Safeguarding public health

MHRA

Annual Report and Accounts

2008/09

Medicines and Healthcare products Regulatory Agency

Medicines and Healthcare products
Regulatory Agency

Annual Report and Accounts 2008/09

Presented to Parliament pursuant to Section 4(6) of
the Government Trading Funds Act 1973 as amended
by the Government Trading Act 1990

Ordered by the House of Commons
to be printed 30 June 2009

HC661

London: The Stationery Office

£19.15

ISBN: 9780102959642

Contents

Chairman's foreword

The year began with the Agency in reflective mood – April 2008 marked our fifth birthday, and was a chance to look back on some of the major changes and developments of the previous five years.

I am confident that the changes we have made in structure, IT and culture offer us huge opportunities as we move forward.

Given this start to the year, it was appropriate that towards the year-end, our regular annual lecture also had a reflective theme. Prof Sir Michael Rawlins, the Chairman of the National Institute for Health and Clinical Excellence (NICE) spoke about the "Regrets of a Regulator". Drawing on a range of experience at the Committee on the Safety of Medicines, the Advisory Council on the Misuse of Drugs, and at NICE, he reflected on the challenges of monitoring the safety of medicines, the rising complexity and cost of clinical trials and the need for greater transparency and interaction with the public. All of these are key themes for the Agency, as you will see from this report.

On the theme of safety, the discovery of contaminated heparin products within the global supply chain has taxed regulators around the world over the last year. It reinforced concerns we have had for some time, in particular the global nature of supply chains, and the capacity for a contamination incident like this to have huge impact on the supply of life-saving medicines. Responding to the challenge meant drawing on expertise from across the Agency, across the UK and indeed around the world.

Counterfeits pose similar problems, for both medicines and devices, and the UK is recognised internationally as a leading player in the fight against counterfeit medicines and medical devices. On the one hand, we have taken successful action to prosecute those engaged in this illegal activity, and in securing strong sentences we have sent out the message that the UK is not a soft target for this type of activity. At the same time, we have to accept that we will never eliminate the criminal element, and it is vital that we take action to inform the public about the risks of counterfeit products – from condoms to heart drugs – and help them to minimise their risk, for example by avoiding inappropriate internet purchasing of products.

Where medicines have been shown to have a suitable safety profile, it is right that we take steps to widen access. A key example of this is our decision to make an antibiotic treatment for chlamydia available from high street chemists. This has only been possible as a result of the agreement on a pharmacy protocol with suitable safeguards and supply of a test kit, which allows for easy confirmation of a chlamydia diagnosis. Chlamydia is now the most commonly diagnosed sexually-transmitted infection in the UK, and these therapeutic developments demonstrate the significant public health impact which can be achieved by medicine and medical technology working in tandem.

We have also taken steps to enhance our performance further over the last year. All of our stakeholders – industry, healthcare professionals, researchers and patients – expect that we will deliver robust regulatory decisions in a timely way. There is no doubt that the timeliness of our decisions has been affected over recent years by some of the necessary but disruptive infrastructure changes we have made. It has been pleasing to see performance in most areas of the business fully back on track after this period of change.

It has also been gratifying to see the Agency gaining national and international recognition for its work in various awards schemes. The success of the Better Regulation of Medicines Initiative (BROMI), particularly in the National Business Awards, is discussed in more detail later in this report. Our Sentinel IT system was also shortlisted as a finalist in the E-Government Excellence Awards, whilst our Finance team was a finalist in the Accountancy Age Awards.

At the conclusion of a strong year for the Agency and with a number of significant new opportunities and challenges ahead of us, it remains only for me to thank all those who have made this possible. In particular, I would like to mention those partner organisations with whom we work both in the UK and abroad, the many and varied experts who sit on our independent advisory committees, and my fellow non-executive directors. We are grateful to all of you for your support in protecting public health.

Professor Sir Alasdair Breckenridge,
Chairman

Chief Executive's foreword

We live in challenging times – the public, industry and health providers are living with difficult constraints, pressures and expectations both of a financial and a cultural variety.

One of the key motivations behind the major changes we have made to the MHRA in the last five or six years – in IT, in financial systems, in structure and in Agency culture – has been to allow us to respond more rapidly and appropriately to the needs of our stakeholders. It is my hope and expectation that we will be able to respond in just such a way to the challenging times ahead.

Sir Alasdair has already referred to the incidents in the past year with heparin products. Although we have now dealt with the immediate issue, and the supply chain is being replenished with uncontaminated heparin, the long-term legacy will be just one of those challenges we have to face over the coming year. Working with others within the UK and internationally, we will have to consider in more detail and with greater urgency than before how we can maintain security of supply, and of the supply chain, within a truly global market. These are not trivial questions, nor are there readily available answers – but we must address these issues properly if we are to safeguard the health of UK and other citizens.

Ensuring acceptable safety is of course at the heart of what we do. A key role we play in safety concerns the regulation of what we call "borderline" products. These sit, as their name suggests, on the border of medicines or devices and other types of product, such as food supplements, cosmetics, dietary supplements or lifestyle products. Sometimes these differences are quite legitimate, but sometimes they are exploited by unscrupulous traders seeking to use loopholes in the law to market useless or even harmful products. As the range of products on the market diversifies, it will be vital for us to continue to work with other regulators to ensure that any such loopholes are closed, and that action is taken against those who violate the regulations and endanger public health.

Our job is to ensure that the benefits of products justify the risks. In taking decisions about the benefits and risks of the products we regulate, it is vital that we are informed by the views of our stakeholders, in particular healthcare professionals, patients and the public. Whilst we have taken steps over the last few years to try to understand the views of healthcare professionals, we have done less well in accessing and responding to the views of patients and the public. Over the course of the last year we have started to address this in the form of a patient and public engagement action plan, which we will implement in the coming months and years. It is only a beginning, and we are learning as we go along, but we hope to be able to work with patients and the public to ensure that their voice can properly influence our processes and decisions.

Seeking to meet the government's Better Regulation agenda is also a key theme for the Agency. Work on the Better Regulation of Medicines Initiative (BROMI) is mentioned elsewhere in this report, but that is very much the beginning and not the end of a process. Other initiatives, such as exploring the possibility of earlier access to medicines and moving to risk-based inspection, are priority areas for the coming year. At the time of writing, we are awaiting the final report from our inspection against the Hampton Principles of Better Regulation, and my hope is that the report will testify both to the work we have already done, and to the importance of the next steps.

The discipline of producing an annual report is in many ways an opportunity to reflect on the past, and to learn for the future. During the course of the last year, we have also been helped to do that by an external Department of Health review, which has for some time been scheduled for the fifth year of our existence. The report of that exercise is also still due at the time of writing, but I am grateful to all those who have been involved in it for giving us the opportunity to reflect on what we have done well, and what we can do better (or more of) as we move forward.

So a challenging future awaits us – whether it is in the field of better regulation, stakeholder engagement, management of the supply chain, or one of the many other issues which confront modern healthcare, there is much we have still to do.

Sir Alasdair concluded his comments by thanking all of our external stakeholders for their support. I would like to echo his comments, and also thank the staff of the Agency for all they have done over the last year. Nothing mentioned in this report could have happened without their enthusiasm, hard work and commitment to public health, and it is those same qualities which give me confidence that we will meet and respond well to the challenges with which the coming years present us.

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 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;
- 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.

Data protection

The protection of sensitive commercial and personal data is a priority for the Agency, which is reflected in the fact that its information governance processes are part of the internal audit review cycle. The Agency has had no incidents of loss of protected personal data in the last 12 months.

The year in review

Landmark events

Although the regulation of medicines and healthcare products has a longer history, the MHRA itself is still relatively young, and 1 April 2008 marked the celebration of our fifth birthday. The first five years saw a number of changes in organisational structure, information technology and Agency culture. The coming years will allow us to capitalise on the benefits of these changes, and ensure that we deliver the best possible service to all of our stakeholders.

> In early 2009 we embarked on a new campaign, and wrote to every GP practice in the country.

Our primary stakeholders are the public and patients who stand to gain most from the benefits, or potentially suffer most from the risks, of the products we regulate. In February 2009 we marked the first anniversary of nationwide patient reporting of suspected adverse drug reactions via the Yellow Card scheme. The purpose of introducing this scheme nationwide was to improve the volume and quality of information flowing into the Agency from patients. Public reports increased by 50 per cent over the course of the year, and the quality and content of these reports provides a valuable source of information from the patient perspective.

The Yellow Card scheme is of course not the only set of data we use for analysing safety issues. For example, we also manage and have access to the General Practice Research Database (GPRD), an anonymised sample of patient records which is a vital resource in tracking the benefits and risks of products. Over the last year, we have expanded the scope of the data to which GPRD researchers have access. In early 2009 we embarked on a new campaign, and wrote to every GP practice in the country seeking their input into a new Risk Management System, ExEtrac and to date we have had a very positive response.

In providing a good service to the public, it is vital that we take independent advice on the benefits and risks of the products we regulate. We have a panel of independent expert committees to fulfil this function, bringing together a diverse range of advisers including doctors, nurses, pharmacists, scientists and lay people. Of particular note in 2008 was the retirement of Mr John Williams CBE, FRCS as Chair of the Committee on Safety of Devices, after many years of valued service. He is replaced by Dr John Perrins, who has served on the committee since its formation.

The regulatory decisions which the Agency takes can have a huge impact on healthcare professionals working on the front line of the health service, and it is vital that we have good links with them. Our seventh national Medical Device Liaison Officer conference in November 2008 brought together staff from the NHS, social care and the private sector, and provided an opportunity for dialogue with this vital stakeholder group.

We also have a responsibility not to impose unnecessary burdens on the industries we regulate, as this serves only to delay the introduction of potentially beneficial new therapies to patients. The Better Regulation of Medicines Initiative (BROMI), which reformed the way in which we regulate basic changes to medicines, introduced a new self-certification scheme for making changes to medicines licences in April 2008, and was accompanied by a training programme for industry on how to use the scheme in May. BROMI won in the Better Regulation category of the National Business Awards in November, and was also a runner up in two categories of the Civil Service Awards.

Safety issues

The core function of the MHRA is to safeguard public health. This means facilitating access to beneficial therapies which have been shown to have an acceptable safety and quality profile. But it also means tackling potentially unsafe products and responding to new information which may change the benefit:risk balance of existing products.

During 2008, there was a worldwide problem with heparin, a product used to prevent blood clotting. Certain batches of this product were found to contain an impurity called oversulphated chondroitin sulphate, causing serious reactions and even fatalities in some parts of the world. Although contaminated product reached the UK, the level of contamination coupled with the way in which the product is used here meant that no serious adverse incidents were reported. However, we had to work closely with experts to assess the risks of the contamination and issue advice to healthcare professionals and the public; and with the Department of Health and the manufacturer to ensure continuation of supply of this vital product. This issue affected both medicines, and also diagnostic testing kits in which heparin is sometimes used.

> We have continued to investigate and, where possible, prosecute those engaged in illegal activities.

This incident involved responding to an unforeseen safety issue, but there are many occasions where we can be more proactive about safety surveillance. During 2008, a vaccination programme was rolled out for human papillomavirus (HPV) infection amongst girls and young women. HPV causes cervical cancer, and preventing HPV infection therefore has the capacity to deliver significant health gains. But as with any new vaccine, we needed to be alert to any unexpected safety issues. We therefore worked with the Department of Health and clinicians to put in place a proactive surveillance programme of suspected adverse drug reactions. The outputs from this have been published regularly on the MHRA website, to ensure full transparency for the public. To date, the vaccine continues to have a good benefit:risk profile.

Counterfeit health products are a major issue globally, and the UK has taken a leading role in tackling this issue. Public awareness, particularly of the dangers of buying medicines from unregulated websites, is crucial and we have used both media and advertising activity to reinforce these messages. Alongside this, we have continued to investigate and, where possible, prosecute those engaged in these illegal activities. The Agency has also conducted a thorough review of the supply chain which has resulted in recommendations to strengthen the current arrangements

Another safety concern has been the use of melanotan, an injectable product used to create an artificial tan. The product is unlicensed, and so there has been no opportunity to review how well it works, the standards to which it is made or its safety profile. Nonetheless, a number of suppliers are selling it illegally to members of the public. In addition, there is evidence that some product is being sold with insufficient needles, raising concerns about re-use or sharing of needles. We are investigating a number of suppliers, and have also taken steps to publicise the dangers widely through the news media.

The growing use of medical devices in patients' homes creates special challenges for regulators. During the year we investigated an increasing number of reports of injuries sustained by the public whilst using wheelchairs and hoists. This resulted in the publication of a wide range of guidance covering the appropriate selection and use of restraints and other safety features, in collaboration with other government agencies.

The year in review

Guidance for the use of intense pulse light sources and lasers in medical, surgical, dental and cosmetic procedures was updated to reflect changes in practice and legislation. The introduction of a Periodic Summary Reporting System for blood glucose meters has provided a more effective means of tracking trends in adverse incidents for this product group, enabling us to identify issues not previously evident from individual incident reports.

As an Agency, we are also the competent authority for blood and blood products. We have continued to operate the SABRE reporting system for adverse incidents and near misses involving these products, and to undertake inspections of blood banks and blood establishments. Where appropriate, we have worked with these organisations to address any concerns or deficiencies identified by the inspection process.

Modernising access to products

Modernising the way in which patients access treatments has been a key policy theme over recent years, whether in expanding the range of healthcare professionals who can prescribe certain products, or in making more products available directly to the public, provided such products have an acceptable safety profile.

Over the past year, the Agency has also reviewed and changed the availability of many cough and cold medicines for children.

In 2008, a major step forward in this area was in making the antibiotic azithromycin available without a prescription through pharmacies to patients with a laboratory-confirmed diagnosis of chlamydia infection. Chlamydia is the most commonly diagnosed sexually-transmitted infection in the UK, and rapid access to treatment is key in preventing its spread. The agreement on a robust pharmacy protocol to ensure safe supply, together with the availability of a test kit, was critical to this change in availability of azithromycin, as was careful planning to minimise the unnecessary spread of antibiotic resistance. This is the first oral antibiotic to be made available without a prescription; other possible candidates are under consideration, but the issue of managing resistance will be a key factor in the final decision on the availability of any antibiotic.

Sometimes, modernising access to products means restricting their availability where we think that the benefit:risk balance may have shifted. 1 April 2008 saw restrictions on pack size of decongestant medicines containing pseudoephedrine including a restriction on sale to one pack per transaction. This followed concerns about their use in the manufacturing of the Class A drug, crystal meth.

Over the past year, the Agency has also reviewed and changed the availability of many cough and cold medicines for children. Although there are no new safety concerns about these medicines, which have been used over many years, there is a growing recognition that we have little evidence on how well they work. Like any medicine, they can have side effects, so it makes sense to restrict their availability in younger children to avoid running any risk without the compensatory benefit.

Working with others

A great deal of evidence on the risks and benefits of the products we regulate comes not only from industry, but also from academic researchers.

To deliver successfully on its objectives, the Agency must work closely with other partner organisations. In the field of herbal medicines, for example, we have continued to work closely with the herbals industry to help them bring their products within the framework of the Traditional Herbal Medicines Registration scheme by 2011. The success of that scheme in safeguarding public health depends on effective regulation of herbalists as well, which is a matter for the wider Department of Health. We continue to work with DH colleagues on this as they consider the recommendations of the Pittilo report on the regulation of herbal and traditional Chinese medicine practitioners. The strength of our mandate for regulating these products has been confirmed by market research we commissioned which indicates that 77 per cent of adults believe that it is important that herbal medicines are regulated.

A great deal of evidence on the risks and benefits of the products we regulate comes not only from industry, but also from academic researchers. A good example of this was the ORACLE study, published in mid 2008, on the use of antibiotic treatment in pre-term labour. This was a research programme funded by the Medical Research Council (MRC), and it was helpful that the Agency was able to work with the MRC and the researchers themselves prior to the publication of the study to ensure that clear regulatory advice was communicated alongside the research findings.

User testing of patient information is another area where collaboration with independent researchers has been vital. Over the last few years, a great deal of research has been undertaken into how patient information leaflets (PILs) for medicines can be improved. From summer 2008, it has been a requirement on pharmaceutical companies to have user tested their leaflets for all existing products, and this is already leading to a significant improvement in the content and layout of information. More recently, research at Leeds University has started to explore the clarity of instructions for use of medical devices, and the Agency is discussing the findings with the research team to identify how we can improve the quality of device information.

As well as information on how to use specific devices, we have identified a need to support healthcare professionals in the use of devices generally. The range of devices on the UK market is vast – some 80,000 types of device in all – and pre-registration training for most healthcare professional groups on device use is limited. We have been working with a number of professional bodies to address this need – for example, we have developed a training leaflet with the Royal Pharmaceutical Society of Great Britain which will be sent to their members.

Alongside all this, it is vital that the Agency does more to engage with patients and the public. This emerged strongly as a theme in the Agency's consultation on strategic priorities in 2007, and as a result of that we committed new resource to the development of a patient and public engagement programme. This programme was agreed by the Board and published in March 2009, and will begin implementation immediately.

The year in review

Making information accessible

Managing the benefits and risks of products is not just about the decisions we take as a regulator. It is about the individual preferences expressed and decisions made by patients in discussion with the healthcare professional who is treating them. For these decisions to be informed, it is vital that we make as much information as we can publicly available.

The overall volume of content on our website has grown dramatically since its redesign in 2005.

Our website is one crucial mechanism by which we do this. Over the course of the last year we have developed areas for specific groups of healthcare professionals – in cardiology, obstetrics and gynaecology, ophthalmology, orthopaedics and pharmacy. We plan to expand this to other healthcare professional groups, and also to introduce areas for the public and for industry. The overall volume of content on our website has grown dramatically since its redesign in 2005, and we are also improving our search engine to respond to that.

Across the business, we have sought to prioritise our activities and assign resources accordingly.

The Long Term Leadership Strategy – a joint initiative between government and the pharmaceutical industry – has continued to deliver new initiatives over the course of the year. Two fora on topical issues have taken place – the first on evaluating the benefits and risks of medicines, which has led to new research proposals in this area; and the second on earlier access to medicines, the further exploration of which will involve an information-sharing and discussion exercise with key stakeholders.

For the industry, we have continued to produce guidance on regulatory issues. For example, there have been continuing concerns about problems with certain blood glucose meters, sometimes in relation to poor functionality and sometimes user error. We have developed guidance for industry on what we expect them to do by way of surveillance of these products once they are on the market.

We have also continued to strive to enhance our performance, ensuring that our regulatory decision making processes are thorough and robust but without introducing unnecessary delay or creating backlogs. Across the Agency, we have sought to prioritise our activities and assign resources accordingly, and for a number of areas we publish performance data on our website.

International collaboration

The European Commission has recently issued consultations on three aspects of medicines legislation

The MHRA operates in a global context, and international collaboration is vital to achieving our aims. Many of the standards which we enforce are based on European directives or regulations, and we have an important role in contributing to the European discussions and decision making. In November we completed a project to transpose into UK law the agreed European amendments to the Medical Devices and Active Implantable Medical Devices Directives. More recently, we have been working with European colleagues on the planned recast of Medical Devices Directives which is an ongoing project likely to extend over the coming months and years. In the field of medicines, we continue to play a key role as a rapporteur for European licensing procedures.

The European Commission has also recently issued consultations on three aspects of medicines legislation – enhancing pharmacovigilance provision across Europe, tackling counterfeit medicines, and improving the supply of information to patients. These are all critical issues for the UK, and the Agency is playing a central part in shaping the regulations or directives.

Beyond Europe, the Agency has a strong and growing range of international contacts. In the last year, this has included India, China, Singapore, Australia, Saudi Arabia, Ghana, the USA and Canada. With China, for example, we undertook a visit in October to develop further the links we had made on signing a Memorandum of Understanding in 2007. This allows us to exchange information and expertise on issues as diverse as traditional Chinese medicines, the supply of active pharmaceutical ingredients, and the management of counterfeit medicines.

Corporate Governance

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.

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

The Agency Board

The Agency Board consists of the Agency Chairman and seven non-executive Directors. 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 (see pages 20-21 for Agency Board meeting attendance and Register of Interests).

The Risk and Audit Committee

The Risk and Audit Committee is a sub-committee of the Agency Board and 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 Director.

The Executive Board

The Executive Board comprises the Chief Executive, the Chief Operating Officer and the other 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 also has responsibility for the Agency's resources.

The Board Members

The Board Members have no significant interests to disclose which may conflict with their responsibilities.

The Remuneration Report on pages 39 to 43 of the Annual Accounts gives details of the remuneration paid to the members of the Agency and Executive Boards.

External auditors

The Comptroller and Auditor General is appointed as the MHRA's external auditor. The cost of the statutory audit for 2008/09 was £98k. (2007/08: £98k)

During the year the Comptroller and Auditor General undertook an audit review of the Agency's restated balance sheet as at 1 April 2008 (31 March 2008 restated) as part of the HM Treasury trigger points measuring progress on the implementation of International Financial Reporting Standards which are being fully introduced from the start of the 2009/10 Financial Year. The cost for this work was £11k.

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

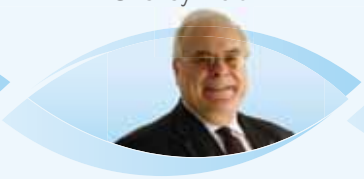

Lisa Arnold


Shelley Dolan


Michael Fox


Charles Kernahan


Angus MacKay


Barrington Furr


Vincent Lawton

Executive Board


Kent Woods


Peter Commins


Ian Hudson


June Raine

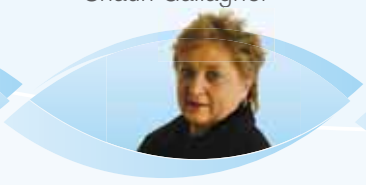

Gerald Heddell


Shaun Gallagher


Geoff Le Fevre


Clive Bray


Alison Davis


Susanne Ludgate


Simon Gregor

Corporate Governance

Agency Board meeting attendance 2008/09

	Sir Alasdair Breckenridge	Lisa Arnold	Shelley Dolan	Michael Fox
16 April 2008	✓	✓	✓	✓
22 May 2008	✓	✓	✓	✓
25 June 2008	✓	✓	✓	✓
23 July 2008	✓	✓		✓
24 September 2008	✓	✓		✓
15 October 2008	✓	✓		✓
19 November 2008	✓	✓	✓	✓
10 December 2008	✓	✓		✓
21 January 2009	✓	✓		✓
16 February 2009	✓	✓	✓	✓
18 March 2009	✓	✓	✓	✓
Total Meetings held = 11	11	11	6	11

Agency Board Awayday attendance 2008/09

	Sir Alasdair Breckenridge	Lisa Arnold	Shelley Dolan	Michael Fox
22 May 2008	✓	✓	✓	✓
19 November 2008	✓	✓	✓	✓

Risk and Audit Committee attendance 2008/09

	Lisa Arnold	Michael Fox	Charles Kernahan
12 June 2008	✓	✓	✓
15 October 2008	✓	✓	✓
21 January 2009	✓	✓	✓
18 March 2009	✓	✓	✓

	Charles Kernahan	Professor Angus MacKay	Garry Watts (Resigned May 2008)	Professor Barrington Furr (appointed July 2008)	Professor Vincent Lawton (appointed July 2008)
		✓	✓		
	✓	✓	✓		
	✓	✓			
		✓			
	✓	✓		✓	✓
	✓	✓		✓	✓
	✓	✓		✓	✓
	✓	✓		✓	✓
	✓	✓		✓	✓
		✓		✓	✓
	✓	✓		✓	✓
	8	11	2	7	7

	Charles Kernahan	Professor Angus MacKay	Garry Watts (Resigned May 2008)	Professor Barrington Furr (appointed July 2008)	Professor Vincent Lawton (appointed July 2008)
	✓	✓	✓		
	✓	✓		✓	✓

Corporate Governance

Register of interests

Lisa Arnold

Name of organisation	Nature of interest	Fee earning	Whether current
Allied Domecq Pension Funds Investment Committee	Independent Chairman	Yes	Current
Futura Medical PLC	Non Executive Director	Yes	Current
Kraft Foods Pension Fund	Independent Investment Specialist	Yes	Current
The Cheltenham Ladies' College	Council Member	No, voluntary	Current
The Restoration of Appearance and Function Trust (RAFT) - a medical research charity in the burns, wound healing area.	Trustee	No, voluntary	Current

Shelley Dolan

Name of organisation	Nature of interest	Fee earning	Whether current
Royal College of Nursing	Chair of RCN Cancer Forum	No	Current
The Royal Marsden NHS Foundation Trust	Executive Director	Yes	Current

Michael Fox

Name of organisation	Nature of interest	Fee earning	Whether current
Barnet, Enfield and Haringey NHS Mental Health Trust	NHS Mental Health Chairman	Yes	Current

Barrington Furr

Name of organisation	Nature of interest	Fee earning	Whether current
Abingworth	Consultancy	Yes	Current
Almac	Consultancy	Yes	Current
Almirall	Consultancy	Yes	Current
Astex	Consultancy	Yes	Current
AstraZeneca	Employee and Pension	Yes, salary	Current
Avesthagen	Consultancy	Yes	Not current
Avila	Consultancy	Yes	Current
Breast Cancer Campaign	Trustee	No payment	Current
CRUK	Trustee	No payment	Not current
CRUK Research Strategy Committee	Member	No payment	Current
Enkam	Consultancy	Yes	Not Current
Genus	Employee	Yes, salary	Current
Manchester Technology Fund	Board member	No payment	Current
Medivir	Consultancy	Yes	Current
Modern Biosciences	Consultancy	Yes	Current
MVM	Consultancy	Yes	Current
Palatin	Consultancy	Yes	Not current
Pharma Profiles	Consultancy	Yes	Not Current
Sequella	Consultancy	Yes	Current
Shroders Life Sciences	Consultancy	Yes	Current
Welsh Cancer Tissue Bank	Advisory Board member	No payment	Current

Corporate Governance

Charles Kernahan

Name of organisation	Nature of interest	Fee earning	Whether current
Assessor for the Advisory Committee on Clinical Excellence Awards (ACCEA)	Committee member	No, voluntary unpaid	Current
Bristol-Myers Squibb	Previous employee	Yes, salary and shares Pension	Not current Current
Cardio Vascular Coalition (CVC)	Committee member	No, voluntary unpaid	Current
European Kidney Alliance	Committee member	No, voluntary unpaid	Current
International Federation of Kidney Foundations	Committee member	No, voluntary unpaid	Current
Kidney Alliance	Committee member	No, voluntary unpaid	Current
Kidney Research UK	Employee	Yes, salary and benefits	Current

Vincent Lawton

Name of organisation	Nature of interest	Fee earning	Whether current
IMS	Consultancy	Yes	Current
Medeo Ltd	Shares	Shares	Current
Merck Sharpe & Dohme Ltd	Shares / options	Shares / options	Current

Angus Mackay

Name of organisation	Nature of interest	Fee earning	Whether current
AstraZeneca	Lecture	Yes - one off June 2008	No
Eli Lilly	Informal advice on antidepressants	No fee or other benefit accepted	Not current
The Sackler Foundation	Chair of the Scientific Advisory Committee of the Sackler Institute in Glasgow	No – but a substantial research grant to Glasgow University	Current

Performance against key targets 2008/09

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: 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;	Not Achieved All but **one** of the **8,909** adverse incident reports involving death or serious injury were available on AITS (Adverse Incident Tracking System) within 3 days of the report's receipt by MHRA during 2008/09.
b. For fatal UK adverse drug reactions: 90 per cent within 24 hours, 100 per cent within 72 hours;	Achieved
c. For serious UK adverse drug reactions: 95 per cent within 72 hours, 100 per cent within 5 working days;	Achieved
d. For medication error notifications: identification and transmission to National Patient Safety Agency within 7 days.	Achieved

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:	
a. Feedback monitoring of effectiveness of alerts;	Achieved
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;	
a. Deal with 90 per cent of reports of suspected counterfeits within 24 hours, and 100 per cent within 72 hours;	Achieved
b. Host and chair two anti-counterfeit stakeholder meetings (Police/Customs/ Regulators/Industry);	
c. Conduct at least two 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.	

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:	
a. Delivery of ongoing communications plan for the Yellow Card Scheme;	Achieved
b. Minimum 10 per cent increase in reporting from all sectors from the Yellow Card Scheme by the end of 2008/2009;	
c. Increase volume of UK ADR reports via electronic systems - 80 per cent from industry and 30 per cent from yellow cards by end 2008/2009.	

5

Take steps to improve the Agency's communications with healthcare professionals:	
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' communication needs. Recommendations for action to be agreed by Sept 2008, specifying certain actions which are to be completed by March 2009;	Achieved
b. Produce Drug Safety Update monthly and promote its uptake;	
c. Produce six 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.	

Performance against key targets 2008/09

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:	
a. Action plan to be agreed by 31 March.	Achieved

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:	
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	Achieved
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:	
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;	Achieved
b. Progress implementation of risk-based inspections for medicines, following consultation during 2007/8;	
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.	

9

Ensure the Agency's finances are sound and stable:	
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.	Achieved

10

Ensure further improvement in the efficiency and performance of the core medicines licensing functions, in particular in areas where backlogs remain: 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;	Achieved
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):	
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;	Not Achieved All National new MAAs (not including MR and DCP) are at 11.6% as eCTDs (target 100%). Total new MAA (not including Centralised) 7.6%
b. European harmonised guidelines on eCTD published.	Guidelines in draft form

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:	
a. Develop an Annual Training Plan for the Agency, based on the needs identified by individuals and their line managers from Divisional Training Plans;	Achieved
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 three month evaluation information are able to put their learning in to practice when they have the opportunity to do so.	

Key targets 2009/10

1

Ensure all reported adverse incidents (medicines and devices) are dealt with promptly and efficiently; and promote and develop the Agency's reporting systems:

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 days;

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

Promotion and development:

a. Delivery of ongoing communications plan for the Yellow Card Scheme;

b. Ensure 98 per cent of ADR reports from industry are submitted in electronic form by end of 2009/10;

c. Work with Connecting for Health on the introduction of direct to database ADR reporting from General Practice IT systems.

2

Issue, through an effective process, central alerting system messages for medicines, medical device alerts (MDAs) and other safety warnings, supported by relevant media activity where appropriate, which identify clear and appropriate action which recipients can achieve within realistic timescales:

a. Monitor effectiveness of alerts and take steps to improve where appropriate;

b. Publish medical device alerts within 60 working days of senior management agreement to issue a MDA;

c. Immediate action MDAs within 20 working days of senior management agreement;

d. Issue central alerting system message in a timescale proportionate to the risk.

3

Tackle the threat from counterfeit medicines and devices:

a. Assess 90 per cent of reports of suspected counterfeits within 24 hours, and 100 per cent within 72 hours;

b. Implement the actions set out in the Agency's Anti-Counterfeit Strategy;

c. Implement an Internet Awareness campaign;

d. Identification of potential changes to legislation or practice by March 2010;

e. Continue to work closely with Trading Standards Departments and Her Majesty's Revenue and Customs Intelligence Unit to identify and control counterfeit devices through undertaking customs awareness sessions during the year; and actively participating in the RAMS project to protect UK borders against counterfeit goods.

4

Take steps to improve the Agency's communications with its various stakeholders, with particular emphasis on healthcare professionals:

a. Implement specific, targeted sections on the website for the pharmaceutical industry and patients, and to develop targeted pages for healthcare professional specialists;

b. Identify and develop content for five new subject areas on the website by March 2010;

c. Develop and implement three marketing strategies a year which support the Agency's business objectives;

d. Produce Drug Safety Update on a monthly basis and take steps to promote uptake;

e. Produce six editions of One-Liners;

f. Ensure that the Agency continues to be highly ranked in the major Internet search engines; and ensure at least 10 additional links are in place between the MHRA website and other priority sites.

5

Roll out 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:

a. Publish the two-year action plan;

b. Implement the first year of the patient and public engagement action plan.

6

Pursue UK objectives in EU negotiations on changes to the regulatory framework; and implement EU legislation through changes in UK law:

Pursue and achieve UK objectives in EU negotiations on:

a. Proposed Recast of Medical Devices framework;

b. Proposals to strengthen pharmacogivilance provisions;

c. Proposals on information to patients;

d. Proposals to tackle counterfeit medicines.

Take steps at national level to implement:

a. The new Variation Regulation for medicines;

b. Amendments to the Medical Devices Regulations, to reflect changes in the accreditation and Market surveillance Regulation by consulting stakeholders and completing by Jan 2010.

7

Invest in regulatory science by further developing links with external research groups to support regulatory decisions or assess outcome of action:

a) Establish a programme of work with external academic groups, with a view to defining and commissioning research studies, to support regulatory decisions or assess outcome of action;

b) Develop and deliver a training course on methods for carrying out post-authorisation safety studies;

c) Hold four meetings of the New Technologies Forum (two on medicines, two on devices).

Key targets 2009/10

8

Ensure the Agency's finances are sound and stable:

a. Achieve an income and expenditure surplus during 2009/10, and as a minimum, exceed a 3.5 per cent per annum return on capital employed.

9

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

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, non4-safety) variations to Marketing Authorisations;

c. New Parallel Import Licences;

d. Variations and label/leaflet changes to Parallel Import Licences.

10

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. Training plan published and appropriate courses delivered:

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

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

c. Talent management proposals developed and published by November 2009;

d. Investors in People standard achieved in re-assessment, by December 2009.

Medicines and Healthcare products Regulatory Agency

Accounts for the year ended 31 March 2009

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 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 2009-2014 (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 twelve key targets (set by the Minister) for 2008/09, for the successful achievement of its business objectives. An internal audit review of the outcome confirmed that ten had been achieved and two not wholly achieved, although elements of the latter had been achieved.

The key targets for 2008/09 and their outcomes are detailed within the Annual Report.

The key targets for 2009/10 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 2008 to 31 March 2009.

9 Financial Review

Agency Financial Position

The MHRA is required to achieve at least a 3.5% return on average capital employed over the period 1 April 2008 to 31 March 2013, as detailed in the HM Treasury minute dated 27 March 2008 attached at the end of the Annual Report and Accounts.

Income and Expenditure

The total income for the year at £112.8M was 21% higher than 2007/08 income (£93.5M). This increase was attributable to two main reasons; an overall fees increase of 7%, coupled with an improvement in workflow throughout the financial year. Income from Licences and Inspections was £66.0M compared with £51.3M in 2007/08. Service fees were higher at £25.8M against £21.6M in 2007/08. Department of Health income was marginally higher at £11.3M (2007/08 £11.0M). Additional income from GPRD (General Practice Research Database), RAMA (Remote Access to Marketing Authorisations) and British Pharmacopeia of £4.6M, £1.1M and £2.2M respectively, was the main reason for the increase in Other income from miscellaneous activities from £9.6M in 2007/08 to £9.7M in 2008/09.

Total costs for 2008/09 at £86.7M were 3% lower than the level of £89.6M in 2007/08. Staff numbers increased by 5% and total staff costs increased by 8% from £45.9M to £49.5M, whilst other operating costs decreased from £38.8M to £31.9M as a result of the one-off charges incurred in 2007/08 not being repeated in 2008/09. The depreciation charge increased by £0.4M to £5.3M.

The operating surplus for 2008/09 was £26.2M, compared to £3.8M in 2007/08. For 2009/10 there is a planned operating surplus of £10.0M, based on both higher revenues and higher operating costs. An average increase in fees of 3% has been put in place with effect from 1 April 2009.

Management Commentary

Interest receivable less payable amounted to £1.3M in 2008/09, compared with £1.3M in 2007/08.

After charging a public capital dividend amount of £0.9M (2006/07 £0.3M), the net surplus in 2008/09 was £26.6M, leaving a retained surplus carried forward into 2009/10 of £37.0M.

Assets and liabilities

At 31 March 2009, the Agency had tangible fixed assets of £22.7M, an increase of £0.9M in the year. Net current assets were £54.8M. After allowing for deferred revenue of £32.3M and long-term creditors and provisions of £5.1M, the total net assets were £40.1M.

Staff Resources

The most important asset of the Agency is its staff, and during the year an average of 923 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 again 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 2008 and 31 March 2009, 97 per cent of invoices by number (2007/08: 96 per cent) 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/.

Management Commentary

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.

Agency Remuneration Report

Service Contracts

Civil service appointments are made in accordance with the Civil Service Commissioners' Recruitment Code. The Code requires appointments 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 a fixed term appointment) the Agency Board Directors are appointed by the Appointments Commission. 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.

Agency Remuneration Report

Renumeration

Executive Board - Salaries - £000	2008/09	2007/08
Professor Kent Woods - Chief Executive[1]	**215 - 220**	215 - 220
Mr Peter Commins - Chief Operating Officer	**150 - 155**	135 - 140
Dr June Raine - Director of Vigilance & Risk Management of Medicines	**145 - 150**	130 - 135
Dr Ian Hudson - Licensing Director	**140 - 145**	135 - 140
Mr Shaun Gallagher - Director of Policy	**105 - 110**	105 - 110
Mr Gerald Heddell - Director of Inspection, Enforcement and Standards Division	**120 - 125**	110 - 115
Mr Clive Bray - Director of Device Technology & Safety	**105 - 110**	95 - 100
Mrs Alison Davis - Director of Information Management	**105 - 110**	95 - 100
Mr Simon Gregor - Director of Communications	**100 - 105**	85 - 90
Mr Geoff LeFevre - Director of Human Resources	**100 - 105**	105 - 110
Dr Susanne Ludgate - Clinical Director - Devices	**100 - 105**	90 - 95

Agency Board - Salaries - £000		
Professor Sir Alasdair Breckenridge - Chairman	**100 - 105**	90 - 95
Ms Lisa Arnold - Non Executive Director	**10 - 15**	10 - 15
Miss Shelley Dolan - Non Executive Director	**5 - 10**	5 - 10
Mr Michael Fox - Non Executive Director	**5 - 10**	5 - 10
Professor Barrington Furr - Non Executive Director[2]	**5 - 10**	-
Mr Charles Kernahan - Non Executive Director	**5 - 10**	5 - 10
Professor Vincent Lawton - Non Executive Director[3]	**5 - 10**	-
Professor Angus Mackay - Non Executive Director	**5 - 10**	5 - 10
Mr Garry Watts - Non Executive Director[4]	**0 - 5**	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.

(Footnotes)

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 2008/09 the MHRA paid a total of £270,308 (2007/08: £271,161) 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. Professor Barrington Furr was appointed as a Non Executive Director on 21st July 2008.
3. Professor Vincent Lawton was appointed as a Non Executive Director on 21st July 2008.
4. 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:

	Accrued pension at pension age as at 31/3/09 and related lump sum	Real increase in pension and related lump sum at pension age	*CETV at 31/3/09	*CETV at 31/3/08	Real increase in CETV
	£000	£000	£000	£000	£000
Mr Peter Commins Chief Operating Officer	60 - 65	0.0 - 2.5	942	860	2
Dr June Raine Director of Vigilance & Risk Management of Medicines	35 - 40 plus lump sum of 105 - 110	0.0 - 2.5 plus lump sum of 0.0 - 2.5	780	706	9
Dr Ian Hudson Licensing Director	25 - 30	0.0 - 2.5	446	386	23
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	235	208	7
Mr Gerald Heddell Director of Inspection and Standards Division	5 - 10	0.0 - 2.5	150	109	28
Mr Clive Bray Director of Devices Technology & Safety	40 - 45 plus lump sum of 125 - 130	(2.5) - 0.0 plus lump sum of (2.5) - 0.0	1,012	955	-3
Mrs Alison Davis Director of Information Management	5 - 10	0.0 - 2.5	67	44	16
Mr Simon Gregor Director of Communications	15 - 20	0.0 - 2.5	145	125	6
Mr Geoff LeFevre Director of Human Resources	15 - 20 plus lump sum of 55 - 60	0.0 - 2.5 plus lump sum of 0.0 - 2.5	448	409	13
Dr Susanne Ludgate Clinical Director - Devices	35 - 40 plus lump sum of 105 - 110	0.0 - 2.5 plus lump sum of 0.0 - 2.5	818	791	0

* The figure may be different from the closing figure in last year's accounts. This is due to the CETV factors being updated to comply with The Occupational Pension Schemes (Transfer Values) (Amendment) Regulations 2008

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

Agency Remuneration Report

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 who joined from October 2002 could 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 for service before 1 October 2002 calculated broadly as per classic and benefits for service from October 2002 worked out 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, immediately after the scheme year end, 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 plus 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 buying additional pension benefits at their own cost. CETVs are calculated in accordance with The Occupational Pension Schemes (Transfer Values) (Amendment) Regulations and do not take account of any actual or potential reduction to benefits resulting from Lifetime Allowance Tax which may be due when pension benefits are taken.

Real increase in CETV

This reflects the increase in CETV that is 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
10 June 2009

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 chapter under *Accounting Officers* in *Managing Public Money*, published by HM Treasury.

Statement on Internal Control Year ended 31 March 2009

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 and Accounting Officer on 1 January 2004. I have held both positions since then and throughout the year to 31 March 2009.

The Agency Board, the Risk and Audit Committee and the Executive Board 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 to 31 March 2009, conducted in accordance with the Government Internal Auditing Standards, were provided by PricewaterhouseCoopers LLP, engaged on a three-year contract commencing 1 April 2008. The external audit is carried out 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 2009 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 team 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 Risk and Audit Committee and the Executive Board, and have been in existence throughout the year to 31 March 2009, 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.

Statement on Internal Control Year ended 31 March 2009

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 review in 2008/09 of corporate governance and risk management by the new internal audit team, maintained the outcome of recent years' audits in that a *high level of assurance* was given on the adequacy and operating effectiveness of controls in place over governance and risk management. Some areas of good practice were highlighted for example the maintenance of a corporate risk register which details the assurances obtained for every corporate risk identified. The cross-Agency Risk Management and Audit Liaison Group and the Audit Recommendations Tracker were also cited as examples of good practice.

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 subject to regular review by the Risk and Audit Committee. In addition any risks that are considered by divisional management to be of a corporate nature are communicated to the corporate risk management team either directly or through the divisional representative at the quarterly meetings of the Risk Management and Audit Liaison Group.

The cross-Agency Risk Management and Audit Liaison Group, formed in 2004/05 to strengthen the Agency's risk management system, held four meetings during the year to 31 March 2009. 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 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 opportunities and the threats that may arise during the daily course of business operations.

Divisional Heads in accordance with their duty of accountability, are required to complete an annual statement, confirming if appropriate that effective systems of internal control have been in place within their areas of responsibility, throughout the particular period under review. All such accountability statements have been received for the year to 31 March 2009.

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 has been 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 Agency's servers and client workstations have virus protection. User access to systems 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. Agency laptops have encrypted hard disks. The Agency has BS7799 accreditation.

In compliance with a Cabinet Office and Department of Health request, the Agency completed a self-assessment questionnaire on its security policy, in the last quarter of the year to 31 March 2009. This review covered physical security, IT security and security within the Human Resources function. Aspects on IT security are as noted in the immediately preceding two paragraphs. An independent review by the Department of Health of the Agency's self assessment of the physical security at Market Towers, the MHRA's main business location, revealed no cause for concern. The Agency believes that physical security at its regional offices is also adequate and further that there are no security issues arising within its Human Resources area. However one possible weakness that has been identified is the lack of an Agency policy on Counter-Terrorism; this will be developed in 2009/10 in co-operation with the Department of Health.

The internal audit services are conducted in accordance with the Government Internal Auditing Standards and those of the International Auditing and Assurance Standards Board. 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 annual internal audit plan, which is discussed by the Risk and Audit Committee and the Executive Board. During the year follow-up audits are also conducted to monitor management's compliance with the previously agreed responses to recommendations. The outcome of these internal audits is reported to the Risk and Audit Committee by the Internal Auditors via their progress reports at each Risk and Audit Committee meeting. The results are summarised in an internal audit annual report, together with an overall assurance opinion on the system of internal control, for the attention of 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 Risk and Audit Committee and the Executive Board, and a plan to address weaknesses and ensure continuous improvement of the system is in place.

Agency Board

The Agency Board consists of the Agency Chairman and seven non-executive directors. The Agency Board had regular meetings during the year to 31 March 2009, 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.

Risk and Audit Committee

The Risk and Audit Committee, a subcommittee of the Agency Board, 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 an Agency Board non-executive director, held four meetings during the year to 31 March 2009. The main agenda items were the corporate risk register, the 2007/08 Internal Audit annual report, the 2007/08 Statement on Internal Control, the 2007/08 Annual

Statement on Internal Control Year ended 31 March 2009

Report and Accounts, the 2007/08 National Audit Office Management Letter, the strategy and timetable for the external audit of the 2008/09 Annual Accounts, the various Internal Audit progress reports for 2008/09 and the Internal Audit plan for 2009/10. These reviews in aggregate played a significant part in the Risk and Audit Committee's advice to the Accounting Officer on the effectiveness of the Agency's corporate governance, risk management and internal control systems.

Agency Board and Risk and Audit Committee members are required to declare any conflicts of interest at the start of each meeting.

Executive Board

The Executive Board, consisting of the Chief Executive and the Heads of Divisions, also convened regularly during the year to 31 March 2009, to undertake their executive responsibility for the strategy, operational management, corporate risk management and service delivery of the Agency. As the Accounting Officer, the Chief Executive is responsible for the financial management of the Agency and for the Agency's resources.

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.

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 to 31 March 2009 was provided by PricewaterhouseCoopers (PwC) under a three-year contract, which commenced on 1 April 2008. The previous internal audit contract with RSM Bentley Jennison expired on 31 March 2008. The PwC appointment was made under an Office of Government Commerce (OGC) Framework Agreement.

The PwC Engagement Director in charge of the Agency's internal audit service performed the role of Head of Internal Audit. He produced regular reports on the adequacy and effectiveness of the systems of internal control in the various operational areas under audit, including finance, and suggested ways of improvement in these reports, by detailing the findings and recommendations.

The internal audit plan for 2008/09, the first year under PwC, was designed to focus mainly on the high and medium risk areas within the Agency. Consequently the plan devoted 60% of the total resources to financial systems (including a review of payroll procedures), IT systems (including IT contract management) and corporate governance and risk management. The remaining resources (excluding administration) were deployed on other business systems.

In total eleven audit reviews were conducted. Two internal audits, namely on corporate governance and risk management and budget management and monitoring, received high assurances. Four others relating to payments received on account, debtors, risk management procedures within the enforcement unit and the follow-up audit, received moderate assurances. The review of the self-assessment on communications and information sharing was not subject to an assurance rating. Limited assurances however were assigned to the internal audits on payroll, purchases and payments, IT general controls and IT contract management. These latter four audits contained between them eleven high priority weaknesses which management have agreed to address. All the other internal audit recommendations, with the exception of one regarded as medium priority and one as low priority, were also accepted by management. A programme of implementation has been agreed, with anticipated completion during the current year 2009/10.

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. This report identified certain control weaknesses within the areas mentioned in the preceding paragraph, on which limited assurance opinions were given. However the internal audit annual report concluded that on balance, moderate assurance could be given on the design, adequacy and effectiveness of the Agency's overall system of internal control. This is the second highest of four categories used by PwC in their assurance classification and which they have emphasised should be seen in the context of the Agency seeking scrutiny of the highest risk areas of activity.

Significant internal control issues

The internal audit reports on payroll, purchases and payments, IT general controls and IT contract management each contained elements of high risk areas where the controls were not adequate, as a result of which only limited assurances were given. These reports were specifically brought to my attention. They have also been discussed at the various Risk and Audit Committee meetings during the year. Management action to rectify these weaknesses has been agreed and a programme of implementation designed for completion during the current year 2009/10.

Accounting Officer's comment

I am satisfied, based on the advice given to me by the Head of Internal Audit, the Agency Board, the Risk and Audit Committee and the Executive Board, that on balance 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
10 June 2009.

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 (the Agency) for the year ended 31 March 2009 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 in the 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 included in the Annual Report, is consistent with the financial statements. I also report whether, in all material respects, the expenditure and income have been applied to the purposes intended by Parliament and the financial transactions conform to the authorities which govern them.

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

I review whether the Statement on Internal Control reflects the Agency's compliance with HM Treasury's guidance, and I report if it does not. I am not required to consider whether this statement covers all risks and controls, or form an opinion on the effectiveness of the Agency's corporate governance procedures or its risk and control procedures.

I read the other information contained in the Annual Report and consider whether it is consistent with the audited financial statements. This other information comprises remaining parts of the annual report and the unaudited part of the renumeration report. I consider the implications for my report if I become aware of any apparent misstatements or material inconsistencies with the financial statements. My responsibilities do not extend to any other information.

Basis of audit opinion

I conducted my audit in accordance with International Standards on Auditing (UK and Ireland) issued by the Auditing Practices Board. My audit includes examination, on a test basis, of evidence relevant to the amounts, disclosures and regularity of financial transactions included in the financial statements and the part of the Remuneration Report to be audited. It also includes an assessment of the significant estimates and judgments made by the Agency and Chief Executive in the preparation of the financial statements, and of whether the accounting policies are most appropriate to the Agency's circumstances, consistently applied and adequately disclosed.

I planned and performed my audit so as to obtain all the information and explanations which I considered necessary in order to provide me with sufficient evidence to give reasonable assurance that the financial statements and the part of the Remuneration Report to be audited are free from material misstatement, whether caused by fraud or error, and that in all material respects the expenditure and income have been applied to the purposes intended by Parliament and the financial transactions conform to the authorities which govern them. In forming my opinion I also evaluated the overall adequacy of the presentation of information in the financial statements and the part of the Remuneration Report to be audited.

Opinions

In my opinion:

- the financial statements give a true and fair view, in accordance with the Government Trading Fund Act 1973 and directions made thereunder by HM Treasury, of the state of the Agency's affairs as at 31 March 2009 and of its surplus, recognised gains and losses and cash flows for the year then ended;
- the financial statements and the part of the Remuneration Report to be audited have been properly prepared in accordance with the Government Trading Fund Act 1973 and HM Treasury directions made thereunder; and
- information, which comprises the management commentary 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.

Amyas C E Morse
Comptroller and Auditor General
National Audit Office
151 Buckingham Palace Road
Victoria
London SW1W 9SS
22 June 2009

Income and Expenditure Account for the year ended 31 March 2009

Notes		2008/09 £'000	2007/08 £'000
3	Trading income	**101,517**	82,460
	Income from Department of Health	**11,295**	11,003
		112,812	93,463
5	Staff costs	**49,465**	45,902
7	Other operating costs	**31,858**	38,835
9	Depreciation	**5,277**	4,888
		86,600	89,625
	Operating surplus on ordinary activities	**26,212**	3,838
8	Interest receivable	**1,579**	1,458
8	Interest payable	**(256)**	(148)
	Surplus for the year on ordinary activities	**27,535**	5,148
	Dividend payable	**(932)**	(322)
14	**Retained surplus for the year**	**26,603**	4,826
	Opening retained surplus	**10,435**	5,609
	Retained surplus carried forward	**37,038**	10,435

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 2009

Notes		2008/09 £'000	2007/08 £'000
	Surplus for the year excluding dividend payment	**27,535**	5,148
	GPRD impairment	**-**	(3,795)
14	Unrealised surplus on revaluation	**26**	31
	Total recognised gains	**27,561**	1,384

The Notes to the Accounts form part of these Accounts

Balance Sheet

as at 31 March 2009

Notes		31 March 2009 £'000	31 March 2008 £'000
	Fixed assets		
9	Tangible fixed assets	**22,702**	21,758
	Current assets		
10	Debtors	**17,424**	20,842
17	Cash at bank and in hand	**51,439**	21,861
		68,863	42,703
11	Creditors: amounts falling due within one year	**(14,020)**	(16,137)
	Net current assets	**54,843**	26,566
	Total assets less current liabilities	**77,545**	48,324
11	Creditors: amounts falling due after more than one year	**(1,328)**	(1,728)
12	Provisions for liabilities and charges	**(3,793)**	(3,926)
13	Deferred revenue	**(32,348)**	(29,510)
	Net assets	**40,076**	13,160
14	**Capital and reserves**		
	Public dividend capital	**1,329**	1,329
	Revaluation reserve	**168**	142
	Income & Expenditure reserve	**954**	954
	Government Grant reserve	**587**	300
	Retained surplus	**37,038**	10,435
	Total capital employed	**40,076**	13,160

The Notes to the Accounts form part of these Accounts

Professor Kent Woods
Chief Executive and Accounting Officer
Medicines and Healthcare products Regulatory Agency
10 June 2009.

Cash Flow Statement

for the year ended 31 March 2009

Notes		2008/09 £'000	2007/08 £'000
15	**Net cash inflow from operating activities**	**36,250**	8,276
	Returns on investments and servicing of finance		
	Interest received	**1,684**	1,383
	Interest paid	**(377)**	(744)
	Dividend paid	**(1,183)**	(1,190)
	Loan Repayment	**(1,000)**	(1,000)
	Net cash outflow from returns on investments and servicing of finance	**(876)**	(1,551)
	Capital expenditure		
	Payments to acquire fixed assets	**(6,196)**	(3,183)
	Financing		
	Government Grant received	**400**	200
17	**Increase in cash for the year**	**29,578**	3,742

The Notes to the Accounts form part of these Accounts

Notes to the 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 2008/09. 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 and RAMA XL 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.

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

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 Civil Service Pension Schemes (CSPS) which are defined benefit schemes or a "money purchase" stakeholder pension scheme. 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 CSPS of amounts calculated on an accruing basis. Liability for payment of future benefits is a charge on the CSPS. Further details are contained in the Remuneration Report.

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 27 March 2008, 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% return on average capital employed;

Net asset values are shown on the Balance Sheet. The actual operating surplus for the year was £26.212M (2007/08 £3.838M). 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 £0.932M (2007/08 £0.322M).

The Agency plans its fee strategy so as to achieve a return averaged over the period 1 April 2008 to 31 March 2013 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.

Notes to the Accounts

3. Income

	2008/09		2007/08	
	£'000	**£'000**	£'000	£'000
Licences and inspections income recognised during the year	**66,015**		51,268	
Service fee income recognised during the year	**25,829**		21,552	
Income from miscellaneous activities	**9,673**		9,640	
Trading Income		**101,517**		82,460
Income from Department of Health		**11,295**		11,003
		112,812		93,463

	2008/09		2007/08	
	£'000	**£'000**	£'000	£'000
Licences and inspections				
Applications	**31,988**		25,483	
Clinical trials	**2,376**		1,748	
EMEA	**6,310**		4,259	
Inspection	**8,502**		7,394	
Renewals	**93**		99	
Variations	**15,129**		11,016	
Other	**1,617**		1,269	
		66,015		51,268
Service fees		**25,829**		21,552
Miscellaneous income				
British Pharmacopoeia	**2,208**		2,104	
GPRD	**4,629**		4,230	
Remote Access to Marketing Authorisations	**1,054**		974	
Seminar and twinning	**485**		1,175	
Other	**1,297**		1,157	
		9,673		9,640
Trading Income		**101,517**		82,460
Department of Health funding		**11,295**		11,003
		112,812		93,463

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. Segment 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.

	2008/09		2007/08	
	Devices	**Medicines**	Devices	Medicines
	£'000	**£'000**	£'000	£'000
Trading income	**431**	**101,086**	376	82,084
Income from Department of Health	**11,295**	**-**	11,003	-
	11,726	**101,086**	11,379	82,084
Operating costs	**(9,750)**	**(76,850)**	(9,980)	(79,645)
Operating surplus	**1,976**	**24,236**	1,399	2,439

5. Staff Costs

	2008/09	2007/08
	£'000	£'000
Salaries and wages	**37,240**	34,361
Social security costs	**3,334**	3,107
Pension contributions	**7,643**	7,180
	48,217	44,648
Agency and other staff costs	**1,379**	1,069
Early retirement and redundancy costs	**(131)**	185
	49,465	45,902

6. Employee Details

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

	2008/09	2007/08
Chairman	**1**	1
Executive Directors	**10**	10
Senior Civil Servants	**94**	87
Other Civil service staff	**741**	710
Secondees	**4**	2
Short-term contracts	**74**	65
	924	875

Notes to the Accounts

7. Other Operating Costs

	2008/09 £'000	2007/08 £'000
Computing	**9,216**	10,146
Accommodation	**7,863**	7,254
Travel and subsistence	**2,399**	1,800
Net increase in debt and credit note provision	**1,534**	41
Medicines testing and laboratory expenses	**1,843**	1,878
Legal services	**1,587**	1,236
Other administration costs	**1,554**	1,661
Consultancy	**1,178**	801
Training	**1,013**	738
Telecommunication costs	**869**	855
Committee costs	**697**	601
Printing, stationery and distribution	**672**	754
Contracted-out administration services	**582**	477
Pharmacovigilance database and other costs	**171**	322
Contracted-out personnel and payroll services	**460**	525
Marketing	**164**	143
Auditors remuneration - audit fee	**104**	98
GPRD fixed asset impairment	**-**	4,280
Increase in Provisions	**-**	3,550
Net credit notes issued in respect of service fees	**-**	1,750
Debt written off	**(8)**	-
Foreign exchange gain	**(40)**	(75)
	31,858	38,835

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:

	2008/09 £'000	£'000	2007/08 £'000	£'000
Plant & Equipment				
Catering equipment	**4**		4	
Office equipment	**59**		46	
IT equipment	**-**		539	
		63		589
Other:				
Rent		**4,321**		4,051
		4,384		4,640

8. Interest Receivable and Payable

	2008/09 £'000	2007/08 £'000
Interest Receivable from banks	**1,579**	1,458
Interest Payable	**(256)**	(148)
	1,323	1,310

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 £0.256M (2007/08: £0.148M) is in respect of the loans from the Department of Health (see note 11).

Notes to the Accounts

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 2008	**47,107**	**2,741**	**28,893**	**1,110**	**4,155**	**1,056**	**1,561**	**7,591**
Additions	6,196	2,968	1,922	157	95	1,054	-	-
Indexation	53	-	-	11	42	-	-	-
Transfers	-	(284)	1,299	-	-	(1,015)	-	-
At 31 March 2009	**53,356**	**5,425**	**32,114**	**1,278**	**4,292**	**1,095**	**1,561**	**7,591**
Depreciation								
At 1 April 2008	**25,349**	**1,775**	**12,424**	**840**	**1,906**	**-**	**813**	**7,591**
Indexation	28	-	-	9	19	-	-	-
Charge for the year	5,277	488	3,698	108	593	-	390	-
At 31 March 2009	**30,654**	**2,263**	**16,122**	**957**	**2,518**	**-**	**1,203**	**7,591**
Net book value								
At 31 March 2009	**22,702**	**3,162**	**15,992**	**321**	**1,774**	**1,095**	**358**	**-**
At 1 April 2008	21,758	966	16,469	270	2,249	1,056	748	-

10. Debtors

	31 March 2009	31 March 2008
	£'000	£'000
Trade debtors	**12,867**	15,901
Other debtors	**238**	214
Prepayments	**1,529**	2,411
Accrued income	**2,194**	1,527
Value Added Tax	**596**	789
	17,424	20,842

Trade debtors are shown net of a provision for irrecoverable debts and credit notes of £8.918M (31 March 2008 £6.268M).

Debtors includes £0.840M (31 March 2008: £0.789M) due to the MHRA by the Department of Health as follows:

	31 March 2009	31 March 2008
	£'000	£'000
Trade debtors	**244**	-
Value Added Tax	**596**	789
	840	789

Notes to the Accounts

11. Creditors

	31 March 2009 £'000	31 March 2008 £'000
Amounts falling due within one year		
Payments received on account	**8,703**	10,028
Trade creditors	**535**	1,386
Loan Repayment	**400**	1,000
Other creditors	**1**	-
Accrued expenses	**4,381**	3,723
	14,020	16,137

Creditors includes £1.463M (31 March 2008: £2.342M) due to the Department of Health as follows:

	31 March 2009 £'000	31 March 2008 £'000
Loan, Interest & Dividend Repayment	**1,400**	1,470
Accrued expenses	**63**	872
	1,463	2,342

	31 March 2009 £'000	31 March 2008 £'000
Amounts falling due after more than one year		
Due to Department of Health	**1,328**	1,728

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

	Total 2008/09 £'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	2007/08 £'000
Fixed interest rate							
4.30%	**-**	-	-	-	-	-	1,000
4.35%	**400**	400	-	-	-	-	400
3.50%	**1,328**	-	-	-	-	1,328	1,328
At 31 March 2009	**1,728**	400	-	-	-	1,328	-
At 31 March 2008	**2,728**	1,000	400	-	-	1,328	2,728

The third tranche of loan repayment was made during 2008/09 when £1M was repaid to the Department of Health

12. Provision for liabilities and charges	31 March 2009	31 March 2008
	£'000	£'000
Early retirement / voluntary severance		
Opening balance	**235**	293
Utilised during year	**(79)**	(76)
Unwinding of provision	**10**	18
Closing balance	**166**	235
Other provisions		
Opening position	**3,691**	-
Utilised during year	**(141)**	-
Provided in year	**-**	3,691
Unwinding of provision	**77**	-
	-	-
Closing balance	**3,627**	3,691
Total provisions	**3,793**	3,926

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 are in respect of building costs.

13. Deferred revenue	31 March 2008	Movement	31 March 2009
	£'000	£'000	£'000
Licence fees (applications and variations)	26,677	2,768	**29,445**
Other fees	2,833	70	**2,903**
Total	29,510	2,838	**32,348**

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 2009, is carried forward to future periods.

Notes to the Accounts

14. Capital and reserves

	Total	PDC	Revaluation reserve	Income & Expenditure reserve	Government Grant reserve	Retained surplus
	£'000	£'000	£'000	£'000	£'000	£'000
Balance at 31 March 2008	13,160	1,329	142	954	300	10,435
Movements 2008/09						
Impairment of Fixed Assets	-	-	-	-	-	-
Indexation	26	-	26	-	-	-
Receipt of Government grant	400	-	-	-	400	-
Depreciation of Government grant	(113)	-	-	-	(113)	-
Surplus for year	26,603	-	-	-	-	26,603
Balance at 31 March 2009	40,076	1,329	168	954	587	37,038

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

	2008/09	2007/08
	£'000	£'000
Operating surplus	**26,212**	3,838
Depreciation	**5,277**	4,888
Fixed Asset Indexation	**28**	-
Amortisation of Government Grant Reserve	**(113)**	-
Indexation of Grant	**(26)**	-
Fixed Asset impairment	**-**	4,280
Loss and write-off of Fixed Assets	**-**	741
Revenue deferred to future periods (Note 13)	**2,838**	5,693
Decrease in debtors	**3,312**	(2,029)
Increase in creditors	**(1,145)**	(12,768)
Decrease in provisions	**(133)**	3,633
Net cash inflow from operating activities	**36,250**	8,276

16. Reconciliation of net cash flow to movement in net funds

	2008/09	2007/08
	£'000	£'000
Increase in cash for year	**29,578**	3,742
Movement in net funds	**29,578**	3,742
Net funds at end of previous year	**21,861**	18,119
Net funds at end of year	**51,439**	21,861

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

	Total	Cash at bank and in hand
	£'000	£'000
Balance at 1 April 2008	21,861	21,861
Movements 2008/09		
Increase in cash at bank	29,578	29,578
Balance at 31 March 2009	51,439	51,439

18. Capital commitments

	31 March 2009	31 March 2008
	£'000	£'000
Contracted	**732**	-
Authorised by the Management Board but not contracted	**870**	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.

Notes to the Accounts

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 (£1,058,000);
- The University of Leicester for the secondment of the Agency's Chief Executive (£226,563);
- 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 (£316,134);
- 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 (£31,980)

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	Balance at 31 Mar 2009	Total value	Balance at 31 Mar 2009
	£'000	£'000	£'000	£'000
Department of Health	12,235	245	51,297	-
Various NHS Trusts	1,952	1,169	164	12
Department for Work and Pensions	-	-	1,058	-
Other government bodies	674	222	897	1
Local Authorities	-	-	65	-
Educational Bodies	425	162	354	-
	15,286	1,798	53,835	13

During 2008/09, none of the Board, 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 (2007/08: £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:

	2008/09	2007/08
	£'000	£'000
Land and buildings		
Expiry within 1 year	**56**	56
Expiry within 2 - 5 years	**3,553**	3,518
Leases which expire after 5 years	**37**	72
Other		
Expiry within 1 year	**-**	419
Expiry within 1 - 2 years	**64**	113
Expiry within 2 - 5 years	**-**	-

Notes to the Accounts

23. Financial instruments

FRS 25 'Financial Instruments: Disclosure and Presentation', FRS 26 'Financial Instruments: Measurement, Recognition and Derecognition' and FRS 29 'Financial Instruments: Disclosure' have been adopted for the first time during 2008/09. These reporting standards require 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 (2007/08: £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.

	2008/09		2007/08	
	£'000	**Interest rate***	£'000	Interest rate*
Accounts				
Paymaster	**50,971**	**0.00%**	20,303	4.09%
Commercial	**468**	**0.00%**	1,558	0.50%
	51,439		21,861	

* 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 £1.728M (2007/08: £2.728M). This resulted in interest payable of £0.256M (2007/08: £0.148M) out of total expenditure in excess of £86.600M (2007/08: £89.625M)

Currency risk

The level of currency risk is determined by the level of income generated by activity undertaken on behalf of the EMEA. For 2008/09 this was £6.310M (Euro 8.267M) (2007/08: £4.259M; Euro 5.982M). This represents 5.6% (2007/08: 4.6%) 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.

HM Treasury Minute

dated 27 March 2008

1. Section 4(1) of the Government Trading Funds Act 1973 ("the 1973 Act") provides that a trading fund established under the 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:
        (1) consists principally of receipts in respect of goods or services provided in the course of the funded operations; and
        (2) 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. The 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 2008 to 31 March 2013 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 consist of the capital (PDC and long-term element of loans) and Reserves.
4. This minute supersedes that dated 9 February 2004.
5. 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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ID6133389 07/09
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