period of transition before and beyond the UK's exit from the EU. 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 2017/18	KPIs for 2017/18
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 90% of targets set out in the IT strategy. 2.2 To achieve at least 99% uptime for VMD's IT systems.

3. To maintain the VMD principle of Digital by Default and seeking opportunities for further development of digital services. 4. Ensure that risks are actively identified, escalated 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 Assurance Committee, and key risks at Management Board meetings. 5. To continue to develop and improve the VMD's Quality Management System in line with the needs of the business and the requirements of the revised ISO 9001 standard. 6. Maintain a well-trained, motivated and content workforce.	4. No serious risks on risk register materialise. 5. To maintain whole business re-certification against ISO 9001:2015 6.1 Maintain a top quartile staff engagement score in the 2017 Civil Service People Survey. 6.2 Training days per FTE to be at least 5 days per year. 6.3 Sickness absence – to maintain in 2017/18 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.