ASSURING THE SAFETY, QUALITY AND EFFICACY OF VETERINARY MEDICINES

Veterinary Medicines Directorate Annual Report & Accounts 2007/08

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 2007/08

INVESTOR IN PEOPLE

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Chief Executive's Foreword

The Veterinary Medicines Directorate (VMD)[1] continues to deliver an efficient regulatory service to the pharmaceutical industry by meeting its published standards in respect of assessment and authorisation times. This sustained level of performance has been recognised by the pharmaceutical industry and represents considerable value for money. As a result our authorisations work in Europe is growing rapidly.

The VMD has also worked hard to improve the availability of medicines in the UK and, for example, the on-line Special Import Certificate (SIC) system and the Special Treatment Certificate (STC) system are allowing important veterinary medicines to be imported and used in the UK where they are urgently needed to treat cases where no suitable UK authorised product exists. We also appear to have made progress on the cascade with reports suggesting veterinary surgeons have increased understanding of their responsibilities in this area.

In support of the regulatory effort we have worked hard to ensure the legislation is adequately enforced and prosecutions have followed where it is clear the illegal supply or use of Veterinary Medicinal Products (VMPs) is a deliberate act. We have had considerable success here with at least two major prosecutions in the UK and some collaborative work with our French colleagues to stop an illegal supply through the internet. As a first step, we still use enforcement to provide advice to those using VMPs and try to match our actions to the severity of the risk involved in the illegal use.

Our residue surveillance team has worked hard as usual and in addition are busy negotiating on the revision of the Regulations governing Maximum Residue Limits (MRLs) in the European arena. This is a major piece of their work and is an important part of our de-regulation ambitions whilst retaining the level of assurance on the safe use of veterinary medicines in food producing animals.

During the year the VMD dealt with two crises each capable of seriously affecting our performance. The outbreak of Foot and Mouth Disease (FMD) during the summer involved our small Good Manufacturing Practice (GMP) inspection team with considerable extra work. They rose to this challenge with enthusiasm and professionalism and thanks to some careful management were able to provide assurance on the GMP status of the vaccine plant and maintain their service to our key customers without serious disruption. A power failure on our New Haw site provided our second challenge and I am pleased to report that once again thanks to several people at the VMD stepping into the breach we were able to contain the effects of this incident with minimal disruption for our customers. This was also a useful practical demonstration of the effectiveness of our recently revised Disaster Recovery Plan.

Bluetongue

A major focus of work this year in both the policy and authorisation areas has related to Bluetongue virus serotype 8 which has spread rapidly and widely throughout northern Europe and is a major threat to the livestock industry of the EU, including the UK. The VMD has provided extensive support to core Defra and Ministers by seeking to make available a suitable vaccine to protect UK livestock. Although in an emergency situation member states can use unauthorised vaccines under Article 8 of Directive 2001/82/EC, there is an unequivocal preference to use vaccines with an appropriate Marketing Authorisation (MA). The first serotype 8 vaccine was provisionally authorised in the UK at the beginning of April 2008. It is provisional because the data available lacks definitive proof of efficacy but initial trial data indicates that the vaccine should be of value in controlling this disease and we will review its efficacy after a year of field usage. This was only possible because the VMD encouraged early submission of applications, assessed the data as it became available and did so to much shorter timelines than usual and held an extraordinary meeting of the Veterinary Products Committee (VPC) to facilitate rapid authorisation. This was achieved without a discernible reduction in the routine service standards to other applicants and for this the immunologicals team deserve considerable credit for their hard work. As a result UK farmers had an authorised vaccine available during May 2008.

Europe

The influence of Europe on the nature of our work continues to grow. Whereas five years ago much of our work involved national applications and issues, more than half of our current authorisation effort is focused on European applications. In addition, much work is carried out in Europe to facilitate the regulatory process. The VMD is very active at the EU level and is engaged in many working groups as well as the formal committees that we attend regularly. In particular, at the Heads of Medicines Agencies (HMA) meetings we have taken a leading role on resource planning and telematic issues (i.e. IT infrastructure in Europe) as two important areas for the efficient working of the network of National Competent Authorities (NCAs). Under the telematics banner the development of the Eudrapharm database (providing information on VMPs to the public), the Eudravigilance database

Steve Dean

1. You can find out more about the VMD and its work via www.vmd.gov.uk

(providing a useful tool to track adverse reactions across the EU) and the e-Submissions activity (preparing the network for electronic submission of data) are three areas that will be vital to the efficient operation of the regulatory network.

The European network of NCAs plays a key role. As a member of the HMA group, and up until recently also a member of the HMA Management Group, I am acutely aware of all the effort put into the authorisation of veterinary medicines across Europe and the VMD plays a very full role in this. The work of various committees, working groups and task forces helps to ensure that issues affecting veterinary medicines are dealt with effectively and steps are taken to secure improvements for the future.

Carrying out a representational role for HMA on the European Technology Platform Group for Global Animal Health (ETPGAH) and being involved with the associated UK mirror group shadowing this initiative for the UK, will also help in the longer term to ensure that appropriate veterinary medicines are developed efficiently and effectively to meet the future animal health needs of both the EU and specifically the UK.

The spectrum of our work in Europe justifies our change project to provide improved co-ordination of our efforts within the EU network. The creation of a specific post carrying out the dual role of Committee for Veterinary Medicinal Products (CVMP) member and EU co-ordination has recognised this change and started to bring considerable benefit to the operation and deployment of VMD resources. We expect this improvement to continue into the coming year.

Veterinary Medicines Regulations[2]

Three major areas are under development for the coming year to improve the way veterinary medicines are regulated. Firstly, we are seeking to adopt clear regulations relating to the use of controlled drugs by veterinary surgeons. Secondly, taking account of the viewpoints of representatives from the Home Office, the Royal College of Veterinary Surgeons (RCVS) and clinical research staff from the teaching schools and the Animal Health Trust, a proposal was drafted to revise the Animal Test Certificate (ATC) scheme to include small scale clinical research trials within the Regulations and place these under the regulatory control of the VMD. Thirdly, we have made progress with plans to introduce Practice Registration which will allow an inspection system to be set up thus bringing veterinary practices into line with other regularly inspected premises (pharmacies and Suitably Qualified Person (SQP) outlets) handling veterinary medicines thus ensuring veterinary medicines are being stored and supplied in line with the Regulations throughout the distribution chain.

Finance

For the third year in succession we have been able to maintain our fee increase at or below inflation thanks to the work of our 'behind the scenes' teams who administer and support our regulatory activities. The efficiencies they bring to bear on our work area continue to ensure we can deliver 'value for money' services.

Data Security

In this respect we were asked by the Cabinet Office to ensure our security for electronic data storage was fit for purpose. As our IT team have worked hard in the past to achieve and maintain our ISO27001 accreditation this investment has proven its worth as this assurance could be readily provided. Data security is an integral part of the VMD's operations protecting both personal and business sensitive information for our customers and stakeholders.

Hampton[3]

One of our key activities during the year was to prepare a business case considering the merger options for the VMD under the 'Hampton' initiative. The business case identifies three merger options with the Animal Health Agency, the Medicines and Healthcare products Regulatory Agency (MHRA) and the new joint Health and Safety Executive (HSE)/Pesticides Safety Directorate (PSD) Agency. It also considers the option of the VMD remaining as an Agency of Defra. We will be having discussions with HM Treasury and the Better Regulation Executive to agree the options to be included in a formal consultation on possible changes to the VMD. This consultation is likely to be held during 2008.

There are so many achievements in the past year it is likely I have missed some notable examples. However, as in past years, I remain immensely proud of the people I work with at the VMD. They provide dedication to their delivery of the regulatory processes, they are diligent in their work, they truly work in teams supporting each other and they are also good people to work with. I would like to thank them all for their hard endeavour over the past 12 months and for making the VMD an Agency which is respected worldwide for its work.

Steve Dean
Chief Executive
23 May 2008

2. You can find out more about the Veterinary Medicines Regulations via www.vmd.gov.uk under General Information/ Veterinary Medicines Regulations and Guidance
3. You can find out more about the Hampton Report at www.hm-treasury.gov.uk/budget/budget_05/other_documents/bud_bud05_hampton.cfm

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 VMPs. In working towards achieving this vision the VMD aims to protect public health, animal health and the environment and promote animal welfare by assuring the safety, quality and efficacy of veterinary medicines. The VMD aspires to continue to move in the direction of being an outward facing organisation with a strong focus on the needs of our customers and stakeholders. In doing so we support the Department for Environment, Food and Rural Affairs (Defra)[4] 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 MAs 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 VMPs 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 in the area of antimicrobial resistance via the Defra Antimicrobial Resistance Coordination (DARC)[6] Group.

We do this by validating, assessing and interpreting data provided to us on veterinary medicines. Where necessary we seek independent expert advice from the VPC[7] and the VRC[8]. We subcontract analytical tests or other procedures that have to be carried out.

Under the provisions of EC and UK legislation, no VMP 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. This inspection work is carried out by the MHRA[9] except for sites manufacturing veterinary immunological products or products marketed under the UK Small Animal Exemption Scheme 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) 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)[11], the latter of which was absorbed into the VMD in January 2006. 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.

4. You can find out more about the work of Defra via www.defra.gov.uk
5. You can find out more about the work of the FSA via their website www.foodstandards.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 AMI via www.vmd.gov.uk under Industry Information

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

How We Are Organised

Our structure

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

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

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

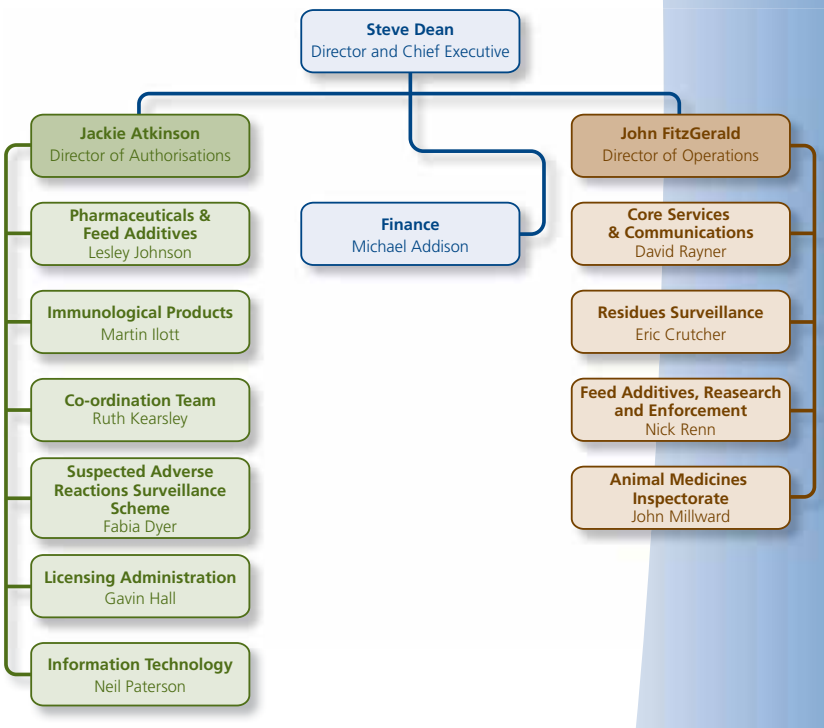
Authorisations, responsible for the assessment of applications; issuing and maintenance of Marketing Authorisations; pharmacovigilance for veterinary medicines; and the licensing and inspection of manufacturers and wholesale dealers of veterinary medicines. The main customers are Marketing Authorisation holders; manufacturers and importers of veterinary medicines; manufacturers of medicated animal feedingstuffs; retailers of veterinary medicines and medicated animal feedingstuffs; the veterinary profession; other stakeholders including farmers and keepers of animals; the European Medicines Evaluation Agency (EMEA)[12]; Department of Health (DH)[13]; 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.

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 (Animal Health and Welfare Directorate, 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 2008



12. You can find out more about the EMEA via www.emea.europa.eu
13. 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 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[14];
- 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 sit as our Audit & Risk Committee – see Appendix E) to provide an independent critique of our performance. The two Directors and Heads of the two scientific disciplines (Immunologicals and Pharmaceuticals), Finance, Information Technology (IT) and Training & Liaison Unit (TLU) complete the formal membership. Staff have a standing invitation to propose items for the agenda and to attend as observers. During 2007/08 four members of staff attended the meetings. The Board secretary posts papers on the Management Board intranet site and issues an office notice covering key messages directly after each meeting so that staff can be engaged in the Board's work.

The Regulatory Agencies Strategy Board (RASB)

The RASB provides strategic direction for the VMD and the PSD[15], and maximises the opportunities between the two Agencies for synergies and strategic performance management. The RASB does not cover policy work. The RASB met in April, July, October and February when, *inter alia,* it agreed its terms of reference and procedures.

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

EXTERNAL MEMBERS		INTERNAL MEMBERS		DEVOLVED MEMBERS	
Quintin McKellar	Chair	Andrew Robinson	Delivery Strategy Team	Charles Milne	Scottish Executive Environment and Rural Affairs Department
Chris Payne		Kerr Wilson	Pesticides Safety Directorate	Norma Barry (April, July and October meetings)	National Assembly for Wales Agricultural Department
		Steve Dean	VMD		
		Fred Landeg	Animal Health & Welfare	Chris Lea (Appointed February)	National Assembly for Wales Agricultural Department
		Peter Unwin	Environment		
		Bob Watson	Science Directorate	Michael Camlin	Department of Agriculture and Rural Development (Northern Ireland)
		Richard Wilkinson	Finance		
		Tim Foster	Food Standards Agency		
		Les Philpott	Health & Safety Executive		

Our Finances

For the authorisation of veterinary medicines, inspection and approval of manufacturers of medicated/zootechnical animal feedingstuffs, post authorisation surveillance of SARs and supporting activities, the VMD recovers its costs through fees and charges to industry. For statutory residues monitoring, fees are levied on abattoirs and other food processors. The costs of policy advice, non-statutory residues monitoring and R&D are financed wholly by Defra.

The Agency is required to achieve full cost recovery across the four business areas of Authorisations, Residues, Operations and AMI whilst at the same time improving its cost efficiency and service delivery.

Certain elements of the work for which the VMD is responsible are sub-contracted. The VMD's sub-contractors include LGC Limited[16], the Central Science Laboratory (CSL)[17], Animal Health (AH), the Medicines and Healthcare Products Regulatory Agency (MHRA) and the Meat Hygiene Service (MHS)[18].

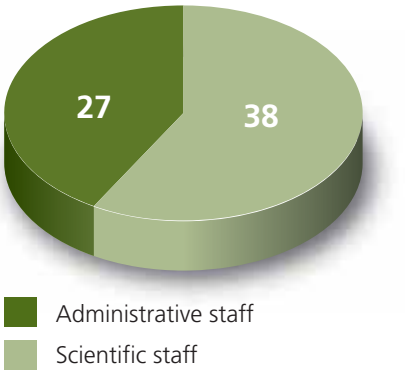
14. You can find a copy of our Business Plan on our website www.vmd.gov.uk under About
15. You can find out more about the work of the Pesticides Safety Directorate via their website www.pesticides.gov.uk
16. You can find out more about LGC Limited via www.lgc.co.uk
17. You can find out more about the CSL via www.csl.gov.uk
18. You can find out more about the MHS via www.food.gov.uk/foodindustry/meat/mhservice

Our People

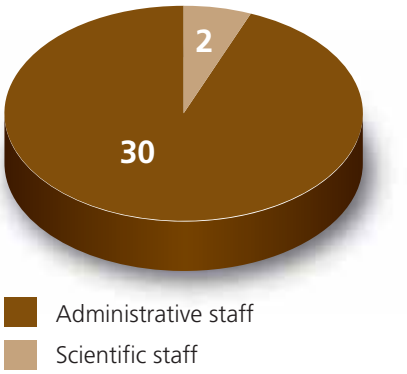
At 31 March 2008 we employed 136 permanent staff, both full and part-time. This included veterinarians, pharmacists, chemists, toxicologists, biologists, IT specialists, administrative and support staff. We supplemented our permanent workforce with 16 colleagues who work on a temporary basis and are supplied by local employment agencies.

Average Permanent Staff Numbers 2007/08

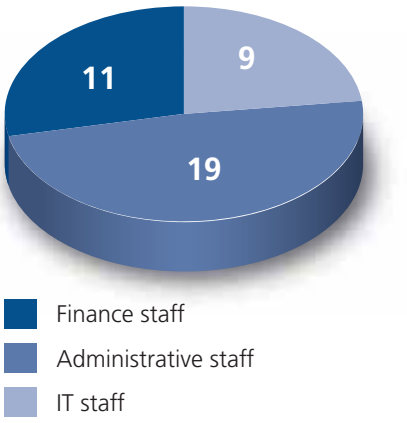
Authorisations



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 Directorate.

Employee Involvement

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

The VMD was re-accredited as an Investor in People (IiP) in 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. The VMD was accredited under the IiP Recruitment and Selection Model in 2005. The next review is due in 2008.

The VMD benchmarks against the European Foundation for Quality Management (EFQM) Excellence Model recommended by the Cabinet Office. In addition the VMD took part in the EU Benchmarking process led by the HMA[19] in 2007/08.

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

The VMD adheres to the "Better Payment Practice Code". In 2007/08 the VMD paid 100% of validated invoices within 30 days.

19. 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 11 December 2007 in pursuance of Section 7(2) of the Government Resources and Accounts Act 2000 and audited by the Comptroller and Auditor General.

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

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

Management Commentary

Our work in 2007/08

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

- the Veterinary Medicines Regulations 2007 came into force on 1 October 2007 and introduced changes to clarify some of the provisions of the 2005 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 introduction of the on-line Special Import Certificate (SIC) system and the Special Treatment Certificate (STC) system;
- the VMD were the first RMS to end decentralised procedures earlier than the 210 day timeframe;
- unplanned and extensive additional inspection work associated with the outbreak of Foot and Mouth disease;
- the examination of the Provisional Marketing Authorisation applications for Bluetongue vaccine;
- the seizure in France of 1m Euro worth of medicines destined for the UK and the customer list of the company involved;
- a trader in illegal medicines was sent to prison and ordered to pay nearly £250,000 following a recovery of assets case; and
- we prepared a business case considering options for the VMD's status following the Hampton Report.

The Secretary of State of Defra announced our targets to Parliament on 27 April 2007. 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 2007/08.

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 performance standard defined as effective with the majority of individual parameters monitored achieving the excellent performance standard.

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.

Highlights The seizure in France of 1m Euro worth of medicines destined for the UK and the customer list of the company involved leading to a number of raids on premises in the UK. Another trader in illegal medicines was sent to prison and ordered to pay nearly £250,000 following a recovery of assets case.

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.

Highlight The overall sampling and analysis targets for the Statutory Programme were met in spite of the difficulties caused by the FMD, Bluetongue and Avian Influenza outbreaks.

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 Note 2 to the accounts shows that the overall cost recovery was 104.8% 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.

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

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

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

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

Director of Authorisations' Review

Jackie Atkinson

The Authorisations Division has had another very busy, at times exciting and certainly productive year.

The volume of European applications this year and, in particular, the number of decentralised procedures for both pharmaceutical and immunological products where the VMD has been asked to act as RMS, exceeded by a long way our predictions at the start of the year. The signs are that this work will continue to grow at a similar rate. I believe the VMD's popularity as an RMS can be attributed to our scientific integrity, our transparent and helpful approach to the pharmaceutical industry and our predictable and consistent service standards, together with the knowledge that our decisions are respected by our counterparts in Europe. The demanding timeframes associated with the decentralised procedure require careful resource planning. Nevertheless, the VMD were the first RMS to end decentralised procedures earlier than the 210 day timeframe. Despite the significant increases in the number of applications, the people in the Authorisations Division have largely met or exceeded our published standards.

For the first time this year we have calculated an overall score for our service standards and this shows that we are very comfortably in the "effective" performance standard. When the detailed results are examined, it is clear that for most parameters we scored "excellent". In a very small number of European applications, intermediate targets were missed by a matter of days with the reasons for being unable to meet the originally set target being clearly identified and outside of our direct control. One example of a target which we failed to achieve was the 60 day target for preparation of GMP inspection reports within 60 days. It was impossible to meet this because of the unplanned and extensive additional inspection work associated with the outbreak of FMD. The high workload in the inspections team was further compounded by the need to inspect and often re-inspect a much higher number of sites than expected, for companies who were planning to market products under the Small Animal Exemption Scheme. The inspectors rose admirably to this challenge and at times worked very long hours to ensure the necessary work was completed.

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

Each of the teams has had different challenges to deal with, usually relating to resources making these achievements remarkable. Assessors and administrators are used to working to demanding timelines, but at times and to address specific problems, they have worked to much shorter timelines. A good example of this has been the examination of the Provisional Marketing Authorisation applications for Bluetongue vaccine.

The SARSS team has continued to be an important presence in Europe. A considerable amount of effort has been put into the revision of Volume 9B of the Rules governing medicinal products in the EU as well as work to ensure that Eudravigilance Vet is properly supported. The SARSS team has once again coped with an increasing number of reports of SARs. This is a reflection of the increased awareness of this scheme and part of this will be because of the publications and presentations made by members of the team throughout the year. Pharmacovigilance inspections, a new responsibility for regulatory agencies, are proving to be an important tool for improving the data submitted to the VMD by MA holders.

The IT team have continued to support and develop new systems for the VMD, whilst continuing to ensure that high security standards are met. Significant developments include the new intranet for VMD staff and an improved application and authorisation tracking system. The list of new systems and developments is too long to include here, but what is clear is that the VMD benefits from bespoke systems that meet our business needs. The VMD's ability to respond quickly to change and to work efficiently is to a large part due to our IT staff.

The Authorisations Division plays a key role in Europe, with people regularly attending and actively participating in meetings such as the CVMP[20], CVMP working parties and Co-ordination Group for Mutual Recognition and Decentralised Procedures – veterinary (CMD-v). There have been a number of areas where the UK has taken the lead. For example a significant European achievement was to prepare and gain agreement on a CMD-v document designed to deal with some of the difficulties surrounding generic products.

It is not possible to list all of the highlights from this year, but very notable are the results of the Customer Survey of which we are all proud but not complacent. The challenge for the coming year is to maintain this level of service delivery and to introduce improvements where we can.

20. You can find out more about the work of the CVMP via the EMEA website www.emea.europa.eu

Looking to the future we have some important projects planned for the forthcoming year, including: preparing for e-submissions, planning for and implementing changes arising from the Variation Regulations, completing the work on variations to bring SPCs and product literature into line with the requirements of the VMRs and taking forward a number of initiatives to encourage applications for limited market products. We will also be increasing the number of staff in certain areas so that we can cope with the increasing volume of work.

Finally, I would like to thank all of the staff in the Authorisations Division, and also the people in the Operations Division who provide us with support and advice, for their hard work, commitment and professionalism. The impressive results and the VMD's excellent reputation in Europe are a reflection of a team working industriously together for a common goal which we all believe in.

Jackie Atkinson

Director of Operations' Review

John FitzGerald

2007/08 has been a year of transition for the Operations Division with much work on long term projects that will conclude next year. We also saw the retirement of Heather Oliver who had worked in many areas of the VMD and whose drive and experience was inevitably missed.

Looming over the VMD for the whole year was the uncertainty of a possible merger with another organisation. Personally, much of my time was spent developing a business case to consider the options for the VMD's future status and position in the Civil Service and we shall be consulting stakeholders on these during 2008.

The 2007 VMRs were put in place on time and included a requirement for veterinary practices to register for the retail supply of veterinary medicinal products from April 2009. This will enable veterinary practices to be inspected for both normal and controlled drug (CD) supply. Discussions were held with the veterinary profession on the details of registration and inspection and these were included in the consultation for the 2008 Regulations which began in March. Detailed changes to bring the CD controls in line with the Shipman Inquiry[21] recommendations were still being discussed with the Home Office at the end of the year. The Legislation team also spent much time on the distribution category review, organising VPC discussion and a number of consultations. We are nearing the end of this long review which will be concluded in 2008.

Our Enforcement team worked closely with colleagues in Defra, the police and other member state Governments to try to reduce the amount of medicines being sold illegally in the UK. There were some major successes with the seizure in France of 1m Euro worth of medicines destined for the UK and the customer list of the company involved. This led to a number of raids on premises in the UK. Another trader in illegal medicines was sent to prison and ordered to pay nearly £250,000 following a recovery of assets case. Towards the end of the year we set up a team to review internet sites supplying veterinary medicines.

Our antimicrobial resistance work developed as new resistance issues emerged in cattle, pets and, abroad, in pigs. Our close liaison with human health agencies meant that we were able to consider quickly any implications for human treatment. The Annual Sales Data Report was published on time and I gave a presentation to the Royal Society[22] on antimicrobial use and resistance in animals.

The Feed Additives team had to deal with a varied range of new issues consulting on the appropriate legislative base for coccidiostats and histomonostats, the use of medicines in liquid pig feed and concerns about farmers mixing nutritional supplements with wormers before administration. Results from the Government's R&D work on human health implications of long term low level exposure to organophosphates (OPs) through dipping sheep were given to the Committee on Toxicity for review. Work also continued on determining whether synthetic pyrethroid (SP) sheep dips could be used in an environmentally sustainable way.

The Animal Medicines Inspectors worked on a risk basis to reduce the frequency of routine inspections as they became more involved in investigation work associated with the illegal supply of medicines especially under the Small Animal Exemption Scheme. To help them co-ordinate their varied roles and improve efficiency, the inspectors' database was redeveloped providing better planning and reporting tools. A Defra audit provided substantial assurance that the control framework for Official Feed and Food Controls implemented by the AMI adequately manages and controls the risks in this area, confirming the quality of the AMI's work.

The Commission proposed changes to their Maximum Residue Limit (MRL) legislation which were negotiated throughout the year. Both surveillance programmes ran to plan despite difficulties with on-farm sampling because of FMD movement restrictions. The Residues team provided training to colleagues in Croatia and Slovenia.

Those of you who visit the VMD will have seen first hand the results of the Core Services team not just in the provision of refreshments but also our improved reception area which now boasts wireless access and will soon have VMD TV to keep you up to date with news, weather and travel information. The team also worked on our revised Sustainable Development Plan and updated Freedom of Information (FOI)[23] guidance and dealt admirably with glitches in systems provided by others. They were particularly positive dealing with the headcount controls introduced by HM Treasury. These added to our normal financial controls and led to delayed recruitments which then had to be activated as the year ended and the headcount controls were removed.

The VMD has the benefit of being a comparatively small group of people focussed on clear objectives. We work well together as one big team and deliver good results as evidenced by the customer survey. Thank you to all staff who contributed to this success and especially to those working in the Operations Division for all your efforts in another positive year.

John FitzGerald

21. You can find out more about the Shipman Inquiry via www.the-shipman-inquiry.org.uk
22. You can find out more about the RPSGB via their website www.rpsgb.org
23. You can find out more about the Freedom of Information Act via the Ministry of Justice website www.justice.gov.uk

Looking Forward

Targets for 2008/09

Ministers have agreed four targets for the VMD.

The four targets are:

Target 1 – To authorise veterinary medicines against legislative requirements, according to published standards, and monitor reports of SARs 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 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 and provides value for money* and the VMD achieves full cost recovery.

The VMD's work contributes to the achievement of five of Defra's Intermediate Objectives.

- **Public health and the economy protected from animal diseases**
  Veterinary medicines are used to prevent and treat animal diseases. Authorised veterinary medicines are assessed for safety, quality and efficacy providing reassurance that they will deliver their label claims and will not harm the public (consumer/user/third party) if used in accordance with the manufacturer's instructions.
- **Farming has an improving net environmental impact**
  VMD's assessment includes environmental safety so that any risks to the environment from the use of an authorised VMP are identified and managed.
- **Profitable and competitive farm businesses**
  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 the farm business.
- **Improved welfare of kept animals**
  Authorised veterinary medicines are assessed to ensure they are effective and safe to be used in the target species. They are used to prevent disease and treat sick animals improving their health and welfare.
- **Protection of the economy, human health and ecosystems from environmental risks and emergencies**
  VMD's assessment work contributes to Defra's use of hazard assessment, risk assessment and risk management of chemicals.

Key challenges for next year

The key challenges to the VMD throughout 2008/09 and its plans for meeting them have been outlined in the VMD's Business Plan, 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 2008;
- European Community proposals to amend EC residues legislation;
- European Network of medicine regulatory authorities and the continuing expansion of the EU, and our interface with these developments;
- implementation of our Business Plan, our Improvements Plan and our Change Programme to drive delivery and continuous improvement; and
- outcome of the consultation on the recommendations contained in the HM Treasury Report entitled 'Reducing Administrative Burdens: Effective Inspections and Enforcement' (the Hampton Report) expected in 2008. Whatever the outcome of the consultation process, the existing targets and activities are likely to remain as they fulfil EU statutory obligations.

* 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**.

Financial Review

The VMD was set one key financial performance target in 2007/08: to achieve cost recovery for the VMD as a whole. The accounts show an operating surplus for the year of £665,000, achieving an overall cost recovery of 104.8%.

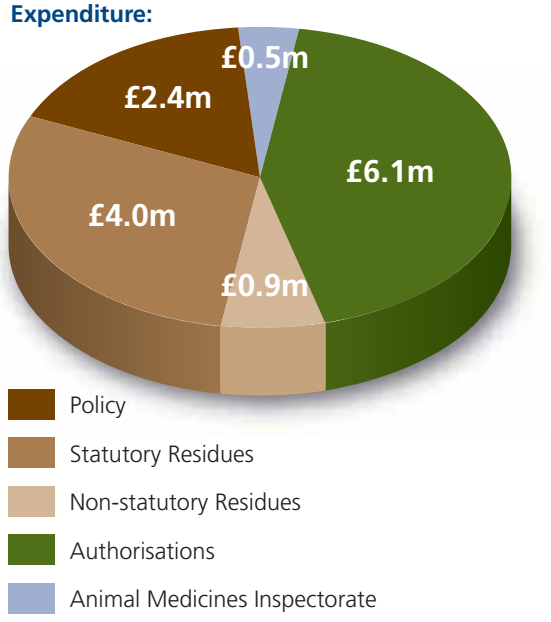
Income & Expenditure

The results of the VMD's main business activities during 2007/08 were as follows:

	Income £,000	Expenditure £,000	Cost recovery %
Authorisations	6,826	6,129	111.4
Statutory Residues	3,997	4,020	99.4
Non-statutory Residues	873	873	100
Policy	2,345	2,377	98.7
Animal Medicines Inspectorate	508	485	104.7
Total VMD	14,549	13,884	104.8

Details of the above income and expenditure are shown in Note 2 to the Accounts.

Expenditure:



Authorisations cost recovery

Authorisation fees are monitored and revised annually to ensure, as far as possible, that the fees charged for a particular service reflect the cost of the work undertaken. The costs on which fees are based are estimated up to 11 months in advance. The cost recovery outcome is largely dependent on these estimated costs and industry activity levels during the year, both of which cannot be predicted with certainty.

The Authorisations result for the year of 111.4% reflects an unanticipated 45% increase in volumes of European Marketing Authorisation applications in 2007/08. Savings in salary costs due to delayed recruitment of scientific staff also contributed to the result.

Balance Sheet

The VMD is funded by Defra and the position is shown in the "Financed by" section of the Balance Sheet by means of the General Fund. Within this Fund there are two distinct parts:

(a) The General Account 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. This reserve is not distributable.

(b) The Operating Account represents the accumulated operating cost recovery surplus or deficit transferred from the Income and Expenditure Account.

The Revaluation Reserve represents the unrealised cumulative balance of indexation and revaluation adjustments to fixed assets. The Balance Sheet at the year-end shows a General Fund balance of £8.5m and Revaluation Reserve of £2.6m.

Events since the Balance Sheet date

There have been no significant post balance sheet events up to the date on which the accounts were approved.

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 March 2009.

Salaries and pension benefits (Audited)

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

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

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. The salary and pension entitlements of the senior managers of the Agency were as follows:

Salaries and pension benefits (Audited)

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
	£	£	£
Employer contribution to partnership pension account including risk benefit cover – to nearest £100	–	–	–

2006-07	S Dean – Director and Chief Executive	J FitzGerald – Director of Policy	J Atkinson – Director of Licensing (Appointed 8 January 2007)	J O'Brien – Director of Licensing (Retired 31 May 2006)	C J Bean – Director of Corporate Business (Retired 27 October 2006)
	£000	£000	£000	£000	£000
Salary (as defined above)	90-95 including 5-10 bonus	85-90 including 10-15 bonus	10-15 including 0-5 bonus	10-15 including 0-5 bonus	35-40 including 0-5 bonus

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.

Regulatory Agencies Strategy Board (RASB)

Membership details of the RASB are shown on page 10. With the exception of the VMD and PSD Chief Executives and the external members, the RASB members served only in their capacity as senior managers of the parent or other Government department. Defra bears the cost of its 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 has held any company directorships or other significant interests during the year that, in the opinion of the members, may conflict with their management responsibilities.

Civil Service Pensions

Pension benefits are provided through the Civil Service pension[24] arrangements. From 1 October 2002, civil servants may be in one of three statutory based 'final salary' defined benefit schemes (Classic, Premium, and Classic Plus). The schemes are unfunded with the cost of benefits met by monies voted by Parliament each year. Pensions payable under Classic, Premium, and Classic Plus are increased annually in line with changes in the Retail Prices Index. New entrants after 1 October 2002 may choose between membership of Premium or joining 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 and Classic Plus. Benefits in Classic accrue at the rate of 1/80th of pensionable salary 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 (but members may give up (commute) some of their pension to provide a lump sum). Classic Plus is essentially a variation of Premium, but with benefits in respect of service before 1 October 2002 calculated broadly in the same way as in Classic.

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 selection of approved products. 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).

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

Cash Equivalent Transfer Values (CETV)

A CETV is the actuarially assessed capitalised value of the pension scheme benefits accrued by a member at a particular point in time. The benefits valued are the member's accrued benefits and any contingent spouse's pension payable from the scheme. A CETV is a payment made by a pension scheme or arrangement to secure pension benefits in another pension scheme or arrangement when the member leaves a scheme and chooses to transfer the benefits accrued in their former scheme. The pension figures shown relate to the benefits that the individual has accrued as a consequence of their total membership of the pension scheme, not just their service in a senior capacity to which disclosure applies. The CETV figures, and from 2003/04 the other pension details, include the value of any pension benefit in another Scheme or arrangement which the individual has transferred to the Civil Service scheme and for which the Scheme has received a transfer payment commensurate to the additional pension liabilities being assumed.

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

They also include any additional benefit accrued to the member as a result of their purchasing additional years of pension service in the Scheme at their own cost. CETVs are calculated within the guidelines and framework prescribed by the Institute and Faculty of Actuaries.

Real increase in CETV

This reflects the increase in CETV effectively funded by the employer. It takes account of the increase in accrued pension due to inflation, contributions paid by the employee (including the value of any benefits transferred from another pension scheme or arrangement) and uses common market valuation factors for the start and end of the period.

Steve Dean
23 May 2008

Environmental Matters and Social and Community Issues

Working closely with Defra and the Sustainable Development Commission (SDC) www.sd-commission.org.uk we produced our second Sustainable Development (SD)[25] Action Plan. It covers the period from October 2007 to the end of 2009 and continues our work as part of the commitment to the UK Government Sustainable Development Strategy – *Securing the Future* (March 2005), under which all Government departments and their Executive Agencies produced focused sustainable development action plans based on the Strategy.

Our first plan set out how, by using sound science responsibly and implementing good governance to develop policy and regulate veterinary medicines (our core business since 1990), we contributed to outcomes that are now included under the SD banner. The second plan builds on those achievements and takes account of the lessons we learned during the implementation of the first plan; and the advice we received from Defra and the SDC. It includes a number of actions across a range of our activities, such as operations, travel, policy, IT, leadership and accountability which we believe will contribute further to the Government's SD objectives. It also shows how we are increasingly embedding SD principles and priorities in our decision making, whilst also delivering the requirements set down in European and UK legislation for veterinary medicines.

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

Meeting Our Targets

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.

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

The overall score for our performance, as judged against our published standards, was 120 out of a maximum of 140 which corresponds to the top half of effective. Of the 78 individually monitored parameters, all of these were in the excellent performance standard except just six of these.

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

The VPC judged the VMD assessment standards for three national MAs to be excellent overall.

The VMD regularly acts as the Reference Member State in European procedures. This year the VMD has acted in this capacity for 60 separate 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

The percentage of unreturned authorisation documentation for the period 1 April 2007 to 31 March 2008 is 95.55% which corresponds to the performance standard defined as excellent.

There have been 12 customer care visits during 2007/08 which is in the excellent measure. An article on key themes from all the visits completed during 2007/08 will be published in the July edition of MAVIS[26].

Customer Care visits continue to be a useful two way forum for exchanging information with individual companies; allowing the VMD to communicate key messages and also to act on areas of concern expressed by the Company. During the year we also introduced a company meetings questionnaire to help us ensure that the advice we give continues to be relevant and of a high quality.

Identify changes in the patterns of adverse reactions from pharmacovigilance data and take proportionate action

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 forward reports on centrally authorised products to the EMEA within 15 days of receipt of the information. The team achieved the excellent performance level for all but one of these targets. In the case of forwarding reports to the EMEA the performance standard was judged to be effective. The excellent performance standard was not achieved because of the EMEA's withdrawal of IT support for the system for a five month period from February 2007 onwards, which was beyond the control of the VMD. Concerns raised by the SARSS team over this issue played a large part in the restoration of support for the system by the EMEA.

26. You can access MAVIS via www.vmd.gov.uk under Publications

During the year the SARSS team received 3,069 SAR reports (animal and human) and 1,050 Periodic Safety Update Reports (PSURs), increases of 17.5% and 18.4% respectively compared to the previous year. The team was responsible for the publication of two papers and changes were made to the SPCs for more than 49 products during MA renewal assessments. A warning was added to the SPC for a centralised product following a PSUR assessment carried out by the team. Fifteen pharmacovigilance audits were also completed in the period.

Ensure the continued quality of veterinary medicines by regular inspection of manufacturers to the principles of Good Manufacturing Practice (GMP) and by taking proportionate corrective action when deficiencies are identified

The VMD Inspection team performed a total of 26 inspections, ten of these inspections were of IVMP manufacturers to ensure compliance with the principles of GMP and seven inspections were in third countries. Manufacturers of products exempt under the Small Animal Exemption scheme accounted for ten inspections and contract test sites for a further five inspections. The remaining GMP inspections were performed jointly with another Member State on behalf of the EU and related to centralised applications.

In addition, the team played a significant role supporting the HSE led and independent investigations into the FMD outbreak during the second half of 2007. As a direct result of this and additional unscheduled inspections, a number of inspection reports were issued out-with the performance target (68% within target). However, to address this, the Inspection Team prepared and issued a list of corrective actions to all companies at the end of each inspection. This ensured that companies could commence work on addressing any shortcomings prior to issue of the report.

GMP Certificates were issued to 11 companies, with 100% of Certificates being issued within the performance target. The remaining certificates will be issued on receipt of satisfactory responses to the inspection reports.

The Inspection Team are currently introducing a new quality system in preparation for the HMA's Joint Audit Programme audit scheduled for June 2008.

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 (VMRs) and associated guidance to come into force on 1 October 2007 and initiate the project to revoke and remake the Regulations for 2008

The Veterinary Medicines Regulations 2007 came into force on 1 October.

The project for the 2008 Regulations is well underway with the final drafting instructions being completed prior to consultation. Key issues will include whether legislation for controlling the use and storage of controlled drugs post Shipman should be included in the VMRs and formalising the details for veterinary practice registration. Discussions have been held on these with the RCVS, British Veterinary Association (BVA) and Home Office.

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

Good progress is being made in this complex exercise. All 30 product groups have been reviewed by the VPC sub-group. Consultations on their proposals have either begun or the responses are being considered.

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

Enforcement activity on illegal medicines usage is based on risk assessment in accordance with Hampton. The strategy paper has yet to be published. The paper is drafted; however we are now considering the implementation of risk based inspections, details of which will need to be included within the paper. Publication of the results of Court cases has been implemented in line with the strategy. The number of cases referred to the Defra Investigation Service (DIS) for subsequent legal action is reducing as a result of the introduction of the 'seize and destroy' policy which is also part of the strategy.

Monitor sales of veterinary antimicrobials in the UK by publishing the Antimicrobial Sales Data Report for 2006

The report[27] was published in December 2007.

Ensure the appropriate quality of feedingstuffs containing veterinary medicinal premixes 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 undertook a total of 1,673 visits during 2007/08, comprising 1,379 routine inspections and 294 "other" visits.

The AMI therefore achieved 81% of the planned 1,703 routine inspections. The shortfall was partly due to the significant increase in other visits which are not accounted for in the AMI's planned inspection statistics. The statistics only reflect routine inspections of approved premises.

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

The 294 other visits were as follows:

153 were investigations into unlawful activities e.g. the illegal importation of VMPs and the unlawful marketing of Small Animal Exemption Scheme (SAES) products; and the investigation of food safety incidents i.e residues of specified feed additives or VMPs in foodstuffs or non-target animal species.

26 visits were made to trade fairs, exhibitions and livestock markets to look for unlawful products.

The remaining 115 were neither a "routine inspection" nor an investigation. Investigations are visits to those persons or businesses allegedly committing serious breaches of the Regulations. These included: "follow up visits" e.g. visits to check that deficiencies drawn to a business' attention at an earlier routine inspection had been rectified; "special visits" e.g. to a feed manufacturer to discuss a labelling deficiency noted on a bag of their feed; visits made at the request of a business e.g. to discuss the Regulations or relevant procedures arising from them; and "check" visits to premises that failed to renew their approval, to establish that they were not operating unlawfully.

The planned number of routine inspections was therefore not achieved for several reasons:

(i) the greater than envisaged number of investigations conducted. Investigations generally take longer to conduct than routine inspections and require far more planning and administration time;

(ii) inspection of "on-farm" feedingstuffs manufacturers i.e. livestock premises was suspended between 8 August 2007 and 5 November 2007 due to FMD; and

(iii) the size of the Inspectorate means that any absences or failure to undertake the required number of inspections by an inspector has a significant effect on inspection figures. During 2007/08, the Head of AMI who has an inspection role, was unable to undertake the required number of inspections due to a greater involvement in Corporate and Policy issues.

A business case for an additional inspector has been made and agreed and is included in the 2008/09 budget.

A Defra audit in March provided substantial assurance that the control framework for Official Feed and Food Controls implemented by the AMI adequately managed and controlled the risks in this area confirming the quality of the AMI's work.

Work with EU colleagues to improve the availability of veterinary medicines to develop and prepare for implementation of an agreed EU strategy and, specifically in the UK, by continuing to implement with industry the exemption scheme for products marketed for use in non-food species as detailed in the legislation

The VMD has continued to participate in the discussions at CVMP linked to defining products that would fall under the definition of limited market and also the discussions surrounding the extension of the EMEA scheme offering free scientific advice.

Comments have been sought from interested parties within the VMD and these have been incorporated into a VMD action plan following up the recommendations of the Task Force on Availability of Veterinary Medicines. A separate action plan for VMD actions is being compiled that will allocate resources and deadlines. The action plan has yet to be completed.

An article has been published in MAVIS highlighting those medicines regularly imported into the UK with the aim of encouraging companies to submit MA applications in the UK.

Industry have been consulted on a paper to identify forms of assistance including financial and non-financial incentives for companies wishing to obtain authorisations for minor market products in the UK. Comments have been analysed and proposals made for the areas to be explored first including: designated personal advisors, VMD training courses for industry, wider use of provisional MAs and staged assessment.

The Schedule 6 SAES was fully implemented in November 2007 in accordance with the VMRs.

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

The Pollution Reduction Programme is now nearing completion. Two research studies which investigated ways in which cypermethrin dips could pollute during dipping have been made available to the Pollution Reduction Programme for sheep dip steering group and published on the VMD website. The VMD has also contributed to the development of a Policy Options Appraisal for sheep dip. We have commented on a paper costing the policy options appraisal and a further R&D study to investigate the effects of drying sheep after dipping is underway.

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

A presentation was made to the Veterinary Pharmaceutical Committee in March and Defra contacts have been asked to attempt to get the changes to the Directive added to their simplification workplan.

The VMD has asked Defra to attempt to add the review of this legislation to proposals for the Commission Simplification Workplan. A meeting with the Defra Regulation team took place on 11 July to provide an update on the Better Regulation initiatives at the VMD. The information was well received and it was noted that this is a long term exercise which will progress slowly.

An agenda item on Simplification of Administrative Burdens in the EU in respect of veterinary medicines has been added to the agendas for meetings with Romania and Poland over the next few months.

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.

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 (more information is available on page 58).

To ensure that they were prepared for surveillance in 2008, they

- agreed the 2008 statutory residues plan with the European Commission in accordance with the time frame laid down in Council Directive 96/23; and
- agreed the non-statutory plan for 2008 with the Veterinary Residues Committee (VRC) by March 2008.

Agree 2007 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 slightly ahead of schedule at their request.

Agree 2008 non-statutory plan with Veterinary Residues Committee by 31 December 2007

The VRC planning meeting was held in September, following which the VMD undertook a consultation exercise with stakeholders on behalf of the VRC. This asked them what they thought should be included in the 2008 programme. The VRC Chairman signed off the provisional plan by the end of December. The full Committee discussed the detailed plan in January, with the final plan being agreed following its March 2008 meeting.

Ensure sampling and analysis targets are met to complete the 2007 plans

The collection of on-farm samples for the statutory programme by Animal Health Agency staff was affected in 2007 by the FMD, Bluetongue and Avian Influenza outbreaks. Contingency plans were implemented and outstanding milk samples were collected by authorised dairy tanker drivers. Other samples were transferred to the MHS for collection in abattoirs. The Commission was notified and indicated that it was sympathetic to the situation. The overall plan has been met with minor shortfalls in a small number of individual matrix/analyte combinations. Sampling and analysis for the statutory programme was completed to the required deadlines.

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 three samples were referred to Defra's Investigation Service.

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

Council Working Group meetings continue on the proposal to replace and repeal Council Regulation 2377/90 establishing procedures for setting MRLs in animal foodstuffs. The UK has submitted position papers and more detailed discussion papers on prohibited substances and biocides to the Presidency and Member States. The VMD held an Open Meeting on 10 January, which was well attended. The VRC has been kept fully informed of progress.

A proposal to amend Council Directive 96/22 (the "hormones ban") was agreed at Council Working Group and will be discussed at a plenary session of the European Parliament in April 2008. Submissions to Ministers on both issues have gone forward with Explanatory Memoranda for Parliament.

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

Both surveillance programmes are within contracted budgets. A consultation exercise with industry on amended charges for the statutory programme was held and the Statutory Instrument (SI) amending the charges came into force on 1 October 2007, as planned. The LGC prices for the 2008 calendar year have been agreed and the VMD is closely monitoring the costs of the MHS and Animal Health Agency as the other major costs of the programme.

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.

Achieve full cost recovery for the VMD

Note 2 to the accounts shows that the overall cost recovery was 104.8% 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.

Prepare business case for consideration in relation to the Hampton initiative

The Hampton business case has been prepared.

Develop plans to implement changes agreed under the VMD's Change Programme

Good progress has been made on implementing the recommendations of the European project. The intranet and skills audit projects are also progressing but a decision to incorporate a content management facility has increased the time needed for technical development. However, the design stage is complete and content is now being added.

The Quality project has been delayed due to the outbreak of FMD. This is a long term project and work will now continue, with the first major step being towards achieving a positive outcome of the HMA inspection audit in Spring 2008.

Prepare an action plan from the 2006/07 EFQM Benchmarking exercise and implement it

Achieved – the EFQM action plan has been included in the Change Programme.

Prepare an action plan from the 2006/07 Staff Survey and implement it

Achieved – the Staff Survey action plan has been included in the Change Programme.

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

Information of staff numbers submitted and accepted by Defra as having met the requirements for headcount reductions.

Make information available in line with relevant legislation

VMD Communications Plan

Work is progressing on developing a VMD communications vision and strategy. The VMD has a Communications Plan supporting the Business Plan and the Change Programme has been subject to a full consultation with staff and will continue to do so.

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* 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**.

Access To Information (ATI)[28]

Guidance

In November 2007 we jointly published with the MHRA revised guidance for those involved in making and receiving requests to release information relating to human and veterinary medicines authorised for use in the UK. It replaced the guidance in the Memorandum Of Understanding (MOU) between the Association of the British Pharmaceutical Industry (ABPI) www.abpi.org.uk, Proprietary Association of Great Britain (PAGB) www.pagb.co.uk, the MHRA, and National Office of Animal Health (NOAH) www.noah.co.uk and VMD, in place since late 2004, which had used a 'traffic light' coding system to differentiate between types of information.

During 2007, the ABPI, PAGB, MHRA, NOAH and VMD carried out a review of the MOU and consulted other interested parties including the Food Ethics Council (FEC) www.foodethicscouncil.org. The review concluded that the MOU had not adequately reflected the greater spirit of openness and commitment to disclosure that the ATI legislation was designed to foster in public bodies. The new guidance was developed to reflect this and to help those making and receiving requests.

In practice the existence of the MOU had not adversely affected what the regulatory bodies disclosed because they treated each request on its own merits in accordance with the ATI legislation and the accompanying legislative guidance.

You can find out more about the ATI legislation, which includes the Environmental Information Regulations (EIR), the Freedom of Information Act (FOIA) and the Data Protection Act 1998, at www.defra.gov.uk/corporate/opengov/accessinfo.htm

Requests

We have received and dealt with 17 ATI requests since 1 April 2007. One case from 2005 has been reviewed by Tribunal[29] who fully vindicated the line taken by the VMD and the Information Commissioner. We are in contact with the Information Commissioner's office (ICO) over two further cases that have been sent to the ICO by the applicant.

Summary assessment reports (United Kingdom Public Assessment Reports)[30]

All UKPARs have been published within timescales as set out in the published standards and MA holders have been consulted on the content of the scientific discussion relating to their products. Feedback on the website and content of scientific discussions from customer care visits has been positive.

A new website is being developed incorporating the information currently available on the UKPARs and e-SPCs websites, as well as some additional product information. The new site will therefore be more comprehensive and easier to use. It will also include an on-line questionnaire to record feedback on the new website and the content of the summary assessment reports.

Implement the VMD's IT Strategy

IT developments are on target but subject to any impact arising from changes following Defra's Transformational Government Website Rationalisation project.

Deliver Training and Liaison services to internally published standards

TLU have prepared standards for internal circulation.

IiP Standards are embedded in operations and are reviewed via external and internal reviews. An overview of IiP policies is maintained through information received from Penna who are the central training providers.

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 on an on-going basis.

Programme and Project Management underpins the VMD's Change Programme and associated projects. Licensing Administration apply strong Project Management principles to its delivery programme.

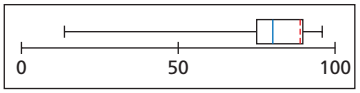
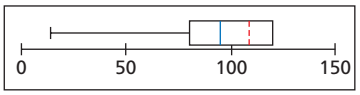
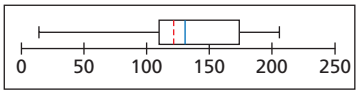
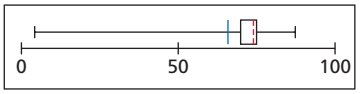
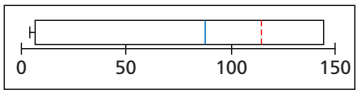
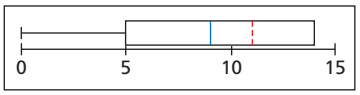
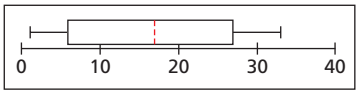
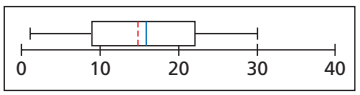
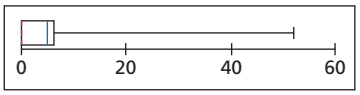
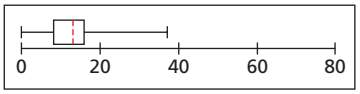
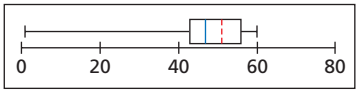
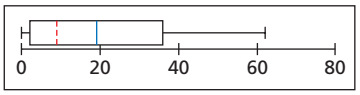
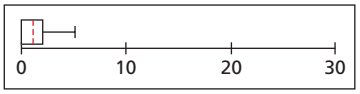
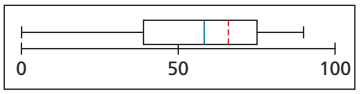
28. You can find out more about ATI legislation via the Ministry of Justice website www.justice.gov.uk
29. You can find out more about the Information Tribunal website and judgment via www.informationtribunal.gov.uk/Documents/decisions/Jenkins_Judgment_EA2006_0067121107.pdf
30. You can find out more about UKPARs via www.vmd.gov.uk under Product Information

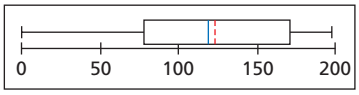
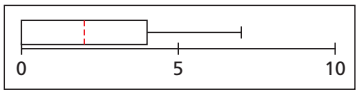
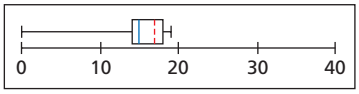
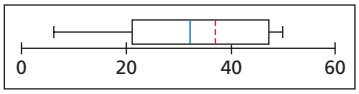
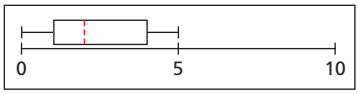
Carry out an independent survey of our core customers in 2007 and implement and publish business improvements in 2008 based on the survey findings

Independent consultants have completed the qualitative and quantitative stages of the licensing survey. The results were presented to staff on 8 February 2008 and a summary has been published on our website. The information is now being analysed and an action plan will follow.

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	45	EXCELLENT	90	78	
Sign off, VPC or further questions	34	EXCELLENT	120	96	
Sign off and issue	39	EXCELLENT	210	130	
MAPIs for MR products & copy-cats					
Initial assessment	17	EXCELLENT	75	66	
Sign off, VPC or further questions	8	UNACCEPTABLE	120	88	
Sign off and issue	4	EXCELLENT	210	63	[2]
Variations					
Type IA – decision	399	EXCELLENT	14	9	
Type IB admin – issue	73	EXCELLENT	30	17	
Type IB – initial assessment	269	EXCELLENT	30	16	
Type IB – sign off	260	EXCELLENT	30	5	
Harmonisation – sign off	11	EXCELLENT	60	15	
Type II – initial assessment	636	EXCELLENT	60	47	
Type II – sign off	530	EXCELLENT	60	19	
Renewals					
Administrative – sign off	185	EXCELLENT	30	1	
Full and conditional – initial assessment	44	EXCELLENT	90	58	

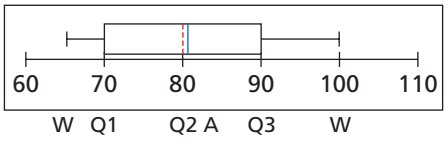
Category/application type	Number (of Applications)	Performance level (excellent, effective, unacceptable)	Target (days[1])	Average time in days	Box Whisker Plots Key: - - - = Median —— = Average
Full and conditional – sign off	110	EXCELLENT	180	118	
ATCs					
Type A and B – validate	41	EXCELLENT	5	2	
Type A – sign off	16	EXCELLENT	30	15	
Type B – sign off	23	EXCELLENT	50	32	
Type A and B – issue	39	EXCELLENT	5	2	
Batch release (Immunologicals)					
Issue	1989	EXCELLENT	15	4	
AVAs and NFABBAs (inc variations)					
Assess	4	EXCELLENT	45	28	
Specific Batch Control					
Validate	44	EXCELLENT	3	<1	
Initial assessment	44	EXCELLENT	10	2	
Assess response	50	EXCELLENT	10	<1	
Issue	49	EXCELLENT	3	<1	
Validation/Issue					
Validate	1373	EXCELLENT	10	4	
Issue	1847	EXCELLENT	10	6	
UKPARs					
Module 1	131	EXCELLENT	30	16	
Module 2	110	EXCELLENT	120	48	
Module 3	142	EXCELLENT	60	36	
Import Certificates[3]					
SIC – urgent/non-urgent	3118	EXCELLENT	2/10	<1	
STC – urgent/non-urgent	3891	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	1	EXCELLENT	70
Co-Rapp – Provide comments on assessment report by 85 days	2	EXCELLENT	85
UK as Member only – LOQ by 100 days	1	EXCELLENT	100
Mutual Recognition RMS			
Production of Final Assessment Report by 1st 90 days	33	EXCELLENT	90
Assessment of Responses by 2nd 70 days	29	EXCELLENT	70
Procedure completed by 2nd 90 days	28	EXCELLENT	90
CMS			
Procedure completed by 2nd 90 days	17	EXCELLENT	90
Decentralised RMS			
Production of Assessment Report within 70 days	27	EXCELLENT	70
Production of Assessment Report within 120 days	14	EXCELLENT	120
Assessment of Responses by 70 days	10	EXCELLENT	70
Procedure completed by 90 days [210 in total]	9	EXCELLENT	90 [210]
CMS			
UK comments sent by 100 days	35	UNACCEPTABLE	100
Procedure completed [decision made] by 120 days	10	EXCELLENT	120
UK acceptance/referral sent by 90 days [2nd phase] [210 days]	20	EXCELLENT	90 [210]
MRL (No. 6.i)			
Report for CVMP	1	EXCELLENT	120
European Variations Type II – Mutual Recognition RMS			
PAR circulated	57	EXCELLENT	40
CLOQ circulated	55	EXCELLENT	60
Procedure completed	42	EXCELLENT	90
Type IB – Mutual Recognition RMS			
CLOQ circulated	47	EXCELLENT	30
Procedure completed	46	EXCELLENT	60
Type IA – Mutual Recognition RMS			
Determined within 14 days	27	EXCELLENT	14
Type IA – Mutual Recognition CMS			
Determined within 14 days	33	EXCELLENT	14
Type II Mutual Recognition CMS			
UK comments sent by 55 days	39	UNACCEPTABLE	55
UK comments sent by 85 days	21	EXCELLENT	85
Type IB Mutual Recognition CMS			
UK comments sent by 20 days	28	EXCELLENT	20

Category/application type	Number (of Applications)	Performance level (excellent, effective, unacceptable	Target (days[1])
UK comments sent by 50 days	43	EXCELLENT	50
European Renewals Mutual Recognition RMS			
PAR circulated by 40 days	25	EXCELLENT	40
CLOQ circulated by 60 days	31	EXCELLENT	60
Procedure completed by 90 days	21	EXCELLENT	90
Mutual Recognition CMS			
UK Comments sent by 55 days	20	UNACCEPTABLE	55
UK Comments sent by 85 days	33	EXCELLENT	85[5]
Customer Relations Customer Care Visits			
Number of Visits	12	EXCELLENT	
Publishing themes	2006/07	EXCELLENT	
Unreturned authorisation documents			
Right first time (Authorisations)	2,022	EXCELLENT	
Right first time (SIC/STCs Certificates)	5,749	EXCELLENT	
Right first time (Export Certificates)	1,185	EXCELLENT	
SARs			
Enter human SARs	147	EXCELLENT	2
Enter serious animal SARs	1,260	EXCELLENT	2
Enter environmental SARs	44	EXCELLENT	2
Enter non-serious SARs	1,585	EXCELLENT	10
Report to Eudravigilance	417	EFFECTIVE	5
Inspections			
Inspect	26	EXCELLENT	
Prepare report	19	UNACCEPTABLE	60
Issue Certificate	9	EXCELLENT	90
Annual VPC evaluation of Assessment Reports Others			
Evaluation	3	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] 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.

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

Appendix B

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; and

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; and
- 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 sub-groups 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[31] and Statutory Instruments

Publications 2007/08

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) and guidance for the registration of retail premises (updated version)

Statutory Instruments coming into effect in 2007/08

The Veterinary Medicines Regulations 2007

SI 2007 No 2539

Made: 30 August 2007

Coming into force: 1 October 2007

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

Appendix D

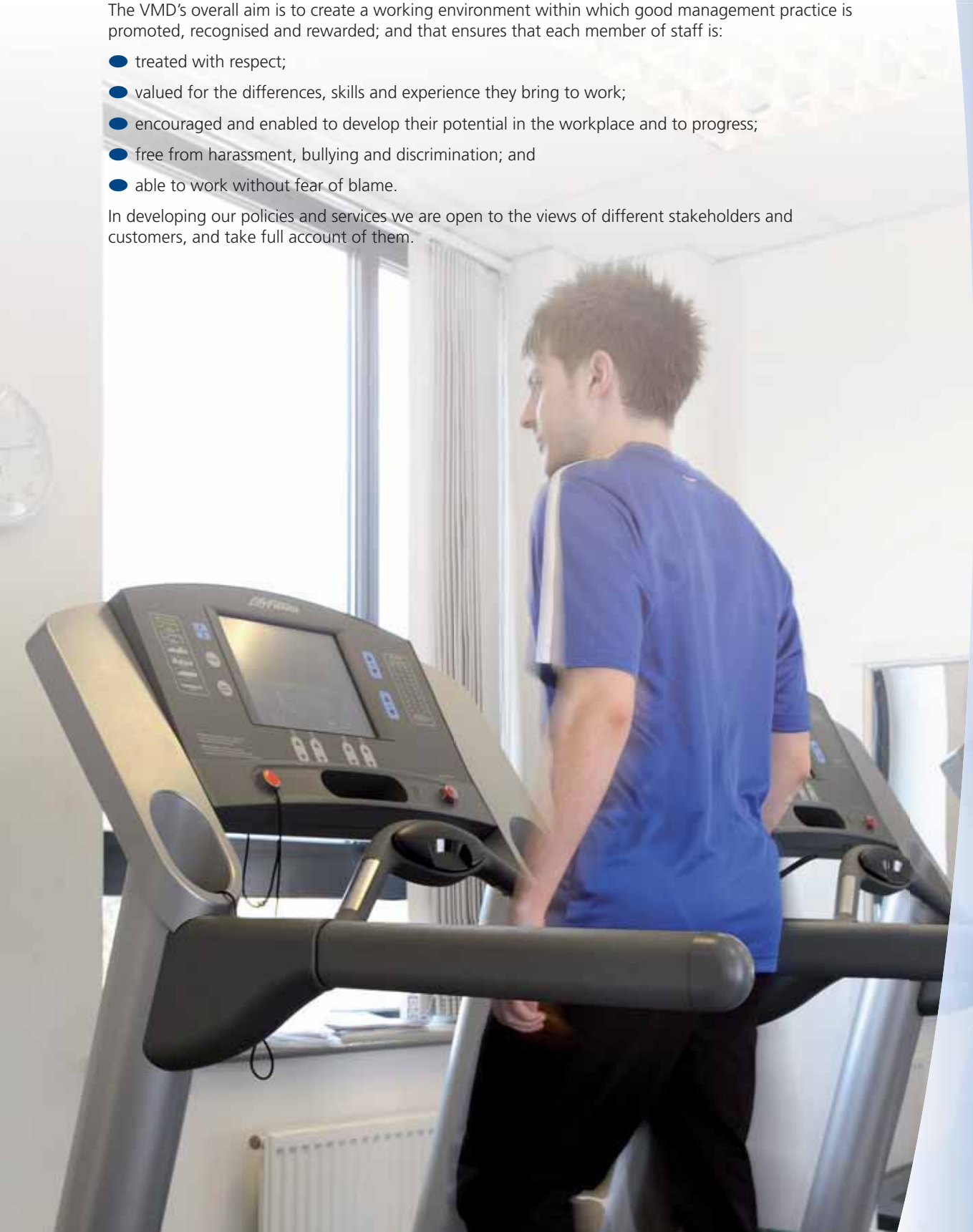
VMD People Strategy – Our Commitment to Staff

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

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

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

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



Appendix E

Audit & Risk Committee Annual Report 2007/08 to the VMD Chief Executive and Accounting Officer

Introduction

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

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

Membership

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

Brian Morris (Chairman) – External member of the VMD Management Board

David Skilton – External member of the VMD Management Board

John Preston – External member of the VMD Management Board

Heather Oliver (Secretary) – March-October, VMD, Head of Legislation & Core Services

David Rayner (Secretary) – October-March, VMD, Head of Core Services and Communications

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

Steve Dean – VMD CEO

Michael Addison – VMD Head of Finance

In addition, representatives from Internal Audit, the National Audit Office and its contracted external auditors all attend meetings of the Committee and contribute to its work.

Meetings

The Committee met formally on four occasions in 2007/08. The frequency and timing of meetings were scheduled to fit in with the stages of the financial year.

Work of the Committee

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

1. Tracking and monitoring the annual cycle of processes through which are prepared the Annual Accounts and the Statement of Internal Control.
2. Similarly monitoring the strategy and processes through which internal and external audit and risk management are planned, executed, implemented and appraised.
3. Examining selected areas of the VMD's infrastructure in relation to its governance, audit and potential risks; in particular:
   - enforcement arrangements (June 2007);
   - business continuity (in the context particularly of a recently-experienced site power shutdown in July 2007);
   - arrangements for the prescribing cascade (December 2007); and
   - arrangements for GMP approval and inspection (March 2008).

The Chairman attended the Best Practice for Audit Committee Conference held by HM Treasury on 22 October 2007.

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.

Brian Morris
Chairman

Veterinary Medicines Directorate

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

Accounts 2007/08

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 & 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 Agency assets for which I am personally responsible, in accordance with the responsibilities assigned to me in Government Accounting.

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 Corporate 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). The role of 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 VMD's 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 the VMD's 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 2008 and up to the date of approval of the annual report and accounts, and accords with HM 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.

Data security is an integral part of the VMD's operations, protecting both personal and business-sensitive information for our customers and stakeholders. The VMD's ISO27001 accreditation provides assurance that our security for electronic data storage is fit for purpose.

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, 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 plan is the budget, which sets out the resources required to achieve the objectives in the coming financial year. The Business and Financial Plan is considered by Defra's Regulatory Agencies Strategy Board (RASB) and signed off at Ministerial level following RASB 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 Regulatory Agencies Strategy Board (RASB) and the Food and Farming Group's (FFG) Heads of Delivery Partners Group (HDPG). The RASB is chaired by one of its two non-executive members and is composed of senior officials from Defra, the devolved administrations and the FSA and is responsible for advising Ministers on matters concerning the Agency. The FFG HDPG is the forum through which the FFG Director General discusses Animal Health and Welfare strategy.

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 an 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. Internal Audit services were provided by Defra during the year. However since January 2008 the work of Internal Audit, including provision of the 2007/08 annual report and opinion, has been outsourced to RSM Bentley Jennison.

The National Audit Office is responsible for the audit of the VMD's Annual Report and Accounts. The audit work is subcontracted to PKF (UK) LLP Chartered Accountants.

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

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

Statement on Internal Control (continued)

Management of Change

A programme to drive change at the VMD in the areas of Europe, quality and structure is in progress. Recommendations from the initial reviews have been brought into a single improvement plan that will improve the quality culture, develop a clearer strategy for VMD's role in Europe, provide training/information for staff on European matters and make slight adjustments to the VMD's organisational design. This is being formally overseen by a Programme Board comprised of the Directors and the VMD Head of Finance.

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.

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 engaged during 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 Authorisations 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 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, 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; and
- discuss progress reports and the management letter from the external auditors.

The VMD's Management Board:

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

Statement on Internal Control (continued)

The Internal Audit Service, provided by Defra's Internal Audit Division in 2007/08:

- operates under Government Internal Audit Standards;
- provides regular reports to review various aspects of the Agency's corporate governance and risk management systems, making recommendations for improvements where appropriate;
- facilitates workshops to help the Audit & Risk Committee and senior staff make informed judgments on risk management.

During the year the VMD introduced the following improvements relating to internal controls.

Description of change	**Internal control improvement**
Powers to reduce and waive certain fees have been clarified and delegated by the CEO.	The delegated powers are set out in an internal document signed by the CEO; A further internal document sets out precedents for fee reductions and waivers; The Finance team is aware of the delegated powers and performs cross-checks.
European co-ordination team formed.	VMD European Steering Group formed; Head of Team responsible for ensuring close working links with the other teams across the VMD; Series of VMD European information meetings organised for staff; General Assessment Team and Committee Support formed.

The Head of Internal Audit has provided an independent opinion on the adequacy and effectiveness of the Agency's risk management framework and key control processes during the year. The report concluded that for the 12 months ended 31 March 2008, the Veterinary Medicines Directorate had adequate and effective internal control and risk management processes to manage the achievement of the organisation's objectives.

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

Steve Dean
Chief Executive
23 May 2008

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 2008 under the Government Resources and Accounts Act 2000. These comprise the Income and Expenditure Account and 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 being 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 the sections entitled 'About Us', 'Preparation and Audit of the Accounts', 'Management Commentary', the unaudited parts of the 'Remuneration Report', 'Meeting Our Targets' and 'Appendices', 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 sections entitled 'About Us', 'Preparation and Audit of the Accounts', 'Management Commentary', the unaudited parts of the 'Remuneration Report', 'Meeting Our Targets' and '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 2008, 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
- information, which comprises the sections entitled 'About Us', 'Preparation and Audit of the Accounts', 'Management Commentary', the unaudited parts of the 'Remuneration Report', 'Meeting Our Targets' and 'Appendices', included within the Annual Report, is consistent with the financial statements.

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

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
29 May 2008

151 Buckingham Palace Road
Victoria
London SW1W 9SS

Income and expenditure account for the year ended 31 March 2008

Notes		2008		2007	
		£'000	**£'000**	£'000	£'000
	Income				
2	Income from activities	**14,549**		13,970	
3	Less – Direct subcontracting costs	**(4,494)**		(4,564)	
	Net Income		**10,055**		9,406
	Operating Unit expenditure				
4	Staff costs	**(6,542)**		(6,343)	
8 & 9	Depreciation and revaluation losses	**(372)**		(380)	
5	Other operating costs	**(1,425)**		(1,431)	
	VMD operating costs for year		**(8,339)**		(8,154)
	Operating result before departmental charges and other costs		**1,716**		1,252
	Departmental charges and other costs				
	Defra service recharges	**(665)**		(534)	
	Independent Expert Committees	**(182)**		(134)	
			(847)		(668)
	Operating surplus before interest on capital		**869**		584
7	Interest on capital		**(204)**		(195)
	Operating surplus for the year		**665**		389
	Operating surplus brought forward		**1,120**		731
	Operating surplus for the year		**665**		389
14	**Operating surplus carried forward**		**1,785**		1,120

Statement of total recognised gains and losses

		£'000	£'000
	Operating surplus for the year	**665**	389
13	Fixed asset revaluations not reported in the operating surplus	**303**	480
	Total gains recognised since the last annual report	**968**	869

All activities arise from continuing operations.
The notes on pages 56 to 66 form part of these accounts.

Balance Sheet as at 31 March 2008

Notes		2008		2007	
		£'000	**£'000**	£'000	£'000
	Fixed assets				
8	Intangible assets	**135**		121	
9	Tangible assets	**5,810**		5,635	
			5,945		5,756
	Current assets				
10	Debtors and prepayments	**1,832**		2,464	
11	Cash at bank	**5,415**		4,366	
		7,247		6,830	
	Creditors: amounts falling due within one year				
12	Creditors and deferred income	**(2,102)**		(2,058)	
	Net current assets		**5,145**		4,772
	Total assets less current liabilities		**11,090**		10,528
	Financed by				
13	Revaluation Reserve		**2,588**		2,285
14	General fund		**8,502**		8,243
			11,090		10,528

S P Dean
Chief Executive and Agency Accounting Officer
23 May 2008

The notes on pages 56 to 66 form part of these accounts.

Cash flow statement for the year ended 31 March 2008

Notes		2008	2007
		£'000	£'000
19(i)	**Net cash inflow from operating activities**	**2,656**	1,859
	Capital expenditure and financial investment:		
	– Payments to acquire intangible fixed assets	**(81)**	(55)
	– Payments to acquire tangible fixed assets	**(226)**	(99)
	Cash inflow before management of liquid resources and financing	**2,349**	1,705
	Financing:		
	Repayment of Defra operational funding	**(1,300)**	(950)
19 (ii)	**Increase in cash in the year**	**1,049**	755

The notes on pages 56 to 66 form part of these accounts.

Notes to the accounts

1. Statement of accounting policies

The financial statements have been prepared in accordance with the 2007/08 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 published indices.

1.3 Depreciation

Tangible fixed assets are depreciated at rates calculated to write them 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 Value Added Tax (VAT)

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

1.7 Defra service recharges

Central Department for Environment, Food and Rural Affairs (Defra) overheads are charged on a notional basis and included in the accounts. The charges cover central services such as Establishments, Human Resources, Legal Services and IT.

1.8 Deferred income

Deferred income represents the portion of fees and charges that are invoiced in advance of the provision of services to which they relate.

1.9 Recovery from Government Funds

From 1 April 1991 the VMD took over responsibility for managing the research and development programme on veterinary medicines. These costs do not form part of the cost recovery targets and are not borne by industry.

Notes to the accounts (continued)

1.10 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.

1.11 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.

Notes to the accounts (continued)

2 Income

(a) Income from activities

Income was earned from the following main business activities:

	2008 £'000	2007 £'000
Authorisations	**6,826**	6,263
Residues – Statutory scheme	**3,997**	3,844
– Non-statutory scheme	**873**	905
Policy	**2,345**	2,541
Animal Medicines Inspectorate	**508**	417
	14,549	13,970

(b) Key Performance Target

The VMD had been set one key financial performance target in 2007-08: to achieve cost recovery for the VMD as a whole.

Results:

An overall cost recovery of 104.8% was achieved. Cost recovery performance within each of the VMD principal business areas was as follows:

Authorisations	2008 £'000	2007 £'000
Income	**6,826**	6,263
Staff costs	**(4,358)**	(4,101)
Depreciation and revaluation losses	**(248)**	(246)
Subcontracting costs	**(250)**	(280)
Other costs	**(1,273)**	(1,251)
Total income less costs (cost recovery) = 111.4%	**697**	385

Residues – statutory scheme	2008 £'000	2007 £'000
Income	**3,997**	3,844
Staff costs	**(394)**	(370)
Depreciation and revaluation losses	**(22)**	(22)
Subcontracting costs – testing and collection	**(3,477)**	(3,429)
Other costs	**(127)**	(174)
Total income less costs (cost recovery) = 99.4%	**(23)**	(151)

Residues – non-statutory scheme	2008 £'000	2007 £'000
Income	**873**	905
Staff costs	**(67)**	(65)
Depreciation and revaluation losses	**(4)**	(4)
Subcontracting costs – testing and collection	**(761)**	(800)
Other costs	**(41)**	(34)
Total income less costs (cost recovery) = 100.0%	**–**	2
Total residues result (cost recovery) = 99.5%	**(23)**	(149)

Notes to the accounts (continued)

Policy	**2008 £'000**	2007 £'000
Income	**2,345**	2,541
Staff costs	**(1,382)**	(1,483)
Depreciation and revaluation losses	**(79)**	(89)
Other costs	**(916)**	(752)
Total income less costs (cost recovery) = 98.7%	**(32)**	217

Animal Medicines Inspectorate	**2008 £'000**	2007 £'000
Income	**508**	417
Staff costs	**(341)**	(324)
Depreciation and revaluation losses	**(19)**	(19)
Subcontracting costs – testing and collection	**(6)**	(55)
Other costs	**(119)**	(83)
Total income less costs (cost recovery) = 104.7%	**23**	(64)

The information in Note 2 is provided for fees and charges purposes, not for SSAP25 purposes.

Notes to the accounts (continued)

Results: (continued)

In arriving at the cost recovery result for each business area some costs, such as salaries and training, have been apportioned on the basis of the VMD's work recording system. The results of this exercise during 2007-08 show that staff time was utilised as follows:

	2008	2007
	%	%
Authorisations	**67**	65
Policy	**21**	23
Residues – statutory scheme	**6**	6
– non-statutory scheme	**1**	1
Animal Medicines Inspectorate (from 1 January 2006)	**5**	5
Total	**100**	100

Some costs, such as residues testing costs, have been allocated specifically. Other costs, such as legal services, have been allocated on the basis of usage.

For 2007-08, 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 £9,000 in 2007-08 (2006-07: £11,000).

3 Direct subcontracting costs

Amounts charged in the Income & Expenditure Account for subcontractors' costs:	**2008**	2007
	£'000	£'000
Costs of authorisation and inspection activities payable to the Medicines and Healthcare products Regulatory Agency	**(250)**	(280)
Costs of non-statutory residues surveillance, including sample collections, and analysis work performed by the Central Science Laboratory	**(761)**	(800)
Costs of statutory residues surveillance, including sample collections, and analysis work performed by LGC Limited	**(3,477)**	(3,429)
Costs of Animal Medicines Inspectorate sample analysis	**(6)**	(55)
	(4,494)	(4,564)

Notes to the accounts (continued)

4 Staff costs

(a) Staff costs consist of:

	2008			2007
	Permanently employed staff	**Others**	**Total**	Total
	£'000	**£'000**	**£'000**	£'000
Wages and salaries	**(4,712)**	**(467)**	**(5,179)**	(5,021)
Social security costs	**(404)**	**–**	**(404)**	(394)
Other pension costs	**(959)**	**–**	**(959)**	(928)
	(6,075)	**(467)**	**(6,542)**	(6,343)

There were no recoveries in respect of outward secondments.

The Agency Chief Executive's total remuneration including non-pensionable performance bonus in 2007-08 was £97,034 (2006-07: £93,928).

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 2007-08, employers' contributions of £949,000 were payable to the PCSPS (2006-07: £915,000) at one of four rates in the range 17.1% to 25.5% of pensionable pay, based on salary bands (the rates in 2006-07 were between 17.1% and 25.5%). The scheme's Actuary reviews employer contributions every four years following a full scheme valuation. From 2008-09, the salary bands will be revised but the rates will remain the same (the rates will be changing with effect from April 2009). The contribution rates are set to meet the cost of the benefits accruing during 2007-08 to be paid when the member retires, and not the benefits paid during this period to existing pensioners. Employees can opt to open a partnership pension account, a stakeholder pension with an employer contribution. Employer's contributions of £10,000 (2006-07: £13,000) 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. No employer contributions (2006-07: £nil) were payable to the PCSPS to cover the cost of the future provision of lump sum benefits on death in service and ill health retirement of these employees. Contributions due to the partnership pension providers at the balance sheet date were £nil (2006-07: £nil) and contributions prepaid at that date were £nil (2006-07: £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 whole-time equivalent persons employed during the year was as follows:

	2008			2007		
	Total	**Permanently employed staff**	**Others**	Total	Permanently employed staff	Others
Scientific	**41**	**40**	**1**	40	39	1
Administrative	**111**	**96**	**15**	112	97	15
	152	**136**	**16**	152	136	16

"Others" shown above comprises temporary staff.

Notes to the accounts (continued)

5 Other operating costs

These are made up as follows:

	2008	2007
	£'000	£'000
Travel and subsistence	**(173)**	(142)
Training	**(151)**	(157)
Provision for bad debts	**70**	(151)
IT systems maintenance costs	**(221)**	(228)
Communications	**(107)**	(92)
Audit fees (notional)	**(25)**	(24)
Accommodation utility charges	**(119)**	(101)
Operating leases	**(61)**	(61)
Other costs	**(638)**	(475)
	(1,425)	(1,431)

No remuneration was paid to the auditors in respect of non-audit work.

6 Research and development

From 1 April 1991 the VMD took over responsibility for the management of the Research and Development programme on veterinary medicines on behalf of the Defra policy customer. These costs are borne by Defra and therefore do not form part of the VMD cost recovery targets or appear in the VMD's Income & Expenditure Account.

The work is currently commissioned with several providers and amounts to £2.0m (2006-07: £2.0m).

7 Interest on capital

In accordance with the HM Treasury Financial Reporting Manual, the interest on capital charge is notional and applies to all assets and liabilities in the balance sheet, with liabilities attracting a negative charge (ie a credit). The charge is at a rate set by HM Treasury of 3.5% (2006-07: 3.5%), with the exception of cash balances with the Office of HM Paymaster General where the charge is at a nil rate.

8 Intangible fixed assets

Computer Software Licences

	£'000
Cost or Valuation:	
At 1 April 2007	645
Additions	90
Disposals	–
At 31 March 2008	735
Amortisation:	
At 1 April 2007	(524)
Provided during year	(76)
Disposals	–
At 31 March 2008	(600)
Net Book Value:	
At 31 March 2008	**135**
At 31 March 2007	121

Notes to the accounts (continued)

9 Tangible fixed assets

	Freehold Property £'000	IT Equipment £'000	Office Equipment £'000	Furniture & Fittings £'000	Total £'000
Cost or Valuation:					
At 1 April 2007	5,566	918	66	251	6,801
Additions	67	62	13	26	168
Disposals	–	(57)	–	(9)	(66)
Revaluation	321	(43)	–	9	287
At 31 March 2008	5,954	880	79	277	7,190
Depreciation:					
At 1 April 2007	(261)	(682)	(29)	(194)	(1,166)
Provided during year	(133)	(117)	(6)	(28)	(284)
Disposals	–	56	–	8	64
Revaluation	(20)	33	–	(7)	6
At 31 March 2008	(414)	(710)	(35)	(221)	(1,380)
Net Book Value:					
At 31 March 2008	**5,540**	**170**	**44**	**56**	**5,810**
At 31 March 2007	5,305	236	37	57	5,635

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

The depreciation and revaluation losses figure of £372,000 shown in the Income & Expenditure Account includes £10,000 indexation losses (2006-07: £13,000) and £2,000 losses on disposal (2006-07: £9,000).

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.

10 Debtors and prepayments

Amounts falling due within one year:	**2008**	2007
	£'000	£'000
Trade debtors – Authorisations	**361**	327
– Residues	**76**	144
Balances with other central government bodies	**–**	714
Other debtors	**34**	5
VAT recoverable	**187**	154
Prepayments and accrued income	**1,174**	1,120
	1,832	2,464

Debtors are shown net of a provision of £545,000 (2006-07: £609,000) for bad and doubtful debts. Included in debtors there are no balances with local authorities, NHS Trusts, public corporations or trading funds (2006-07: £nil).

Balances with other central government bodies in 2007-08 includes £nil (2006-07: £678,000) with Defra and its agencies.

Notes to the accounts (continued)

11 Cash at bank

	2008	2007
	£'000	£'000
At Office of HM Paymaster General	**5,333**	4,304
At commercial banks and cash in hand	**82**	62
	5,415	4,366

The VMD pays amounts collected from its customers into a commercial bank account. As soon as the funds are cleared by the bank, they are transferred to VMD's Paymaster account. The balance at commercial banks and cash in hand represents deposits that have not been cleared by the year end plus a petty cash balance.

12 Creditors and deferred income

	2008	2007
Amounts falling due within one year:	**£'000**	£'000
Trade creditors	**(379)**	(354)
Balances with other central government bodies	**(340)**	(348)
Balances with public corporations and trading funds	**(132)**	(154)
Other taxation and social security	**(159)**	(154)
Accruals and deferred income	**(1,092)**	(1,048)
	(2,102)	(2,058)

Included in creditors there are no balances with local authorities or NHS Trusts (2006-07: £nil).
Balances with other central government bodies in 2007-08 includes £245,000 (2006-07: £305,000) owing to Defra and its agencies.

13 Revaluation reserve

	2008	2007
	£'000	£'000
At 1 April 2007	**2,285**	1,805
Arising on revaluation during the year:		
– on revaluation of land and buildings	**–**	–
– on indexation	**303**	480
	303	480
At 31 March 2008	**2,588**	2,285

Notes to the accounts (continued)

14 General Fund

The VMD is funded by the Department for Environment, Food and Rural Affairs and the position is shown in the "Financed by" section of the Balance Sheet by means of the General Fund. Within this Fund there are two distinct parts:

(a) The General Account 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. This reserve will not be distributable.

(b) The Operating Account represents the accumulated operating cost recovery surplus or deficit transferred from the Income and Expenditure Account.

	General Account	Operating Account	General Fund
	£'000	£'000	£'000
Balance at 1 April 2007	7,123	1,120	8,243
Non-cash charges:			
Notional Interest cost	204	–	204
Audit Fee	25	–	25
Defra Service Charges	665	–	665
Repayment of Defra Operational Funding	(1,300)	–	(1,300)
Surplus for the year	–	665	665
Balance at 31 March 2008	6,717	1,785	8,502

15 Capital commitments

	2008	2007
	£'000	£'000
Contracted commitments at 31 March for which no provision has been made in the accounts.	–	–

16 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.

	2008	2007
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 after 1 year but not more than 5 years	–	20
Other		
Expiry after more than 5 years	12	12
	38	38

17. Related party transactions

As the VMD is an Executive Agency of the Department for Environment, Food & Rural Affairs and is sponsored by them, the Department is regarded as a related party. During the year, the VMD has had significant material transactions with the Department and a number of its agencies, including Veterinary Laboratories Agency, Central Science Laboratory, State Veterinary Service and Centre for Environment, Fisheries and Aquaculture Science.

In addition, the VMD has had various material transactions with other central Government bodies. Most of these transactions have been with the Medicines and Healthcare products Regulatory Agency and the Meat Hygiene Service. 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 Agency is required to disclose the role financial instruments had during the period, in creating or changing the risks faced in undertaking its activities. The non-trading nature of the Agency's activities and the way Government departments are financed, means the Agency is not exposed to the degree of financial risk faced by business entities. The VMD has no powers to borrow or invest surplus funds. Financial assets and liabilities generated by day to day operational activities are not held to change the risks facing the Agency in undertaking its activities.

Liquidity Risk: There is no significant exposure to this, given that the Agency's net resource requirement is financed through resources voted annually by Parliament.

Interest Rate Risk: There is no exposure to this, as the Agency's main financial assets and liabilities have either nil or fixed rates of interest.

Foreign Currency Risk: This is not significant, as there is negligible income and expenditure in foreign currencies.

19. Notes to the cash flow statement

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

	2008	2007
	£'000	£'000
Operating surplus for the year	**665**	389
Depreciation and revaluation losses	**372**	380
Defra service charges	**665**	534
Other notional charges added back	**229**	219
Adjustment for decrease/(increase) in fixed asset accruals	**49**	(53)
Decrease in debtors and prepayments	**632**	136
Increase in creditors	**44**	254
Net cash inflow from operating activities	**2,656**	1,859

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

	2008	2007
	£'000	£'000
Increase in cash in the year	**1,049**	755
Cash at bank at 1 April 2007	**4,366**	3,611
Cash at bank at 31 March 2008 (Note 11)	**5,415**	4,366

20. Post Balance Sheet events

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.

The authorised date for issue is 29 May 2008.

Glossary

ABPI	Association of the British Pharmaceutical Industry
AH	Animal Health
AMI	Animal Medicines Inspectorate
ATC	Animal Test Certificate
ATI	Access to Information
BVA	British Veterinary Association
CD	Controlled Drug
CEO	Chief Executive Officer
CETV	Cash Equivalent Transfer Value
CMD-v	Co-ordination Group for Mutual Recognition and Decentralised Procedures – veterinary
CMS	Concerned Member State
CSL	Central Science Laboratory
CVMP	Committee for Veterinary Medicinal Products
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
EIR	Environmental Information Regulations
EMEA	The European Agency for the Evaluation of Medicinal Products
ETPGAH	European Technology Platform Group for Global Animal Health
EU	European Union
FEC	Food Ethics Council
FFG	Food and Farming Group
FOI	Freedom of Information
FOIA	Freedom of Information Act
FMD	Foot and Mouth Disease
FreM	Financial Reporting Manual
FSA	Food Standards Agency
GMP	Good Manufacturing Practice
HDPG	Heads of Delivery Partners Group
HMA	Heads of Medicines Agencies
HSE	Health and Safety Executive
ICO	Information Commissioner's Office
IiP	Investors in People
IT	Information Technology
IVMPs	Immunological Veterinary Medicinal Products
MA	Marketing Authorisation
MAFF	Ministry of Agriculture, Fisheries and Food
MHRA	Medicines and Healthcare products Regulatory Authority
MHS	Meat Hygiene Service
MOU	Memorandum of Understanding
MRLs	Maximum Residue Limits
NCAs	National Competent Authorities
NFA-VPS	Non-Food Animal – Veterinarian, Pharmacist, Suitably Qualified Person
NOAH	National Office of Animal Health
NSAID	Non-Steroidal Anti-Inflammatory Drug
NSS	National Surveillance Scheme
OCs	Organochlorine Compounds
OPs	Organophosphates
PAGB	Proprietary Association of Great Britain
PCBs	Polychlorinated Biphenyls
POM-VPS	Prescription Only Medicine – Veterinarian, Pharmacist, Suitably Qualified Person
PSD	Pesticides Safety Directorate
PSURs	Periodic Safety Update Reports
R&D	Research and Development
RASB	Regulatory Agencies Strategy Board
RCVS	Royal College of Veterinary Surgeons
RMS	Reference Member State
RPSGB	Royal Pharmaceutical Society of Great Britain
SAES	Small Animal Exemption Scheme
SAR	Suspected Adverse Reaction
SARSS	Suspected Adverse Reaction Surveillance Scheme
SD	Sustainable Development
SDC	Sustainable Development Commission
SI	Statutory Instrument
SIC	Special Import Certificates
SP	Synthetic Pyrethroid
SPC	Summary of Product Characteristics
SQP	Suitably Qualified Person
STC	Special Treatment Certificate
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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