Safeguarding public health

MHRA

07/08

Annual report and accounts 2007/08

Medicines and Healthcare products Regulatory Agency

HC 623

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Medicines and Healthcare products
Regulatory Agency

Annual Report and Accounts 2007/08

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Medicines and Healthcare products Regulatory Agency

Annual report and accounts 2007/08

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Chairman's foreword

Welcome to the fifth Annual Report of the Medicines and Healthcare products Regulatory Agency (MHRA).

Last year I wrote that science should lead regulation, and this continues to be a key theme of our work. But reflecting on this year's activity highlights another important challenge for regulation – to keep pace with an increasingly complex global manufacture, supply and distribution chain for medicines and medical devices. There has been an increase in the number of counterfeit medicines entering the supply chain and counterfeit devices continue to pose a problem. We also have had to consider how best to manage the supply and distribution of over-the-counter medicines which can be misused to manufacture class A illegal drugs.

Better regulation initiatives have also come to the fore. Too often, better regulation is merely seen as reducing unnecessary administrative burdens on the industries we regulate, and of course that is a part of it. But equally crucial is that it allows us, as a regulator, to focus our attention, effort and resources on those areas of greatest risk. If we accept that the business of regulating medicines, medical devices and blood products is becoming more complex, then our ability to identify and target high risk areas effectively will be critical to our success in safeguarding public health.

As a regulator, one of our key outputs is information, and so another indicator of success is our ability to communicate effectively with our stakeholders including, in particular, healthcare professionals at the front line of patient care. In our annual lecture this year Niall Dickson from the King's Fund highlighted some of the challenges facing doctors as we move into the 21st century, and we are well aware of the huge expectations placed on doctors and other healthcare professionals. It is the responsibility of the Agency to ensure that they are provided with accurate and helpful information in a timely way. Through publications such as our device and drug alerts, *One Liners* on medical devices and the new publication *Drug Safety Update*, we are able to offer authoritative information to these stakeholders. We wish to continue to develop information sources, including our website, and we welcome feedback from healthcare professionals on how they might be improved further.

Better regulation, improved information and other similar initiatives are all aimed at tackling benefit:risk issues in a proactive way, and wherever possible taking action to prevent harm to the public. However, no matter how strong a regulatory system is, there will always be those who deliberately seek to break the law for their own gain. It is here that tough enforcement action is needed, both to bring to an end the particular activity in question, and to serve as a deterrent to others. Over the last year, our successful prosecution of a gang of counterfeiters, leading to convictions and custodial sentences, sends out a strong message that the UK will take the toughest action possible against those who break the laws on medicines regulation.

Many of these issues will continue to be themes for the coming year, and I look forward to working with colleagues across the Agency in responding to them and to new challenges. In particular, I would like to extend my thanks to the Agency and Executive Boards for their support and hard work over the past year.

Professor Sir
Alasdair Breckenridge
Chairman

Chief Executive Officer's report

The fifth anniversary of the MHRA provides an opportunity to reflect on what we have achieved, and the challenges we face now and in the future.

At the time of writing, the Agency has just celebrated its fifth anniversary. The changes at the time of the merger, and further developments since, have positioned us as a real focus of expertise in the regulation of a range of products including medicines, medical devices, blood and blood products, herbal medicines and homoeopathic products. We have a network of links with other bodies around the world, and I believe the Agency is well placed to exploit its regulatory influence on both the national and the international stage. The achievements of the past year underscore that.

But this is no cause for complacency. Our fifth anniversary provides a salutary opportunity to reflect not just on what we have achieved, but on the challenges that we face now, and will continue to face in the future. In the second half of 2007/08, we embarked on a major consultation exercise with patient and consumer groups, healthcare professionals, industry and partner organisations to help identify strategic challenges for the coming years. This involved seeking both written and face-to-face feedback on what our priorities should be over the second five years of our life.

The exercise was hugely valuable, and a couple of issues struck me particularly forcibly. First was the rich volume of feedback we received from a very diverse range of stakeholders. With around 100 written responses, some of them very detailed, and a number of face-to-face meetings and discussion groups, we had a strong evidence base from which to make our plans for the future. It was striking to see how willing people were to engage with us – previous market research suggests that the process and detail of regulation is little understood by healthcare professionals and patients - but our experience with this consultation underscores how its impact is felt on a daily basis by those who access and deliver healthcare. I would like to put on record here my personal thanks to all those who contributed their views to this exercise.

Another issue which came through strongly in the consultation was the need for the Agency to do more on an ongoing basis to engage directly with our stakeholders. Amongst patients and consumers, there appears to be a real appetite to get more involved in regulatory issues, not just in relation to individual products which affect them, but in the field of wider regulatory policy.

Amongst healthcare professionals, there is a desire for greater dialogue and better access to information. And the industries we regulate remain keen to work with us on ensuring that patients have access to medicines and devices that work and are acceptably safe.

Elsewhere in this report we reflect on some of the things we have done over the last year to address those views; but we need to do more, and our business and corporate plans published early in 2008/09 set out some of the ways in which we plan to respond to the feedback.

Of course, one of the key challenges for the future is to build on the useful contacts we have made as part of this consultation exercise. Speaking at our annual conference in Birmingham this year, I was pleased to see delegates from very varied backgrounds chatting together, with each other and with MHRA staff, and sharing their perspectives on current regulatory issues. It is that kind of dialogue which is critical to ensuring that regulation continues to meet the challenges presented to it, and I hope that we can continue to find opportunities to engage in conversations with our stakeholders over the coming year.

The staff of the Agency have continued to rise to the challenges presented to them over the last year – and of course nothing that we have achieved could have been done without their continued commitment and hard work. I would like to conclude by thanking them all for their efforts, and I look forward to working with them in 2008/09.

Professor Kent Woods
Chief Executive Officer

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

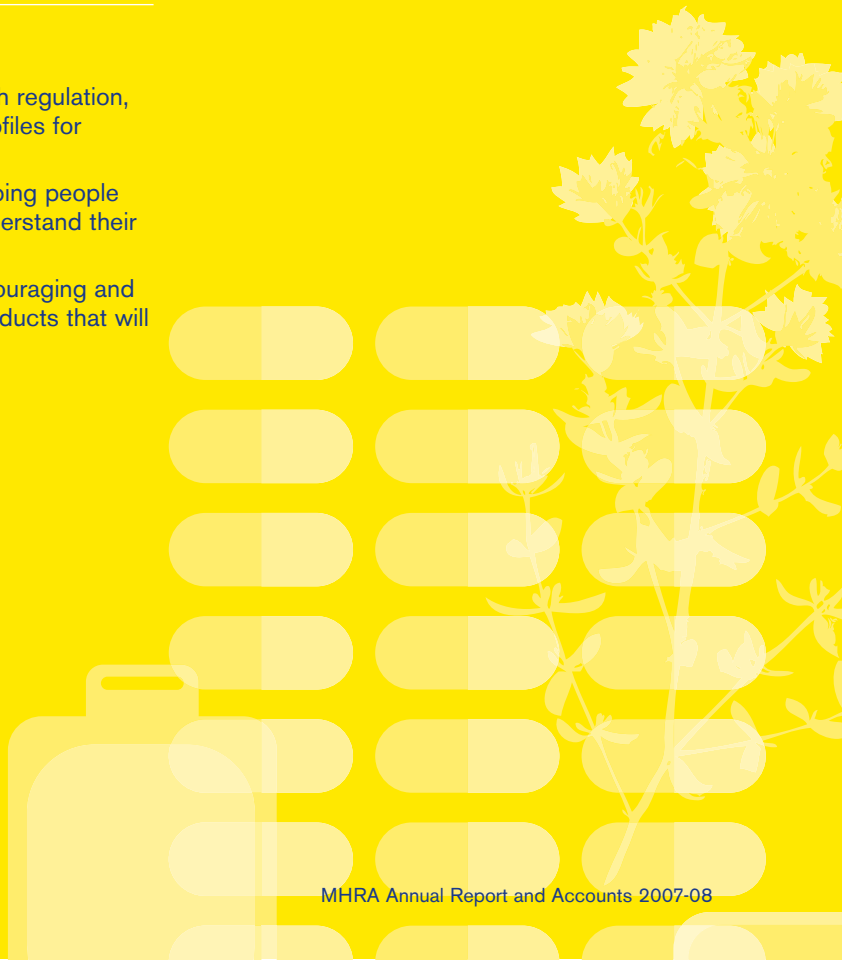
The Agency's aims are:

- Protecting public health through regulation, with acceptable benefit-risk 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 strategic objectives are to:

- Safeguard public heath through our primary role in ensuring that the products we regulate meet required standards, that they work and are acceptably safe;
- Carry out our communication role through the provision of accurate, timely and authoritative information to healthcare professionals, patients and the public;
- Support research, ensuring through the application of Better Regulation principles that regulation does not stifle innovation;
- Influence the shape of the future regulatory framework through use of our effective European and International relationships;
- Run an organisation with a skilled and equipped workforce that is fit for the future.



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 vigilance and other systems for reporting, investigating and monitoring adverse reactions to medicines, adverse incidents involving medical devices, and blood and blood products, 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.

The year in review

A year of challenges – striving to improve our performance, tackling counterfeit medicines and devices, pursuing key regulatory initiatives in Europe and major criminal investigations at home have been themes behind much of this year's activity.

Agency performance

The performance of the Agency has improved significantly over the course of the year. As we entered 2007, we were conscious that the legacy of the changeover to our new electronic ways of working had increased work queues in a number of areas. We made an explicit commitment to tackling this in our business plan. Performance is important both for industry and for patients – for industry, because it affects their business planning, and for patients because it affects the timeliness of the availability of new medicines.

We have made a concerted effort during the year to address these issues, with significant effect. By the end of the year, well over 90 per cent of marketing authorisation (MA) assessments were being completed within our 150 day target; a figure which rose to 100 per cent for applications handled under the European procedure. In most work areas, we are processing more applications than are coming in, meaning that the work queues are reducing.

A particular concern has been the area of clinical trial authorisations for certain novel compounds. Following the TGN1412 clinical trial incident in 2006, in which six healthy volunteers suffered severe side effects to a trial drug, the procedures for the authorisation of certain types of clinical trials have been changed. However, there was concern that in making these changes, the process of authorising certain clinical trials for particularly novel medicines might be delayed, thereby potentially postponing the development of important new medicines. In this context, we are pleased that the new procedures are now working well.

Following on from the TGN1412 incident and in response to the recommendations of the Expert Scientific Group, the Agency has implemented a voluntary accreditation scheme for Phase I units in the UK. This scheme is one of a series of measures taken by the MHRA to address concerns following the TGN1412 incident. The aim of this accreditation scheme is to increase the scope and depth of current inspections in order to provide the MHRA and ethics committees with more information about the facilities seeking to conduct these trials, so that approval decisions made are even more robust. The scheme would give assurance both to industry and the public that facilities within the scheme meet satisfactory standards for avoiding harm to trial subjects and for handling medical emergencies if they arose, therefore reducing risk to the volunteers that take part in these studies.

Performance on devices regulation has faced different challenges, as funding constraints over recent years have required us to reconsider our priorities. We have continued to withdraw from international standards work in order to allow ourselves to focus our resources on the investigation of safety issues. We are aware that this concerns many of our stakeholders, and we keep our involvement in standards work under regular review. However, the decision to focus on safety has been critical over the past year, when we have issued around 100 medical device alerts, and investigated over 8000 device-related incidents.

30,000

Over 30,000 phone

calls received on the MHRA Central Enquiry Point.

Our regulatory system for blood and blood products, introduced two years ago, is now well embedded within the Agency's systems, and the blood banks and blood establishments which it regulates are themselves becoming more familiar with the regulatory requirements. Similarly, the Traditional Herbal Registration Scheme is becoming well established now, with a number of products being granted registrations in 2007/08.

The Inspection and Standards Division and the Enforcement and Intelligence Group continued to benefit from working to a formal, registered, quality management system. Inclusion of the British Pharmacopoeia Secretariat within the scope of registration was a feature of our continuing commitment to extend the scope of the quality management system across the Agency. The MHRA continued to play a leading role in the Heads of Medicines Agencies benchmarking project, designed to produce a network of European medicines agencies working to best practices.

Criminal investigation

Our four-year investigation into allegations about GlaxoSmithkline (GSK) reached its conclusion during 2007/08. This high-profile investigation focussed on the suggestion that GSK had knowingly withheld trial data which showed an increased risk of suicidal behaviour in children. The investigation was the largest of its kind ever undertaken by the Agency, with around a million pages of documentation reviewed. We were also the only regulatory agency to conduct a criminal investigation into this issue.

On completion of our investigation, government prosecutors took the view that there was no realistic prospect of a conviction, and that the case should not proceed to criminal prosecution. However, we remain concerned that GSK could and should have passed important information to us sooner. We will be strengthening UK legislation and working with EU colleagues to do the same at European level to ensure that the responsibilities of pharmaceutical companies to provide information are clearly and robustly insisted upon with the full force of the law.

Availability of medicines

In tandem with the introduction of the smoking ban in England and Wales in 2007, a number of changes were made in the recommendations for use of nicotine-replacement therapy (NRT). NRT products are now licensed for smoking cessation in adolescents 12 years and over, and in pregnant women and smokers with cardiovascular disease. They are also available to support those who are aiming to reduce their smoking as part of a programme aimed ultimately at quitting. Nicotine inhalers have now been made more widely available as they no longer have to be sold by a pharmacist.

During the year, we also consulted on proposals to restrict access to certain decongestant and other products containing ephedrine and pseudoephedrine. Experience from other countries suggests that the relative ease of access to such products may be helping to fuel the use of the Class A drug crystal meth, for which ingredients can be extracted from them. Following extensive consultation, it was decided to restrict pack sizes and the number of packs that can be sold per transaction rather than to reclassify the medicines to prescription-only status. The option remains to reclassify in the future should the current strategy prove to be less effective than we hope, but in the first instance we are working with the pharmacy profession to ensure that we strike a balance between helping to prevent crystal meth abuse and maintaining the availability of these medicines.

£2.5m

worth of counterfeit medicines seized.

Better Regulation

The Hampton and Macrory reports from central government have challenged regulators in many sectors to reconsider the way in which they operate, and the MHRA is no exception. We are implementing a number of better regulation initiatives, with a focus on ensuring that regulatory activity is targeted at areas of most risk and where we can make greatest impact.

The Better Regulation of Over-the-counter Medicines Initiative (BROMI) is one example. BROMI allows pharmaceutical companies to self-certify some simple changes to product packaging and information – this reduces unnecessary bureaucracy, and allows us to focus our resources on more substantial changes which have a potential impact on public health. BROMI won one award and was shortlisted for another during the course of 2007/08.

At the same time, we have consulted on and plan to roll out a risk-based approach to medicines inspection. In the past, most inspections conducted by the Agency have taken place on a rolling basis, with a fixed time cycle. Moving forward, the frequency and length of inspection will be based on an assessment of the risks posed by a particular inspection site. Again, this should help us to target our resources at those areas most likely to cause a risk to public health.

We are also looking at other ways of further developing regulatory good practice. We have developed the General Practice Research Database (GPRD), which contains confidential and anonymised patient records for research purposes, by linking it into other data sources particularly in secondary care. This new tool, called Exetrac, will allow both regulators and industry to conduct far more powerful studies into the benefits and risks of products.

We have set up a Regulatory Forum to debate topical issues in regulation, and to provide the Agency with a sounding board to help it develop new policies and strategies. Each time the Forum convenes, it discusses a different subject, and a panel is drawn together including industry, healthcare professionals, patient representatives and lay people to debate the issue. We plan to develop this model over the coming year, in particular to extend it into devices as well as medicines issues.

8000

Over 8000 device-related

incidents investigated.

Safety issues

Responding to safety issues is a core part of Agency business. During the course of the year, the Food and Drug Administration (FDA) in the United States seized products from a company called Shelhigh, which makes implantable devices used in cardiac and vascular surgery, such as heart valves and conduits. Our understanding is that the FDA had concerns about sterility, and their action had an impact on the supply of these products to the UK and wider European markets. We ensured that cardiac surgeons were informed of the likely impact on the availability of products, and were aware of alternative suppliers. At the same time, we worked closely with the FDA and our EU partners to assess the issue, but concluded that there were no grounds for regulatory action in Europe. Longstanding work into the risks and benefits of metal-on-metal hip implants has continued this year. Concerns originally arose when research suggested that some of these products might lead to genetic changes in surrounding tissue in patients in whom they had been implanted. What was unclear was whether this had any significant impact on the health of the patients. A review by the Committee on Safety of Devices concluded that there is currently no evidence to suggest a clinical risk, but that further long term research is needed. It also recommended more information for patients about the possible risks.

In early June, we were notified that certain batches of an active ingredient used in the HIV drug Viracept had become contaminated due to a manufacturing error. As a result we issued an urgent drug alert recalling the product in the UK, and indeed a worldwide recall followed.

At about the same time, four further recalls were issued after the discovery of counterfeit medicines within the supply chain. Three medicines were involved – Casodex, Zyprexa, and Plavix. A major investigation was launched into these incidents, and three people were arrested early on in the investigation process. At the time of writing, work is continuing to gather evidence about these incidents. The incidents were also noteworthy as they represent the first time that parallel trade – the system of reselling medicines from one EU country to another – is known to have been used as a means of distributing counterfeit medicines. The European Commission is currently reviewing the legal framework for tackling counterfeits in Europe, and we are contributing to that review.

During the year, we were also successful in bringing an earlier counterfeiting case to prosecution. The case, involving a number of defendants, was the largest of its kind to date in the UK, and involved the counterfeiting and distribution of products for erectile dysfunction and hair loss. A number of the defendants were convicted, including some who were given substantial prison terms. This sends a clear signal to counterfeiters that the UK will take tough action to stamp out this illegal trade. Our anti-counterfeiting strategy, launched in November 2007, reinforces that message.

70

UK contributions to CHMP

scientific advice procedures, 22 more than last year.

The year in review continued

It is not just medicines which are subject to counterfeit activity. During the year we also dealt with a number of cases of counterfeit devices. Our main concern was over counterfeit condoms, which appeared to be distributed primarily via small local outlets. We issued advice to consumers about these incidents and worked closely with Trading Standards departments and Her Majesty's Revenue and Customs to stop the supply of these products.

Access to information

Information is one of our products, and it is critical that we communicate important safety information to our stakeholders in a timely and accessible way. There have been a number of innovations on this front over the past year. We have developed a new monthly publication – *Drug Safety Update* – to replace the older and less frequent *Current Problems in Pharmacovigilanc*e. For the first time ever, we have also produced the seminal reference work, the *British Pharmacopoeia*, in electronic format. We have further consulted on and re-published a short paper setting out how we make regulatory decisions about medicines and medical devices, which we hope will help to improve the transparency of our processes.

We also strive to communicate directly with stakeholders face-to-face. Over the course of the year we have run a number of events and conferences, including an annual conference in Birmingham in February which attracted several hundred delegates.

International activity

The Agency led the UK input into some important new changes to regulation at EU level, in particular a new framework for regulating advanced therapies including products made from human tissue; and also revisions to the main Medical Devices Directives – the product of several years' work – with the main aim of improving consistent interpretation and clarifying manufacturer responsibilities, particularly as to the clinical evidence needed for their products. The Agency also made a strong contribution to putting in place the new arrangements for delivering better medicines for children, following the implementation of the Paediatric Regulation. As the year ended, a number of major EU proposals – including the reform of pharmacovigilance – were under way, indicating a busy EU agenda for the coming year.

92

responses received

from organisations to the MHRA consultation on challenges and priorities for the Agency over the next five years.

The trade in medicines and medical devices is global in nature, and so it is vital that we have links with other regulators beyond the EU. During the course of the year, we signed an agreement with China's State Food and Drug Administration which covered a number of areas including developing cooperation in the fight against counterfeit medicines, and the exchange of information on herbal medicines. We also contribute to the International Conference on Harmonisation, and the Global Harmonisation Task Force with a view to developing greater consistency and cooperation in the regulation of medicines and medical devices respectively.

22,000

Over 22,000 Yellow Cards

received reporting suspected side effects or adverse reactions from medicines.

The EU Commission has proposed that to support inspections and quality management, the concept and scope of Good Vigilance Practices (GVP) should be established in legislation and a legal basis should be created for the Commission to adopt a Regulation on GVP. In advance of this development, the MHRA has developed Good Pharmacovigilance Practices guidance to be published in 2008, which clarifies MHRA's expectations with respect to existing EU legislation and guidance.

General Practice Research Database (GPRD)

GPRD showed increased use across all types of researchers; specifically exemplified by the fact that the Independent Scientific Advisory Committee (ISAC) of the MHRA had to increase its membership to cover the number of studies requiring review. The plans for enabling record linkage of GPRD to other key UK NHS datasets also came to fruition. This will enable a further extended range of research options around additional hospitalisation data and disease specific data from other NHS data collections. The pharmaceutical industry has also responded well to the GPRD group new product offering, ExEtrac, a new data collection and analysis methodology system, specifically designed to further the needs of regulatory required risk management plans.

As well as being an operational and public health asset, GPRD is also a financial asset of the Agency and recorded in the accounts as such. It is valued for accounting purposes on the basis of value in use by an independent consultant who takes into account business factors in determining his financial valuation. As a result of his review the financial asset was impaired to zero value as at 31 March 2008. This accounting change has no impact on GPRD's continuing operations.

4000

Nearly 4000 marketing

authorisations for medicines granted.

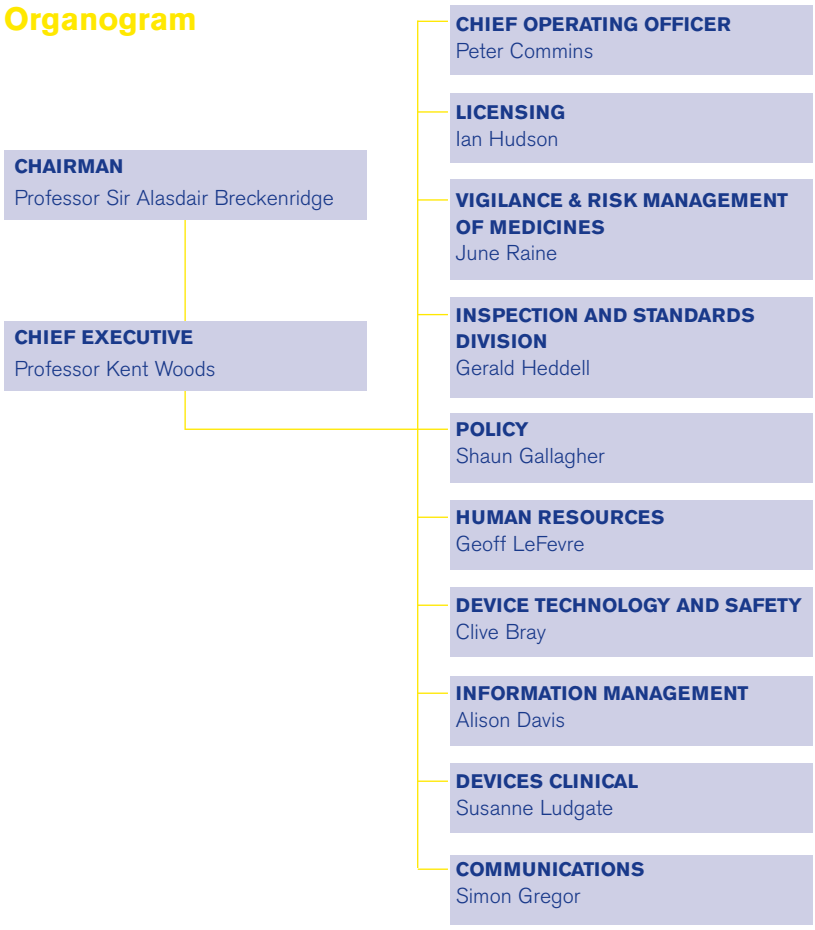
Corporate Governance

The MHRA is an executive agency of the Department of Health and operates as a trading fund. The Agency came into existence on 1 April 2003 on the merger of the Medicines Control Agency and the Medical Devices Agency.

The Secretary of State for Health determines the policy and financial framework within which the MHRA operates, but is not involved in the day-to-day management of the Agency. The terms under which the Agency operates are set out in its Framework Document.

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.

Organogram



The Agency Board consists of the Chairman and six non-executive members. 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 Board Members have no significant interests to disclose which may conflict with their responsibilities.

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 Lisa Arnold, a non-executive Agency Board Member.

External auditors. The Comptroller and Auditor General is appointed as the MHRA's external auditor. The cost of the statutory audit for 2007/08 was £0.098M (2006/07: £0.121M).

No non-audit work was undertaken by the Comptroller and Auditor General.

Post balance sheet events. There have been no significant post balance sheet events between the period under review and the date of issue of this Annual Report and Accounts.

Agency Board


Sir Alasdair Breckenridge


Lisa Arnold


Shelly Dolan


Michael Fox


Charles Kernahan


Angus MacKay


Garry Watts
standing down 22 May 2008

Executive Board


Kent Woods


Peter Commins


Ian Hudson


June Raine


Gerald Heddell


Shaun Gallagher


Geoff Le Fevre


Clive Bray


Alison Davis


Susanne Ludgate


Simon Gregor

Performance against key targets 2007/08

1 Move to full electronic working and electronic Common Technical Document (eCTD) standard: a) 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; b) 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; c) Introduction of a plan for full compliance with electronic E2B reporting of adverse drug reaction reports;	Achieved
2 a) 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; b) Lay the Agency's 2006/7 annual accounts, unqualified, before Parliament by the Summer recess; c) Set a balanced budget for 2008-09; and d) Identify the Agency's medium term financial model.	Achieved
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.	Achieved
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: a) New Product Licences granted in National, Mutual Recognition or Parallel Import procedures; b) Variations to National (Type II, non-safety) or Parallel Import licences; c) Introduce the regular publication of a range of performance information agreed, in discussion with the industry associations, on the Agency website from April 2007.	Achieved
5 Complete assessment of clinical trial authorisations for medicines: a) at least 98% in 30 calendar days; and b) with an average of 14 calendar days or less for Phase I (healthy volunteer) trials. Complete assessment of clinical investigation notifications for medical devices: c) at least 98% in 60 days; d) with an average of 54 days or less.	Achieved

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: a) 3 for fatal and serious device adverse incidents; b) 3 for fatal adverse drug reactions and 5 for serious reactions; c) 7 for identification and transmission of suspected medication errors to the National Patient Safety Agency.	(a) - 3 for fatal and serious device adverse incidents – achieved. (b) - 3 for fatal adverse drug reactions and 5 for serious reactions - achieved. (c) - 7 for identification and transmission of suspected medication errors to the National Patient Safety Agency - Partially achieved for reporting year - 86%, due to procedural and IT related issues identified in September 2007. Issues have now been corrected and it is noted that for last quarter target was achieved at 100%.
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.	**Achieved**
8 Continue to improve the transparency of decision making within the Agency and accountability to the public by: a) publishing UK Public Assessment Reports for medicinal products licensed within 60 days of final determination; b) providing summaries of the evidence supporting major safety decisions within one month of final regulatory decision; c) introducing the quarterly publication (as appropriate) of identified drug safety signals and MHRA action to ensure transparency; d) 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.	(a) Not achieved. The total number of UKPARs published over the year was 312 with 144 published within 60 days giving a cumulative performance figure of 46%. All products authorised in March had UKPARs published within 60 days thus meeting the 100% target. The backlog of UKPARs exceeding the 60 day target has been eliminated. (b) Achieved (c) Achieved (d) Not achieved. In 2007/08 as a whole the figure is 81.2%. FOI Policy Unit will adopt a pro-active closer scrutiny of all progress of cases on a weekly basis and alert senior management where the target looks not to be achieved.
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.	**Achieved**
10 Take actions to progress the Government's Better Regulation agenda: a) 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. b) Consider and respond in detail to external suggestions for simplification of regulations within the 90 days set by Cabinet Office; c) Develop and implement risk assessments for all inspection types; d) 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.	**Achieved**

Key targets 2008/09

Safeguarding public health

1 Ensure all reported adverse incidents (medicines and devices) are captured and input to databases as quickly as possible in order to allow prompt action, where necessary, to protect health:

Measures / Indicators

Maximum timescales between receipt of reports and making them available for evaluation and analysis:

a) For fatal and serious device adverse incidents: 100 per cent within 3 working days;

b) For fatal UK adverse drug reactions: 90 per cent within 24 hours, 100 per cent within 72 hours;

c) For serious UK adverse drug reactions: 95 per cent within 72 hours, 100 per cent within 5 working days;

d) For medication error notifications: identification and transmission to National Patient Safety Agency within 7 days.

2 Issue, through an effective process, public health link messages for medicines, 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:

Measures / Indicators

a) Feedback monitoring of effectiveness of alerts;

b) Publish medical device alerts within 60 working days of senior management agreement to issue a MDA; and immediate action MDAs within 20 working days of senior management agreement;

c) Issue public health link message in a timescale proportionate to the risk.

3 Tackle the threat from counterfeit medicines and devices through:

a) Implementing the actions set out in the Agency's Anti-Counterfeit Strategy;

b) Undertaking an examination of any weaknesses in the regulatory framework and proposing changes to legislation or practice.

Measures / Indicators

a) Deal with 90 per cent of reports of suspected counterfeits within 24 hours, and 100 per cent within 72 hours;

b) Host and chair 2 anti-counterfeit stakeholder meetings (Police/Customs/Regulators/Industry);

c) Conduct at least 2 targeted market surveillance programmes;

d) Provide support to the WHO IMPACT Counterfeiting taskforce;

e) Provide training in support of Council of Europe anti-counterfeiting initiatives;

f) Identification of potential changes to legislation or practice by March 2009.

Communicating effectively

4 Develop and promote the Agency's reporting systems for adverse events from medicines or medical devices to ensure the Agency has information to support effective decision-making:

Measures / Indicators

a) Delivery of on-going communications plan for the Yellow Card Scheme;

b) Minimum 10 per cent increase in reporting from all sectors from the Yellow Card Scheme by the end of 2008/09;

c) Increase volume of UK ADR reports via electronic systems - 80 per cent from industry and 30 per cent from yellow cards by end 2008/09.

5 Take steps to improve the Agency's communications with healthcare professionals:

Measures / Indicators

a) Implement a new cross-Agency suite of communications with pharmacists to ensure they have access to the right information at the right time and in an accessible way by implementing any agreed recommendations arising from the market research into pharmacists' communications needs. Recommendations for action to be agreed by September 2008, specifying certain actions which are to be completed by March 2009;

b) Produce *Drug Safety Update* monthly and promote its uptake;

c) Produce 6 editions of *One-Liners* and three education modules on individual devices;

d) Produce speciality specific web pages on the MHRA website starting with a pilot for Ophthalmology.

6 Agree a two-year action plan to develop the involvement of patients and the public with a view to improving the quality of decision-making within the Agency and the level of understanding of its work, and with reference to both product-specific decisions and wider policies:

Measures / Indicators

a) Action plan to be agreed by 31 March.

Key targets 2008/09 continued

Communicating effectively

7 Pursue agreed UK objectives agreed by Ministers in EU negotiations on changes to the regulatory framework, in order to improve safeguards and advance regulatory science, achieving outcomes consistent with better regulation principles; and transpose the revised Medical Devices Directives, meeting timescales and producing guidance for industry on new requirements:

Measures / Indicators

a) Pursue and achieve UK objectives on:
   - Changes to pharmacovigilance legislation
   - Revision of regulations governing variations to medicines licences
   - Possible further changes to the Medical Devices Directives

b) Draft Regulations and guidance published for consultation by May 2008;

c) Guidance published and Regulations laid before Parliament by December 2008.

8 Take actions to progress the Government's Better Regulation agenda, to ensure that the regulation of medicines and devices is proportionate and risk-based:

Measures / Indicators

a) Pursue MHRA actions set out in Department of Health Simplification Plan, and work with industry to monitor delivery of administrative burdens savings up to 2010;

b) Progress implementation of risk-based inspections for medicines, following consultation during 2007/08;

c) Take forward the Better Regulation of Medicines Initiative (BROMI), encouraging uptake of arrangements already introduced, and working to identify further changes;

d) Initiate project to revise and consolidate medicines legislation within Policy Division from 1 April 2008, publishing a formal work plan by September 2008;

e) If review takes place during 2008/09, achieve external accreditation of the Agency's compliance with Hampton and Macrory principles.

Running a Successful Organisation

9 Ensure the Agency's finances are sound and stable:

Measures / Indicators

a) Achieve an income and expenditure surplus during 2008/09, and as a minimum, exceed a 3.5 per cent per annum return on capital employed.

10 Ensure further improvement in the efficiency and performance of the core medicines licensing functions, in particular in areas where backlogs remain:

Measures / Indicators

Over the year as a whole, the numbers of applications determined (completed) to exceed the predicted numbers received by at least 10 per cent in each of the following areas of activity:

a) New Marketing Authorisations granted in National, Decentralised or Mutual Recognition procedures;

b) Major (Type II, non-safety) variations to Marketing Authorisations;

c) New Parallel Import Licences;

d) Changes to update Parallel Import Licence labels and patient leaflets.

11 Continue to work with external stakeholders to increase the submission of electronically formatted Marketing Authorisation submissions (eCTD):

Measures / Indicators

a) All UK national applications for new active substances to be received in eCTD format. 10 per cent of all new licensing applications to be in eCTD format from 31 March 2009;

b) European harmonised guidelines on eCTD published.

12 Ensure that the Agency trains and develops its staff to meet current and future needs for skills and expertise throughout the Agency's area of work:

Measures / Indicators

a) Develop an Annual Training Plan for the Agency, based on the needs identified by individuals and their line managers from Divisional Training Plans;

b) Achieve evaluation scores of at least 75 per cent for all courses, to demonstrate they are successful and meeting the Agency's needs;

c) Ensure that at least 80 per cent of staff who complete 3 month evaluation information are able to put their learning in to practice when they have the opportunity to do so.

Medicines and Healthcare products Regulatory Agency

Accounts for the year ended 31 March 2008

Contents

Management Commentary

1 Description of the business

The MHRA is an executive agency of the Department of Health and operates as a government trading fund. The Agency came into existence on 1 April 2003 on the merger of the Medicines Control Agency and the Medical Devices Agency. The Secretary of State for Health determines the policy and financial framework within which the MHRA operates, but is not involved in the day-to-day management of the Agency.

2 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.

3 Aims

The Agency's aims are:

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

4 Objectives

The Agency's strategic objectives are to:

- safeguard public health through our primary role in ensuring that the products we regulate meet required standards, that they work and are acceptably safe;
- carry out our communication role through the provision of accurate, timely and authoritative information to healthcare professionals, patients and the public;
- support research, ensuring through the application of Better Regulation principles that regulation does not stifle innovation;
- influence the shape of the future regulatory framework through use of our effective European and International relationships; and
- run an organisation with a skilled and equipped workforce that is fit for the future.

5 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 vigilance and other systems for reporting, investigating and monitoring adverse reactions to medicines, adverse incidents involving medical devices, and blood and blood products, and taking any necessary action to safeguard public health;
- 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 and the British Pharmacopeia (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.

6 Legal, Regulatory and External environment.

The Agency's Corporate Plan 2008-2013 (available on the MHRA website at http://www.mhra.gov.uk/home/groups/comms-sp/documents/publication/con014980.pdf) gives details of the legal, regulatory, operational and external environment, including key relationships with stakeholders.

7 Performance targets

The MHRA had ten key targets (set by the Minister) for 2007-08, for the successful achievement of its business objectives. An internal audit review of the outcome of the nine non-financial key targets confirmed that seven had been achieved and two not wholly achieved, although elements of the latter had been achieved. The one financial key target had also been achieved.

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

The key targets for 2008-09 are detailed within the Annual Report.

8 Statement of accounts

The Statement of Accounts has been prepared in accordance with a direction given by HM Treasury in pursuance of Section 4(6) of the Government Trading Funds Act 1973. The Accounts cover the period from 1 April 2007 to 31 March 2008.

9 Financial Review

Agency Financial Position

The MHRA was required to achieve at least a 3.5% return on average capital employed over the period 1 April 2003 to 31 March 2008, as detailed in the HM Treasury minute dated 9 May 2004 attached at the end of the Annual Report and Accounts. The total surplus required to be earned in the period was £2.4M, and following the surpluses earned in 2006-07 and 2007-08 as detailed below the total surplus earned over the 5 years was £4.5M, giving an excess return of £2.1M, which represents less than 1% of the Agency's turnover over the 5 year period.

Income and Expenditure

The total income for the year at £93.5M was 15% higher than 2006-07 income (£81.3M). This increase was attributable to two main reasons, an overall fees increase of 5%, coupled with an improvement in workflow throughout the financial year. Income from Licences and Inspections was £51.3M compared with £39.2M in 2006-07. Service fees were lower at £21.6M against £22.1M in 2006-07. Department of Health income was marginally lower at £11.0M (2006-07 £11.2M). Additional income from GPRD (General Practice Research Database), RAMA (Remote Access to Marketing Authorisations) and British Pharmacopeia of £4.2M, £1.0M and £2.1M respectively, was the main reason for the increase in Other income from miscellaneous activities from £8.9M in 2006-07 to £9.6M in 2007-08.

Total costs for 2007-08 at £89.6M were13% higher than the level of £79.7M in 2006-07. Staff numbers increased by 5% and total staff costs increased by 8% from £42.4M to £45.9M, whilst other operating costs increased from £31.1M to £38.8M. The depreciation charge decreased by £1.3M to £4.9M.

The operating surplus for 2007-08 was £3.8M, compared to £1.7M in 2006-07. For 2008-09 there is a planned operating surplus of £5.0M, based on both higher revenues and higher operating costs. An average increase in fees of 7% has been put in place with effect from 1 April 2008.

Interest receivable less payable amounted to £1.3M in 2007-08, compared with £0.5M in 2006-07.

After charging a public capital dividend amount of £0.3M (2006-07 £0.3M), the net surplus in 2007-08 was £4.8M, leaving a retained surplus carried forward into 2008 of £10.4M.

Assets and liabilities

At 31 March 2008, the Agency had tangible fixed assets of £21.8M, a reduction of £10.4M in the year, mainly due to the impairment of the GPRD asset to zero value following a value in use review by an independent consultant. Net current assets were £26.6M. After allowing for deferred revenue of £29.5M and long-term creditors and provisions of £5.7M, the total net assets were £13.2M.

Staff Resources

The most important asset of the Agency is its staff, and during the year an average of 875 full-time equivalent staff were employed which included those on short term contracts. The MHRA has undertaken a busy recruitment programme, successfully attracting suitably qualified staff covering the complete range of specialist and corporate roles in delivering medicines and medical devices regulation. Its recruitment practices are in accordance with the Civil Service Commissioners Code and this was recently confirmed in a recruitment audit.

The Agency has maintained and developed its knowledge capability through a comprehensive career development programme built on the individual, specialist and corporate needs of staff. A key feature has been the management and leadership programme which has delivered excellent results demonstrating improved performance for individuals and the Agency. Continuing professional development (CPD) has been actively encouraged across all professions and the Agency recently introduced an in-house programme of CPD for medical officers.

Diversity

The MHRA joined the Department of Health in making a commitment to the Single Equality Scheme which, as well as providing the mechanism for meeting the employment legislation duties, promotes the value of diversity including disabled people. As well as valuing and encouraging the contribution of diverse teams and individuals, we provide targeted support for those in need.

Staff Involvement and Consultation

Regular contact with staff is actively encouraged to involve them in the work of their team and the Agency. A performance management system is operated to enable managers and staff to discuss and agree objectives and measure performance on a half and full year basis. There are a variety of mechanisms for achieving two-way exchange of information including monthly team briefing, one to one, unit, divisional and Agency all-staff meetings. There is also regular consultation and negotiation with trade union representatives.

10 Risk Management

The Agency's risk management and internal control systems are the responsibility of the Executive Board, who are assisted by the Agency Board and the Risk and Audit Committee in a monitoring role. The Executive Board are responsible for the detailed identification, monitoring and review of the Agency's corporate risks, which range from public health, operational, reputational, financial and personnel issues to the Agency's stakeholder interests with the public, service users, ministers and other organisations both inside and outside of government.

Divisional risk registers maintained at operational level record the divisional risks identified and the actions taken to mitigate those risks in similar manner as for the corporate risk register. These are dynamic working documents, which are updated regularly in order to ensure that the risk registers reflect the current position.

An internal audit is commissioned annually to review various aspects of the Agency's corporate governance and risk management systems in order to ensure continuous improvement by identifying new areas where best practice could be adopted.

11 Sentinel

The MHRA's key business IT system, Sentinel, is used to manage all aspects of its activities related to the licensing of medicines, in addition to all of the Agency's core financial and HR processes. This is a bespoke system, integrating a number of commercial software applications with business workflow. The system was implemented between 2003 and 2006, to enable the Agency to fully adopt electronic working and move to new standards for electronic submission of information from clients. The MHRA continues to enhance the system, in order to fully exploit the capabilities which it provides.

12 Contractual arrangements

Accenture provide an outsourced IT contract to MHRA covering information technology infrastructure support, applications development, and maintenance services essential to the business of the Agency.

13 Payment of suppliers

The MHRA complies with the Better Payment Practice Code. Unless the amounts charged are considered to be in dispute, Agency policy is to settle invoices within contractual periods and, in the absence of contractual provisions, within 30 days of the date of receipt of goods and services or receipt of a valid invoice, whichever is later.

For invoices received between 1 April 2007 and 31 March 2008, 96% of invoices by number (2006-07: 95%) were paid in accordance with these terms.

No interest payments have been made under the provisions of the Late Payment of Commercial Debts (Interest) Act 1998.

14 Going concern

Based on normal business planning and control procedures, the Agency Board has reasonable expectation that the MHRA has adequate resources to continue in operational existence for the foreseeable future. For this reason the Board continues to adopt the going concern basis for preparing the financial statements.

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

15 Sustainable development

The Agency will continue to contribute to and support the UK Strategy for Sustainable Development through all of its working practices. The MHRA has an action plan that incorporates measurable targets for the Agency as well as encouraging best practice amongst its staff. The Agency's Sustainable Development Action Plan is available on the MHRA website at http://www.mhra.gov.uk/Aboutus/Sustainabledevelopment/CON014854 .

16 Data protection

The MHRA recognises the importance of respecting the privacy of all data subjects and the need for appropriate safeguards as defined by the Data Protection Act 1998. The Agency complies with the principles of the Act. As the MHRA is an Executive Agency of the Department of Health, the required data protection notification lodged with the Information Commissioner is included within the Department's notification. This can be viewed on the website of the Office of the Information Commissioner at http://www.ico.gov.uk/.

The protection of commercial and sensitive personal data is a priority for the Agency. In common with other Government bodies, the MHRA has been required to examine its processes for handling sensitive personal data and, while content that these are adequate, will be introducing further enhancements during the coming 12 months.

17 Freedom of information

The Freedom of Information Act creates a general right of access to all types of recorded information held by public authorities. The Act sets out exemptions from that right and places a number of obligations on public authorities. The MHRA seeks to be as open and transparent as possible and is committed to the implementation of the Act. The Agency already routinely places large volumes of information on its website. Information disclosed under the Act is published on the website as part of the Agency's disclosure log.

Remuneration Report

Service Contracts

Civil service appointments are made in accordance with the Civil Service Commissioners' Recruitment Code, which requires appointment to be on merit on the basis of fair and open competition but also includes the circumstances when appointments may otherwise be made.

With the exception of the Chief Executive (see below), the members of the Senior Management Team (Executive Board Directors) hold appointments which are open-ended. Early termination, other than for misconduct, would result in the individual receiving compensation as set out in the Civil Service Compensation Scheme.

Further information about the work of the Civil Service Commissioners can be found at www.civilservicecommissioners.gov.uk.

With the exception of the Chairman (who holds an open-ended appointment) the Agency Board Directors are appointed by the Department of Health. Appointments are for a four year term.

Salary and pension entitlements

The following sections provide details of the remuneration and pension interests of the most senior management (i.e. Executive and Agency Board members) of the Agency. Executive Board members salary and bonus awards were decided in a meeting between Professor Kent Woods, Lisa Arnold (Non Executive Director) and Harbhajan Singh Brar (DH HR Director). Professor Kent Woods', Professor Sir Alasdair Breckenridge's and Non Executive Directors' salary and bonus awards are set by DH through the Department's senior salaries review processes.

Remuneration

Executive Board	**2007-08 Salary £000**	2006-07 Salary £000
Professor Kent Woods - Chief Executive[1]	**215 - 220**	195 - 200
Mr Peter Commins - Chief Operating Officer	**135 - 140**	65 - 70[2]
Dr Ian Hudson - Licensing Director	**135 - 140**	125 - 130
Dr June Raine - Director of Vigilance & Risk Management of Medicines	**130 - 135**	120 - 125
Mr Gerald Heddell - Director of Inspection and Standards Division	**110 - 115**	100 - 105
Mr Shaun Gallagher - Director of Policy	**105 - 110**	90 - 95
Mr Geoff LeFevre - Director of Human Resources	**105 - 110**	90 - 95
Mr Clive Bray - Director of Device Technology & Safety	**95 - 100**	90 - 95
Mrs Alison Davis - Director of Information Management	**95 - 100**	90 - 95
Dr Susanne Ludgate - Clinical Director - Devices	**90 - 95**	90 - 95
Mr Simon Gregor - Director of Communications	**85 - 90**	80 - 85
Agency Board		
Professor Sir Alasdair Breckenridge - Chairman	**90 - 95**	80 - 85
Ms Lisa Arnold - Non Executive Director	**10 - 15**	5 - 10
Miss Shelley Dolan - Non Executive Director	**5 - 10**	5 - 10
Mr Michael Fox - Non Executive Director	**5 - 10**	5 - 10
Mr Charles Kernahan - Non Executive Director	**5 - 10**	5 - 10
Professor Angus Mackay - Non Executive Director	**5 - 10**	5 - 10
Mr Garry Watts - Non Executive Director[3]	**5 - 10**	5 - 10

The disclosures in this table are subject to audit by the Comptroller and Auditor General.

Salary

'Salary' includes gross salary; performance pay or bonuses; reserved rights to London weighting or London allowances; and any other allowance to the extent that it is subject to UK taxation. No benefits in kind are paid.

This presentation is based on payments made by the Agency and thus recorded in these accounts.

1 The Chief Executive is on secondment to the Agency from the University of Leicester commencing 1 January 2004 and ending on 31 May 2013. During 2007-08 the MHRA paid a total of £271,161 (2006-07: £244,400) to the University of Leicester to reimburse the University of Leicester for his annual salary and achievement bonus, employers national insurance and superannuation contributions.

2 The salary range quoted is for the period from when Peter Commins joined the Agency as Director of Operations & Finance on 29 August 2006 through to 31 March 2007. The full year equivalent would have been in the range of £115 - £120 p.a.

3 Mr Gary Watts resigned as a Non Executive Director with effect from 22 May 2008.

Pension Benefits

Neither the Chairman, nor Chief Executive, nor Agency Board Directors have any pension entitlement arising from their service with the MHRA.

The following table provides details of the pension entitlements of Executive Board Directors:

Name and title	Accrued pension at pension age as at 31/3/08 and related lump sum £000	Real increase in pension and related lump sum at pension age £000	CETV at 31/3/08 £000	CETV at 31/3/07 £000	Real increase in CETV £000
Mr Peter Commins - Chief Operating Officer	55 - 60	2.5 - 5.0	926	768	36
Dr Ian Hudson - Licensing Director	25 - 30	0.0 - 2.5	413	332	25
Dr June Raine - Director of Vigilance & Risk Management of Medicines	30 - 35 *Plus lump sum of* 100 - 105	0.0 - 2.5 *Plus lump sum of* 2.5 - 5.0	742	642	9
Mr Gerald Heddell - Director of Inspection and Standards Division	5 - 10	0.0 - 2.5	118	71	35
Mr Shaun Gallagher - Director of Policy	15 - 20 *Plus lump sum of* 50 - 55	0.0 - 2.5 *Plus lump sum of* 2.5 - 5.0	242	185	19
Mr Geoff LeFevre - Director of Human Resources	15 - 20 *Plus lump sum of* 50 - 55	0.0 - 2.5 *Plus lump sum of* 0.0 - 2.5	404	371	-15
Mr Clive Bray - Director of Devices Technology & Safety	40 - 45 *Plus lump sum of* 120 - 125	0.0 - 2.5 *Plus lump sum of* 0.0 - 2.5	942	896	-68
Mrs Alison Davis - Director of Information Management	0 - 5	0.0 - 2.5	49	23	18
Dr Susanne Ludgate - Clinical Director - Devices	30 - 35 *Plus lump sum of* 100 - 105	0.0 - 2.5 *Plus lump sum of* 0.0 - 2.5	862	774	-7
Mr Simon Gregor - Director of Communications	10 - 15	0.0 - 2.5	132	100	8

The disclosures in this table are subject to audit by the Comptroller and Auditor General.

Civil Service Pensions

Pension benefits are provided through the Civil Service pension arrangements. From 30 July 2007, civil servants may be in one of four defined benefit schemes; either a 'final salary' scheme (**classic, premium** or **classic plus**); or a 'whole career' scheme (**nuvos**). These statutory arrangements are unfunded with the cost of benefits met by monies voted by Parliament each year. Pensions payable under **classic, premium, classic plus** and **nuvos** are increased annually in line with changes in the Retail Prices Index (RPI). Members joining from October 2002 may opt for either the appropriate defined benefit arrangement or a good quality 'money purchase' stakeholder pension with a significant employer contribution (**partnership** pension account).

Employee contributions are set at the rate of 1.5% of pensionable earnings for **classic** and 3.5% for **premium, classic plus** and **nuvos.** Benefits in **classic** accrue at the rate of 1/80th of final pensionable earnings for each year of service. In addition, a lump sum equivalent to three years' pension is payable on retirement. For **premium**, benefits accrue at the rate of 1/60th of final pensionable earnings for each year of service. Unlike **classic**, there is no automatic lump sum. **Classic plus** is essentially a hybrid with benefits in respect of service before 1 October 2002 calculated broadly as per **classic** and benefits for service from October 2002 calculated as in **premium**. In **nuvos** a member builds up a pension based on his pensionable earnings during their period of scheme membership. At the end of the scheme year (31 March) the member's earned pension account is credited with 2.3% of their pensionable earnings in that scheme year and the accrued pension is uprated in line with RPI. In all cases members may opt to give up (commute) pension for lump sum up to the limits set by the Finance Act 2004.

The **partnership** pension account is a stakeholder pension arrangement. The employer makes a basic contribution of between 3% and 12.5% (depending on the age of the member) into a stakeholder pension product chosen by the employee from a panel of three providers. The employee does not have to contribute but where they do make contributions, the employer will match these up to a limit of 3% of pensionable salary (in addition to the employer's basic contribution). Employers also contribute a

further 0.8% of pensionable salary to cover the cost of centrally-provided risk benefit cover (death in service and ill health retirement).

The accrued pension quoted is the pension the member is entitled to receive when they reach pension age, or immediately on ceasing to be an active member of the scheme if they are already at or over pension age. Pension age is 60 for members of **classic, premium** and **classic plu**s and 65 for members of **nuvos**.

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

Cash Equivalent Transfer Values
A Cash Equivalent Transfer Value (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 figures include the value of any pension benefit in another scheme or arrangement which the individual has transferred to the Civil Service pension arrangements. They also include any additional pension benefit accrued to the member as a result of their purchasing additional pension benefits at their own cost. CETVs are calculated within the guidelines and framework prescribed by the Institute and Faculty of Actuaries.

Real increase in CETV
This reflects the increase in CETV effectively funded by the employer. It does not include 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.

Professor Kent Woods
Chief Executive and Accounting Officer
Medicines and Healthcare products Regulatory Agency
18 June 2008

Statement of Agency's and Chief Executive's Responsibilities

Under Section 4(6)(a) of the Government Trading Funds Act 1973, HM Treasury has directed the Medicines and Healthcare products Regulatory Agency (MHRA) 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 state of affairs of the MHRA and of its income and expenditure, recognised gains and losses and cash flows for the financial year.

In preparing the accounts, the Accounting Officer is required to comply with the requirements of the *Government Financial Reporting Manual* and in particular to:

- observe the Accounts Direction issued by HM Treasury, including the relevant accounting and disclosure requirements, and apply suitable accounting policies on a consistent basis;
- make judgements and estimates on a reasonable basis;
- state whether applicable accounting standards as set out in the *Government Financial Reporting Manual* have been followed, and disclose and explain any material departures in the accounts;
- prepare the accounts on a going concern basis.

HM Treasury has appointed the Chief Executive of the MHRA 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 MHRA's assets, are set out in the Accounting Officer's Memorandum, issued by HM Treasury and published in *Government Accounting*.

Statement on Internal Control

Year ended 31 March 2008

Scope of responsibility

As Accounting Officer, I have responsibility for maintaining a sound system of internal control that supports the achievement of the Medicines and Healthcare products Regulatory Agency's policies, aims and objectives, whilst safeguarding the public funds and Agency assets for which I am personally responsible, in accordance with the responsibilities assigned to me in Managing Public Money.

The Medicines and Healthcare products Regulatory Agency (MHRA) is an executive agency of the Department of Health and operates as a trading fund. The MHRA came into existence on 1 April 2003 on the merger of the Medicines Control Agency and the Medical Devices Agency. I was appointed as Chief Executive on 1 January 2004 and I have been the Accounting Officer throughout the year to 31 March 2008.

The Agency Board, the Executive Board and the Risk and Audit Committee support me in my role as Accounting Officer. The Agency's risk management system was developed on guidance from the Department of Health, HM Treasury, the National Audit Office and Internal Audit. A representative from the Department of Health attends the Agency Board and Risk and Audit Committee meetings. Internal audit services during the year have been provided by RSM Bentley Jennison, who operate in accordance with the Government Internal Audit Standards. The external audit is conducted by the Comptroller and Auditor General.

The purpose of the system of internal control

The Agency's system of internal control is designed to manage risk to a reasonable level rather than to eliminate all risk of failure to achieve policies, aims and objectives; it can therefore only provide reasonable and not absolute assurance of effectiveness. The system of internal control is based on an ongoing process designed to identify and prioritise the risks to the achievement of the Agency's policies, aims and objectives, to evaluate the likelihood of those risks being realised and the impact should they be realised, and to manage them efficiently, effectively and economically. The system of internal control has been in place in the Medicines and Healthcare products Regulatory Agency for the year ended 31 March 2008 and up to the date of approval of the annual report and accounts, and accords with Treasury guidance.

Capacity to handle risk

The Agency's Standard Operating Procedure on Risk Management and the associated Guide to Risk Management are both reviewed and updated as appropriate; these documents are available to staff on the MHRA Intranet. Information about corporate governance and risk management is also included in the induction pack for new staff.

A dedicated corporate risk management unit provides support and advice on risk management issues where required. This unit also chairs the cross-agency Risk Management and Audit Liaison Group.

The systems for corporate governance, risk management and internal control are monitored by the Agency Board, the Executive Board and the Risk and Audit Committee, and have been in existence throughout the year, except as noted in the section on significant internal control issues.

The Executive Board are responsible for the identification, monitoring and review of the Agency's corporate risks and they maintain corporate responsibility for the operation of the risk management system.

An internal audit is commissioned annually to review various aspects of the Agency's corporate governance and risk management systems in order to ensure continuous improvement by identifying new areas where best practice could be adopted. The current year's review on corporate governance centred on the Agency's governance arrangements with particular reference to the extent of the Agency's compliance with the Treasury's 2007 Audit Committee Handbook. Substantial assurance was received in this area, with the audit report confirming inter alia that the terms of reference for the Agency's Risk and Audit Committee had been updated to comply with the Treasury Handbook. The audit on risk management evaluated the process by which management manage and mitigate identified risks and also considered the exercise undertaken by management to refresh the corporate risk register. The report concluded with a substantial assurance that risks material to the achievement of the Agency's objectives for this area were adequately managed and controlled.

The risk and control framework

Risk assessments are undertaken through various means, including round table discussions. The consideration of risk includes those on public health in relation to the safety, quality and efficacy of all medicines and devices, operational, financial and human resource issues, the Agency's reputation, public interests, service user interests, ministerial interests and other aspects of relationships both inside and outside of government. The identification and management of risks are integrated into the Agency's planning system.

The Agency's corporate risk register is reviewed quarterly by the Executive Board and updated as appropriate. Each corporate risk is vested in a specific Executive Board member, who owns and monitors the particular risk. The corporate risk register is also subjected to regular review by the Risk and Audit Committee.

During the year a thorough re-examination of the Agency's corporate risk register was undertaken by means of a dedicated seminar facilitated by the National Audit Office, at which the Executive Board revisited the corporate risks facing the Agency. This resulted in a more focussed corporate risk register containing the Agency's major corporate risks.

Divisional risk registers maintained at operational level record the divisional risks identified and the actions taken to mitigate those risks in a similar manner as for the corporate risk register. These are dynamic working documents, which are updated regularly in order to ensure that the risk registers reflect the current position.

The cross-agency Risk Management and Audit Liaison Group, formed in 2004-05 to strengthen the Agency's risk management system, have had regular meetings through the year. It is a forum where divisional risk and audit issues are discussed and monitored by senior representatives from all Divisions of the Agency. If appropriate, remedial action is recommended to the Executive Board.

Divisional Heads in accordance with their stewardship roles, are required to complete an annual statement of accountability, confirming that effective systems of internal control have been in place within their areas of responsibility, throughout the particular period under review.

Following a number of high profile incidents of data losses in other public sector organisations, the Agency submitted a return to the Department of Health on its arrangements for data security and re-stated its position that all laptops and removable media devices containing person-identifiable data must be encrypted. I am aware of my responsibilities in respect of personal data and am taking steps to address any identified issues.

Information assets within the Agency are handled in accordance with GSI (Government Secure Intranet) standards. Information Governance risks are reviewed regularly and escalated to the Agency's corporate risk register where appropriate. The Agency is now involved in the Department of Health's Information Governance Assurance Programme (IGAP) and is working to ensure that all appropriate policies are adhered to. The Agency already has in place policies regarding the acceptable use and security of data.

Information is retained centrally on servers in a secure remote hosting facility and is backed up on a daily basis. The information is scanned regularly for viruses. User access is strictly controlled in accordance with written procedures. The Agency has a clear disaster recovery plan, with ITSR (Information Technology Service Restoration) exercises being carried out twice yearly. Secure transfer of information to companies takes place via the MHRA Portal, this being SAFE (Signatures and Authentication For Everyone) compliant. The Agency has BS7799 accreditation.

The Internal Auditors adopt a risk based approach in their annual programme of audits of the Agency's operations. This programme is detailed in an audit needs assessment, which is discussed by the Executive Board and the Risk and Audit Committee. During the year follow-up audits are conducted to monitor management's compliance with the previously agreed recommendations. The outcome of these internal audits is summarised in an annual report, prepared by the Internal Auditors for the Agency's Accounting Officer.

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 Divisional Heads within the Agency who have responsibility for the development and maintenance of the internal control framework, and comments made by the external auditors in their management letter and other reports. I have been advised on the implications of the result of my review of the effectiveness of the system of internal control by the Agency Board, the Executive Board, and the Risk and Audit Committee, and a plan to address weaknesses and ensure continuous improvement of the system is in place.

Agency and Executive Boards

The Agency Board consists of a Chairman, six non-executive members and the Chief Executive (CE) of the Agency. The Agency Board had regular meetings during the year to 31 March 2008, 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, consisting of the Heads of Divisions and the CE, also convened regularly during the year to 31 March 2008, to undertake their executive responsibility for the strategy, operational management, corporate risk management and service delivery of the Agency.

Quarterly reports were received by the Executive Board, setting out the Agency's key performance targets and monitoring their progress. The reports also brought to the Executive Board's attention any control issues through the early warning processes embedded within the Agency's business operations.

A register of interests is maintained for all staff including Executive Board members. Agency Board and Risk and Audit Committee members declare any interests at the start of each meeting.

Risk and Audit Committee

The Risk and Audit Committee is an integral part of the Agency's risk management system, and reports independently to the Accounting Officer and the Agency Board on the effectiveness of the operation of the Agency's corporate governance, risk management and internal control systems. The Committee which is chaired by a non-executive Agency Board member, held four meetings during the year to 31 March 2008. The main issues discussed were the effectiveness of the Agency's corporate governance, risk management and internal control systems, including the 2006-07 Internal Audit annual report, the 2006-07 Statement on Internal Control, the 2006-07 Annual Report and Accounts, the 2006-07 National Audit Office management letter on internal control, the various Internal Audit progress reports for 2007-08, and the strategy and timetable for the 2007-08 external audit of the MHRA financial statements. All of these influenced the Risk and Audit Committee in its advice to the Accounting Officer on the level of assurance in relation to corporate governance, risk management and internal control within the Agency.

Internal Audit

The role of the internal audit service is to provide an independent and objective opinion to the Accounting Officer on risk management, governance and control, by measuring and evaluating their effectiveness in achieving the organisation's agreed objectives. Risk management, governance and control comprise the policies, procedures and operations established to ensure the achievement of objectives, the appropriate assessment of risk, the reliability of internal and external reporting and accountability processes, compliance with applicable laws and regulations, and compliance with the behavioural and ethical standards set for the organisation.

The Agency's internal audit service during the year was provided by RSM Bentley Jennison under a three-year contract, which commenced on 1 April 2005, on the expiry of the previous three-year contract, also with Bentley Jennison. From 1 April 2008, the firm of PricewaterhouseCoopers has been appointed as the Agency's internal auditors for a period of three years.

The partner in charge of the Agency's internal audit service performs the role of Head of Internal Audit. He produces regular reports on the adequacy and effectiveness of the systems of internal control in various operational areas, including finance, and suggests recommendations for improvement, through an action plan.

The internal audit plan for 2007-08 devoted just over a third of its resources to the financial control systems with the remaining effort being deployed on other aspects of the Agency's operations, including information technology, risk management and corporate governance. The internal audit team completed seventeen audits, which support the annual assurance statement. Seven of these audits (including risk management, corporate governance and financial follow up) received substantial assurances, eight received adequate assurances and although two (conference income & expenditure and payroll) received limited assurances, there were no fundamental recommendations.

Action plans to address the recommendations in the internal audit reports were agreed by operational management, and co-ordinated by the Agency's risk management team. The implementation of the non-financial recommendations made in a number of previous reports was subject to a follow-up audit during the year and received an assurance of 'reasonable progress'. Where the implementation of recommendations was not achieved by 31 March 2008, the action plans were carried forward into 2008-09.

The Head of Internal Audit has in addition provided an independent opinion and an overall annual assessment of the Agency's systems of corporate governance, risk management and internal control. The report concluded that in his opinion for the twelve months ended 31 March 2008, with the exception of conference income & expenditure and payroll, the Agency had adequate and effective risk management, control and governance processes to manage the achievement of the organisation's objectives and further that the Agency continued to develop and maintain a sound control structure to mitigate its risks.

Significant internal control issues
The recommendations made in the conference income & expenditure and payroll internal audit reports have been brought to my attention. Action plans where appropriate have been agreed and implementation is to be completed early in the coming year.

Accounting Officer's comment
I am satisfied, based on the advice given to me by the Head of Internal Audit, the Agency Board, the Executive Board and the Risk and Audit Committee, that with the exception of the two areas highlighted above where effective remedial action is being undertaken, there are adequate and effective risk management, corporate governance and internal control systems to manage the achievement of the Agency's objectives.

Professor Kent Woods
Chief Executive and Accounting Officer
Medicines and Healthcare products Regulatory Agency
18 June 2008.

The Medicines and Healthcare products Regulatory Agency The Certificate and Report of The Comptroller and Auditor General to The Houses of Parliament

I certify that I have audited the financial statements of the Medicines and Healthcare products Regulatory Agency for the year ended 31 March 2008 under the Government Trading Funds Act 1973. These comprise the Income & Expenditure Account, the Balance Sheet, the Cashflow Statement and Statement of Total Recognised Gains and Losses and the related notes. These financial statements have been prepared under the accounting policies set out within them. I have also audited the information inthe Remuneration Report that is described in that report as having being audited.

Respective responsibilities of the Agency, 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 Trading Funds Act 1973 and HM Treasury directions made thereunder and for ensuring the regularity of financial transactions. These responsibilities are set out in the Statement of the Agency's and Chief Executive'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 the Government Trading Funds Act 1973 and HM Treasury directions made thereunder. I report to you whether, in my opinion, the information which comprises the management commentary and Chairman's foreword, Chief Executive Officer's report, MHRA at a glance, The year in review, Corporate Governance, Performance Against Key targets 2007-08 and Key targets 2008-09, included in the Annual Report, is consistent with the financial statements. I also report whether, in all material respects, the expenditure and income have been applied to the purposes intended by Parliament and the financial transactions conform to the authorities which govern them.

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

I review whether the Statement on Internal Control reflects the Agency's compliance with HM Treasury's guidance, and I report if it does not. I am not required to consider whether this statement coves all risks and controls, or 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 opinions

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 Trading Fund Act 1973 and directions made thereunder by HM Treasury, of the state of the Agency's affairs as at 31 March 2007 and of its surplus 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 the Government Trading Fund Act 1973 and HM Treasury directions made thereunder; and
- information, which comprises the management commentary and Chairman's Foreword, Chief Executive Officer's Report, MHRA at a glance, The year in review, Corporate Governance, Performance against key targets 2007-08 and Key targets 2008-09, included within the Annual Report, is consistent with the financial statements.

Opinion on Regularity

In my opinion, in all material respects, the expenditure and income have been applied to the purposes intended by Parliament and the financial transactions conform to the authorities which govern them.

Report

I have no observations to make on these financial statements.

T.J Burr
Comptroller and Auditor General
National Audit Office
151 Buckingham Palace Road
Victoria
London
SW1W 9SS
24 June 2008

Income and expenditure account

for the year ended 31 March 2008

Notes		2007-08 £000	2006-07 £000
3	Trading income	**82,460**	70,118
	Income from Department of Health	**11,003**	11,190
		93,463	81,308
5	Staff costs	**45,902**	42,371
7	Other operating costs	**38,835**	31,094
9	Depreciation	**4,888**	6,180
		89,625	79,645
	Operating surplus on ordinary activities	**3,838**	1,663
8	Interest receivable	**1,458**	644
8	Interest payable	**(148)**	(155)
	Surplus for the year on ordinary activities	**5,148**	2,152
	Dividend payable	**(322)**	(293)
14	**Retained surplus for the year**	**4,826**	1,859
	Opening retained surplus	**5,609**	3,750
	Retained surplus carried forward	**10,435**	5,609

NOTE: All operations were continuing during the year.

The Notes to the Accounts form part of these Accounts

Statement of total recognised gains and losses

for the year ended 31 March 2008

Notes		2007-08 £000	2006-07 £000
	Surplus for the year excluding dividend payment	**5,148**	2,152
	GPRD impairment	**(3,795)**	(610)
14	Unrealised surplus on revaluation	**31**	61
	Total recognised gains	**1,384**	1,603

The Notes to the Accounts form part of these Accounts.

Balance Sheet

as at 31 March 2008

Notes		31 March 2008 £000	31 March 2007 £000
	Fixed assets		
9	Tangible fixed assets	**21,758**	32,167
	Current assets		
10	Debtors	**20,842**	18,638
17	Cash at bank and in hand	**21,861**	18,119
		42,703	36,757
11	Creditors: amounts falling due within one year	**(16,137)**	(30,288)
	Net current assets	**26,566**	6,469
	Total assets less current liabilities	**48,324**	38,636
11	Creditors: amounts falling due after more than one year	**(1,728)**	(2,728)
12	Provisions for liabilities and charges	**(3,926)**	(293)
13	Deferred revenue	**(29,510)**	(23,817)
	Net assets	**13,160**	11,798
14	**Capital and reserves**		
	Public dividend capital	**1,329**	1,329
	Revaluation reserve	**142**	3,906
	Income & Expenditure reserve	**954**	954
	Government Grant reserve	**300**	-
	Retained surplus	**10,435**	5,609
	Total capital employed	**13,160**	11,798

The Notes to the Accounts form part of these Accounts

Professor Kent Woods
Chief Executive and Accounting Officer
Medicines and Healthcare products Regulatory Agency
18 June 2008

Cash flow statement

for the year ended 31 March 2008

Notes		2007-08 £000	2006-07 £000
15	**Net cash inflow from operating activities**	**8,276**	17,543
	Returns on investments and servicing of finance		
	Interest received	**1,383**	594
	Interest paid	**(744)**	-
	Dividend paid	**(1,190)**	-
	Loan Repayment	**(1,000)**	(1,000)
	Net cash inflow from returns on investments and servicing of finance	**(1,551)**	(406)
	Capital expenditure		
	Payments to acquire fixed assets	**(3,183)**	(6,253)
	Financing		
	Government grant received	**200**	-
17	**Increase/(Decrease) in cash for the year**	**3,742**	10,884

The Notes to the Accounts form part of these Accounts

1 Accounting policies

The financial statements have been prepared in compliance with the Government Trading Funds Act (1973) and with the accounting principles and disclosure requirements of the Government Financial Reporting Manual issued by HM Treasury which is in force for 2007-08. The accounting policies contained in the Guidance follow UK generally accepted accounting practice for companies (UK GAAP) to the extent that it is meaningful and appropriate to the public sector. Where the Guidance permits a choice of accounting policy, the accounting policy which has been judged to be most appropriate to the particular circumstances of the MHRA for the purpose of giving a true and fair view has been selected. The MHRA's accounting policies have been applied consistently in dealing with items considered material in relation to the Accounts.

a Accounting conventions

The Accounts have been prepared under the Historical Cost Convention, modified to allow for the revaluation of fixed assets other than IT assets and assets under the course of construction, at their value to the business by reference to their current costs.

b Fixed assets

Fixed assets include tangible fixed assets and the costs of acquiring or creating computer systems or software. The threshold for capitalising expenditure is £5,000. Only items or groups of related items with a combined value in excess of £5,000 are capitalised.

All assets excepting IT assets, assets under construction, RAMA XL and GPRD data are revalued annually using HM Treasury and appropriate Health Services Cost indices.

Assets under construction and IT assets, including the RAMA XL system, are shown at Historic Cost. Modified Historic Cost valuations are applied at the point the asset comes into use.

GPRD data assets are valued via an assessment of the future cash flows arising from exploitation of these assets discounted to net present values. Impairments arising from valuations are offset against the revaluation reserve as long as there is sufficient balance in the reserve, otherwise they are taken to other operating costs in the Income and Expenditure Account.

Surpluses and deficits arising on revaluation on non-GPRD data assets are treated in accordance with financial reporting standards. Where deficits occur these are taken to the revaluation reserve as long as there is sufficient balance in the reserve, otherwise they are taken to other operating costs in the Income and Expenditure Account.

Depreciation is provided on a straight line basis on all fixed assets, excepting assets under construction, at rates calculated to write off the cost or valuation (less any estimated residual value) of each asset over its expected useful life as shown below. Depreciation commences when assets are brought into use.

Personal computers and faxes	3 years
RAMA XL	4 years
Laboratory equipment	5 years
Computer servers, laptops and associated applications, Software, Office equipment, Furniture, Fixtures and Fittings	5 years
GPRD equipment	6 years
Sentinel architecture costs	10 years
Sentinel Software	remaining life of the Sentinel architecture
Office refurbishment costs, other than at Agency Headquarters	10 years
Office refurbishment costs, at Agency Headquarters	remaining life of the lease
GPRD database	20 years
Annual payments to GP's	remaining life of the GPRD database

The GPRD asset has been written down to a net book value of zero at the end of 2007-08. Depreciation has been charged for the whole year because the asset was in use up to 31 March 2008 with the impairment review taking place after the year end.

The depreciation calculations are detailed in note 9 of the accounts

c Recognition of income

The proportion of the fees receivable for licence applications, representing the work estimated to be outstanding to complete the processing of such applications, is carried forward to future periods.

d Foreign currencies

Transactions denominated in foreign currencies are translated into sterling at the rates of exchange ruling at the date of the transaction and open balances are translated at the balance sheet date. Monetary assets and liabilities denominated in foreign currencies at the balance sheet date are translated at the rates ruling at that date. The resulting exchange differences are dealt with in the Income and Expenditure Account for the year.

e Staff terms and conditions

The Agency's staff are civil servants in the Department of Health and are subject to centrally determined terms and conditions. Staff who are members of the Senior Civil Service (SCS), including members of the Executive Board, are covered by SCS central arrangements and the Department of Health's terms and conditions and other procedures governing implementation of the SCS, including the Senior Salaries Review Body's performance-related pay recommendations.

Past and present employees are covered by the provisions of the Principal Civil Service Pension Scheme (PCSPS) which is a defined benefit scheme and is unfunded and non-contributory. The Agency recognises the expected cost of providing pensions 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.

f Debtors provision

The provision for bad debt and credit note provision is reviewed each year and reflects the level of trade debtors that it is anticipated may result in either a bad debt or a requirement to issue a credit note.

g Operating leases

Operating lease rentals are charged to the Income and Expenditure account on a straight-line basis.

2 Financial objectives

The MHRA's financial objectives are set out in full in a HM Treasury Minute dated 9 February 2004, which is reproduced at the end of the notes to the accounts. The objectives are that the MHRA should be managed so that its revenue:

a) consists principally of receipts in respect of goods and services provided in the course of its funded operations;

b) is sufficient, taking one year with another, to meet outgoings that are properly chargeable to revenue account and to achieve an operating surplus equivalent to a 3.5% average return on net assets employed at current values;

Net asset values are shown on the Balance Sheet. The actual operating surplus for the year was £3.838M (2006-07 £1.663M). The Agency is required to pay dividends and interest to HM Treasury via the Department of Health each year equivalent to the 3.5% required rate of return after deducting interest payable. The dividend payable is £0.322M (2006-07 £0.293M).

The Agency plans its fee strategy so as to achieve a return averaged over the period 1 April 2003 to 31 March 2008 of at least 3.5% in the form of a surplus on ordinary activities before interest and dividends expressed as a percentage of average capital employed. This strategy will continue to apply for the period 1 April 2008 to 31 March 2013 when the Agency is again required to average a 3.5% return.

3 Income

	2007-08 £000	£000	2006-07 £000	£000
Licences and inspections income recognised during the year	**51,268**		39,167	
Service fee income recognised during the year	**21,552**		22,056	
Income from miscellaneous activities	**9,640**		8,895	
Trading Income		**82,460**		70,118
Income from Department of Health		**11,003**		11,190
		93,463		81,308

	2007-08 £000	£000	2006-07 £000	£000
Licences and inspections				
Applications	**25,483**		18,149	
Clinical trials	**1,748**		1,598	
EMEA	**4,259**		3,881	
Inspection	**7,394**		6,327	
Renewals	**99**		159	
Variations	**11,016**		8,023	
Other	**1,269**		1,030	
		51,268		39,167
Service fees		**21,552**		22,056
Miscellaneous income				
British Pharmacopoeia	**2,104**		1,772	
GPRD	**4,230**		3,947	
Remote Access to marketing Authorisations	**974**		912	
Seminar and twinning	**1,175**		1,053	
Other	**1,157**		1,211	
		9,640		8,895
Trading Income		**82,460**		70,118
Department of Health funding		**11,003**		11,190
		93,463		81,308

Income is stated net of trade discounts, VAT and other taxes.

EMEA income relates to assessments of medicines and drugs, scientific advice provided and inspections undertaken on behalf of the European Medicines Evaluation Agency.

4 Segmental analysis

Treasury Guidance on Fees and Charges is applied when setting fee levels for the MHRA. Fees are set following consultation with Industry, the Department of Health and HM Treasury, and are intended, taking one year with another, to cover the costs of the Agency. Department of Health funding in relation to devices activities is intended to cover the costs of providing this specific service.

	2007-08 Devices £000	**2007-08 Medicines £000**	2006-07 Devices £000	2006-07 Medicines £000
Trading income	**376**	**82,084**	339	69,779
Income from Department of Health	**11,003**	**-**	11,190	-
	11,379	**82,084**	11,529	69,779
Operating costs	**(9,980)**	**(79,645)**	(10,583)	(69,062)
Operating surplus/(deficit)	**1,399**	**2,439**	946	717

5 Staff costs

	2007-08 £000	2006-07 £000
Salaries and wages	**34,361**	31,784
Social security costs	**3,107**	2,928
Pension contributions	**7,180**	6,513
	44,648	41,225
Agency and other staff costs	**1,069**	1,038
Early retirement and redundancy costs	**185**	108
	45,902	42,371

6 Employee details

The average number of full-time equivalent persons employed by the Agency during the year was:

	2007-08	2006-07
Chairman	**1**	1
Executive Directors	**10**	10
Senior Civil Servants	**266**	248
Other Civil service staff	**531**	506
Secondees (includes Chief Executive)	**2**	2
Short-term contracts	**65**	64
	875	831

7 Other operating costs

	2007-08 £000	2006-07 £000
Computing	**10,146**	9,468
Accommodation	**7,254**	8,276
GPRD fixed asset impairment	**4,280**	610
Increase in Provisions	**3,550**	-
Medicines testing and laboratory expenses	**1,878**	1,570
Travel and subsistence	**1,800**	1,935
Net credit notes issued in respect of service fees	**1,750**	-
Other administration costs	**1,661**	2,006
Legal services	**1,236**	1,398
Telecommunication costs	**855**	771
Consultancy	**801**	1,125
Printing, stationery and distribution	**754**	712
Training	**738**	820
Committee costs	**601**	494
Contracted-out personnel and payroll services	**525**	466
Contracted-out administration services	**477**	624
Pharmacovigilance database and other costs	**322**	218
Marketing	**143**	221
Auditors remuneration - audit fee	**98**	121
Net increase in debt and credit note provision	**41**	-
Debt written off	**-**	53
Foreign exchange (gain)/loss	**(75)**	206
	38,835	31,094

a) The audit fee represents the cost for the audit of the financial statements carried out by the Comptroller and Auditor General. There was no fee payable for non-audit work.

b) Operating surplus is stated after charging the following for operating leases:

	2007-08 £000	£000	2006-07 £000	£000
Plant & Equipment:				
Catering equipment	**4**		28	
Photocopiers	**46**		32	
IT equipment	**539**		938	
		589		998
Other:				
Rent		**4,051**		4,737
		4,640		5,735

8 Interest Receivable and Payable

	2007-08 £000	2006-07 £000
Interest Receivable from banks	**1,458**	644
Interest Payable	**(148)**	(155)
	1,310	489

Until 31 January 2007 funds held in the Paymaster General's account earned interest at the rate payable on 'ways and means' advances. Since 1 February 2007 funds held in the Paymaster General's account earned interest at the REPO Rate minus 0.25%.

Interest payable of £0.148M (2006-07: £0.155M) is in respect of the loans from the Department of Health (see note 11).

9 Tangible Fixed Assets

	Totals £000	Computer and telecom. equipment £000	Computer systems and software £000	Laboratory equipment £000	Fittings, furniture and office equipment £000	Assets under construction £000	RAMA XL £000	GPRD data £000
Cost or valuation								
At 1 April 2007	52,809	2,123	28,899	1,099	3,962	184	1,834	14,708
Additions	3,265	618	663	-	153	872	-	959
Disposals	(942)	-	(669)	-	-	-	(273)	-
Indexation	51	-	-	11	40	-	-	-
Revaluation	(8,076)	-	-	-	-	-	-	(8,076)
Transfers	-	-	-	-	-	-	-	-
At 31 March 2008	**47,107**	**2,741**	**28,893**	**1,110**	**4,155**	**1,056**	**1,561**	**7,591**
Depreciation								
At 1 April 2007	20,642	1,414	9,803	699	1,313	-	497	6,916
Disposals	(201)	-	(201)	-	-	-	-	-
Indexation	20	-	-	7	13	-	-	-
Charge for the year	4,888	361	2,822	134	580	-	316	675
At 31 March 2008	**25,349**	**1,775**	**12,424**	**840**	**1,906**	**-**	**813**	**7,591**
Net book value								
At 31 March 2008	**21,758**	**966**	**16,469**	**270**	**2,249**	**1,056**	**748**	**-**
At 1 April 2007	32,167	709	19,096	400	2,649	184	1,337	7,792

The GPRD data asset was valued at 31 March 2008 by consultants from the Agency's internal auditor, RSM Bentley Jennison (Chartered Accountants and Professional Services firm), on the basis of value in use. This has resulted in an impairment of £8.076M and reduces the Net Book Value to zero. £3.796M of this impairment has been charged against the balance held in the revaluation reserve and the remainder (£4.280M) has been charged to the Income & Expenditure account. The discount rate used was 2.2%, which is the Treasury discount rate.

During the course of the annual physical verification of Fixed Assets, a small number of assets were identified as being duplicated within the Agency's records. The adjustments for these items are shown in the disposals lines above.

10 Debtors

	31 March 2008 £000	31 March 2007 £000
Trade debtors	**15,901**	15,930
Other debtors	**214**	271
Prepayments	**2,411**	351
Accrued income	**1,527**	1,293
Value Added Tax	**789**	793
	20,842	18,638

Trade debtors are shown net of a provision for irrecoverable debts and credit notes of £6.268M (31 March 2007 £6.226M).

Debtors includes £0.789M (31 March 2007: £1.949M) due to the MHRA by the Department of Health as follows:

	31 March 2008 £000	31 March 2007 £000
Trade debtors	**-**	1,156
Value Added Tax	**789**	793
	789	1,949

11 Creditors

	31 March 2008 £000	31 March 2007 £000
Amounts falling due within one year		
Payments received on account	**10,028**	10,889
Trade creditors	**1,386**	8,945
Taxation and social security	**-**	969
Loan Repayment	**1,000**	1,000
Other creditors	**-**	1
Accrued expenses	**3,723**	8,484
	16,137	30,288

Creditors includes £2.342M (31 March 2007: £15.021M) due to the Department of Health as follows:

	31 March 2008 £000	31 March 2007 £000
Trade Creditors	**-**	8,230
Taxation and social security	**-**	969
Loan, Interest & Dividend Repayment	**1,470**	1,603
Accrued expenses	**872**	4,219
	2,342	15,021

	31 March 2008 £000	31 March 2007 £000
Amounts falling due after more than one year		
Due to Department of Health	**1,728**	2,728

An analysis of the maturity and interest rates of the medium-term loans is as follows:

	Total 2007-08 £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	2006-07 £000
Fixed interest rate							
4.15%	**-**	-	-	-	-	-	1,000
4.30%	**1,000**	1,000					1,000
4.35%	**400**		400				400
3.50%	**1,328**					1,328	1,328
At 31 March 2008	**2,728**	1,000	400	-	-	1,328	
At 31 March 2007	**3,728**	1,000	1,000	400	-	1,328	3,728

The second tranche of loan repayment was made during 2007-08, when £1M was repaid to the Department of Health

12 Provision for liabilities and charges

	31 March 2008 £000	31 March 2007 £000
Early retirement / voluntary severance		
Opening balance	**293**	249
Utilised during year	**(76)**	-
Provided in year	**-**	121
Unwinding of provision	**18**	(77)
Closing balance	**235**	293
Other provisions		
Opening position	**-**	-
Provided in year	**3,691**	-
Closing balance	**3,691**	-
Total provisions	**3,926**	293

Early retirement / voluntary severance
The provision is to cover the MHRA's estimated liability for pensions, until normal retirement date, of employees who, at the year end, had retired before normal retirement date.

Other provisions
Other provisions have been established during the year in respect of dilapidations on leases and also in respect of a claim arising from a medical retirement case.

13 Deferred revenue

	31 March 2007 £000	Movement £000	31 March 2008 £000
Licence fees (applications and variations)	21,494	5,183	**26,677**
Other fees	2,323	510	**2,833**
Total	23,817	5,693	**29,510**

The proportion of the fees receivable for licence applications, representing the work estimated to be outstanding to complete the processing of such applications at 31 March 2008, is carried forward to future periods.

14 Capital and reserves

	Total £000	PDC £000	Revaluation reserve £000	Income & Expenditure reserve £000	Government Grant reserve £000	Retained surplus £000
Balance at 31 March 2007	11,798	1,329	3,906	954	-	5,609
Movements 2007-08						
Impairment of Fixed Assets	(3,795)	-	(3,795)	-	-	-
Indexation	31	-	31	-	-	-
Receipt of Government grant	300	-	-	-	300	-
Surplus for year	4,826	-	-	-	-	4,826
Balance at 31 March 2008	13,160	1,329	142	954	300	10,435

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

	2007-08 £000	2006-07 £000
Operating surplus/(deficit)	**3,838**	1,663
Depreciation	**4,888**	6,180
Fixed Asset impairment	**4,280**	-
Loss and write-off of Fixed Assets	**741**	3,837
Revenue deferred to future periods (Note 13)	**5,693**	2,802
Increase in debtors	**(2,029)**	(259)
Decrease in creditors	**(12,768)**	3,276
Increase in provisions	**3,633**	44
Net cash inflow from operating activities	**8,276**	17,543

16 Reconciliation of net cash flow to movement in net funds

	2007-08 £000	2006-07 £000
Increase in cash for year	**3,742**	10,884
Movement in net funds	**3,742**	10,884
Net funds at end of previous year	**18,119**	7,235
Net funds at end of year	**21,861**	18,119

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

	Total £000	Cash at bank and in hand £000
Balance at 1 April 2007	18,119	18,119
Movements 2007-08		
Increase in cash at bank	3,742	3,742
Balance at 31 March 2008	21,861	21,861

18 Capital commitments

	31 March 2008 £000	31 March 2007 £000
Contracted	-	-
Authorised by the Management Board but not contracted	1,123	-

19 Contingent liabilities

The Department of Health has agreed that it will meet the costs of any liabilities arising from legal claims in respect of functions performed by the Agency and that such costs should not be met from the Agency's Trading Fund. Consequently, the Agency does not have any contingent liability in this regard.

20 Related party transactions

The MHRA is a Government Trading Fund and an executive agency of the Department of Health. The Department of Health is regarded as a related party. During the year, the MHRA has had a significant number of material transactions with the Department and with other entities for which the Department is regarded as the parent Department, notably various NHS Trusts.

In addition, the MHRA has had various material transactions with other government departments and other central government bodies. Most of these transactions have been with

- The Department of Work and Pensions, primarily for the purchase of legal services from the DWP (£1,024,000);
- The University of Leicester for the secondment of the Agency's Chief Executive (£212,335)
- The Veterinary Medicines Directorate (an Executive Agency of the Department for Environment, Food and Rural Affairs) primarily for the costs of inspections carried out by the MHRA on their behalf (£272,609);
- The National Audit Office (NAO – see Note 7 for details of the Audit fees) for the statutory audit; and
- The National School of Government for the MHRA's share of the investment funding of the National School of Government as agreed by the Civil Service Management Board (£78,000)

The value of total transactions and balances outstanding at the end of the year are set out below. No amounts were written off during the year.

	Income		Expenditure	
	Total value £000	Balance at 31 March 2008 £000	Total value £000	Balance at 31 March 2008 £000
Department of Health	13,881	789	47,037	2,342
Various NHS Trust	1,522	154	342	45
Department for Work and Pensions	16	-	1,024	1
Other government bodies	647	300	734	72
Local Authorities	-	-	1,221	8
Educational Bodies	260	0	213	-
	16,326	1,243	50,571	2,468

During 2007-08, none of the Board members, members of the key management staff or other related parties has undertaken any material transactions with the MHRA.

21 Losses and special payments

There were no other material losses or special payments during the year (2006-07: £nil) than elsewhere disclosed in the financial statements

22 Financial commitments

The MHRA has the following financial commitments due to expire in the following years:

	2007-08 £000	2006-07 £000
Land and buildings		
Expiry within 1 - 2 years	**56**	350
Expiry within 2 - 5 years	**3,518**	4,677
Leases which expire after 5 years	**72**	37
Other		
Expiry within 1 year	**419**	1
Expiry within 1 - 2 years	**113**	1
Expiry within 2 - 5 years	**-**	956

23 Financial instruments

FRS 13 'Derivatives and Other Financial Instruments' requires disclosure of the role financial instruments have had during the period in creating or changing the risks an entity faces in undertaking its activities. Because of the nature of the MHRA's activities, financial instruments play a much more limited role in creating or changing risk than is typical of the listed companies to which the FRS mainly applies.

The MHRA has very limited powers to borrow or invest surplus funds. Financial assets and liabilities are generated by day-to-day operational activities and are not held to change the risks facing the Agency in undertaking its activities.

As permitted by FRS 13, debtors and creditors that mature or become payable within 12 months from the balance sheet date have been omitted from the currency profile.

Fair value is not significantly different from book value.

Liquidity risk

The MHRA's resource and capital expenditure requirements are financed by revenues generated from its activities, with the exception of a loan facility with the Department of Health of £10.0M. (2006-07: £10.0M) This requires the Agency to ensure it has sufficient reserves of cash to enable it to undertake its statutory activities.

The table below provides details of cash balances held at the end of the year and the average rate during the year. Balances held in the commercial accounts are denominated in Euros and US dollars.

	2007-08 £000	Interest rate*	2006-07 £000	Interest rate*
Accounts				
Paymaster	**20,303**	4.09%	17,308	4.09%
Commercial	**1,558**	0.50%	811	0.50%
	21,861		18,119	

* The interest rates for both types of account are variable.

Interest rate risk

The MHRA is not exposed to significant interest rate risk. The average total of loans, which are at a fixed rate of interest, held throughout the year was £2.728M (2006-07:£3.728M). This resulted in interest payable of £0.148M (2006-07: £0.155M) out of total expenditure in excess of £90M (2006-07: £80M)

Currency risk

The level of currency risk is determined by the level of income generated by activity undertaken on behalf of the EMEA. For 2007-08 this was £4.259M (Euro 5.928M) (2006-07: £3.881M; Euro 5.712M). This represents 4.6% (2006-07: 4.8%) of the total gross income for the year. The Agency is potentially exposed to significant falls in the value of this currency; however, the risk is mitigated by the regular transfer of funds to the sterling accounts of the Agency.

Credit risk

The Agency is not exposed to significant credit risk.

24 Post-balance sheet events

There are no post-balance sheet events to report.

These accounts have been authorised to be issued on 24 June 2008 by the Accounting Officer.

HM Treasury minute dated 9 February 2004

1 Section 4(1) of the Government Trading Funds Act 1973 ("the 1973 Act") provides that a trading fund established under that Act shall be under the control and management of the responsible Minister and, in the discharge of his function in relation to the fund, it shall be his duty:

a to manage the funded operations so that the revenue of the fund:

- consists principally of receipts in respect of goods or services provided in the course of the funded operations; and

- is not less than sufficient, taking one year with another, to meet outgoings which are properly chargeable to revenue account; and

b to achieve such further financial objectives as the Treasury may from time to time, by minute laid before the House of Commons, indicate as having been determined by the responsible Minister (with Treasury concurrence) to be desirable of achievement.

2 A Trading Fund for the Medicines and Healthcare products Regulatory Agency was established on 1 April 2003 under the Medicines and Healthcare Products Regulatory Agency Trading Fund Order 2003 (SI 2003 No. 1076).

3 The Secretary of State for Health, being the responsible Minister for the purposes of section 4(1)(a) of the 1973 Act, has determined (with Treasury concurrence) that a further financial objective desirable of achievement by the Medicines and Healthcare products Regulatory Agency Trading Fund for the five-year period from 1 April 2003 to 31 March 2008 shall be to achieve a return, averaged over the period as a whole, of at least 3.5% in the form of a surplus on ordinary activities before interest (payable and receivable) and dividends expressed as a percentage of average capital employed. Capital employed shall equate to the total assets from which shall be deducted the total liabilities with the exception of the long-term element of the voted loans. However, in determining the value of the total assets, the following proportion of the value of the General Practice Research Database may be disregarded:

2003-04 - 100%
2004-05 - 75%
2005-06 - 50 %
2006-07 - 25%
2007-08 - 0%

4 Let a copy of this Minute be laid before the House of Commons pursuant to section 4(1)(b) of the Government Trading Funds Act 1973.

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