# Veterinary Medicines Directorate (VMD) Deliverables and KPIs for 2021/22

## 1. Business Priority 1 – Policy:

**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 | KPIs |
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| 1. Policy lead and policy advice on veterinary medicines to Defra and others. In particular to ensure the UK Veterinary Medicines Regulations remain fit for purpose. | 1. Publish consultation on revisions to the Veterinary Medicines Regulations (Q3). |
| 2. Review the policy on zinc oxide use. | 2. Assess the evidence of environmental impacts of zinc oxide (Q2) |
| 3. Develop policy on anthelmintic resistance. | 3. Establish a VMD Working Group (Q1) and identify evidence gaps and commission research to close gaps (Q4). |
| 4. Reconsider authorisation routes of companion animal imidacloprid and fipronil products. | 4. Commission evidence to close evidence gaps on topical pet flea products contribution to environmental levels and impacts, (Q2). |
| 5.Support Government policy on biodiversity and on zero carbon by:<br><br>5.1considering how to incorporate biodiversity in authorisation process.<br><br>5.2 considering climate change impact reduction opportunities in the medicines chain.<br><br>5.3 supporting research into medicines for pollinators. | 5.1 Consider options on biodiversity impact assessment and develop a plan for incorporation into the authorisation process (Q3).<br><br>5.2 Explore authorisation routes for medicinal products that reduce greenhouse gas emissions, including liaison with the FSA (Q3).<br><br>5.3 Provide funding to projects exploring development of medicines for pollinators. |
| 6. Continued review of supply chain resilience and emergency response | 6.1 Annual test of VADAR response exercise or for it to be stood up and staffed within 24 hours of need.<br><br>6.2 Contribute to the work on project Defend. |

## 2. Business Priority 2 – Delivering effective regulation as an independent trading nation and operationalisation of the Northern Ireland Protocol:

**Why are we doing this?** The UK has left 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 applications and complying with all post authorisation regulations.

| **Key Activities** | **KPIs** |
|---|---|
| 1.Ensure preparedness for implementation of the revised EU veterinary medicines regulations in Northern Ireland. | 1. Completed IT requirements (including testing and communications) and prepare authorisation processes (Q3).<br><br>1.1 Maintain regular liaison meetings with DAERA, DOH and DAFM<br><br>1.2 Regular liaison and cooperation with the HPRA on authorisation and other policy aspects as they relate to NI. |
| 2. Attain membership of international bodies and committees relevant to medicines regulations. | 2. Regain membership of VeDDRA, WGEO and VBRN and attain membership of TATFAR (Q2). |
| 3. To work with other global regulatory jurisdictions to facilitate the assessment of products and post authorisation regulations for our respective marketplaces. | 3.1 Maintain monthly liaison meetings with the regulatory bodies with responsibility for veterinary medicines in the USA, Australia, Canada and New Zealand, establish at least one operational network (Q3), and have processes in place to accept joint marketing authorisation applications (Q4).<br><br>3.2 Complete agreement with the FDA (USA) for mutual recognition of GMP inspections (Q2)<br><br>3.3 Establish a Memorandum of Understanding with at least two medicines national competent authorities (Q3).<br><br>3.4 Participate in trade and technical co-operation negotiations to secure agreements for collaborative working. |
| 4. Develop a working relationship with the committee that coordinates mutual and decentralised authorisation processes in the EU (CMDv) | 4. Establish regular liaison with CMDv chair, particularly for the operation of authorisation procedures that include Northern Ireland (Q1). |

## 3. Business Priority 3 – Delivery of core regulatory services

### A) Facilitate optimal availability and safe use of veterinary medicine

**Why are we doing this?** We authorise veterinary medicines in the UK. 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 and biodiversity. It also ensures that unsafe medicines can be identified, and appropriate corrective action taken including, where appropriate, removal from the market.

| Key Activities | KPIs |
|---|---|
| 1. Provide scientific assessment and assurance to meet legislative requirements to ensure the benefits of authorised medicines outweigh potential risks to human, animal and environmental safety, and protects biodiversity | 1.1 Monthly reporting against all Published Standards which set out the timelines and performance indicators for a range of key functions[1]. Overall performance against published standards to be at or above the effective level (≥92% of performance indicators met) (Q4)<br><br>1.2 Formalise and publish a regulatory science strategy and plans to operationalise the strategy (Q3). |
| 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 cooperation agreements with other regulators and through earned recognition of appropriate industry assurance schemes. | 2. To review the requirements of vet practice inspections and identify improved approaches to securing required assurance (Q2). |
| 3. Monitor adverse events from pharmacovigilance (PhV) data, identify emerging trends or signals. Encourage the reporting of adverse events. | 3. Report PhV findings to the Veterinary Products Committee and publish findings. Take proportionate action. |
| 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. | 4.1 Meet the assessment and issuing of import certificates as detailed within the published standards.<br><br>4.2 Report on availability issues and import patterns to the Veterinary Products Committee at each of its meetings. |

[1] 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.

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| | 4.3 Enhance MAH reporting and wholesale dealer intelligence of availability and inform others as required (Q2).<br>4.4 Work with the pharmaceutical industry to develop resilience within the supply chain (Q2). |
| 5. Respond to Product Defect and Rapid Alert Notifications. Evaluate risk, issue advice and recommend action where appropriate. | 5. Respond to 'High risk' product defect reports within five working days and all others within ten working days. |
| 6. Maintain an emergency response capability for reduced medicines availability and for disease outbreak response. | 6. Annual test of our emergency response capability (Q4). |

**B) Surveillance, research and enforcement activities that influence the responsible, safe and effective use of veterinary medicines in the UK and protection from medicines residues in food**

**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 | KPIs |
|---|---|
| 1. Deliver an efficient surveillance programme for residues of veterinary medicines and unauthorised substances in UK food of animal origin to fulfil our statutory obligations. | 1. Residues surveillance plan for 2021 delivered and results published (Q4); Residues surveillance programme for 2022 agreed (Q3); and publish summary results on a two-monthly basis. |
| 2. Support the Defra UK Office SPS Trade Assurance (OSPSTA) for visits to third countries for assurance on control of medicines residues in food, and for hosting third country visits to the UK for reciprocal assurance. | 2. Establish resource to fulfil the function and agree an SLA with the UKOSPSTA (Q1) |
| 3. Contribute to the animal health specific aspects of the cross-government 20-year AMR vision[2] and 5 year AMR action plan[3]. | 3. Milestones and deliverables led by the VMD in the UK 5 year AMR national action plan achieved, namely:<br>• Implement a new veterinary pathogen surveillance programme (Q1).<br>• Annual report on antibiotic sales and antibacterial susceptibility data published (Q3). |
| 4. Investigate and deal with breaches of the Veterinary Medicines Regulations. | 4. Publish summary data including cases handled, internet listings removed, enforcement notices served, and outcomes of successful prosecutions on a quarterly basis. |

[2] https://www.gov.uk/government/publications/uk-20-year-vision-for-antimicrobial-resistance
[3] https://www.gov.uk/government/publications/uk-5-year-action-plan-for-antimicrobial-resistance-2019-to-2024

**C) Effective customer and stakeholder engagement**

**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** | **KPIs** |
|---|---|
| 1. Develop a new Communications and Stakeholder Engagement Strategy | 1.1 Complete (Q1).<br>Successful delivery of 90% of 2021/22 priorities as set out in Action Plans under the Strategy<br>1.2 Establish a network of social media champions in the VMD to increase VMD social media impact by achieving:<br>1.3 10-15% increase in VMD followers on Twitter, Facebook and Linked In<br>1.4 10-15% increase in posts on social media<br>1.5 90% of feedback from Company meetings and open days and other stakeholder engagement activities give the VMD a positive rating e.g. for company meetings, at least 4 out of 5. |
| 2. Engage and communicate effectively and pro-actively with main customer groups (industry, vets, farmers and pet owners) and stakeholders (Other Government Departments, Devolved Administrations, professional bodies e.g. BVA) in line with the VMD's Communications and Stakeholder Engagement strategy. | 2.1 Fewer than ten negative feedback comments received on the accuracy and completeness of VMD's GOV.UK material. Ensure all new material meets accessibility standards.<br>2.2 At least quarterly liaison with NOAH and with other stakeholders in line with the VMD's communications strategy |
| 3. Respond to requests under access to information legislation in accordance with statutory guidelines. | 3. Access to information requests: at least 95% cases responded to on time. |
| 4. Make VMD datasets publicly available unless commercial in confidence or risk of breach of data protection. | 4. Continue to publish VMD datasets on the product information database and on data.gov.uk. |

## 4. Business Priority 4 - To support the capacity building efforts of international regulatory authorities to ensure high quality veterinary medicines that are used safely and effectively to protect human and animal health and the environment

**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 as well as development of livestock business for low and middle-income countries. UK international action is expected to support the cross-government 20 year antimicrobial resistance (AMR) vision and 5 year AMR national action plan, and the UN Sustainable Development Goals. The expertise of the VMD to support capacity development is recognised by our designation (together with our partner agencies APHA and CEFAS) as an FAO AMR Reference Centre. Non-government funding is available to be accessed.

| **Key Activities** | **KPIs** |
|---|---|
| 1. Deliver phase 2 of the Bill & Melinda Gates Foundation project to engage regional and national stakeholders in a regional harmonisation approach to improve medicines regulation in Sub Sahara Africa | 1. Objectives and activities set out in the project initiation document, and/or if subsequently mutually amended, are achieved. Global directory of vet med regulators (Q1); draft benchmarking tool (Q2); harmonised marketing application form and common electronic submission portal criteria (Q4). |
| 2. Develop a tailored curriculum of regulatory, policy and surveillance training activities for external candidates. | 2. Three countries participate in VMD e-learning (Q4) |
| 3. Provide international scientific and technical capability, governance and policy and regulatory expertise and support relating to antimicrobial resistance and use internationally. | 3.1 Support the development of regulatory capability and resistance and use surveillance capability and capacity in five lower/middle income countries.<br>3.2 Establish in the UK a One-Health UK AMR Reference collaborative by coordinated governance of the UK based FAO, WHO and OIE reference centres for AMR (Q3). |

## 5. Business Priority 5 – Capacity and Capability:

**To ensure funding streams are used efficiently to maintain capability and capacity to deliver business objectives in a sustainable and environmentally friendly way**

**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 remains 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 | KPIs |
|---|---|
| 1. Business support functions delivered to agreed timelines and/or internally published standards. | 1.1 Internal Audit opinion to be “moderate” or better.<br>1.2 External Audit assurance to report an ’unqualified’ opinion. |
| 2. Implement the VMD’s ICT strategy according to priorities set by the VMD’s IT, and the redevelopment of legacy systems Programme Board. | 2.1 Delivery of 90% of targets set out in the IT strategy.<br>2.2 To achieve at least 95% uptime for VMD’s IT systems.<br>2.3 Develop and implement a new system for pharmacovigilance reporting (Q3). |
| 3. 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. | 3. No serious risks on risk register materialise. |
| 4. 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 ISO 9001 standard. | 4. To maintain business certification against ISO 9001 and ISO 27001 by end Q3 2021. |
| 5. Maintain a well-trained, motivated and content workforce. | 5.1 Maintain a top quartile staff engagement score in the 2021 Civil Service People Survey.<br>5.2 Training days per FTE to be at least 5 days per year.<br>5.3 Sickness absence – to maintain in 2021/22 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). |

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| | 5.4 To prepare for possible changed working patterns (home/office) and practices following easement of covid-19 restrictions and further embed well-being support (Q2). |

**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.

## 6. Business Priority 6 – 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. 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. To ensure that the costs of activities that are carried out to support delivery of our international capacity building objectives are adequately financed, outside our policy budget and industry fee structure.

| Key Activities | KPIs |
|---|---|
| 1. Achieve full cost recovery for the VMD, in line with Treasury Guidance on fees and charging demonstrated through the Annual Report and Accounts audited by National Audit Office. | 1. Cost recovery for charged for regulatory services to be within the range 100-102% of full cost recovery. |
| 2. Ensure that fee levels reflect the work done and continue to identify and reduce regulatory burdens required by Government. | 2. To have identified further reductions in regulatory burden. |
| 3. Ensure that the 2021-22 budget reduction for policy work is met. | 3. Assurance from Defra. |
| 4. Exceed the standard set by Government for prompt payment to support the supply chain and SMEs. | 4. Pay 97% of all undisputed and valid invoices within 5 working days. |