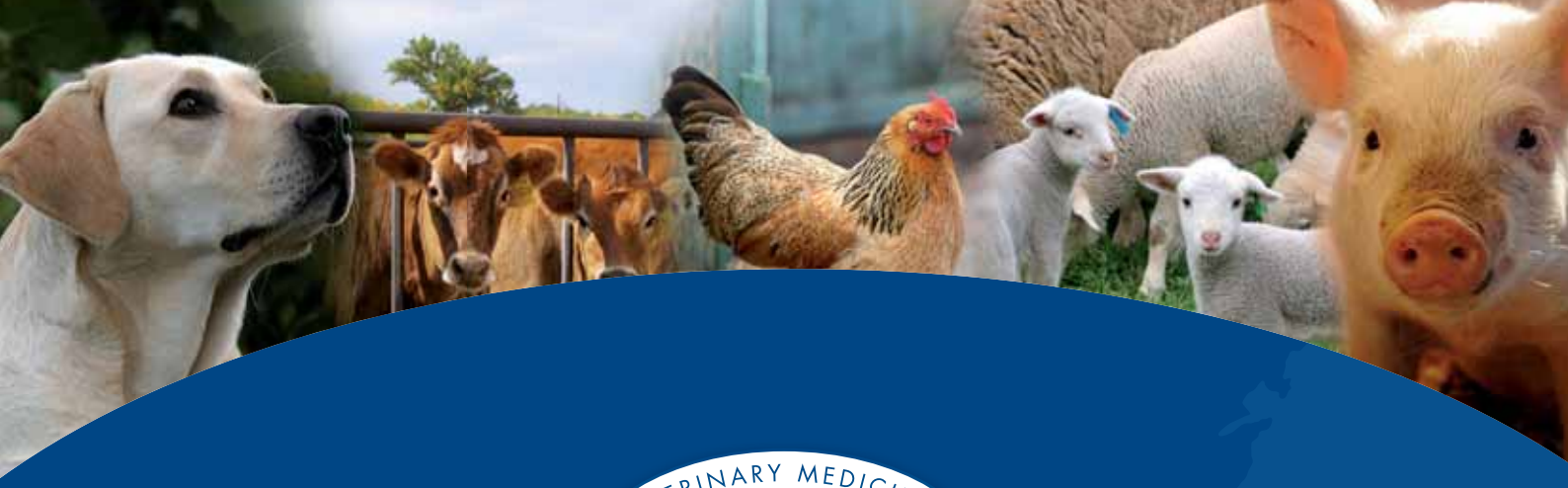

ASSURING THE SAFETY, QUALITY & EFFICACY OF VETERINARY MEDICINES

Veterinary Medicines Directorate Annual Report & Accounts

2008/09

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 2008/09

INVESTOR IN PEOPLE

Presented to Parliament in pursuance of section 7 of the Government Resources and Accounts Act 2000.
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Contents

Chief Executive's Foreword

Our year opened against the background of the ongoing threat of a merger that few seemed to want (including customers, stakeholders, the potential merger partners and our staff). Nevertheless, the Veterinary Medicines Directorate (VMD)[1] and the Department for Environment, Food and Rural Affairs (Defra)[2] staff, with considerable input from the other potential merger partners, were able to prepare a constructive and impartial business case as the basis for a public consultation. The outcome was strong support for retaining the VMD as an Agency of Defra and this led to a Ministerial decision at the end of our financial year. Thus the VMD will remain as a stand alone Defra Agency for the foreseeable future and this is very good news for the Pharmaceutical Industry, stakeholders and the staff of the VMD and we will start the 2009/10 business year with a clear way forward.

Steve Dean

With our future status agreed, we can focus on developing the business of the VMD, paying particular attention to the economic downturn, which will affect all of those we serve. This past year we were able to contain fee rises across our authorisations work as a result of increased efficiency, driven largely by our Information Technology (IT) improvements and related procedural processes. We continue to try to apply the regulations related to animal medicines in a practical and effective manner wherever possible. Our constant aim is the protection of animal and human health and shielding the environment from unwanted damage, but doing so with the minimum of bureaucratic interference in people's businesses and lives.

I was immensely proud of our staff when we were able to authorise the use of vaccines against the serotype 8 Bluetongue Virus (BTV8) and in time for the risk period in the summer months. BTV8 threatened to be a devastating outbreak of disease for the UK agricultural community and the timely availability of a vaccine was a crucial factor in the Defra plan to combat the disease. VMD staff spent many hours working with our colleagues in the Pharmaceutical Industry to resolve the regulatory issues in time and despite the urgency of this work they were also able to maintain the standards our customers expect for all our authorisation work. Thus there was no adverse effect on the many other product application timetables running at the same time. This tremendous achievement required the support of too many VMD staff to mention but I remain immensely proud of what they achieved together.

We have laid the foundations of several changes in the way the regulations for veterinary medicines operate during the year. The registration of veterinary practice premises became mandatory in April 2009 and it is pleasing to report the successful launch of this objective, with the VMD working efficiently alongside colleagues in the Royal College of Veterinary Surgeons (RCVS)[3] to bring this into effect smoothly. Whilst it is an added burden on the veterinary profession, it is one that will allow the public to be reassured that the quality of veterinary medicines supplied to them by their local veterinary surgeons meet all the regulatory requirements. This is surely important in a world where the public is being constantly offered medicines of unknown quality on the Internet, where the reliability of advice and guarantees of safety and effectiveness are not always assured. For this reason the VMD has also been working hard to ensure that Internet suppliers of veterinary medicines are also meeting the requirements of the law. We have had considerable success in this but there is much more work to be done here if the public are to be protected from illicit and illegal offers of medication for the treatment of their animals. On the same issue of illegal medicines, we continue to pursue those in society who seek to market illegal products and we have several significant prosecutions pending against those who blatantly seek to flout the law in this regard. We have also provided advice and specialist support to colleagues in the Serious Organised Crime Agency (SOCA)[4] where potential misuse of veterinary medicines has arisen as a factor in drug abuse cases. Finally on the issue of controlling drug abuse, the Home Office and the Agency have liaised several times during the year to draft revised legal requirements for Controlled Drugs (CD). We anticipate some legislation will be in operation by October 2009 subject, as always, to the outcomes of a public consultation. The outcome should be increased clarity for veterinary surgeons in delivering their professional and public responsibilities in this area.

The VMD is increasingly required to work in a European environment as the market in veterinary medicines heads towards harmonisation. VMD staff have been focused on several key policy areas including improving the availability of veterinary medicines for a broader range of animal species and ailments; the important issue of antimicrobial resistance; the application of pharmacovigilance; better regulation proposals for improving the authorisation of veterinary medicines and the

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 RCVS at www.rcvs.org.uk
4. You can find out more about SOCA and its work at www.soca.gov.uk

surveillance of residues arising from their use; and the transparency of regulatory decisions. We have also focused our efforts on a number of practical and procedural issues such as: improved pan European Union (EU) telematics IT systems (including preparing for electronic submission of dossiers); improving the efficient use of the resources available to the European Medicines Regulatory Network; streamlining regulatory processes and procedures; and implementing the full range of legislative requirements. All of this work has required many VMD people to engage with their EU counterparts in other national regulatory bodies. I am pleased to report our good reputation for the quality of our work and our enthusiasm for engagement in the various projects is well established with those engaged in regulating human and veterinary medicines across the EU.

I hope my annual review demonstrates how much of our work increasingly goes beyond the routines of veterinary medicine authorisation (including the surveillance of adverse reaction reports and inspection work) and residue monitoring, the backbone of our 'routine day job'. The majority of the VMD are heavily engaged in our day-to-day routine work and they consistently deliver a high quality performance, year after year. We are not complacent however, and constantly strive to improve the quality and efficiency of our regulatory work, with a sharp eye on economy. Much of this is reported elsewhere in this Annual Report but I wish to publicly pay tribute to all VMD staff on their performance for, despite being obviously concerned about the future of the Agency at the outset of the year, they have maintained a highly professional attitude throughout and from the results of various customer surveys and the direct feedback I receive from customers and stakeholders, I know this is appreciated by many people whose lives we influence in some way or another. The VMD prides itself on being practical and approachable and I sincerely believe we have achieved this.

Steve Dean
Chief Executive
22 May 2009

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. The vision of the VMD 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 Defra 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)[5] 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 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[6].

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)[7] and the Veterinary Residues Committee (VRC)[8]. 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 this financial year this inspection work was carried out by the Medicines and Healthcare products Regulatory Agency (MHRA)[9] except for sites manufacturing veterinary immunological products or products marketed under the UK Small Animal Exemption Scheme (SAES) which are inspected by the VMD.

Once a product has been authorised, post authorisation surveillance is co-ordinated by the VMD. The Suspected Adverse Reaction Surveillance Scheme (SARSS)[10] monitors and responds to reports of SARs to veterinary medicines in both animals and humans. The National Surveillance Scheme (NSS)[11] 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 of veterinary medicines. The non-statutory residues surveillance programme supplements the statutory scheme by analysing samples of imported and home produced 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)[12], 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.

5. You can find out more about the work of the FSA via their website www.food.gov.uk
6. You can find out more about the DARC Group via www.vmd.gov.uk under General Information
7. You can find out more about the work of the VPC via their website www.vpc.gov.uk
8. You can find out more about the work of the VRC via their website www.vet-residues-committee.gov.uk
9. You can find out more about the MHRA via their website www.mhra.gov.uk
10. You can find out more about the SARSS via www.vmd.gov.uk under General Information
11. You can find out more about the NSS via www.vmd.gov.uk under General Information
12. You can find out more about the work of the AMI via www.vmd.gov.uk

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 MAs; pharmacovigilance for veterinary medicines; and the licensing and inspection of manufacturers and wholesale dealers of veterinary medicines. The main customers are Marketing Authorisation Holders (MAHs); 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 (EMEA)[13]; Department of Health (DH)[14]; FSA and consumers.

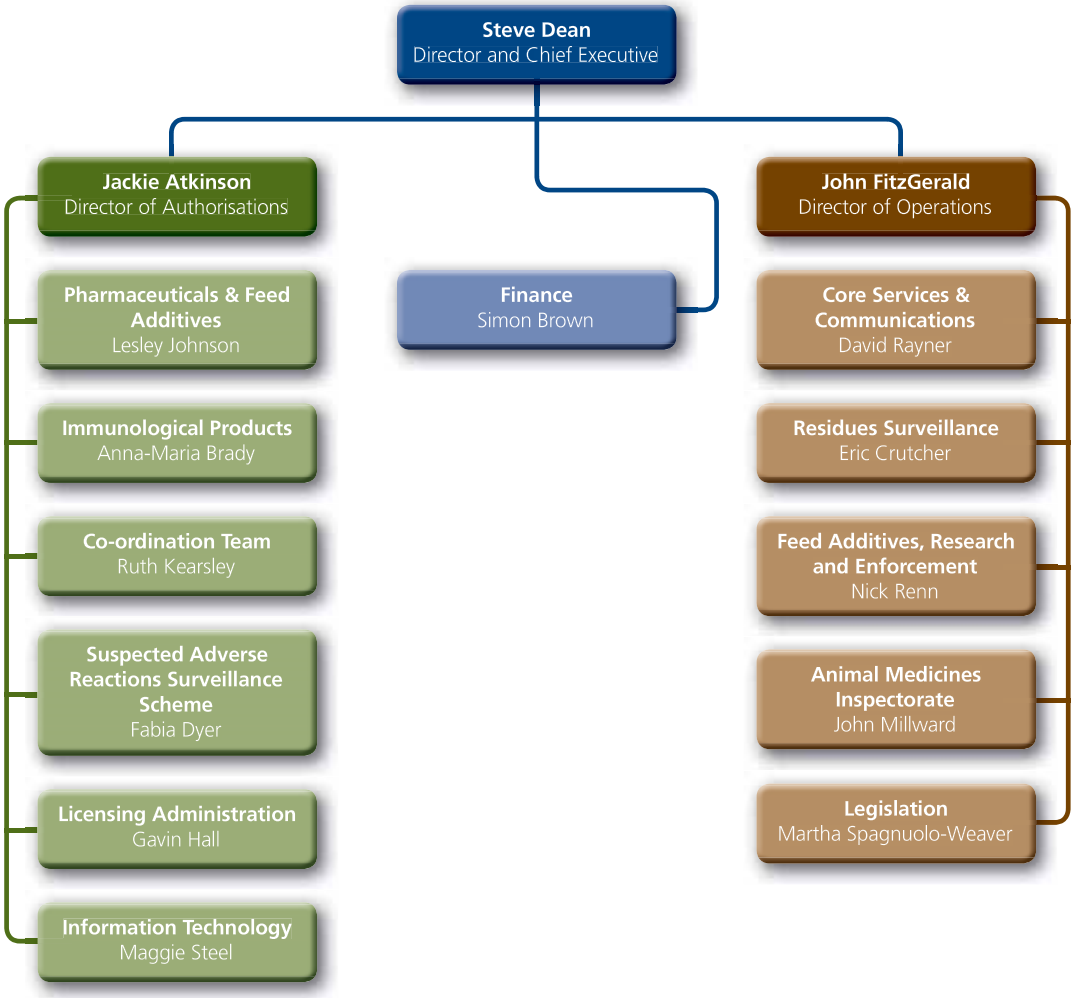
Residues, responsible for the surveillance for residues of veterinary medicines and banned substances in home produced livestock and animal products and imported animal products, reporting of results and co-ordinating follow-up action. The Residues business has contracts with other agencies and companies 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 stakeholders including consumer representative groups, the EC and the FSA who are responsible for food safety follow-up action.

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

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; 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 Operations team also includes the ***Core Services team,*** which is responsible for providing strategic support and Training and Liaison services as well as the provision of information to customers about our activities and achievements.

The Management Team at 31 March 2009



13. You can find out more about the EMEA via www.emea.europa.eu
14. You can find out more about the DH via www.dh.gov.uk

Management Board

The VMD's Management Board meets four times a year, in June, 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 Chief Executive Officer (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 (TLU) complete the formal membership. Staff have a standing invitation to propose items for the agenda and to attend as observers. During 2008/09 seven members of staff attended the meetings. 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.

The Regulatory Agencies Strategy Board (RASB)/VMD Ownership Advisory Board (OAB)

The RASB provided strategic direction for the VMD and the Pesticides Safety Directorate (PSD) until October 2008, and aimed to maximise the opportunities between the two Agencies for synergies and strategic performance management. Following the merger of PSD with the Health and Safety Executive (HSE)[15] the VMD OAB was formed under the Chairmanship of the Chief Veterinary Officer (CVO), Defra's VMD owner, with similar terms of reference and membership to the RASB. The RASB/OAB met in October, December and February.

The members of the RASB/OAB who served during the year were:

EXTERNAL MEMBERS

Quintin McKellar	Chair (March-September)
Chris Payne	
John Preston	VMD Audit & Risk Committee

INTERNAL MEMBERS

Nigel Gibbens (Chair)	Chief Veterinary Officer
Andrew Robinson	Delivery Strategy Team (October and December meetings)
Kerr Wilson	Pesticides Safety Directorate (October meeting)
Steve Dean	VMD
Fred Landeg	Food & Farming Group (retired mid-2008)
Peter Unwin	Environment
Bob Watson	Science Directorate
Richard Wilkinson	Finance
Tim Foster	Food Standards Agency (October and December meetings)
Alison Gleadle	Food Standards Agency (February meeting)
Les Philpott	Health & Safety Executive
Brian Harding	Food & Farming Group

DEVOLVED MEMBERS

Charles Milne	Scottish Executive Environment and Rural Affairs Department
Christianne Glossop	Chief Veterinary Officer for Wales
Chris Lea	National Assembly for Wales Agricultural Department (appointed February)
Michael Camlin	Agri-Food and Biosciences Institute (Northern Ireland)

Our Finances

The VMD is required to achieve full cost recovery across the three main business areas of Authorisations, Residues and Operations whilst continually striving to improve its efficiency and service delivery.

The costs of authorisation, inspection and statutory residues work are recovered through fees and charges to the relevant industries. 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.

The costs of non-statutory residues, enforcement and other operational work are funded by Defra.

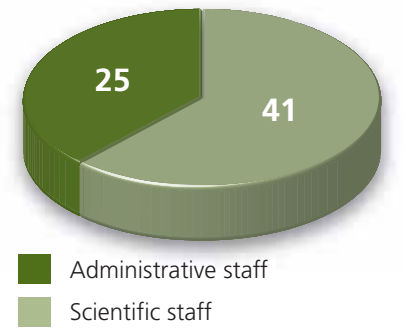
15. You can find out more about the HSE (Health and Safety Executive) at www.hse.gov.uk

Our People

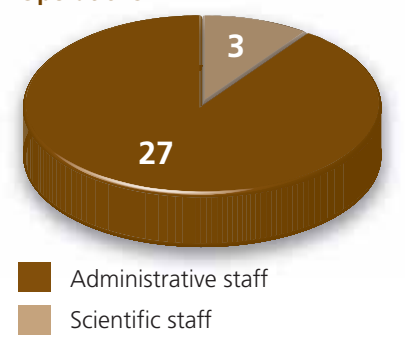
At 31 March 2009 we employed 149 permanent staff, both full and part-time. This included veterinarians, pharmacists, chemists, toxicologists, biologists, IT specialists, administrative and support staff. We supplemented our permanent workforce with 18 colleagues who work on a temporary basis and are supplied by local employment agencies. During the year we lost a total of 1,329 full-time-equivalent days through sickness absence.

Average Permanent Staff Numbers 2008/09

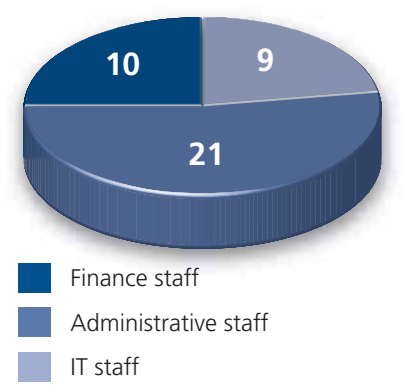
Authorisations



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 delivered 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 2006 in recognition of the continuing efforts in the development and training of its staff. Accreditation was renewed to a higher standard following an inspection against IiP Profiles. Our next assessment under the profile system will take place during June 2009.

The VMD benchmarks itself biennially against the European Foundation for Quality Management (EFQM) Excellence Model recommended by the Cabinet Office. The results of the 2008/09 benchmarking will form part of the 2009/10 Business Improvement Plan. In addition the VMD took part in the EU Benchmarking process led by the Heads of Medicines Agencies (HMA)[16].

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 4 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 government contracts and the legislative periods within the Late Payment of Commercial Debts (Interest) Act 1998 remains at 30 days. In 2008/09 the VMD paid 100% of validated invoices within 30 days and from 1 November 2008 paid 81% of validated invoices within 10 days.

16. You can find out more about the HMA via www.hma.eu

Preparation and Audit of the Accounts

The Accounts have been prepared in accordance with a Treasury Direction dated 18 December 2008 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 are monitored under a net control total by HM Treasury and is 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 2008/09

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)[17] 2008 came into force on 1 October 2008 and introduced changes to clarify some of the provisions of the 2007 Regulations following feedback from stakeholders. They are the result of the annual update to the Regulations and provide a single set of current legislation on veterinary medicines;
- the finalisation and successful implementation of a Quality System in the Good Manufacturing Practice (GMP) inspection team and the initiation of a VMD wide Quality System project;
- the start of registration of veterinary practice premises by the RCVS and the agreement and publication of inspection criteria;
- the introduction of electronic reporting of adverse events by companies to the VMD;
- the implementation of the new intranet; and
- the conclusion of consideration of the recommendation in the Hampton Report[18], with the Secretary of State accepting the overwhelming result of the Defra consultation that the VMD should remain a Defra Agency.

Personal data-related incidents

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

17. You can find out more about the Veterinary Medicines Regulations via www.vmd.gov.uk under General Information/Veterinary Medicines Regulations and Guidance
18. You can find out more about the Hampton Report at www.hm-treasury.gov.uk/hampton

The Secretary of State for Defra announced our targets to Parliament on 11 June 2008. 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 2008/09.

Target 1

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

Highlight The overall performance met the standard defined as effective. The overall score achieved was 132 out of a maximum of 140. Almost all the individual parameters met the standard 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.

Highlight The Key Performance Indicators (KPI) supporting this target were met.

Target 3

To ensure 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.

Highlight Both residues programmes have been completed in accordance with their plans and all results published. The percentage of positive samples 0.6% was similar to previous years.

Target 4

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

Highlight The overall cost recovery was 100.2%. The infrastructure was appropriate and enabled targets one to three to be met.

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* To determine value for money the VMD follows the definitions cited by the National Audit Office (NAO) 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

The Authorisations Division has had another year characterised by change, either in terms of actual implementation of change or in readiness for future developments. Whilst many of the changes are driven by European legislation, others are driven by the staff of the VMD in a desire to improve the services that the VMD offers and to improve efficiency. Despite the focus of some resources on projects the overall score for our service against our published standards has improved slightly on that of last year and shows that we are now at the very top of the 'effective' overall performance standard.

The assessment teams (pharmaceuticals, immunologicals and general) and the administrative team have performed to a high standard over the past year to ensure that almost all of the individual business targets have been met or exceeded.

It is with some relief to all of us that we have almost completed the exercise to consider variations to update Summary of Product Characteristics (SPC), labels and leaflets in accordance with the Veterinary Medicines Regulations 2005. This has tied up a significant amount of both VMD and company resource and we look forward to being able to use this resource in other areas. We have learnt a number of lessons from this exercise, most notably in relation to any proposed global changes to labels or leaflets.

The volume of applications this year has remained steady, with the trend of increasing European applications and reducing national applications continuing. Companies continued to regularly select the UK as the RMS in decentralised procedures; there are however signs that a number of other member states are now becoming more engaged in this role and so this shows signs of becoming a truly competitive arena. The VMD will seek to continue to secure work in this area and one way we aim to achieve this is by emphasising that unlike some member states, we have no waiting lists or restrictions as to when a decentralised application can be submitted to us.

Europe continues to play an important role in all aspects of the Authorisations Division's work. This provides opportunities, but it also comes with some significant frustrations. The UK has taken the lead on many occasions on topics discussed at meetings such as HMA, Co-ordination Group for Mutual Recognition and Decentralised Procedures – veterinary (CMD-v), Committee for Veterinary Medicinal Products (CVMP)[19] and its working parties. One significant area where the VMD has been active is in relation to article 35 referrals on community interest grounds. Whilst these referrals may not have been welcomed by some individuals, we consider that where there is an important issue relating to safety, we have an obligation to address this and not to hide behind resource issues. The referral for ivermectin containing injectable products indicated for use in cattle will lead to consistent and logical withdrawal periods being set for each concerned product. This is important in terms of safety but also in terms of the reputation of the EU network.

I have spent some of my time this year trying to find ways to improve the availability of veterinary medicines in the UK. This has involved an industry information meeting held at the VMD, the introduction of fee waivers for Animal Test Certificates (ATC) intended to generate data in support of limited market products, the development of a number of schemes, with the 'Limited MAs' scheme now being the subject of a formal consultation, and publication of several articles in Marketing Authorisations Veterinary Information Service (MAVIS)[20] intended to share information with industry regarding therapeutic gaps. I am not so deluded to think that we can solve the issue of availability of veterinary medicines, but I do hope we are illustrating that we are keen to do our bit to try to help improve the current situation.

The inspections team (for GMP) has had a productive and busy year. The team were inspected themselves by a French inspector on behalf of the HMA early in the year and we were pleased with the outcome of this, especially as the Quality System in this team was in its infancy at the time of the inspection. The results and advice will also help to form the basis of the VMD wide Quality System. The team has also been working closely with colleagues in Licensing Administration in order to be ready to take over responsibility from the MHRA for inspecting and regulating sites producing medicines exclusively for use in animals. The changes from 1 April 2009 will increase the work in these teams significantly. I am confident that we are ready to take on this extra work and that in the medium term we will be able to demonstrate a significant improvement in service for these sites.

The SARSS team has once again coped with an increasing number of reports of suspected adverse events, which reflects an increased awareness of this scheme. This awareness is expected to increase still further with the introduction of a new Adverse Event Reporting leaflet for veterinarians. A significant achievement this

year has been the implementation of electronic reporting by companies to the VMD and onward transmission to the EudraVigilance Veterinary database. The team, along with our IT team, has overcome a number of significant hurdles to achieve this and has worked very closely with the 10 companies who are now submitting their reports electronically.

The IT team has continued to support and develop new IT systems for the VMD, whilst also ensuring that high security standards are met. An important achievement this year was that the external audit report against the ISO 27001 standard described our Information Security Management System (ISMS) as 'well developed'. Significant developments include the implementation of the new intranet for VMD staff which is underpinned with content management software and a major redevelopment of our Licence Management System, which introduced a new technological template for our in-house systems. It is very clear to me that our IT team is a truly invaluable asset and the results of our recent staff survey indicate that others also recognise this.

Looking to the future in addition to ensuring that we secure the appropriate level of work in the European arena, we have some important projects to implement including the acceptance of e-submissions and the handling of variations systems for European MAs under the revised Variations Regulation, both from January 2010.

Finally, I would like to recognise that all of the achievements set out above are only made possible by the hard work, commitment and professionalism of the VMD staff. I would like to thank everyone in the Authorisations Division; I know at times it has not been without adversity, but you have delivered to and beyond expectations.

Jackie Atkinson

19. You can find out more about the work of the CVMP via the EMEA website www.emea.europa.eu
20. MAVIS is published online at www.vmd.gov.uk under Publications

Director of Operations' Review

John FitzGerald

A major part of my work during the year related to the recommendation in the Hampton Report that the VMD should be merged with a thematic Agency. Much of my time was spent developing a business case to analyse the merger options against maintaining the VMD as an Agency of Defra. The final business case was made available to consultees during Defra's consultation on the future of the VMD. It was reassuring for all VMD staff to receive strong stakeholder support to retain the VMD as a Defra Agency and we were delighted to have this endorsed by the Secretary of State.

Needless to say it was important to continue to provide high quality services to all VMD customers throughout the year. Our Legislation team was heavily involved in the introduction of veterinary practice premises registration with the RCVS. Much discussion took place on the details and the RCVS was able to begin registering premises from 1 November 2008. Discussions, led by the AMI, also took place on the inspection criteria to ensure that the same standards were applied to premises inspected by the VMD or under the RCVS' Practice Standards Scheme. The Legislation team also introduced the Veterinary Medicines Regulations 2008 and began work on the 2009 version. This included work to clarify the controls on the supply of veterinary controlled drugs.

The AMI was closely involved in the inspection discussions with the RCVS and the consideration of more new work inspecting veterinary only wholesale dealers. We welcomed a new inspector following a retirement and recruited an additional inspector for the North East in preparation for additional inspections. Work continued on the development of risk based inspections which will enable us to use the Inspectorate's resources more effectively.

Antimicrobial resistance continued to be a significant policy issue. I chair the DARC Group which considered the results of research projects and the impact of Methicillin Resistant Staphylococcus Aureus (MRSA) and Extended Spectrum Beta-Lactamase (ESBL) in animals. We continued to work with human medicine colleagues on antimicrobial resistance issues to ensure that concerns about human health were properly addressed.

Work continued on Organophosphate (OP) and Synthetic Pyrethroid (SP) sheep dips. The final OP research projects neared completion and their final reports will be published and sent to the Committee on Toxicity of Chemicals in Food (COT) as part of their major review of public and private funded research into the effects of the long term low level use of OPs on sheep farmers. The work on SP (cypermethrin) sheep dips neared its conclusion as the final evidence on whether these products can be used without presenting an unacceptable risk to the environment was collected.

Our Enforcement team addressed the increasing problem of illegal sales of medicines over the Internet. We liaised closely with colleagues in France and Belgium who raided the stores of an illegal website seizing some 2m Euros worth of products destined for the UK market. We are considering the UK customer lists to determine whether further enforcement action is required. We also set up a Website Project team to check websites selling veterinary medicinal products and contacted over 150 websites to help them sell medicines in accordance with the Veterinary Medicines Regulations.

Our residues surveillance programmes were completed to plan and budget with only a small number of positives found despite more targeted sampling. We began the retendering of the analytical services contract which will end in December 2010. Negotiation on the EC proposals to change the Maximum Residue Limit (MRL) Regulations continued and was awaiting European Parliament approval at the end of the year. Another consultation on these changes will take place as part of the implementation process.

As our work expanded we undertook a large number of recruitment exercises in line with the Civil Service Commissioners' Recruitment Code. These were time consuming but successful. The increased staff numbers put pressure on our accommodation and we will be reviewing our use of the available space in 2009/10. A rolling programme of maintenance was introduced with the internal painting of our building and new energy efficient lighting. The Operations team kept a close eye on changes in the way Defra operates as these can affect personnel procedures at the VMD. This liaison will continue.

On a personal note it is normal to thank all VMD staff for their help in achieving our objectives. This is more heartfelt this year because of the additional work necessary to cover my absence during part of the year. It was a great reassurance to be able to rely on the team knowing that they would continue to deliver.

John FitzGerald

Looking forward

Targets for 2009/10

Ministers have agreed four targets for the VMD.

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.

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.

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.

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 VMD's work contributes to the achievement of five of Defra's Departmental 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 2009/10 and its plans for meeting them have been outlined in the VMD's Business Plan[21], 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;
- outcome of the public consultation on the Veterinary Medicines Regulations 2009;
- 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;
- European Network of medicine regulatory authorities and the continuing expansion of the EU, and our interface with these developments;
- further implementation of electronic working;
- implementation of our Business Plan and our Improvements Plan to drive delivery and continuous improvement; and
- action to control illegal sales of medicines on the Internet.

* To determine value for money the VMD follows the definitions cited by the National Audit Office (NAO) 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**.

21. 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 2008/09: to achieve cost recovery for the VMD as a whole. The accounts show an operating surplus for the year of £24,000, achieving an overall cost recovery of 100.2%.

The results of the VMD's main business activities during 2008/09, as shown in Note 3 to the accounts, were as follows:

	Income £000	Expenditure £000	Cost recovery %
Authorisations	7,117	6,945	102.5
Statutory Residues	4,011	4,030	99.5
Non-statutory Residues	967	967	100.0
Policy	2,386	2,517	94.8
Animal Medicines Inspectorate	489	487	100.4
Total VMD	**14,970**	**14,946**	**100.2**

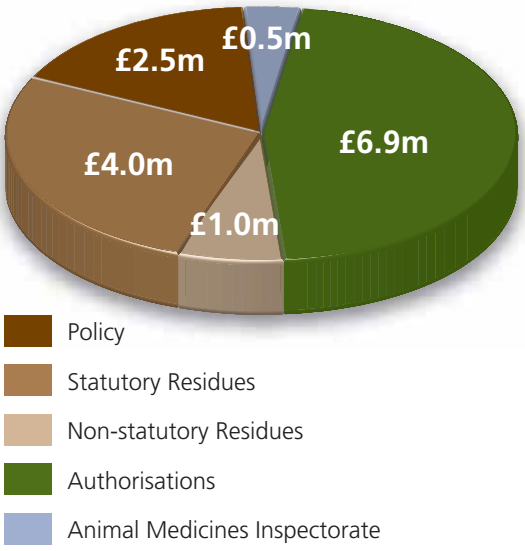
Expenditure

The costs of authorisation and inspection work, including the AMI, are recovered through fees and charges to industry. The costs of the Statutory Residues scheme are recovered through charges levied on abattoirs and other food processors. The costs of the Non-statutory Residues scheme, enforcement and other operational work are funded by Defra.

We thoroughly monitor our financial performance and continue to seek efficiency measures while maintaining our standards of performance. We managed to achieve our targets in 2008/09 while maintaining Authorisation fees at 2007/08 levels.

The operating surplus or deficit for each year is transferred from the Income and Expenditure account to the General Fund. 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 operating cost recovery surplus or deficit transferred from the Income and Expenditure account. This reserve is not distributable.

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



Events since the Balance Sheet date

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 that demonstrate value for money. On 1 April 2009 the responsibility for managing the delivery of accommodation-related services transferred from the VMD to Defra under the Sustainable Workplace Management (SWM) programme. At the same time the land and buildings occupied by VMD staff transferred from the VMD's to Defra's Balance Sheet.

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, which requires appointment to be on merit on the basis of fair and open competition but also includes the circumstances when appointments may otherwise be made.

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

'Salary' includes gross salary; performance pay or bonuses; overtime; reserved rights to London weighting or London allowances; recruitment and retention allowances; and any other allowance to the extent that it is subject to UK taxation.

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.

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.

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 (CETV)

This 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 pension 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. CETVs are calculated in accordance with The Occupational Pension Schemes (Transfer Values) (Amendment) Regulations 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 is effectively the element of the increase in accrued pension funded by the Exchequer. It excludes increases due to inflation and contributions paid by the employee and is worked out using common market valuation factors for the start and end of the period.

2008/09	S Dean – Director and Chief Executive	J FitzGerald – Director of Operations	J Atkinson – Director of Authorisations
	£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

* 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.

2007/08	S Dean – Director and Chief Executive	J FitzGerald – Director of Operations	J Atkinson – Director of Authorisations
	£000	£000	£000
Salary (as defined above)	95-100 including 5-10 bonus	85-90 including 10-15 bonus	60-65 including 0-5 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 2.5-5 lump sum	0-2.5 plus 0-2.5 lump sum
Total accrued pension at age 60 and related lump sum	10-15 plus 35-40 lump sum	30-35 plus 100-105 lump sum	10-15 plus 25-30 lump sum
CETV at 31 March 2007	229	637	176
CETV at 31 March 2008	284	746	223
Real increase in CETV after adjustment for inflation and changes in market investment factors	21	18	13

No employer contributions were made to partnership pension accounts (2007/08: £nil).

Regulatory Agencies Strategy Board/ VMD Owner Advisory Board

Membership details of the RASB/OAB are shown on page 10. With the exception of the VMD and PSD Chief Executives and the external members, the RASB/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 RASB/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 62. The three external members also sit on the Management Board. The following salaries and benefits-in-kind were paid to the external members:

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

2007/08	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

'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[22]

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

22. Further details about the Civil Service pension arrangements can be found at www.civilservice-pensions.gov.uk

Retail Prices Index (RPI). Members who joined from October 2002 could opt for either the appropriate defined benefit arrangement or a good quality 'money purchase' stakeholder arrangement with a significant 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' 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 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, immediately after the scheme year end, the accrued pension is uprated in line with RPI. In all cases members may opt to give up (commute) pension for 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-pensions.gov.uk.

Steve Dean
Chief Executive
22 May 2009

Environmental Matters and Social and Community Issues

The highlights of the VMD's progress against its Sustainable Development Action Plan[23] over the past year have been:

- a significant number of environmental impact assessments have been carried out on applications for veterinary medicines;
- the VMD is working with Defra's sustainable procurement experts to ensure tendering of the next contract for analytical services under the residues surveillance scheme meets the government's sustainability requirements;
- some 90% of staff have had an awareness presentation on Sustainable Development (SD) and the VMD, which they found informative; and
- 12 members of staff volunteered to clear the big cat pens and enclosures at the Wildlife Heritage Foundation in Kent as part of Defra's SD volunteering initiative. More staff are expected to follow in 2009/10.

The key challenges for the future are to:

- make more realistic Defra and the Sustainable Development Commission's (SDC) expectations of what improvements a small agency with limited resources like the VMD can achieve year on year (over and above the on-going contribution made by its core business); and
- to work with them in 2009/10 to maximise and realise our delivery potential.

23. 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 RASB/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 according to legislative requirements and 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 132 out of a maximum of 140 which corresponds to the very top score in the 'effective' overall performance category. The published standards consist of 24 individual categories which further sub-divide to give 77 individually monitored parameters. Twenty-two out of 24 categories met the top performance category. Performance for customer care visits met the 'effective' performance level and for EU procedures performance was categorised as 'unacceptable'. In the case of EU procedures for a very small number of applications, the timelines were not met at every stage. The maximum number of days the timelines were exceeded by was 12.

The detailed results can be found in Appendix A.

Provide scientific assurance that the benefits of authorisation 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 63 new MA applications and numerous more variation and renewal applications. The assessment and opinions of 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 2008/09 was 97.67%, which corresponds to the performance standard defined as 'excellent'.

Seventy-three letters were sent to companies resulting in seven customer care visits during 2008/09. Minutes were sent out within four weeks of the meeting in five out of seven cases. The performance as measured by the published standard was 'effective'.

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 3,443 SAR reports (animal and human) and 1,312 Periodic Safety Update Reports (PSURs), increases of 11% and 20% 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 Immunological Inspection team carried out 31 inspections, 10 of which were of Immunological Veterinary Medicinal Products (IVMP) manufacturers to ensure compliance with the principles of GMP and eight were in third countries including four joint inspections with the MHRA.

Manufacturers of products exempt under the SAES accounted for five inspections and contract test sites for a further four. Seven more inspections were performed jointly with the MHRA in readiness for the hand over of veterinary-only site inspections from the MHRA to the VMD on 1 April 2009. The remaining GMP inspection was performed jointly with another Member State on behalf of the EU and related to centralised applications. Other inspections included five relating to autogenous vaccine authorisations and two relating to non-food animal blood bank authorisations.

In all cases inspection reports were sent to the company within 60 days of the visit.

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

During early 2008 the Immunologicals Inspection team introduced a formalised quality system that was subject to audit as part of the Heads of Medicines Agencies Joint Audit Programme. The team achieved a positive outcome to this audit.

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 2008 and initiate the project to revoke and remake the Regulations for 2009

The Veterinary Medicines Regulations 2008 came into force on 1 October 2008.

An omission in the Regulations required an amending Statutory Instrument (SI) to allow the RCVS to charge a £40 registration fee for each practice on the new statutory practice premises register. This amending SI came into force on 1 November 2008 and will be incorporated into the main body of the Veterinary Medicines Regulations in 2009.

The third meeting of the Regulations Strategy Board to plan the changes for the 2009 Regulations was held on 13 February 2009. The expected date to initiate the formal consultation on the proposed changes was 4 March but this deadline could not be met. Nevertheless, it is envisaged that the commencement date of 1 October 2009 for the 2009 Regulations is still achievable.

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

Work in this area has progressed throughout the year and the consultation for the final group of products has been carried out. The companies' comments on the first group of products have been received prior to seeking Ministers' agreement to the changes. A meeting of the VPC subgroup to discuss the summary of responses from consultation on minerals and multi species vaccines reclassifications was held on 23 January 2009. The VPC endorsed the subgroup's recommendations on 19 March 2009 and a further meeting took place on 15 May 2009 to discuss multi species vaccines reclassification and local anaesthetics.

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

Risk assessment is built into the day to day enforcement work. All cases involving food producing animals are treated as high risk. Cases concerning repeat offenders involving non-food producing animals are also deemed to be high risk. The potential high risk to consumer safety, animal welfare and the environment requires a rigorous regime.

On behalf of the VMD, Defra Investigation Service (DIS) is currently working up a prosecution case against a company selling illegal veterinary medicines to the UK from France and Belgium. DIS is working closely with the French and Belgian authorities and has identified a UK customer base of approximately 1,800 names. This customer base includes farmers, breeders of cats and dogs, stud farms and hunts. The medicines being purchased illegally include antibiotics, wormers and vaccines.

We have also set up a website project team engaged in reviewing sites selling veterinary medicines on-line. Approximately 70 Internet sites selling veterinary medicines have been investigated since the project began, with most companies responding positively to the VMD's correspondence.

Monitor sales of veterinary antimicrobials in the UK by publishing the Antimicrobial Sales Data report[24] for 2007 by 31 December 2008

The 2007 report was published in August 2008, four months ahead of schedule. Following consultation with the manufacturers the report gave an estimate of the breakdown in use of the products authorised for both pigs and poultry.

24. You can access the Antimicrobial Sales Data report via www.vmd.gov.uk under Publications

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

The AMI carried out a total of 1,588 visits during 2008/09 against a target of 1,746. Of those visits, 1,254 were scheduled inspections, which included 266 approval inspections. The number and types of non-scheduled visits were:

144 Follow-up/Special visits to approved premises;

139 Enforcement visits to non-approved premises;

17 Enforcement visits to approved premises; and

34 Residue investigations.

The reprioritisation of AMI work in favour of enforcement visits and investigations (which can be more complex and time consuming) and reduced resources because the Head of AMI had to focus on strategic developments and so was only able to conduct a limited number of inspections, meant that not all scheduled visits had been undertaken by year end. However, these inspections were prioritised so that those businesses of potentially higher 'risk' were targeted. The appointment of an additional inspector for the North East of England should have a beneficial effect during 2009/10.

On 1 January 2009, 183 Suitably Qualified Person (SQP) Retailers' premises had their approval suspended due to not having a registered SQP. This was as a result of some SQPs failing to undertake or complete a conversion examination set by their registration body by 31 December 2008. The AMI made enforcement visits to a number of suspended premises, several of which resulted in improvement notices being served.

During the year, AMI Inspectors served 13 seizure notices and 22 improvement notices. All notices were published on the VMD's website.

Play an active part in negotiations with EU colleagues, particularly in HMA, CVMP and CMDv, to improve the availability of veterinary medicines in line with EU strategy

The HMA(v) action plan has been updated and shows that where VMD actions are required, these are either already in place, are not relevant or are under investigation for implementation.

The VMD ran a well attended Information Afternoon for industry on 11 September 2008 on products for limited markets.

A new scheme, based on the existing Provisional Marketing Authorisation scheme, has been developed and will be formally consulted on as part of the VMR 2009 package. This introduces the concept of Limited Marketing Authorisations which are aimed at products intended for use in minor species or in major species for minor use.

The VMD continued to play an active part in the HMA's Task Force on improving veterinary medicines legislation.

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

All the evidence arising from the joint VMD/Environment Agency Stakeholder Pollution Reduction Programme has now been completed and reports arising from the research elements are available on the VMD's website. Accordingly, Ministers will be able to consider the future of the authorisations for the three cypermethrin sheep dip products in 2009/10.

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 Department of Health led on the review of OP published literature in consultation with the VMD. Liaison with the secretariat of COT continues. The new Minister has been informed of the issues and of planned publication of the latest Defra funded research project reports.

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

Options are being considered by HMA Task Force for improving veterinary medicines legislation. The VMD has been represented on the task force and proposals for change to the EU legislation continue to be developed, taking account of stakeholders' views.

Work has continued on the progression of the revision to the EU Variations Regulation. National plans for implementation are being developed and communicated.

Target 3

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

To monitor that internationally set safety limits are being observed, the VMD Residues Surveillance team manages two extensive surveillance programmes. One is statutory, which helps fulfil our obligations under EU law. The other is a non-statutory programme, which complements and supplements the statutory programme.

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 3 to the accounts).

To ensure that they were prepared for surveillance in 2009, they:

- agreed the 2009 statutory residues plan with the EC in accordance with the time frame laid down in Council Directive 96/23; and
- agreed the non-statutory plan for 2009 with the VRC by March 2009.

Agree 2009 statutory 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 2009.

Agree 2009 non-statutory plan with Veterinary Residues Committee by 31 December 2008

The VMD carried out a consultation exercise with stakeholders on behalf of the VRC from 26 August to 13 October 2008. This asked them what they thought should be included in the 2009 programme. The VRC planning subgroup meeting was held on 24 October 2008 to comment on the received proposals and prepare a draft plan for consideration by the full Committee at their Open Meeting on 12 November 2008. The detailed plan was circulated to the Committee following the meeting and the final plan was agreed.

Ensure sampling and analysis targets are met to complete the 2008 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. The results for two samples were referred to DIS.

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

The French Presidency secured agreement on the replacement for EC Regulation 2377/90 between the Council, European Parliament (EP) rapporteur and Commission. This was adopted by the Council of Ministers in December 2008 and awaits final EP clearance. The agreed compromise text was acceptable to the UK, although the UK argued that the text on Reference Points for Action could have been clearer. The revision to Council Directive 96/22 was published in November and will be implemented in UK legislation. It seems unlikely that the Commission will publish proposals to amend Council Directive 96/23 in the near future.

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

Both the statutory and non-statutory plans for 2008 were delivered on budget. The VMD will continue to seek value for money when negotiating costs for the 2009 programmes with service providers.

Target 4

To ensure that the appropriate infrastructure is in place to achieve targets 1, 2 and 3 and provides value for money* and the VMD achieves 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 3 to the accounts shows that the overall cost recovery was 100.2% and shows how this has been achieved over the VMD's principal business areas. The cost recovery outcome is largely dependent on industry activity levels during the year, which cannot be predicted with certainty when setting fees and charges.

Finalise the business case on options for the VMD in relation to the Hampton initiative and implement any changes agreed after Defra's consultation with stakeholders

The Secretary of State wrote to the Treasury on 28 January 2009 advising that, based on the results of the consultation, he proposes the VMD continues to be an Agency of Defra.

Implement changes agreed under the VMD's Change Programme

All actions under the Change Programme have been completed with the exception of the major projects on 'quality' and electronic submission of MAs, both of which are on target and closely managed. Work on the Communications strategy has been delayed by the need to address a number of central initiatives and policies.

Carry out the 2008/09 European Foundation for Quality Management (EFQM) Benchmarking exercise

We benchmarked our operation for the sixth time against the nine criteria in the EFQM's Business Excellence Model. Volunteers from across the VMD along with the VMD's Directors and CEO formed a team led by an EFQM independent specialist to identify the VMD's strengths and areas in which we could improve. There is ample evidence of a lot of good practice across the VMD in particular in how we develop, describe and manage our key processes and how we monitor delivery in key areas. We have identified a number of areas for improvement and these will be taken forward as part of the VMD's Business Improvement Plan 2009/10.

Carry out the 2008/09 Staff Survey

We commissioned an independent market research company to conduct a web based survey of staff in November. The results were presented to staff by the researcher at open meetings in December 2008. We had an 83% response rate, just 1% lower than 2002, higher than in 2000, 2004 and 2006 and higher than other Government staff surveys (60-70%). The positive headlines were that 84% of staff were satisfied working for the VMD, compared to other Government staff surveys (approximately 65% satisfied) and staff generally felt that the VMD was a respected organisation fulfilling an important role. There were a number of areas for improvement identified including a more consistent approach to line management across the agency which we will take forward during 2009/10.

Continue to provide data and information into the Defra Efficiency Programme and implement agreed efficiency changes

Defra's efficiency requirements took a different line this year. The CEO led on work to improve the relationship between Defra and its Agencies. We provided comments on the Defra Policy Cycle, which reflected the way policy is developed at the VMD, and arranged for data to be sent to Defra on website usage and the costs of facilities management. Defra developed its Sustainable Workplace Management (SWM) programme, with far reaching Facilities Management (FM) proposals which took effect from 1 April 2009.

Make information available in line with relevant access to information legislation

Access to Information (ATI)[25]

The VMD posted on its website the anonymised question and response to all the 113 ATI cases answered up to the end of 2008. These have been presented in PDF format under the 'About Us/ Freedom of Information' button and the site will be updated on a regular basis.

VMD Publication Scheme

The VMD has updated and published on its website its Publication Scheme in accordance with the revised requirements of the Information Commissioner's Office (ICO)[26].

VMD Service Standards and Complaints Procedure

The VMD reviewed and refreshed its service standards and complaints procedure. Under the revised procedure the VMD received two complaints, one related to the classification of a medical product, the other to Special Treatment Certificates (STC) and Special Import Certificates (SIC). Owing to its complexity, one reply exceeded the 15 day target for a response. Service standards are available on our website.

Public Assessment Reports

Publication of United Kingdom Public Assessment Reports (UKPAR)[27] and European Public Assessment Reports (PuAR) has continued according to published targets, achieving 'excellent' status. Comments from MAHs on draft public assessment reports are few in number and minor in content.

A new product area of the VMD website is currently under development. It will combine the current eSPC and UKPAR web pages to produce a more comprehensive, user friendly website.

Implement the VMD's IT Strategy

The new Licence Management System, Medical Scientific Panel Forum and the VMD intranet have been implemented live. The new Pharmacovigilance, Inspection Management and Statutory Residues IT systems have been developed and work is continuing to fine-tune the systems in line with user requirements. Further IT developments, including the VMD and EU eSubmission projects are on target.

Deliver Training and Liaison services to internally published standards

The Training and Liaison Unit's standards have been posted on the VMD intranet for internal use. The team has delivered to these throughout the year despite a high volume of trawl/recruitment work and the absence of a colleague for six months of the year.

IiP standards continue to be embedded in operations and are reviewed via external and internal reviews. Preparations are in hand for the next external review which will take place in June 2009.

Deliver core services to internally published standards

Core Services teams have delivered services according to the well established delivery standards. These are updated annually and reviewed regularly. Programme and Project Management has continued to underpin the VMD's work.

Implement the business improvements in 2008 based on the 2007 customer survey findings

In 2007 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 February 2008. Overall the results were very good but there were some areas highlighted for improvement. As a result of these the VMD produced a report

25. You can find out more about ATI legislation via the Ministry of Justice website www.justice.gov.uk
26. You can find out more about ICO at www.ico.gov.uk
27. You can find out more about UKPARs via www.vmd.gov.uk under Product Information

showing the VMD's response and the action planned for 2008/09 and beyond. The majority of actions have already been completed, for example:

- the questions being asked at Customer Care visits have been revised with the aim of being able to identify more accurately any specific areas of concern;
- a series of topical presentations have been introduced for VMD staff to make them more aware of current practices in farming and veterinary medicines;
- the VMD/Irish Medicines Board (IMB) harmonisation procedures have been improved to allow for better co-ordination;
- finance and validation teams have learnt more about each other's work to improve knowledge and understanding; and
- an article has been published in MAVIS which explains each of the steps that follow the end of a procedure so that companies can have a better understanding of likely timescales for issuing documents.

The only remaining action is to initiate a redesign of the VMD website, including stakeholders in the project. This project is due to commence early Summer 2009.

Participate in the Benchmarking of European Medicines Agencies (BEMA) exercise

The BEMA II three year cycle is underway with the first assessment being conducted at the EMEA. The VMD will complete its self assessment prior to the formal benchmarking process which is due in the second quarter of 2010.

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 its income and expenditure, total recognised gains and losses 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 and 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'.

Statement on Internal Control

1. Scope of Responsibility

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.

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.

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 Secretary of State exercises the ownership function in relation to the VMD and receives advice on the Agency's strategic direction and performance from the Regulatory Agencies Strategy Board (RASB) until December 2008 and from the VMD Owner Advisory Board (OAB) thereafter. The role of the OAB, and previously the RASB, includes assuring Ministers 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 2009 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 active consideration of the possible options for managing each risk down to an acceptable level.

The VMD's Risk Register contains the top ten risks facing the Agency. It is reviewed 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 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. Progress against them is reported to Directors at regular intervals. Operational Risk Registers are currently being developed to facilitate this process.

Statement on Internal Control (continued)

Programme and Project Management

Once the Business Plan is approved, action plans are formulated in order to facilitate its successful achievement. Business cases are prepared and, where appropriate, Office of Government Commerce (OGC) Gateway Reviews are conducted to inform significant investment decisions.

Programmes are governed by a Programme Board, which has a senior sponsor and which appoints Project Managers for specific projects. Programme and Project Management training is available to all staff and this helps to ensure that the appropriate skills and disciplines are applied. Risk registers are maintained for each programme/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 plans 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 before it the RASB) and signed off at Ministerial level following OAB and Corporate Owner advice.

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 Plans are 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 reported on by 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 (and previously the RASB). 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.

The Head of Internal Audit provides 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. Internal Audit also facilitate a workshop covering elements of Risk Management, Control and Governance. Our Internal Audit work was provided by RSM Bentley Jennison during the year.

The National Audit Office is responsible for the audit of the VMD's Annual Report and Accounts. Having subcontracted this work for a number of years, the NAO have conducted the work 'in-house' for the 2008/09 financial year.

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 the VMD's website.

The VMD is accredited to Investors in People (IiP) following assessment against the higher standard of IiP profiles.

Our commitment and competency in relation to IT security is recognised by accredited policies and procedures through the ISO 27001 standard. An Internal Audit review of our data security during the year concluded that the VMD can take substantial assurance that the controls upon which the organisation relies for data management, as currently laid down and operated, are effective.

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

Statement on Internal Control (continued)

financial risks through Service Level Agreements 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) programme. At the same time the land and buildings occupied by VMD staff transferred from the VMD's to Defra's Balance Sheet. 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 time of this report, Key Performance Indicators are still under development and the VMD will provide input to this process to ensure that the measures are closely aligned to the VMD's business objectives.

Management of Change

A programme to drive change at the VMD in the areas of Europe and Quality is in progress. Our recently-formed 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. A Quality Systems Assurance project has begun to establish an agency-wide quality management system over the next three years and a dedicated Quality Manager has been appointed.

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 completed in March 2009.

Adherence to the IiP principles and periodic re-assessment against the standard helps to embed a culture of performance improvement.

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

Performance Management

All staff are involved in the development of the Business Plan and individuals are expected to be able to relate the objectives in their Personal Development Plan with 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. Authorisations performance against published standards of service is published in MAVIS on a quarterly basis.

The VMD conducts formal Customer Surveys every two years and 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 the internal auditors and the executive managers within the agency who have responsibility for the development and maintenance of the internal control framework, and comments made by the external auditors 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 the National Audit Office.

Statement on Internal Control (continued)

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 was previously provided by Defra's Internal Audit Division. For 2008/09 however the service has been provided by RSM Bentley Jennison, who:

- operate under the requirements set out in Government Internal Audit Standards and the IIA-UK's International Standards for the Professional Practice of Internal Auditing;
- provide regular reports following review and evaluation of the Agency's risk management, control and governance arrangements, making recommendations for improvements where appropriate; and
- facilitate workshops to help the Audit & Risk Committee and senior staff make informed judgments on risk management.

The Head of Internal Audit has provided an independent opinion on the adequacy and effectiveness of the Agency's governance, risk management framework and key control processes during the year. The report concluded that for the 12 months ended 31 March 2009, the VMD had adequate and effective governance, 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
22 May 2009

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 for the year ended 31 March 2009 under the Government Resources and Accounts Act 2000. These comprise the Income and Expenditure account, the Statement of Total Recognised Gains and Losses, the Balance Sheet, the Cash Flow Statement 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 Agency, the Chief Executive and auditor

The Agency and Chief Executive, as Accounting Officer, are responsible for preparing the Annual Report, which includes the Remuneration Report, and the financial statements in accordance with the Government Resources and Accounts Act 2000 and HM Treasury directions made thereunder and for ensuring the regularity of financial transactions. These responsibilities are set out in the Statement of Accounting Officer's Responsibilities.

My responsibility is to audit the financial statements and the part of the Remuneration Report to be audited in accordance with relevant legal and regulatory requirements, and with International Standards on Auditing (UK and Ireland).

I report to you my opinion as to whether the financial statements give a true and fair view and whether the financial statements and the part of the Remuneration Report to be audited have been properly prepared in accordance with HM Treasury directions issued under the Government Resources and Accounts Act 2000. I report to you whether, in my opinion, the information, which comprises 'How We are Organised', the 'Management Commentary', the 'Environmental Matters and Social and Community Issues' and 'Meeting Our Targets', included in the Annual Report, is consistent with the financial statements. I also report whether 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.

In addition, I report to you if the Agency has not kept proper accounting records, if I have not received all the information and explanations I require for my audit, or if information specified by HM Treasury regarding remuneration and other transactions is not disclosed.

I review whether the Statement on Internal Control reflects the Agency's compliance with HM Treasury's guidance, and I report if it does not. I am not required to consider whether this statement covers all risks and controls, or to form an opinion on the effectiveness of the Agency's corporate governance procedures or its risk and control procedures.

I read the other information contained in the Annual Report and consider whether it is consistent with the audited financial statements. This other information comprises the 'Chief Executive's Forward', 'Our Aims and Responsibilities', the unaudited parts of the 'Remuneration Report' and the 'Appendices'. I consider the implications for my report if I become aware of any apparent misstatements or material inconsistencies with the financial statements. My responsibilities do not extend to any other information.

Basis of audit opinion

I conducted my audit in accordance with International Standards on Auditing (UK and Ireland) issued by the Auditing Practices Board. My audit includes examination, on a test basis, of evidence relevant to the amounts, disclosures and regularity of financial transactions included in the financial statements and the part of the Remuneration Report to be audited. It also includes an assessment of the significant estimates and judgments made by the Agency and Chief Executive in the preparation of the financial statements, and of whether the accounting policies are most appropriate to the Agency's circumstances, consistently applied and adequately disclosed.

I planned and performed my audit so as to obtain all the information and explanations which I considered necessary in order to provide me with sufficient evidence to give reasonable assurance that the financial statements and the part of the Remuneration Report to be audited are free from material misstatement, whether caused by fraud or error, and that 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. In forming my opinion I also evaluated the overall adequacy of the presentation of information in the financial statements and the part of the Remuneration Report to be audited.

Opinions

In my opinion:

- the financial statements give a true and fair view, in accordance with the Government Resources and Accounts Act 2000 and directions made thereunder by HM Treasury, of the state of the Agency's affairs as at 31 March 2009, and of the surplus, total recognised gains and losses and cash flows for the year then ended;
- the financial statements and the part of the Remuneration Report to be audited have been properly prepared in accordance with HM Treasury directions issued under the Government Resources and Accounts Act 2000; and

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

- information, which comprises 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, is consistent with the financial statements.

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.

Report

I have no observations to make on these financial statements.

T J Burr
Comptroller and Auditor General
National Audit Office
151 Buckingham Palace Road
Victoria
London
SW1W 9SS
29 May 2009

Income and expenditure account for the year ended 31 March 2009

Notes		2009 £'000	2008 £'000
2	**Income**	**14,970**	14,549
	Expenditure		
4	Staff costs	**(7,073)**	(6,542)
7&8	Depreciation, amortisation and revaluation losses	**(354)**	(372)
5	Other operating costs	**(7,298)**	(6,766)
	Total operating costs for year	**(14,725)**	(13,680)
	Operating surplus before cost of capital charge	**245**	869
6	Cost of capital charge	**(221)**	(204)
13	**Operating surplus for the year**	**24**	665

Statement of total recognised gains and losses

		£'000	£'000
	Operating surplus for the year	**24**	665
12	Fixed asset revaluations not reported in the operating surplus	**(232)**	303
	Total (losses)/gains recognised since the last annual report	**(208)**	968

All activities arise from continuing operations.
All of the VMD's income and expenditure is classified as Administration for Resource Accounting and Budgeting purposes.
The notes on pages 45 to 54 form part of these accounts.

Balance Sheet as at 31 March 2009

Notes		2009 £'000	2009 £'000	2008 £'000	2008 £'000
	Fixed assets				
7	Intangible assets	**100**		135	
8	Tangible assets	**5,534**		5,810	
			5,634		5,945
	Current assets				
9	Debtors	**2,756**		1,832	
10	Cash at bank	**3,528**		5,415	
		6,284		7,247	
	Creditors: amounts falling due within one year				
11	Creditors	**(1,860)**		(2,102)	
	Net current assets		**4,424**		5,145
	Total assets less current liabilities		**10,058**		11,090
	Taxpayers' Equity				
12	Revaluation Reserve		**2,356**		2,588
13	General fund		**7,702**		8,502
			10,058		11,090

S P Dean
Chief Executive and Agency Accounting Officer
22 May 2009

The notes on pages 45 to 54 form part of these accounts.

Cash flow statement for the year ended 31 March 2009

Notes		2009 £'000	2008 £'000
19(i)	**Net cash (outflow)/inflow from operating activities**	**(73)**	2,656
	Capital expenditure and financial investment:		
	– Payments to acquire intangible fixed assets	**(51)**	(81)
	– Payments to acquire tangible fixed assets	**(263)**	(226)
	Cash (outflow)/inflow before management of liquid resources and financing	**(387)**	2,349
	Financing:		
13	Surrender of surplus income	**(1,500)**	(1,300)
19(ii)	**(Decrease)/increase in cash in the year**	**(1,887)**	1,049

The notes on pages 45 to 54 form part of these accounts.

Notes to the accounts

1. Statement of accounting policies

The financial statements have been prepared in accordance with the 2008/09 Financial Reporting Manual (FReM) issued by HM Treasury. Where the FReM permits a choice of accounting policy, the accounting policy which 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 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.

1.2 Tangible fixed assets

Tangible fixed assets are capitalised if the purchase cost equals or exceeds £500 and where there is an expected useful economic life of more than one year. All tangible fixed assets are stated at the lower of replacement cost and recoverable amount. On initial recognition they are measured at cost including any costs such as installation directly attributable to bringing them into working condition. Fixed assets are restated to current value each year. Land and buildings are restated to current value using professional valuations in accordance with FRS 15 every five years and in the intervening years by the use of published indices appropriate to the type of land or building. Non-property operational assets are restated to current value using indices provided by the office of National Statistics.

1.3 Depreciation

Tangible fixed assets 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	3-4 years
Computer software licences	2-20 years
Furniture and fittings	10 years
Office equipment	10 years

1.4 Intangible fixed assets

Purchased computer software licences are capitalised as intangible fixed assets where expenditure of £500 or more is incurred. Such assets are revalued only where it is possible to obtain a reliable estimate of their market 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.

1.5 Income from activities

Income from activities 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.

1.6 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.

1.7 Defra service recharges

Defra service recharges are charged to the Income and Expenditure account. Where service recharges are not invoiced they are accounted for as a movement on the General Fund.

1.8 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% (2007/08: 3.5%).

1.9 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.

Notes to the accounts (continued)

1.10 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.

1.11 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 4(a). The defined benefit schemes are unfunded and are non-contributory except in respect of dependants' benefits. The department 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.

1.12 Leases

All payments under operating leases are charged to the income and expenditure account 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.

1.13 Change in format of primary statements

The format of the Income & Expenditure Account has been revised for 2008/09 in order to improve its clarity. A number of categories of expenditure have been moved to Note 5 to the accounts.

1.14 Financial Assets and Liabilites

The Agency classifies its non-derivative financial assets as loans and receivables. Financial assets and liabilities are recognised at fair value (the transaction price plus any directly attributable transaction costs).

1.15 Derivative Financial Instruments and Hedging

The Agency does not use derivative financial instruments such as interest rate swaps or any other hedging facilities.

Notes to the accounts (continued)

2. Income

Income was earned from the following main business segments:

	2009			2008
	External £'000	**Defra £'000**	**Total £'000**	Total £'000
Authorisations	**7,117**	**–**	**7,117**	6,826
Statutory Residues Scheme	**3,963**	**48**	**4,011**	3,997
Non-statutory Residues Scheme	**–**	**967**	**967**	873
Policy	**–**	**2,386**	**2,386**	2,345
Animal Medicines Inspectorate	**425**	**64**	**489**	508
Total	**11,505**	**3,465**	**14,970**	14,549

3. Key Performance Target

The VMD was set one key financial performance target in 2008/09: to achieve cost recovery for the VMD as a whole. However the VMD seeks to achieve 100% cost recovery for each of its five business segments.

Results:
An overall cost recovery of 100.2% was achieved. The cost recovery results for each of the VMD business segments were as follows:

	2009				2008			
	Income £'000	**Expend-iture £'000**	**Surplus/ (deficit) £'000**	**Cost recovery %**	Income £'000	Expend-iture £'000	Surplus/ (deficit) £'000	Cost recovery %
Authorisations	**7,117**	**(6,945)**	**172**	**102.5**	6,826	(6,129)	697	111.4
Statutory Residues Scheme	**4,011**	**(4,030)**	**(19)**	**99.5**	3,997	(4,020)	(23)	99.4
Non-statutory Residues Scheme	**967**	**(967)**	**–**	**100.0**	873	(873)	–	100.0
Policy	**2,386**	**(2,517)**	**(131)**	**94.8**	2,345	(2,377)	(32)	98.7
Animal Medicines Inspectorate	**489**	**(487)**	**2**	**100.4**	508	(485)	23	104.7
Total	**14,970**	**(14,946)**	**24**	**100.2**	14,549	(13,884)	665	104.8

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.

	2009	2008
	%	%
Authorisations	**69**	67
Statutory Residues Scheme	**5**	6
Non-statutory Residues Scheme	**1**	1
Policy	**20**	21
Animal Medicines Inspectorate	**5**	5
Total	**100**	100

For 2008/09, as required by the HM Treasury Financial Reporting Manual, notional insurance costs have not been charged. Notional insurance is however still charged in arriving at costs recovered from industry under statute, as required by HM Treasury. This cost amounted to £12,000 in 2008/09 (2007/08: £9,000).

The information in Notes 2 and 3 are provided for fees and charges purposes, not for SSAP25 purposes.

Notes to the accounts (continued)

4. Staff costs

(a) Staff costs consist of:

	2009			2008
	Permanently employed staff	**Temporary staff**	**Total**	Total
	£'000	**£'000**	**£'000**	£'000
Wages and salaries	**5,009**	**641**	**5,650**	5,179
Social security costs	**410**	**–**	**410**	404
Other pension costs	**1,013**	**–**	**1,013**	959
Total net costs	**6,432**	**641**	**7,073**	6,542

During the year there were no recoveries of staff costs in respect of outward secondments (2007/08: £nil).

Included in the permanently-employed staff costs for 2008/09 is an accrual for untaken annual leave of £147,000 (2007/08 £nil). This comprises of £115,000 wages and salaries, £9,000 social security costs and £23,000 other pension costs.

The Agency Chief Executive's total remuneration including non-pensionable performance bonus in 2008/09 was £99,123 (2007/08: £97,034).

The salary and pension entitlements of the senior managers of the agency, and an explanation of pension benefits is included in the Remuneration Report.

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. The scheme actuary valued the scheme as at 31 March 2007. You can find details in the resource accounts of the Cabinet Office: Civil Superannuation (www.civilservice-pensions.gov.uk).

For 2008/09, employers' contributions of £974,000 were payable to the PCSPS (2007/08: £949,000) at one of four rates in the range 17.1% to 25.5% of pensionable pay, based on salary bands (the rates in 2007/08 were between 17.1% and 25.5%).

The scheme's Actuary reviews employer contributions every four years following a full scheme valuation. From 2009/10, the rates will be in the range 16.7% to 24.3%. The contribution rates are set to meet the cost of the benefits accruing during 2008/09 to be paid when the member retires, and not the benefits paid during this period to existing pensioners. Employees can opt to open a partnership pension account, a stakeholder pension with and employer contribution. Employer's contributions of £16,000 (2007/08: £10,000) 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. 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).

Contributions due to the partnership pension providers at the balance sheet date were £nil (2007/08: £nil) and contributions prepaid at that date were £nil (2007/08: £nil).

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

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

	2009			2008
	Permanently employed staff	**Temporary staff**	**Total**	Total
Scientific	**44**	**1**	**45**	41
Administrative	**92**	**19**	**111**	111
	136	**20**	**156**	152

Notes to the accounts (continued)

5. Other operating costs

	2009	2008
	£'000	£'000
(a) Direct subcontracting costs		
Services provided by Other Government Departments:		
Food and Environment Research Agency	**848**	778
Meat Hygiene Service	**482**	586
Animal Health	**464**	301
Medicines and Healthcare products Regulatory Agency	**309**	250
Fisheries Research Services	**92**	88
Centre for Environment, Fisheries and Aquaculture Science	**12**	9
Services provided by Industry	**2,509**	2,482
	4,716	4,494
(b) Others		
IT systems maintenance	**276**	221
Consultancy	**202**	143
Travel and subsistence	**201**	173
Training	**169**	151
Accommodation	**164**	182
Communications	**132**	107
Accommodation utility charges	**112**	119
Independent expert committees	**158**	182
Stationery & publications	**117**	117
Operating leases	**51**	61
Movement in provision for bad debts (Note 16)	**(68)**	(70)
Other costs	**165**	196
	1,679	1,582
(c) Departmental recharges		
Defra service recharges:		
Invoiced	**448**	–
Charged to the General Fund (Note 13)	**419**	665
Audit fees	**36**	25
	903	690
Total other operating costs	**7,298**	6,766

Invoiced Defra service recharges relate to Human Resources, Estates and Legal services. Defra service charges charged to the General Fund relate to Investigation Services.

Included in audit fees for the year is £6,000 (2007/08: £nil) audit work in readiness for International Financial Reporting Standards. No remuneration was paid to the auditors in respect of non-audit work.

6. Cost of capital charge

The cost of capital 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% (2007/08: 3.5%).

Notes to the accounts (continued)

7. Intangible fixed assets

Computer Software Licences	£'000
Cost or Valuation:	
At 1 April 2008	735
Additions	42
At 31 March 2009	777
Amortisation:	
At 1 April 2008	(600)
Provided during year	(77)
At 31 March 2009	(677)
Net Book Value:	
At 31 March 2009	**100**
At 31 March 2008	135

8. Tangible fixed assets

	Freehold Property £'000	IT Equipment £'000	Office Equipment £'000	Furniture & Fittings £'000	Total £'000
Cost or Valuation:					
At 1 April 2008	5,954	880	79	277	7,190
Additions	117	108	–	8	233
Disposals	–	(72)	–	(5)	(77)
Revaluation	(278)	(15)	–	9	(284)
At 31 March 2009	5,793	901	79	289	7,062
Depreciation:					
At 1 April 2008	(414)	(710)	(35)	(221)	(1,380)
Provided during year	(142)	(104)	(8)	(19)	(273)
Disposals	–	70	–	5	75
Revaluation	44	13	–	(7)	50
At 31 March 2009	(512)	(731)	(43)	(242)	(1,528)
Net Book Value:					
At 31 March 2009	**5,281**	**170**	**36**	**47**	**5,534**
At 31 March 2008	5,540	170	44	56	5,810

Revaluation movements result from the indexation and/or the revaluation of fixed assets.

Depreciation, amortisation and revaluation losses figure of £354,000 shown in the Income & Expenditure Account includes £2,000 indexation losses (2007/08: £10,000) and £2,000 losses on disposal (2007/08: £2,000).

Freehold property was valued at 1 April 2005 by the Valuation Office Agency at existing use value, in accordance with guidance issued by the Royal Institution of Chartered Surveyors.

Notes to the accounts (continued)

9. Debtors

	2009	2008
	£'000	£'000
Amounts falling due within one year:		
Trade debtors	**461**	437
Balances with other central government bodies	**885**	–
Other debtors	**33**	34
VAT recoverable	**139**	187
Prepayments and accrued income	**1,238**	1,174
	2,756	1,832

Debtors are shown net of a provision of £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. The significant reduction in provision is the result of claims abandoned in the year (Note 16).

Included in debtors there are no balances with local authorities, NHS Trusts, public corporations or trading funds (2007/08: £nil). Balances with other central government bodies at the year end, includes £885,000 (2007/08: £nil) with Defra and its agencies.

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

10. Cash at bank

	2009	2008
	£'000	£'000
At Office of HM Paymaster General	**3,500**	5,333
At commercial banks	**28**	82
	3,528	5,415

11. Creditors

	2009	2008
	£'000	£'000
Amounts falling due within one year:		
Trade creditors	**48**	379
Balances with other central government bodies	**213**	340
Balances with public corporations and trading funds	**147**	132
Other taxation and social security	**179**	159
Accruals and deferred income	**1,273**	1,092
	1,860	2,102

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

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

12. Revaluation reserve

	2009	2008
	£'000	£'000
At 1 April 2008	**2,588**	2,285
Arising on revaluation during the year:		
on indexation	**(232)**	303
At 31 March 2009	**2,356**	2,588

Notes to the accounts (continued)

13. General Fund

	2009	2008
	£'000	£'000
Balance at 1 April 2008	8,502	8,243
Non-cash charges:		
Interest on Capital	221	204
Audit Fee	36	25
Defra Service Charges not invoiced (Note 5)	419	665
Surrender of surplus income	(1,500)	(1,300)
Operating surplus for the year	24	665
Balance at 31 March 2009	7,702	8,502

14. Capital commitments

	2009	2008
	£'000	£'000
Contracted commitments at 31 March for which no provision has been made in the accounts.	39	–

15. Commitments under operating leases

Commitments under operating leases to pay annual rentals during the year following the year of these accounts are given in the table below, analysed according to the period in which the lease expires.

	2009	2008
Obligations under operating leases comprise:	£'000	£'000
Land and buildings		
Expiry within 1 year	6	6
Contract Hire cars		
Expiry within 1 year	–	20
Expiry within 2 to 5 years	4	–
Other		
Expiry after more than 5 years	12	12
	22	38

16. Losses statement

	2009		2008	
	No. of cases	Value £000	No. of cases	Value £000
Claims waived	39	142	38	132
Claims abandoned	292	326	–	–
	331	468	38	132

No individual case exceeded £250,000 in value.

Claims abandoned in the year relate to the write-off of bad debts incurred from customer accounts in liquidation. All of this cost has been fully provided in previous years. As a result the provision for bad debt at the year-end is significantly less than at the beginning of the year (Note 9). The provision for bad debt at the year-end has also been reduced by £68,000 to take into account recent sector-specific debt-recovery information. This movement in provision has been recognised as a credit against 'other operating costs' (Note 5).

17. 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, Central Science Laboratory, 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 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.

Notes to the accounts (continued)

18. Financial instruments

The VMD does not face the degree of exposure to financial risk that commercial businesses do. In addition financial assets and liabilities generated by day-to-day operational activities are not held in order to change the risks facing the Agency in undertaking its activities. The VMD relies upon Defra for its cash requirements, having no power itself to borrow or invest surplus funds and the Agency's main financial assets and liabilities have either a nil or a fixed rate of interest related to the cost of capital (currently 3.5%). The short-term liquidity and interest rate risks are therefore slight. All material assets, liabilities and expenditure are denominated in Sterling. A small amount of income accrued in the year is denominated in foreign currencies. These transactions are subject to the risk of exchange rate fluctuations until settled but the total transactions and therefore the potential gain or loss is insignificant.

Financial Assets by category

Financial Assets per balance Sheet:	**Loans and Receivables £'000**
Cash	3,528
Trade debtors	461
Other debtors	2,060
Total	**6,049**

The above figures exclude statutory debtors which relate to VAT due from HM Revenue and Customs. None of the Financial Assets have been subject to impairment.

An analysis of the ageing of the non-impaired trade debtors as at 31 March 2009 is shown below.

	0-30 days £'000	**30-60 days and over £'000**	**Total £'000**
Trade debtors	191	270	**461**

Financial Liabilities by category

Financial Liabilities per balance Sheet:	**Financial Liabilities £'000**
Trade creditors	48
Other creditors	360
Accruals	1,273
Total	**1,681**

The above figures exclude statutory creditors which relate to Tax and Social Security due to HM Revenue and Customs. All of the liabilities are payable within one year.

Credit Risk

The Agency's principal financial assets are bank balances and trade and other receivables. These represent the VMD's maximum exposure to credit risk in relation to financial assets. The credit risk is primarily attributable to its trade receivables. The amounts presented in the Balance Sheet are net of provisions for doubtful receivables estimated by the Agency's management based on prior experience and their assessment of current economic value. Due to the nature of the VMD's business, it is not possible to credit-check potential customers before transacting with them. Management of this risk is therefore exercised by timely collection procedures. Note 16 shows that the VMD abandoned claims totalling £326,000 in 2008/09 although this cost had been incurred over several years.

Set out below is the movement in the provision for bad and doubtful debts relating to the Agency's trade receivables.

	£'000
Provision at 1 April 2008	545
Charges to Income & Expenditure Account (Note 5)	(68)
Provision used	(403)
Balance at 31 March 2009	**74**

Hedging

The Agency does not involve itself in any hedging transactions.

Notes to the accounts (continued)

19. Notes to the cash flow statement

(i) Reconciliation of operating surplus to net cash inflow from operating activities

	2009	2008
	£'000	£'000
Operating surplus for the year	24	665
Depreciation and revaluation losses	354	372
Defra service charges not invoiced	419	665
Other notional charges added back	257	229
Adjustment for decrease in fixed asset accruals	39	49
(Increase)/decrease in debtors and prepayments	(924)	632
(Decrease)/increase in creditors	(242)	44
Net cash (outflow)/inflow from operating activities	(73)	2,656

(ii) Reconciliation of net cash flow to movement in cash at bank

	2009	2008
	£'000	£'000
(Decrease)/increase in cash in the year	(1,887)	1,049
Cash at bank at 1 April 2008	5,415	4,366
Cash at bank at 31 March 2009 (Note 10)	3,528	5,415

20. Post Balance Sheet events

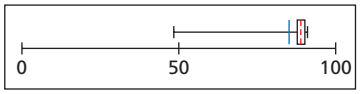
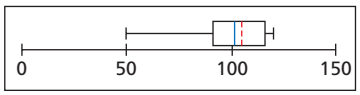
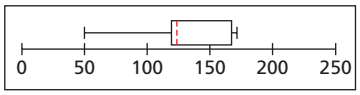
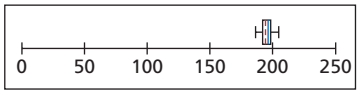
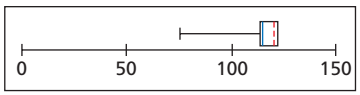
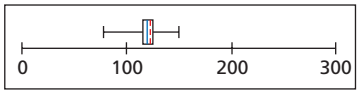
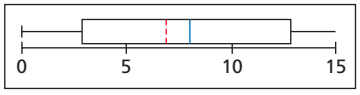
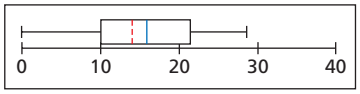
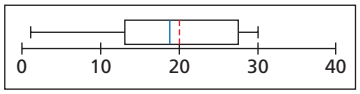
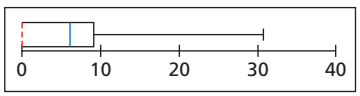
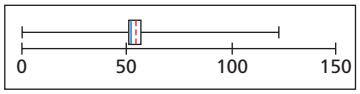
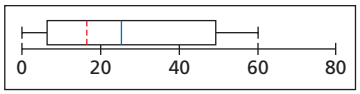
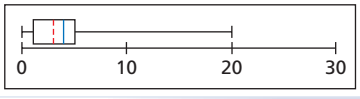
A significant proportion of the VMD's non-pay overhead costs are recharges for services provided by other Defra bodies. Accountability for these costs lies with the Agency Chief Executive, who seeks to manage operational and financial risks through Service Level Agreements that demonstrate value for money. On 1 April 2009 the responsibility for managing the delivery of accommodation-related services transferred from the VMD to Defra under the Sustainable Workplace Management (SWM) programme. At the same time the land and buildings occupied by VMD staff transferred from the VMD's to Defra's balance sheet.

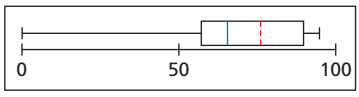
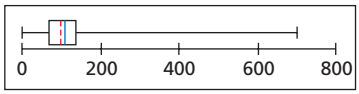
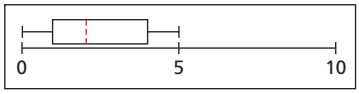
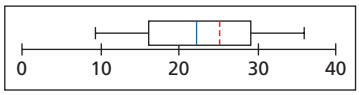
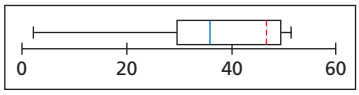
The VMD's financial statements are laid before the House of Parliament by the Secretary of State for Defra. FRS21 requires the VMD to disclose the date on which the accounts are authorised for issue by the Agency Accounting Officer.

The authorised date for issue is 29 May 2009.

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	31	EXCELLENT	90	85	
Sign off, VPC or further questions	26	EXCELLENT	120	102	
Sign off and issue (180)	13	EXCELLENT	180	121	
Sign off and issue (210)	5	EXCELLENT	210	195	
MAPIs for MR products and copy-cats					
Initial assessment	4	EXCELLENT	75	75	[2]
Sign off, VPC or further questions	17	EXCELLENT	120	112	
Sign off and issue (180)	18	EXCELLENT	180	116	
Sign off and issue (210)	0	EXCELLENT	210	0	[2]
Variations					
Type IA – decision	373	EXCELLENT	14	8	
Type IB admin – issue	86	EXCELLENT	30	15	
Type IB – initial assessment	283	EXCELLENT	30	19	
Type IB – sign off	285	EXCELLENT	30	6	
Harmonisation – sign off	2	EXCELLENT	60	26	[2]
Type II – initial assessment	747	EXCELLENT	60	51	
Type II – sign off	791	EXCELLENT	60	24	
Renewals					
Administrative – sign off	146	EXCELLENT	30	5	

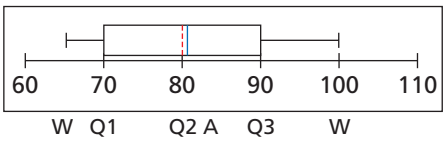
Category/application type	Number (of Applications)	Performance level (excellent, effective, unacceptable)	Target (days[1])	Average time in days	Box Whisker Plots Key: - - - = Median —— = Average
Full and conditional – initial assessment	50	EXCELLENT	90	67	
Full and conditional – sign off	77	EFFECTIVE	180	113	
ATCs					
Type A and B – validate	30	EXCELLENT	5	2	
Type A – sign off	10	UNACCEPTABLE	30	22	
Type B – sign off	23	EFFECTIVE	50	36	
Type A and B – issue	33	EXCELLENT	5	3	
Batch release (Immunologicals)					
Issue	2,428	EXCELLENT	15	5	
AVAs and NFABBAs (inc variations)					
Assess	2	EXCELLENT	45	19	
Specific Batch Control					
Validation	98	EXCELLENT	3	<1	
Initial assessment	95	EXCELLENT	10	2	
Assess response	90	EXCELLENT	10	<1	
Issue	86	EXCELLENT	3	<1	
Validation/Issue					
Validation	1,310	EXCELLENT	10	5	
Issue	2,195	EXCELLENT	10	5	
UKPARs					
Module 1	160	EXCELLENT	30	17	
Module 2	134	EXCELLENT	120	34	
Module 3	126	EXCELLENT	60	37	
Import Certificates[3]					
SIC – urgent/non-urgent	2,779	EXCELLENT	2/10	<1	
STC – urgent/non-urgent	4,785	EXCELLENT	2/10	1	

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	3	EXCELLENT	70
Co-Rapp – Provide comments on assessment report by 85 days	3	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	17	EXCELLENT	90
Assessment of Responses by 2nd 70 days	10	EXCELLENT	70
Procedure completed by 2nd 90 days	23	EXCELLENT	90
CMS			
Procedure completed by 2nd 90 days	24	EXCELLENT	90
Decentralised RMS			
Production of Assessment Report within 70 days	34	EXCELLENT	70
Production of Assessment Report within 120 days	33	EXCELLENT	120
Assessment of Responses by 70 days	43	EXCELLENT	70
Procedure completed by 90 days [210 in total]	43	EXCELLENT	90 [210]
CMS			
UK comments sent by 100 days	29	UNACCEPTABLE	100
Procedure completed [decision made] by 120 days	30	EXCELLENT	120
UK acceptance/referral sent by 90 days [2nd phase] [210 days]	32	EXCELLENT	90 [210]
MRL (No. 6.i)			
Report for CVMP	0	EXCELLENT	120
European Variations Type II – Mutual Recognition RMS			
PAR circulated	16	EXCELLENT	40
CLOQ circulated	43	EXCELLENT	60
Procedure completed	40	UNACCEPTABLE	90
Type IB – Mutual Recognition RMS			
CLOQ circulated	32	UNACCEPTABLE	30
Procedure completed	34	EXCELLENT	60
Type IA – Mutual Recognition RMS			
Determined within 14 days	65	UNACCEPTABLE	14
Type IA – Mutual Recognition CMS			
Determined within 14 days	17	EXCELLENT	14
Type II Mutual Recognition CMS			
UK comments sent by 55 days	62	UNACCEPTABLE	55
UK comments sent by 85 days	25	EXCELLENT	85
Type IB Mutual Recognition CMS			
UK comments sent by 20 days	12	EXCELLENT	20
UK comments sent by 50 days	27	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	8	EXCELLENT	40
CLOQ circulated by 60 days	24	EXCELLENT	60
Procedure completed by 90 days	24	EXCELLENT	90
Mutual Recognition CMS			
UK Comments sent by 55 days	23	UNACCEPTABLE	55
UK Comments sent by 85 days	14	EXCELLENT	85
Customer Relations Customer Care Visits			
Number of letters sent	73	EXCELLENT	
Number of visits	7	EXCELLENT	
Publishing themes	2008/09	EXCELLENT	
Unreturned authorisation documents			
Right first time (Authorisations)	2,404	EXCELLENT	
Right first time (SIC/STCs Certificates)	7,564	EXCELLENT	
Right first time (Export Certificates)	1,076	EXCELLENT	
SARs			
Enter human SARs	154	EXCELLENT	2
Enter serious animal SARs	1,461	EXCELLENT	2
Enter environmental SARs	2	EXCELLENT	2
Enter non-serious SARs	1,608	EXCELLENT	10
Report to Eudravigilance	1,226	EXCELLENT	5
Inspections			
Inspect	38	EXCELLENT	
Prepare report	23	EXCELLENT	60
Issue Certificate	9	EXCELLENT	90
Annual VPC evaluation of Assessment Reports Others			
Evaluation	2	EXCELLENT	

[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.
[3] These are presented for information only – they do not form part of the VMD's formal published standards. They relate to paper based applications. The combined figures are for both the Scientific and Administrative teams.

ATC – Annual Test Certificate
AVA – Autogenous Vaccine Authorisation
CLOQ – Consolidated List of Questions
CMS – Concerned Member State
MA – Marketing Authorisation
MAPI – Marketing Authorisation Parallel Import
MR – Mutual Recognition
MRL – Maximum Residue Level
NFABBA – Non-Food Animal Blood Bank Authorisation
PAR – Preliminary Assessment Report
RMS – Reference Member State
SAR – Suspect Adverse Reaction
SIC – Special Import Certificate
STC – Special Treatment Certificate
UKPAR – United Kingdom Public Assessment Report

Appendix B
Advisory Committees

Veterinary Products Committee (VPC)

The VPC was established in 1970 under Section 4 of the Medicines Act 1968 (the Act).

On 30 October 2005 the Act was disapplied to veterinary medicines by the Veterinary Medicines Regulations 2005 SI No 2745 (the Regulations). However, whilst the statutory requirement for the VPC was retained in the Regulations, its terms of reference were not. In October, following the recommendation of the Committee, Ministers agreed the following terms of reference for the Committee, effective from 30 October:

"The Veterinary Products Committee 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 Veterinary Products Committee publishes a report of its activities and those of its sub-committees."

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

Medical and Scientific Panel

The Medical and Scientific Panel, a sub-committee of the VPC, was established in 1994 to:

- evaluate research currently available, and in progress, on organophosphorus 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 organophosphorus sheep dip;
- advise on the suitability of any projects submitted for research; and
- report its findings to the VPC, as its sub-committee.

Appraisal Panel on Human SARs

The Appraisal Panel, a sub-committee of the VPC, was established in November 1991 to:

- evaluate all SARs 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.

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 and Statutory Instruments[28]

Publications 2008/09

Veterinary Medicines Guidance Notes 1-27 (updated versions)

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 2008/09

The Veterinary Medicines Regulations 2008

SI 2007 No 2297

Made: 26 August 2008

Coming into force: 1 October 2008

The Veterinary Medicines (Amendment) Regulations 2008

SI 2008 No 2648

Made: 3 October 2008

Coming into force: 1 November 2008

The Charges for Residues Surveillance (Amendment) Regulations 2008

SI 2008 No 2999

Made: 15 November 2008

Coming into force: 12 December 2008

28. 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 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

Annual Report of the VMD's Audit & Risk Committee

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 2008/09. The frequency and timing of meetings were scheduled to correspond with the stages of the financial year.

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:
   - fees menu and cost recovery (May 2008)
   - risk management – risk register, policy and procedures (September 2008)
   - drug availability (1), herbal medicines and homeopathics (December 2008)
   - drug availability (2), proposals for improvement (March 2009)

The Chairman attended the Best Practice for Audit Committees Conference (Striking the right balance) sponsored by HM Treasury and The National School of Government on 27 November 2008.

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
ATC	Animal Test Certificate
ATI	Access to Information
BEMA	Benchmarking of European Medicines Agencies
BTV8	8 Bluetongue Virus
CD	Controlled Drug
CEO	Chief Executive Officer
CETV	Cash Equivalent Transfer Value
CLOQ	Consolidated List of Questions
CMD-v	Co-ordination Group for Mutual Recognition and Decentralised Procedures – veterinary
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
DIS	Defra Investigation Service
EC	European Commission
EFQM	European Foundation for Quality Management
EMEA	European Medicines Agency
EP	European Parliament
ESBL	Extended Spectrum Beta-Lactamase
eSPC	Electronic Summary of Product Characteristics
EU	European Union
FM	Facilities Management
FreM	Financial Reporting Manual
FSA	Food Standards Agency
GMP	Good Manufacturing Practice
HMA	Heads of Medicines Agencies
HSE	Health and Safety Executive
ICO	Information Commissioner's Office
IiP	Investors in People
IMB	Irish Medicines Board
ISMS	Information Security Management System
IT	Information Technology
IVMPs	Immunological Veterinary Medicinal Products
KPIs	Key Performance Indicators
MA	Marketing Authorisation
MAH	Marketing Authorisation Holder
MAFF	Ministry of Agriculture, Fisheries and Food
MAVIS	Marketing Authorisations Veterinary Information Service
MHRA	Medicines and Healthcare products Regulatory Authority
MRLs	Maximum Residue Limits
MRSA	Methicillin Resistant *Staphylococcus Aureus*
NAO	National Audit Office
NSS	National Surveillance Scheme
OAB	Ownership Advisory Board
OCs	Organochlorine Compounds
OPs	Organophosphates
PAR	Preliminary Assessment Report
PCBs	Polychlorinated Biphenyls
PCSPS	Principal Civil Service Pension Scheme
PSD	Pesticides Safety Directorate
PSURs	Periodic Safety Update Reports
PuARs	European Public Assessment Reports
R&D	Research and Development
RASB	Regulatory Agencies Strategy Board
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
SI	Statutory Instrument
SIC	Special Import Certificate
SOCA	Serious Organised Crime Agency
SP	Synthetic Pyrethroid
SPC	Summary of Product Characteristics
SQP	Suitably Qualified Person
STC	Special Treatment Certificate
SWM	Sustainable Workplace Management
TLU	Training and Liaison Unit
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

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