Safeguarding public health

MHRA

06/07

Annual report and accounts 2006/07

Medicines and Healthcare products Regulatory Agency

HC 677

MHRA at a glance

Mission

The MHRA's mission is to enhance and safeguard the health of the public by ensuring that medicines and medical devices work, and are acceptably safe.

Values

In pursuing its mission the Agency will strive to act with:

- integrity;
- openness;
- courtesy;
- responsiveness;
- timeliness;
- professionalism;
- impartiality; and
- consistency

Aims

The Agency's aims are:

- Protecting public health through regulation, with acceptable risk:benefit profiles for medicines and devices.
- Promoting public health by helping people who use these products to understand their risks and benefits.
- Improving public health by encouraging and facilitating developments in products that will benefit people.

Objectives

The Agency's key objectives are to:

- maintain rigorous authorisation and inspection programmes;
- maintain and develop pro-active surveillance and enforcement programmes;
- communicate authoritative and reliable information and advice to improve public and professional awareness;
- engage with and influence other Government bodies and European and worldwide regulators concerned with medicines or medical devices;
- support innovation and product development, offering constructive and impartial advice to scientific communities and health services;
- minimise the cost of regulation so far as is compatible with our public health role; and
- run a successful business with a skilled and equipped workforce dedicated to the Agency's aims.

Activities

The Agency's main activities are:

- assessing the safety, quality and efficacy of medicines, and authorising their sale or supply in the UK for human use;
- overseeing the UK Notified Bodies that audit medical device manufacturers;
- operating post-marketing surveillance and other systems for reporting, investigating and monitoring adverse reactions to medicines and adverse incidents involving medical devices and taking any necessary action to safeguard public health, for example through safety warnings, removing or restricting the availability of products or improving designs;
- operating a proactive compliance programme for medical devices;
- operating a quality surveillance system to sample and test medicines and to address quality defects, monitoring the safety and quality of imported unlicensed medicines and investigating Internet sales and potential counterfeiting of medicines;
- regulating clinical trials of medicines and medical devices;
- monitoring and ensuring compliance with statutory obligations relating to medicines and medical devices through inspection, taking enforcement action where necessary;
- promoting good practice in the safe use of medicines and medical devices;
- managing the General Practice Research Database (GPRD) and the British Pharmacopoeia (BP) and contributing to the development of performance standards for medical devices;
- offering scientific, technical and regulatory advice on medicines and medical devices; and
- providing the public and professions with authoritative information to enable informed dialogue on treatment choices

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MHRA

06/07

Accounts, prepared pursuant to section 4(6) of the Government Trading Funds Act 1973 as amended by the Government Trading Act 1990, of the MHRA Trading Fund as at 31 March 2007 together with the Report of the Comptroller and Auditor General thereon

Presented pursuant to Act 1973, c.63, s.4(6)

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Medicines and Healthcare products Regulatory Agency

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Chairman's Foreword

Professor
Sir Alasdair Breckenridge
Chairman

Welcome to the Fourth Annual Report of the activities of the MHRA.

This year we have changed our approach to the Annual Report. We have given readers a more selective overview of the events which have had most impact on the Agency, and have highlighted the more strategic developments that have influenced the way we operate as an Agency or the regulatory system itself. The Report illustrates clearly how we have interacted successfully with a range of stakeholders in order to deliver operational and policy objectives across a very broad front. It also examines the changing landscape in medicines and devices regulation.

Science should lead regulation. This has characterised the approach we have taken to a number of key issues and our interactions with a number of different stakeholders. The best illustration of this is the process put in place by the government to enquire fully into the causes of the adverse effects associated with the TGN1412 clinical trial incident and the potential impact on the clinical trial regime. The changes to the systems for dealing with the authorisation of novel high risk treatments such as that at the centre of this incident have involved negotiations at European level. We have worked with other Member States in a number of fora, and together we have made a variety of changes to our own procedures and to those of others involved in clinical trials in industry, academia and in the NHS. This is still important work in progress.

The Agency has been very active in the European regulatory legislative programme involving many discussions with other European stakeholders. The position that the UK adopted on the Regulation on medicines for paediatric use was based on meeting the clear clinical needs of children and young people. I was particularly pleased to see the adoption of the EU legislation as this was a priority during the UK presidency. Allied with the range of other initiatives (such as the launch of a children's BNF) and strengthening research in paediatric medicines, this is a clear advance in provision of medicines for this vulnerable group.

Likewise, our position in the negotiations on the proposals on legislation for Advanced Therapies (such as tissue engineering) and the revision of the Medical Devices Directives, are founded on strong public health protection principles. New technologies offer the potential for significant medical advances and patient benefits (as was identified by Sir Chris O'Donnell in his MHRA lecture in January 2007) but they need to be regulated proportionately and according to the risks associated with novel treatments. To ensure that we represent the broader national interest in these European negotiations, we work closely with industry and other stakeholders to ensure that their positions are reflected.

The Agency has also recognised the importance of engaging with patients and lay people. The survey work done to establish what patients (and healthcare professionals) understand about the risks and benefits associated with medicines and medical devices and to seek views on how these products are regulated, is a key building block in this strand of our work. We will come back to it in the forthcoming year.

Finally, I would particularly like to thank my colleagues on both the Agency Board and the Executive Board for the valuable role that they continue to play guiding the strategic direction of the Agency and ensuring that we fulfil the tasks set for us by Ministers.

Professor Sir
Alasdair Breckenridge
Chairman

Chief Executive Officer's report

Professor Kent Woods
Chief Executive Officer

I would like to add my own words of welcome to those of the Chairman and, as he has done, take the opportunity to reflect on the Agency's business in the past year. It has been another busy year and one that has been particularly challenging on a number of fronts.

I should say at the outset that the IT change programme which began with the roll out of the first Sentinel Case Folder for Clinical Trials in August 2004 and ended with the roll out of the Pharmacovigilance Case Folder in June 2006, and the accompanying reorganisation of the medicines divisions (Business Realignment) have had a much greater impact than predicted. This has led to an unfortunate deterioration in service for industry in the Product Licensing field and problems with some aspects of the processing of adverse drug reactions. My Executive Board colleagues and I have been closely involved in resolving these issues and the situation at year end is much better than it was in the middle of the year.

This is demonstrated in several different ways – for example, the improvement in assessment times for abridged new marketing authorisations (MAs) and the rapid move to electronic communication with industry in various aspects of the processing of adverse drug reactions. The commitment and cooperative effort of staff across the Agency has been a key factor in the recovery to date. There has been close cooperation with key trade associations and on-going dialogue about the current levels of performance and what steps might be taken on both sides to improve performance. These steps range from the publication of performance metrics, to closer cooperation on the use of eCTD for the submission of applications and supporting documents. This will continue to receive high priority during the coming year, ensuring that we can deliver the benefits originally identified by the change programme.

The operational issues described above have not caused the Agency to neglect its other stakeholders or its wider remit in the protection of public health. The Chairman has already referred to the on-going work dealing with the strategic and operational changes needing to be implemented across Europe following the publication of Professor Sir Gordon Duff's report on phase one clinical trials following the TGN1412 trial. Later sections of this report mention some of the safety issues that have been dealt with and I would not want to single any one out but I would like to emphasise that day-to-day monitoring of products is key to our patient safety role and it is a field where we are a leader in Europe – in both medicines and devices. Similarly the General Practice Research Database continues to make its mark as one of the most accessible and useful epidemiological databases and is used increasingly by regulators and industry to conduct drug safety studies.

The regulator has a key role to play in the innovation agenda, ensuring patients have safe access to cutting edge therapies in a timely manner and I was pleased to co-chair the Regulatory Working Group of the Ministerial Industry Strategy Group's Long-Term Leadership Strategy (LTLS), exploring ways to achieve and sustain a UK and European regulatory environment that will support the innovative pharmaceutical industry in the UK and meet the needs of government, patients and prescribers. The publication of the LTLS Report in January 2007 was a milestone but there still remains a complex work programme to deliver. The same can be said of the Cooksey Review into Funding for Health Research and the final output from the Health Industries Task Force (HITF) Strategic Implementation Group, which published its report *Innovation for Health* in February 2007.

All of this goes to show that regulation does not stand still and I was pleased that the Agency embraced the better regulation agenda this year, publishing the report *Better Regulation of Over the Counter Medicines* (BROMI) in May 2006 and contributing to the Department of Health's Simplification Plan. The benefits to industry are obvious but the benefits for the Agency and for the public come from being able to focus our efforts and expertise on those areas of regulation where the benefits for public health are greatest.

I would like to close by remarking on the commitment shown by members of staff across the Agency to its work and its key goal, the protection of public health through the regulation of medicines and devices. The staff survey conducted in July 2006 highlighted that this was one of the key strengths of the Agency and I would like to thank all members of staff for their continuing contribution and cooperation.

Professor Kent Woods
Chief Executive Officer

The Year in Review

This is a brief overview of a busy year's activity. The issues here have been identified because of the impact that they have had on patients, on healthcare delivery, the industries we regulate or the way that we operate as an Agency.

TGN1412

Although the TGN 1412 clinical trial (which resulted in serious injuries to six trial participants) happened in March 2006 and is thus outside the scope of this Annual Report, much of the year was spent in dealing with issues which arose from it. As well as dealing with a very high level of public and media attention following the incident, all parts of the Agency devoted considerable time and resource to investigating the events more thoroughly, inspecting the manufacture of the investigational medicinal product used, the conduct of the preclinical studies and the clinical trial and reviewing our own procedures.

In particular, at the request of the Department of Health, the Agency provided the secretariat to an independent Expert Scientific Group (ESG) charged with examining the incident and advising on the assessment of such trials in the future. The ESG was chaired by Professor Gordon Duff, chairman of the Commission on Human Medicines. After consulting on an interim report during the summer, the final report was published in December 2006. The ESG was satisfied that the adverse incidents that occurred were not as a result of any errors made in the manufacture of TGN1412, its formulation, dilution or administration to trial participants. The ESG did, however, make a number of recommendations concerning the approval of such novel substances and the need for those to be reflected in revised European guidelines, the training of the professional staff involved in clinical trials, and better information sharing. It also proposed an accreditation scheme for clinical trial units involved in Phase 1 clinical trials. Although not all of the Recommendations of the Report were directed at the MHRA, the Agency has been actively implementing those that were, and promoting the take up of those with wider implications during the course of the year.

Medicines safety issues

There were other medicines safety issues arising during the course of the year involving a number of widely used products on which action had to be taken. The MHRA worked hard to ensure that safety messages were properly understood by health care professionals and by patients and also played its role in the European drug safety process. For example, the MHRA issued a letter to health professionals in October 2006 to inform them of the outcome of the Europe-wide review of the cardiovascular safety of Non-Steroidal Anti-Inflammatory Drugs, following consideration by the Committee on Medicinal Products for Human Use (CHMP) of the latest available data on this issue. The Agency also took further action to limit the use of selective serotonin re-uptake inhibitors (SSRIs) in young adults following new information on the risk:benefit of the products being released by the FDA.

Device safety issues

The Agency issued 80 Medical Device Alerts and eight "One Liners", both of which are designed to give safety information to users of devices in healthcare establishments and social care settings. Action taken to limit the spread of infections such as hepatitis by the misuse of single-use lancing devices is a good example of where the Agency has to interact with a variety of stakeholders, including manufacturers, the Health Protection Agency and the Commission for Social Care Inspection, as well as local social care providers, to ensure that devices are used safely. The Agency has also moved quickly to investigate the potential of metal-on-metal toxicity of hip replacement joints, examining the risks for patients associated with metal debris and has made recommendations for future management and research. An Expert Scientific group has also been established to consider these issues further.

Criminal activity

Pharmaceutical crime continued to be a major issue during the course of the year. In the past, this has centred largely on the illegal supply of lifestyle medicines, either over the internet or in person, but this year has seen small scale penetration of the legal supply chain in the UK with counterfeit prescription only medicines (POM) designed to treat high cholesterol. The Agency has developed a strategy to deal with counterfeits involving major stakeholders in the UK (other law enforcement bodies, health care professionals and industry) and is active on the EU and international stage in this field. The Agency has also initiated proactive analytical surveillance programmes to detect counterfeit medicines in the UK supply chain. We have also encountered counterfeit medical devices, such as condoms, during the past year, many of which have required close collaboration with our EU partners as well as other stakeholders.

Risk and benefits

Explaining concepts of risk and benefit in the use of medicines and devices, and getting messages across to patients, carers and healthcare practitioners, is part of our wider role. This year we commissioned research to find out what the public and healthcare professionals think about the risks and benefits associated with medicines, medical devices and medical equipment. We also sought views on how well we regulate these products and how we communicate on their risks and benefits. The findings offered some reassurance about the public's confidence in medicines and medical devices and provide us with a good platform to track views on these issues in this time of change and reform in the NHS and in the regulatory system. We published this research in December 2006.

Patient involvement

Further important steps were taken to involve patients more directly in the regulatory process. In particular an Expert Advisory Group (EAG) of the Commission on Human Medicines was established in July 2006 to examine how the MHRA can involve patients more directly in medicines safety issues. As well as looking at

> **Better regulation remains high on the Government agenda and has formed a key strand of work in the Agency in this year and will continue to be an important activity.**

further ways to improve patient information leaflets, the EAG will offer advice on how the Agency communicates to patients about the risk:benefit debate and on how to encourage patients to use the Yellow Card scheme to report suspected adverse reactions. As part of its contribution to this work, the Agency has published three examples of improved patient information leaflets designed with the direct assistance of patient groups. The Agency has also been working with industry to ensure that it can implement user testing of all patient information leaflets in line with the legal requirements which came into force in July 2005 and need to be implemented by the end of 2008.

Healthcare professional involvement

In a similar vein, the Agency also commissioned research on how to encourage more doctors, patients and carers using medical devices to report suspected adverse incidents. A leaflet, which will be available in GP surgeries and many community pharmacies, was launched in March 2007.

Ministerial Working Group

The Agency played a key role in developing the Ministerial Industry Strategy Group's Long term Leadership Strategy (LTLS), with the aim of improving the UK and European environments for medicines. The Strategy has three main work streams and the Agency co-chaired with an industry representative the Regulatory Working Group - which explored ways to achieve and sustain a UK and European regulatory environment to support the innovative pharmaceutical industry in the UK and meet the needs of government, patients and prescribers. The Regulatory Working Group focused on a number of areas in which progress in the short term can bring real value to the UK. It also made longer term recommendations to be championed by the UK at EU level to improve the competitiveness of Europe as a whole. Focus was given both to improving the process for licensing medicines and for post-approval monitoring of medicines.

Innovation

The Agency played its part in the broader agenda for innovation in medicines and healthcare products. The Agency contributed actively to the Review of UK Health Research Funding (the Cooksey Review) and is now considering with industry how to implement the recommendations relating to the impact of regulation on the drug development pathway. The Agency was also represented on the Strategic Implementation Group (SIG) set up by the Health Industries Task Force (HITF) to oversee the key recommendations of the HITF report. This strand of work is key to ensuring that the quality of patient care is enhanced by having access to innovative medical devices and identifying how regulation can assist, rather than hinder this. It was in this context that we invited Sir Chris O'Donnell, the Chief Executive of Smith and Nephew, to give the MHRA Annual Lecture on the subject of "Biological solutions for healthcare in the NHS".

Better regulation

Better regulation remains high on the Government agenda and has formed a key strand of work in the Agency in this year and will continue to be an important activity. In March 2005, the Government accepted the Better Regulation Commission's recommendation that each government department should prepare simplification plans, measuring the administrative burdens imposed by Government activity and regulation, setting a target to reduce these burdens and identifying specific actions to deliver this reduction. The Department of Health's administrative burden was calculated at £1.2 billion and the Department committed to reduce this burden by 25 per cent, a reduction of £300 million by 2010. A potential £132 million reduction has already been identified across the Department, of which the MHRA's share is £104.4 million. The Better Regulation of over the Counter Medicines Initiative (BROMI) is an important part of this contribution. Initially limited to Over The Counter (OTC) medicines, the first report was

> **The Agency continues to play a major role in the operation and development of the European regulatory system for medicines and devices.**

published in May 2006, and work has also taken place to roll BROMI out to Prescription Only Medicines (POM) during the course of the year.

Inspection

Whilst much of our regulatory work takes place within MHRA offices and laboratories, our inspection and enforcement staff visit some of our stakeholders' locations. We inspected 1,372 sites both in the UK and overseas over the last year, including 61 blood banks which we inspected as the interim competent authority for blood and blood components; we considered adverse regulatory action in only 2 per cent of these 1,372 visits, which in itself is a measure of the effectiveness of the inspection and enforcement regime.

Alternative medicines

As well as regulating conventional medicines the Agency also regulates alternative medicines and this year saw two landmark events. After the successful implementation in the UK of the European Directive on traditional herbal medicinal products, the first traditional herbal registration was granted in October 2006. The new scheme will ensure that registered products meet assured standards of safety and quality and have appropriate patient information. The previous month, following an extensive consultation process, the Agency introduced a National Rules Scheme for homeopathic medicines. This was not without controversy, attracting Parliamentary and media interest, including concerns that the Agency was giving scientific endorsement to homeopathy. The National Rules Scheme makes no judgement of the clinical efficacy of homeopathic products, in the way this is understood for conventional medicines, but it sets standards of safety, quality and the inclusion of appropriate patient information so that those people who choose to use homeopathic remedies can be assured that the products they buy meet these standards.

Haemovigilance

The haemovigilance arrangements introduced in late 2005 continued to operate smoothly throughout their first full year, with reporters using the online SABRE reporting system to submit over 800 reports of serious adverse events and reactions involving blood and blood components. We publish comprehensive Frequently Asked Questions on our website and provided a series of training workshops and a one day conference to help raise the profile not only of the MHRA as the UK competent authority for blood safety and quality, but also of our relationship with SHOT (Serious Hazards of Transfusion). As well as consenting to share all their MHRA reports with SHOT, reporters also used SABRE to provide SHOT separately with details of over 500 other incidents that did not require a report to the MHRA as competent authority.

Europe

The Agency continues to play a major role in the operation and development of the European regulatory system for medicines and devices. During 2006, the UK was rapporteur for 20 and co-rapporteur for seven new medicines in the European centralised procedure, and as Chair of the Pharmacovigilance Working Party of the Committee on Human Medicinal Products pushed forward a number of key drug safety issues at EU level. The UK also took the Chair of Study Group 5: Clinical Evaluation of the Global Harmonisation Task Force for devices this year. The Agency continued to be active in twinning, entering into a twinning project along with France in June 2006 to assist the Czech regulatory body to develop its capacity in the field of clinical assessment of medicines, the regulation of tissues and cells and of medical devices.

On the legislative front, the Agency represented the UK in the negotiation of several key pieces of EU legislation. In June 2006 agreement was reached on a European regulation on medicines for children. A key priority for the UK under its Presidency of the EU in 2005, this legislation is an important step in making medicines safer for children, ensuring that medicines will be available for children in the appropriate formulation. The UK has also been active in the negotiations

on the Regulation on Advanced Therapy medicinal products, ensuring that key stakeholders have been consulted as negotiations develop and lobbying actively as the proposals were discussed in the European Parliament. The UK view has been to support the proposals in principle but to ensure that the regulatory regime which is established by the legislation is risk based and proportionate. Closely linked in many ways, the Agency has also represented the UK in the negotiations on the revision of the Medical Devices Directives. While many of the proposed amendments are technical in nature, key issues such as the overlap with the proposed Regulation on Advanced Therapy; clarifying the circumstances in which clinical data is required by manufacturers to support CE-marking; describing how such data may be obtained; and relaxing the Directive's confidentiality requirements thus allowing more information to be made publicly available, have all required close consultation across government and with industry.

Staff

The staff of the MHRA remain its most important asset. In June the Agency launched its second staff survey. There was a high response rate of 68 per cent which is more than would normally be expected from a public sector organisation. The findings were presented to the Agency in August. When compared with the earlier staff survey conducted in 2004, there was progress in some areas and, compared to many public sector bodies, there was real pride in the work of the Agency and individual job satisfaction was high. There were however areas of concern including some on which the Agency had hoped to make greater progress: for example, staff were still unhappy about the pace and extent of change, and seemed unsure of the long term benefit. Some of these findings were subsequently explored further by the National Audit Office's health check – a qualitative survey of Agency opinion using a technique called "appreciative inquiry".

The Executive Board used both sources of information in order to develop a series of actions to resolve the issues identified in the Survey and in the health check. The way forward was the subject of a consultation with staff at an innovative All Staff meeting held in November. In December, the Agency underwent Investors in People re-assessment. The assessor was satisfied that MHRA meets all of the indicators of the IiP Standard, and the Agency was therefore given full IiP accreditation in January 2007.

Service delivery

Finally, this year has seen the bedding in of some big changes in the Agency. The final phase of the "Sentinel" IT development programme was in the Pharmacovigilence area and was rolled out in June, but work continued through the year to enhance the system and ensure that it was able to deliver all that had been expected of it. A large re-organisation of the medicines divisions, Business Realignment, was also launched at the start of this year and a lot of time and effort has been spent on delivering the benefits of the changes which were introduced. It is clear that the transition from the old information management system to the new; the implementation of new business processes and ways of working; and the new management arrangements have all had an impact on service delivery. Management action, and cooperation from across the Agency, has enabled us to resolve some of these issues but there is more to do to restore our service and deliver the benefits initially envisaged from the change programme. This is the key challenge for 2007/08.

Agency Board

Executive Board

Executive Board

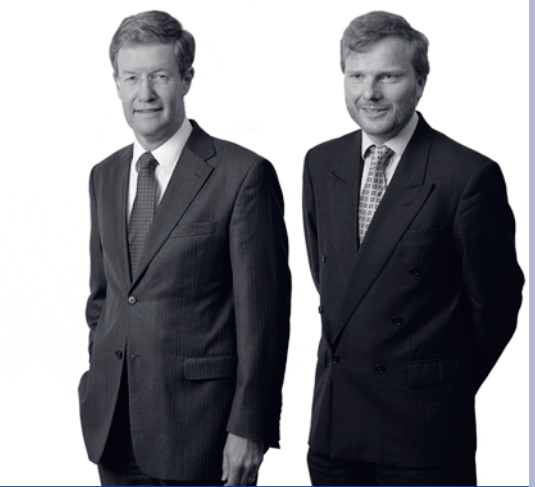
Top row, from left to right
June Raine, Simon Gregor, Louise Loughlin, Alison Davis, Geoff Le Fevre, Simon Rogers, Peter Commins

Bottom row, from left to right
Ian Hudson, Kent Woods, Susanne Ludgate, Clive Bray, Gerald Heddell, Shaun Gallagher

Corporate Governance

Agency Board

From left to right
Kent Woods, Shelly Dolan, Simon Rogers, Angus MacKay, Lisa Arnold, Charles Kernahan, Garry Watts, Michael Fox, Sir Alasdair Breckenridge, Damien Bishop



MHRA has an Agency Board, an Executive Board and a Risk and Audit Committee. Together these three entities oversee the Agency's corporate governance and risk management systems to ensure that the highest standards of integrity, accountability and operational capability are maintained.

The Agency Board consists of a Chairman, six non-executive members and the Chief Executive Officer of the Agency. The Agency Board's role is to monitor the Agency's strategic direction and to take action as appropriate. The Chairman is directly accountable to Ministers for the performance of the Agency and its decisions.

The Executive Board comprises the Chief Executive Officer and the Heads of Divisions, who take executive responsibility for the strategy, operational management and service delivery of the Agency, including risk management. As the Accounting Officer, the Chief Executive Officer also has responsibility for the Agency's resources.

The Risk and Audit Committee reports independently to the Accounting Officer and the Agency Board on the effectiveness of the operation of the Agency's corporate governance and risk management systems. The Committee is chaired by a non-executive Agency Board member.

Organogram

CHAIRMAN
Professor Sir Alasdair Breckenridge

CHIEF EXECUTIVE
Professor Kent Woods

LICENSING
Ian Hudson

VRMM
June Raine

DEVICE TECHNOLOGY AND SAFETY
Clive Bray

DEVICES CLINICAL
Susanne Ludgate

INSPECTION AND STANDARDS
Gerald Heddell

INFORMATION MANAGEMENT
Alison Davis

HUMAN RESOURCES
Geoff Le Fevre

OPERATION AND FINANCE
Peter Commins

POLICY
Shaun Gallagher

COMMUNICATIONS
Simon Gregor

ENFORCEMENT AND INTELLIGENCE GROUP
Michael Deats (Group Manager)

Performance against key targets 2006/07

Before each quarter, agree a risk-based plan for Good Practice inspections in the medicines sector; during the quarter, inspect 95% of the sites in that plan, including all those deemed to be of high risk.	Achieved
Promptly capture reports of adverse drug reactions and adverse incidents involving devices, initiating timely and appropriate action to protect public health, particularly for those reports in which medication error is suspected. Maximum number of working days between receipt of reports and making them available for evaluation and analysis: • 3 for fatal and serious device adverse incidents • 3 for fatal adverse drug reactions and 5 for serious reactions • 7 for the identification and transmission of suspected medication errors to the National Patient Safety Agency	Achieved for the first bullet point. Not achieved for bullet points two and three: For the second bullet point – 99 % accomplished for fatal ADRs; 98% accomplished for serious ADRs. For the third bullet point – the introduction of the new Sentinel pharmacovigilance system in May 2006 impacted the ability to promptly identify medication error reports and transmit to NPSA. This has been resolved and reports are now being transmitted within 7 working days.
Issue safety warnings, which identify clear and appropriate action which recipients can achieve within realistic timescales, reviewing the effectiveness of these alerts through feedback monitoring and their quality through independent assessment: • Medical Device Alerts and other safety warnings • Drug Alerts • Other medicines safety warnings	Achieved

Develop by September an anti-counterfeiting strategy aimed at disrupting those enterprises engaged in the importation, wholesale, distribution and supply of counterfeit medicines, through public awareness, targeted market surveillance, international co-operation between regulators, and co-ordinated and focused investigations and prosecutions. Implement all actions in strategy that are designated for the remainder of 2006-07.	Not achieved. Although the strategy has not yet been published, actions were undertaken throughout 2006-07 which broadly cover the requirements of this target.
Continue to improve the transparency of decision making within the Agency and accountability to the public by: • publishing UK Public Assessment Reports for medicinal products licensed • providing summaries of the evidence supporting major safety decisions • ensuring that all requests under the Freedom of Information Act, where the balance of public interest does not apply, are replied to within 20 working days, with internal reviews showing 90% of them complying with the principles contained in the Act and guidance issued by Department of Constitutional Affairs and the Information Commissioner	Achieved for the first two bullet points but not achieved for the third bullet point in respect of answering all requests within 20 working days, where performance was 84.7% (the internal reviews target was met).
Consult with patients, healthcare professionals and other stakeholders to refine the Agency's model for weighing risks against benefits in its regulatory decisions, and publish the resulting model in language accessible to the public.	Achieved
a) Assessment of clinical trial authorisations for medicines: • Phase I (healthy volunteer) trials: 100 per cent in 21 calendar days with an average of 14 calendar days or less; • All other trials: 100 per cent in 30 calendar days b) Assessment of clinical investigation notifications for medical devices: • 100 per cent in 60 days with an average of 54 days or less	Not achieved in respect of part (a), where the performance was 99.6% and 99.8% respectively for the two bullets (the 14 day average for phase I trials was exceeded at 13.5 days). Achieved in respect of part (b).
Achieve an expenditure and income out-turn for 2006-07 in line with the published budget; and set a balanced budget for 2007-08 which would allow the Agency to deliver HM Treasury's requirement for a 3.5% return on capital employed over the first five years of its life.	Achieved
Realise the expected benefits for the medicines sector of the investment in the Sentinel IT system and the restructuring of the organisation, achieving the savings set out in the business case for Sentinel and improving the service to industry stakeholders, to be measured in a survey of them.	Not achieved. Additional staff were deployed in information processing, so planned savings were not achieved in full.
Repeat the staff satisfaction survey of two years' earlier to measure progress and to establish new priorities for action and new targets for achievement.	Achieved
Continue to improve the management and development of people in the Agency, taking full account of the results of the Investor in People assessment of March 2006.	Achieved
Create a cross-divisional, public facing Medicines and Devices Vigilance (MDV) Group within the Agency which will develop a strategy to improve knowledge of risk-benefit relationships and to present risk-benefit information to patients more effectively.	Achieved

Key targets 2007/08

1 Move to full electronic working and electronic Common Technical Document (eCTD) standard:

- Encourage companies to submit eCTD applications to achieve increases in line with the joint commitment made in the Ministerial Industry Strategy Group. Monitor numbers of incoming applications and provide quarterly feedback to industry to track progress and any emerging constraints.
- Work with other EU Member states to develop and implement a harmonised approach to electronic applications by representation on European telematics committee. A draft proposal to have been circulated to all Member States by Summer 2007, with the aim of having a harmonised guidance document, with local appendices, by March 2008.
- Introduction of a plan for full compliance with electronic E2B reporting of adverse drug reaction reports.

2 Achieve an expenditure and income out-turn for 2007-08 in line with the published budget and deliver the requirement for a 3.5% per annum return on capital employed over the first five years of the Agency's life; lay the Agency's 2006/7 annual accounts, unqualified, before Parliament by the Summer recess; set a balanced budget for 2008-09; and identify the Agency's medium term financial model.

3 To develop and introduce a programme of continuous learning for all staff, building on the achievement of the IiP Standard in December 2006 through the provision of relevant and effective training delivery to improve leadership skills and personal development including the introduction of core behaviours

4 Improve performance across the Agency's medicines licensing operations by targeting areas where there are backlogs. Ensure that, over the year as a whole, the number of determinations exceeds the predicted numbers received by at least 10% in each of the following areas of activity:

- New Product Licences granted in National, Mutual Recognition or Parallel Import procedures;
- Variations to National (Type II, non-safety) or Parallel Import licences.

Introduce the regular publication of a range of performance information agreed. In discussion with the industry associations, on the Agency website from April 2007.

5 Complete assessment of clinical trial authorisations for medicines:
- at least 98% in 30 calendar days; and
- with an average of 14 calendar days or less for Phase I (healthy volunteer) trials.

Complete assessment of clinical investigation notifications for medical devices.
- at least 98% in 60 days;
- with an average of 54 days or less.

6 Promptly capture reports of adverse drug reactions and device adverse incidents, initiating timely and appropriate action to protect public health. Ensuring maximum number of working days between receipt of reports and making them available for evaluation and analysis:

- 3 for fatal and serious device adverse incidents
- 3 for fatal adverse drug reactions and 5 for serious reactions
- 7 for identification and transmission of suspected medication errors to the National Patient Safety Agency

7 Issue, through an effective process, drug alerts, medical device alerts and other safety warnings, supported by relevant media activity where appropriate, which identify clear and appropriate action which

recipients can achieve within realistic timescales, reviewing the effectiveness of these alerts through feedback monitoring.

8 Continue to improve the transparency of decision making within the Agency and accountability to the public by:

- publishing UK Public Assessment Reports for medicinal products licensed within 60 days of final determination;
- providing summaries of the evidence supporting major safety decisions within one month of final regulatory decision;
- introducing the quarterly publication (as appropriate) of identified drug safety signals and MHRA action to ensure transparency
- working towards achieving 100% compliance, the Agency will ensure that at least 85% of requests under the Freedom of Information Act are replied to within 20 working days.

9 Pursue agreed UK objectives in EU negotiations in order to improve safeguards and advance regulatory science, achieving outcomes consistent with better regulation principles, in the following areas:

- advanced therapies;
- the revision of the Medical Devices Directive;
- the revision of regulations governing variations to medicines licences;
- proposals to strengthen pharmacovigilance provisions.

10 Take actions to progress the Government's Better Regulation agenda:

- Pursue actions set out in the Department of Health Simplification Plan, published November 2006, relating to the regulation of medicines and devices, and work with industry to monitor delivery of administrative burdens savings up to 2010
- Consider and respond in detail to external suggestions for simplification of regulations within the 90 days set by Cabinet Office;
- Develop and implement risk assessments for all inspection types
- Take forward the Better Regulation of Medicines Initiative (BROMI):
- encourage and monitor uptake of new arrangements already introduced
- identify and implement further ways to reduce regulatory burden and cost to industry through the second and third workstreams of BROMI.

Financial statements 2006/07

Risk management

The Agency prepares an annual statement on internal control, which is detailed later in the Accounts.

Strategy and business objectives

Corporate governance

Protecting public health

Promoting public health

Improving public health

The compositions of the Agency Board, the Executive Board and the Risk and Audit Committee are detailed under Corporate Governance in the Accounts.

Review of operations

The Agency's main activities are detailed in 'The Year in Review' within the Annual Report.

The Chief Executive Officer's Report is within the Annual Report.

The Chairman's Foreword is within the Annual Report.

Performance targets

The key targets for 2006-07 and their outcomes are detailed within the Annual Report.

The key targets for 2007-08 are detailed within the Annual Report.

Financial review

Income and Expenditure

Future outlook

Assets and liabilities

Staff resources

Remuneration Report
Details of the remuneration and other benefits to the members of the Agency and Executive Boards are contained within the Remuneration Report.

Statement of accounts

External auditors

/

/

Further details on the above are contained within the Remuneration Report and note 6 to the Accounts.

Employment policies and training

Persons with whom the entity has contractual or other arrangements which are essential to the business of the entity

Payment of suppliers

Recruitment Code

Staff involvement and consultation

/

Social, community and environmental issues

Statement on health and safety policy and practice

Data protection

//

Freedom of information

Board members remuneration

The remuneration details are set out in the Remuneration Report.

The Agency Board

The Executive Board

The Risk and Audit Committee

Post balance sheet events

Going concern

Professor Kent Woods
Chief Executive and Accounting Officer
Medicines and Healthcare products Regulatory Agency
27 June 2007.

Appointment Policy

Executive Board Remuneration

Name and title	2006 07 Salary 000	Bonus 000	/
	80 85	0 5[1]	
	175 180	20 25	
	90 95	0 5	
	90 95		
	85 90	5 10	
	80 85	0 5	
	95 100	0 5	
	110 115	5 10	
	85 90	0 5	
	80 85	5 10	
	115 120	10 15	
	5 10		
	25 30		
	65 70		

/

/

Pension

/

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a Classic sche e

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re iu sche e

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/

/

c Classic lus sche e

d artnershi ension account

Cash equivalent transfer values (CETV)

Agency Board Remuneration

	2006 07 Salary 000	/
	5 10	
	5 10	
	5 10	
	5 10	
	5 10	
	5 10	

Certain disclosures are subject to audit

/

Professor Kent Woods
Chief Executive and Accounting Officer
Medicines and Healthcare products Regulatory Agency
27 June 2007

tatement o Agenc s and ie ecutive s Responsibilities

Government Financial Reporting Manual

Government Financial
Reporting Manual

Government Accounting.

tatement on nternal ontrol

Scope of responsibility

The risk and control framework

The purpose of the system of internal control

Capacity to handle risk

Review of effectiveness

Internal Audit

Agency and Executive Boards

Risk and Audit Committee

Significant internal control issues

Accounting Officer's comment

Professor Kent Woods
Chief Executive and Accounting Officer
Medicines and Healthcare products Regulatory Agency
27 June 2007.

e erti icate and Report o e omptroller and Auditor eneral to e Houses o arliament

Basis of audit opinion

Respective responsibilities of the Agency, Chief Executive and auditor

Opinions
Audit Opinion

/ /

/

/

Audit Opinion on Regularity

Report

ohn Bourn
Comptroller and
Auditor General
5 July 2007

National Audit Office
157-197 Buckingham
Palace Road
London, SWIW 9SP

ncome and e penditure account

	2006 07 000 /
	70,118
	11,190
	81,308
	42,371
	31,094
	6,180
	79,645
Operating surplus deficit on ordinary activities	1,663
	644
	155
Surplus Deficit for the year on ordinary activities	2,152
	293
Retained surplus deficit for the year	1,859
	3,750
Retained surplus carried forward	5,609

tatement o total recognised gains and losses

	2006 07 000 /
/	**2,152**
	610
	61
/	**1,603**

alance eet

	31 March 2007 000
Fixed assets	
	32,167
Current assets	
	18,638
	18,119
	36,757
	30,288
Net current assets liabilities	**6,469**
Total assets less current liabilities	**38,636**
	2,728
	293
	23,817
Net assets	**11,798**
Capital and reserves	
	1,329
	3,906
	954
	5,609
Total capital employed	**11,798**

Professor Kent Woods
Chief Executive and Accounting Officer
27 June 2007

	2006 07 000 /
Net cash inflow from operating activities	**17,543**
Returns on investments and servicing of finance	
	594
	1,000
	406
Capital expenditure	
	6,253
Management of li uid resources	
Financing	
Increase Decrease in cash for the year	**10,884**

otes to t e Accounts

1 Accounting policies

/

a Accounting conventions

b Fixed assets

c Recognition of income

d Foreign currencies

e Staff terms and conditions

2 Financial objectives

/

f Bad debt and credit note provision

/

g Operating leases

/

3 Income

	2006 07 000	/
	39,167	
	22,056	
	8,895	
	11,190	
	81,308	

	000	2006 07 000	/
	18,149		
	1,598		
	3,881		
	6,327		
	159		
	8,023		
	1,030		
		39,167	
		22,056	
	1,772		
	3,947		
	912		
	1,053		
	1,211		
		8,895	
		11,190	
		81,308	

4 Segmental analysis

	2006 07 Devices 000	2006 07 Medicines 000	/
	339	69,779	
	11,190		
	11,529	69,779	
	10,583	69,062	
Operating surplus deficit	946	717	

5 Staff costs

	2006 07 000	/
	31,784	
	2,928	
	6,513	
	41,225	
	1,038	
	108	
	42,371	

6 Employee details

	2006 07	/
	11	
	754	
	2	
	64	
	831	

7 Other operating costs

	2006 07 000 /
	8,276
	121
	494
	9,468
	1,125
	624
	466
/	
	53
/	206
	1,398
	221
	1,570
	2,616
	218
	712
	771
	820
	1,935
	31,094

/ /

	2006 07 000 /

	000	2006 07 000	/
Plant E uipment			
	28		
	32		
	938		
		998	
Other			
		4,737	
		5,735	

8 Interest Receivable and Payable

	2006 07 000	/
	644	
	155	
	489	

/

9 Tangible Fixed Assets

Cost or valuation

Depreciation

Net book value

/

/

10 Debtors

	31 March 2007 000
	15,930
	271
	351
	1,293
	793
	18,638

	31 March 2007 000
	1,156
	793
	1,949

11 Creditors

	31 March 2007 000
Amounts falling due within one year	
	10,889
	8,945
	969
	1,000
	1
	8,484
	30,288

	31 March 2007 000
	8,230
	969
	1,603
	4,219
	15,021

	31 March 2007 000
Amounts falling due after more than one year	
	2,728

	Total 000	Less than one year 000	Between one to two years 000	Between two and three years 000	Between three and five years 000	More than 5 years 000	/
	1,000						
	1,000						
	400						
	1,328						
	3,728						
	4,728						

/

/

/

12 Provision for liabilities and charges

	31 March 2007 000
/	
	249
	121
	77
	293
	293

Early retirement / voluntary severance

Other provisions

/

/

13 Deferred revenue

	31 March 2007 000
	21,494
	2,323
	23,817

14 Capital and reserves

15 Reconciliation of surplus deficit to net cash inflow from operating activities

	2006 07 000 /
/	1,663
	6,180
	3,837
	23,817
	21,015
	259
	3,276
/	44
	17,543

16 Reconciliation of net cash flow to movement in net funds

	2006 07 000 /
/	10,884
	10,884
	7,235
	18,119

17 Analysis of net funds as shown in the reconciliation of net cash flow

/

18 Capital commitments

	31 March 2007 000

19 Contingent liabilities

20 Related party transactions

/

21 Losses and special payments

/

22 Financial commitments

	2007 000
	350
	4,677
	37
	1
	1
	956

23 Financial instruments

Liquidity risk

/

	2006 07 000	/
Accounts		

Interest rate risk

Currency risk

/

Credit risk

24 Post balance sheet events

HM Treasury minute dated 9 February 2004

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