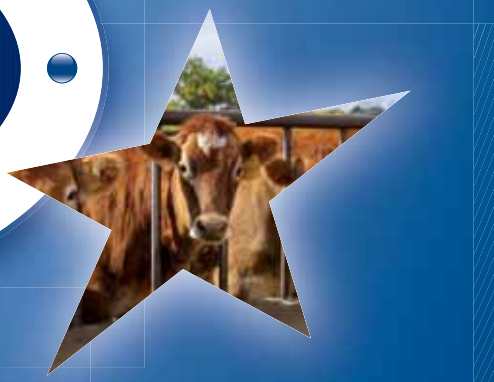
ASSURING THE SAFETY, QUALITY AND EFFICACY OF VETERINARY MEDICINES

Veterinary Medicines Directorate Annual Report & Accounts 2006/07



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 2006/07

INVESTOR IN PEOPLE

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

Chief Executive's Foreword

Rising to the Challenge

Throughout the year, VMD[1] staff have responded positively and creatively to ensure the VMD remained focused on its core activities and strategies. These are aimed at developing an environment where safe and effective veterinary medicines are available for veterinary surgeons and animal owners to use either to treat or prevent disease in farm and companion animals in the UK. We place an emphasis on ensuring veterinary medicinal products are used responsibly, safely and to their best effect. We put much effort into making the VMD an outward facing organisation with a strong focus on the needs of our customers and stakeholders and most importantly the health of their animals. This report sets out in detail the work we carried out to meet all of our key targets, and the majority of our key performance indicators for the year, which form the essence of our day-to-day work.

Change has become the norm at the VMD and the risks and challenges this brings to the business are what we aim to predict and deal with as effectively as possible. There were nevertheless some changes that were unexpected. Perhaps our staff resources illustrate this best for we had planned for the retirement of the Director of Corporate Business, but the Director of Licensing's early retirement came a little sooner than we had anticipated. Chris Bean, our Director of Corporate Business, retired in October 2006 and John O'Brien, our Director of Licensing, retired in May 2006 and both had worked for the VMD in various capacities for many years. Inevitably we have missed their experience, knowledge and presence in the organisation. I would like to thank them both for their long and excellent service to the VMD and wish them well in retirement.

We also temporarily lost some people in key areas either through long-term illness, maternity leave or, in one case, to nearly 12 months of jury service. It is difficult for small organisations to compensate for these unavoidable and important absences and the inevitable effects on resources, yet my VMD colleagues rose to the occasion and stepped forward to meet the challenges focusing upon the needs of the customer in such a way that no appreciable decline in performance was apparent, although this has had a cost in terms of stress and staff well being.

As a result people temporarily took on additional responsibilities until posts were filled or staff returned. They ensured that the VMD delivered in key business areas such as our Licensing Business, the revoking and remaking of the Veterinary Medicines Regulations, and our corporate business responsibilities. I want to take this opportunity publicly to thank them all for helping us to meet these challenges.

Some of our key customers have told me that one of the reasons why the VMD was able to meet its targets and in particular, maintain its 'excellent' performance in the Licensing Business, despite an increase in applications and the loss of key staff, was that our people communicated regularly with interested parties to discuss and resolve issues. This is compelling evidence that we are outward facing and responsive to the needs of our customers and stakeholders.

One specific area that deserves mention is our success in the European negotiation on batch release testing of veterinary vaccines. This has been an area of considerable debate for the EU network over many years and the outcome has resulted in a sensible and rational approach to batch release for the entire EU. For the UK, it represents an outcome that closely matches our national policy; for the pharmaceutical industry this is a reasonable and cost effective approach. Perhaps most importantly, it represents a significant reduction in the requirements for animal testing across the EU without any compromise to safety. Internally it was also a good example of cross discipline working, something the VMD management team encourage.

Jackie Atkinson became our new Director of Licensing in January 2007 after more than five years as head of the VMD's Quality assessment team. As part of an internal facing project looking at the VMD's structure we have decided not to retain the post of Director of Corporate Business and will be redeploying the associated resource to other areas of our work. This decision has arisen from a project on the VMD structure, which was one of three projects carried out in the latter half of the financial year. This suite of related projects, carried forward under the title of a change programme, aimed to embrace the predicted future challenges for the VMD. Apart from our structure and its 'fit for purpose' objective, we

Steve Dean

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

also considered the increasing amounts of work carried out at the EU level and the need for the VMD to be better organised and more visionary in delivering this growing sector of our business. The third strand of the programme was driven by the feedback we have received from Marketing Authorisation holders which has highlighted a need for a review of the quality of our outputs and our work generally. This programme has made a number of important and exciting recommendations, some of which are already being implemented. We will be planning the remainder alongside other improvement initiatives arising from our highly successful Investors in People re-accreditation process; our staff survey; and the results of our benchmarking against the European Foundation for Quality Management (EFQM) Excellence Model. Improvements will be continued into 2007/08 against the backdrop of the routine work of licensing and surveillance which forms the core of the VMD role. It will ensure the VMD's efficiency and effectiveness continues on its upward plane; that the Agency remains organised to deliver its objectives to a high standard; that performance meets the expectations of our stakeholders; and the VMD continues to be respected as a high profile National Competent Authority in the European Network.

My sincere thanks to everyone at the VMD for having applied themselves to their tasks over the past year with tremendous enthusiasm and dedication and for making the VMD an organisation I am immensely proud to lead.

Steve Dean
Chief Executive
24 May 2007

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 Veterinary Medicines Directorate (VMD) is the responsible, safe and effective use of veterinary medicinal products. In working towards achieving this vision the VMD aims to protect public health, animal health and the environment and promote animal welfare by assuring the safety, quality and efficacy of veterinary medicines. The VMD aspires to continue to move in the direction of being an outward facing organisation with a strong focus on the needs of our customers and stakeholders.

In doing so we support the Defra[2] objectives to protect public health and ensure high standards of animal welfare, and promote a sustainable, competitive and safe food supply chain, which meets consumers' requirements.

We also support the aim of the Food Standards Agency (FSA)[3] to protect and improve the safety of food people eat.

The VMD works with the devolved administrations in developing veterinary medicines policy and by doing so contributes to their strategic objectives.

Our responsibilities

The VMD is responsible for:

- the assessment, issue and maintenance of all national Marketing Authorisations (MA) for veterinary medicines in accordance with European Community and UK legislation;
- acting as Reference Member State (RMS), Rapporteur, Co-Rapporteur or Concerned Member State (CMS) for designated European applications for centralised or decentralised or mutual recognition authorisations;
- controls on the manufacture and distribution of veterinary medicinal products including inspections;
- pharmacovigilance through the surveillance of Suspected Adverse Reactions (SARs);
- surveillance for residues of veterinary medicines and illegal substances in animals and animal products;
- the provision and implementation of policy advice on these matters to Ministers;
- the management of the Research & Development (R&D) programme linked to veterinary medicine issues; and
- the co-ordination of Defra's work in the area of antimicrobial resistance via the Defra Antimicrobial Resistance Coordination (DARC)[4] 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 Veterinary Products Committee (VPC)[5] and the Veterinary Residues Committee (VRC)[6]. We subcontract analytical tests or other procedures that have to be carried out.

Under the provisions of EC and UK legislation, no veterinary medicinal product may be marketed without a Marketing Authorisation, 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 Medicines and Healthcare Products Regulatory Agency (MHRA)[7] 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)[8] monitors and responds to reports of suspected adverse reactions 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

2. You can find out more about Defra via www.defra.gov.uk
3. You can find out more about the work of the FSA via their website www.foodstandards.gov.uk
4. You can find out more about the DARC Group via www.vmd.gov.uk under General Information
5. You can find out more about the work of the VPC via their website www.vpc.gov.uk
6. You can find out more about the work of the VRC via their website www.vet-residues-committee.gov.uk
7. You can find out more about the MHRA via their website www.mhra.gov.uk
8. You can find out more about the SARSS via www.vmd.gov.uk under General Information

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

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)[9] 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.

9. You can find out more about the AMI via www.vmd.gov.uk under Industry Information

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 objectives, is the responsibility of our Chief Executive Officer (CEO), supported by Directors of Licensing and Policy. Our policy, legal and resources framework is set out in our Framework Document[10].

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

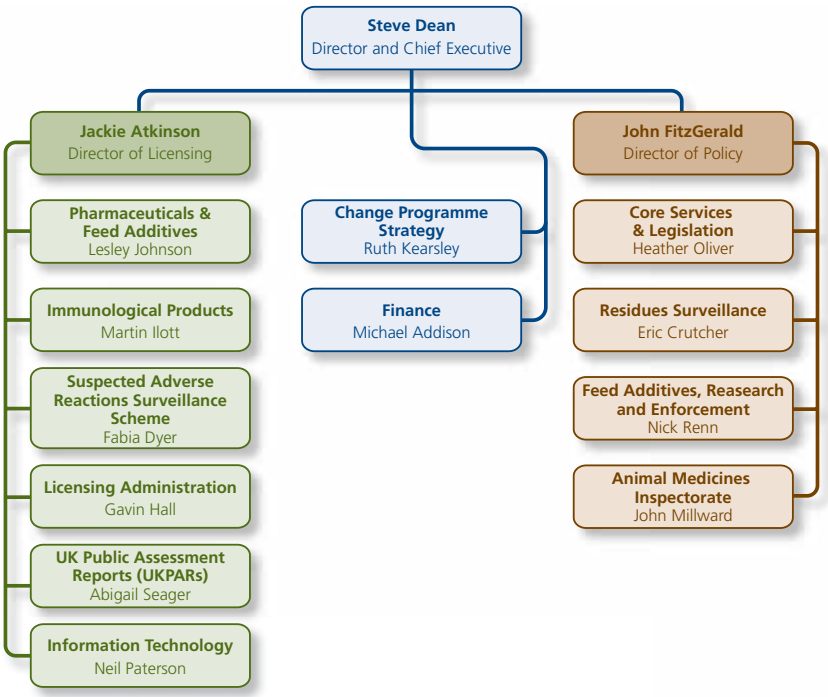
Licensing, responsible for the assessment of applications; issuing and maintenance of Marketing Authorisations; pharmacovigilance for veterinary medicines; and the licensing and inspection of manufacturers and wholesale dealers of veterinary medicines. Licensing's main customers are Marketing Authorisation 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)[11]; Department of Health (DH)[12]; 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.

Policy, 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.

Each business is supported by the ***Corporate Business Group,*** which is responsible for providing strategic support; corporate services of Finance, Information Technology (IT) and Training and Liaison; and for the provision of information to customers about our activities and achievements. In November 2006 the functions of this Group were divided between the CEO and Directors of Licensing and Policy following the retirement of the Director of Corporate Business.

The management team at 31 March 2007



10. Copies of our Framework Document are available free of charge from us (telephone 01932 338337)
11. You can find out more about the EMEA via www.emea.europa.eu
12. 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[13];
- 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 on our Audit & Risk Committee – see Appendix D) to provide an independent critique of our performance. The two Directors and Heads of the two scientific disciplines (Immunologicals and Pharmaceuticals), Finance, IT and TLU complete the formal membership. Staff have a standing invitation to propose items for the agenda and to attend as observers. During 2006/07 nine 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 Pesticides Safety Directorate (PSD)[14], 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, June, 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	Jim Smyllie	Delivery Strategy Team	Ian Anderson	Scottish Executive Environment and Rural Affairs Department
Chris Payne		Kerr Wilson	Pesticides Safety Directorate	Norma Barry	National Assembly for Wales Agricultural Department
		Steve Dean	VMD	Michael Camlin	Department of Agriculture and Rural Development (Northern Ireland)
		Debby Reynolds	Animal Health		
		Bill Stow	Environment		
		Howard Dalton	Science Directorate		
		Ian Grattidge	Finance		
		Tim Foster	Food Standards Agency		
		Les Philpott	Health and Safety Executive		

Our Finances

For the authorisation of veterinary medicines, inspection and approval of manufacturers of medicated/zootechnical animal feedingstuffs, post authorisation surveillance of suspected adverse reactions 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 Directorate is required to achieve full cost recovery across the three business areas of Licensing, Residues and Policy 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[15], the Central Science Laboratory (CSL)[16], Animal Health (AH), the Medicines and Healthcare Products Regulatory Agency (MHRA) and the Meat Hygiene Service (MHS)[17].

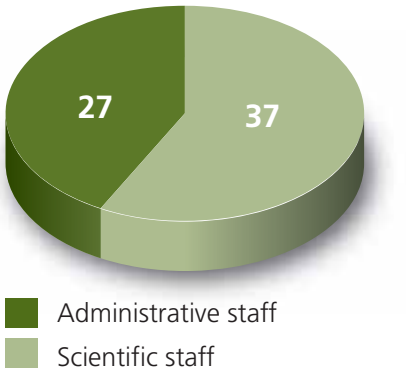
13. You can find a copy of our Business Plan on our website www.vmd.gov.uk under About
14. You can find out more about the work of the Pesticides Safety Directorate via their website www.pesticides.gov.uk
15. You can find out more about LGC Limited via www.lgc.co.uk
16. You can find out more about the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

Our People

At 31 March 2007 we employed 145 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 17 colleagues who work on a temporary basis and are supplied by local employment agencies.

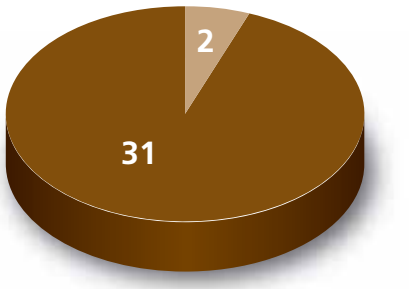
Average Permanent Staff Numbers 2006/07

Licensing



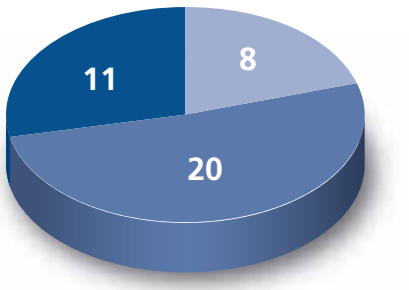
Administrative staff
Scientific staff

Policy & Residues



Administrative staff
Scientific staff

Business Support



Finance staff
Administrative staff
IT staff

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 Legislation 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 Heads of Medicines Agencies[18] in 2006/07.

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 2006/07 the VMD paid 100% of validated invoices within 30 days.

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

Preparation and Audit of the Accounts

The Accounts have been prepared in accordance with a Treasury Direction dated 18 December 2006 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 2006/07

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

- the Veterinary Medicines Regulations 2006 came into force on 1 October 2006 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;
- a Pollution Reduction Programme has been established with the Environment Agency and stakeholders to try to determine if Cypermethrin sheep dips can be used in an environmentally sustainable way;
- the implementation of a menu-based fee system to bring the cost of applications for new Marketing Authorisations more in line with the volume of work required to consider them;
- following the coming into force of the Access to Information (ATI)[19] legislation on 1 January 2005 we have dealt with 85 requests within existing resources;
- accreditation under ISO 27001 European Security Standard for the provision of IT systems and services (previously accredited with BS7799);
- Investors in People (IiP) accreditation was renewed to a higher standard following an inspection against IiP profiles; and
- successful negotiation of revised immunological batch release testing provisions to reduce the number of animals used and the administrative burden and cost to industry.

19. You can find out more about ATI legislation via the DCA's website at www.dca.gov.uk

Achieving Objectives

The Secretary of State of Defra announced our targets to Parliament on 16 May 2006. These provide a framework of actions in which the VMD can provide the best possible service to all its customers.

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 objectives in 2006/07:

Objective 1

Authorise veterinary medicines against legislative requirements according to published targets and fees and ensure the field-use of veterinary medicines is safe and effective principally through the use of best practice in pharmacovigilance and through actively discouraging improper use.

Highlight The VMD's Licensing Business delivered exceptional results, with all of the targets for both National and European applications achieving the performance level defined as 'excellent'.

Objective 2

Ensure that UK policy objectives are reflected in EC legislation and that UK legislation and guidance ensures that veterinary medicines can be used effectively and safely, offering protection to human health, animal health and welfare and the environment.

Highlights We made significant progress in getting Member States to agree to a reduction in the requirement for batch re-testing in relation to veterinary vaccines. We achieved a major success in moving the opinion of Member States away from routinely re-testing all vaccines and the issue has progressed to the extent that batch release under a harmonised system for the EU has been agreed. This is in line with UK policy and has yielded a significant reduction in the number of research animals used for re-testing.

The VMD's Enforcement Team continued to take effective and proportionate (risk-based) sanctions such as the possibility of issuing improvement or seizure notices (allowing inspectors to seize and destroy illegal medicines without compensation, subject to appeal). These are proving effective deterrents while we retain the option of prosecution for persistent or more serious offenders.

Objective 3

Actively monitor the safe use of veterinary medicines authorised in the UK through surveillance of residues and proportionate follow-up action where misuse is detected.

Highlight The Residues Team contributed to food safety by ensuring that the residues sampling and analysis targets were met, that violations were investigated according to standard operating procedures, and penalties were applied appropriately.

Objective 4

Recover the full cost of our operations from the industry and Defra and contribute to the Government's Better Regulation and efficiency agendas.

Highlight The VMD is undergoing a major internal change programme aimed at ensuring that we are in a good position to deal with anticipated developments over the next five to ten years. Individual projects considered the importance of our EU operations, the quality of our outputs and the 'fit for purpose' aspect of the VMD's structure. This work will help to improve efficiency and ensure that the VMD remains a respected and high profile National Competent Authority in Europe.

Note 2 to the Accounts shows that overall cost recovery was 102.9% 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.

Director of Licensing's Review

Jackie Atkinson

I took up the post of Director of Licensing at the VMD on 8 January 2007 and so this is my first such review for the VMD's annual report.

I am very pleased to be able to report that the Licensing Business has delivered exceptional results this year, with all of the targets for both National and European applications having not just been met, but having achieved the performance level defined as excellent.

These results were achieved despite some serious staff shortages in the safety and veterinary teams and against a backdrop of increasing numbers of applications. The results are a reflection of the dedication and commitment of the administrative, IT and scientific staff in the Licensing Business. Further, they indicate that under the helm of Lesley Johnson and Martin Ilott for most of this year the Licensing Business continued on its successful path.

I am also pleased to be able to report that the Licensing Business has achieved a cost recovery of 106.5%.

In terms of the volume of work this year there has been a significant increase in variations, in particular Type II variations where there has been more than a 70% increase. In contrast the number of new national Marketing Authorisations (MAs) was very similar to that of last year. It is in the European arena where the number of new Marketing Authorisation applications has risen significantly. For both National and European procedures, an ever increasing proportion of these are submitted as generic applications. At the end of this year over 100 Mutual Recognition procedures involving the UK are recorded on our database, with the UK acting as Reference Member State (RMS) for over half of these. As expected there has been a significant increase in the number of Decentralised procedures, with over 40 such procedures involving the UK being recorded on our database, with the UK acting as RMS for more than a third of these. It is very rewarding to see that companies are choosing to use the UK as RMS for so many applications. Also on a European level, the VMD has taken an instrumental role in the central authorisation of a number of avian influenza vaccines and has acted as the Rapporteur or Co-Rapporteur for a number of pharmaceutical products. The VMD has continued to play an active role in Europe, taking the lead role for a number of topics in CMDv as well as the various Working Parties of CVMP[20].

Our Suspected Adverse Reaction Surveillance Scheme (SARSS) received a significant increase in the number of reports of reactions in animals and humans during the year, but was able to deal with all of these within the required time frames. This increase in the number of reports is linked to the continuing efforts of the VMD to publicise this scheme. The SARSS team has also continued to log and monitor environmental incidents. In preparation for the full implementation of EudraVigilance Veterinary, the SARSS team has been actively contributing to the continuing development of the system and has worked with the IT team at the VMD to ensure our own systems are compatible and ready for data exchange. During the latter part of the year, preparatory work was carried out in anticipation of the start of pharmacovigilance audits in 2007.

United Kingdom Public Assessment Reports (UKPARs)[21] have now been published for almost 150 products, of which almost 60 products have a module containing the scientific discussion of the data prepared by the UK.

This year saw the issue of the first authorisation for a blood bank for companion animals. The VMD inspectors have approved the relevant premises and operations. The VMD inspectors have also visited for the first time manufacturers in the UK solely involved in the production of medicines marketed under the UK Small Animal Exemption Scheme and are helping these companies reach the required standards for manufacture and control.

The Licensing Administration team have continued to operate the successful customer care visits and these have reaped benefits for both the companies and the VMD. One important message from our customers has been the need to improve the quality of our documentation and we have taken forward a number of initiatives to address this and I anticipate that in the coming year marked improvements will be evident.

The IT team have continued to adapt existing systems and to develop new systems to improve the efficiency of the work of the VMD. Notable developments included the databases to support the VMD's enforcement work and also to support the authorisation of manufacturers of products covered by the UK Small Animal Exemption Scheme. Important work has also been undertaken by the team to ensure that IT systems can be restored quickly and accessed remotely should this be necessary.

In conclusion, this year has been a very successful year for the whole of the Licensing Business and I am very grateful to everyone for their contributions, positive attitudes and hard work.

Jackie Atkinson

20. You can find out more about the work of the CVMP via the EMEA website www.emea.europa.eu
21. You can find out more about UKPARs via www.vmd.gov.uk under Product Information

Director of Policy's Review

In last year's report I focused on change and 2006/07 has continued in the same vein. In particular with the retirement of Chris Bean in October, I also became responsible for all of our Core Services apart from IT and Finance. The transition was all but seamless and I would like to thank all those involved.

Another significant element to the year's work was absent staff. Three members of the Veterinary Medicines Regulations team left within weeks to have their first babies – I am pleased to say all are doing well! We also lost the services of David Lewsey for nearly 12 months while he was on jury service. Losing all this expertise is difficult and those who took over the work have done exceptionally well to maintain standards. The Veterinary Medicines Regulations 2006 were introduced on time and the consultation for the 2007 Regulations began on 5 March.

We worked with our EU colleagues to implement a new batch testing regime for immunological products. This was an excellent example of the VMD taking Government policies on the reduction of animals used in testing and administration burdens on industry into the EU environment. After much negotiation we achieved our aim of a risk-based testing system that will reduce the number of re-tests required and the burden on industry without reducing the necessary controls for the safe use of immunological products.

The suspension of Synthetic Pyrethroid (SP) dips produced a great deal of work on the Pollution Reduction Programme and a raft of associated access to information requests. As we approach the end of the year, more information on the risks and options for using SP dips has been made available for consideration by the project steering group.

The AMI continued to settle into the VMD's ways of working. We completed an internal review which concluded that additional tasks were needed to fully optimise use of the inspectors' time on the road. They have already begun to carry out investigations into the use of illegal medicines in pets. The AMI has developed a system for identifying the risks associated with registered premises and will be introducing a risk-based inspection timetable in 2007/08.

Funding for our non-statutory residues scheme and the new CAP cross-compliance work presented significant challenges for the residues team. Along with a dispute over increased charges from a supplier, these were successfully managed. Nevertheless, reduced funding from Defra will continue to present a challenge in maintaining our levels of service for the next few years.

We continued to review the VMD's business operations and strategies using both external reviewers and staff supported by the independent members of our Management Board. This work is vital to enabling the VMD to maintain and improve the high quality of the services we provide. In particular, we received an excellent report on Investors in People profiles and we completed another benchmarking comparison with the European Foundation for Quality Management model and a staff survey. The results were good and we will use the areas identified for improvement to help us continue to improve the VMD.

Work continued with colleagues on the human medicine side to produce the first joint report on antimicrobial resistance. This will be published in 2007/08. The UK continued to be one of a small number of countries worldwide to produce data on the amounts of antimicrobials used in animal medicines with our sales data report for 2006.

Our enforcement work developed a more international feel with much work on a website based outside the UK selling medicines illegally to UK customers. The same team put the final touches to the exemption scheme for some pet animal medicines that will help to keep these products on the market with proportionate controls.

Another busy and successful year thanks to the efforts of those working in the VMD. This is not surprising as a significant percentage of staff said in the staff survey they enjoyed their work and would recommend the VMD to their friends. Thanks to all the staff who once again rose to the challenges they faced and produced good service to all our customers.

John FitzGerald

John FitzGerald

Looking forward

The CEO asked Defra's Internal Audit Team to carry out an audit on the establishment and monitoring of performance targets in the VMD. The Audit Team made a number of recommendations which we have implemented in the development of the 2007/08 Business Plan. These include some changes to terminology where headline objectives are now defined as 'targets'. This brings the VMD into line with the terminology used in the rest of Defra.

Targets for 2007/08

Ministers have agreed four targets for the VMD. The work we do also contributes towards delivering three of Defra's strategic priorities:

- our work helps towards 'sustainable farming and food including animal health and welfare', and 'sustainable consumption and production' by
  - assuring that veterinary medicines are safe, high quality and efficacious, both for food producing and companion animals;
  - ensuring that the regulatory system is effective and contributes to protecting public health by taking risk-based action on the findings from our surveillance and monitoring programmes;
  - ensuring that UK policy objectives are reflected in EC legislation and guidance and that UK legislation and guidance ensures that veterinary medicines can be used in the farming, food and companion animal sectors responsibly, effectively and safely.
- we also contribute towards 'protecting the countryside and natural resource protection' by the work we do assessing the environmental impact of veterinary medicines.

The four targets are:

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.

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 & 3 and provides value for money* and the VMD achieves full cost recovery.

Key challenges for next year

The key challenges to the VMD throughout 2007/08 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 2007;
- 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;
- outcome of the consultation on the recommendations contained in the HM Treasury Report entitled 'Reducing Administrative Burdens: Effective Inspections and Enforcement' expected in 2008. Whatever the outcome of the consultation process, the existing objectives 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 2006/07: to achieve cost recovery for the VMD as a whole. The Accounts show an operating surplus for the year of £389,000 achieving an overall cost recovery of 102.9%.

The results of the VMD's main business activities during 2006/07 were as follows:

	Income £m	Expenditure £m	Cost recovery %
Licensing	6.3	5.9	106.5
Statutory Residues	3.9	4.0	96.2
Non-statutory Residues	0.9	0.9	100.2
Policy	2.5	2.3	109.3
Animal Medicines Inspectorate	0.4	0.5	86.7
Total VMD	**14.0**	**13.6**	**102.9**

Expenditure

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

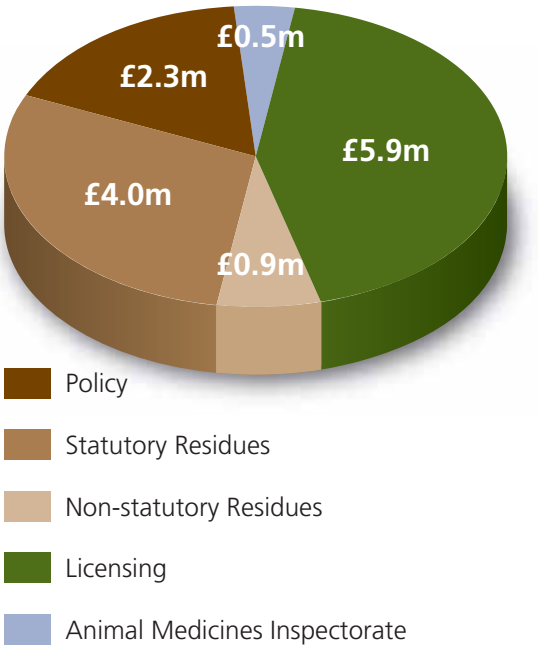
The VMD's AMI business commenced on 1 January 2006, when the function and staff were transferred from the RPSGB[22]. The results shown for the AMI in the previous year (2005/06) therefore represent three months' activity.

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 £8.2m and Revaluation Reserve of £2.3m.



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.

22. You can find out more about the RPSGB via www.rpsgb.org

Remuneration Report

Remuneration Policy

The remuneration of senior civil servants is set by the Prime Minister following independent advice from the Review Body[23] 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;
- 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[24], 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 until they reach the normal retiring age of 60. 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 the 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:

23. Further information about the work of the Review Body can be found at www.ome.uk.com
24. Further information about the work of the Civil Service Commissioners can be found at www.civilservicecommissioners.gov.uk

Salaries and Pension Benefits (Audited)

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
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	0-2.5 plus 0-2.5 lump sum	0-(2.5) plus 0-(2.5) lump sum
Total accrued pension at age 60 and related lump sum	10-15 plus 30-35 lump sum	30-35 plus 95-100 lump sum	10-15 plus 25-30 lump sum	30 – 35 plus 95-100 lump sum	30 – 35 plus 90-95 lump sum
CETV at 31 March 2006	200	597	167	715	809
CETV at 31 March 2007	229	635	174	685	751
Real increase in CETV after adjustment for inflation and changes in market investment factors	18	18	3	1	(19)
	£	£	£	£	£
Employer contribution to partnership pension account including risk benefit cover – to nearest £100	–	–	–	–	–

2005-06	S Dean – Director and Chief Executive	J FitzGerald – Director of Policy	J O'Brien – Director of Licensing	C J Bean – Director of Corporate Business
	£000	£000	£000	£000
Salary (as defined above)	85-90 including 5-10 bonus	75-80 including 0-5 bonus	70-75	60-65
Real increase in pension and related lump sum at age 60	0-5 plus 0-5 lump sum	0-5 plus 5-10 lump sum	0-5 plus 0-5 lump sum	0-5 plus 0-5 lump sum
Total accrued pension at age 60 and related lump sum	5-10 plus 25-30 lump sum	30-35 plus 90-95 lump sum	30-35 plus 95-100 lump sum	30-35 plus 95-100 lump sum
CETV at 31 March 2005	138	445	490	583
CETV at 31 March 2006	200	597	715	809
Real increase in CETV after adjustment for inflation and changes in market investment factors	26	36	24	–6
	£	£	£	£
Employer contribution to partnership pension account including risk benefit cover – to nearest £100	–	–	–	–

J O'Brien retired on 31 May 2006 and his salary range disclosed above (£10,000-£15,000) relates only to the period in which he was in post. His full-year equivalent salary was in the range £75,000-£80,000.

C Bean retired on 27 October 2006 and his salary range disclosed above (£35,000-£40,000) relates only to the period in which he was in post. His full-year equivalent salary was in the range £65,000-£70,000.

J Atkinson was appointed on 8 January 2007 and her salary range disclosed above (£10,000-£15,000) relates only to the period in which she was in a senior management post. Her full-year equivalent of this salary was in the range £60,000-£65,000.

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

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 their representatives and the external members and details of these members' salaries, pensions, company directorships or other significant interests are included in their departments' resource accounts. This cost is included in the notional Defra service recharge.

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[25]

Pension benefits are provided through the Civil Service pension 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

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

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. 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. The factors used to calculate the CETV were revised on 1 April 2006 on the advice of the Scheme Actuary. The CETV figure for 31 March 2006 has been restated using the new factors so that it is calculated on the same basis as the CETV figure for 31 March 2007.

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.

Environmental matters and social and community issues

The VMD continued in its efforts to recycle materials where possible. Action included the following: recycling facilities for plastic cups and bottles in all kitchens; waste paper taken by the Veterinary Laboratories Agency (VLA)[26] for incineration and the resulting energy used for heating; we recycled toner and printer cartridges; 99% of the paper used for photocopying and printing was recycled; and we used a stationery supplier that supplies stock made from recycled material where possible.

We introduced a policy requiring trips to Brussels to be made using Eurostar where possible, to help contribute to reducing carbon emissions and cost. Likewise with travel within the UK we have re-enforced the policy that requires staff to travel via train where possible. We are calculating carbon emissions for air travel on a quarterly basis and will be comparing figures year on year to monitor reductions in emissions.

The VMD continued to dispose of electronic equipment in accordance with the EC Directive on Waste Electrical and Electronic Equipment (WEEE)[27] and the EC Directive on Restricting the use of Certain Hazardous Substances in Electrical and Electronic Equipment. The purpose of the WEEE Directive is to reduce the quantity of waste from electrical and electronic equipment and increase its re-use, recovery and recycling.

During 2007/08 the VMD will be exploring the options of linking with Defra or the VLA Sustainable Development Action Plans and will be reviewing options for undertaking further audits of recycled materials used and measurement of carbon emissions.

We have continued to provide mentors for pupils at a local school.

26. You can find out more about the VLA via www.vla.gov.uk
27. Further information about the EC Directive on WEEE can be found at www.dti.gov.uk/innovation/sustainability/weee/page30269.html


2824
2796

Meeting our objectives

Objective 1

To authorise veterinary medicines against legislative requirements according to published targets and fees and ensure the field-use of veterinary medicines is safe and effective principally through the use of best practice in pharmacovigilance and through actively discouraging improper use.

To authorise veterinary medicines efficiently, using good science, thus ensuring their safety, quality and efficacy, and in accordance with legislative requirements.

Assess, issue and maintain national authorisations for veterinary medicines used in the UK within the prescribed regulatory regime.

For new UK Marketing Authorisations, performance against legislative and internal targets for the assessment process.

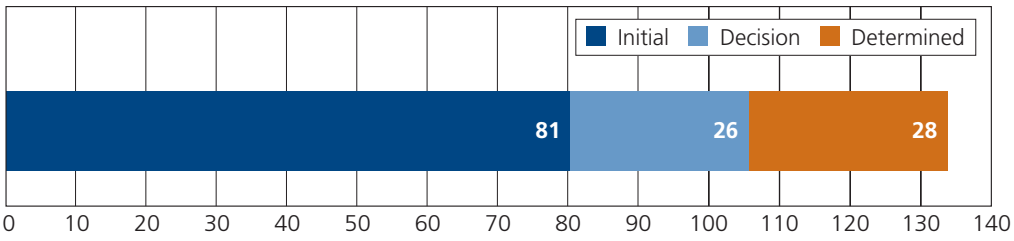
We monitored and reported progress against our objectives at quarterly meetings of the VMD's Management Board and reported progress to Defra's RASB. The achievement of our strategic objectives and key performance targets was subject to an annual independent assessment by Defra Internal Audit.

Expected Outcome

- Initial Assessment to be completed or signed off within 90 days;
- To reach the stage of Further Questions, signed off or refer to Veterinary Products Committee (VPC) within 120 days;
- New Marketing Authorisations to be determined within 210 days.

Outcome

TARGETS (average clock days)
Average days for year for applications completed with each phase



National Assessments Average clock days

For applications received after 1 April 2006

I. A total of 41 applications had an Initial Assessment completed or signed off within 90 days.

II. Twenty seven applications reached the stage of Further Questions, signed off[1] or Referred to VPC, of these one application exceeded the timeframe giving a 96.1% success rate.

III. 13 applications were Determined[2] within 210 days, resulting in 100% success rate.

1 Sign off is the time taken to complete scientific assessment.

2 Determine is the time taken to sign off and issue the authorisation documentation.

The following applications received before 1 April 2006, fall outside the scope of the formal targets for last year;

I. A total of 38 New Marketing Authorisations signed off[1] within 120 days, resulting in 100% success rate.

II. A total of 54 New Marketing Authorisations were determined[2] within 210 days, resulting in 100% success rate.

Evaluated by

>90%	**Excellent**
80%-90%	Effective
<80%	Unacceptable

For applications for variations to UK Marketing Authorisations, performance against internal targets for the assessment process

Expected Outcome

Type IA to complete the process of assessment within 14 days of receipt of the application. For Type IB variations, to complete our initial assessment within 30 days, and sign off applications within 60 days. For Type II variations, complete our initial assessment within 60 clock days and sign off, or refer to VPC, applications within 120 clock days.

Outcome

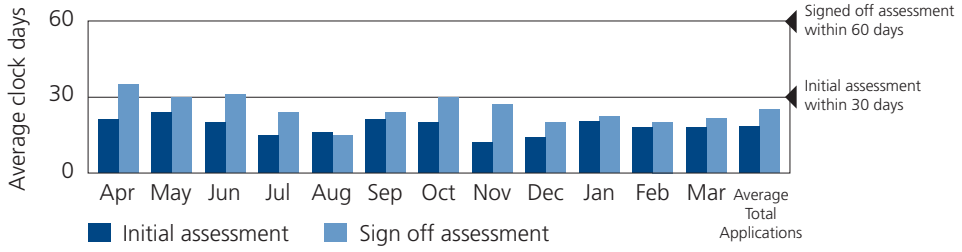
- 295 Type IA national variations completed the process within an average of 5.15 days resulting in a performance of 100%.
- A total of 264 Type IB national variations had an initial assessment completed within 30 days, resulting in a performance of 100%.
- A total of 259 Type IB national variations were signed off within 60 days, resulting in a performance of 100%.
- A total of 435 Type II national variations had an initial assessment within 60 days, resulting in a performance of 99.5%.
- A total of 376 Type II national variations were signed off within 120 days, resulting in a performance of 99.7%.

Evaluated by

>97%	**Excellent**
92%-97%	Effective
<92%	Unacceptable

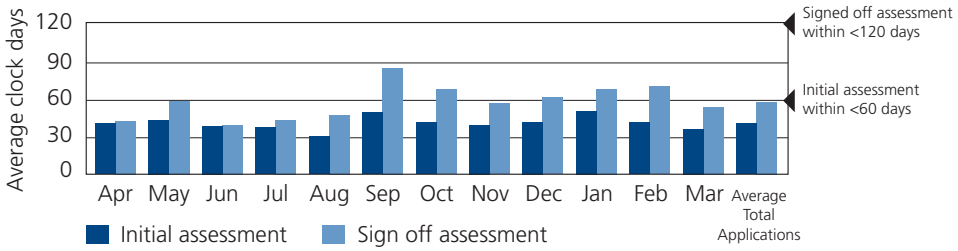
National Type IB Variations

Type IB



National Type II Variations

Type II



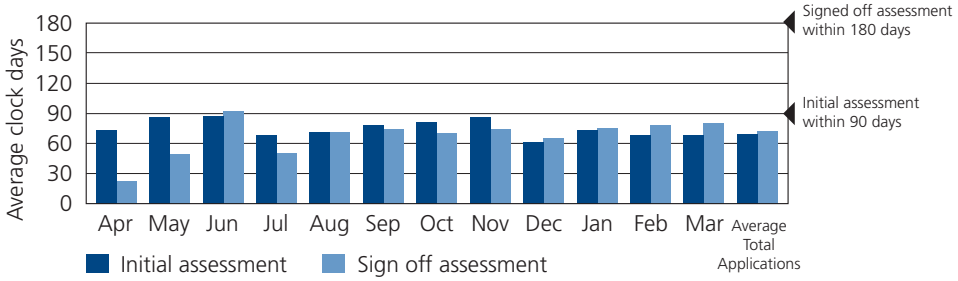
For applications for renewals of UK Marketing Authorisations, performance against internal targets for the assessment process

Expected Outcome

To complete our initial assessment within 90 clock days and sign off applications within 180 clock days for all renewals (full, conditional and admin).

Outcome

- A total of 125 national renewals had an initial assessment completed within 90 days, of these three applications exceeded the timeframe giving a 97.60% success rate.
- A total of 217 national renewals were signed off within 180 days, of these six applications exceeded the timeframe giving a 97.24% success rate.



Evaluated by

>97%	**Excellent**
92%-97%	Effective
<92%	Unacceptable

For applications for Animal Test Certificates (ATCs) in the UK, performance against internal targets for the assessment process

Expected Outcome

To validate within five days for both Type A and Type B applications. To sign off Type A applications within 30 days and Type B applications within 50 days.

Outcome

Five Type IA ATCs were validated within five days and five were signed off within the 30 day target. For both targets 100% compliance was achieved.

Twenty one Type IB ATCs were validated within five days. Nineteen applications were signed off within the 50 day target. For both targets 100% compliance was achieved.

Evaluated by

>97%	**Excellent**
92%-97%	Effective
<92%	Unacceptable

ATC

Type A

No. received	5
No. issued	7

Time taken from receipt of valid application to issue

Days	0-15	16-30
No. Applications	4	3

Type B

No. received	21
No. issued	19

Time taken from receipt of valid application to issue

Days	0-15	16-30	31-50
No. Applications	17	1	1

For all UK applications, other than ATCs, performance against internal targets for the start and end of the authorisation process

Expected Outcome

To validate within ten calendar days of receipt, and issue relevant documentation within ten calendar days of sign off.

Outcome

The validation and sign off performance for the various application types is detailed in the following table:-

Application Type	Validation (No. Applications)	Performance
Type IB Variations	484	98.76%
Type II Variations	475	100%
Renewals	266	99.62%
New Marketing Authorisations	64	100%

Application Type	Issued (No. Applications)	Performance
Type IA Variations	295	100%
Type IB Variations	259	99.61%
Type II Variations	389	100%
Renewals	376	100%
New Marketing Authorisations	68	100%

Evaluated by

>97%	**Excellent**
92%-97%	Effective
<92%	Unacceptable

The following table shows the comparison of applications received and determined for each category for both 2005/06 and 2006/07. The table also shows the number of applications which were in progress at the end of 2006/07.

(Unit: No. of Applications)	Received & validated in year 2005/06 & 2006/07		Determined in year 2005/06 & 2006/07		Work in progress 2006/07
National: New Marketing Authorisations	46	64	89	68	75
New Autogenous Vaccine Authorisations (AVA)	3	3	0	5	3
Type IA Variations	128	295	130	295	42
Type IB Variations	145	484	103	522	28
Type II Variations	251	475	227	401	146
Renewal	189	266	341	245	64
ATC: Type A	11	5	11	7	0
Type B	27	21	28	19	4
Var & Ren	17	10	18	9	0
Centralised: New Rapp/Co-Rapp	1	5	2	4	7
Type I Variations	12	0	11	6	0
Type II Variations	7	9	7	9	2
Type IA Variations	4	3	4	3	1
Type IB Variations	7	7	7	6	1
MRL	4	0	3	2	1
Others	28	46	43	37	24
Zootechnical FA	1	3	6	3	6
Decentralised: UK Reference Member State (RMS)	8	7	0	8	10
UK Concerned Member State (CMS)	1	23	0	2	20

(Unit: No. of Applications)	Received & validated in year 2005/06 & 2006/07		Determined in year 2005/06 & 2006/07		Work in progress 2006/07
Mutual Recognition: UK RMS	22	21	22	24	29
UK CMS	20	36	20	34	21
MR Variations: UK RMS	61	83	63	82	16
UK CMS	86	122	94	124	20
MR Renewals: UK RMS	7	14	9	13	17
UK CMS	13	31	1	16	32
Special Import Certificates (SIC)	–	–	876*	3553	3
Special Treatment Certificates (STC)	–	–	432*	2834	13

*Please note: SIC/STCs were introduced in October 2005.

In addition we also:

- issued 2834 Special Treatment Certificates, 100% within the ten working days deadline;
- issued 3553 Special Import Certificates, 100% within the ten working days deadline;
- issued 1300 Export Certificates, 100% within the four working days deadline.

Evaluated by

>95%	**Excellent**
90%-94%	Effective
<90%	Unacceptable

a) Act as Rapporteur or Co-Rapporteur for applications for Marketing Authorisations for veterinary medicines made in accordance with Community legislation.

All targets complied with the 100% compliance for all the procedures. The UK acted as Rapporteur or Co-Rapporteur for six applications for Marketing Authorisations for veterinary medicines made in accordance with Community legislation received in 2006/07. These consisted of three pharmaceutical products; an aural suspension for dogs, a Non-Steroidal Anti-Inflammatory Drug (NSAID) for cats and dogs and a line extension antimicrobial for use in chickens. The other three products were avian vaccines.

The UK were also appointed Rapporteur for two CVMP[28] referrals. These were both Mutual Recognition procedures which were referred by the Veterinary Co-ordination Group for Mutual Recognition and Decentralised Procedures (CMD-v).

bi) Inspect, to an agreed timetable manufacturers of immunological veterinary products to ensure compliance with the principles of Good Manufacturing Practice (GMP) and maintain efficient cost-effective systems for the batch release of immunological products.

The VMD inspects manufacturers of Immunological Veterinary Medicinal Products (IVMP) and other relevant products and test sites to ensure that products available on the UK Market are manufactured and tested in compliance with GMP.

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

The VMD Inspections team carried out 18 inspections to ensure compliance with the principles of GMP. These included manufacturers of IVMPs, Small Animal Exemption Scheme products and contract test sites. In addition, three Autogenous Vaccine Authorisation/Non Food Animal Blood Bank Authorisation (AVA/NFABBA) sites were inspected as part of the authorisation procedure.

Six of these inspections were new sites. We issued 16 sites with GMP Certificates or AVA/NFBBA, as appropriate. We will issue the appropriate documents to the remaining sites on receipt of satisfactory responses to the inspection reports. All of the inspections were carried out within the approved timetable.

bii) Maintain efficient cost-effective systems for the batch release of immunological products.

The VMD implements in the UK the requirement for official administrative batch release for immunological products in order to maintain control of individual products and ensure they will be safe and efficacious in use.

With cost effectiveness in mind, the VMD improved efficiency of their batch release system by introducing streamlined procedures, a database and enhanced systems for the batch release of immunological products.

The Veterinary Pharmaceutical Committee considered and endorsed the Commission's recommendations for Official Competent Authority Batch Release (OCABR) under Articles 81 and 82 of Directive 2001/82, at their meeting in March 2007. These recommendations will significantly reduce the re-testing of immunological products by Authorities, therefore reducing the costs to industry associated with batch release and also the usage of research animals in product re-testing across the EU.

c) Initiate a project to introduce an accredited quality management system.

The VMD is committed to improving continually how it carries out its business. As part of this commitment, we have evolved a project team from previous work carried out on the feasibility of introducing an accredited quality management system into the Immunological inspection team. The objective of the project is to obtain a neutral or positive outcome to the Head of Medicines Agency's Joint Audit Programme (JAP) equivalence assessment at the end of 2007. The project team has embarked on a gap analysis of the audit process check list, and development and implementation of documentation to meet the requirements of the JAP. However, the project contains important critical success factors that relate to the development of a standard approach to 'quality' that we can replicate across the rest of the Agency. We will consider applying for formal accreditation once these procedures have been implemented in 2008.

d) To ensure the field use of veterinary medicines is safe and effective by monitoring use by using best practice in pharmacovigilance.

The Suspected Adverse Reaction Surveillance Scheme (SARSS) is a national surveillance scheme run by the VMD. The scheme aims to record and monitor reports of suspected adverse reactions to veterinary medicines in both animals (any species) and humans.

An animal suspected adverse reaction (SAR) is a harmful and unintended reaction which may be due to exposure to a veterinary medicine administered to an animal at its normal dose. In other words, it is any harmful side effect to a veterinary medicine. A reaction may occur in an animal undergoing treatment or in an untreated animal in the same household as a treated animal. A human SAR may occur in a person administering a veterinary medicinal product, or a person exposed to a recently treated animal.

A company which holds a Marketing Authorisation (the MA holder) is legally required to report serious adverse reactions within 15 days of receiving a report and non-serious adverse reactions in Periodic Safety Update Reports (PSURs) submitted at intervals specified in the Marketing Authorisation. Guidance for MA holders in the UK is provided in Veterinary Medicines Guidance Note 13 and via the VMD publication entitled MAVIS which is published quarterly. Further guidance for MA holders is available from the EMEA.

The VMD's SARs team continued to participate in the implementation of an electronic system in the EU for the exchange of information about suspected adverse reactions between Marketing Authorisation holders, competent authorities and the EMEA.

Reports of suspected adverse reactions were submitted electronically to the central EU database during the year and numerous technical issues were resolved. The national database was modified to facilitate the receipt of electronic reports, and testing of this capability had started when withdrawal of IT support for the system by the EMEA brought it to a halt.

e) Prompt recording of all reports of suspected adverse reactions (SARs).

The SARs team have 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 14 working days.

The team met these targets, with the exception of the forwarding of reports to the EMEA which, for a two month period in November/December 2006, was suspended due to a problem with the European electronic system, which was beyond the control of the VMD.

f) Report information on pharmacovigilance as transparently as possible under the requirements of the Access to Information (ATI) legislation.

In line with all ATI requests to the VMD, the SARs team are required to respond to requests for pharmacovigilance information within 20 working days following the day of the receipt of the request. The team met this target for all requests made in 2006/07.

In answering ATI requests the team took account of the guidance in the Memorandum of Understanding between the British Pharmaceutical Industry, Medicines and Healthcare Products Regulatory Agency, National Office of Animal Health and the Veterinary Medicines Directorate (the "Traffic Light Document").

Animal Medicines Inspectorate (AMI), Stoneleigh

Objective 2

Ensure that UK policy objectives are reflected in EC legislation and that UK legislation and guidance ensures that veterinary medicines can be used effectively and safely, offering protection to human health, animal health and welfare and the environment

Prepare plans for Official Feed and Food Controls (OFFC) audit arrangements for medicated feed additives and residues surveillance by 1 October 2006.

Under the OFFCs each Member State is required to prepare a 'multi-annual' national control plan. This is essentially a strategic plan setting out the national monitoring and enforcement arrangements, objectives and priorities. It describes the roles and responsibilities of the various competent authorities and provides details of how the various requirements of the Regulation are being met. The plan is a single integrated plan covering arrangements for monitoring and enforcement not only of feed and food law but also animal health and animal welfare rules, as well as plant health controls.

The feed and food elements of the plan are achieved by means of the existing monitoring returns with any necessary amendments to meet the new EU requirements. The VMD's Residues Team and its Medicated Feed Additives Team contributed by drafting the relevant sections of the plan that related to the enforcement and control activities which are consequent to the VMD's surveillance programmes and inspections carried out by the AMI. They met their deadlines and the whole plan was completed by 1 January 2007, with regular updates thereafter.

Review of the role of the AMI by 31 March 2007.

Approve and register manufacturers and suppliers of medicated feed additives and SQP suppliers of POM VPS medicines as required by agreed standard operating procedures (SOPs).

The AMI became part of the VMD on 1 January 2006, following a TUPE transfer from the Royal Pharmaceutical Society of Great Britain. The Inspectorate, which was formerly a branch within the Society's Fitness to Practice and Legal Affairs Directorate, was originally formed in 1988 to register and inspect manufacturers of medicated animal feedingstuffs at the request of MAFF. The Society was already involved in the agricultural sector at that time, as it was responsible for the registration and inspection of agricultural merchants and saddlers retailing PML classified veterinary medicines, under its duty to enforce section 52 of the Medicines Act 1968 (the retail sale of medicines not on a general sales list).

The mutual agreement to transfer the AMI into the VMD was due to the Inspectorate not fitting in with plans for the restructuring of the Society and the introduction of the Veterinary Medicines Regulations 2005, which disapplied the Medicines Act 1968, and therefore the Society's duty, in relation to veterinary medicines.

The Inspectorate comprises two office staff based at its Stoneleigh Park headquarters in Warwickshire, and five regionally based Inspectors, one of whom also heads the department. Its role continues to be the approval and inspection of those businesses retailing POM-VPS and NFA-VPS medicines by Suitably Qualified Persons and those manufacturers and distributors of animal feedingstuffs' products regulated by Schedule 5 of the Veterinary Medicines Regulations. In addition, Inspectors visit trade shows and exhibitions to ensure that unauthorised products are not being marketed, as well as conducting investigations into veterinary medicines or specified feed additive residues in human foods potentially arising from deficiencies in the manufacture or distribution of animal feedingstuffs.

During the year, the Inspectorate carried out a total of 1,698 routine inspections of approved premises against a target of 1,799 (94.4%), as well as 181 other visits, including 20 visits to trade exhibitions and 11 residue investigations.

A review of the role of the AMI was carried out during the latter part of the year and the recommendations arising from the review are currently being considered by the VMD.

Prepare antimicrobial sales data report[29] for 2005 and make available on the VMD website by 31 December 2006.

Antimicrobial resistance is a serious problem in human medicine resulting in increasing concerns about the use of antimicrobial products in human medicine, veterinary medicine, animal production, agriculture and horticulture. The UK Government has made clear that it takes this problem seriously and has developed a comprehensive strategy to address it so that the effectiveness of antimicrobial products in both humans and animals can be maintained. A key element of this strategy is the collection and publication of information on the quantities of antimicrobial products sold each year for veterinary use in the UK.

For the past eight years, in response to recommendations made by the Advisory Committee on the Microbiological Safety of Food (ACMSF), the VMD's Antimicrobial Resistance Team have collected, collated and published figures on UK sales volumes of active antimicrobial ingredients used in products authorised as veterinary medicines, growth promoters or coccidiostats. The report has been extended over time to include antiprotozoal and antifungal products. The 2006 sales data report was published on the VMD website according to plan. Hard copies are also available.

Prepare the first overarching report of human and animal antimicrobial sensitivity.

Another recommendation of the ACMSF was that the organisations responsible for monitoring antimicrobial resistance in animals, people and food should work together to produce a report summarising antibiotic resistance in the food chain, in the UK.

The VMD contributes to this initiative by providing the Chair and secretariat for the Defra Antimicrobial Resistance Co-ordination (DARC) Group, which was tasked with providing support for preparation of this report. The VMD, VLA, Defra, HPA, DH, HPS, FSA, and the Devolved Administrations were all involved in drafting what is the first joint report for the UK dealing with public health and food-producing animal health. The report is awaiting clearance for publication. It brings together data on antimicrobial consumption, significant pathogens and their antimicrobial susceptibilities across both fields.

Continue legal classification review of authorised veterinary medicines.

In March 2006 the VPC agreed to establish a Sub-Group on the Review of the Distribution Categories of Authorised Veterinary Medicinal Products, to provide advice to the VMD on the responses to the consultation on the Government's acceptance of recommendations in the report of the Independent Review of Dispensing by Veterinary Surgeons of Prescription Only Medicines (the Marsh Report) and the Competition Commission[30] report on the supply within the United Kingdom of prescription only veterinary medicines.

The VMD asked for seven groups of products to be considered by the VPC Sub-Group together with documents to explain working procedures. The VPC Sub-Group met in January and March to consider their recommendations for change.

Establish an EU co-ordination team.

The increasing level of work we carry out at EU level has triggered a review of this sector of our work during the past year. This is work we carry out in conjunction with our colleagues in other Member States and the EMEA, alongside the ongoing development of the EU network of Competent Authorities through the Strategic Plan from the Heads of Medicine Agencies (HMA) and the EMEA Roadmap. We are taking forward this review as part of the VMD's Change Programme, which will lead to changes in 2007 and beyond.

29. You can access the Antimicrobial Sales Data report via www.vmd.gov.uk under Publications
30. You can find out more about the Competition Commission via the website www.competition-commission.org.uk

Continue to publicise the work of the Enforcement Team through attendance at trade shows, county shows and by publishing articles regularly in magazines and journals.

The VMD's Enforcement Team visited sixteen county shows including visits to game fairs to publicise the illegalities of using Emtryl for game-birds. The Team worked closely with game-keeper associations in this area and produced a laminated information sheet on Emtryl which has been widely circulated. They gave a number of presentations on the work of the Enforcement Team to a variety of bodies, including representatives from other Member States, and they continued to publish reports of successful prosecutions in a variety of journals.

We all want to be sure that our food is safe. But, we also know that to avoid unnecessary pain and distress to farm animals, they sometimes need to be treated with authorised medicines. We have to balance the use of these medicines and the need to avoid residues in foods. There are internationally set safety limits for residues of the majority of veterinary medicines in food.

Objective 3

To actively monitor the safe use of veterinary medicines authorised in the UK through surveillance of residues and follow-up action where misuse is detected.

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 61).

To ensure that they were prepared for surveillance in 2007, they:

- agreed the 2007 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 2007 with the Veterinary Residues Committee by 31 December 2006.

Negotiate a position on changes to EU legislation informed by stakeholder views.

The Residues Team contributed to changing EU residues surveillance legislation by taking part in early discussions on a discussion paper. The paper presents points that need to be considered and debated. The Commission goal is to determine new means to balance consumer protection, animal health, animal welfare and trade requirements concerning residues in food producing animals. On the basis of the comments received, the Commission intends to make proposals on the necessary amendments of the Community legislative framework in this sector. The VMD will consult fully with stakeholders in 2007/08 once the Commission has made its proposals public.

CAP cross compliance checks are implemented successfully.

Cross compliance is a series of standards that farmers need to meet in order to receive their subsidy payment in full. One standard relates to restrictions on the use of substances having hormonal or thyrostatic action and beta-agonists in farm animals. The VMD's Statutory Residues on-farm sampling programme contributes to the cross compliance initiative by forming the basis of these checks. In 2006 the VMD provided reports on the number of farms visited and the results of sample tests to the authorities responsible for cross compliance in England, Scotland and Wales. No violations were found.

OFFC requirements are integrated into current operations successfully.

The aim of the OFFC is to create a comprehensive, integrated, risk-based, EU wide, 'farm to fork' approach to official controls. The objective is to improve the consistency and effectiveness of controls across the EU and, as a consequence, raise standards of food safety and consumer protection. http://www.food.gov.uk/news/newsarchive/2006/jan/offcguidance

The VMD contributed to this initiative when members of the Residues Team successfully completed the first audit of the residues control procedures under OFFC requirements. They visited the CEFAS laboratory and accompanied a fish health inspector on residue sampling visits to two farms. They

audited CEFAS against their own internal procedures and the fish health inspector against the VMD's sampling protocols – they found that both met the required standards.

Joint VMD/Environment Agency (EA) programme to reduce pollution from sheep dip agreed and implementation started.

In September 2005 the VMD and the EA convened a meeting of pharmaceutical industry stakeholders, farmers' representatives, conservation groups and the regulatory authorities to determine actions needed to minimise the risk of environmental pollution caused by the use of sheep dips. As a result, a Pollution Reduction Programme for sheep dip was developed. The steering group formed to progress the actions met in August and December 2006, where progress with the programme was discussed. The NFU's "STOP every DROP" campaign launched in August at 'Sheep 2006' was developed as part of the Pollution Reduction Programme. Further meetings are planned for 2007/08.

Change in Veterinary Medicines Regulations to require sheep dippers to possess Certificate of Competence for safe use and disposal of dips.

This initiative was successfully completed as part of the remaking of the Veterinary Medicines Regulations 2006 that came into force on 1 October 2006.

Implement strategy for raising public awareness of the regulatory process.

Work to implement a strategy to raise public awareness of the regulatory process will be taken forward in 2007/08 as part of an agency wide communications project. However, the VMD used a variety of ways to raise public awareness of the regulatory process, as described in this report. We also introduced a Communications Plan which sets out for the first time what the key messages are from our 2007/08 Business Plan and how we will communicate them to our stakeholders.

Investigate those involved with the deliberate marketing of illegal veterinary medicinal products including those who knowingly purchase or use unauthorised veterinary medicinal products.[31]

The Enforcement Team aims to protect public health, animal welfare and the environment by seeking to eliminate the use of illegal veterinary medicinal products by reducing the possession, marketing, sale and supply of such products. The team investigated 16 cases in 2006/07, of which 13 related to incidents involving food producing species.

Since the introduction of the Veterinary Medicines Regulations our enforcement policy has been to seize and destroy illegal medicines confiscated by Inspectors. Only where evidence suggests this would not be a sufficient penalty do we pursue with a full investigation leading to possible prosecution. Seizure notices enable the team to seize and destroy illegal products without the need to pursue the costly and time consuming route of prosecution. This measure has the immediate benefit of removing illegal medicines from the market. The details of those persons on whom Notices have been served are published on the VMD website.

In 2006/07 34 Seizure Notices were issued resulting in the seizure and destruction of a wide range of illegal veterinary medicines. Only one appeal against a Notice has been received.

The concept of the Seizure Notice has proved such a useful tool that other agencies are considering replicating it to prevent illegal marketing.

31. You can find out more about successful prosecutions via www.vmd.gov.uk under Publications, MAVIS, MAVIS on-line, Enforcement News

Help the Responsible Use of Medicines in Agriculture Alliance (RUMA)[32] prepare guidelines to encourage the responsible use of veterinary medicines.

The VMD helped RUMA prepare guidelines to encourage the responsible use of veterinary medicines throughout 2006/07. RUMA was established in November 1997 to promote the highest standards of food safety, animal health and animal welfare in British livestock farming. RUMA involves organisations representing every stage of the food chain, facilitating transparency and traceability in the process. RUMA aims to promote a co-ordinated and integrated approach to best practice in the use of medicines.

Work within the EU to develop arrangements for increasing product availability and implement changes that can be applied in the UK.

This is an EU wide issue where the UK cannot act unilaterally. We have taken an active role in EU discussions and focused our work on how we can apply the current rules to improve availability.

As part of the Heads of Medicines Agencies we have agreed an action plan that we will help to implement in future years.

Proposals for interactive SIC applications agreed with site to be available in 2007.

Continue to develop with industry an exemption scheme for products marketed for use in certain non-food species. Full implementation required by October 2007.

We have made good progress on the Small Animal Exemption Scheme[33] and aniticipate that full implementation will take place on 1 November 2007. Regular liaison with industry has ensured successful development of the Scheme and has also enabled us to deal swiftly with a number of challenging issues that have arisen. Inspections of manufacturing sites were undertaken by VMD inspectors. Application forms and procedural guidance notes were made available on the internet.

32. You can find out more about RUMA via www.ruma.org.uk
33. Further information about the Small Animal Exemption Scheme can be found at www.vmd.gov.uk under Industry Information

Objective 4

To recover the full cost of our operations from the industry and Defra and contribute to the Government's Better Regulation and efficiency agendas.

We achieved cost recovery for the Licensing and statutory residues surveillance businesses. For more information see pages 61-62.

Prepare for and seek re-accreditation under the IiP Standard by 30 June 2006.

The VMD was re-accredited as an IiP organisation in June. We exceeded the basic requirement of the Standard in relation to six of the ten indicators. We will implement the IiP assessor's recommendations as part of our 2007/08 Improvements Plan.

Commence consultation on future options for the VMD under Hampton[34] during 2006 and report on outcome by end December 2006.

The aim of Philip Hampton's Report to HM Treasury entitled *'Reducing Administrative Burdens: effective inspection and enforcement'* published in March 2005 was to identify ways in which the administrative burden of regulation on businesses could be reduced, while maintaining or improving regulatory outcomes. The VMD has been working to the key principles in this report for many years and we will continue to do so.

The Hampton Implementation Team has confirmed that a decision on the future of the VMD will not finally be taken until the first quarter of 2008, when the shape of the Defra delivery landscape is clear. The rationale behind this recognised that there are no immediate and obvious significant synergies between the VMD and any of the proposed Hampton Thematic Agencies.

The VMD's senior management team kept VMD staff fully informed of developments under the Hampton initiative. The transparency of information, the regularity of its availability to staff and the extent to which staff were consulted proved a model for communications in the VMD and has enhanced the trust that exists between staff and senior management within the Agency.

Maintain recruitment and selection processes in accordance with the IiP Recruitment and Selection Model.

We continued to operate our recruitment and selection processes in accordance with the IiP Recruitment and Selection model to ensure that the VMD recruited the best available talent, following formal accreditation in November 2005.

Review the VMD's systems and procedures for handling, responding to and monitoring requests to ensure that they comply with the obligations required by the Access to Information (ATI) legislation.

Disclosure of information is our default position. We want to be as open as possible. We believe that transparency is good for the regulatory process as even the best regulatory processes can benefit from broader input and scrutiny.

The VMD is committed to handling requests in accordance with the legislative requirements using the proportionate amount of resources. We reviewed our systems and procedures in the light of experience and found that they fitted the purpose for which we designed them.

The number of requests we receive is quite small compared to other agencies but we find that some of the requests are complex and resource intensive. We received 32 ATI requests in 2006/07. Two cases were subject to requests for internal review. One case from 2005/06 has been referred by the applicant to the Information Tribunal following a review by the Information Commissioner that endorsed the VMD's handling of the request and the exemptions used.

A second case from 2005/06 has been referred by the applicant to the Information Commissioner's Office (ICO) and we await contact from the ICO.

34. You can find out more about the Hampton Report at www.hm-treasury.gov.uk/budget/budget_05/other_documents/bud_bud05_hampton.cfm

Conduct a survey on the provision of Corporate Services by end October 2006.

With the loss of a key member of the Corporate Services team on jury service for nearly twelve months and then the retirement of the Director of Corporate Business in October, we have decided to take forward this initiative in 2007/08 as part of the VMD's Change Programme.

Provide project management support to the Licensing, Residues and Policy businesses on request.

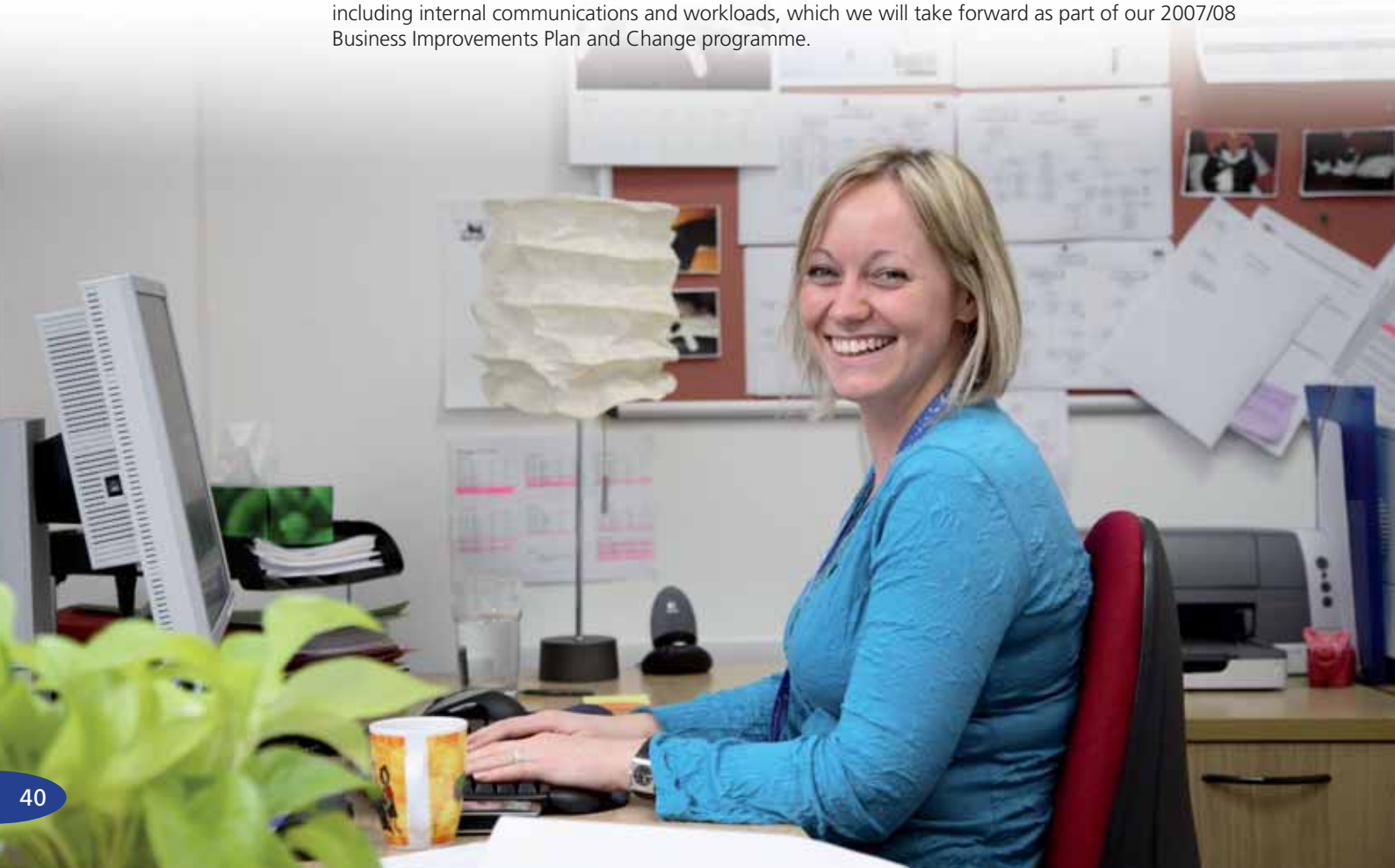
We continued to develop and apply project management skills in the VMD, although our main practitioner was called away on extended jury service. The Licensing team used project principles to complete its work to better understand and record its key processes; and programme and project principles underpinned the Change Programme.

Complete EFQM Benchmarking exercise by 31 March 2007.

We benchmarked our operation for the fifth time against the nine criteria in the European Foundation for Quality Management (EFQM)'s Business Excellence Model. With the Directors and CEO, volunteers from across the VMD formed a team led by an independent specialist in the EFQM model, to identify strengths and areas in which we could improve. It was clear that there is a lot of good practice across the VMD in particular in our Business Planning and Review Processes. We are strong in the support areas including Finance, TLU, IT and Core Services as well as being good at surveying (staff and customers) and involving people in our processes. We have however, identified a number of areas where we can make improvements often by building on existing good practice. We will take forward the findings as part of our 2007/08 Business Improvements Plan and Change Programme.

Conduct a VMD Staff Survey by 31 December 2006.

We commissioned an independent market research company to conduct a web based survey of staff in November. The results were presented to staff for the first time by the researchers at an open meeting in December. The positive headlines were that 81% of staff were satisfied working for the VMD and 72% would recommend it as a place to work. There were a number of areas for improvement identified including internal communications and workloads, which we will take forward as part of our 2007/08 Business Improvements Plan and Change programme.



Appendix A

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[A] 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;

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.

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

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.

Medical and Scientific Panel

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

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

Appraisal Panel on Human SARs

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

- evaluate all SARs to veterinary medicinal products in humans to:

  i) identify any trends and signals of emergent problems;

  ii) generate hypotheses as to possible causes of these trends.
- monitor the consequences of recommendations for changes in working practices or use;
- report its findings to the VPC; and
- produce an Annual Report of its findings.

Veterinary Residues Committee (VRC)

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

– the incidence and concentrations of residues of veterinary medicines[B] in samples collected under the VMD's surveillance programmes, with particular reference to food safety and observance of withdrawal periods for veterinary medicines[C];

– to assess and advise on the scope and operation of the VMD statutory surveillance programme within the requirements of European Community legislation;

– to formulate an annual non-statutory surveillance programme, advise on the scope and results of relevant FSA surveys and consider the need for further analytical surveys;

– to set up 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.

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 B

VMD Publications[35] and Statutory Instruments

Publications 2006/07

- Veterinary Medicines Guidance Notes 1-27 (updated versions).
- Is this medicine safe for my pet? Information leaflet.
- 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).
- Homeopathic Remedies – list of remedies eligible for grandfather rights under the Veterinary Medicines Regulations 2006.

Statutory Instruments coming into effect in 2006/07

The Veterinary Medicines Regulations 2006

SI 2006 No. 2407

Made: 5 September 2006

Coming into force: 1 October 2006

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

Appendix C

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 D

Audit & Risk Committee Annual Report 2006/07 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 is:

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
Chris Bean (Secretary)	– VMD, Director of Corporate Business – April to October
Heather Oliver	– VMD, Head of Legislation & Core Services – October to March

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
Rob Evans	– Defra Internal Audit

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

Meetings

The Committee met formally on four occasions in 2006/07. 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 aspects of the VMD's infrastructure for its operations, governance and audit; in particular:
   - on the Planning and Budgeting Accounting Cycle;
   - the overall process involved in Defra internal audit's work with the VMD;

- VMD's interface with Stakeholders, outlining who the Stakeholders are, how they interact with the VMD and the surveys/feedback processes used to develop the VMD's service; and the
- VMD's interface with Europe and how it determines the VMD's work and priorities; and the risks that follow from this.

The planned programme was fulfilled including ensuring positive emphasis on the importance of business continuity planning and monitoring it. The development of the VMD's Business Continuity Planning arrangements was welcomed and its progress emphasised.

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 2006/07

Statement of Accounting Officer's Responsibilities

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

The accounts are prepared on an accruals basis and must give a true and fair view of the Agency's state of affairs at the year end and of 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 Government Financial Reporting Manual and in particular to:

- observe the Accounts Direction issued by the 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;
- 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 Agency. 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 the Treasury and published in "Government Accounting".

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 Veterinary Medicines Directorate's (VMD) policies, aims and objectives, whilst safeguarding the public funds and departmental assets for which I am personally responsible, in accordance with the responsibilities assigned to me in Government Accounting. I am responsible for the day-to-day management of the VMD including the production of the Agency's resource accounts and resource accounting returns, and to the Secretary of State for the Department for Environment, Food and Rural Affairs (Defra) for the VMD's performance and operation. I am responsible for securing efficiency and the economical conduct of business and for the propriety and regularity of the public funds for which I am responsible.

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.

Internal controls in the VMD are directed towards managing risks threatening the satisfactory discharge of these responsibilities. This Statement on Internal Control describes the arrangements in place within the VMD for risk management.

2. The Purpose of the System of Internal Control

The system of internal control is designed to manage risk to a reasonable level rather than to eliminate all risk of failure to achieve policies, aims and objectives; it can therefore only provide reasonable and not absolute assurance of effectiveness. The system of internal control is based on an ongoing process designed to identify and prioritise the risks to the achievement of departmental policies, aims and objectives, to evaluate the likelihood of those risks being realised and the impact should they be realised, and to manage them efficiently, effectively and economically. The system of internal control reported on has been in place in the VMD throughout the year ended 31 March 2007 and up to the date of approval of the annual report and accounts, and accords with Treasury guidance.

3. Capacity to Handle Risk

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. Information on the VMD's risk management procedures, together with copies of the Risk Register has been made available to all staff via a dedicated site on the VMD's Intranet, although there has been some interruption to this during the year as described below.

This site sets out the procedures through which risk management is integrated into the VMD's operating practices and business planning. In particular, it defines the management structures and the ownership of risk, as well as the audit systems that are in place to check on our risk management systems. These measures are directed towards ensuring a common understanding of the terminology used in relation to the management of risk as well as describing the procedures that have been put in place to manage risk within the Agency. The site also provides cross-links to a more extensive site on the Defra Intranet.

The VMD's Intranet was subject to technical difficulties during the last financial year. This involved the loss of some functionality due to problems in the back-up restoration. As a result, there has been a temporary lapse in the availability of the information described in the above paragraph, although this information was available by other means. All the information is now available through the intranet as above.

The continued use within the Agency of project management processes has increased the awareness of staff towards the management of risk and encouraged the use of good practice.

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 linked with an active consideration of the possible options for managing each risk down to an acceptable level of residual exposure. The VMD's Risk Register, contains the top ten risks facing the Agency, it is reviewed monthly by myself and the VMD's Directors to consider the current status of those risks and to consider whether any new risks are emerging that would mitigate against the achievement of the Agency's objectives. A Change Summary document is completed to enable the date and reason for any changes made to a specific risk to be readily established.

Statement on Internal Control (continued)

In addition to the identification and management of the top ten risks, the VMD seeks to identify all other risks that could affect the successful outcome of its objectives. Risks are also managed within individual business areas of the Agency through the use of branch risk registers or business development plans. These are 'owned' by the respective Departmental Heads, and progress against them is reported at regular intervals to Directors. These measures provide me with assurance that an appropriate level of risk identification, evaluation and control is being maintained within the Agency.

Project and Programme Management

As part of the VMD's Business Planning round, action plans are formulated after the business plans are approved in order to successfully achieve those plans. Business cases, including option analysis, are constructed for separate decisions on plans utilising significant resources. Where investment decisions are required, and if the investments are significant enough to merit an OGC Gateway Review, these are conducted before the decision is made. Programmes required to achieve objectives are governed by a Programme Board, upon which a senior sponsor sits, and which appoints Project Managers for specific projects. Programme and Project Management training is given to any personnel in need of such and the appropriate skills and disciplines applied. Risk registers are maintained for each programme/project and the status of the risks within them are reported on at each programme/project Board meeting. This enables the level of risk to be identified at the planning stage of the programme/project and reviewed throughout its life, and plays an important role in ensuring that its milestones are met and the desired outcomes delivered.

Strategy and Planning

The VMD produces a three year business and financial plan. This sets out the VMD's vision and how the VMD works to deliver Defra objectives and details the VMD's key performance targets. The first year of the financial plans is the budget, which sets out the resources to be provided to achieve the immediate objectives. The plan is considered by Defra's Regulatory Agencies Strategy Board (RASB) and signed off at Ministerial level following RASB advice.

The Directors and senior management attend meetings and away-days during the course of 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.

The VMD is developing a communications policy.

Governance Structures and Processes

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

The CEO is a member of the Regulatory Agencies Strategy Board (RASB) and the Animal Health and Welfare Directorate General (AHWDG) Heads of Delivery Partners Group (HDPG). The RASB is chaired by one of its two non-executive members and is comprised of senior officials from Defra, the devolved administrations and the FSA and is responsible for advising Ministers on matters concerning the Agency. The AHWDG HDPG is the forum through which the AHW Director General discusses AHW strategy.

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 both its intranet and internet sites. The VMD publishes its veterinary medicines' information publication "MAVIS" quarterly on-line and in hard copy.

Statement on Internal Control (continued)

The VMD employs the services of Defra Internal Audit Division for internal audit and internal compliance issues. The National Audit Office is responsible for the external audit of the VMD's published Annual Report and Accounts, which it subcontracts to PKF (UK) LLP Chartered Accountants.

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

Management of Change

A programme to examine the need for change at the VMD in the areas of Europe, quality and structure is in progress. This is being formally overseen by a Programme Board comprised of the Directors and the VMD Accountant. The individual programme strands are led by project managers reporting to a Programme Manager who reports in turn directly to the CEO. Each of the strands of the programme is being championed by a Director/CEO.

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, which provides an environment for effective team and cross-team working, communication and buy-in to change.

Performance Management

The VMD staff are all engaged during the development of the business plan and ultimately individuals are expected to be able to relate the objectives in their Personal Development Plan with the overall targets of the VMD.

Apart from the quarterly Management Board meetings, at least monthly meetings are held by all business groups to monitor performance against defined timelines or other targets and budgets. A series of reports are generated from operational and financial databases and discussions are held to identify specific licensing applications, test results, issues or variances requiring attention. The principles of risk evaluation are embedded and discussed under the section covering risk.

More specifically, a Finance and Operational Performance Report is produced each month and circulated to the Directors and senior management. The summary monthly licensing performance reports are checked and signed off by the Director of Licensing. Licensing performance is published in MAVIS on a quarterly basis.

A formal Customer Survey is conducted every two years by an independent body. In conjunction with this a programme of customer care visits take place; the discussions are recorded and resulting actions communicated to the individual customer and in general terms to the industry.

5. Review of effectiveness

Description of change	Internal controls linked to the change
Introduction of the small animal exemption scheme.	• A formal project, involving all relevant people from across the VMD, has underpinned the introduction of this scheme; • A series of stakeholder meetings have been held and the scale in terms of the products and sites involved was established; • Inspections of the sites is monitored on a monthly basis (via Licensing Business Focus Group (LBFG)).
Introduction of the blood bank scheme for companion animals.	• The VPC has been informed of the new scheme; • An article in MAVIS explained the operation of this scheme; • Inspections of the sites is monitored on a monthly basis (via LBFG); • The operation of blood banks in the UK for human blood has been taken into account in defining the scheme.
Introduction of type II compound variations.	• The guidance note (VMGN) was updated to include this new variation; • The Licensing Management System (LMS) was updated to identify and monitor such applications.

Statement on Internal Control (continued)

Description of change	Internal controls linked to the change
Introduction of pharmacovigilance inspections.	• A telephone survey of all UK MA holders was carried out to inform them of our intention to audit their pharmacovigilance capabilities and to identify areas to be targeted.
Updating and alignment of database systems to allow exchange of information on authorisations, inspections and pharmacovigilance with the EMEA and the EU.	• Data mapping exercises have been performed and LMS and the SARSS database have been adapted in relevant areas.
Introduction of the fees menu for new applications so that the fees are more closely aligned to the complexity of the application and the time that will be required to assess the application.	• In the years leading up to the introduction of the system, the existing and proposed menu system were run side by side to provide assurance that the new scheme would result in the correct level of income based on the volume of work involved; • The fees menu is completed by a validation assessor and the validation Committee checks and confirms the correct completion of the menu and hence the fee.
Improved backup procedures have been implemented so that information held on our file servers is mirrored and can be restored using failover.	• Nightly backups are also taken locally as well as to the Snap Server or backup drives; • Backup tapes are taken off site each Monday and one set a month held for three years; • Both failover and backup restore functions are tested routinely to ensure our data and web sites can be restored.
Introduction of a new information systems standard based on .Net to avoid systems becoming obsolete.	• Rapid Application Development procedures followed; • Two small new systems have been developed first to trial the technology in a live environment; • More rigour has been introduced for both system and user testing; • Existing systems will be migrated to the new standard in order of priority as agreed by the IT Steering Committee (ITSC).

6. Improvements to internal control introduced over the last year

Description of relative weakness	Internal control improvement
Intranet Site was inoperative for a long period of time (noted in last year's Statement on Internal Control (SIC)).	• This was a new untested application, and backup restoration was problematical. A test environment has now been put in place to trial software before installation, and to make changes to information documentation. (See also last two items on previous table.)
No other significant internal control problems have been identified during the course of the year or since.	

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 department 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.

Statement on Internal Control (continued)

Regular Review:

At each of its meetings the VMD's Audit & Risk Committee is given the opportunity to comment on the Risk Register. The Committee has also commenced an ongoing review of the VMD's business processes and this is providing me with further reassurance on the operation, governance and audit of the Agency's business functions. In addition, their advice and contributions continue to be valuable in assisting the Accounting Officer and senior staff in the development of risk management and control strategies. The VMD's Management Board receives reports from the Chairman of the Audit & Risk Committee at each of its meetings. The VMD has an Internal Audit Service provided by Defra's Internal Audit Division under a Service Level Agreement, which operates under Government Internal Audit Standards. It provides regular reports that include the Head of Internal Audit's independent opinion on the adequacy and effectiveness of the Agency's systems on internal control together with recommendations for improvements. In relation to the management of risk within the VMD I recognise however, that the VMD needs to continue to build on the procedures and processes that it already has in place.

Steve Dean
Chief Executive
24 May 2007

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 2007 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 Cashflow 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, certain information given in the Annual Report, which comprises the sections entitled About Us, Preparation and Audit of the Accounts, Management Commentary, the unaudited parts of the Remuneration Report, Meeting Our Objectives and the Appendices, 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. 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 2007, and of the surplus, total recognised gains and losses and cashflows for the year then ended;
- the financial statements and the part of the Remuneration Report to be audited have been properly prepared in accordance with HM Treasury directions issued under the Government Resources and Accounts Act 2000; and
- The information given within the Annual Report, which comprises the sections entitled About Us, Preparation and Audit of the Accounts, Management Commentary, the unaudited parts of the Remuneration Report, Meeting Our Objectives and the Appendices, is consistent with the financial statements.

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

Audit 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.

John Bourn
Comptroller and Auditor General
National Audit Office
31 May 2007

157-197 Buckingham Palace Road
Victoria
London SW1W 9SP

Income and expenditure account for the year ended 31 March 2007

Notes		2007		2006	
		£'000	**£'000**	£'000	£'000
	Income				
2	Income from activities	**13,970**		13,184	
3	Less – Direct subcontracting costs	**(4,564)**		(4,434)	
	Net Income		**9,406**		8,750
	Operating Unit expenditure				
4	Staff costs	**(6,343)**		(5,667)	
8 & 9	Depreciation and revaluation losses	**(380)**		(365)	
5	Other operating costs	**(1,431)**		(1,448)	
	VMD operating costs for year		**(8,154)**		(7,480)
	Operating result before departmental charges and other costs		**1,252**		1,270
	Departmental charges and other costs				
	Defra service recharges	**(534)**		(565)	
	Independent Expert Committees	**(134)**		(166)	
			(668)		(731)
	Operating surplus before interest on capital		**584**		539
7	Interest on capital		**(195)**		(196)
	Operating surplus for the year		**389**		343
	Operating surplus brought forward		**731**		388
	Operating surplus for the year		**389**		343
14	**Operating surplus carried forward**		**1,120**		731

Statement of total recognised gains and losses

		£'000	£'000
	Operating surplus for the year	**389**	343
13	Fixed asset revaluations not reported in the operating surplus	**480**	235
	Total gains recognised since the last annual report	**869**	578

All activities arise from continuing operations.
The notes on pages 59 to 70 form part of these accounts.

Balance Sheet as at 31 March 2007

Notes		2007		2006	
		£'000	**£'000**	£'000	£'000
	Fixed assets				
8	Intangible assets	**121**		148	
9	Tangible assets	**5,635**		5,301	
			5,756		5,449
	Current assets				
10	Debtors and prepayments	**2,464**		2,600	
11	Cash at bank	**4,366**		3,611	
		6,830		6,211	
	Creditors: amounts falling due within one year				
12	Creditors and deferred income	**(2,058)**		(1,804)	
	Net current assets		**4,772**		4,407
	Total assets less current liabilities		**10,528**		9,856
	Financed by				
13	Revaluation Reserve		**2,285**		1,805
14	General fund		**8,243**		8,051
			10,528		9,856

S P Dean
Chief Executive and Agency Accounting Officer
24 May 2007

The notes on pages 59 to 70 form part of these accounts.

Cash flow statement for the year ended 31 March 2007

Notes		**2007**	2006
		£'000	£'000
19(i)	**Net cash inflow from operating activities**	**1,859**	1,054
	Capital expenditure and financial investment:		
	– Payments to acquire intangible fixed assets	**(55)**	(68)
	– Payments to acquire tangible fixed assets	**(99)**	(261)
	Cash inflow before management of liquid resources and financing	**1,705**	725
	Financing:		
	Repayment of Defra operational funding	**(950)**	(1,023)
19 (ii)	**Increase/(decrease) in cash in the year**	**755**	(298)

The notes on pages 59 to 70 form part of these accounts.

Notes to the accounts

1. Statement of accounting policies

The financial statements have been prepared in accordance with the 2006-07 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:

	2007	2006
	£'000	£'000
Licensing	**6,263**	5,387
Residues – Statutory scheme	**3,844**	3,874
– Non-statutory scheme	**905**	978
Policy	**2,541**	2,831
Animal Medicines Inspectorate	**417**	114
	13,970	13,184

(b) Key Performance Target

The VMD had been set one key financial performance target in 2006-07: to achieve cost recovery for the VMD as a whole.

Results:

An overall cost recovery of 102.9% was achieved. Cost recovery performance within each of the VMD principal business areas was as follows:

Licensing	**2007** **£'000**	2006 £'000
Income	**6,263**	5,387
Staff costs	**(4,101)**	(3,449)
Depreciation and revaluation losses	**(246)**	(222)
Subcontracting costs	**(280)**	(150)
Other costs	**(1,251)**	(1,146)
Total income less costs (cost recovery) = 106.5%	**385**	420

Residues – statutory scheme	**2007** **£'000**	2006 £'000
Income	**3,844**	3,874
Staff costs	**(370)**	(366)
Depreciation and revaluation losses	**(22)**	(24)
Subcontracting costs – testing and collection	**(3,429)**	(3,430)
Other costs	**(174)**	(176)
Total income less costs (cost recovery) = 96.2%	**(151)**	(122)

Residues – non-statutory scheme:	**2007** **£'000**	2006 £'000
Income	**905**	978
Staff costs	**(65)**	(82)
Depreciation and revaluation losses	**(4)**	(5)
Subcontracting costs – testing and collection	**(800)**	(839)
Other costs	**(34)**	(41)
Total income less costs (cost recovery) = 100.2%	**2**	11
Total residues result (cost recovery) = 97.0%	**(149)**	(111)

Notes to the accounts (continued)

Policy	**2007 £'000**	2006 £'000
Income	**2,541**	2,831
Staff costs	**(1,483)**	(1,674)
Depreciation and revaluation losses	**(89)**	(108)
Other costs	**(752)**	(968)
Total income less costs (cost recovery) = 109.3%	**217**	81

Animal Medicines Inspectorate	**2007 £'000**	2006 £'000
Income	**417**	114
Staff costs	**(324)**	(96)
Depreciation and revaluation losses	**(19)**	(6)
Subcontracting costs – testing and collection	**(55)**	(15)
Other costs	**(83)**	(44)
Total income less costs (cost recovery) = 86.7%	**(64)**	(47)

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

Notes to the accounts (continued)

Results: (continued)

The VMD's AMI business commenced on 1 January 2006 when the function and staff were transferred from the RPSGB. The results shown for the AMI in 2005-06 therefore represent three months' activity. AMI income and expenditure relate to the approval of:

- premises for the retail supply of veterinary medicinal products by "suitably qualified persons"; and
- the manufacture and distribution of feedingstuffs.

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 2006-07 show that staff time was utilised as follows:

	2007	2006
	%	%
Licensing	**65**	61
Policy	**23**	30
Residues – statutory scheme	**6**	6
– non-statutory scheme	**1**	1
Animal Medicines Inspectorate (from 1 January 2006)	**5**	2
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 2006-07, 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 £11,000 in 2006-07 (2005-06: £10,000).

3 Direct subcontracting costs

Amounts charged in the Income & Expenditure Account for subcontractors' costs:	**2007**	2006
	£'000	£'000
Costs of licensing and inspection activities payable to the Medicines and Healthcare products Regulatory Agency	**(280)**	(150)
Costs of non-statutory residues surveillance, including sample collections, and analysis work performed by the Central Science Laboratory	**(800)**	(839)
Costs of statutory residues surveillance, including sample collections, and analysis work performed by LGC Limited	**(3,429)**	(3,430)
Costs of Animal Medicines Inspectorate sample analysis	**(55)**	(15)
	(4,564)	(4,434)

Notes to the accounts (continued)

4 Staff costs

(a) Staff costs consist of:

	2007			2006
	Permanently employed staff	**Others**	**Total**	Total
	£'000	**£'000**	**£'000**	£'000
Wages and salaries	**(4,565)**	**(456)**	**(5,021)**	(4,483)
Social security costs	**(394)**	**–**	**(394)**	(362)
Other pension costs	**(928)**	**–**	**(928)**	(822)
Sub-total as reported in income and expenditure account	**(5,887)**	**(456)**	**(6,343)**	(5,667)
Less recoveries in respect of outward secondments	**–**	**–**	**–**	4
Total net costs	**(5,887)**	**(456)**	**(6,343)**	(5,663)

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 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 2003 and details can be found in the resource accounts of the Cabinet Office: Civil Superannuation (www.civilservice-pensions.gov.uk).

The Agency Chief Executive's total remuneration including non-pensionable performance bonus in 2006-07 was £93,928 (2005-06: £88,848).

For 2006-07, employer contributions of £915,000 were payable to the PCSPS (2005-06: £812,000) at one of four rates in the range 17.1% to 25.5% of pensionable pay, based on salary bands (the rates in 2005-06 were between 16.2% and 24.6%). The scheme's actuary reviews employer contributions every four years following a full scheme valuation. From 2007-08, the salary bands will be revised but the rates will remain the same. The contribution rates are set to meet the cost of the benefits accruing during 2006-07 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 with an employer contribution. Employer's contributions of £13,000 (2005-06: £10,000) were paid to one or more of a panel of three appointed stakeholder pension providers. Employer contributions are age-related and range from 3 to 12.5 per cent of pensionable pay. Employers also match employee contributions up to 3% of pensionable pay. No employer contributions (2005-06: £nil) were payable to 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 (2005-06: £nil) and contributions prepaid at that date were £nil (2005-06: £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:

	2007			2006		
	Total	**Permanently employed staff**	**Others**	Total	Permanently employed staff	Others
Scientific	**40**	**39**	**1**	37	36	1
Administrative	**112**	**97**	**15**	105	94	11
	152	**136**	**16**	142	130	12

"Others" shown above comprises agency staff.

Notes to the accounts (continued)

5 Other operating costs

These are made up as follows:

	2007	2006
	£'000	£'000
Travel and subsistence	**(142)**	(120)
Training	**(157)**	(110)
Provision for bad debts	**(151)**	(55)
IT systems maintenance costs	**(228)**	(235)
Communications	**(92)**	(68)
Audit fees (notional)	**(24)**	(23)
Accommodation utility charges	**(101)**	(97)
Operating leases	**(61)**	(23)
Other costs	**(475)**	(717)
	(1,431)	(1,448)

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 do not form part of the VMD cost recovery targets, are not reported in the VMD's Income & Expenditure Account, and are not borne by industry.

The work is currently commissioned with several providers and amounts to £2.0m (2005-06: £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% (2005-06: 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 2006	591
Additions	55
Disposals	(1)
At 31 March 2007	645
Amortisation:	
At 1 April 2006	(443)
Provided during year	(81)
Disposals	–
At 31 March 2007	(524)
Net Book Value:	
At 31 March 2007	**121**
At 31 March 2006	148

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 2006	5,066	916	54	247	6,283
Additions	1	123	26	2	152
Disposals	–	(61)	(14)	(2)	(77)
Revaluation	499	(60)	–	4	443
At 31 March 2007	5,566	918	66	251	6,801
Depreciation:					
At 1 April 2006	(118)	(664)	(32)	(168)	(982)
Provided during year	(124)	(124)	(6)	(23)	(277)
Disposals	–	59	9	–	68
Revaluation	(19)	47	–	(3)	25
At 31 March 2007	(261)	(682)	(29)	(194)	(1,166)
Net Book Value:					
At 31 March 2007	**5,305**	**236**	**37**	**57**	**5,635**
At 31 March 2006	4,948	252	22	79	5,301

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

The depreciation and revaluation losses figure of £380,000 shown in the Income & Expenditure Account includes £13,000 indexation losses (2005-06: £8,000) and £9,000 losses on disposal (2005-06: £3,000).

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:	**2007**	2006
	£'000	£'000
Trade debtors – Licensing	**327**	186
– Residues	**144**	132
Balances with other central government bodies	**714**	961
Other debtors	**5**	3
VAT recoverable	**154**	188
Prepayments and accrued income	**1,120**	1,130
	2,464	2,600

Debtors are shown net of a provision of £609,000 (2005-06: £459,000) for bad and doubtful debts. Included in debtors there are no balances with local authorities, NHS Trusts, public corporations or trading funds (2005-06: £nil).

Balances with other central government bodies in 2006-07 includes £678,000 with Defra and its agencies.

The 2005-06 "Trade debors" figures included accrued income of £1,056,000. In 2006-07 accrued income is included in "Prepayments and accrued income". The 2005-06 figures have therefore been restated for comparability.

Notes to the accounts (continued)

11 Cash at bank

	2007	2006
	£'000	£'000
At Office of HM Paymaster General	**4,304**	3,570
At commercial banks and cash in hand	**62**	41
	4,366	3,611

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

	2007	2006
Amounts falling due within one year:	**£'000**	£'000
Trade creditors	**(354)**	(472)
Balances with other central government bodies	**(348)**	(268)
Balances with public corporations and trading funds	**(154)**	(81)
Other taxation and social security	**(154)**	(166)
Accruals and deferred income	**(1,048)**	(817)
	(2,058)	(1,804)

Included in creditors there are no balances with local authorities or NHS Trusts (2005-06: £nil).
Balances with other central government bodies in 2006-07 includes £305,000 owing to Defra and its agencies.

The 2005-06 "Trade creditors" figure included accruals of £337,000. In 2006-07 all accruals are included in "Accruals and deferred income". The 2005-06 figures have therefore been restated for comparability.

13 Revaluation reserve

	2007	2006
	£'000	£'000
At 1 April 2006	**1,805**	1,570
Arising on revaluation during the year:		
– on revaluation of land and buildings	**–**	–
– on indexation	**480**	235
	480	235
At 31 March 2007	**2,285**	1,805

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 2006	7,320	731	8,051
Non-cash charges:			
Notional Interest cost	195	–	195
Audit Fee	24	–	24
Defra Service Charges	534	–	534
Repayment of Defra Operational Funding	(950)	–	(950)
Surplus for the year	–	389	389
Balance at 31 March 2007	7,123	1,120	8,243

15 Capital commitments

	2007	2006
	£'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.

	2007	2006
Obligations under operating leases comprise:	£'000	£'000
Land and buildings		
Expiry within 1 year	6	–
Contract Hire cars		
Expiry after 1 year but not more than 5 years	20	20
Other		
Expiry after more than 5 years	12	–
	38	20

Notes to the accounts (continued)

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.

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

	2007	2006
	£'000	£'000
Operating surplus for the year	**389**	343
Depreciation and revaluation losses	**380**	365
Defra service charges	**534**	565
Other notional charges added back	**219**	219
Adjustment for (increase)/decrease in fixed asset accruals	**(53)**	27
Decrease/(increase) in debtors and prepayments	**136**	(1,243)
Increase in creditors	**254**	778
Net cash inflow from operating activities	**1,859**	1,054

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

	2007	2006
	£'000	£'000
Increase/(decrease) in cash in the year	**755**	(298)
Cash at bank at 1 April 2006	**3,611**	3,909
Cash at bank at 31 March 2007 (Note 11)	**4,366**	3,611

Notes to the accounts (continued)

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. This is the date on which the certified accounts are despatched by the VMD's management to the Secretary of State for Defra.

The authorised date for issue is 15 June 2007.

Glossary

ACMSF	Advisory Committee on the Microbiological Safety of Food
AH	Animal Health
AMI	Animal Medicines Inspectorate
ATI	Access to Information
CAP	Common Agricultural Policy
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
DST	Delivery Strategy Team
EA	Environment Agency
EC	European Commission
EFQM	European Foundation for Quality Management
EMEA	The European Agency for the Evaluation of Medicinal Products
EU	European Union
FReM	Financial Reporting Manual
FSA	Food Standards Agency
GMP	Good Manufacturing Practice
HDPG	Heads of Delivery Partners Group
HMA	Heads of Medicines Agencies
ICO	Information Commissioner's Office
IiP	Investors in People
IT	Information Technology
ITSC	Information Technology Steering Committee
IVMPs	Immunological Veterinary Medicinal Products
JAP	Joint Audit Programme
LBFG	Licensing Business Focus Group
LMS	Licensing Management System
MA	Marketing Authorisation
MAFF	Ministry of Agriculture, Fisheries and Food
MHRA	Medicines and Healthcare products Regulatory Authority
MHS	Meat Hygiene Service
NAWAD	National Assembly for Wales Agriculture Department
NFA-VPS	Non-Food Animal – Veterinary, Pharmacist, or Merchant
NFU	National Farmers Union
NPTC	National Proficiency Test Council
NSAID	Non-Steroidal Anti-Inflammatory Drug
NSS	National Surveillance Scheme
OCABR	Official Competent Authority Batch Release
OFFC	Official Feed and Food Controls
PCSPS	Principal Civil Service Pension Scheme
POM-VPS	Prescription Only Medicine – Veterinary, Pharmacist or Merchant
PSD	Pesticides Safety Directorate
R&D	Research and Development
RASB	Regulatory Agencies Strategy Board
RMS	Reference Member State
RPSGB	Royal Pharmaceutical Society of Great Britain
RUMA	Responsible Use of Medicines in Agriculture
SAR	Suspected Adverse Reaction
SARSS	Suspected Adverse Reaction Surveillance Scheme
SIC	Special Import Certificates
SP	Synthetic Pyrethroid
STC	Special Treatment Certificate
SVS	State Veterinary Service
TLU	Training and Liaison Unit
UKPARs	United Kingdom Public Assessment Reports
VLA	Veterinary Laboratories Agency
VMD	Veterinary Medicines Directorate
VMR	Veterinary Medicines Regulations
VPC	Veterinary Products Committee
VRC	Veterinary Residues Committee
WEEE	Waste Electrical and Electronic Equipment

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