

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 CVMP²⁰.

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 RPSGB²². The results shown for the AMI in the previous year (2005/06) therefore represent three months' activity.

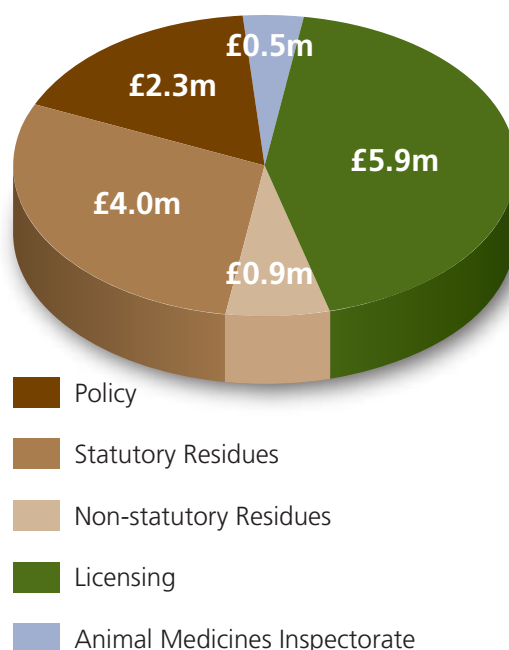
The VMD is funded by Defra and the position is shown in the "Financed by" section of the Balance Sheet by means of the General Fund. Within this Fund there are two distinct parts:

- 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.
- 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