ASSURING THE SAFETY, QUALITY & EFFICACY
OF VETERINARY MEDICINES

# Veterinary Medicines Directorate
# Annual Report & Accounts
# 2009/10

HC44

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

# Veterinary Medicines Directorate

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

# Annual Report & Accounts 2009/10

INVESTORS IN PEOPLE | Silver

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# Contents

# Chief Executive's Foreword

**The VMD is an organisation formed from highly trained scientists working alongside colleagues with highly developed competences in non scientific areas. It is pleasing to note our work on developing and training our staff has been duly recognised this year through the achievement of the Investors in People (IiP) Silver Award.**

Steve Dean

VMD staff seek to make a difference by assuring the availability of veterinary medicines that can be used safely and with a high degree of expectation that the animal will benefit from the treatment. The Annual Report describes our key achievements but VMD work has many facets and to be successful each part of the organisation must deliver its objectives. This the VMD staff do consistently well, often in the face of some serious challenges. In part these challenges arise because nearly all our work is only fully achieved through collaboration with our customers, stakeholders and other government departments (OGDs). We therefore have invested further this year in the development of a communication strategy. This builds on the platform of transparency based around our website where work has been done to improve the content. However, recognising the central importance of this resource, project work is ongoing to restyle and restructure the entire website to deliver the information it contains in a more user friendly fashion. As part of our communication strategy we have invested in a modestly priced conference stand and taken this along with a suite of informative leaflets to various congresses and exhibitions to raise the profile of the VMD with veterinary surgeons and veterinary nurses. For the first time this year we have also targeted dog breeders and exhibitors by attending Crufts dog show. It is particularly pleasing to report that the effort was recognised when the VMD won the Best Stand Award at the British Cattle Veterinary Association (BCVA) Congress.

Our ambitions to make available safe, effective, authorised veterinary medicines of the appropriate quality, are simply stated but the work is complex and thus it is not surprising we are occasionally challenged on our policies and the application of the underlying legislation. By way of example, during the year we have addressed concerns raised on the authorised recommendations for the re-vaccination of companion animals and how these relate to the international guidance developed by the World Small Animal Veterinary Association. We responded by producing a position paper setting out the availability and authorised uses of the many canine vaccines on the UK market and explaining the regulatory processes as they apply to immunological veterinary products. As with many topics related to the use of veterinary medicines, the technical aspects are not as simple as some would wish them to be and this is an issue that is likely to remain on our agenda for some time.

There have been safety concerns surrounding the use of both organophosphate (OP) and synthetic pyrethroid (SP ) sheep dips for many years. These are important treatments to prevent parasitic diseases in sheep with related, highly significant animal welfare concerns were treatments to become unavailable. The concerns differ, for OP dips the expressed concerns relate to the health of the sheep farmer and for SP dips the linked risks relate to their potential to damage aquatic fauna. Balancing any risk against the benefit of treatment for the animal is not always a simple decision and supporting research work takes time to commission and complete. For OP dips, we now await an independent review of all the current research on the effects of the active ingredients on human health, although over time the ongoing measures taken to protect the user from the concentrated formulated dips has markedly reduced the incidence of reported suspected human adverse reactions. For SP dips any regulatory decision has been pre-empted by the manufacturers' voluntary withdrawal of these products from the market in the face of mounting evidence that these dips were not capable of safe use, in terms of potential environmental damage.

Internally the VMD continues its drive to deliver Value for Money (Efficiency, Effectiveness and Economy) alongside initiatives to reduce our use of environmental resources (i.e. water, power and paper) or increase recycling. The launch of our developed capability to accept electronic dossier submissions from the pharmaceutical industry has been well received with close to 20% of all applications being received electronically since January 2010. This has the potential, over time, to reduce both the usage of paper and the storage and transport costs of our archived data. We already securely re-cycle 100% of the paper we dispose of and in the coming year plan to do the same with used batteries.

In terms of effectiveness, biennially, the outputs from staff and customer surveys are used alongside those from benchmarking studies, internal audits and various reviews (this year, IiP, information technology (IT) quality standards and Hampton implementation reviews), to maintain a continuous Business Improvement Delivery Plan (BIDP). The objectives from the BIDP are developed and delivered by the staff working in teams or project groups. Through the BIDP and other initiatives we strive to improve the organisation. Examples of other initiatives

include streamlining of our infrastructure and reporting lines, a significant upgrade to our telephone system and the development of a new work recording system, to mention just three of the major projects.

Improved efficiency has been one of the drivers in the development of a quality system across the entire organisation. This will lead to the achievement of a suitable quality standard for the VMD and will deliver a continuous improvement in processes, contribute to the effectiveness of newly recruited staff and ensure each post at the VMD has clearly defined functions. It will also act as a quality benchmark for our work in the European Medicines Regulatory Network justifying our status as one of the leading National Competent Authorities worldwide for medicines regulation.

Economy has been a necessary driver of cost reduction for the VMD this year. The economic downturn has influenced our customers, although perhaps not as acutely as in some other business areas, and of course, the availability of funding from Defra. We faced some serious funding challenges this year with forecasting being uncertain in all three of our business areas. We were therefore forced to delay spending on some projects, which we hope to be able to complete in the next financial year, suspend some training plans where this would not materially affect the development of our staff skills in the short term and generally economise where possible on consumables and travel costs. It was also necessary to reduce the number of temporary staff we were employing where they were covering relatively non urgent work for the Agency. The outturn for the year will be within the target set for cost recovery and therefore this economic strategy can be deemed to have been successful even though it has curtailed some plans in the short term and placed extra pressure on the remaining resources.

Our work continues on a number of other fronts in Europe. Some examples are our influence on the development of policies on antimicrobial resistance, the review of the Veterinary Medicines Directive, review of the Residues Directive and the development of suitable IT resources across the regulatory network. These headlines however do not do justice to the work of several VMD staff. They act as UK experts on various Committees and working parties leading to greater harmonisation of the authorisation of medicines across the EU, the development of guidance and assessment standards, the health security provided by the surveillance schemes covering suspected adverse events and residues in food animals derived from medicines use and the delivery of functional IT systems to support these endeavours. My sincere thanks go to everyone at the VMD who does this work often staying away from their families for extended periods.

Much of our work also contributes to National policy on Animal Health and Welfare and food security (contributing to the work of the Food Standards Agency (FSA)). The regulatory work we completed this year leading to the issue of a limited marketing authorisation for a Badger TB vaccine and the issue of the first provisional marketing authorisation for Blue Tongue vaccines to protect against serotype 1 will contribute to the control of both of these diseases in the UK. Considerable ongoing discussions have progressed with Defra and the FSA on the future of the residue surveillance schemes and will lead to new plans during the next financial year.

Each year, when I come to reflect upon the past year's performance, a catalogue of achievements can be listed to demonstrate the VMD's commitment to its role as a Government Agency and its commitment to animal health. This year is no different except as my final year as the CEO approaches I find the purpose, need and justification for the VMD's regulatory function is increasingly brought into sharper focus. The economic forecast, the Lisbon Treaty, the move of EU medicines policy under the umbrella of DG SANCO and the outcome of the General Election are additional environmental changes that will influence the development of the VMD over the coming years. These are all factors that will also influence the emerging analysis defining the succession plan for a new VMD CEO following my retirement planned for August 2011. This then will be the background to my last contribution to the VMD's Annual Report and Accounts in 2011. However, for this year, I would simply like to thank the many stakeholders who have contributed to our success and of course to the magnificent VMD staff who have delivered their objectives in a wholly reliable way despite the many obstacles and challenges we have faced together. A couple of our staff have received due recognition for their competence and deserve special mention. Jackie Atkinson became a Fellow of the Royal Pharmaceutical Society and Dr Aileen Lee received an OBE for excellent service as she retired from the VMD earlier in the year. Both of these awards are well deserved and reflect the high standards we expect of our people and the work they deliver on behalf of the UK taxpayer.

**Steve Dean**
Chief Executive
25 May 2010

# About Us

## Our Aims and Responsibilities

**Veterinary medicines benefit animal health and welfare and public health by preventing and treating disease in farm animals, horses and pet animals, even medicines for honey bees are included in our remit. The vision of the Veterinary Medicines Directorate (VMD)[1] is the responsible, safe and effective use of veterinary medicinal products. In working towards achieving this vision the VMD aims to protect public health, animal health and the environment and promote animal welfare by assuring the safety, quality and efficacy of veterinary medicines. The VMD aspires to continue to move in the direction of being an outward facing organisation with a strong focus on the needs of our customers and stakeholders. In doing so we support the Department for Environment, Food and Rural Affairs (Defra)[2] objectives to protect public health and ensure high standards of animal welfare, and promote a sustainable, competitive and safe food supply chain, which meets consumers' requirements. We also support the aim of the Food Standards Agency (FSA)[3] to protect and improve the safety of food people eat. The VMD works with the devolved administrations in developing veterinary medicines policy and by doing so contributes to their strategic objectives. Our work increasingly engages with the European Medicines Regulatory Network regulating veterinary medicines across the European Union (EU) and European Economic Area (EEA). We work closely with our European colleagues to harmonise the authorisation of veterinary medicines and thus empowering the free movement of goods and services.**

### Our responsibilities

The VMD is responsible for:

- the assessment, issue and maintenance of all national Marketing Authorisations (MA) for veterinary medicines in accordance with European Community and UK legislation;
- acting as Reference Member State (RMS), Rapporteur, Co-Rapporteur or Concerned Member State (CMS) for designated European applications for centralised or decentralised or mutual recognition authorisations;
- controls on the manufacture and distribution of veterinary medicinal products including inspections;
- pharmacovigilance through the surveillance of Suspected Adverse Reactions (SARs);
- surveillance for residues of veterinary medicines and illegal substances in animals and animal products;
- the provision and implementation of policy advice on these matters to Ministers;
- the management of the Research & Development (R&D) programme linked to veterinary medicine issues; and
- the co-ordination of Defra's work on antimicrobial resistance via the Defra Antimicrobial Resistance Coordination (DARC) Group[4].

We do this by validating, assessing and interpreting data provided to us on veterinary medicines. Where necessary we seek independent expert advice from the Veterinary Products Committee (VPC)[5] and the Veterinary Residues Committee (VRC)[6]. We subcontract analytical tests or other procedures that have to be carried out.

Under the provisions of European Commission (EC) and UK legislation, no veterinary medicinal product may be marketed without an MA, which is granted only after a detailed scientific assessment of the data relating to safety, quality and efficacy. In addition, inspection of manufacturing premises is required to ensure that quality of the final product is assured. In a change from earlier years all of this work was performed by VMD inspectors, with the exception of sites making human as well as veterinary medicines which were inspected by the Medicines and Healthcare products Regulatory Agency (MHRA)[7].

Once a product has been authorised, post authorisation surveillance is co-ordinated by the VMD. The Suspected Adverse Reaction Surveillance Scheme (SARSS)[8] monitors and responds to reports of suspected adverse reactions to veterinary medicines in both animals and humans. The National Surveillance Scheme (NSS)[9] for veterinary residues is a statutory scheme under which targeted samples from farms and slaughterhouses and other food processors are analysed for the presence of residues arising from veterinary medicines. The non-statutory residues surveillance programme supplements the statutory scheme by analysing samples of mainly imported meat and animal products at the ports or purchased from retail and other outlets. All three strands of surveillance combined with the effective enforcement, investigation and inspection activities ensures the safe and effective use of veterinary medicines in the UK.

Inspection of the wholesale supply chain and the feed-mills mixing animal diets containing veterinary medicines is also carried out under the control of the VMD through the MHRA or Animal Medicines Inspectorate (AMI)[10], which is part of the VMD.

The VMD provides policy advice to Ministers on all aspects of the authorisation and use of veterinary medicines and manages the Department's R&D programme on veterinary medicines.

1. You can find out more about the VMD and its work via www.vmd.gov.uk
2. You can find out more about the work of Defra via www.defra.gov.uk
3. You can find out more about the work of the FSA via their website www.food.gov.uk
4. You can find out more about the DARC Group via www.vmd.gov.uk under General Information
5. You can find out more about the work of the VPC via their website www.vpc.gov.uk
6. You can find out more about the work of the VRC via their website www.vet-residues-committee.gov.uk
7. You can find out more about the MHRA via their website www.mhra.gov.uk
8. You can find out more about the SARSS via www.vmd.gov.uk under General Information
9. You can find out more about the NSS via www.vmd.gov.uk under General Information
10. You can find out more about the AMI via www.vmd.gov.uk under Industry Information Feedingstuffs Manufacturers and Distributors or Vet/SQPs Information (SQPs and Approved Premises)

# How We Are Organised

## Our Structure

**We were established in 1989 and became a Next Steps Agency of the Ministry of Agriculture, Fisheries & Food (MAFF) in 1990. We became an Executive Agency of Defra on 7 June 2001.**

**We operate within an overall policy and financial framework determined by the Secretary of State for Defra, through the Minister of State (Local Environment, Marine & Animal Welfare). Our day-to-day management within this framework, and our performance against our key targets, is the responsibility of our Chief Executive Officer (CEO), supported by Directors of Authorisations and Operations. Our policy, legal and resources framework is set out in our Framework Document.**

**We divide our work into three main areas, or "businesses":**

***Authorisations,*** responsible for the assessment of applications; issuing and maintenance of Marketing Authorisations; the licensing of manufacturers and wholesale dealers of veterinary medicines. Also responsible for considering and issuing import and export certificates for veterinary medicines.

The main customers are Marketing Authorisation holders; manufacturers and importers of veterinary medicines; manufacturers of medicated animal feedingstuffs; retailers of veterinary medicines and medicated animal feedingstuffs; the veterinary profession; other stakeholders including farmers and keepers of animals; the European Medicines Agency (EMA)[11]; Department of Health (DH)[12]; FSA and consumers.

***Residues,*** responsible for the surveillance for residues arising from veterinary medicines and banned substances in home produced livestock and animal products and imported animal products, reporting of results and co-ordinating follow-up action. The Residues business has contracts with other agencies and companies who carry out work on our behalf at abattoirs and other first processing industries, on farms and at retailers of meat and other animal products, and at ports. We also work with other

11. You can find out more about the EMA via www.ema.europa.eu
12. You can find out more about the DH via www.dh.gov.uk

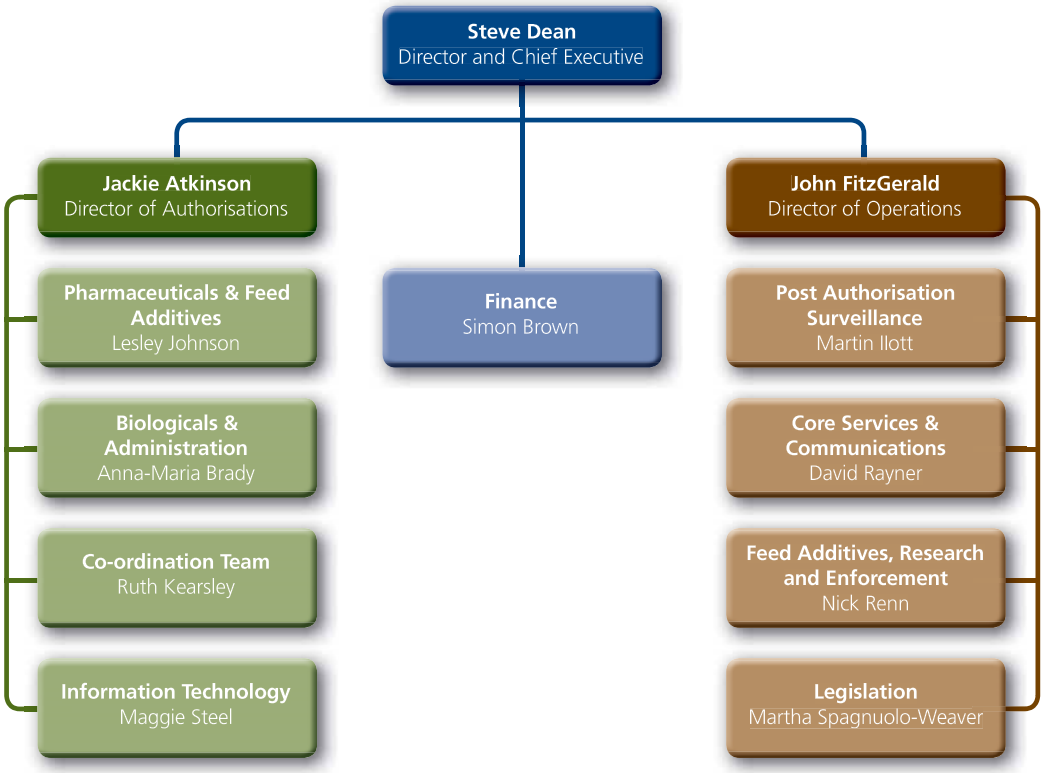
**From the left: Steve Dean, Jackie Atkinson, and John FitzGerald**

stakeholders including consumer representative groups, the EC and the FSA who are responsible for food safety follow-up action.

***Operations,*** responsible for servicing, developing and implementing new policy/ legislation on all aspects of veterinary medicines; providing support to Ministers through briefing and advice on replies to correspondence and Parliamentary Questions; pharmacovigilance for veterinary medicines; inspection of manufacturers, wholesale dealers and retailers of veterinary medicines and day-to-day management of the veterinary medicines R&D programme on behalf of the Policy customer (Food & Farming Group (FFG), Defra). The Policy business works closely with Ministers and officials of Defra and other Government Departments and Agencies including the FSA, the general public, industry, consumer representative groups, the EC, embassies and other representatives of foreign governments.

The three businesses are supported by our dedicated support teams providing Information Technology (IT), strategic support, Staff Training and Liaison services, Finance and providing information to customers about our activities and achievements.

## The management team at 31 March 2010:



## Management Board

The VMD's Management Board meets four times a year, in May, September, December and March, as a key component of our governance arrangements. The Board's aim is to provide advice and re-assurance to the CEO, that effective measures are in place for:

- the delivery of key objectives agreed annually with the Minister and published in the VMD Business Plan;
- achieving good value for money; and
- regularity and propriety in the administration and operation of the Agency.

The CEO chairs the Board and we have three external members (who also form our Audit & Risk Committee – see Appendix E) to provide an independent critique of our performance. The two Directors and Heads of the scientific disciplines, Finance, IT and Training and Liaison Unit complete the formal membership. Staff have a standing invitation to propose items for the agenda and to attend as observers. The Board papers are available on the Management Board intranet site, and an office notice covering key messages is issued directly after each meeting to ensure that staff are engaged in the Board's work.

## VMD Owner Advisory Board

The VMD Owner Advisory Board (OAB) met in May and September 2009 and January and March 2010 under the Chairmanship of Defra's Chief Veterinary Officer (CVO) and has the following terms of reference:

- agreeing a VMD strategy that is suitable for Defra, Northern Ireland, Scottish Government, Welsh Assembly Government and the VMD and takes into account the needs of other key stakeholders;
- ensuring the alignment of the Agency's capacity and capability to deliver on behalf of Defra and Devolved Administrations;
- considering the Ministerial targets and performance indicators to ensure they remain challenging;
- continuous review of 'shared' risks to the business and Defra;
- ensuring that the Chief Executive delivers against Ministerial and corporate performance targets taking account of the level of risk within the business plan;
- ensuring that Defra funding is sufficiently robust to meet the requirements of the Agency's strategy;
- the CEO delivers continued value for money improvements; and
- contingency arrangements are in place.

The Board should advise the corporate owner on agreeing and/or updating the following governance and business documents:

- the VMD Framework Document;
- the VMD Strategic/Corporate Plan;
- the Annual Report & Accounts;
- the Annual Business Plan, including Ministerial targets; and
- the Terms of Reference for this Board.

### Board Membership

The following people and organisations were represented on the Owner Advisory Board during the year:

| | |
|---|---|
| Nigel Gibbens | Chief Veterinary Officer, Defra (Chair) |
| Steve Dean | Chief Executive Officer, VMD |
| John FitzGerald | Director of Operations, VMD |
| Jackie Atkinson | Director of Authorisations, VMD |
| Robert Houston | Northern Ireland |
| Simon Hall | Scottish Government |
| Christianne Glossop | Welsh Assembly Government |
| Brian Harding | Defra Corporate Customer (deputy chair) |
| Chris Pleass | Defra Finance |
| Alison Gleadle | Food Standards Agency |

It was agreed that there should be two non-executives:

| | |
|---|---|
| John Preston | Chair of the VMD Audit & Risk Committee |
| Bruce Jones | |

## Our Finances

The VMD is required to recover the costs of its activities in accordance with HM Treasury rules on fees and charges. The fees charged by the VMD are monitored and revised annually to ensure, as far as possible, that the fees for each particular service reflect the cost of the work undertaken. To minimise the impact of these fees on those charged, the VMD continually strives to improve its efficiency and service delivery.

The VMD's cost recovery result is reported for each of its three business areas: Authorisations, Residues and Operations, which reflect the different sources of funding.

The costs of the Authorisations business are recovered through fees and charges to the Veterinary Pharmaceutical Industry; the costs of the Residues business are recovered through fees and charges to the Food Industry; and the costs of the Operations business are primarily funded by Defra.

## Our People

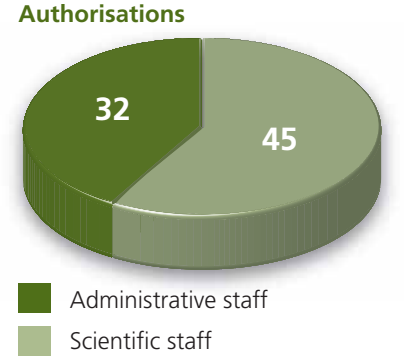
At 31 March 2010 we employed 162 permanent staff, both full and part-time. This included veterinarians, pharmacists, chemists, toxicologists, biologists, IT specialists, administrative and support staff. At 31 March we supplemented our permanent workforce with seven colleagues working on a temporary basis supplied by local employment agencies.

During the year we lost a total of 1,239 full-time-equivalent days through sickness absence, compared to 1,244 days in 2008/09. The average

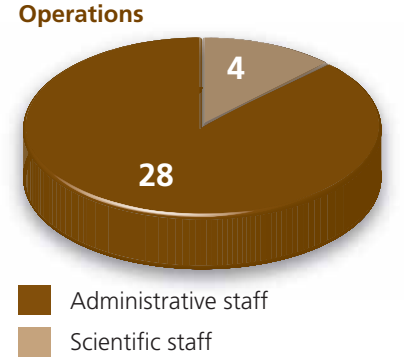
number of days per full-time employee was 8.3, compared to 8.8 in 2008/09. We closely monitor sickness absence, including benchmarking sick absence rates against Cabinet Office figures for the Civil Service. Policies and good working practices are in place to reduce sickness absence including: conducting return-to-work interviews; occupational health professionals advising on the medical and Disability Discrimination Act aspects of cases; training on stress awareness for managers and staff; and support from staff welfare services.

## Average Full-time Equivalent Permanent Staff Numbers During 2009/10

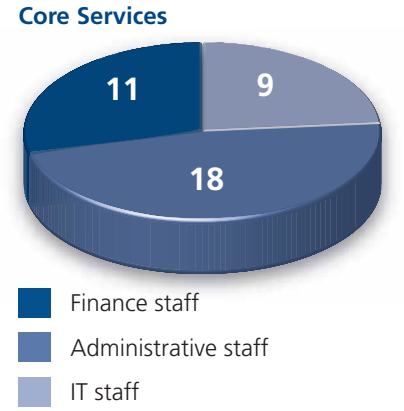
### Authorisations




### Operations




### Core Services




## Disabled Persons

The VMD complies with Equal Opportunities legislation and Departmental policy in relation to disabled employees. Special facilities are provided where required.

## Equal Opportunities and Health and Safety at Work

The VMD applies the Department's policies on equal opportunities and health and safety at work. The VMD's Head of Core Services and Communications is the Equal Opportunities and Diversity champion for the Agency.

## Employee Involvement

The VMD encourages staff involvement in its activities through day-to-day line management contacts and project teams. Regular team meetings review progress against the Business Plan and review risk. A staff suggestions scheme exists to encourage original ideas. Office notices and the intranet are used to disseminate information. An annual staff meeting to review the work of the past year and discuss future plans is addressed by the CEO. Staff have access to the staff welfare facilities offered by the Department and Trade Union membership and representation is in accordance with Departmental policies.

The VMD was re-accredited as an Investor in People (IiP) in 2009. The assessment was made against new IiP standards and the VMD was awarded 'silver' status in recognition of the continuing efforts in the development and training of its staff. Our next IiP assessment will take place during June 2012.

The VMD benchmarks itself biennially against the European Foundation for Quality Management (EFQM) Excellence Model recommended by the Cabinet Office. The results of the 2009 benchmarking, along with results from the staff survey, IiP reassessment and the first Civil Service wide employee engagement survey have formed part of the 2009/10 Business Improvement Delivery Plan. The VMD will take part in the EU Benchmarking process, led by the Heads of Medicines Agencies (HMA), in June 2010.

## Pensions

Future pensions provision is made for all permanent staff through the provisions of either the Principal Civil Service Pension Scheme or a stakeholder pension scheme with employer contributions – see note 5 to the Accounts and the Remuneration Report.

## Payment Policy and Performance

On 8 October 2008 the Prime Minister committed Government organisations to speed up the payments process, paying suppliers wherever possible within 10 days. However the standard terms and conditions in most HMG contracts and the legislative periods within the Late Payment of Commercial Debts (Interest) Act 1998 remain at 30 days. The VMD adheres to the "Better Payment Practice Code". The trade creditor balance at 31 March 2010, as a proportion of the total amount invoiced by suppliers in the year, equates to 3.5 days.

# Preparation and Audit of the Accounts

The Accounts have been prepared in accordance with a Treasury Direction dated 22 December 2009 in pursuance of Section 7(2) of the Government Resources and Accounts Act 2000 and audited by the Comptroller and Auditor General.

The VMD's income and expenditure was monitored under a net control total by HM Treasury and was also incorporated into the Defra Resource Accounting total.

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

# Management Commentary

## Our Work in 2009/10

The main events which took place during the year are reported more fully in the Directors' reviews. Key events included:

- the Veterinary Medicines Regulations (VMR)[13] 2009 came into force in October 2009;
- the completion of work for the action plan agreed by the Pollution Reduction Programme stakeholder steering group following the use of cypermethrin sheep dips and the withdrawal by the companies of the three Marketing Authorisations for cypermethrin sheep dips;
- the successful completion of projects that:
  - implemented from 1 January 2010 Heads of Medicines Agencies' proposals giving Marketing Authorisation Holders the option of submitting applications electronically instead of on paper (on which the VMD led development in Europe);
  - implemented the Commission's proposals to amend the Variations Regulations to increase efficiency and effectiveness both for stakeholders and staff;
  - took over, from the MHRA, responsibility for inspecting and licensing those sites which exclusively manufacture or wholesale veterinary medicines from 1 April 2009 and provided a "one stop veterinary shop" leading to improvements in efficiency; and
  - introduced a Quality System across the Agency to ensure that the VMD continued to be well placed in Europe to lead on the assessment, inspection and surveillance of veterinary medicines.
- The VMD was subject to a review by the Better Regulation Executive's Hampton Implementation Review Team that found the VMD demonstrated a broad and consistent compliance with the Hampton principles and made six recommendations for increased compliance going forward.

## Personal data-related incidents

There were no reported cases of personal data-related incidents during the year.

13. You can find out more about the Veterinary Medicines Regulations via www.vmd.gov.uk under General Information/Veterinary Medicines Regulations and Guidance

**The Secretary of State for Defra announced our targets to Parliament on 17 June 2009. These provide a framework of actions in which the VMD can provide the best possible service to all its customers.**

# Achieving Targets

**In summary, our work continued to support and maintain the high level of public confidence in the safety, quality and efficacy of veterinary medicines in the UK. Authorised veterinary medicines in the UK are accepted as being safe and fit for their purpose, having regard especially to food and environmental safety, animal health and welfare, and protection for those handling such medicines. We believe such confidence to be justified through the achievement of our key targets in 2009/10:**

## Target 1

**To authorise veterinary medicines against legislative requirements, according to published standards, and monitor reports of suspected adverse reactions to identify emerging trends and take proportionate action.**


The overall VMD performance against published standards met the criteria defined as "excellent".

## Target 2

**To ensure that UK policy objectives are reflected in EC legislation and guidance and that UK legislation and guidance enables veterinary medicines to be used responsibly, effectively and safely.**


The key performance indicators for this target were met including completing the first stage of the distribution category review, publishing the VMD Enforcement Strategy, completing the sheep dip Pollution Reduction Programme and consulting Commission officials on changes to EU legislation.

## Target 3

**To ensure that the regulatory system is effective and contributes to protecting public health by taking risk-based action on the findings from surveillance of residues in food-producing animals.**


Both residue surveillance programmes were completed in accordance with their plans and the 0.5% of positive samples was similar to previous years.

## Target 4

**To ensure that the appropriate infrastructure is in place to achieve targets 1, 2 and 3, provide value for money*, and achieve full cost recovery.**


The overall cost recovery was 99.7%. The infrastructure was appropriate and enabled targets one to three to be met.

* To determine value for money the VMD follows the definitions cited by the National Audit Office to report on the economy, efficiency and effectiveness of public spending:
Economy: minimising the cost of resources used or required – **spending less**;
Efficiency: the relationship between the output from goods or services and the resources to produce them – **spending well**; and
Effectiveness: the relationship between the intended and actual results of public spending – **spending wisely**.

# Director of Authorisations' Review

Jackie Atkinson

**This has proved to be another busy and successful year. The volume of application work has remained high and yet we have still committed significant time to new initiatives and ongoing projects which are intended to bring benefits to stakeholders and to the VMD. I would like to thank everyone from across the VMD who has contributed to this important work and to acknowledge the high level of commitment that VMD staff consistently demonstrate.**

The main way in which the work of the Authorisations business is measured is through our performance against a comprehensive set of published standards. This year our overall performance has been evaluated as "excellent", which is an improvement on last year.

I am very proud of the results from the licensing customer survey, which became available in February 2010, and demonstrate that most of our customers consider the service we provide to be good or excellent. Naturally potential areas for improvement were identified and our proactive and transparent approach is nicely illustrated by the series of steps that have already been taken and published to address many of these issues.

This year we have introduced two major changes to the way in which we and the veterinary pharmaceutical industry work: the implementation of the new variation procedures for EU authorisations and the acceptance of electronic only dossier submissions. We made every effort to ensure the industry was ready to adapt to these changes and the results from the customer survey illustrate that our efforts have been appreciated. The VMD had to overcome significant hurdles to be ready on time to implement these changes. Three months of operation of the new systems indicate the planning was effective and that the benefits in terms of reducing regulatory burden and costs are starting to be realised.

The VMD took a European wide perspective when working on the VMD's e-submissions project and was instrumental in producing EU wide guidance to the pharmaceutical industry that was practical. The VMD has also led the way by being the very first national Agency to populate Eudrapharm, which is a database intended to provide information on EU authorised human and veterinary medicines for the public.

The VMD takes its role in the EU seriously and engages in the work of the Heads of Medicines Agencies (HMA)[14], as well as the Committee for Veterinary Medicinal Products (CVMP)[15] and CMDv and their associated Committees. This represents a significant undertaking but we consider this to be important and we are careful to prioritise our areas of focus. The VMD also has a number of schemes which it operates with the Irish Agency, the Irish Medicines Board (IMB). This is a successful collaboration that benefits both parties and we hope that in the future at least one of the schemes can be extended to involve further Agencies.

Whilst the VMD is happy to help other Agencies, we have demonstrated that, even when in a minority position, we will robustly defend a line we consider to be scientifically sound and important for the continuing availability and safety of medicines. We will not stand by and allow others in the EU network to follow the easy option where this contradicts our goals and the stated goals of the EU network. We accept that making difficult decisions, which may be unpopular, is an integral part of our role as Regulators and we hope to convince our colleagues of this in the coming year.

This year the VMD launched the "Product Information Database" which has been widely applauded as a significant step forward in making information on UK authorised veterinary medicines easily accessible. We have also taken every opportunity this year to explain to prescribers and suppliers of veterinary medicines that Summary of Product Characteristics (SPCs), which are available on the Product Information Database, should be used as the definitive source of information. We will continue to work hard to reinforce this message in the coming year.

We currently have some exciting new developments in progress and, in particular, we are looking forward to the live implementation of an on-line form to be used for the reporting of adverse events. I am sure next year will prove to be equally challenging but I am also confident that the team will rise to this challenge.

**Jackie Atkinson**

14. You can find out more about the HMA via www.hma.eu
15. You can find out more about the work of the CVMP via the EMA website www.ema.europa.eu

# Director of Operations' Review

**Life continued to be busy throughout the Operations Division during 2009/10 but our pre-occupation with work problems was brought sharply into proportion by the sudden and untimely death of Janet Rubidge. Janet had worked for the VMD for 16 years and in the Residues team for nine years specialising latterly on R&D and Codex work. Her work in the local community was recognised by the huge turnout to pay respects at her funeral. A very sad loss – may she rest in peace.**

John FitzGerald

Change continued with a vengeance as we revised our structure to create a Post Authorisations team bringing together the work on SARs, residues and inspections under Martin Ilott who returned to the VMD after a year in industry. Martin may have wondered what had hit him as the re-development of the Tigress database and introduction of electronic reporting were live issues for SARs, there were discussions on the future of the non-statutory residues scheme, much preparatory work for a tender for residues analytical services and new inspections of wholesalers and veterinary practices. We made good progress in all of these areas.

Sheep dips continued to exercise the team as Organophosphates (OPs) research projects came to an end and were referred to the Committee on Toxicity (COT) for advice. The Committee has asked for a literature review of all the available research so that its advice to Government will be soundly based. Unfortunately, this review will take time and the outcome of the COT's work is not expected until 2011. The work on the Pollution Reduction Programme (PRP) for Synthetic Pyrethroid (SP) dips was concluded and the companies withdrew their marketing authorisations. This was not a surprising conclusion as the published research for the PRP pointed strongly to the difficulties of using SP sheep dips without creating a high risk of environmental damage.

The Better Regulation Executive reviewed how we have implemented the Hampton Report and recognised that the VMD demonstrated a broad and consistent compliance with the Hampton principles. This was very pleasing and we have already achieved one of the review's recommendations by publishing our Enforcement Strategy for comment. Steady progress was made in collecting evidence in two major cases involving the illegal supply of authorised and unauthorised medicines and it is hoped both cases will reach court in 2010. The VMD's decision on whether a product was a medicine and needed a marketing authorisation was challenged in a Judicial Review with the judgement upholding the VMD's position.

Our antimicrobial resistance (AMR) work developed during the year with a greater involvement of European bodies on the issue. The Heads of Medicines Agencies produced a strategy and action plan and the EMA considered how sales data reporting could be made a requirement for Member States. Further afield, Codex work on risk guidance for food borne AMR continued and will be completed in 2010. The VMD played an active role in all these groups.

We led two Codex residues working groups on bees and analytical methods and took over responsibility for managing veterinary medicines R&D from Defra with no resource transfer.

The Legislation team once again successfully masterminded the revocation and remaking of the VMR in October and were well advanced on the changes for 2010. They also completed the initial part of the distribution category review securing company and Ministerial agreement to change the category of 31 products. Some areas of dispute remained at the end of the year and will be pursued in 2010.

Work also began on preparing for the review of the medicines and medicated feed directives with direct and early involvement of the Commission and UK stakeholders.

Operationally, Defra's introduction of new facilities management arrangements took a little time to settle in but were handled well by VMD staff. The need for in-year savings was actively and innovatively embraced with many good ideas coming forward which can be carried over into 2010/11. The successful IiP review was led by the team as were two equally successful staff surveys.

This has been a difficult year for the Division with a number of colleagues suffering from long-term illness and, of course, Janet's sudden death. Nevertheless, the spirit has remained high and everyone has worked hard to ensure we continued to deliver the high quality services our customers demand. Thanks to all the team – it is a pleasure working with you.

**John FitzGerald**

# Looking Forward

## Targets for 2010/11

Ministers have agreed five targets for the VMD.

### Target 1 – Value For Money*:

Achieve full cost recovery and demonstrate progress in the three elements of Value for Money (Economy, Efficiency and Effectiveness).

### Target 2 – Customers:

a) At least 70% of customers in the veterinary pharmaceutical industry to consider the level of service provided by the VMD to be good or excellent and for the VMD to act on areas identified requiring improvement within the confines of the available resources.

b) Policy customers in Defra and OGDs consider the level of service provided by the VMD to be satisfactory.

### Target 3 – Operations/Policy Delivery:

a) Authorise veterinary medicines according to legislative requirements and to monitor their ongoing safety and efficacy and to take proportionate action.

b) Encourage the responsible, safe and effective use of Veterinary Medicinal Products (VMPs) according to the legislative requirements through proportionate action and act to detect and deter illegal use.

c) Ensure UK policy principles influence EU legislative change.

### Target 4 – Capacity and Capability:

Ensure the VMD utilises its funding streams efficiently to ensure that it maintains capability and capacity to deliver its business objectives and is fit for purpose.

### Target 5 – Sustainability:

Increase recycling by 4%.

* To determine value for money the VMD follows the definitions cited by the National Audit Office to report on the economy, efficiency and effectiveness of public spending:

"Economy: minimising the cost of resources used or required – **spending less;**

Efficiency: the relationship between the output from goods or services and the resources to produce them – **spending well**; and

Effectiveness: the relationship between the intended and actual results of public spending – **spending wisely**."

The VMD's work contributes to the achievement of five of Defra's Strategic Objectives:

- **An economy and society that are resilient to environmental risk**

  Authorised veterinary medicines are assessed for safety and part of this assessment provides reassurance that they will deliver their label claims and will not harm the public (consumer/user/third party) or environment if used in accordance with the manufacturer's instructions.

- **A thriving farming and food sector with an improving net environmental impact** and

- **A sustainable, secure and healthy food supply**

  Livestock are a key asset for many farmers and authorised veterinary medicines are used to maintain the health and welfare of farm stock thus helping the profitability of UK farming through livestock efficiency and by reducing waste associated with premature death.

  Authorised veterinary medicines are assessed to ensure any residues of the active ingredients found in meat, milk or other foodstuffs derived from treated livestock will not harm the consumer when used in accordance with the manufacturer's instructions thus ensuring food remains a healthy source of nutrition. The VMD carries out residues monitoring work to give further assurance regarding food safety.

  Authorised veterinary medicines are assessed to provide assurance that they will deliver their label claims and will not harm the public when used in accordance with the manufacturer's instructions.

- **A healthy, resilient, productive and diverse natural environment**

  The VMD's work contributes to Defra's use of hazard assessment, risk assessment and risk management of chemicals.

- **A respected department delivering efficient and high quality services and outcomes**

  In delivering our Aim, as one of the leading Veterinary Medicinal Products regulatory bodies within the EU and internationally, the VMD contributes to the reputation of the Department by delivering efficient, high quality services and outcomes.

## Key challenges for next year

The key challenges to the VMD throughout 2010/11 and its plans for meeting them have been outlined in the VMD's Business Plan[16], which is available on our website.

The VMD's key drivers for the future will be:

- the economic state of the veterinary pharmaceutical industry and its effect on the volume of licensing work the VMD receives coupled with the impact the change to the Variation Regulations will have on the VMD's income from variations;
- the future financial structure of the VMD following the Government's decision to retain the VMD as a Defra Agency after the outcome of the public consultation in 2008 on the future structure of the VMD following the recommendations contained in the HM Treasury Report entitled Reducing Administrative Burdens: Effective Inspections and Enforcement;
- the continuing development of the European Network of medicine regulatory agencies, the European Technology Platform and the continuing expansion of the European Union;
- making any changes required in respect of laboratory services when the current contract for the statutory analytical programme expires in December 2010;
- the implementation of changes recommended by the Hampton Review Team;
- the implementation of our Business Plan and changes following staff surveys, an Investors in People review and benchmarking the VMD against the European Foundation for Quality Management model and in comparison to other Member States' regulatory agencies;
- outcome of the public consultation on the Veterinary Medicines Regulations 2010;
- European Community proposals to amend EC legislation on residues and medicated feed additives;
- European Commission's preparations to review the veterinary medicines legislation in 2010;
- further implementation of electronic working;
- action to control illegal sales of medicines on the internet; and
- the EMA's roadmap for 2010-15 and the HMA Strategy for 2010-15.

16. You can find a copy of our Business Plan on our website www.vmd.gov.uk under About

# Financial Review

**The VMD was set one key financial performance target in 2009/10: to achieve cost recovery (±2%) for the VMD as a whole. The Operating Cost Statement shows a Net Operating Cost of £38,000, equivalent to 99.7% cost recovery.**

The results of the VMD's main business areas during 2009/10, as shown in notes 3 and 4 to the accounts, were as follows:

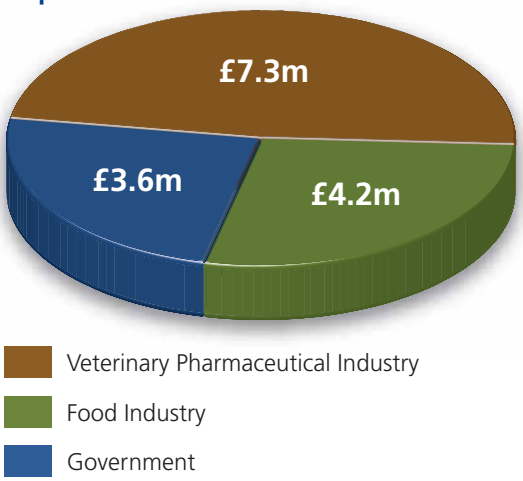
| | Income £m | Expenditure £m | Cost recovery % |
|---|---|---|---|
| Veterinary Pharmaceutical Industry | 7.3 | (7.3) | 99.8% |
| Food Industry | 4.0 | (4.2) | 97.3% |
| Government | 3.7 | (3.6) | 102.5% |
| **Total VMD** | **15.0** | **(15.1)** | **99.7%** |

The VMD's total income outturn was £15.0m, an increase of 0.4% against 2008/09. Defra income increased by 8.3% on 2008/09 of which 5.8% compensated for increased Defra service recharges. Income collected from the Veterinary Pharmaceutical Industry decreased by 3.8%. This was mostly due to fluctuations in application volumes relating to marketing authorisations and lower than anticipated industry turnover growth. Income collected from the Food Industry grew by 1.0% reflecting the volumes and mix of food sector activity.

Total operating costs were £15.1m, a 1.7% increase against 2008/09. Staff costs increased by 4.6% on 2008/09, of which 2.5% was due to increases in permanent staff salaries, 1.5% was due to increased headcount (with a significant shift in numbers from temporary to permanent staff) and 0.5% was due to an increase in untaken annual leave.

Capital expenditure was £285,000, a 3.6% increase on 2008/09. Land & Buildings are carried in the Statement of Financial Position at "Depreciated Replacement Cost" applying to specialist buildings, having previously been carried at Open Market Value. 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." This change in asset value is the result of an independent valuation, which concluded that all of the buildings within the Weybridge site are specialist assets, as the site is contained within a defined boundary accessed via a shared estate road and "therefore the VMD building cannot be operated as a separate entity". The valuation resulted in a £1.06m reduction in the net book value of the Land and a £1.65m increase in the net book value of the Building.

## Expenditure




The VMD is funded by Defra and the position is shown in the 'Taxpayers' Equity' section of the Statement of Financial Position. The General Fund represents the value of the VMD's net current assets 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 Operating Cost Statement. This reserve is not distributable. The Revaluation Reserve represents the unrealised cumulative balance of indexation and revaluation adjustments to non-current assets.

## Events since the Balance Sheet date

Up to the date of issue, there have been no events since the balance sheet date that would have a significant impact on the Annual Report & Accounts.

# Remuneration Report

## Remuneration Policy

The remuneration of senior civil servants is set by the Prime Minister following independent advice from the Review Body on Senior Salaries. In reaching its recommendations, the Review Body has regard to the following considerations:

- the need to recruit, retain and motivate suitably able and qualified people to exercise their different responsibilities;
- regional/local variations in labour markets and their effects on the recruitment and retention of staff;
- Government policies for improving the public services including the requirement on departments to meet the output targets for the delivery of Departmental services;
- the funds available to departments as set out in the Government's Departmental expenditure limits; and
- the Government's inflation target.

The Review Body takes account of the evidence it receives about wider economic considerations and the affordability of its recommendations. Further information about the work of the Review Body can be found at www.ome.uk.com.

## Service Contracts

Civil Service appointments are made in accordance with the Civil Service Commissioners' Recruitment Code. The code requires appointment to be on merit on the basis of fair and open competition, but also includes the circumstances when appointments may be made otherwise.

Unless otherwise stated below, the Directors 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 Civil Service Commissioners can be found at www.civilservicecommissioners.gov.uk.

Steve Dean was appointed on a fixed term contract which has been extended to expire on 31 August 2011.

## Salaries and Pension Benefits (Audited)

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

'Salary' includes gross salary; performance pay or bonuses; 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.

Staff are appraised annually against a set of competencies and individually targeted objectives. Bonuses, which form only a small percentage of total salaries, are the only form of remuneration subject to performance conditions.

No amounts have been 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 has held any company directorships or other significant interests during the year that, in the opinion of the Directors, may conflict with their management responsibilities.

The Agency Chief Executive's salary, as defined above, was £102,683 for the year (2008/09 £99,123).

## 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.

## Pension Benefits

### 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.

The figures include the value of any pension benefit in another scheme or arrangement which the member has transferred to the Civil Service pension arrangements. They also include any additional pension benefit accrued to the member as a result of their buying additional pension benefits at their own cost. CETVs are

worked out within the guidelines and framework prescribed by the Institute and Faculty of Actuaries 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

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.

| **2009/10** | S Dean – Director and Chief Executive | J FitzGerald – Director of Operations | J Atkinson – Director of Authorisations |
|---|---|---|---|
| | £000 | £000 | £000 |
| Salary (as defined above) | 100-105 including 5-10 bonus | 90-95 including 5-10 bonus | 80-85 including 5-10 bonus |
| Real increase in pension and related lump sum at age 60 | 0-2.5 plus 2.5-5 lump sum | 0-2.5 plus 5-7.5 lump sum | 2.5-5 plus 2.5-5 lump sum |
| Total accrued pension at age 60 and related lump sum | 15-20 plus 45-50 lump sum | 35-40 plus 110-115 lump sum | 15-20 plus 30-35 lump sum |
| CETV at 31 March 2009* | 304 | 746 | 215 |
| CETV at 31 March 2010 | 359 | 830 | 269 |
| Real increase in CETV after adjustment for inflation and changes in market investment factors | 37 | 37 | 35 |

* The figure may be different from the closing figure in last year's accounts. This is due to the CETV factors being updated to comply with The Occupational Pension Schemes (Transfer Values) (Amendment) Regulations 2008.

| **2008/09** | S Dean – Director and Chief Executive | J FitzGerald – Director of Operations | J Atkinson – Director of Licensing |
|---|---|---|---|
| | £000 | £000 | £000 |
| Salary (as defined above) | 95-100 including 5-10 bonus | 85-90 including 5-10 bonus | 75-80 including 10-15 bonus |
| Real increase in pension and related lump sum at age 60 | 0-2.5 plus 0-2.5 lump sum | 0-2.5 plus 0-2.5 lump sum | 0-2.5 plus 0-2.5 lump sum |
| Total accrued pension at age 60 and related lump sum | 10-15 plus 40-45 lump sum | 35-40 plus 105-110 lump sum | 15-20 plus 25-30 lump sum |
| CETV at 31 March 2008 | 269 | 699 | 194 |
| CETV at 31 March 2009 | 309 | 756 | 228 |
| Real increase in CETV after adjustment for inflation and changes in market investment factors | 17 | – | 12 |

No employer contributions were made to partnership pension accounts during 2009/10 or 2008/09.

## VMD Owner's Advisory Board

Membership details of the OAB are shown on page 10. With the exception of the VMD and the external members, the OAB members served only in their capacity as senior managers of the parent or other government department. Defra bears the cost of their representatives and the external members and details of these members' salaries, pensions, company directorships or other significant interests are included in their departments' resource accounts.

None of the external members of the OAB has held any company directorships or other significant interests during the year that, in the opinion of the members, may conflict with their management responsibilities.

## External Board Members

Membership details of the Audit & Risk Committee are shown on page 63. The three external members also sit on the Management Board. David Skilton chairs the Veterinary Products Committee. The following salaries and benefits-in-kind were paid to the external members:

| **2009/10** | J Preston £000 | B Morris £000 | D Skilton £000 |
|---|---|---|---|
| Salary (as defined above) | 0-5 | 0-5 | 5-10 |
| Benefits-in-kind | 0-5 | 0-5 | 5-10 |
| Total | 0-5 | 5-10 | 10-15 |

| **2008/09** | J Preston £000 | B Morris £000 | D Skilton £000 |
|---|---|---|---|
| Salary (as defined above) | 0-5 | 0-5 | 0-5 |
| Benefits-in-kind | 0-5 | 0-5 | 0-5 |
| Total | 0-5 | 0-5 | 5-10 |

Members' 'salaries' relate to attendance fees, from which payroll taxes are deducted at source. Benefits-in-kind relate to the reimbursement of travel expenses to the VMD's offices. The VMD settles the members' income tax liability on the benefits-in-kind through a 'PAYE Settlement Agreement'.

The external members did not receive any pension benefits as part of their remuneration.

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

## Civil Service Pensions

Pension benefits are provided through the Civil Service pension arrangements. From 30 July 2007, civil servants may be in one of four defined benefit schemes; either a final salary scheme (Classic, Premium or Classic Plus); or a whole career scheme (Nuvos). These statutory arrangements are unfunded with the cost of benefits met by monies voted by Parliament each year. Pensions payable under Classic, Premium, Classic Plus and Nuvos are increased annually in line with changes in the Retail Prices Index (RPI). Members joining from October 2002 may opt for either the appropriate defined benefit arrangement or a 'money purchase' stakeholder pension with an employer contribution (Partnership pension account).

Employee contributions are set at the rate of 1.5% of pensionable earnings for Classic and 3.5% for Premium, Classic Plus and Nuvos. Benefits in Classic accrue at the rate of 1/80th of final pensionable earnings for each year of service. In addition, a lump sum equivalent to three years' initial pension is payable on retirement. For Premium, benefits accrue at the rate of 1/60th of final pensionable earnings for each year of service. Unlike Classic, there is no automatic lump sum. Classic Plus is essentially a hybrid with benefits for service before 1 October 2002 calculated broadly as per Classic and benefits for service from October 2002 worked out as in Premium. In Nuvos a member builds up a pension based on his/her pensionable earnings during their period of scheme membership. At the end of the scheme year (31 March) the member's earned pension account is credited with 2.3% of their pensionable earnings in that scheme year and the accrued pension is uprated in line with RPI. In all cases members may opt to give up ("commute") pension for a lump sum up to the limits set by the Finance Act 2004.

The Partnership pension account is a stakeholder pension arrangement. The employer makes a basic contribution of between 3% and 12.5% (depending on the age of the member) into a stakeholder pension product chosen by the employee from a panel of three 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 0.8% of pensionable salary to cover the cost of centrally-provided risk benefit cover (death in service and ill health retirement).

The accrued pension quoted is the pension the member is entitled to receive when they reach pension age, or immediately on ceasing to be an active member of the scheme if they are already at or over pension age. Pension age is 60 for members of Classic, Premium and Classic Plus and 65 for members of Nuvos.

Further details about the Civil Service pension arrangements can be found at the website www.civilservice.gov.uk/my-civil-service/pensions.

**Steve Dean**
Chief Executive
25 May 2010

# Environmental Matters and Social and Community Issues

Working closely with Defra and the Sustainable Development Commission (SDC) www.sd-commission.org.uk we produced our third Sustainable Development (SD) Action Plan[17]. It covers the period from January 2010 to December 2011 and continues our work as part of the commitment to the UK Government Sustainable Development Strategy – *Securing the Future* (March 2005), under which all Government departments and their executive agencies produced focused sustainable development action plans based on the Strategy.

Our previous plans set out how, by using sound science responsibly and implementing good governance to develop policy and regulate veterinary medicines (our core business since 1990), we contributed to outcomes that are now included under the SD banner. The third plan takes this work further, and by building on our experiences from implementation of the earlier plans (both achievements and lessons learned) and the advice we received from Defra and the SDC we have delivered a far reaching and challenging plan. It sets out a series of actions to guide our business operations and allow us to contribute as far as possible to the Government's SD objectives. It also shows how we are increasingly embedding SD principles and priorities in our decision making, whilst also delivering the requirements set down in European and UK legislation for veterinary medicines.

17. You can find out more about the VMD's Sustainable Development Plan via www.vmd.gov.uk under About

# Meeting Our Targets

**We monitored and reported progress against our objectives at quarterly meetings of the VMD's Management Board and reported progress to Defra's OAB. The achievement of our strategic objectives and key performance targets was subject to an annual independent assessment by Defra Internal Audit.**

## Target 1

### To authorise veterinary medicines against legislative requirements, according to published standards, and monitor reports of suspected adverse reactions to identify emerging trends and take proportionate action

The overall score for our performance, as judged by our published standards, was 348 out of a maximum of 354 which corresponds to 98% and the "excellent" overall performance category. The published standards consist of 75 individual categories. Most of the individual categories met the performance standard defined as "excellent", with a small number (three) being classed as "effective". Only one category was considered to be "ineffective", which was the signing-off of Type A ATCs in 30 days where one out of eight applications did not meet the stated target.

The detailed results can be found in Appendix A.

## Provide scientific assurance that the benefits of authorised medicines outweigh the potential risks to human, animal and environmental safety by assessing data and information provided in support of applications against standards, which will be published on the VMD website

The VPC judged the VMD assessment standards against the published standards for two National applications for MAs, one of which was a provisional MA. The VPC rated the VMD's assessment as excellent in both cases.

The VMD regularly acts as the RMS in European procedures. This year the VMD has acted in this capacity for 50 new MA applications and numerous more variation and renewal applications. The assessment and opinions of the VMD assessors are respected by other Member States and companies.

No products have been removed from the UK market this year as a consequence of referral proceedings initiated by other Member States.

## Ensure that the quality of authorisation documentation issued by the VMD meets published standards by monitoring the quality of authorisation documentation issued following completion of the application procedure (European and National); identifying trends in errors and implementing corrective action accordingly

The percentage of unreturned authorisation documentation for the period 2009/10 was 96.7%, which corresponds to the performance standard defined as "effective".

132 letters were sent to companies resulting in two customer visits during 2009/10. Minutes were sent out within four weeks of the meeting in both cases. The performance as measured by the published standard was "excellent".

## Identify changes in the patterns of adverse reactions from pharmacovigilance data and take proportionate action by monitoring the adverse reaction database for emerging trends and signals. Reporting results to the VPC on a regular basis

The SARSS team has a target to enter human reports onto its database within two working days, serious animal reports within two working days, non serious reports within ten working days and to send serious reports involving nationally authorised, Mutual Recognition/Decentralised products and centralised products to EudraVigilance Veterinary within 15 days of receipt of the complete information. The team achieved the "excellent" performance level for all of these targets.

During the year the SARSS team received 3,258 SAR reports (animal and human) and 1,426 Periodic Safety Update Reports (PSURs), a decrease of 5.4% and an increase of 8.7% respectively compared to the previous year.

## Ensure the continued quality of veterinary medicines by risk-based inspection of manufacturers to the principles of Good Manufacturing Practice (GMP) to an agreed timetable and by taking proportionate corrective action when deficiencies are identified

The VMD Inspection team carried out 41 inspections, 21 of which were of Pharmaceutical Veterinary Medicinal Products manufacturers to ensure compliance with the principles of GMP. A further three inspections were in third countries, one of which was performed jointly with another Member State on behalf of the EU and related to centralised applications. Seven manufacturers of immunological veterinary medicinal products were also inspected with five of these located outside the UK.

Manufacturers of products exempt under the Small Animal Exemption Scheme (SAES) accounted for one inspection and contract test sites for a further two. Other inspections included two autogenous vaccine manufacturers, one equine stem cell centre and one non-food animal blood bank.

The inspectors were also involved in an inspection by the Food and Veterinary Office, DG Sanco as part of the evaluation of the biosecurity at a high-containment manufacturing facility in the UK.

In all cases inspection reports were sent to the company within 31 days of the visit, the performance target was 60 days.

GMP certificates were issued to all companies having satisfactory inspection outcomes, with 100% of certificates being issued within the performance target. There were no GMP non compliance certificates issued.

## Target 2

### To ensure that UK policy objectives are reflected in EC legislation and guidance and that UK legislation and guidance enables veterinary medicines to be used responsibly, effectively and safely

#### Revoke and re-make the Veterinary Medicines Regulations and associated guidance to come into force on 1 October 2009 and initiate the project to revoke and remake the Regulations for 2010

The Veterinary Medicines Regulations (VMR) 2009 came into force on 1 October 2009.

Formal consultation on VMR 2010 was delayed by the complexity of some of the legal changes being made and will be further delayed in 2010/11 by the General Election.

#### Complete the legal classification review of authorised veterinary medicines and implement agreed changes following consultation with stakeholders according to the project plan

The first stage of the review has been completed and agreement has been reached to change the distribution category on 31 products. Work has started on preparing an information package to transfer the project to the Authorisations side of the VMD to carry out implementation. An information package will also go on the internet.

#### Encourage the responsible use of veterinary medicines through the implementation of a published risk-based enforcement strategy working in conjunction with other agencies

The draft Enforcement Strategy was published on the VMD's website on 30 March 2010 inviting comments from stakeholders.

#### Monitor sales of veterinary antimicrobials in the UK by collecting and publishing the antimicrobial sales data report[18] for 2008 by 31 October 2009

The 2008 report was published on the VMD's website on 30 October 2009.

#### Ensure the appropriate quality of feedingstuffs containing veterinary medicinal products and/or specified feed additives and ensure the appropriate supply of such feedingstuffs and POM-VPS and NFA-VPS medicines, through the approval and risk-based inspection of relevant businesses

625 inspections of premises of Suitably Qualified Person (SQP) retailers were performed to ensure effective controls of POM-VPS and NFA-VPS medicines. 103 inspections of commercial feedingstuffs manufacturers, 256 inspections of on-farm manufacturers and 193 distributors were completed and formed the basis of a risk-based inspection strategy of manufacturers and distributors of medicated feedingstuffs and specified feed additives. As part of the business plan strategy that identified need for veterinary practice inspections and the transfer of veterinary-only wholesale dealer inspections from the MHRA from 1 April 2009, the AMI completed 219 Veterinary Practice Premise (VPP) inspections and 46 Good Distribution Practice (GDP) inspections of holders of Wholesale Dealer Authorisations (WDAs).

18. You can access the Antimicrobial Sales Data report via www.vmd.gov.uk under Publications
19. You can find out more about the RCVS at www.rcvs.org.uk

The following table sets out the number of inspections carried out in 2009/10 by the Animal Medicines Inspectorate (AMI):

| Category | No. of premises | Target scheduled inspections | Actual scheduled inspections | Follow Up & Special visits | Enforcement visits |
|---|---|---|---|---|---|
| SQP Retailers | 1,341 | 458 | 625 | 29 | 5 |
| Commercial feedingstuffs manufacturers | 147 | 101 | 103 | 6 | 0 |
| On-farm feedingstuffs manufacturers | 648 | 247 | 256 | 7 | 1 |
| Feedingstuffs distributors | 376 | 150 | 193 | 6 | 0 |
| Veterinary Practice Premises | 2,242 | 200 | 219 | 0 | 0 |
| Veterinary-only Wholesale Dealers | 104 | 28 | 46 | 0 | 0 |

All premises are risk assessed as part of their inspection and the assessments transposed into re-inspection dates. During the year, the VMD met with representatives of the National Farmers Union, Assured Food Standards and Scottish Food Quality Certification to explore the possibility of Assurance Scheme Auditors inspecting on-farm feedingstuffs manufacturers on behalf of the VMD. Discussions are ongoing.

## Play an active part in negotiations with EU colleagues, particularly in HMA, CVMP and CMDv

Work as a member of the HMA taskforce on veterinary legislation has continued. The VMD presented on the Variation Regulations at the HMA meeting in May and also on Prudent use of Antimicrobials at the subsequent HMA/EMEA meeting focusing on antimicrobials. The VMD is a member of the HMA taskforce responsible for updating the HMA strategy. The Commission official leading on the proposed review of Directive 2001/82 spoke at the VMD open meeting and is aware of the UK's proposals for change.

The VMD remained active at CVMP and Co-ordination Group for Mutual Recognition and Decentralised Procedures – veterinary (CMD-v) meetings with focuses including referrals and Rapporteur work on applications and implementation of the Variations Regulation and RMS work respectively. The VMD's CEO continues to lead the HMA Telematics Support Group.

## To improve EU veterinary medicines legislation and the availability of veterinary medicines in line with EU strategy, taking part in the discussions regarding the review of Directive 2001/82

The VMD's stakeholder event on the review of the Directive took place on 13 January. Following earlier discussions with Commission officials they gave a presentation at the meeting and heard the issues that interest UK stakeholders.

## Reduce the risk of pollution from sheep dip by implementing agreed actions from the joint VMD/Environment Agency Pollution Reduction Programme for sheep dip

Project completed. The VMD announced on 3 March 2010 that letters requesting expiry of the three cypermethrin sheep dip products had been received from the manufacturers, in effect this removes all of the previously authorised cypermethrin sheep dip products from the UK market.

## Continue to facilitate the COT review of the R&D into human health impacts of low dose, long term use of OP sheep dips

The three final reports were considered by COT at their September 2009 meeting. This information is being fed into the literature review currently being undertaken by the COT secretariat for final consideration by the COT in late 2010. An Official Group for Organophosphates (OGOP) meeting will take place on 6 April 2010.

## Negotiate with other Member States and the European Commission to take forward the Cabinet Office initiative on the reduction of administrative burdens to industry

The VMD has been engaged at a number of levels across the EU to help develop strategies and legislation for the future. We are active in the HMA's Task Force on how the medicines legislation could be changed to improve availability and reduce the administrative burden. We have informed the Commission of the UK's wish to simplify the Directive during the proposed review. We are also members of the groups reviewing the HMA's strategy. Much work was done in negotiation with other Member States and the Commission in developing the new Maximum Residue Limit (MRL) Regulation and we have been routinely active in CVMP and CMDv.

## Target 3

### To ensure that the regulatory system is effective and contributes to protecting public health by taking risk-based action on the findings from surveillance of residues in food-producing animals

To monitor that internationally set safety limits are being observed, the VMD Residues Surveillance team manages two surveillance programmes. One is defined under EU legislation and is described as the Statutory Scheme. The other is a non-statutory programme, which complements and supplements the statutory programme by sampling food products imported into the UK from outside of the EU.

The Residues team contributed to ensuring that food was safe by:

- ensuring that the sampling and analysis targets in these plans were met;
- investigating violations found under the surveillance programmes according to standard operating procedures; and
- applying penalties appropriately.

They also contributed to the VMD's financial targets by ensuring that the non-statutory residue surveillance programme operated to budget (see Note 4 to the accounts).

#### Agree 2010 statutory residues plan with the European Commission in accordance with the time frame laid down in Council Directive 96/23

Achieved – the statutory plan was sent to the Commission by 31 March 2010.

#### Agree 2010 non-statutory residues plan with Veterinary Residues Committee by 31 December 2009

The VMD carried out a consultation exercise on the draft Plan with stakeholders on behalf of the VRC from 28 September to 9 November 2009. This asked them what they thought should be included in the 2010 programme. The suggestions received were considered by the full Committee and the final plan was agreed on 9 December 2009.

#### Ensure sampling and analysis targets are met to complete the 2009 plans

The sampling and analysis targets for both the statutory and non-statutory surveillance plans were completed on target.

#### Investigate each positive result according to risk-based standard operating procedures and apply penalties proportionately

Follow up investigations were undertaken by officers from the Animal Health Agency, the Fish Health Inspectorates in England and Scotland and the National Bee Unit. Details of follow up investigations are published in the VMD's quarterly information publication, Marketing Authorisations Veterinary Information Service (MAVIS)[20].

#### Negotiate changes to EC Residues legislation to ensure that the EC residues programme is risk based and reflects UK interests. Implement agreed changes to meet statutory deadlines

Negotiations were completed on Regulation 470/2009, which establishes the procedures for setting Maximum Residue Limits for pharmacologically active substances. Commission Regulation 37/2010, which helpfully sets out the list of authorised substances alphabetically with prohibited substances listed separately, also come into effect. These replace Council Regulation 2377/90.

The Commission is planning proposals to replace Council Directive 96/23, which sets out the rules for operating national surveillance programmes for residues of authorised veterinary medicinal products and other substances.

20. MAVIS is published online at www.vmd.gov.uk under Publications

## To ensure value for money, manage the residues analytical and sampling contracts

Both the statutory and non-statutory plans for 2009 were delivered on budget. The VMD will continue to seek value for money when negotiating costs for the 2010 programmes with service providers.

## Tender the analytical work to achieve a smooth transition to the selected service provider(s) from January 2011

This Key Performance Indicator was achieved as the VMD was prepared to issue tender documentation in accordance with the project plan. The documents were not issued as Ministers decided in March 2010 that the tender should not proceed and that the analytical work should be done in-house by Fera.

## Target 4

### To ensure that the appropriate infrastructure is in place to achieve targets 1, 2 and 3, provide value for money*, and achieve full cost recovery

* To determine value for money the VMD follows the definitions cited by the National Audit Office to report on the economy, efficiency and effectiveness of public spending:

Economy: minimising the cost of resources used or required – **spending less**;

Efficiency: the relationship between the output from goods or services and the resources to produce them – **spending well**; and

Effectiveness: the relationship between the intended and actual results of public spending – **spending wisely**.

### Achieve full cost recovery (±2%) for the VMD

Note 4 to the Accounts shows that the overall cost recovery was 99.7% and shows how this has been achieved across the VMD's principal business areas.

### Implement changes agreed following the consultation on the VMD's future under the Hampton proposal

In September 2009 the Better Regulation Executive carried out a Hampton Implementation Review which concluded that the VMD demonstrated a broad and consistent compliance with the Hampton principles.

### Implement changes agreed under the VMD's Change Programme

The VMD's Change Programme 2009/10 Business Improvement Delivery Plan (BIDP) implemented recommendations for change arising from the 2009 EFQM Benchmarking exercise, the 2008 and 2009 staff surveys, and the 2009 IiP reassessment. Staff were consulted on the document with comments sought on whether issues had been interpreted correctly, the priority to be placed against the different elements of the plan, and whether individuals wished to be involved in the development of one or more issues. The outcome from the 2009 Civil Service wide staff survey has been considered and these results broadly follow and strengthen those in the 2008 survey. A comparison between the 2008 and 2009 results, as well as percentage differences between the Civil Service wide average and the VMD result was made available to staff in February together with a request for views on these results. The 2009 survey did not raise any new themes for inclusion in the BIDP.

An initiative from the earlier VMD Change Programme was the project to implement a VMD wide Quality System. This project has progressed according to the project plan and all VMD teams have now identified and progressed the necessary Standard Operating Procedures. A programme of internal audits has been initiated.

### Report on the 2008/09 EFQM Benchmarking exercise, and implement appropriate changes

See action under Change Programme above.

### Implement agreed changes in response to the 2008/09 Staff Survey

See action under Change Programme above.

### Make information available in line with relevant access to information legislation

#### Access to Information

The VMD continued to work to the requirements of the Freedom of Information Act and the Environmental Information Regulations. 31 requests for information under this legislation were received during 2009/10. They covered a range of subjects from information relating to staff contacts and the VMD's corporate structure, to requests for medicine-related information. The VMD published details of all requests and the responses under this legislation on the website at www.vmd.gov.uk under About.

### VMD Publication Scheme

The VMD has a publication scheme in line with section 19 of the Freedom of Information Act. It focuses on information relating to the VMD's key regulatory activities and also on the standards and guidance by which it makes decisions. The scheme document is available via the VMD's website www.vmd.gov.uk under About.

### VMD Service Standards and Complaints Procedure

The VMD's Service Standards document defines the standard of service that its customers and stakeholders can expect to receive. It explains the steps that they can take if they feel that the VMD has failed to meet this standard. The VMD received and dealt with one complaint during the last year. The standards are available via the VMD's website www.vmd.gov.uk under About.

### Public Assessment Reports

Publication of United Kingdom Public Assessment Reports (UKPARs)[21] and European Public Assessment Reports (PuAR) has continued according to published targets, achieving "excellent" status against publication of UKPARs and "effective" status for publication of SPCs. Company comments on specific scientific discussions have been dealt with to the satisfaction of all parties.

The new combined UKPAR and Electronic Summary of Product Characteristics (eSPC) page of the VMD website known as the "Product Information Database" holds up to date information on all currently authorised veterinary medicinal products, expired and suspended products, homeopathic products and specified feed additives. In most cases, within 30 days of issue, high level details about the product and, if appropriate, the SPC have been made available online. For applicable products within 120 days of issue the public assessment report has been made available, and any changes to a product made post authorisation have been listed within 60 days of issue of that variation or renewal.

The product information database has proved a popular and useful source of information for industry, public and regulators within and outside the UK.

## Implement the VMD's IT Strategy

The new Inspection Management System was implemented live in June 2009 and the routine to update EudraPharm went live on 12 February 2010. New websites to provide a Codex Forum and a VPC Forum were implemented in November 2009 and January 2010 respectively. Work is underway to redevelop the Biologicals/Scientific Secretariat forum.

The project to redevelop the VMD's Internet website began in June 2009 and a great deal of preparation work has been done. Technical development work began in January 2010. A consultation exercise was launched on the existing Internet website on 17 February 2010 to gather feedback about what customers would like to see in the new site. The VMD's exception case to retain control of the website was accepted by the Cabinet Office and the VMD is incorporating measures to fulfil the conditions of this decision in the new development.

The Licence Management System was redeveloped to support European Grouped Variations and the new version was implemented on 4 January 2010. The redevelopment of Tigress, the system to support the Suspected Adverse Reaction Surveillance Scheme (SARSS), has been delayed to allow the integrated Veddra system to be updated. A plan to implement the system live during the first quarter of 2010/11 has been agreed. The SARSS online reporting form is expected to be implemented in April 2010. The redevelopment of the Statutory Residues system is underway and the priority for this work has been raised to high to ensure the new system is in place in time to support the implementation of the 2011 plan.

## Deliver Training and Liaison services to internally published standards

The Training and Liaison Unit has delivered to its standards throughout the year.

The team worked with the VMD Quality Manager to prepare Standard Operating Procedures as part of the next phase of the VMD's Quality project.

The VMD's Investors in People status was reassessed in June and the Agency achieved the 'silver standard' having met 134 of the evidence requirements. The new IiP framework introduced a series of core indicators that had to be met and investigated and reported on other areas. Recommendations from the assessor are being taken forward as part of the Business Improvement Delivery Plan (see under Change Programme above).

21. You can find out more about UKPARs via www.vmd.gov.uk under Product Information

## Deliver core services to internally published standards

Core Services teams have delivered services according to the established delivery standards. Programme and Project management continues to underpin the VMD's work.

## Improve VMD's customer focus including planning and carrying out a Customer Survey during 2009

During 2009/10 the VMD consulted its licensing customers on the quality of the service provided. A summary of the results was published on the VMD website in March 2010. Overall results were good and the VMD is reviewing the areas for improvement that have been identified.

## Participate in the BEMA benchmarking exercise

The BEMA II self assessment was sent to the lead assessor (Poland) by the agreed deadline of 6 April. The BEMA assessors are due to visit the VMD to start the audit in June 2010. A member of the VMD has acted as a BEMA lead assessor for four audits at other EU National Competent Authorities and has contributed to the work of the BEMA Steering Group.

# Statement of Accounting Officer's Responsibilities

Under the Government Resources and Accounts Act 2000 HM Treasury has directed the Veterinary Medicines Directorate to prepare a statement of accounts for each financial year 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 Veterinary Medicines Directorate and of its net operating cost, changes in taxpayers' equity 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 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 Financial Reporting Manual have been followed, and disclose and explain any material departures in the accounts; and
- prepare the accounts on the going concern basis.

The Accounting Officer for the Department for Environment, Food & Rural Affairs has designated the Chief Executive of the Veterinary Medicines Directorate as Accounting Officer of the Veterinary Medicines Directorate. 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 the Accounting Officers' Memorandum issued by HM Treasury and published in "Managing Public Money*".

* Further information about "Managing Public Money" can be found at http://www.hm-treasury.gov.uk/psr_mpm_index.htm

# Statement on Internal Control

## 1. Scope of responsibility

As Chief Executive I am accountable to the Secretary of State for Defra for the performance and operation of the VMD in accordance with the Framework Document and the VMD's Business Plan. I am responsible for securing efficiency and the economical conduct of business and for the propriety and regularity of the public funds allocated to the VMD.

As Accounting Officer, I have responsibility for maintaining a sound system of internal control that supports the achievement of the VMD's policies, aims and objectives, whilst safeguarding the public funds and departmental assets for which I am personally responsible, in accordance with the responsibilities assigned to me in Managing Public Money.

The Secretary of State for Defra determines the overall policy and financial framework within which the VMD operates but is not involved in the day-to-day management of the Agency. The Defra ownership function in relation to the VMD is exercised by the CVO and he receives advice on the Agency's strategic direction and performance from the VMD Owner Advisory Board (OAB). The role of the OAB includes assuring the Minister that the VMD has appropriate and effective mechanisms for financial control, audit and risk management.

## 2. The purpose of the system of internal control

The system of internal control is designed to manage risk to a reasonable level rather than to eliminate all risk of failure to achieve policies, aims and objectives; it can therefore only provide reasonable and not absolute assurance of effectiveness. The system of internal control is based on an ongoing process designed to identify and prioritise the risks to the achievement of departmental policies, aims and objectives, to evaluate the likelihood of those risks being realised and the impact should they be realised, and to manage them efficiently, effectively and economically. The system of internal control has been in place in the VMD for the year ended 31 March 2010 and up to the date of approval of the annual report and accounts, and accords with Treasury guidance.

## 3. Capacity to handle risk

The VMD has a comprehensive risk-management process reaching every level of the business under the leadership of the Chief Executive and taking advice from the independent Audit & Risk Committee. As Chairman of the VMD's Management Board, I have responsibility for providing the strategic leadership necessary to endorse the VMD's risk management procedures and to ensure that they are being implemented appropriately throughout the Agency.

The VMD's Risk Register, minutes of Audit & Risk Committee meetings and information on risk management procedures have been made available to all staff via a dedicated risk-management site on the VMD's Intranet. The continued use within the Agency of project management principles has increased the awareness of staff towards the management of risk and encouraged the use of good practice.

These measures are directed towards ensuring a common understanding of the terminology used in relation to the management of risk, identifying areas where best practice can be adopted and describing the procedures that have been put in place to manage risk within the Agency.

## 4. The risk and control framework

The procedures in place at the VMD are designed to ensure a regular review of the risks facing the Agency and encourage active consideration of the possible options for managing each risk down to an acceptable level.

The VMD's Risk Register contains the top risks facing the Agency. It is reviewed at least monthly by the Accounting Officer and the VMD's Directors to consider the current status of the risks and to consider whether any new risks are emerging that would threaten the achievement of the Agency's objectives. A Change Summary document is maintained to identify the date and reason for any significant changes made to each risk.

The VMD seeks to identify other risks that, although not significant enough to appear on the Risk Register, could still affect the successful outcome of the VMD's objectives. These risks are managed within individual business areas and are 'owned' by the respective Departmental Heads or Project Leaders. Progress against them is reported to Directors at regular intervals. During the year our risk management processes including the register were reviewed against a model used by our internal auditors. A revised risk register format was introduced together with a table of standing controls (for control measures that have been embedded within normal business processes). These are complemented by a document which sets out the VMD approach to risk management. We have also documented the existing process for the review and escalation of risks to ensure the Agency Accounting Officer and Directors are fully aware of the changing risk landscape to enable timely action to be taken.

# Statement on Internal Control (continued)

## Project Management Principles

The general principles of project management have been developed and applied across the VMD for many years. Used effectively and in a fit-for-purpose way, these principles have helped the Agency to ensure that:

- projects are goal-oriented;
- projects deliver real benefits and outcomes on time using resources efficiently and effectively;
- all stakeholders are identified and properly engaged;
- links and dependencies between different projects, policies and the Business Plan are identified;
- risks are identified and effectively managed.

Project Management training is available to all staff and this helps to ensure that the appropriate skills and disciplines are applied. Each formal project has a Senior Responsible Officer and a project plan. Risk registers are maintained for each project to ensure the level of risk is identified at the planning stage and monitored throughout the life of the project. This plays an important role in ensuring that milestones are met and the desired outcomes are delivered.

## Strategy and Planning

The VMD produces a three year Business and Financial Plan. This describes the VMD's vision, how the VMD works to deliver Defra objectives and the VMD's key performance targets. The first year of the financial plan is the budget, which sets out the resources required to achieve the objectives in the coming financial year. The Business and Financial Plan is considered by the OAB and signed off at Ministerial level following OAB and Corporate Owner advice.

Once the Business Plan is approved, action plans are formalised in order to facilitate its successful achievement. Business cases are prepared and, where appropriate, OGC Gateway Reviews are conducted, to inform significant investment decisions.

The Directors and senior managers meet during the year to discuss their understanding of the VMD's operating environment, including anticipated political, operational and financial developments. From this, the VMD's Business and Financial Plan is formulated, discussed and integrated into one common corporate view of how the VMD's business is to be conducted.

Priority tasks are identified to deliver each target, which is owned by one or more Directors. The targets form the basis of group action plans that feed into personal work objectives for VMD staff. Performance against the key targets, including the financial targets, is monitored quarterly by the Management Board and the OAB and reported on by Defra's Internal Audit following an end of year review.

## Governance Structures and Processes

The VMD operates according to the principles and responsibilities set out in the Agency's Framework Document. The Chief Executive Officer is appointed by and is directly accountable to the Minister for the day to day management of the VMD. As CEO, I am entitled to direct contact with HM Treasury with regard to the proper conduct of the Agency's finances. I am advised and assisted in my responsibilities by a Management Board and Governance oversight is provided by an Audit & Risk Committee. Three external non-executive Directors sit on the Management Board and form the Audit & Risk Committee. These committees are supported by the provision of a full range of management information, including financial performance, to support their deliberations.

As CEO I am a member of the OAB. The OAB is chaired by the Chief Veterinary Officer (the Defra Agency Owner) and is composed of two external members, senior officials from Defra (including the Defra Agency Customer), the devolved administrations and the FSA and is responsible for advising Ministers on strategic matters concerning the Agency.

Our Internal Audit work is currently provided by RSM Tenon, who provide an annual opinion on the adequacy and effectiveness of internal control including financial controls. This is based on a selection of risk-based audits carried out during the year, internal audit's annual Key Control Testing exercise, which seeks to provide assurance on the VMD's core systems, and other advice work on risk, control systems and governance given by Internal Audit during the year.

Each year the VMD conducts a control workshop, facilitated by Defra's Internal Audit team, covering elements of Risk Management, Control and Governance. The workshop allows an opportunity for VMD staff to express their opinions on a number of assertions relating to the control and risk framework by identifying strengths and weaknesses, providing assurance on the control framework and identifying possible issues for disclosure and actions to be taken.

The VMD holds regular internal and external meetings with a variety of stakeholders, including representatives of the veterinary profession, pharmaceutical companies, consumers and staff. A full range of information about the VMD, its governance and operations is kept available on its internet site.

# Statement on Internal Control (continued)

The VMD is accredited to Investors in People (IiP) at the silver standard following a reassessment in 2009 against the new IiP standard.

Towards the end of March, Defra confirmed that sub-contracted provision of analytical services in support of our National Residues Surveillance Programme would, from January 2011, be provided by Defra. This service is currently provided by an industry partner under a commercial contract, which is due to expire in December 2010. At the date of this report no performance standards have been defined and no cost has been agreed with the new sub-contractor and these and other operational risks will be taken up during the first quarter of the 2010/11 financial year.

A significant proportion of the VMD's non-pay overhead costs are recharges for services provided by other Defra bodies. Accountability for these costs lies with the Agency Chief Executive, who seeks to manage operational and financial risks through Service Level Agreements[1] that demonstrate value for money. On 1 April 2009 the responsibility for managing the delivery of a number of accommodation-related services transferred from the VMD to Defra under the Sustainable Workplace Management (SWM) contract. Defra has negotiated a centrally-managed performance measurement mechanism with the service provider that is designed to encourage effective service delivery across the Defra family. At the date of this report, Key Performance Indicators are still not in place. As the Agency Chief Executive I therefore have limited control over the costs and the effectiveness of service delivery in this area.

## Management of Change

A programme to drive through change at the VMD in the areas of European engagement and Quality is in progress. The Agency European Steering Committee has progressed the development of a clear strategy for the VMD's role in Europe and is providing training and information for staff on European matters. The appointment of a Quality Manager has provided significant progress in establishing an agency-wide quality management system. This view has been supported by an Internal Audit review during the year, which concluded that the VMD can take substantial assurance from the progress made so far.

Every two years the VMD reviews its performance against the European Foundation for Quality Management standards and implements changes considered necessary to enhance the VMD's performance. A benchmarking process was last completed in March 2009.

A VMD staff survey in 2008 and inclusion of VMD's staff in the Civil Service wide staff survey in 2009 provided a strong and consistent view of the organisation's strengths and areas for development. Adherence to the IiP principles and periodic re-assessment against the standard helps to embed a culture of performance improvement.

The findings from the staff surveys, EFQM assessment, IiP reassessment and Hampton Review have been included in the VMD's Business Improvement Delivery Plan.

Project Management principles are followed and this provides an environment for effective team and cross-team working, communication and buy-in to change.

## Information Security

VMD staff have all received training on information security, are experienced in handling commercially confidential data and are aware of the specific procedures that must be followed. Our commitment and competency in relation to IT security is recognised by accredited policies and procedures through the ISO 27001 standard. Our IT Security Forum reviews the specific information security risk register every six months. An Internal Audit review during the year concluded that the VMD can take substantial assurance that the controls upon which the organisation relies for planned and coordinated IT strategy are effective.

## Performance Management

All staff have the opportunity to engage in the development of the Business Plan and individuals are expected to be able to relate the objectives in their Personal Development Plan to the VMD targets.

Monthly meetings are held by all business groups to monitor performance against defined targets and budgets and to evaluate risk. Quarterly meetings are held by the Authorisation Division to review progress against their workplan and progress of projects.

Operational, Authorisation and Financial Performance Reports are produced monthly and circulated to the Directors and senior managers and reported formally to the Management Board on a quarterly basis. Authorisations performance against published standards of service is published in MAVIS on a quarterly basis.

An Internal Audit review during the year provided substantial assurance over Budget monitoring controls.

1. A Service Level Agreement is a part of a service contract where the level of service is formally defined. This will normally include a number of Key Performance Indicators, which are used to inform an evaluation of the effectiveness of service delivery.

# Statement on Internal Control (continued)

The VMD conducts formal Customer Surveys of our pharmaceutical industry customers every two years and operates a programme of customer care visits throughout the year. The results and discussions are recorded and follow-up actions are communicated to the individual customers and in more general terms to the industry.

## 5. Review of effectiveness

As Accounting Officer, I have responsibility for reviewing the effectiveness of the system of internal control. My review of the effectiveness of the system of internal control is informed by:

- the work of our internal auditors and their audit reports;
- the executive managers within the agency, who have responsibility for the development and maintenance of the internal control framework;
- comments made by the National Audit Office in their management letter and other reports.

I have been advised on the implications of the result of my review of the effectiveness of the system of internal control by the Management Board and the Audit & Risk Committee and a plan to address weaknesses and ensure continuous improvement of the system is in place.

The Audit & Risk Committee's advice continues to be valuable in assisting the VMD in the development of corporate governance, risk management and control strategies. At each meeting the Committee is given the opportunity to:

- comment on the Risk Register;
- advise the Chief Executive and the Management Board on issues of risk, control and governance;
- review the VMD's business processes, providing assurance on the effectiveness of the systems of internal control;
- review the work and performance of Internal Audit and its recommendations, including the adequacy of management's responses;
- discuss progress reports and the management letter from our external auditors, the National Audit Office.

The VMD's Management Board:

- reviews the VMD's operational management, risk management and service delivery;
- reviews progress towards achievement of key performance targets;
- receives reports from the Chairman of the Audit & Risk Committee.

The Internal Audit Service, currently provided by RSM Tenon:

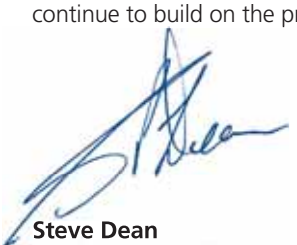
- operates under the requirements set out in Government Internal Audit Standards and the IIA-UK's International Standards for the Professional Practice of Internal Auditing;
- provides regular reports following review and evaluation of the Agency's risk management, control and governance arrangements, making recommendations for improvements where appropriate.

Defra's Internal Audit team:

- facilitates a workshop to help the Audit & Risk Committee and senior staff make informed judgments on risk management.

RSM Tenon's Head of Internal Audit has provided an independent opinion on the adequacy and effectiveness of the Agency's risk management framework and key control processes during the year. The report concluded that for the 12 months ended 31 March 2010, the VMD had adequate and effective internal control and risk management processes to manage the achievement of the organisation's objectives.

While no significant internal control problems have been identified during the year, I recognise that the VMD needs to continue to build on the procedures and processes that it already has in place to manage risk.



**Steve Dean**
Chief Executive
25 May 2010

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

I certify that I have audited the financial statements of the Veterinary Medicines Directorate (the Agency) for the year ended 31 March 2010 under the Government Resources and Accounts Act 2000. These comprise the Operating Cost Statement, the Statement of Changes in Taxpayers' Equity, the Statement of Financial Position, the Statement of Cash Flows and the related notes. These financial statements have been prepared under the accounting policies set out within them. I have also audited the information in the Remuneration Report that is described in that report as having been audited.

## Respective responsibilities of the Chief Executive and auditor

As explained more fully in the Statement of Accounting Officer's Responsibilities, the Chief Executive is responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view. My responsibility is to audit the financial statements in accordance with applicable law and International Standards on Auditing (UK and Ireland). Those standards require me and my staff to comply with the Auditing Practices Board's Ethical Standards for Auditors.

## Scope of the audit of the financial statements

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. This includes an assessment of: whether the accounting policies are appropriate to the Agency's circumstances and have been consistently applied and adequately disclosed; the reasonableness of significant accounting estimates made by the Agency; and the overall presentation of the financial statements.

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

## Opinion on Regularity

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

## Opinion on the financial statements

In my opinion:

- the financial statements give a true and fair view, of the state of the Agency's affairs as at 31 March 2010, and of the net operating cost, changes in taxpayers' equity and cash flows 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 other matters

In my opinion:

- the part of the Remuneration Report to be audited has been properly prepared in accordance with HM Treasury directions made under the Government Resources and Accounts Act 2000; and
- the information given in the 'How We are Organised', the 'Management Commentary', the 'Environmental Matters and Social and Community Issues', and 'Meeting our Targets', included within the annual report for the financial year for which the financial statements are prepared, is consistent with the financial statements.

## 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
- the financial statements are not in agreement with the accounting records or returns; or
- I have not received all of the information and explanations I require for my audit.
- the Statement on Internal Control does not reflect compliance with HM Treasury's guidance.

# The Certificate and Report of the Comptroller and Auditor General to the House of Commons (continued)

## Report

I have no observations to make on these financial statements.

**Amyas C E Morse**
Comptroller and Auditor General
National Audit Office
157-197 Buckingham Palace Road
Victoria
London
SW1W 9SP
27 May 2010

# Operating Cost Statement
## for the year ended 31 March 2010

| | Note | 2010 | | | 2009 |
|---|---|---|---|---|---|
| | | Staff costs £000 | Other costs £000 | Income £000 | £000 |
| **Administration Costs:** | | | | | |
| Staff costs | 5 | **(7,230)** | | | (6,909) |
| Other administrative costs | 6 | | **(7,859)** | | (7,873) |
| Operating Income | 3 | | | **15,051** | 14,970 |
| **Totals** | | **(7,230)** | **(7,859)** | **15,051** | 188 |
| **Net Operating (Cost)/Income** | | | | **(38)** | 188 |

All activities arise from continuing operations.

All of the above income and expenditure is classified as "Administration" for Resource Accounting purposes.

The notes on pages 46 to 55 form part of these accounts.

# Statement of Financial Position
## as at 31 March 2010

| | Note | 2010 | | 2009 | | 2008 | |
|---|---|---|---|---|---|---|---|
| | | £000 | £000 | £000 | £000 | £000 | £000 |
| **Non-current assets:** | | | | | | | |
| Property, plant and equipment | 7 | **6,091** | | 5,534 | | 5,810 | |
| Intangible assets | 8 | **102** | | 100 | | 135 | |
| **Total non-current assets** | | | **6,193** | | 5,634 | | 5,945 |
| **Current assets:** | | | | | | | |
| Trade and other receivables | 9 | **2,984** | | 2,756 | | 1,832 | |
| Cash and cash equivalents | 10 | **2,468** | | 3,528 | | 5,415 | |
| **Total current assets** | | | **5,452** | | 6,284 | | 7,247 |
| **Total assets** | | | **11,645** | | 11,918 | | 13,192 |
| **Current liabilities:** | | | | | | | |
| Trade and other payables | 11 | **(1,746)** | | (1,860) | | (2,266) | |
| **Total current liabilities** | | | **(1,746)** | | (1,860) | | (2,266) |
| **Assets less liabilities** | | | **9,899** | | 10,058 | | 10,926 |
| **Taxpayers' equity** | | | | | | | |
| General fund | | | **6,922** | | 7,702 | | 8,338 |
| Revaluation Reserve | | | **2,977** | | 2,356 | | 2,588 |
| **Total taxpayers' equity** | | | **9,899** | | 10,058 | | 10,926 |

**S P Dean**
Chief Executive and Agency Accounting Officer

25 May 2010

The notes on pages 46 to 55 form part of these accounts.

# Statement of Cash Flows
## for the year ended 31 March 2010

| | Note | 2010 | 2009 |
|---|---|---|---|
| | | £000 | £000 |
| **Cash flows from operating activities:** | | | |
| Net operating (cost)/ income | | **(38)** | **188** |
| | | | |
| Adjustments for non-cash transactions: | | | |
| Depreciation, amortisation and revaluation losses | 6 | 347 | 354 |
| Cost of capital charged to General Fund | 6 | 217 | 221 |
| Defra service charges to General Fund | 6 | 953 | 419 |
| Auditors remuneration charged to General Fund | 6 | 38 | 36 |
| Increase in accruals for non-current assets | | 29 | 39 |
| Increase in trade and other receivables | | (228) | (924) |
| Decrease in trade and other payables | | (114) | (406) |
| | | | |
| **Net cash inflow/(outflow) from operating activities** | | **1,204** | **(73)** |
| | | | |
| **Cash flows from investing activities:** | | | |
| Purchase of property, plant and equipment | | (246) | (263) |
| Purchase of intangible assets | | (68) | (51) |
| | | | |
| **Net cash outflow from investing activities** | | **(314)** | **(314)** |
| | | | |
| **Cash flows from financing activities:** | | | |
| Repayment of Defra operational funding | | (1,950) | (1,500) |
| | | | |
| **Net financing:** | | | |
| | | | |
| **Net decrease in cash and cash equivalents** | | **(1,060)** | **(1,887)** |
| | | | |
| **Cash at the beginning of the year** | | **3,528** | **5,415** |
| **Cash at the end of the year** | 10 | **2,468** | **3,528** |

The notes on pages 46 to 55 form part of these accounts.

# Statement of Changes in Taxpayers' Equity
## for the year ended 31 March 2010

| | Note | General Fund £000 | Revaluation Reserve £000 | Total Reserves £000 |
|---|---|---|---|---|
| **Balance at 1 April 2008** | | **8,502** | **2,588** | **11,090** |
| Changes in accounting policy – IFRS transition adjustment | *2* | (164) | – | (164) |
| **Restated balance at 1 April 2008** | | **8,338** | **2,588** | **10,926** |
| **Changes in taxpayers' equity for 2008/09:** | | | | |
| Net loss on revaluation of property, plant and equipment | | – | (232) | (232) |
| Cost of capital charged to General Fund | *6* | 221 | – | 221 |
| Defra service charges to General Fund | *6* | 419 | – | 419 |
| Auditors remuneration charged to General Fund | *6* | 36 | – | 36 |
| Net operating income for the year | | 188 | – | 188 |
| **Total recognised income and expense for 2008/09** | | 864 | (232) | 632 |
| Repayment of Defra operational funding | | (1,500) | – | (1,500) |
| **Balance at 31 March 2009** | | 7,702 | 2,356 | 10,058 |
| **Changes in taxpayers' equity for 2009/10:** | | | | |
| Net gain on revaluation of property, plant and equipment | | – | 621 | 621 |
| Cost of capital charged to General Fund | *6* | 217 | – | 217 |
| Defra service charges to General Fund | *6* | 953 | – | 953 |
| Auditors remuneration charged to General Fund | *6* | 38 | – | 38 |
| Net operating cost for the year | | (38) | – | (38) |
| **Total recognised income and expense for 2009/10** | | **1,170** | **621** | **1,791** |
| Repayment of Defra operational funding | | (1,950) | – | (1,950) |
| **Balance at 31 March 2010** | | **6,922** | **2,977** | **9,899** |

The notes on pages 46 to 55 form part of these accounts.

# Notes to the Accounts

## 1. Statement of accounting policies

The financial statements have been prepared in accordance with the 2009/10 Financial Reporting Manual (FReM) 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.

Where the FReM permits a choice of accounting policy, the accounting policy that has been judged to be most appropriate to the particular circumstances of the agency for the purpose of giving a true and fair view has been selected. The agency's accounting policies have been applied consistently in dealing with items considered material in relation to the accounts.

## 1.1 Judgements and key sources of estimation uncertainty

The preparation of financial statements requires management to make judgements, estimates and assumptions that affect the amounts reported for assets and liabilities as at the Statement of Financial Position date and amounts reported for income and expenditure during the year. However the nature of estimation means that actual outcomes could differ from those estimates.

In the process of applying the Agency's accounting policies, management has made the following judgements, apart from those involving estimations, which have the most significant effect on the amounts recognised in the financial statements:

**Deferred Income**
The Agency is responsible for managing scientific assessment progress and income received for each assessment. 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 stage of completion of any ongoing assessments.

**Indexation of Non-Current Assets**
The Agency restates the non-current assets at current cost each year as stated in note 1.3 below. Depreciation of the assets is spread across the deemed useful economic life, which also requires the use of judgement.

## 1.2 Accounting convention

These accounts have been prepared under the historical cost convention modified to account for the revaluation of fixed assets at their value to the business by reference to their current costs.

## 1.3 Property, plant and equipment

Items of property, plant and equipment costing £500 or more, where there is an expected useful economic life of more than one year, are carried in the Balance Sheet as non-current assets at fair value. Property is valued by means of a quinquennial valuation supplemented by annual indexation with no interim professional valuation. Non-property assets are carried at fair value using indices provided by the Office for National Statistics. Losses on revaluation are debited to the Revaluation Reserve to the extent that gains have been recorded previously, and otherwise to the Operating Cost Statement.

## 1.4 Depreciation

Property, plant and equipment are depreciated at rates calculated to write down to estimated residual value on a straight-line basis over their estimated useful lives. Depreciation is charged in the month of disposal but not in the month of purchase. Asset lives are normally in the following ranges:

| | |
|---|---|
| Freehold land | Not depreciated |
| Freehold buildings | 40 years |
| IT equipment | 3 years |
| Furniture and fittings | 10 years |
| Office equipment | 10 years |

## 1.5 Intangible non-current assets

Software licences costing £500 or more, where there is an expected useful economic life of more than one year, are carried in the Balance Sheet as intangible non-current assets at depreciated replacement cost as a proxy for fair value. Software licences are amortised over the shorter of the term of the licence and the useful economic life. The useful economic life of software licences is normally estimated to be three years.

# Notes to the Accounts (continued)

### 1.6 Operating income

Operating income is income which relates directly to the operating activities of the agency. It principally comprises fees and charges for services provided on a full cost recovery basis to external customers, as well as public repayment work.

### 1.7 Income recognition

Income received in advance of work done is deferred to future periods to the extent necessary to cover the work estimated to be outstanding at the year end. Income receivable for work done in the year is accrued to the extent necessary to cover the work estimated to be complete at the year end.

### 1.8 Defra service recharges

Defra service recharges are charged to the Operating Cost Statement. Where Defra service recharges are not invoiced they are credited to the General Fund.

### 1.9 Financial instruments

Financial assets and financial liabilities are recognised in the Agency's balance sheet when the Agency becomes a party to the contractual provisions of the instrument.

### 1.10 Cost of capital charge

The cost of capital charge is a notional cost designed to ensure an appropriate return on the taxpayers' equity. The charge applies to the average net assets in the Balance Sheet, with the exception of cash balances, and is accounted for as a movement on the General Fund. The charge is set by HM Treasury and is currently 3.5% (2008/09: 3.5%).

### 1.11 Value Added Tax (VAT)

Most of the activities of the agency are outside the scope of VAT and, in general output tax does not apply and input tax on purchases is not recoverable. Irrecoverable VAT is charged to the relevant expenditure category or included in the capitalised purchase cost of fixed assets. Where output tax is charged or input VAT is recoverable, the amounts are stated net of VAT.

### 1.12 Research and development

The VMD is responsible for the management of Defra's veterinary medicines Research and Development programme. However the programme costs are borne by Defra and not by the VMD. Therefore only the costs of administering the programme are recognised in the VMD accounts.

### 1.13 Pensions

Past and present employees are covered by the provisions of the Principal Civil Service Pension Scheme (PCSPS) which are described in the Remuneration Report and Note 5(iii). The defined benefit schemes are unfunded and are non-contributory except in respect of dependants' benefits. The agency recognises the expected cost of these elements on a systematic and rational basis over the period during which it benefits from employees' services by payment to the PCSPS of amounts calculated on an accruing basis. Liability for payment of future benefits is a charge on the PCSPS. In respect of the defined contribution schemes, the agency recognises the contributions payable for the year.

### 1.14 Leases

All payments under operating leases are charged to the Operating Cost Statement as they are incurred. 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.

### 1.15 Administration and programme expenditure

All of the VMD's income and expenditure is classified as "Administration" for Resource Accounting purposes.

# Notes to the Accounts (continued)

### 1.16 General Fund

The net operating result for each year is transferred from the Operating Cost Statement 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 Operating Cost Statement. This reserve is not distributable.

### 1.17 Revaluation Reserve

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

### 1.18 Disclosure of IFRSs in issue not yet effective

The VMD has reviewed the IFRSs in issue but not yet effective, to determine if it needs to make any disclosures in respect of those new IFRSs that are or will be applicable. References to 'new IFRSs' include new Interpretations and any new amendments to IFRSs and Interpretations. It has been determined the following new IFRSs are relevant to the VMD but will have no significant impact on the VMD's financial statements.

Amendments to IFRSs

- IAS 24 Related Party Disclosures

Amendments to IFRSs resulting from Annual Improvements to IFRSs (May 2008 and April 2009)

- IAS 7 Statement of Cash Flows
- IAS 17 Leases

### 1.19 Major FReM changes for 2010/11

The VMD has reviewed the major FReM changes for 2010/11 and determined the following will have no significant impact on the financial statements.

- Chapter 8 Impairments

The VMD has identified the following accounting change as significant.

- Chapter 11 Income and Expenditure. The removal of Cost of Capital charging from the accounts. From 1 April 2010 notional costs should not be recorded for cost of capital. Cost of Capital charging will be excluded from VMD's accounts. The initial application will have an impact of £217,000 on VMD's financial statements. However the VMD Is required to continue to use a cost of capital charge when setting fees, with the resulting surplus surrendered to Defra by means of a departmental recharge. This will reduce the impact of the initial application on the VMD's financial statements to approximately £40,000.

## 2. First time adoption of IFRS

| | £000 |
|---|---|
| **Net operating income for 2008/09 under UK Generally Accepted Accounting Standards (UK GAAP)** | 24 |
| Adjustment for employee benefit obligations | 164 |
| **Net operating income for 2008/09 under IFRS** | 188 |

There is no adjustment to reported taxpayers' equity or cash flows in 2008/09 between UK GAAP and IFRS.

The employee benefit obligations adjustment relates to an accrual for untaken annual leave in accordance with IAS 19. The accrual was included in the 2008/09 accounts under UK GAAP but was not included in the 2007/08 accounts. The 2008/09 net operating income has therefore been restated to reflect the opening accrual that would have been recorded in the 2008/09 accounts under IFRS.

# Notes to the Accounts (continued)

## 3. Operating income

Income was earned from the following main business segments:

| | 2010 | | | 2009 |
|---|---|---|---|---|
| | **External £000** | **Defra £000** | **Total £000** | Total £000 |
| Veterinary Pharmaceutical Industry | **7,291** | **26** | **7,317** | 7,542 |
| Food Industry | **4,004** | **48** | **4,052** | 4,011 |
| Government | **3** | **3,679** | **3,682** | 3,417 |
| Total | **11,298** | **3,753** | **15,051** | 14,970 |

## 4. Key performance target

The VMD was set one key financial performance target in 2009/10: to achieve cost recovery for the VMD as a whole. However the VMD seeks to achieve 100% cost recovery for each of its business segments.

The 2009/10 results are reported separately for three business segments. The 2008/09 accounts reported the VMD's cost recovery results by five business segments. The prior year results shown below have been adjusted to reflect this change.

For 2009/10 an overall cost recovery of 99.7% was achieved. The cost recovery results for each of the VMD business segments were as follows:

| | 2010 | | | | 2009 | | | |
|---|---|---|---|---|---|---|---|---|
| | **Income £000** | **Expend-iture £000** | **Surplus/ (deficit) £000** | **Cost recovery %** | Income £000 | Expend-iture £000 | Surplus/ (deficit) £000 | Cost recovery % |
| Veterinary Pharmaceutical Industry | **7,317** | **(7,331)** | **(14)** | **99.8** | 7,542 | (7,273) | 269 | 103.7 |
| Food Industry | **4,052** | **(4,166)** | **(114)** | **97.3** | 4,011 | (4,022) | (11) | 99.7 |
| Government | **3,682** | **(3,592)** | **90** | **102.5** | 3,417 | (3,487) | (70) | 98.0 |
| Total | **15,051** | **(15,089)** | **(38)** | **99.7** | 14,970 | (14,782) | 188 | 101.3 |

Costs that cannot be directly allocated to individual business segments are allocated according to staff time utilised. Staff time utilised during the year was as follows.

| | **2010** | 2009 |
|---|---|---|
| | **%** | % |
| Veterinary Pharmaceutical Industry | **74** | 74 |
| Food Industry | **6** | 5 |
| Government | **20** | 21 |
| Total | **100** | 100 |

The information in Notes 3 and 4 is provided for fees and charges purposes.

# Notes to the Accounts (continued)

## 5. Staff costs

(i) Staff costs consist of:

| | 2010 | | | 2009 |
|---|---|---|---|---|
| | **Permanently employed staff** | **Temporary staff** | **Total** | Total |
| | **£000** | **£000** | **£000** | £000 |
| Wages and salaries | **5,377** | **399** | **5,776** | 5,486 |
| Social security costs | **438** | **–** | **438** | 410 |
| Other pension costs | **1,016** | **–** | **1,016** | 1,013 |
| Total net costs | **6,831** | **399** | **7,230** | 6,909 |

During the year there were no recoveries of staff costs in respect of outward secondments (2008/09: £nil).

Included in the permanently-employed staff costs for 2009/10 is an accrual for untaken annual leave of £180,000 (2008/09: £147,000). This comprises of £141,000 (2008/09: £115,000) wages and salaries, £11,000 (2008/09: £9,000) social security costs and £28,000 (2008/09: £23,000) other pension costs.

(ii) Details of the Chief Executive's and senior managers' salaries and pension entitlements are shown in the Remuneration Report.

(iii) The Principal Civil Service Scheme (PCSPS) is an unfunded multi-employer defined benefit scheme but the VMD is unable to identify its share of the underlying assets and liabilities. A full actuarial valuation was carried out at 31 March 2007. Details can be found in the resource accounts of the Cabinet Office: Civil Superannuation (www.civilservice-pensions.gov.uk).

For 2009/10, employers' contributions of £997,000 were payable to the PCSPS (2008/09: £997,000) at one of four rates in the range 16.7% to 24.3% of pensionable pay, based on salary bands (the rates in 2008/09 were between 17.1% and 25.5%).

The scheme's Actuary reviews employer contributions every four years following a full scheme valuation. The salary bands and contribution rates were revised for 2009/10 and will remain unchanged until 2013/14. The contribution rates reflect benefits as they are accrued, not when the costs are actually incurred, and reflect past experience of the scheme. Employees can opt to open a partnership pension account, a stakeholder pension with an employer contribution. Employer's contributions of £19,000 (2008/09: £16,000) were paid to one or more of a panel of three appointed stakeholder pension providers. Employer contributions are age-related and range from 3% to 12.5% of pensionable pay. Employers also match employee contributions up to 3% of pensionable pay.

At the balance sheet date, no contributions were payable to the partnership pension providers (2008/09: £nil) and no contributions were prepaid (2008/09: £nil).

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

(iv) The average number of full-time equivalent persons employed during the year was as follows.

| | 2010 | | | 2009 |
|---|---|---|---|---|
| | **Permanently employed staff** | **Temporary staff** | **Total** | Total |
| Scientific | **49** | **1** | **50** | 45 |
| Administrative | **98** | **11** | **109** | 111 |
| | **147** | **12** | **159** | 156 |

## 6. Other administrative costs

| | Note | 2010 | 2009 |
|---|---|---|---|
| | | £000 | £000 |
| **(i) Direct subcontracting costs** | | | |
| Services provided by Industry | | **2,517** | 2,509 |
| Services provided by Other Government Departments: | | | |
| Food and Environment Research Agency | | **855** | 848 |
| Meat Hygiene Service | | **483** | 482 |
| Animal Health | | **459** | 464 |
| Fisheries Research Services | | **112** | 92 |
| Medicines and Healthcare products Regulatory Agency | | **62** | 309 |
| Centre for Environment, Fisheries and Aquaculture Science | | **13** | 12 |
| | | **4,501** | 4,716 |
| **(ii) Other costs** | | | |
| IT systems maintenance | | **284** | 276 |
| Consultancy | | **224** | 202 |
| Travel and subsistence | | **240** | 201 |
| Training | | **137** | 169 |
| Accommodation | | **82** | 164 |
| Communications | | **125** | 132 |
| Accommodation utility charges | | **–** | 112 |
| Independent expert committees | | **129** | 157 |
| Stationery and publications | | **113** | 117 |
| Operating leases | | **34** | 51 |
| Movement in provision for bad debts | | **21** | (68) |
| Other costs | | **127** | 166 |
| | | **1,516** | 1,679 |
| **(iii) Departmental recharges** | | | |
| Defra service recharges: | | | |
| Invoiced | | **287** | 448 |
| Charged to the General Fund | | **953** | 419 |
| Auditors remuneration | | **38** | 36 |
| | | **1,278** | 903 |
| **(iv) Depreciation, amortisation and revaluation losses** | | | |
| Depreciation of property, plant and equipment | *7* | **272** | 273 |
| Amortisation of intangible assets | *8* | **75** | 77 |
| Losses on disposal of non-current assets | | **–** | 2 |
| Downward revaluation of non-current assets | | **–** | 2 |
| | | **347** | 354 |
| **(v) Cost of capital charge** | | **217** | 221 |
| **Total other administrative costs** | | **7,859** | 7,873 |

Invoiced Defra service recharges relate to Human Resources and Legal services. Defra service charges charged to the General Fund relate to Estates Maintenance and Investigation Services. Within the Operating Cost Statement the full cost of occupation is reflected in relation to buildings that are leased by Defra or specialised properties held on the Agencies' Statement of Financial Position. The costs are proportionate to occupation and include rates, utilities, management overheads and facilities management. For Defra leasehold properties this also includes rental costs.

Included in Auditors Remuneration for the year is £5,000 (2008/09: £6,000) audit work in readiness for International Financial Reporting Standards. No remuneration was paid to the auditors in respect of non-audit work.

# Notes to the Accounts (continued)

## 7. Property, plant and equipment

| | Land £000 | Buildings £000 | IT Equipment £000 | Furniture, Fittings & Equipment £000 | Total £000 |
|---|---|---|---|---|---|
| **Cost or Valuation:** | | | | | |
| At 1 April 2009 | 1,533 | 4,260 | 901 | 368 | 7,062 |
| Additions | – | 69 | 128 | 11 | 208 |
| Disposals | – | – | (130) | (2) | (132) |
| Revaluation | (1,063) | 1,005 | 152 | 3 | 97 |
| At 31 March 2010 | 470 | 5,334 | 1,051 | 380 | 7,235 |
| **Depreciation:** | | | | | |
| At 1 April 2009 | – | (512) | (731) | (285) | (1,528) |
| Charged in year | – | (132) | (126) | (14) | (272) |
| Disposals | – | – | 130 | 2 | 132 |
| Revaluation | – | 644 | (118) | (2) | 524 |
| At 31 March 2010 | – | – | (845) | (299) | (1,144) |
| **Net Book Value:** | | | | | |
| **At 31 March 2010** | **470** | **5,334** | **206** | **81** | **6,091** |
| At 31 March 2009 | 1,533 | 3,748 | 170 | 83 | 5,534 |
| **Cost or Valuation:** | | | | | |
| At 1 April 2008 | 1,460 | 4,494 | 880 | 356 | 7,190 |
| Additions | – | 117 | 108 | 8 | 233 |
| Disposals | – | – | (72) | (5) | (77) |
| Revaluation | 73 | (351) | (15) | 9 | (284) |
| At 31 March 2009 | 1,533 | 4,260 | 901 | 368 | 7,062 |
| **Depreciation:** | | | | | |
| At 1 April 2008 | – | (414) | (710) | (256) | (1,380) |
| Charged in year | – | (142) | (104) | (27) | (273) |
| Disposals | – | – | 70 | 5 | 75 |
| Revaluation | – | 44 | 13 | (7) | 50 |
| At 31 March 2009 | – | (512) | (731) | (285) | (1,528) |
| **Net Book Value:** | | | | | |
| At 31 March 2009 | 1,533 | 3,748 | 170 | 83 | 5,534 |
| At 31 March 2008 | 1,460 | 4,080 | 170 | 100 | 5,810 |

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

The Land and Buildings were valued at 1 April 2010 by an independent valuer 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."

# Notes to the Accounts (continued)

## 8. Intangible assets

| | £000 | | £000 |
|---|---|---|---|
| **Cost or Valuation:** | | **Cost or Valuation:** | |
| At 1 April 2009 | 777 | At 1 April 2008 | 735 |
| Additions | 77 | Additions | 42 |
| Disposals | (175) | Disposals | – |
| At 31 March 2010 | 679 | At 31 March 2009 | 777 |
| **Amortisation:** | | **Amortisation:** | |
| At 1 April 2009 | (677) | At 1 April 2008 | (600) |
| Charge in year | (75) | Charge in year | (77) |
| Disposals | 175 | Disposals | – |
| At 31 March 2010 | (577) | At 31 March 2009 | (677) |
| **Net Book Value:** | | **Net Book Value:** | |
| **At 31 March 2010** | **102** | At 31 March 2009 | 100 |
| At 31 March 2009 | 100 | At 31 March 2008 | 135 |

Intangible assets comprise software licences.

## 9. Trade and other receivables

| | **2010** | 2009 | 2008 |
|---|---|---|---|
| | **£000** | £000 | £000 |
| Amounts falling due within one year: | | | |
| Trade receivables | **551** | 461 | 437 |
| Balances with other central government bodies | **1,015** | 885 | – |
| Other receivables | **35** | 33 | 34 |
| VAT recoverable | **186** | 139 | 187 |
| Prepayments and accrued income | **1,197** | 1,238 | 1,174 |
| | **2,984** | 2,756 | 1,832 |

Trade receivables are shown net of a provision of £94,000 (2008/09: £74,000) (2007/08: £545,000) for bad and doubtful debts. The provision is calculated according to the age and status of the debt and recent sector-specific debt-recovery information.

Included in receivables there are no balances with local authorities, NHS bodies, public corporations or trading funds (2008/09: £nil) (2007/08: £nil).

Balances with other central government bodies at the year end includes £1,015,000 with Defra and its agencies (2008/09: £885,000) (2007/08: £nil).

At the year end the VMD had no receivables falling due after more than one year (2008/09: £nil) (2007/08: £nil).

## 10. Cash and cash equivalents

| | **2010** | 2009 |
|---|---|---|
| | **£000** | £000 |
| Balance at 1 April | **3,528** | 5,415 |
| Net change in cash and cash equivalent balances | **(1,060)** | (1,887) |
| Balance at 31 March | **2,468** | 3,528 |
| The following balances at 31 March were held: | | |
| At Office of HM Paymaster General | **2,453** | 3,500 |
| At commercial banks | **15** | 28 |
| Balance at 31 March | **2,468** | 3,528 |

# Notes to the Accounts (continued)

## 11. Trade and other payables

| | 2010 | 2009 | 2008 |
|---|---|---|---|
| | £000 | £000 | £000 |
| Amounts falling due within one year: | | | |
| Trade payables | 50 | 48 | 379 |
| Balances with other central government bodies | 219 | 213 | 340 |
| Balances with public corporations and trading funds | 12 | 147 | 132 |
| Other taxation and social security | 186 | 179 | 159 |
| Accruals and deferred income | 1,279 | 1,273 | 1,256 |
| | 1,746 | 1,860 | 2,266 |

Included in payables there are no balances with local authorities or NHS bodies (2008/09: £nil) (2007/08: £nil). Balances with other central government bodies at the year end includes £189,000 owing to Defra and its agencies (2008/09: £190,000) (2007/08: £245,000).

At the year end the VMD had no payables falling due after more than one year (2008/09: £nil) (2007/08: £nil).

## 12. Capital commitments

| | 2010 | 2009 |
|---|---|---|
| | £000 | £000 |
| Contracted commitments at 31 March for which no provision has been made in the accounts. | – | 39 |

## 13. Commitments under operating leases

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

| | 2010 | 2009 |
|---|---|---|
| **Obligations under operating leases comprise:** | £000 | £000 |
| **Land and buildings** | | |
| Not later than one year | 7 | 6 |
| **Contract Hire cars** | | |
| Not later than one year | 24 | 4 |
| Later than one year not later than five years | 26 | 1 |
| **Other** | | |
| Not later than one year | – | 6 |
| Later than one year not later than five years | – | 18 |
| | 57 | 35 |

The Land & Buildings commitment relates to the occupation of a Defra leasehold property. The arrangement between the Agency and Defra reflects a future commitment to reimburse Defra for the underlying rental paid to the landlord for the provision of leasehold accommodation.

## 14. Other financial commitments

Defra has entered into a non-cancellable contract (which is not a lease or Private Finance Initiative (PFI) 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. The payments to which the agency is committed at the year-end, analysed by the period during which the commitment expires are as follows.

| | 2010 | 2009 |
|---|---|---|
| | £000 | £000 |
| Later than 10 years but not later than 15 years | 261 | 288 |

# Notes to the Accounts (continued)

## 15. Losses statement

| | 2010 | | 2009 | |
|---|---|---|---|---|
| | **No. of cases** | **Value £000** | No. of cases | Value £000 |
| Claims waived | **2,192** | **109** | 39 | 142 |
| Claims abandoned | **2** | **–** | 292 | 326 |
| | **2,194** | **109** | 331 | 468 |

No individual case exceeded £250,000 in value.

## 16. Related party transactions

As the VMD is an Executive Agency of Defra and is sponsored by them, 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 Veterinary Laboratories Agency, Food and Environment Research Agency, Animal Health and Centre for Environment, Fisheries and Aquaculture Science.

The VMD has transacted with various other central Government bodies. Most of these transactions have been with the Medicines and Healthcare products Regulatory Agency, Meat Hygiene Service, Fisheries Research Services, Government Car and Despatch Agency and the National School of 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 reimbursement for travel and subsistence in the normal course of business.

## 17. Financial instruments

As the cash requirements of the VMD are met 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. 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.

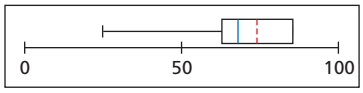
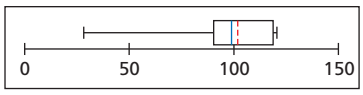
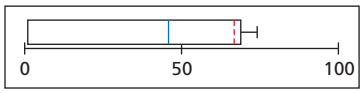
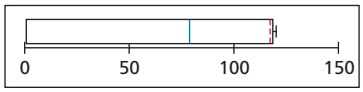
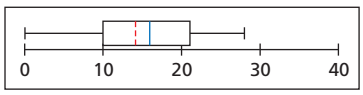
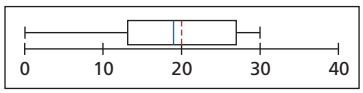
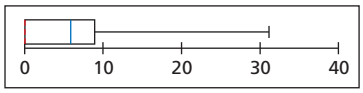
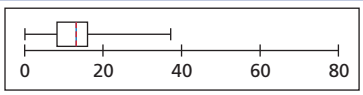
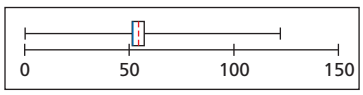
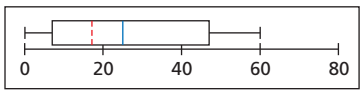
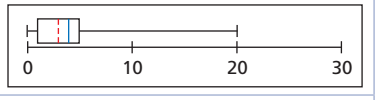
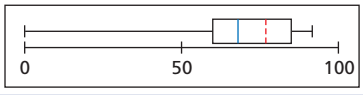
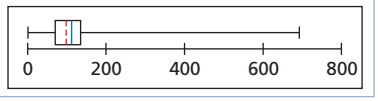
## 18. Post Balance Sheet events

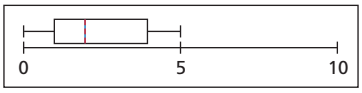
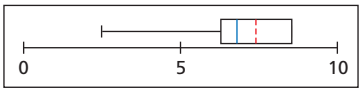
The VMD's financial statements are laid before the House of Parliament by the Secretary of State for Defra. IAS10 requires the VMD to disclose the date on which the accounts are authorised for issue.

The authorised date for issue is 27 May 2010.

# Appendix A

## Meeting our published standards – detailed results

| Category/application type | Number (of Applications) | Performance level (excellent, effective, unacceptable) | Target (days[1]) | Average time in days | Box Whisker Plots Key: - - - = Median —— = Average |
|---|---|---|---|---|---|
| **National MAs and MAPIs** | | | | | |
| Initial assessment | 18 | EXCELLENT | 90 | 64 |  |
| Sign off, VPC or further questions | 30 | EXCELLENT | 120 | 96 |  |
| Sign off and issue (210) | 5 | EXCELLENT | 210 | 194 | [2] |
| **MAPIs for MR products and copy-cats** | | | | | |
| Initial assessment | 20 | EXCELLENT | 75 | 44 |  |
| Sign off, VPC or further questions | 16 | EXCELLENT | 120 | 71 |  |
| Sign off and issue (210) | 15 | EXCELLENT | 210 | 75 | [2] |
| **Variations** | | | | | |
| Type IA – decision | 256 | EXCELLENT | 14 | 8 |  |
| Type IB admin – issue | 132 | EXCELLENT | 30 | 13 |  |
| Type IB – initial assessment | 218 | EXCELLENT | 30 | 14 |  |
| Type IB – sign off | 209 | EXCELLENT | 30 | 4 |  |
| Harmonisation – sign off | 9 | EXCELLENT | 60 | 25 |  |
| Type II – initial assessment | 214 | EXCELLENT | 60 | 42 |  |
| Type II – sign off | 251 | EXCELLENT | 60 | 33 |  |
| **Renewals** | | | | | |
| Administrative – sign off | 33 | EXCELLENT | 30 | 19 |  |
| Full and conditional – initial assessment | 65 | EXCELLENT | 60 | 44 |  |
| Full and conditional – sign off | 24 | EXCELLENT | 120 | 29 |  |

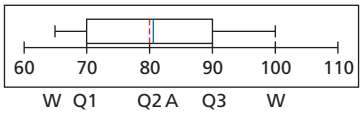
| Category/application type | Number (of Applications) | Performance level (excellent, effective, unacceptable) | Target (days[1]) | Average time in days | Box Whisker Plots Key: – – – = Median —— = Average |
|---|---|---|---|---|---|
| **ATCs** | | | | | |
| Type A, S and B – validate | 24 | EXCELLENT | 5 | 3 |   |
| Type A and S – sign off | 8 | INEFFECTIVE | 30 | 25 | [2] |
| Type B – sign off | 7 | EXCELLENT | 50 | 40 | [2] |
| Type A, S and B – issue | 14 | EFFECTIVE | 5 | 4 |   |
| **Batch release (Immunologicals)** | | | | | |
| Issue | 2,141 | EXCELLENT | 15 | 3 | |
| **AVAs and NFABBAs (inc variations)** | | | | | |
| Assess | 3 | EXCELLENT | 45 | 36 | |
| **Specific Batch Control** | | | | | |
| Validation | 135 | EXCELLENT | 3 | <1 | |
| Initial assessment | 135 | EXCELLENT | 10 | 1 | |
| Assess response | 120 | EXCELLENT | 10 | <1 | |
| Issue | 125 | EXCELLENT | 3 | 1 | |
| **Validation/Issue** | | | | | |
| Validation | 758 | EXCELLENT | 10 | 5 | |
| Issue | 1,380 | EXCELLENT | 10 | 6 | |
| **UKPARs** | | | | | |
| Module 1 | 146 | EFFECTIVE | 30 | 17 | |
| Module 2 | 77 | EXCELLENT | 120 | 89 | |
| Module 3 | 172 | EXCELLENT | 60 | 22 | |

## Box-and-Whisker Plots

Box-and-whisker plots are helpful in interpreting the distribution of days an application may take. The median of a set of data separates the data into two equal parts and data can then be further separated into quantities.

E.g. Application days for 10 applications: 80, 75, 90, 95, 65, 65, 80, 85, 70, 100
65, 65, 70, 75, 80, 80, 85, 90, 95, 100
W Q1 Q2 A Q3 W

Q1 The 1st quartile is the median of the lower part of the data.
Q2 The 2nd quartile is the median of the entire set.
Q3 The 3rd quartile is the median of the upper part of the data.
W The whiskers represent the smallest and largest value.
A The average number of days.



| Category/application type | Number (of Applications) | Performance level (excellent, effective, unacceptable) | Target (days[1]) |
|---|---|---|---|
| **European Centralised** | | | |
| Rapp – Initial assessment | 4 | EXCELLENT | 70 |
| Co-Rapp – Provide comments on assessment report by 85 days | 2 | EXCELLENT | 85 |
| UK as Member only – LOQ by 100 days | 10 | EXCELLENT | 100 |
| **Mutual Recognition RMS** | | | |
| Production of Final Assessment Report by 1st 90 days | 12 | EXCELLENT | 90 |
| RMS Circulate the Consolidated List of Questions by Day 57 | 11 | EXCELLENT | 57 |
| Assessment of Responses by 2nd 70 days | 10 | EXCELLENT | 70 |
| Procedure completed by 2nd 90 days | 10 | EXCELLENT | 90 |
| **CMS** | | | |
| CMS send any UK comments by Day 54 | 27 | EXCELLENT | 54 |
| Procedure completed by 2nd 90 days | 16 | EXCELLENT | 90 |
| **Decentralised RMS** | | | |
| Production of Assessment Report within 70 days | 26 | EXCELLENT | 70 |
| Production of Assessment Report within 120 days | 17 | EXCELLENT | 120 |
| RMS Circulate the Consolidated List of Questions in Phase 2 by Day 30 | 13 | EXCELLENT | 30 |
| Assessment of Responses by 70 days | 13 | EXCELLENT | 70 |
| **CMS** | | | |
| UK comments sent by 100 days | 53 | EXCELLENT | 100 |
| CMS Send any UK Comments in Phase 2 by Day 25 | 30 | EXCELLENT | 120 |
| UK acceptance/referral sent by 90 days [2nd phase] [210 days] | 24 | EXCELLENT | 90 [210] |
| **European Variations Type IB EUCE Rapp** | | | |
| Initial Assessment Completed | 19 | EXCELLENT | |
| **Type II EUCE Rapp** | | | |
| Initial Assessment Completed | 12 | EXCELLENT | |
| **Type II – Mutual Recognition RMS** | | | |
| PAR circulated | 58 | EXCELLENT | 40 |
| CLOQ circulated | 61 | EXCELLENT | 59 |
| **Type IB – Mutual Recognition CMS** | | | |
| CLOQ circulated | 58 | EXCELLENT | 30 |
| **Type IA – Mutual Recognition CMS** | | | |
| Determined within 14/30 days | 103 | EXCELLENT | 14/30 |
| **Type II Mutual Recognition CMS** | | | |
| UK comments sent by 55 days | 57 | EXCELLENT | 55 |
| UK comments sent by 85 days | 45 | EXCELLENT | 85 |
| **Type IB Mutual Recognition CMS** | | | |
| UK comments sent by 20 days | 53 | EXCELLENT | 20 |
| UK comments sent by 50 days | 9 | EXCELLENT | 50 |

| Category/application type | Number (of Applications) | Performance level (excellent, effective, unacceptable) | Target (days[1]) |
|---|---|---|---|
| **European Renewals Mutual Recognition RMS** | | | |
| PAR circulated by 40 days | 26 | EXCELLENT | 40 |
| CLOQ circulated by 59 days | 24 | EXCELLENT | 59 |
| **Mutual Recognition CMS** | | | |
| UK Comments sent by 55 days | 46 | EXCELLENT | 55 |
| UK Comments sent by 85 days | 48 | EXCELLENT | 85 |
| **Customer Relations Customer Care Visits** | | | |
| Number of letters sent | 132 | EXCELLENT | |
| Number of visits | 2 | EXCELLENT | |
| Minutes sent (within 4 weeks) | 2 | EXCELLENT | |
| Publishing themes | 2008/09 | EXCELLENT | |
| **Unreturned authorisation documents** | | | |
| Right first time (Authorisations) | 1,894 | EFFECTIVE | |
| **SARs** | | | |
| Enter human SARs | 103 | EXCELLENT | 2 |
| Enter serious animal SARs | 1,555 | EXCELLENT | 2 |
| Enter environmental SARs | 3 | EXCELLENT | 2 |
| Enter non-serious SARs | 1,580 | EXCELLENT | 10 |
| Report to Eudravigilance | 1,530 | EXCELLENT | 15 |
| **Inspections** | | | |
| Inspect | 38 | EXCELLENT | |
| Prepare report | 34 | EXCELLENT | 60 |
| Issue Certificate | 23 | EXCELLENT | 90 |

[1] The days are specified as either calendar days or clock days according to the target and as set out in detail in the published standards.
[2] Box whiskers have been omitted due to low numbers of applications.

# Appendix B
# Advisory Committees

## Veterinary Products Committee (VPC)

The VPC is a statutory committee established to:

i) provide the Secretary of State with scientific[†] advice on any aspect of veterinary medicinal products and specified feed additives;

ii) hear representations on decisions relating to the granting, refusal, variation, suspension or revocation of a marketing authorisation for a veterinary medicinal product or an animal test certificate;

iii) promote the collection of information relating to suspected adverse reactions for the purpose of enabling the advice at i) above to be given.

Each year the VPC will publish a report of its activities and those of its sub-committees.

[†] Scientific advice means all aspects, including benefit/risk analysis, of the safety, quality and efficacy of a veterinary medicinal product apart from regulatory issues.

## Appraisal Panel for Human Suspected Adverse Reactions to Veterinary Medicines

The Appraisal Panel's terms of reference are to:

- evaluate all suspected adverse reactions to veterinary medicinal products in humans to:
  - i) identify any trends and signals of emergent problems,
  - ii) generate hypotheses as to possible causes of these trends;
- monitor the consequences of recommendations for changes in working practices or use;
- report its findings to the VPC; and
- produce an Annual Report of its findings.

## Medical and Scientific Panel (MSP)

The terms of reference of the MSP are to:

- evaluate research currently available, and in progress, on OP sheep dip products in relation to possible human exposure;
- advise on any additional work that may be needed to elucidate the potential long-term effects on humans of OP sheep dip;
- advise on the suitability of any projects submitted for research; and
- report its findings to the VPC, as its sub-committee.

## Veterinary Residues Committee (VRC)

The VRC was established in January 2001. Following a review in 2004 it produced revised terms of reference. These are to advise Ministers[A] (where appropriate) and the CEOs of the VMD and the FSA on:

- the incidence and concentrations of residues of veterinary medicines[B] in samples collected under the VMD's surveillance programmes, with particular reference to food safety and observance of withdrawal periods for veterinary medicines[C];
- to assess and advise on the scope and operation of the VMD statutory surveillance programme within the requirements of European Community legislation;
- to formulate an annual non-statutory surveillance programme, advise on the scope and results of relevant FSA surveys and consider the need for further analytical surveys;
- to set up subgroups as necessary to further the work and objectives of the VRC; and
- to publish an Annual Report on Veterinary Residues Surveillance, and to communicate the VRC's findings and recommendations to Government and stakeholders in a comprehensive, understandable and timely way.

[A] The Ministers referred to are: The Secretary of State for Environment, Food and Rural Affairs, Ministers of the Scottish Executive, the National Assembly for Wales and the Minister for Agriculture and Rural Development Northern Ireland.

[B] In addition to veterinary medicines, surveillance also covers banned substances, heavy metals (lead and cadmium), malachite green, organochlorines (OCs), organophosphates (OPs), and polychlorinated biphenyls (PCBs).

[C] A withdrawal period is the length of time after end of treatment with a veterinary medicine that must pass so that any residues in edible tissues will have depleted to below the Maximum Residue Limit (MRL).

# Appendix C

## VMD Publications[22] and Statutory Instruments

### Publications 2009/10

Veterinary Medicines Guidance Notes 1-27 (updated versions)

Veterinary Medicines Guidance Note 28 – Practice Premises Registration and Inspection (new)

Veterianary Medicines Guidance Note 29 – Controlled Drugs (new)

Veterinary Medicines Guidance Note 30 – Guidance for Manufacturers – GMP Requirements (new)

Code of Practice for the responsible use of animal medicines on the farm (updated version)

Code of Practice for Suitably Qualified Persons (SQPs)

### Statutory Instruments coming into effect in 2009/10

The Veterinary Medicines Regulations 2009

SI 2009 No 2297

Made: 12 August 2009

Came into force: 1 October 2009

22. VMD publications can be found at www.vmd.gov.uk under Publications

# Appendix D

## VMD People Strategy – Our Commitment to Staff

The VMD recognises the diversity of our staff and the role this plays in focusing our performance on our business. We seek to treat everyone fairly and encourage, value and recognise everyone's views and contribution.

The VMD's overall aim is to create a working environment within which good management practice is promoted, recognised and rewarded; and that ensures that each member of staff is:

- treated with respect;
- valued for the differences, skills and experience they bring to work;
- encouraged and enabled to develop their potential in the workplace and to progress;
- free from harassment, bullying and discrimination; and
- able to work without fear of blame.

In developing our policies and services we are open to the views of different stakeholders and customers, and take full account of them.

# Appendix E

## Audit & Risk Committee Annual Report 2009/10 to the VMD Chief Executive and Accounting Officer

### Introduction

The purpose of the VMD's Audit & Risk Committee is to reassure the VMD's Chief Executive Officer and Accounting Officer that effective measures are in place to justify confidence in:

- the accuracy of financial information;
- the control of risk; and
- the efficacy of corporate governance, managerial controls and audit procedures.

### Membership

The membership of the VMD Audit & Risk Committee during the year was:

John Preston (Chairman) – External member of the VMD Management Board
Brian Morris – External member of the VMD Management Board
David Skilton – External member of the VMD Management Board
David Rayner (Secretary) – VMD Head of Core Services & Communications.

The following persons are normally invited to attend meetings to provide advice to the Committee:

Steve Dean – VMD CEO
John FitzGerald – VMD Operations Director
Jackie Atkinson – VMD Authorisations Director
Simon Brown – VMD Head of Finance.

In addition, representatives from Internal Audit and the National Audit Office participate in the meetings.

### Meetings

The Committee met formally on four occasions in 2009/10. The frequency and timing of meetings were scheduled to correspond with the key stages of the budgetary and reporting cycle.

### Work of the Committee

Overall, the Committee's work during the year included:

1. Tracking and monitoring the annual cycle of processes through which are prepared the Annual Accounts and the Statement on Internal Control.
2. Monitoring the strategy and processes through which internal and external audit and risk management are planned, executed, implemented and evaluated.
3. Examining selected aspects of the VMD's infrastructure for its operations, governance and audit; in particular:
   - Internal Audit (September 2009)
   - Budgeting (December 2009)
   - Antimicrobials (March 2010).

Two of the external members attended the Best Practice for Audit Committees in Government Conference (New Challenges for the Audit Committee) sponsored by HM Treasury and The National School of Government on 16 November 2009.

### Conclusion

The VMD Audit & Risk Committee concludes that it is reasonable for the VMD Accounting Officer to feel confident in relying on the particular processes that the Committee has reviewed in the course of the year. From these examinations, more general confidence in the VMD's operations, governance and audit seems reasonable, after allowing for the Committee's limited role and resources.

**John M Preston**
Chairman

# Glossary

| | |
|---|---|
| AMI | Animal Medicines Inspectorate |
| BEMA | Benchmarking of European Medicines Agencies |
| CEO | Chief Executive Officer |
| CETV | Cash Equivalent Transfer Value |
| CMS | Concerned Member State |
| COT | Committee on Toxicity of Chemicals in Food |
| CVMP | Committee for Veterinary Medicinal Products |
| CVO | Chief Veterinary Officer |
| DARC | Defra Antimicrobial Resistance Coordination Group |
| Defra | Department for Environment, Food & Rural Affairs |
| DH | Department of Health |
| EC | European Commission |
| EFQM | European Foundation for Quality Management |
| EMA | European Medicines Agency |
| eSPC | Electronic Summary of Product Characteristics |
| EU | European Union |
| Fera | Food and Environment Research Agency |
| FReM | Financial Reporting Manual |
| FSA | Food Standards Agency |
| GMP | Good Manufacturing Practice |
| HMA | Heads of Medicines Agencies |
| HSE | Health and Safety Executive |
| IFRS | International Financial Reporting Standards |
| IiP | Investors in People |
| IT | Information Technology |
| IVMPs | Immunological Veterinary Medicinal Products |
| MA | Marketing Authorisation |
| MAFF | Ministry of Agriculture, Fisheries and Food |
| MAVIS | Marketing Authorisations Veterinary Information Service |
| MHRA | Medicines and Healthcare products Regulatory Authority |
| MRLs | Maximum Residue Limits |
| NSS | National Surveillance Scheme |
| OAB | Owner Advisory Board |
| OGOP | Official Group for Organophosphates |
| OPs | Organophosphates |
| PCBs | Polychlorinated Biphenyls |
| PCSPS | Principal Civil Service Pension Scheme |
| PSURs | Periodic Safety Update Reports |
| PuARs | European Public Assessment Reports |
| R&D | Research and Development |
| RCVS | Royal College of Veterinary Surgeons |
| RMS | Reference Member State |
| RPI | Retail Prices Index |
| SAES | Small Animal Exemption Scheme |
| SARs | Suspected Adverse Reactions |
| SARSS | Suspected Adverse Reaction Surveillance Scheme |
| SBEWS | Sustainable Built Environment Workplace Support |
| SD | Sustainable Development |
| SDC | Sustainable Development Commission |
| SIC | Special Import Certificate |
| SP | Synthetic Pyrethroid |
| SPC | Summary of Product Characteristics |
| SQP | Suitably Qualified Person |
| STC | Special Treatment Certificate |
| SWM | Sustainable Workplace Management |
| UKPARs | United Kingdom Public Assessment Reports |
| VMD | Veterinary Medicines Directorate |
| VMP | Veterinary Medicinal Product |
| VMR | Veterinary Medicines Regulations |
| VPC | Veterinary Products Committee |
| VRC | Veterinary Residues Committee |

**ASSURING THE SAFETY, QUALITY & EFFICACY OF VETERINARY MEDICINES**

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