

Veterinary Medicines Directorate Annual Report & Accounts

2018/19

THE VETERINARY MEDICINES DIRECTORATE IS AN EXECUTIVE AGENCY OF THE DEPARTMENT FOR ENVIRONMENT, FOOD & RURAL AFFAIRS

HC 2456

Veterinary Medicines Directorate

An Executive Agency of the Department for Environment, Food & Rural Affairs

Annual Report and Accounts 2018/19

Presented to the House of Commons pursuant to Section 7(3)(c) of the Government Resources and Accounts Act 2000

Ordered by the House of Commons to be printed 18 July 2019



© Crown copyright 2019

This publication is licensed under the terms of the Open Government Licence v3.0 except where otherwise stated. To view this licence, visit nationalarchives.gov.uk/doc/open-government-licence/version/3

Where we have identified any third party copyright information you will need to obtain permission from the copyright holders concerned.

This publication is available at: www.gov.uk/official-documents

Any enquiries regarding this publication should be sent to us at postmaster@vmd.defra.gsi.gov.uk

ISBN 978-1-5286-1219-7

CCS0419040708 07/19

Printed on paper containing 75% recycled fibre content minimum

Printed in the UK by the APS Group on behalf of the Controller of Her Majesty's Stationery Office

Contents

Performance Report	1
Overview	1
Chief Executive's Statement	1
About the Veterinary Medicines Directorate	2
Performance Summary	4
Performance Analysis	5
Business Priority 1 – Policy	5
Business Priority 2 – Delivery	7
Business Priority 3 – Customer and interest groups	10
Business Priority 4 – Value for money	11
Business Priority 5 – Capacity and capability	12
Social and Community Issues and Environmental Matters	13
Accountability Report	16
Corporate Governance Report	16
Director's Report	16
Statement of Accounting Officer's Responsibilities	17
Governance Statement	18
Remuneration and Staff Report	25
Remuneration Policy	25
Staff Report	29
Parliamentary Accountability and Audit Report (Audited)	33
The Certificate and Report of the Comptroller and Auditor General	to the House of
Financial Statements	
Statement of Comprehensive Net Expenditure	
Statement of Financial Position	
Statement of Cash Flow	
Statement of Changes in Taxpayers' Equity	
Notes to the Accounts	42

Performance Report

Overview

Chief Executive's Statement

The Veterinary Medicines Directorate (VMD) is the UK regulator of veterinary medicines and policy adviser on this to ministers. We facilitate wide availability of safe and effective medicines for prevention and treatment of diseases and improved welfare in all animal species. In doing so we ensure that this is not at the expense of human health or the environment. Veterinary medicines are important to ensure a viable livestock and fish-farming industry and healthy lives for companion and working animals. We deal with all applications for a Marketing Authorisation for veterinary medicines to specified timelines, and when necessary urgency of need. We seek to ensure compliance with the regulatory framework by providing guidance and advice.

Where necessary, we take formal action against the illegal supply of veterinary medicines in order to protect human and animal health. We continue to seek opportunities to reduce regulatory burden and to improve our operational efficiency.

The VMD had a very successful year, delivering the Business Plan with in-year savings and reduced costs to industry and the taxpayer, while maintaining services independently assessed as excellent, and maintaining a high staff engagement index. We have retained whole business ISO 9001:2015 certification, and ISO 27001:2013 for Information Security Management Systems.

Throughout the year we have been preparing for EU exit to ensure smooth continuation of medicines availability and over-sight at the point of EU exit, and opportunities that arise from exit. We have also undertaken extensive engagement with stakeholders.

The VMD leads activity across government on antimicrobial resistance (AMR) in animal health. We continued to work closely with the veterinary profession, livestock industry and other stakeholders across the public and private sectors to implement the government's 2013-2018 AMR strategy. Our collaborative approach has been a key factor in achieving a 40% reduction in the use of antibiotics in agriculture. The government's 20-year vision on AMR and the 5-year action plan, published in January 2019, sets the strategic framework for our future work. Also in January, we published the latest "One Health" AMR report with Public Health England (PHE). This brings together all the UK data on antimicrobial resistance and usage from the human health and veterinary sectors. As part of the UK's global leadership on AMR, we established, with the support of Defra and the Fleming Fund, the first Food and Agriculture Organisation AMR reference centre. This reference centre supports the development of technical and regulatory capability on AMR in South East Asia and Sub-Saharan Africa.

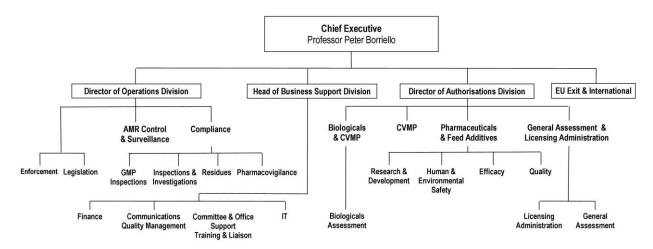
About the Veterinary Medicines Directorate

Purpose

The VMD is the UK competent authority for veterinary medicines regulation. We seek to ensure maximum availability of safe and effective medicines for prevention and treatment of diseases and improved welfare in all animal species. We also ensure that the medicines pose minimal possible risk to human health and the environment. The breadth of our functions in support of our purpose are presented in the three boxes below.

The Overview section of this report summarises our organisation, objectives, key risks to the achievement of our objectives, and how we have performed during the year.

Our structure



We are responsible for:

Government:

- Servicing, developing and implementing relevant government policy and legislation
- Supporting Ministers through briefing and advice on correspondence and Parliamentary Questions
- Collaborating with Defra (Department for Environment Food and Rural Affairs)
 Ministers and officials, other government departments and agencies, and other stakeholder groups
- Working with the EU Commission (EC), embassies and other representatives of foreign governments
- Enforcement of the Veterinary Medicines Regulations
- Day-to-day management of the veterinary medicines Research and Development programme
- The co-ordination of Defra's work on antimicrobial resistance

Veterinary pharmaceutical industry:

- Assessing, issuing and maintaining all national Marketing Authorisation (MA) applications in accordance with EC and UK legislation
- Acting as Reference Member State, Rapporteur, Co-Rapporteur or Concerned Member State for European applications
- Post-authorisation surveillance (pharmacovigilance) through the collation of suspected adverse event reports
- Licensing and/or inspection of manufacturers, wholesale dealers and retailers of veterinary medicines

Food industry:

 The surveillance for residues of veterinary medicines and banned substances in home-produced livestock and animal products, reporting of results and co-ordinating follow-up action. We have contracts with other agencies who carry out work on our behalf at abattoirs, other first processing premises and on farms

Future developments, performance and risk

Our key challenges throughout 2018/19 and our plans for meeting them have been outlined in the VMD's Business Priorities which are available on www.gov.uk.

Key future developments and/or risks are the:

- UK's exit from the EU
- economic climate affecting the veterinary pharmaceutical industry and the number of authorisation applications the VMD receives
- European Commission's work to implement the EU legislation on veterinary medicines, medicated feeds and residues surveillance
- implementation of the new UK strategy on antimicrobial resistance
- broadening externally funded outreach work on developing medicines regulation and antimicrobial resistance control capability

Our approach to managing the principal risks is described in the Governance Statement in this report.

Operating framework

We operate within an overall policy and financial framework determined by the Secretary of State for Defra, through the Parliamentary Under Secretary of State for Rural Affairs and Biosecurity. More information on our governance is set out in our Framework Document.

Going concern

The Statement of Financial Position at 31 March 2019 shows Taxpayers' Equity and other reserves of £9.84m (at 31 March 2018 this was £11.46m).

The VMD received its operational funding from Defra and through fees and charges. These income streams are expected to continue to meet the future funding for our

liabilities. Parliament approves this funding annually and we have already received approval for Defra funding for 2019/20. Therefore it is appropriate to adopt a going concern basis for these financial statements.

Performance Summary

In 2018/19 the VMD delivered regulatory services to the veterinary pharmaceutical industry (VPI) to a total cost of £7.2m, these costs for authorisations and inspections work are fully recovered through fees and charges to this industry. The costs of regulation of the food industry £3.6m, are recovered through charges levied on abattoirs and other food processors. Through these fees we achieved full cost recovery.

We thoroughly monitor our financial performance and continue to seek efficiency while maintaining our standards of performance. We managed to achieve our 2018/19 targets, while making real term reductions to charges.

The VMD also delivered a core programme of work for Defra customers. Activities include policy, enforcement and management of the Research and Development (R&D) and AMR programmes. The VMD receive parliamentary funding for this work through Defra to an agreed budget. The approved budget for these activities was set at £4.05m, of which £3.53m was utilised, inclusive of non-cash and notional recharges. Funding of £0.4m available for R&D was not fully utilised due to delays through the procurement and contract letting processes.

Additional parliamentary funding was made available for the 2018/19 year as we have continued preparing for EU exit, to ensure smooth continuation of medicines availability and over-sight at the point of EU exit and to explore the opportunities that arise from exit. Resources to support EU exit work were £3.95m, including £1.26m for the development of IT solutions to replace those we may no longer have access to and £0.22m for the development of the antibiotic resistance reference centre.

Our total operating expenditure for the financial year was £18.9m.

Cash flow

Cash and cash equivalents have reduced to £1.91m as at 31 March 2019 from £5.64m as at 31 March 2018, a decrease of £3.73m. In year, the VMD's net cash draw down was £3.0m. The net cash requirement under the gross control funding arrangement was £6.73m.

We aim to follow and support the principles of the <u>Better Payment Practice Code</u> in compliance with the Public Sector Payment Policy to pay 80% of undisputed invoices within five working days. During the year we paid all undisputed invoices within five working days.

Business priorities and Key Performance Indicators (KPIs)

Our <u>Business Plan</u> provided a framework of deliverables and KPIs through which we provide the best possible service to all our customers. We successfully delivered against this plan.

Performance Analysis

About the performance analysis

This report outlines our performance against our priorities for the financial year from 1 April 2018 to 31 March 2019. It gives examples of how we are achieving our aims and highlights important events from the year. It follows the structure of our <u>Business Plan</u> for 2018/19 to show how we are meeting our objectives.

The Defra Strategy

A clear, shared framework is provided to staff across the whole group of Defra organisations (including non-ministerial departments, executive agencies, non-departmental and other public bodies) in <u>Defra's Single Departmental Plan</u>. Actions to achieve Defra's strategic objectives are described in detail in the plan.

Our performance

We successfully delivered against our Business Plan, with the exception of the KPI for the revised fees schedule, the details of which are given against our business priorities below.

Business Priority 1 – Policy



A) Policy lead on behalf of Defra for veterinary medicines and AMR

Why are we doing this? We have 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 performance indicators:

Veterinary Medicines Regulations revised fees schedule complete and laid by quarter three



Milestones and deliverables relevant to the VMD in the UK 5-year AMR Strategy achieved



Annual report on antibiotic sales and antibacterial susceptibility data published by quarter three



Supply sales and resistance data to the EC to meet reporting obligations



One Health report published (jointly with PHE) in quarter three

The anticipated increased demands on parliamentary time needed to prepare for EU exit meant that the government had to bring forward and prioritise "Business As Usual" Statutory Instruments (SIs). It was agreed in April that it would not be possible to consult on and lay the fees SI in Parliament by the end of June. So these amendments will be rolled into a future SI to revise and update the legislative framework for veterinary medicines and medicated feeds.

Animal AMR commitments deriving from the UK 5-year AMR Strategy have been met. This has been measured by the 40% drop in sales of antibiotics for use in animals over the course of the Strategy, and clear engagement from the animal industry and associated stakeholders. All reporting of AMR-related surveillance data to the EC was

completed on time. The Veterinary Antibiotic Sales and Surveillance report (VARSS-UK 2017) was published on schedule in October 2018, and reported a further drop in UK antibiotic sales to an all-time low of 37 mg/kg. This publication was followed in January 2019 by the One Health report, a joint report on antibiotic use and antibiotic resistance which was authored by the VMD in collaboration with PHE, Food Standard Agency (FSA) and other cross-government colleagues. The One Health report publication was aligned with the publication of the new UK 5-year national action plan and 20-year vision, both are cross-government UK strategic documents detailing our plans to tackle AMR in the coming years.



B) Preparing for EU exit

Why are we doing this? 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 performance indicators:

Ensure day 1 readiness projects completed early quarter four

Ensure all IT replacement build and testing completed by quarter four and systems operational in quarter four*



Identify and be in a position to influence (or attain membership) of non-EU international bodies and committees relevant to medicines regulations by quarter three

On 23 June 2016, the EU referendum took place and the people of the UK voted to leave the EU. Until the United Kingdom leaves the EU all the rights and obligations of EU membership remain in force. During this period the Government will continue to negotiate, implement and apply EU legislation. The Government has negotiated with the Union on the terms of its withdrawal, and future relationship with, the Union. The terms on which the UK leaves the EU will determine what arrangements apply in relation to EU legislation in future once the UK has left the EU.

We have continued to develop plans for all possible outcomes, including no deal, to ensure that a stable regulatory framework for veterinary medicines is in place from the point we leave the EU. This has included developing IT systems to replace those that we may no longer have access to.

We launched our online EU Exit Information Hub in February 2019 which shows what areas of the regulation of veterinary medicines will and will not change and provides draft guidance that will be current on EU exit day, in the event of a no deal, to help our stakeholders prepare.

Together with the animal medicines industry, we are working to ensure that supplies of veterinary medicines remain available. We already have well-established procedures to deal with medicine shortages and we have also put in place a multi-layered approach to support the industry to reduce any supply disruption. These plans include:

• Minimising changes to, or providing clarifications of, regulatory requirements so companies can continue to sell their products in the UK in a no deal scenario.

^{*}IT systems were ready for March 31 with minimal capability and contingency work arounds.

- Strengthening the established processes and resources used to deal with shortages in the event that they do occur. This includes extending our industry supply reporting system in order to understand the reasons for potential supply issues and take appropriate action.
- Permitting the use of medicines authorised in other countries which can be imported through the VMD's Special Import scheme.
- They also included: Securing additional space for veterinary medicines on government-procured ferries.

Business Priority 2 – Delivery

A) Facilitate optimal availability and safe use of veterinary medicines



Why are we doing this? Our authorisation 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 performance indicators:

Monthly report against 46 Published Standards. Overall performance against published standards to be at or above the effective level (≥92%)



Report pharmacovigilance findings to the Veterinary Products Committee and publish findings



Respond to 'high risk' product defect reports within five working days; and all others within 10 working days



The expectations for the VMD's performance (time and quality) in terms of handling applications, inspections and pharmacovigilance matters are set out in the published standards. Of the 46 published standards, 42 were within scope. The four other standards did not meet the minimum volume criteria for inclusion. Exceptionally this year all the 42 published standards had a 100% score and thus met the 'excellent' performance standard. The independent Veterinary Products Committee (VPC) rated the quality of our initial assessments for marketing authorisation applications as level 1, the highest level, confirming that we properly identified potentially serious risks to human and animal health and the environment and that questions were comprehensive, clear and justified.

Performance against the published standards for pharmacovigilance have been maintained above the effective level. All changes to products resulting from pharmacovigilance have been published in the monthly updates provided in the Veterinary Record.

100% of inspections of veterinary only Wholesale Dealer Authorisations have been conducted within 5 years of the previous inspection. Performance against published standards for sending reports have been maintained at above the effective level at 97% for deficiency reports and 98% for final reports.

Published standards for conducting Good Manufacturing Practice (GMP) inspections within 3 years of the previous inspection have been maintained at above the effective

level (97%), whilst 100% of GMP certificates and reports have been issued within the published standards.

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

Key performance indicators:

Statutory residues plan agreed with the Commission according to the timeframe set out in Council Directive 96/23



Publish summary results of statutory residues surveillance programme on a two-monthly basis and completion of the 2018 programme achieved and published by end of quarter one 2019



Publish summary data of VMR breaches including cases handled, internet listings removed, enforcement notices served, and outcomes of successful prosecutions on a quarterly basis in the Enforcement Newsletter and (Marketing Authorisation Veterinary Information Service (MAVIS) (newsletter for industry)



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



Work went as planned for this residues target and success is shown by the continuing low number of non-compliant residue samples and no trends detected or reports received that required immediate action.

The Enforcement Newsletter is published quarterly, and is circulated widely to our enforcement stakeholders and partners. The newsletter focusses on particular issues relevant to veterinary medicines. As well as giving a summary of cases handled and internet listings removed, it also provides a link at www.gov.uk to the enforcement notices published, prosecutions taken and Police Cautions issued.

We actively set out to increase the number of enforcement partners we regularly work with. This enabled us to deal more effectively with the illegal marketing, sale and administration of veterinary medicines, and to deliver successful enforcement outcomes benefitting the business and citizens.

Our focus on tackling the illegal marketing and sale of veterinary medicines led to us establish a good working relationship with Facebook. We now have in place procedures to facilitate the removal of illegal veterinary medicines listings, along with the illegal advertising of veterinary products. In addition our good working relationships with ebay and Amazon continues. We are now looking to work with other internet marketing platforms.

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 AMR and Sustainable Development Goals. Our 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 performance indicators:

To secure at least one externally funded capacity building contract



To provide at least one on-site training event to a third country with full cost-recovery



Official participation in development or implementation of AMR action plans for at least one third country.

The VMD was part of a successful tender by the Spanish Association for Standardisation and Certification (AENOR) consortium for the organisation and implementation of training activities on prevention, monitoring and control of antimicrobial resistance for non-EU countries. This was in the context of an overall 'One Health' approach under the Better Training for Safer Food initiative. A number of VMD staff have been involved in delivering this training along with EU colleagues.

The following capacity building training was delivered to Ethiopia's Veterinary Drug and Animal Feed Administration and Control Authority:

- Pharmaceutical dossier evaluation training
- Introduction to Feed & Inspection of Feed Manufacturers Workshop
- Biologicals dossier evaluation training
- Biologicals GMP Inspection workshop
- Alignment/Enforcement workshop
- Good Distribution Practice (GDP) workshop

The VMD hosted the Ugandan National Drug Authority for a benchmarking exercise in March 2019.

The VMD CEO is an active board member for a third country AMR Action Plan in Asia, and attended the last meeting in March 2019.

Business Priority 3 – Customer 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 performance indicators:

Develop an action plan to implement the areas for improvement identified as part of the 2017/18 biennial survey of pharmaceutical industry customers and report on this by end 2018/2019



The overall median score from feedback surveys for individual VMD company meetings to be at least good for 90% or more of the meetings, and for 90% satisfaction for inspections.



The biennial customer satisfaction survey feedback was delivered to staff and the full and summary slides decks published on the VMD's intranet. The summary slide deck has been published on www.gov.uk.

An action plan was developed and published on www.gov.uk. A presentation was given at the VMD Information Day reminding Industry of the survey results, thanking them for their contribution and summarising the action plan and the steps taken by the VMD.

An article was published in MAVIS which highlight the 2017/18 results.



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 performance indicators:

Carry out the annual survey of policy customers in Quarter 1 and the median overall score to be at least 'good'



To maintain close liaison, particularly for revisions of medicines legislation and for AMR.



During May 2019 we carried out a survey of colleagues in government that use the VMD's policy services or who we work with to make and deliver policy. We hold the survey each year to complement the regular in-year assessment of the delivery of specific policy areas. Our survey covered services provided by the VMD's Antimicrobial Resistance, Legislation, Residues and 'EU Exit' Teams.

We asked 2 questions about the service we provided in 2018/19 based on Defra's formal approach to policy making. With a rating system from '1 = unacceptable service: radical overhaul required' through to '5 = excellent service: no changes required'.

Overall, 88% of responses rated the quality of the policy the VMD provided as 'excellent: no changes required' with 12% rating us as 'good'. 100% of responses rated the way the VMD provided policy services as 'excellent'.

On the specific comments-based question "On the basis of your scores what changes do the VMD need to make", we received positive, confirmatory comments, particularly about our Residues Team.

The AMR team has coordinated and maintained regular contact with policy and scientific colleagues on AMR through quarterly Defra Antimicrobial Resistance Coordination (DARC) group meetings, and has engaged policy colleagues in the Devolved Administrations in the cross-Defra working group on delivery of the 2013-2018 UK AMR Strategy and development of the new 5-year AMR National Action Plan.

C) Communications, engagement 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 performance indicators:

To have positive feedback from stakeholders: including from shows and events we attend, open days, company meetings



Access to information requests: at least 95% cases responded to on time.



Maintain and review datasets published on <u>data.gov.uk.</u> Continue to publish VMD datasets.

The VMD received positive feedback from its range of stakeholder groups in respect of the series of events that it attended in 2018/19.

The 2017/18 biennial Pharmaceutical Industry customer Satisfaction survey gave the VMD very high scores for companies' satisfaction with our open days and company meetings.

Business Priority 4 – Value for money

A) 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.

Key performance indicators:

Cost recovery for charged for regulatory services to be within the range 100 - 102% of full cost recovery.



To have identified further reductions in regulatory burden

We recovered all of our costs (including a Cost of Capital charge) from the provision of services to industry. Additional analysis of the fees and costs to industry is provided within the Parliamentary Accountability and Audit Report section.

Over the course of the year we achieved value for money by:

- preparing and implementing a savings plan which generated savings on the previous year funding requirement from Defra
- managing contracts to keep cost within or below budget, whilst maintaining its level of service, to enable reduced charges to industry.

Business Priority 5 – Capacity and capability

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



Why are we doing this? To deliver our 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 performance indicators:

Positive Internal/External Audit opinion on effectiveness of financial controls to be "moderate" or better.



Delivery of 90% of targets set out in the IT strategy and to achieve at least 99% uptime for VMD's IT systems.



No serious risks on risk register materialise.

To maintain whole business re-certification against ISO 9001:2015



Maintain a top quartile staff engagement score in the 2018 Civil Service People Survey



Training days per full-time equivalent to be at least 5 days per year.



Sickness absence – to maintain in 2018/19 the low number of days lost per full-time equivalent for short-term sickness and to perform well compared to Defra and wider public sector benchmarks for equivalent periods



All targets have been met.

Social and Community Issues and Environmental Matters

Social and community issues

Defra launched its <u>Equality</u>, <u>Diversity and Inclusion Strategy</u> in January 2017 covering the period 2017 to 2020. The aim of the strategy is to ensure Defra group, which includes the VMD, is a great place to work and to deliver our aspirations to be an organisation with a diverse, open and inclusive culture.

The Strategy's four themes of: respect; include; support; and engage, incorporate our strategic priorities which include: promoting inclusive behaviours; tackling discrimination, bullying and harassment, and improving career support.

All our staff are required to complete training on:

- unconscious bias
- health and safety awareness
- disability awareness

- equality and diversity essentials
- counter fraud, bribery and corruption

All our assessments of Marketing Authorisations include an environmental impact assessment to ensure that the use and disposal of veterinary medicines do not adversely affect the environment.

Environmental matters: sustainability report for 2018/19

For more information please see Defra's Annual Report and Accounts – section headed: "Commentary on Sustainable Performance", which covers the VMD.

Under the Greening Government Commitments we have a commitment to reduce our greenhouse gas emissions, the amount of waste we generate and our water consumption. Defra's Built Environment Sustainability Team (BEST) provides us with quarterly figures on each of the following categories.

In previous reports these figures were provided on a calendar year basis. To align this data to the reporting year we have re-stated the previous figures for comparison.

SUSTAINABILITY DATA		2018/19	2017/18	2016/17
	Total gross emissions	174.5	180.6	169.2
Non-Financial Indicators	gross emissions: Scope 1	67.9	67.7	32.9
(tonnes CO ²)	gross emissions: Scope 2	85.3	101.7	130.5
	gross emissions: Scope 3	21.3	11.2	5.8
Non-Financial Indicators (tonnes)	Total Waste - incinerated with energy recovery	9.8	10.1	11.6
Related Energy	Electricity: non-renewable	301.2	271.7	276.7
Consumption (1000 KWh)	Gas	32.5	32.3	31.0
Financial Indicators (£'000)	Expenditure on domestic official business travel	7.5	3.5	*
Non-Financial Indicators	Water consumption supplied	747	811	1185
(m ³)	Water consumption per full time equivalent (FTE)	4.9	5.2	7.7
Mileage ('000)	Total mileage travelled in vehicles owned or leased by VMD	130.3	*	*

^{*} records are not available

The costs for our energy, water and waste disposal are part of the overall Defra Corporate Recharge costs and are not billed separately. The VMD building is located on a shared site with the Animal and Plant Health Agency (APHA) in Weybridge and all our waste goes into one system to help the site incinerator burn less flammable waste such as animal bedding and carcasses. The glass and metals are extracted and flash heat treated to ensure biosecurity.

Greening Government Commitment targets and performance

Commitment	Target	2018/19 Performance			
Total gross emissions:					
to reduce carbon emissions by	2009/10 baseline	254 tCO ²			
38% from the estate and business related travel	2019/20 target	157.5 tCO ²	174.5 tCO ²		
Domestic travel:					
to cut domestic business travel	2013 baseline*	34 flights+	E6 flights†		
flights by 30%	2019/20 target	24 flights+	56 flights+		
Waste:					
to reduce the amount of waste	2009/10 baseline	43.7 tonnes	9.8 tonnes		
generated by 25%	2019/20 target	32.8 tonnes	9.6 tonnes		
Water:					
an overall reduction in water	2009/10 baseline	1,000 m ³	747 m ³		
consumption	2019/20 target	reduction	/4/ ///		

^{*} Flight records are not available prior to 2013, therefore this figure is used for our baseline.

Greenhouse gas emissions

The main direct impacts for the VMD are in our electricity and gas consumption. Significant changes to consumption cannot be made without considerable capital investment, for example to introduce more energy efficient heat sources, to reduce solar gain.

Our energy consumption for last two years reflects the unseasonably hot summer and cold winter weather and the additional use of fans and heaters throughout these periods.

Domestic travel

Staff undertake nearly all domestic business travel using the train with the exception of travel to Northern Ireland and Scotland. The impact of carbon emissions for these is balanced with economic and efficiency factors and is limited to essential travel. The number of domestic flights this year increased significantly as a result of mitigating actions for EU exit preparedness.

Waste

Our main direct impacts of waste are in relation to paper and other office related waste. However, we have produced 78% less waste against the target for 2019/20. We continue to work to reduce the Agency's paper usage by moving to digital working.

⁺ Figures are given as the number of airline journeys.

Water consumption

Since the water leak in 2016/17 we have continued to reduce our water usage. Our main use is in the toilet facilities which have 'water pigs' in the cisterns to reduce flush rates. We cannot do more to reduce toilet facility water usage without capital investment in new hardware. The two showers are already low volume units.

Professor SP Borriello

S. P. Bernett

Chief Executive 11 July 2019

Accountability Report Corporate Governance Report

Director's Report

Board and Executive Directors

The VMD employs two Directors in addition to the Chief Executive.

Position	Position holder
Chief Executive	Peter Borriello
Director of Authorisations	Abigail Seager
Director of Operations	Paul Green

The notice period for Executive Directors is three months.

The composition of the Management Board (including non-executive members) having authority or responsibility for directing or controlling the major activities during the year is described within the Governance Statement in this report.

The Board members had no company directorships or other significant interests which conflicted with their management responsibilities in the financial year 2018/19.

Protecting personal data

There were no personal data-related incidents in the VMD in 2018/19. Incidents, the disclosure of which would in itself create an unacceptable risk of harm, may be excluded in accordance with the exemptions contained in the Freedom of Information Act 2000 or may be subject to the limitations of other UK information legislation. However, there was the Data Protection vulnerability incident as detailed in the Information management and data security section.

Statement of Accounting Officer's Responsibilities

Under the Government Resources and Accounts Act 2000 HM Treasury has directed the VMD to prepare for each financial year a statement of accounts in the form and on the basis set out in the Accounts Direction.

The Accounts are prepared on an accruals basis and must give a true and fair view of the state of affairs of the VMD and of its income and expenditure, statement of financial position and cash flows for the financial year.

In preparing the Accounts the Accounting Officer is required to comply with the requirements of the Government Financial Reporting Manual (FReM) and in particular to:

- observe the Accounts Direction issued by HM Treasury, including the relevant accounting and disclosure requirements, and apply suitable accounting policies on a consistent basis
- make judgements and estimates on a reasonable basis
- state whether applicable accounting standards as set out in the Government FReM have been followed, and disclose and explain any material departures in the Accounts
- prepare the accounts on the going concern basis
- confirm that the Annual Report and Accounts as a whole is fair, balanced and understandable and take personal responsibility for the Annual Report and Accounts and the judgements required for determining that it is fair, balanced and understandable

The Accounting Officer for Defra has designated the Chief Executive of the VMD as Accounting Officer of the VMD. The responsibilities of an Accounting Officer, including responsibility for the propriety and regularity of the public finances for which the Accounting Officer is answerable, for keeping proper records and for safeguarding the Agency's assets, are set out in Managing Public Money published by HM Treasury.

Preparation and audit of the Accounts

The Accounts have been prepared under a direction issued on 19 December 2018 by HM Treasury under Section 7(2) of the Government Resources and Accounts Act 2000 and are audited by the Comptroller and Auditor General.

Our income and expenditure was monitored under a gross control total by HM Treasury and was also incorporated into the Defra Resource Accounting total.

As the Accounting Officer, I have taken all steps that I ought to have taken to make myself aware of any relevant audit information and to establish that VMD's auditors are aware of that information. So far as I am aware, there is no relevant audit information of which the auditors are unaware.

Governance Statement

The Accounting Officer is responsible for maintaining a system of internal control that supports the achievement of the Agency's policies, aims and objectives, while safeguarding public funds and departmental assets. This is in accordance with the responsibilities assigned in the HM Treasury publication; Managing Public Money.

Assurance and audit findings in this governance statement overall confirm that we have complied with the governance arrangements effectively.

Governance framework

The VMD is an Executive Agency of Defra. We are the UK policy lead on veterinary medicines and, as the national competent authority, are responsible for the implementation of all aspects of the VMD and related legislation.

The Agency is led by the Chief Executive Officer (CEO), who is accountable to the Secretary of State for Defra for our performance and operation and for the achievement of our business priorities in accordance with its targets and key deliverables.

The Secretary of State for Defra determines the overall policy and financial framework within which we operate and the Defra ownership function is exercised by the Defra Director General for Food, Farming and Biosecurity (DG FFaB). The DG FFaB provides advice and challenge on our strategic direction and performance to the VMD management. The CEO formally reports on Agency performance to Defra through the quarterly DG FFaB meetings.

Committee structure

The VMD Management Board (MB) meets quarterly and is the internal governance board providing advice, support and challenge on: the delivery of the key objectives; achieving value for money, and regularity and propriety in the administration and operation of the VMD. Chaired by a Non-executive Director (NED) Julia Drown, the MB consists of the CEO, the two Directors, the Head of the Business Support Division, the Head of Finance and two other NEDs, David Corner and Andrew Coulson until May 2018 then David Catlow from December 2018. The Chief Veterinary Officer, a Defra representative and selected Heads of Teams, as appropriate and applicable to the tabled agenda, are also invited to attend. Minutes of MB meetings are published on gov.uk.

The Audit and Risk Assurance Committee (ARAC), a sub-committee of the MB, also meets quarterly and provides advice to the CEO on the adequacy and effectiveness of the VMD's governance and risk management frameworks. Chaired by a NED, David Corner, and consisting of the other two NEDs. The committee considers reports from a number of senior staff, Defra's internal auditors (for 2018/19 this was KPMG; for 2019/20 this is the Government Internal Audit Agency (GIAA) and the National Audit Office). Minutes of ARAC meetings are published on www.gov.uk.

Executive Management Board (EMB) is formed of the CEO, the two Directors and the Head of Business Support Division who collectively form the Executive Team that sets the direction for the Agency and has the overall authority to run the Agency on a day-to-day basis.

The Veterinary Products Committee is an independent scientific advisory committee which advises the VMD on veterinary medicinal products and animal feed additives.

The VPC held meetings in June, September and February. Minutes of meetings and further information is published on gov.uk. The Committee considered and gave advice to the VMD for an application to change the legal category of a range of authorised products. It also considered an appeal from a Marketing Authorisation Holder against the suspension of a product. It continued to monitor veterinary pharmacovigilance activities through the reports compiled by the VMD's Pharmacovigilance team. In addition, the Committee held an open meeting in September and gave a presentation on the environmental effects of parasiticides.

The overall governance structure and associated assurance, as well as advice and challenge, are enriched by the VPC and discussions between the CEO and the CVO. We take part in the EU's Benchmarking of European Medicines Agencies peer-assessment for our medicines functions and we hold external certification to ISO 9001:2015 (Quality Management), which covers all our operational processes. We also hold external certification to ISO 27001:2013 (Information Security).

During the year we have worked effectively with KPMG to review: our finance system; our implementation of the General Data Protection Regulations (GDPR); international work streams, and workforce planning to confirm the VMD's assurance and control framework is fit for purpose.

Audits

In November 2018 the VMD's Good Manufacturing Practice (GMP) inspectorate was subject to audit under the Heads of Medicines Agencies' (HMA) Joint Audit Programme (JAP). In addition to the audit team, the audit was observed by representatives from the United States Food and Drug Administration (US FDA) as part of the ongoing process to include veterinary medicinal products within the scope of the Mutual Recognition Agreement (MRA) between the EU and the US FDA. A small number of observations were made and we are liaising with the inspections administration team to address them.

In September 2018 our independent external auditor, SGS, confirmed the VMD's continuing certification under ISO 9001 (Quality Management) and ISO 27001 (Information Security) following their surveillance visit. There were no non-conformities identified under the ISO 9001 standard and the auditors made only a small number of recommendations for minor improvements to our systems and processes under this standard. There were no breaches, only a small number of non-conformities under ISO 27001 which the IT team is addressing.

We have continued to focus on performance management both at an individual and business level. We achieved a Civil Service People Survey engagement index score of 64% in 2018 which represents the 14th highest score out of 111 in the survey.

Compliance with the Corporate Governance Code

The focus of <u>HM Treasury's Corporate Governance Code</u> (CGC) is on ministerial departments and sets out the protocol, accountabilities and role of Departmental Boards. We apply the principles of the code, which requires that Boards operate according to recognised precepts of good corporate governance in business: leadership; effectiveness; accountability; and sustainability. It also requires that arrangements are in place for an annual evaluation of the effectiveness of the Board and for results of the evaluation to be acted on.

The MB and ARAC assessed their effectiveness and the quality of the management information and performance data at each meeting and found both to be acceptable. A more formal assessment was carried out following their March 2019 meetings whereby Committee members and regular attendees of the Boards completed a questionnaire. The results were discussed at the May meetings.

The EMB has formally assessed its compliance with the CGC and its effectiveness as evidenced by the full delivery of the 2018/19 targets and key deliverables, and the results of the 2018 annual staff survey. The outcomes of the EMB are reported to staff through the weekly Chief Executive's Newsletter and where appropriate Office Notices. To increase involvement and increase challenge from outside the Executive Team, individual Heads of Team are invited on a rolling basis for a month each to attend and contribute to the meeting.

Conflicts of interest

All VMD staff and Board members are required annually to declare interests which could emerge as a conflict of interest. There is a standing agenda item on declarations of interest at the start of every Board meeting and members who have declared a specific conflict leave the meeting during the discussion of that item. During 2018/19 no Board member conflicts of interest were identified.

Governance and control

Whistleblowing

We are committed to high standards, reinforced by the Civil Service Code, of integrity, honesty and professionalism in all that we do.

We encourage all employees to use Defra's Whistleblowing Policy if they need to raise a concern about a past, present or imminent wrongdoing within Defra/VMD; or any wrongdoings which conflict with the Civil Service Code.

Business critical models and quality assurance

An appropriate quality assurance framework is in place to assess business models relevant to the Agency. We obtain, through MB and ARAC, assurance that the associated risks are properly managed. There are no business models which currently fall within the definition 'business critical models' as set out by HM Treasury.

Quality Management System

Our Quality Management System (QMS) ensures processes and procedures are documented and managed effectively. Trained VMD auditors, Defra Internal Auditors (for 2018/19 this was KPMG; for 2019/20 this is GIAA), the National Audit Office (NAO) and

external consultants – SGS – provide assurance that processes are being followed and improvements are made on an ongoing basis. Our QMS is certified to ISO 9001:2015.

Business continuity plans

We operate a Business Continuity (BC) Management system to ensure the operation of key activities in the event of a serious incident, including our off-site IT back-up systems. Our senior management team also carried out its annual 'desk-top' test of the plan; we held BC awareness-raising workshops for all our people.

Information management and data security

We have an established governance structure to ensure that information assets are handled appropriately. To support the Information Systems Security Officer (ISSO), the Agency's IT Security Officer provides a focal point for Information Asset Owners to seek guidance on effective approaches to managing risk. Information data handling courses are embedded in induction processes and each year we are required to complete the Responsible for Information training course.

Data security remains critical and is assured by the VMD's maintenance of the Cabinet Office Security Standards and external certification to ISO 27001:2013.

There were no data security lapses that were deemed to be significant or critical during 2018/19. However, In February 2019, officials discovered a 'Data Protection' vulnerability on the Shared Services Connected Limited (SSCL) HR system, that Defra uses, relating to training information. Defra quickly rectified this fault and notified the Information Commissioner – it found no evidence that anyone had exploited the vulnerability, that the information at risk was not highly sensitive and overall, the vulnerability 'resulted in a low amount of risk to data subjects' (i.e. the staff in Defra and its agencies). Defra's Chief Operating Officer also confirmed to the VMD that they were content that security failings were not more widespread in the system; that the configuration error was not easily discoverable through routine security checks, and that SSCL/Defra had now properly contained risks.

We were also part of a wider Defra Group Data Protection Programme that was working with Data Protection teams and other stakeholders to prepare for the implementation of the General Data Protection Regulations (GDPR) in May 2018. We are confident that through the work we did with the Programme, including carrying out data impact assessments and preparing privacy notices, the VMD implemented GDPR in accordance with Defra and the Information Commissioner's expectations. Since that time we have been a part of Defra Group's formal 'Data Protection Community', which meets regularly to share knowledge as GDPR beds-in and develops through custom and practice. We have also worked with our IT systems developers to ensure we apply the requirements of GDPR to our new systems by carrying out further data impact assessments and posting new privacy notices.

Managing our risks and significant issues

Our primary role is in the authorisation of veterinary medicines, which is always based on assessing the benefit of medicines against their risks. Consequently the very nature of our work is to examine risks, to reduce these to an acceptable level, and then to consider the residual risks against the benefits. This philosophy in managing risks is adopted in the approach to risk management across the organisation to identify key risks that could threaten the achievement of the VMD's objectives.

Our Strategic Risk Register and significant issues are regularly reviewed by the EMB, MB and ARAC and updated as necessary. The degree of risk is measured by considering the likelihood and impact of those risks and issues, and in 2018/19 these were:

Operational

- inadequate business continuity procedures
- inadequate IT services
- reduction in funding

Reputational

- reduced confidence in veterinary medicines, food safety and/or the VMD
- risk of litigation
- failure to deliver on newly secured contracts with third sector funders for medicines regulation capability development work

Financial

- EU Exit and potential reduction in revenue
- failure to deliver statutory requirements
- overspending budget
- fraud

Staffing

- failure to attract and retain experienced professional staff for certain skills, particularly in buoyant veterinary medicines and IT sectors where demand for scarce experience and talent is high. This is despite high staff engagement scores
- delays in Defra and Government Recruitment Service (GRS) processing candidates

Governance or structural changes

imposed change to estate and/or other support services

EU exit and International

- consideration of EU exit and its impact on the VMD
- international process/regulation changes that adversely impact UK interests including exit from the EU

Delivery by partners

- · inability of partner organisations to deliver on our behalf
- decreasing resilience of others to deliver commissioned services
- inability of centralised government services to deliver support needed

Mitigation of risks

All of these were managed appropriately by the VMD through:

- careful workforce and succession planning
- providing first-class learning and development that develops talent within the Agency
- strong management focus on efficiencies
- contract management
- project management
- escalating unresolved business continuity issues with central Defra
- collaboration with central Defra, especially in relation to EU exit

The UK's exit from the EU continued to be a high risk area for the Agency, in particular, the impact of potential new legislation and the uncertainty over our new relationship with the EU.

Some of the specific actions we implemented and progressed to help control risks included:

- secured funds
- dedicated work force planning
- · operational readiness
- working with Defra, Department of Health and the Medicines and Healthcare products Regulatory Agency (MHRA)

The Strategic Risk Register is supplemented by a list of 'standing' controls setting out routine control measures, to ensure as far as possible we incorporate risk mitigations into our business-as-usual activities.

We also seek to identify risks that, while not significant enough to appear on the Strategic Risk Register, could still affect the successful outcome of our objectives. These risks are managed within individual business areas and are 'owned' by the respective Departmental Heads or Project Leaders who report progress to Directors at regular intervals. This includes a process for escalation to the Strategic Risk Register.

Internal audit arrangements

For the financial year 2018/19 KPMG were responsible for VMD's internal audit service. From 1 April 2019 the Government Internal Audit Agency has been responsible for providing VMD's internal audit service. Internal auditors carry out their work in line with the Annual Internal Audit Plan that is informed by our risk profile and approved by the ARAC on an annual basis. Internal auditors complete their Internal Audit responsibilities using a methodology that is aligned to Public Sector Internal Audit Standards. Regular reports are issued making recommendations for improvements where appropriate. These four reports were issued relating to 2018/19:

- the finance system overall rating "substantial"
- GDPR overall rating "moderate"
- international work streams overall rating "substantial"
- Work force planning overall rating "substantial"

In their Annual Report, which offers their opinion on the adequacy and effectiveness of risk management, control and governance, the Head of Internal Audit Opinion is one of "Substantial Assurance".

Using staff trained as auditors in ISO 9001:2015 standards we have also carried out an internal audit of our Good Distribution Practice inspection process.

Whilst no significant internal control problems have been identified during the year, we continually strive to build on the procedures and processes that we already have in place to manage risk. This year VMD implemented a new Finance IT system and continued to embed it within the business.

Remuneration and Staff Report

Remuneration Policy

The remuneration of the Senior Civil Service (SCS) is set by the Prime Minister following independent advice from the Senior Salaries Review Body (SSRB). The Cabinet Office advises departments in March or April each year of the Government's response to the SSRB recommendations and produces guidance for departments and network bodies to follow.

Defra develops the SCS Reward Strategy within the Cabinet Office Framework, ensuring that the overall pay awards for the SCS are within the cost ceiling allowed.

Members of the SCS, excluding the Permanent Secretary, are eligible to be considered for individual levels of bonus as non-pensionable, non-consolidated variable pay (NCVP), based on their performance. NCVP is paid in the financial year after that in which it was earned. NCVP values, informed by each individual's appraisal grade, are paid within Cabinet Office guidelines.

Service contracts

The Constitutional Reform and Governance Act 2010 requires Civil Service appointments to be made on merit, on the basis of fair and open competition. The Recruitment Principles published by the Civil Service Commission specify the circumstances when appointments may be made otherwise.

Unless otherwise stated below, the officials covered by this report hold appointments which are open ended. Early termination, other than for misconduct, would result in the individual receiving compensation as set out in the Civil Service Compensation Scheme.

Further information about the work of the <u>Civil Service Commission</u> can be found on the Civil Service Commission website.

Remuneration – salary, benefits-in-kind and pensions (audited)

The following sections provide details of the remuneration and pension interests of the VMD's Directors.

	Single total figure of remuneration										
Officials		Salary £'000		Bonus payments £'000		Benefits-in-kind to nearest £100		Pension benefits to nearest £1000 ⁽¹⁾		Total £'000	
	2018/19	2017/18	2018/19	2017/18	2018/19	2017/18	2018/19	2017/18	2018/19	2017/18	
SP Borriello Chief Executive	120-125	115-120	-	-	-	-	47,000	46,000	165-170	165-170	
A Seager Director of Authorisations	60-65(2)	-	-	-	-	-	53,000	-	115-120	-	
P Green Director of Operations	70-75	70-75	-	-	-		7,000	5,000	80-85	75-80	
M-O Hendrickx Director of Authorisations	-	30-35(3)	-	-	-	-	1	12,000	-	40-50	

- (1) The value of pension benefits accrued during the year is calculated as (the real increase in pension multiplied by 20) plus (the real increase in any lump sum) less (the contributions made by the individual). The real increases exclude increases due to inflation or any increase or decreases due to a transfer of pension rights.
- (2) A Seager took up the post of Director of Authorisations on 1 May 2018. Figures quoted are for the period 1 May 2018 to 31 March 2019. The full year equivalent banding is £65,000 to £70,000.
- (3) M-O Hendrickx left the VMD on 4 August 2017. Figures quoted are for the period 1 April 2017 to 4 August 2017. The full year equivalent banding is £90,000 to £95,000.

Salary

'Salary' includes gross salary; overtime; reserved rights to London weighting or London allowances; recruitment and retention allowances; private office allowances, and any other allowance to the extent that it is subject to UK taxation. This report is based on accrued payments made by the Agency and thus recorded in these accounts.

Benefits-in-kind

The monetary value of benefits-in-kind covers any benefits provided by the employer and treated by HM Revenue and Customs as a taxable emolument. None of the Directors received any benefits-in-kind during the year.

Bonuses

Bonuses are based on performance levels attained and are made as part of the appraisal process. Bonuses paid in 2018/19 relate to performance in the prior financial year, comparative bonuses for 2017/18 relate to the 2016/17 performance.

Pay multiples (audited)

Reporting bodies are required to disclose the relationship between the remuneration of the highest paid director in their organisation and the median remuneration of the organisation's workforce.

The full-time equivalent annualised total banded remuneration of the highest paid Director and the median member of staff excluding the highest paid Director are as shown in the following table:

Total remuneration	Highest paid Director £'000	Median of other staff £	Pay multiple ratio
2018/19	120-125	33,469	3.7
2017/18	115-120	33,787	3.5

In 2018/19, no employees received remuneration in excess of the highest paid Director (2017/18, nil). Remuneration ranged from £16,000 to £121,000 (2017/18: £18,000 to £120,000).

Total remuneration includes salary, non-consolidated performance-related pay and benefits-in-kind. It does not include severance payments, employer pension contributions and the cash equivalent transfer value of pensions.

There have been no ex gratia payments or amounts paid during the year in respect of compensation to former senior managers or to third parties for services of a senior manager.

None of the VMD Directors have held any company directorships or other significant interests during the year that, in the opinion of the Directors, may conflict with their management responsibilities.

No employer contributions were made to partnership pension accounts during 2018/19 or 2017/18 in respect of the VMD's Directors.

Civil service pensions

Pension benefits are provided through the Civil Service pension arrangements. From 1 April 2015 a new pension scheme for civil servants was introduced which provides benefits on a career average basis with a normal pension age equal to the member's State Pension Age (or 65 if higher). Prior to this, civil servants participated in the Principal Civil Service Pension Scheme (PCSPS). Further details about the Civil Service pension features and benefits can be found in the resource accounts of the Cabinet Office: Civil Superannuation, www.civilservicepensionscheme.org.uk.

These statutory arrangements are unfunded with the cost of benefits met by monies voted by Parliament each year and increased annually in line with Pensions Increase legislation.

Other arrangements include money purchase pensions known as a 'partnership' are available as an alternative for employees joining on or after the 1 October 2002. The employer makes an age related basic contribution of between 8% and 14.75% into a stakeholder pension product chosen by the employee from a panel of providers. The employee does not have to contribute but where they do make contributions, the employer will match these up to a limit of 3% of pensionable salary (in addition to the employer's basic contribution). Employers also contribute a further 0.5% of pensionable salary to cover the cost of death in service and ill health retirement lump sum benefits.

The pension figures quoted for officials in this report show combined pension earned in all schemes as appropriate.

Cash equivalent transfer values

A Cash Equivalent Transfer Value (CETV) is the actuarially assessed capitalised value of the pension scheme benefits accrued by a member at a particular point in time. The benefits valued are the member's accrued benefits and any contingent spouse's pension payable from the scheme. A CETV is a payment made by a pension scheme or arrangement to secure pension benefits in another pension scheme or arrangement when

the member leaves a scheme and chooses to transfer the benefits accrued in their former scheme.

The pension figures shown relate to the benefits that the individual has accrued as a consequence of their total membership of the pension scheme, not just their service in a senior capacity to which disclosure applies. These figures also include the value of any pension benefit in another scheme or arrangement which has been transferred to the Civil Service pension arrangements and any additional pension benefit accrued as a result of buying additional pension benefits at their own cost. CETVs are worked out in accordance with The Occupational Pension Schemes (Transfer Values) (Amendment) Regulations 2008 and do not take account of any actual or potential reduction to benefits resulting from Lifetime Allowance Tax which may be due when pension benefits are taken.

Real increase in CETV (audited)

This reflects the increase in CETV that is funded by the employer. It does not include the increase in accrued pension due to inflation, contributions paid by the employee (including the value of any benefits transferred from another pension scheme or arrangement) and uses common market valuation factors for the start and end of the period.

	Accrued pension at pension age as at 31/3/19 and related lump sum	Real increase in pension and related sum at pension age	CETV at 31/3/19	CETV at 31/3/18	Real Increase in CETV
	£'000	£'000	£'000	£'000	£'000
SP Borriello Chief Executive	30-35 plus lump sum of 0	2.5-5.0 plus lump sum of 0	570	498	41
A Seager Director of Authorisations	15-20 plus lump sum of 0	2.5-5.0 plus lump sum of 0	214	155	28
P Green Director of Operations	20-25 plus lump sum of 65-70	0-2.5 plus lump sum of 0-2.5	494	438	7

External Management Board members (audited)

Membership details of the Management Board are detailed in the Governance Statement in this report. The Non-executive members also form the ARAC. The following salaries and benefits-in-kind were paid to the external members:

2018/19	D Corner	J Drown	D Catlow
	£'000	£'000	£'000
Salary (as defined above)	0-5	0-5	0-5
Benefits-in-kind (1)	0-5	0-5	0-5
Total	0-5	0-5	0-5

2017/18	D Corner	J Drown	A Coulson
	£'000	£'000	£'000
Salary (as defined above)	0-5	0-5	0-5
Benefits-in-kind (1)	0-5	0-5	0-5
Total	0-5	0-5	0-5

1. Benefits-in-kind relate to reimbursement of home to office travel and subsistence.

Staff Report

Staff numbers

At 31 March 2019 we employed 156 permanent staff (151.9 FTE) and 16 temporary staff (15.4 FTE) supplied by local employment agencies. The average number of full-time equivalent permanent and temporary staff during the year and an analysis of staff-in-post (headcount) as at 31 March 2019 by gender are shown below.

We comply with equal opportunities legislation and departmental policy in relation to disabled employees, and Defra's policies on equal opportunities and health and safety at work.

Staff recruitment

Following a Civil Service Commission (CSC) annual 'Recruitment Compliance' visit in January, the CSC observed excellent compliance with the CSC's Recruitment Code.

The average FTE number of persons employed during the year was as follows (audited):

		2018/19		2017/18
	Permanently employed staff	Temporary staff	Total	Total
	Stail	Stair	Total	IOtal
Scientific	57	1	58	61
Administrative	95	10	105	99
	152	11	163	160

The number of staff-in-post (headcount) by gender as at 31 March 2019 was as follows:

	2018/19			2017/18		
	Male	Female	Total	Male	Female	Total
Directors	2	1	3	2	-	2
Other staff - Scientific	24	35	59	24	37	61
Other staff - Administrative	39	55	94	39	58	97
	65	91	156	65	95	160

Early departure costs (audited)

Redundancy and other departure costs are paid in accordance with the provisions of the Civil Service Compensation Scheme, a statutory scheme made under the Superannuation Act 1972. Exit costs are accounted for in full in the year of departure or earlier where a demonstrable commitment exists.

For all staff, there were no early departures in 2018/19 (2017/18: nil). For all staff, there were no compulsory exits in 2018/19 (2017/18: nil).

Staff costs (audited)

Staff costs consist of the following:		2018/19		2017/18
· ·	Permanently employed staff	Temporary staff	Total	Total
	£'000	£'000	£'000	£'000
Wages and salaries Social security costs	6,324 704	478 -	6,802 704	6,375 657
Other pension costs	1,297		1,297	1,214
Sub-total as reported in Statement of Comprehensive Net Expenditure	8,325	478	8,803	8,246
Less recoveries in respect of outward secondments	(216)	-	(216)	(218)
	8,109	478	8,587	8,028

Senior managers' remuneration

Details of the Chief Executive's and Directors' salaries and pension entitlements are shown in the Remuneration and Staff Report section.

Pensions

Pension benefits provided through the Civil Service pension arrangements are unfunded multi-employer defined benefit scheme and we are unable to identify our share of the underlying assets and liabilities. The Scheme Actuary valued the scheme as at 31 March 2012. You can find details in the resource accounts of the Cabinet Office: Civil Superannuation, www.civilservicepensionscheme.org.uk.

For 2018/19, employers' contributions of £1,266,170 were payable to the PCSPS (2017/18 £1,189,126) at one of four rates in the range 20.0% to 24.5% of pensionable earnings, based on salary bands. The Scheme Actuary reviews employer contributions usually every four years following a full scheme valuation. The contribution rates are set to meet the cost of the benefits accruing during 2018/19 to be paid when the member retires and not the benefits paid during this period to existing pensioners.

Employees can opt to open a partnership pension account, a stakeholder pension with an employer contribution. Employers' contributions of £29,551 (2017/18: £19,037) were paid to one or more of the panel of three appointed stakeholder pension providers.

In addition, employer contributions of £913, 0.5% of pensionable pay (2017/18: £734) were payable to the PCSPS to cover the cost of the future provision of lump sum benefits on death in service or ill-health retirement of these employees.

Contributions due to the partnership pension providers at the balance sheet date were £3,000 (2017/18: £1,608). Contributions prepaid at that date were nil.

No individuals retired early on ill-health grounds during the year and therefore no additional pension liabilities have been accrued for this purpose.

Sickness absence data

The total full-time equivalent days lost through staff sickness absence in the year was 639 compared to 740 in 2017/18. The average working days lost per employee during the year was 4.2 compared to 5.0 in 2017/18. The 2017/18 comparatives above have been restated, the difference is due to a backdated retirement that was not confirmed when last year's figures were reported.

Short term sickness absences of 10 days or less slightly rose from 1.8 days per FTE in 2017/18 to 1.9 days per FTE in 2018/19.

Tax arrangements of public sector appointees

As part of HM Treasury's review of tax arrangements of public sector appointees, departments and their arms-length bodies are required to publish information in relation to the number of off payroll engagements lasting more than six months and costing over £245 per day that were in place as at 31 March 2019.

Number of existing engagements as of 31 March 2019	
Of which	
Number that have existed for less than one year at time of reporting	5
Number that have existed for between one and two years at time of reporting	1
Number that have existed for between two and three years at time of reporting	-
Number that have existed for between three and four years at time of reporting	-
Number that have existed for four or more years at time of reporting	-

Number of new engagements, or those that reached six months in duration, between 1 April 2018 and 31 March 2019	5
Of which	
Number assessed as caught by IR35	-
Number assessed as not caught by IR35	6
Number engaged directly (via a Personal Services Company contracted to the department) and are on the departmental payroll	-
Number of engagements reassessed for consistency/assurance purposes during the year	1
Number of engagements that saw a change to IR35 status following the consistency review	-

Off-payroll engagements of Board members and/or senior officials with significant financial responsibility between 1 April 2018 and 31 March 2019

Number of off-payroll engagements of Board	
members, and/or senior officials with significant	-
financial responsibility, during the financial year	
Total number of individuals on-payroll and off-	Board members/senior officials x 3
payroll that have been deemed "board members,	(1 CEO, 2 Directors)
and/or senior officials with significant financial	,
responsibility", during the financial year.	3 x Non-Executive Directors

Consultancy and temporary staff expenditure

	2018/19	2017/18
	£'000	£'000
Consultancy expenditure	1,453	61
Temporary staff expenditure	478	549
Total	1,931	610

Comparative to the prior year, additional specialised skills were required to support plans for EU exit. Consultants are engaged when it is better value for money to do so on specific programme work and when specialised skills are required. Expenditure on temporary staff is a consequence of a backlog on recruitment into vacancies.

Employee involvement

We encourage staff involvement in our activities through a variety of channels including: a VMD intranet; topic meetings; day-to-day line management contacts; diverse membership of project teams, and regular meetings reviewing progress against the Business Plan and risk. VMD staff also took part in the Food, Farming and Biosecurity 'System Conversion' during 2018, which was an appreciative inquiry exercise which identified areas of good practice as well as issues staff wanted to improve. Office Notices and the intranet are used to disseminate information. An annual staff meeting to review the work of the past year and expected key future issues is addressed by the CEO. We work with Defra on wellbeing activities and staff have access to both occupational health and employee assistance services. Trade Union membership and representation is in accordance with Defra's policies.

The VMD was re-accredited to the Investors in People Silver standard in July 2018.

Health and safety

Due to mainly low risk activities and the size of the organisation we continue to use the policies and advice services from Defra's Safety, Health and Wellbeing team. Four minor work-related incidents were reported by employees during 2018/19 and changes have been made to address the cause of two cases and we have raised awareness for the other two.

Parliamentary Accountability and Audit Report (Audited)

Regularity of expenditure

We have considered all of our activities during the year and confirm that they are in accordance with the legislation authorising them.

Sources of funding and associated costs

2018/19	Income	Expenditure	Net Income / Defra Funding				
Reconciliation to the Statement of Comprehensive Net Expenditure							
Industry Fees and Charges							
Veterinary pharmaceutical industry	7,326	7,179	147				
Food industry	3,577	3,577	-				
Sub-total Industry Fees and Charges	10,903	10,756	147				
Other external income							
International	600	600	-				
Recovery of secondments out	216	216	-				
Other income	11	11	-				
Sub-total Other external income	827	827	-				
Government funded activities							
Services for Government (1) and (2)	99	2,658	(2,559)				
Research and Development	-	935	(935)				
EU Exit	-	3,946	(3,946)				
Food Industry (Honey)	-	35	(35)				
Defra Budget - funding requirement (3)	99	7,574	(7,475)				
Less: Cost of Capital Charge (4)	-	(245)	245				
Statement of Comprehensive Net Expenditure	11,829	18,912	(7,083)				

- (1) Services for Government include: Policy; enforcement; AMR programmes.
- (2) An EU grant (£16,000) and a contribution from the devolved administrations (£83,000) was received in 2018/19, contributing to the cost of the AMR programme.
- (3) From the 1 April 2016, the VMD converted its financial reporting status from Net Controlled Agency to a Gross Controlled Agency. This resulting accounting policy change means that the VMD's work for Defra is no longer reported as income within the SoCNE, rather the VMD receives an allocated expenditure budget.
- (4) The VMD is required to include a notional cost of capital charge in the calculation of fees and charges. In line with HM Treasury guidance, this figure is excluded from the results presented in the Annual Accounts.

Fees and charges

Our fees and charges are set in statute. Our objective for charging is to ensure that we recover our costs for delivering the service. In assessing performance against this target a notional cost of capital charge is recorded in addition to the costs included in the Statement of Comprehensive Net Expenditure. The table below sets out the amount of income we have received and associated costs for the different areas of service which we provide to industry.

2018/19	Income £000	Cost £000	Net Income £000	Cost Recovery %
Veterinary pharmaceutical industry	7,326	7,179	147	102%
Food industry	3,577	3,577	-	100%
Total	10,903	10,756	147	101%

2017/18	Income £000	Cost £000	Net Income £000	Cost Recovery %
Veterinary pharmaceutical industry	7,841	7,703	138	102%
Food industry	3,506	3,506	-	100%
Total	11,347	11,209	138	101%

Losses and special payments

Managing Public Money requires a statement showing losses and special payments by value and type to be shown where they exceed £300,000 in total, and those individually that exceed £300,000.

Losses may relate to: cash and stores losses; book-keeping losses; losses arising from failure to make adequate charge for the use of public property or services; fruitless payments, and claims abandoned as well as frauds. Special payments may relate to extra contractual, extra statutory, and ex gratia payments and compensation.

There were no losses or special payments that need to be reported in accordance with Managing Public Money.

Contingent liabilities

There were no contingent liabilities as at 31 March 2019 (31 March 2018: nil).

Professor SP Borriello

S. P. Bernett

Chief Executive 11 July 2019

The Certificate and Report of the Comptroller and Auditor General to the House of Commons

Opinion on financial statements

I certify that I have audited the financial statements of the Veterinary Medicines Directorate for the year ended 31 March 2019 under the Government Resources and Accounts Act 2000. The financial statements comprise: the Statements of Comprehensive Net Expenditure, Financial Position, Cash Flows, Changes in Taxpayers' Equity; and the related notes, including the significant accounting policies. These financial statements have been prepared under the accounting policies set out within them. I have also audited the information in the Accountability Report that is described in that report as having been audited.

In my opinion:

- the financial statements give a true and fair view of the state of the Veterinary Medicines Directorate's affairs as at 31 March 2019 and of the net operating expenditure for the year then ended; and
- the financial statements have been properly prepared in accordance with the Government Resources and Accounts Act 2000 and HM Treasury directions issued thereunder.

Opinion on regularity

In my opinion, in all material respects the income and expenditure recorded in the financial statements have been applied to the purposes intended by Parliament and the financial transactions recorded in the financial statements conform to the authorities which govern them.

Basis of opinions

I conducted my audit in accordance with International Standards on Auditing (ISAs) (UK) and Practice Note 10 'Audit of Financial Statements of Public Sector Entities in the United Kingdom'. My responsibilities under those standards are further described in the Auditor's responsibilities for the audit of the financial statements section of my certificate. Those standards require me and my staff to comply with the Financial Reporting Council's Revised Ethical Standard 2016. I am independent of the Veterinary Medicines Directorate in accordance with the ethical requirements that are relevant to my audit and the financial statements in the UK. My staff and I have fulfilled our other ethical responsibilities in accordance with these requirements. I believe that the audit evidence I have obtained is sufficient and appropriate to provide a basis for my opinion.

Conclusions relating to going concern

I am required to conclude on the appropriateness of management's use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Veterinary Medicines Directorate's ability to continue as a going concern for a period of at least twelve months from the date of approval of the financial statements. If I conclude that a material uncertainty exists, I am required to draw attention in my auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify my opinion. My conclusions are based on the audit evidence obtained up to the date of my auditor's report. However, future events or conditions may

cause the entity to cease to continue as a going concern. I have nothing to report in these respects.

Responsibilities of the Accounting Officer for the financial statements

As explained more fully in the Statement of Accounting Officer's Responsibilities, the Chief Executive as Accounting Officer is responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view.

Auditor's responsibilities for the audit of the financial statements

My responsibility is to audit, certify and report on the financial statements in accordance with the Government Resources and Accounts Act 2000.

An audit involves obtaining evidence about the amounts and disclosures in the financial statements sufficient to give reasonable assurance that the financial statements are free from material misstatement, whether caused by fraud or error. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs (UK) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As part of an audit in accordance with ISAs (UK), I exercise professional judgment and maintain professional scepticism throughout the audit. I also:

- identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for my opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Veterinary Medicines Directorate's internal control.
- evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management.
- evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and whether the consolidated financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

I communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that I identify during my audit.

I am required to obtain evidence sufficient to give reasonable assurance that the expenditure and income recorded in the financial statements have been applied to the purposes intended by Parliament and the financial transactions recorded in the financial statements conform to the authorities which govern them.

Other Information

The Chief Executive as Accounting Officer is responsible for the other information. The other information comprises information included in the annual report, but does not include the parts of the Accountability Report described in that report as having been audited, the financial statements and my auditor's report thereon. My opinion on the financial statements does not cover the other information and I do not express any form of assurance conclusion thereon. In connection with my audit of the financial statements, my responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or my knowledge obtained in the audit or otherwise appears to be materially misstated. If, based on the work I have performed, I conclude that there is a material misstatement of this other information, I am required to report that fact. I have nothing to report in this regard.

Opinion on other matters

In my opinion:

- the parts of the Accountability Report to be audited have been properly prepared in accordance with HM Treasury directions made under the Government Resources and Accounts Act 2000;
- in the light of the knowledge and understanding of the entity and its environment obtained in the course of the audit, I have not identified any material misstatements in the Performance Report and Accountability Report; and
- the information given in the Performance Report and Accountability Report for the financial year for which the financial statements are prepared is consistent with the financial statements and have been prepared in accordance with the applicable legal requirements.

Matters on which I report by exception

I have nothing to report in respect of the following matters which I report to you if, in my opinion:

- adequate accounting records have not been kept or returns adequate for my audit have not been received from branches not visited by my staff; or
- the financial statements and the parts of the Accountability Report to be audited are not in agreement with the accounting records and returns; or
- I have not received all of the information and explanations I require for my audit;
 or
- the Governance Statement does not reflect compliance with HM Treasury's guidance.

Date: 12 July 2019

Report

I have no observations to make on these financial statements.

Gareth Davies
Comptroller and Auditor General
National Audit Office
157-197 Buckingham Palace Road
Victoria
London
SW1W 9SP

Financial Statements

Statement of Comprehensive Net Expenditure

for the year ended 31 March 2019

	Note	2018/19	2017/18
		£'000	£'000
Revenue from contracts with customers	2	11,503	11,339
Other operating income	2	326	490
Total operating income		11,829	11,829
Staff costs	3	(8,803)	(8,246)
Purchase of services	4	(4,910)	(4,852)
Non-cash costs	4	(2,272)	(1,006)
Other operating expenditure	4	(2,927)	(1,265)
Total operating expenditure		(18,912)	(15,369)
Net operating expenditure		(7,083)	(3,540)
Other comprehensive expenditure Items that will not be reclassified to net operation	ng costs		
Net gain on revaluation of property, plant and	equipment	544	458
Comprehensive net expenditure			
for the year ended 31 March 2019		(6,539)	(3,082)

All income and expenditure is derived from continuing operations.

The notes on pages 42 to 54 form part of these accounts.

Statement of Financial Position

as at 31 March 2019

	Note	31 March	2019	31 March	2018
		£'000	£'000	£'000	£'000
Non-current assets:					
Property, plant and equipment	5	6,427		6,165	
Intangible assets	6	141		70	
Total non-current assets			6,568		6,235
Current assets:					
Trade and other receivables					
and contract assets	7	5,196		2,527	
Cash and cash equivalents	8	1,907	_	5,635	
Total current assets			7,103		8,162
Total assets		_	13,671		14,397
Current liabilities:					
Trade and other payables		(3,679)			
and contract liabilities	9	(0,070)	(0.000)	(2,934)	,, ,, ,,
Total current liabilities			(3,679)		(2,934)
Total assets less current liabil	ities		9,992		11,463
Non-current liabilities			(150)		_
Total assets less total liabilitie	s	_	9,842		11,463
		_			-
Taxpayers' equity and other re	eserves:				
General Fund			4,292		6,457
Revaluation Reserve			5,550		5,006
Total equity		<u> </u>	9,842	<u> </u>	11,463
				===	

The notes on pages 42 to 54 form part of these accounts.

Professor SP Borriello

S. P. Berneth

Chief Executive and Agency Accounting Officer 11 July 2019

Statement of Cash Flow

for the year ended 31 March 2019

	Note	2018/19	2017/18
		£'000	£'000
Cash flows from operating activities			
Net operating expenditure		(7,083)	(3,540)
Adjustments for non-cash transactions arising in the year	4	2,272	1,006
(Increase)/decrease in trade and other receivables	7	(2,669)	1,497
Increase in trade and other payables	9	895	488
less movement in trade payables relating to items not		(-)	
passing through the SoCNE	. <u>-</u>	(3)	
Net cash inflow from operating activities		(6,588)	(549)
Cash flows from investing activities			
Purchase of property, plant and equipment	5	(43)	-
Purchase of intangible assets	6	(97)	
Net cash outflow from investing activities		(140)	-
Cash flows from financing activities			
Supply current year		3,000	2,000
Net financing	·	3,000	2,000
Net (decrease)/increase in cash and cash equivalents	-	(3,728)	1,451
Cash at the beginning of the year	8	5,635	4,184
Cash at the end of the year	8	1,907	5,635
	=		

The notes on pages 42 to 54 form part of these accounts.

Statement of Changes in Taxpayers' Equity

for the year ended 31 March 2019

for the year ended 31 march 2019		General	Revaluation	Total
	_	Fund	Reserve	Reserves
		£'000	£'000	£'000
Balance at 1 April 2017	Note	7,348	4,548	11,896
·		·		•
Changes in taxpayers' equity for 2017/18:				
Net Parliamentary Funding		2,000	-	2,000
Comprehensive net expenditure for the year		(3,540)	-	(3,540)
Non-Cash adjustments:				
Defra corporate recharges	4	506	-	506
Defra Investigation Services	4	107	-	107
Auditors' remuneration	4	36	-	36
Movements in Reserves:				
Net gain on revaluation of property, plant and equip	ment	-	458	458
	_			
Total recognised income and expense for 2017/18		(891)	458	(433)
Balance at 31 March 2018	=	6,457	5,006	11,463
Changes in taxpayers' equity for 2018/19:				
Net Parliamentary Funding		3,000	-	3,000
Net operating expenditure for the year		(7,083)	-	(7,083)
Non-Cash adjustments:				
DDTS	4	1,255	_	1,255
Defra corporate recharges	4	489	-	489
Defra Investigation Services	4	129	-	129
Auditors' remuneration	4	45	-	45
Mayamanta in Daganyaa				
Movements in Reserves: Net gain on revaluation of property, plant and equip	ment	_	544	544
The second secon			.	0.1
Total recognised income and expense for 2018/1	9	(2,165)	544	(1,621)
Balance at 31 March 2019		4,292	5,550	9,842
	=	<u> </u>		

The notes on pages 42 to 54 form part of these accounts.

Notes to the Accounts

1. Statement of accounting policies

The financial statements have been prepared in accordance with the 2018/19 Government Financial Reporting Manual (FReM) and the Accounts Direction issued by HM Treasury. The accounting policies contained in the FReM apply International Financial Reporting Standards (IFRS), as adapted or interpreted for the public sector context. Where the FReM permits a choice of accounting policy, the accounting policy that is judged to be most appropriate to the particular circumstances of the VMD, for the purpose of giving a true and fair view has been selected. The particular policies adopted by the VMD are described below. They been applied consistently in dealing with items which are considered material in relation to the accounts.

1.1 Accounting convention

These accounts have been prepared on an accruals basis under the historical cost convention, modified to account for the revaluation of property, plant and equipment. The accruals basis of accounting means reporting income and expenditure when it is incurred rather than when it is received or paid. The financial statements are based on the going concern principle.

1.2 Significant Judgements and Estimation Uncertainty

In the preparation of financial statements VMD is required to make estimates and assumptions that affect the amounts reported of assets and liabilities, the disclosure of contingent assets and liabilities and the reported amount of income and expenditure. All estimates are based on knowledge of current facts and circumstances, assumptions concerning past events, and forecast of future events.

In the process of applying the accounting policies VMD has made the following judgements, which have the most significant effect on the amounts recognised in the financial statements.

Contract Assets/Deferred Income: The Agency is responsible for managing the progress of, and income earned from, scientific assessments. Individual assessments may span across more than one financial year and the preparation of the financial statements requires the Agency to determine, based on an evaluation of the terms and conditions of the arrangements, that it fully and accurately reflects the completeness of any deferred income in this regard by reference to the stage of completion of any ongoing assessments. (The revenue measurement model is reported in Note 2)

Non-current Assets/Depreciation: The Agency carries its non-current assets at fair value as stated in note 1.3 below. The charge for depreciation for each non-current asset is based on an estimate of its useful life.

1.3 Property, plant and equipment and intangible assets

Freehold Land and Buildings

Land and Buildings are subject to professional valuation at no more than five yearly intervals. These are carried out by professionally qualified independent valuers, who adhere to the principles outlined in the Royal Institute of Chartered Surveyors (RICS) Red Book. These assets are stated at fair value, which is valued at Depreciated Replacement Cost applying to specialist buildings. Depreciated Replacement Cost is defined as "the current cost of replacing an asset with its modern equivalent asset less deductions for physical deterioration and all relevant forms of obsolescence and optimisation". Between professional valuations, annual desk top revaluations are conducted, which have regard for prevailing local and national conditions.

Non-property assets costing £10,000 or more on a grouped or individual basis, where there is an expected useful economic life of more than one year, are carried in the Statement of Financial Position at fair value, using appropriate indices provided by the Office for National Statistics.

Intangible non-current assets comprise software development and licences.

Losses on revaluation are charged to the Revaluation Reserve to the extent that gains have been recorded previously and otherwise to the Statement of Comprehensive Net Expenditure.

Depreciation and amortisation

Depreciation and amortisation are provided at rates estimated to write-off the valuation of property, plant and equipment, software development and licences on a straight-line basis over the estimated useful life of the asset. Componentisation has been adopted for the VMD's freehold building asset, with each component capitalised and depreciated separately. Estimated useful lives, component values and residual values are revised annually.

Asset lives are normally within the following ranges:

Freehold land	Not depreciated
Freehold buildings	38 years (residual life)
Furniture, fittings and office equipment	15 years
IT Hardware	5 years
IT Software development and licences	5-10 years

Impairment

Impairments are recognised when the recoverable amount of non-current assets falls below their carrying amount. An impairment review is carried out on an annual basis.

Any permanent diminution in the value of an asset due to clear consumption of economic benefit or service potential is recognised in full as an impairment loss in the SoCNE. An amount up to the value of the impairment is transferred from the revaluation reserve (to the extent that a balance exists) to the General Fund for the individual asset concerned.

Downward revaluations, resulting from changes in market value, only result in impairment where the asset is revalued below its historical cost carrying amount. In these cases the

accounting treatment is as for any other impairment, with amounts being firstly set against any accumulated balance in the revaluation reserve, and any amount in addition to this being recognised as impairment and recorded in the SoCNE.

Assets under construction

Assets under construction are shown at the accumulated cost with the depreciation commencing when the asset is completed and brought into service.

1.4 Research and development

Expenditure on R&D is treated as an operating cost in the year in which it is incurred and taken to the statement of comprehensive net expenditure.

1.5 Operating income

As of the 1 April 2016 the way in which we are funded by Core Defra changed with the aim of improving accountability and transparency of funding. Instead of the funding being recorded as Income within the Income Statement and inflating the income figure, it is now treated via our Equity under Parliamentary funding.

As a Gross Accounting Agency, activity for Defra is not invoiced or reported as income, but an authority to spend is delegated to the VMD along with deliverable objectives.

1.6 Revenue from contracts with customers

IFRS 15 Revenue from Contracts with Customers is applied by HM Treasury in the Government Financial Reporting Manual (FReM) from 2018-19. IFRS 15 introduces a new five stage model for the recognition of revenue from contracts with customers replacing the previous IAS 18 Revenue. The core principle of IFRS 15 is that an entity recognises revenue to depict the transfer of services to customers in a way that reflects the consideration to which the entity expects to be entitled to in exchange for services.

A contract asset – is an entity's right to consideration in exchange for goods or services that the entity has transferred to a customer when that right is conditioned on something other than the passage of time (for example, the entity's future performance). A contract liability is an entity's obligation to transfer goods or services to a customer for which the entity has received consideration (or the amount is due) from the customer.

Revenue from contracts with customers comprises fees and charges for services provided to industry or contractually entitled income for services provided to market customers. This revenue is measured based on the consideration specified in a contract with a customer. The Agency recognises revenue from contracts with customers in accordance with the five stage model set out in IFRS 15.

Details of Agency's main performance obligations, how and when they are satisfied, and the determination of transaction prices, is detailed in Note 2. In the comparative period, revenue was measured at the fair value of the consideration received or receivable, and revenue from the sale of goods and services was recognised when the significant risks and rewards of ownership had been transferred to the customer.

There has been no material impact to the recognition points of revenue as a result of applying this accounting standard.

1.7 Pensions

Pension benefits are provided through the civil service pension arrangements, full details of which can be found in the Remuneration Report.

Although the PCSPS and the CSOPS, known as alpha, are unfunded defined benefit schemes, in accordance with explicit requirements in the FReM, the VMD account for the schemes as if they were defined contribution plans. Costs of the elements are recognised on a systematic and rational basis over the period during which it benefits from employees' services by payment to the schemes of amounts calculated on an accruing basis. Liability for payment of future benefits is a charge on the schemes. The PCSPS and alpha pension schemes undergo a reassessment of the contribution rates by the Government Actuary at four-yearly intervals. In respect of defined contribution schemes, the VMD recognises the contributions payable for the year.

1.8 Defra notional service recharges

Notional costs are amounts charged against the SoCNE by virtue of an interdepartmental non-cash adjustment via the General Fund, with Core Defra recording the associated credit. Defra corporate services recharges comprises Defra Digital Technical Solutions (DDTS), legal, human resources, estates, investigation and enforcement services.

1.9 Value Added Tax (VAT)

Most of the VMD's activities are outside the scope of VAT and, in general, output tax does not apply. Input VAT can be recovered on certain contracted-out services. Irrecoverable VAT is charged to the relevant expenditure category or, if appropriate, capitalised with additions to non-current assets. Where output tax is charged or input tax is recoverable, the amounts are stated net of VAT.

1.10 Apprenticeship Levy

The Apprenticeship Levy was introduced in April 2017, requiring employers with a pay bill of over £3 million each year to pay the levy. The expense element of the apprenticeship levy is recorded against social security costs, within the staff costs note. If bodies utilise the levy for training expense, a notional charge is recognised. The corresponding credit element is recorded against grant income. Amounts are recognised on an accruals basis.

1.11 Financial instruments

VMD holds few financial instruments. Financial assets comprise of receivables that are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. Receivables are initially recognised at fair value and subsequently held at amortised cost after an appropriate provision for expected credit loss. Financial liabilities comprise trade and other payables, and other financial liabilities. They are initially recognised at the fair value of consideration received, less directly attributable transaction costs. They are subsequently measured at amortised cost.

1.12 Cash and Cash Equivalents

Cash and cash equivalents comprise cash in hand and current balances with banks.

1.13 General Fund

The net operating result for each year is transferred from the SoCNE to the General Fund. The General Fund represents the value of the VMD's net assets less liabilities as at 1

April 1991, which is the date from which the first Accounts Direction became effective, plus subsequent external funding movements, plus the accumulated net operating result transferred from the SoCNE.

1.14 Revaluation Reserve

The Revaluation Reserve represents the unrealised cumulative balance of indexation and revaluation adjustments to non-current assets.

1.15 Leases

All payments under operating leases are charged to the SoCNE. An operating lease is a lease other than a finance lease. A finance lease is one which transfers substantially all the risks and rewards of ownership to the lessee. The Agency does not have any finance leases.

1.16 Impending application of newly issued standards not yet effective

IAS 8, Accounting Policies, Changes in Accounting Estimates and Errors, requires disclosures in respect of new IFRSs, amendments and interpretations that are, or will be applicable after the reporting period. There are a number of IFRSs, amendments and interpretations that have been issued by the International Accounting Standards Board that are effective for future reporting periods. Those with relevance to the Agency are outlined below. The Agency has not adopted any new IFRS standards early.

IFRS 16 - Leases. This standard is generally effective in government from 1 April 2020. It will supersede all existing IFRS standards on leases. It is likely to result in a uniform accounting treatment for all leases, with the distinction between operating and finance leases removed for lessees.

The Agency will apply this standard upon formal adoption in the FReM. It is not anticipated that material adjustments to the financial statements will be required following the introduction of the standard. The impact will be reassessed when further guidance is forthcoming from HM Treasury.

2. Operating income

	2018/19	2017/18
	£'000	£'000
Revenue from contracts with customers:		
Veterinary pharmaceutical industry:		
Authorisations	3,238	3,496
Graded annual and fixed fees	3,058	3,115
Inspections	1,030	1,125
Food industry	3,577	3,506
International	600	97
Other Income		
Government: Devolved Administrations (1)	83	81
Government: EU Grant (1)	16	63
Government: Core Defra (1)	-	120
Recoveries in respect of outward secondments	216	218
Other recovery of cost (2)	11_	8
	11,829	11,829

⁽¹⁾ Income for work undertaken for Government comprise of: contributions from Devolved Administrations £83,000 (2017/18: £81,000) and receipt of EU grant paid in support of the AMR programme £16,000 (2017/18: £63,000). In 2017/18, Core Defra provided a contribution to support the development of the AMR Reference Centre £120,000

Transaction price to remaining performance obligations

The following table includes revenue expected to be recognised in the future related to performance obligations that are (partially) unsatisfied at the reporting date:

	2019/20	2020/21	Total
	£'000	£'000	£'000
Authorisations	787	150	937
Inspections	147	-	147
International	278	1	278
Total	1,212	150	1,362

As at 31 March 2019, the aggregate amount of the transaction price allocated to the remaining performance obligation is £1.362 million and the entity will recognise this revenue as contracts are progressed to completion, which is expected to occur over the next 12–18 months.

Impact of IFRS 15

Each contract with a customer has been reviewed in line with the five step model.

An assessment of the related performance obligations determined that there is no impact on timing or amount under IFRS15.

⁽²⁾ Other recovery of costs includes the cost of dossier copying and UK training delivered by VMD.

The VMD's major type of income streams are detailed in the table below:

Contract Type	Amount £000	Categories of performance obligation	Basis of income recognition
AUTHORISATIONS			
Application for a Marketing Authorisation	2,660	Assessment of application to market a veterinary medicines product	Invoiced on validation of an application. Income deferred and recognised on basis of the level of completion of an assessment to the date when the application is determined
Graded Annual and fixed fees	3,058	Provision of services as the competent authority, including post authorisation surveillance/pharmacovigilance	Charge based on cost recovery for the financial year. Invoiced in last quarter of each financial year
INSPECTIONS			
Inspections	592	Inspection of manufacturers, wholesaler dealers, retailers of veterinary medicines	Invoiced upon completion of the inspection report
Annual fees	359	Licencing and maintenance of the register of manufacturers, wholesaler dealers, retailers of veterinary medicines	Income recognised over a year. Accrued for any non-invoiced element or deferred proportionate to the number of months before the next renewal date.
FOOD INDUSTRY			
Food Industry fees	3,577	Provision of the Statutory Residues Surveillance Programme	Charge based on cost recovery for the financial year. Invoiced quarterly or biannually or accrued for any non-invoiced elements
INTERNATIONAL			
International	600	Set out in individual contracts for services and/or provision of training	At agreed milestones, or if, as is generally the case, contract stipulates that money spent up to a specific date can be recovered from the customer prior to completion of the project

- 1. This analysis reflects the major types of income streams and are a component of the figures disclosed above in Note 2 Revenue from contracts with customers.
- 2. See Note 15: International Financial Standards 15 transition reporting showing contract balances and changes during the year.

3. Staff costs

Staff costs consist of the following:			2017/18	
	Permanently employed staff £'000	Temporary staff £'000	Total £'000	Total
Wages and salaries	6,324	478	6,802	6,375
Social security costs	704	-	704	657
Other pension costs	1,297	-	1,297	1,214
Sub-total as reported in Statement of Comprehensive Net Expenditure	8,325	478	8,803	8,246
Less recoveries in respect of outward				0,240
secondments	(216)	-	(216)	(218)
	8,109	478	8,587	8,028

Included in the permanently-employed staff costs is an accrual for untaken annual leave of £287,000, (2017/18: £287,000). This comprises of £225,000 (2017/18: £225,000) wages and salaries, £17,000 (2017/18: £17,000) social security costs and £45,000 (2017/18: £45,000) other pension costs.

4. Other non-staff operating expenditure

		2018/19	2017/18
		£'000	£'000
	Note		
(i) Purchase of services			
Statutory Residues Surveillance		3,222	3,139
Research and Development Programme		864	958
Antimicrobial Resistance Programme and Surveillance		536	717
Antimicrobial Resistance Reference Centre		220	-
Other direct sub-contracted services		68	38
		4,910	4,852
(ii) Non-cash items			
Depreciation of property, plant and equipment	5	325	323
Amortisation of intangible assets	6	29	34
Defra service recharges:			
DDTS		1,255	-
Estates maintenance		339	334
Human resources		111	117
Defra Investigation Services		129	107
Legal services		39	55
Auditors' remuneration (1)		45	36
		2,272	1,006
(iii) Other operational expenditure (2)			
Professional, programme and technical fees		1,453	61
IT systems maintenance		453	446
Travel and subsistence		492	224
Training		105	84
Staff related costs		31	94
Communications		80	67
Office related goods and services		86	48
Operating leases		36	48
Internal Audit		60	27
Stationery and publications		35	27
Independent expert committees		24	31
Customer relations and publicity		32	31
Movement on provision for expected credit loss		28	59
Other costs		12	18
		2,927	1,265
Total non-staff operating expenditure		10,109	7,123
			_

⁽¹⁾ No remuneration was paid to the external auditors (National Audit Office) in respect of non-audit work.

⁽²⁾ Other operational expenditure for the prior year has been represented to align with the expense categories used for the 2018/19 financial and management information reporting.

5. Property, plant and equipment

	Land	Buildings	Information Technology	Furniture & Fittings	Total
	£'000	£'000	£'000	£'000	£'000
Cost or Valuation:			_		
At 1 April 2018	316	5,728	791	259	7,094
Additions	-	-	43	-	43
Disposals	-	-	(66)	(7)	(73)
Revaluation	<u> </u>	268	4		272
At 31 March 2019	316	5,996	772	252	7,336
Depreciation:					
At 1 April 2018	-	-	(685)	(244)	(929)
Charged in year	_	(275)	(46)	(4)	(325)
Disposals	-	-	66	7	73
Revaluation	-	275	(3)	-	272
At 31 March 2019	_		(668)	(241)	(909)
Carrying Value					
At 31 March 2019	316	5,996	104	11	6,427
Cost or Valuation: At 1 April 2017	291	5,550	778	262	6,881
Additions	291	5,550	-	202	0,001
Disposals	_	_	(2)	(4)	(6)
Revaluation	25	178	15	1	219
At 31 March 2018	316	5,728	791	259	7,094
Depreciation:					
At 1 April 2017	-	_	(607)	(244)	(851)
Charged in year	_	(252)	(68)	(3)	(323)
Disposals	-	-	2	4	6
Revaluation	-	252	(12)	(1)	239
At 31 March 2018	-		(685)	(244)	(929)
Carrying Value	040	F 700	400	45	0.405
At 31 March 2018	<u>316</u>	5,728	106	15_	6,165
At 31 March 2017	291	5,550	171	18	6,030

Revaluation movements result from the indexation and/or the revaluation of non-current assets.

The Land and Buildings were valued at 31 March 2019 by an independent valuer (Montagu Evans) in accordance with guidance issued by the Royal Institution of Chartered Surveyors. Buildings were valued at Depreciated Replacement Cost applying to specialist buildings in accordance with IAS 16, defined as "the current cost of replacing an asset with its modern equivalent asset less deductions for physical deterioration and all relevant forms of obsolescence and optimisation".

6. Intangible assets

	IT Software
	£'000
Cost or valuation:	
At 1 April 2018	678
Additions	100
Disposals At 31 March 2019	778
At 31 Watch 2019	
Amortisation:	
At 1 April 2018	(608)
Charged in year	(29)
Disposals	
At 31 March 2019	(637)
Carrying Value	
At 31 March 2019	141
Continue leations	
Cost or valuation:	678
At 1 April 2017 Additions	070
Disposals	_
At 31 March 2018	678
Amortisation:	(1)
At 1 April 2017	(574)
Charged in year	(34)
Disposals At 31 March 2018	(600)
At 31 March 2016	(608)
Carrying Value	
At 31 March 2018	70
At 31 March 2017	104
7. C. 1 Maron 2017	
Reconciliation of cash flows to intang	gible asset additior
Intangible asset additions	100
Movement in accruals for intangible assets	(3)
Cash flows for intangible asses	97
cash hono for mangiolo accord	

7. Trade receivables and other current assets

	31 March 2019	31 March 2018
	£'000	£'000
Amounts falling due within one year:		
Trade receivables	3,686	1,784
Other receivables	24	7
VAT recoverable	349	102
Prepayments	156	133
Accrued Income	13	501
Contract Assets	968	-
Total trade receivables and other current assets	5,196	2,527

Trade receivables are shown net of a provision of £52,000 (2017/18: £52,000) for expected credit loss. The provision is calculated according to the age and status of the debt and recent sector-specific debt-recovery information.

8. Cash and cash equivalents

	2018/19	2017/18
	£'000	£'000
Balance at 1 April	5,635	4,184
Net change in cash and cash equivalents	(3,728)	1,451
Balance at 31 March	1,907	5,635

All balances were held in accounts administered by Government Banking Services.

9. Trade payables and other current liabilities

	31 March 2019	31 March 2018
	£'000	£'000
Amounts falling due within one year:		
Trade payables	258	180
Balances with other central government bodies	580	498
Other taxation and social security	223	201
Accruals	1,406	691
Deferred Income	-	1,364
Contract liabilities	1,212	
Total trade payables and other current liabilities	3,679	2,934
Amounts falling due after more than one year:		
Contract liabilities	150	-
Total trade payables and other liabilities	3,829	2,934

At the year end the VMD had contract liabilities (£150,000) falling due after more than one year (2017/18: nil).

10. Capital commitments

There were no contracted commitments at 31 March 2019 (2017/18: nil).

11. Commitments under operating leases

Total future minimum lease payments under operating leases are given in the table below for each of the following periods:

Obligations under operating leases comprise:

	2018/19	2017/18
	£'000	£'000
Contract hire cars		
Not later than one year	34	22
Later than one year not later than five years	65_	12
Total	99	34

12. Other financial commitments

Defra has entered into a contract (which is not a lease or Public Finance Initiative contract) for Estate Maintenance and Facilities Management services associated with buildings that are either leased by Defra or held on the Agency's Statement of Financial Position. The Agency incurs a charge proportionate to the benefit it receives from this contract. Based on Defra's estimate, the payments to which the Agency is committed at the year end, analysed by the period during which the commitment expires are as follows:

	2018/19	2017/18
	£'000	£'000
Not later than one year	154	183
Later than one year but not later than five years	617	731
Later than five years but not later than ten years	1	183
Total	772	1,097

13. Related party transactions

As the VMD is an Executive Agency of Defra, Defra is regarded as a related party. During the year, the VMD has had significant transactions with Defra and a number of its agencies, including Animal and Plant Health Agency.

The VMD has transacted with various other central government bodies. Most of these transactions have been with the Medicines and Healthcare products Regulatory Agency, Food Standards Agency and The Scottish Government.

None of the Board members, key managerial staff or other related parties has undertaken any material transactions with the VMD during the year other than salaries and reimbursement for travel and subsistence in the normal course of business.

14. Financial instruments

As the cash requirements of the VMD are met from income from industry and funding through the Estimates process, financial instruments play a more limited role in creating and managing risk than would apply to a non-public sector body of a similar size. The majority of financial instruments relate to contracts to buy non-financial items in line with the Agency's expected purchase and usage requirements and the Agency is therefore exposed to little credit, liquidity or market risk.

15. International Financial Standard 15 transition reporting

Contract Balances

	31 March 2019
	£'000_
Trade Receivables, which are included in Note 7	3,686
Contract Assets, which are included in Note 7	968
Contract Liabilities included in Note 9	1,362_
	6,016

Contract assets (accrued income) primarily relate to the VMD's right to consideration for work completed but not billed at the reporting date. Contract liabilities (deferred income) primarily relates to the consideration received from customers in advance of a service.

Changes in the contract assets and contract liabilities balance during the period are as follows:

Tollows.		
	Contract Assets	Contract Liabilities
_	£'000	£'000
Balance transferred from deferred income following adoption of IFRS 15	-	1,364
Balance transferred from receivables following adoption of IFRS 15	470	
Increases due to cash received	-	4,290
Decrease due to revenue recognised in the period	-	(4,292)
Decrease due to balance transfer to trade receivables	(470)	-
New contract assets	968	
Contract assets/liabilities at the end of the period	968	1,362

16. Events after the reporting period

The VMD's financial statements are laid before the House of Parliament by the Secretary of State for Defra. In accordance with the requirements of IAS 10, events after the reporting period are considered up to the date on which the Accounts are authorised for issue. This is interpreted as the date of the Certificate and Report of the Comptroller and Auditor General.

Up to the date of issue, there have been no other events since 31 March 2019 that would have a significant impact on the Annual Report and Accounts or would be likely to have a significant impact on the future performance of the VMD.