Safeguarding public health

MHRA

Medicines and Healthcare products Regulatory Agency

Annual Report and Accounts 2010/11

Medicines and Healthcare products Regulatory Agency

Annual Report and Accounts 2010/11

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 on 14 July 2011

HC1195 London: The Stationery Office £20.50

Any enquiries regarding this publication should be sent to us at:

Medicines and Healthcare products Regulatory Agency
151 Buckingham Palace Road
London
SW1W 9SZ

Telephone (weekdays 9:00 – 17:00): 020 3080 6000
Email: info@mhra.gsi.gov.uk

This publication is also available for download at www.official-documents.gov.uk and from our website at: http://www.mhra.gov.uk/Publications/Corporate/AnnualReports/index.htm

ISBN: 9780102970180

Printed in the UK for The Stationery Office Limited
on behalf of the Controller of Her Majesty's Stationery Office

ID 2409594 07/11

Printed on paper containing 75% recycled fibre content minimum.

CONTENTS

Chairman and Chief Executive's Review

2010/2011 was a significant year for MHRA, as it included a change of government, the publication of the Department of Health's arms-length-bodies report and the Agency's relocation to a new head office.

The year began with an unexpected event (the Icelandic volcanic ash cloud) that caused many MHRA staff, including its Chief Executive, to be temporarily stranded overseas. However, the flexibility and robustness of our IT systems allowed our staff, whether in Paris, Mumbai or Hong Kong to work as normal. That same agility would ensure that when the Agency moved head office in October and November - a complex task involving over 860 staff - there was a minimum of disruption to business.

Throughout all this we have continued to maintain our key function of safeguarding the health of the public. Some of the highlights of the year are as follows.

Safeguarding Public Health

We continue to make a major contribution to the regulation of medicines in Europe through our work as Reference Member State or rapporteur in Decentralised (DCP) and Centralised Procedures, where we are appointed more often than any other Member State and with the highest number of procedures finalised. The UK was Lead Member State in 12 out of 27 procedures within the new Voluntary Harmonisation Procedure to harmonise the clinical trial approval process across Europe. In support of product innovation and development the MHRA continues to provide frequent advice to companies and is a major contributor to scientific advice at the European Medicines Agency.

In the field of drug safety we have further developed the Yellow Card Scheme for the reporting of adverse drug reactions (ADRs) by enabling GPs to report ADRs directly using their practice IT systems and by piloting a system for pharmacist ADR reporting which we hope to roll out nationwide, once evaluation is completed.

ALB review

In July, the Department of Health published its report of the arms-length bodies (ALBs) review in the health and social care sector. We were identified as one of six Departmental ALBs with a clear future, operating in a most 'cost effective and efficient way'. We were pleased that there is no intention to change the status of the MHRA or transfer any of our functions to other bodies; indeed, we may gain further responsibilities. As a result of the review, good regulation (proportionate, accountable, consistent, transparent, and targeted) will be further embedded in the culture of the MHRA.

Global summit

In October we hosted the 5th Global Summit of Heads of Medicines Regulatory Agencies. This annual event provides an opportunity for world regulatory agencies to meet and discuss common challenges and concerns. Attendees included a delegation from the Chinese State Food and Drugs Administration (SFDA) which provided the opportunity to renew the Memorandum of Understanding (MOU) between the SFDA and the MHRA. The British Pharmacopoeia also signed a separate MOU with the Chinese Pharmacopoeia, allowing for greater collaboration between the two Pharmacopoeias. We also signed confidentiality agreements with Japan and New Zealand. This very successful summit was closed by the Parliamentary under Secretary of State for Health, Earl Howe, with a speech that stressed the value of such meetings to strengthen global ties and deepen co-operation.

Strategy for the Heads of Medicines Agencies 2011-15

October also saw the adoption by the Heads of (European) Medicines Agencies (HMA) of a five year strategy for the European Medicines Regulatory Network (*A Strategy for the Heads of Medicines Agencies 2011-15*) at their meeting in Antwerp. The Agency had been extensively involved in the production of this strategy document and Kent Woods chaired the multi-agency Task Force charged with delivering it. The strategy outlines how the HMA will combine its efforts along three themes of protecting public health; supporting innovation and making decentralised and mutual recognition procedures of market authorisation work better. The MHRA is pleased to continue its close work with other European regulators through the HMA to make a real difference over the next five years.

Key Legislative Changes

The Agency has been actively involved in the consultation on, and implementation of, several pieces of legislation at the national and European level. The Falsified Medicines Directive was finalised this year and is likely to come into force in Autumn 2012. The Directive strengthens regulatory controls across the pharmaceutical supply chain, including an obligation on companies to protect certain medicines from the threat of counterfeiting by applying a seal and a unique identifier to each pack and greater controls on active pharmaceutical ingredients so that their sources and transit can be tracked.

The Agency is working towards implementation of the new pharmacovigilance legislation in July 2012 which aims to clarify the roles and responsibilities of everyone involved in pharmacovigilance. It will strengthen EU decision-making on drug safety issues, firmly embed risk management planning in legislation, increase transparency and improve coordination of the communication of safety issues across Europe.

Herbal Medicines

We welcomed the announcement by the Secretary of State for Health in February that a statutory register for practitioners supplying unlicensed herbal medicines is to be set up by the Health Professions Council (HPC). We also propose that use of the longstanding provision under the Medicines Act 1968, allowing practitioners to prepare unlicensed herbal remedies on their premises in order to meet the needs of individual patients identified in consultation, should be limited to registered practitioners. These reforms, which replace previous open-ended provisions, should significantly improve protection of the public while maintaining consumer choice. There will be a public consultation on the proposed changes in medicines legislation in due course. Ahead of the implementation of mandatory registration of traditional herbal medicines from April 2011, MHRA has approved over 100 traditional herbal registrations.

Nicotine Replacement Therapy products

Reducing the impact of smoking remains a public health priority for the Department of Health and the MHRA. Following advice from the Commission on Human Medicines (CHM), the use of licensed Nicotine Replacement Therapy (NRT) products has been extended to include "harm reduction". This means that NRT's medicinal uses now include smokers who do not wish to expose others to their second-hand smoke, temporarily cannot smoke (i.e. in smoke-free areas) or who wish to cut down but have no immediate plan to quit. We have published the outcome of a consultation exercise which sought views on the regulation of nicotine containing products such as 'electronic cigarettes' which are widely available, claim to contain nicotine but are not licensed medicines and so are sold without the safeguards built into the regulation of medicinal products. The consultation highlighted that there are outstanding questions to be answered before a decision can be made on the regulation of these products as medicines and a period of further research is being coordinated by the MHRA to help answer these questions.

Combating counterfeit medicines - Operation Pangea III

To raise awareness of the dangers of buying medicines online we took part in Operation Pangea III, an international enforcement operation coordinated by INTERPOL which targeted the online sale of counterfeit and illegal medicines. This was the largest internet-based enforcement action of its kind to date and in the UK our enforcement officers, with police assistance, raided premises linked to websites being run from locations across the country. A range of different medicines being supplied with no prescription and stored in unacceptable conditions by persons unqualified to dispense them were recovered and 188 websites were investigated. Working with the UK Border Agency, we seized 280,000 tablets at Coventry Postal Hub.

Medical Devices

During the year we continued our education programme for healthcare professionals who use devices. The pilot Medical Device Driving Licence e-learning module was launched in early September in Doncaster with excellent feedback. Further pilots are being carried out with a view to national roll out. We have worked with the Royal College of Obstetricians and Gynaecologists and the British Society for Gynaecological Endoscopy to produce guidance for all gynaecologists around endometrial ablation with emphasis on the device and user issues. In association with several Royal Colleges we produced a booklet to provide guidance on the resources that are considered essential for providing a safe endovascular aneurysm repair service.

During the year, we worked closely with professional bodies and international colleagues about the safety of Poly Implant Prosthese silicone gel filled breast implants. A medical device alert was issued and advice for patients was posted on MHRA's website. In October, MHRA published the final report of the Expert Advisory Group that looked at the issue of soft tissue reactions associated with metal-on-metal hip replacement devices. We are also continuing to develop the section on the MHRA website providing information specific to a number of healthcare professional specialties.

Eliminating backlogs

Last year we made considerable progress on reducing or eliminating backlogs in all areas of medicines licensing, a particular concern of the pharmaceutical industry in the past. We are pleased that we have continued with further performance improvements in this area, in particular clearing our assessment backlogs, both for new applications and non-safety variations, while at the same time successfully maintaining all European procedure timelines.

Danish Medicines Agency

A new and innovative area of work for the Agency was formally launched in December when the Danish Medicines Agency started to use a tailored version of the MHRA's Sentinel Pharmacovigilance Case Folder. Such close collaboration with another national competent authority on a project of this kind is an important "first" for this Agency and can only be positive for pharmacovigilance in the future.

ISO 9001 Certification

We have continued to strive to refine and improve our internal processes. Much work has been undertaken in the past year to develop and implement quality management systems. We are delighted that this effort has been recognised this year by the British Standards Institute with award of ISO 9001 certification.

BEMA

Last year the Agency participated in an external assessment of a number of performance indicators as part of the Benchmarking of European Medicines Agencies (BEMA) programme. The results of the assessment reflected the high quality of the work of the Agency, with fourteen examples of best practice cited, confirming our position as a leader in medicines regulation in Europe.

Operational and Regulatory Excellence

Two key initiatives were established to ensure that the work of the Agency is aligned with the new government's agenda to reduce the burdens of regulation, while ensuring excellence in public health. Our Regulatory Excellence programme will look at opportunities to simplify regulation while continuing to deliver our public health outcomes, whilst an Operational Excellence programme will focus on opportunities to streamline our processes while retaining the quality of the work that we deliver. As a result of efficiencies already achieved, fees increased by just 1 per cent in 2010/11 and there will be no increase for 2011/12.

Investors in People

The commitment of our staff to the Agency's purposes and objectives is regularly reflected in our staff survey results and in the high quality of work maintained across the organisation. In this context we were delighted to be awarded the Investors in People Bronze Standard in July 2010.

Relocation

The move to new headquarters in Victoria was much more than a change of address, as it entailed a range of operational and cultural changes for the Agency. The working environment has been designed after a thorough analysis of how we use space and what we need to work efficiently. There are no personal offices – not even for the Chairman or Chief Executive – but the space saved allows for ample meeting rooms and common areas. The move was 'cost neutral' to 2016. Moreover, it was carried out with minimum disruption to our business and is a great credit to the teams from across the Agency who contributed to the planning work throughout the year.

Finally, we would like to thank everyone involved with the work of the Agency for a successful year, and for the dedication and commitment they have shown.

Professor Sir Alasdair Breckenridge
Chairman

Professor Sir Kent Woods
Chief Executive

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 consists of the Agency Chairman and eight 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.

The Risk and Audit Committee consists of three non-executive Directors. It 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.

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 have no significant interests to disclose which may conflict with their responsibilities. The Remuneration Report on pages 29 to 33 of this report 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 2010/11 was £96k (2009/10: £98k).

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

Events after the reporting period - There have been no significant events between the period under review and the date of issue of this Annual Report and Accounts.

Agency Board

Professor Sir Alasdair Breckenridge, CBE
Ms Lisa Arnold
Dr Shelley Dolan
Mr Michael Fox
Professor Barrington Furr, OBE
Professor Vincent Lawton, CBE
Sir John Lilleyman
Professor Angus Mackay, OBE
Mr John Williams, CBE

Executive Board

Professor Sir Kent Woods
Mr Peter Commins
Mrs Alison Davis
Mr Gerald Heddell
Dr Ian Hudson
Mr Geoff Le Fevre
Dr Susanne Ludgate
Mr Jonathan Mogford
Dr June Raine, CBE
Mr Simon Gregor (to October 2010)
Mrs Diane Leakey (from October 2010)
Mr Clive Bray (to August 2010)

Agency Board meeting attendance and Register of Interests

The attendance of the Agency Board Non-Executive Directors at the Agency Board meeting, the Agency Board Awayday, and the Risk and Audit Committee, together with the Agency Board Register of Interests, can be found on the MHRA website at the following location: **http://www.mhra.gov.uk/Aboutus/Ourstructure/AgencyBoard/AgencyBoardmembers/index.htm**

Performance Against Targets 2010/11

TARGETS	EVIDENCE AND MEASURES	STATUS	COMMENTS
PM1 Medicines Licensing time targets	Assessment timescale targets: National new licence/registration applications for chemical, biological, homeopathic and traditional herbal medicines: - 80% in 100 days - 98% in 150 days	Achieved 95% achieved	95% in 150 days
	EU new licence applications for chemical and biological medicines: - MRP: 99% in 50 days - DCP RMS: 99% in 70 days - CP: 99% in 80 days - DCP CMS: 99% in 100 days	Achieved	All Targets met.

PM1 Medicines Licensing time targets	Type 1A: - Nationals validated within 30 days - RMS validated 30 days from receipt of application and Despatch Date List (DDL)	Not achieved	Overall compliance at the end of 2010-2011 76% of UK and RMS IA variations within 30 days.
	Type 1B: - 80% in 20 days - 98% in 30 days	Achieved Not achieved	91% in 30 days
	Type II: - 80% in 60 days - 98% in 90 days	Achieved Not achieved	89% in 90 days
	Type II reduced: - 98% in 30 days	Achieved	
	Type II extended: - 98% in 120 days	Achieved	

PM2 Clinical trials and investigations time targets	Timescales for clinical trial authorisations for medicines: - at least 98% in 30 calendar days - with an average of 14 calendar days or less for Phase I (healthy volunteer) trials	Achieved	
	Timescales for clinical investigation notifications for medical devices: Maximum of 60 days with an overall average of 54 days or less	Achieved	
PM3 Timescales for capturing and analysing adverse event reports	Maximum timescales between receipt of reports and making them available for evaluation and analysis: For fatal and serious device adverse incidents: 100% within 3 working days	Achieved	
	For fatal UK adverse drug reactions: - 90% within 24 hours - 100% within 72 hours	Achieved	
	For serious UK adverse drug reactions: - 95% within 72 hours - 100% within 5 days	Achieved	
	For medication error notifications; identification and transmission to National Patient Safety Agency (NPSA) within 7 days	Achieved	
	Publish medical device alerts (MDA) within 55 working days of senior management agreement to issue a MDA Immediate action MDAs within 18 working days of senior management agreement	Achieved Achieved	

PM4 Transparency of decision-making in the Agency and accountability to the public	In working towards achieving 100% compliance, ensure that at least 90% of requests under the Freedom of Information Act are replied to within 20 working days	Achieved	
	Publish 98% of UK Public Assessment Reports for medicines licensed within 60 days of final determination	Achieved	
PM5 Ensure excellent service to Ministers by securing the quality and effectiveness of MHRA's policy responsibilities across Government and by the management and quality assurance of MHRA Parliamentary and Ministerial business	Meet DH deadlines for responses to Parliamentary Questions (PQs) in at least 80% of cases, with less than 10% rewrite rate Meet Ministerial correspondence deadlines in at least 80% of cases with less than 10% rewrite rate	Not achieved Achieved	Cumulative total for Parliamentary Questions is 76%, with a less than 5% rewrite rate.
PM6 Finance target	Achieve an income and expenditure surplus during 2010/11, and as a minimum, exceed a 3.5% per annum return on capital employed	Achieved	

PM7 The recruitment, development and retention of a workforce of the necessary size, motivation and skill to undertake the objectives of the Agency	Achieve evaluation scores of an average overall of 75% for courses, to demonstrate they are successful and meeting the Agency's needs	Achieved	
	Ensure that at least 80% of staff who complete 3 month evaluation information are able to put their learning into practice within the following 3 months	Achieved	
	Develop and implement a continuous learning action plan to maximise the development opportunities identified in the Agency's recent successful IiP by March 2011	Achieved	

Performance Targets 2011/12

NO.	TARGET AREA	INDICATORS
PM1	Medicines Licensing time targets	The assessment of applications for new Marketing Authorisations for UK only: • 80% assessed in 100 days • 98% assessed in 150 days The assessment of applications for new Marketing Authorisations in European (MR, DC & centralised) procedures: • 97% assessed within the designated time
		The assessment of Type IB minor and Type II major variation applications in National and European (MR, centralised) procedures: • 97% assessed within the designated time
PM2	Clinical trials and investigations time targets	The assessment of applications for clinical trials of medicines and investigations of medical devices in the UK: • 98% in 30 days (all trial phases) an average time of 14 days (Phase I trials)
		Timescales for clinical investigation notifications for medical devices: • maximum of 60 days with an overall average of 54 days or less

PM3	Timescales for capturing and analysing adverse event reports	• Maximum timescales between receipt of reports and making them available for evaluation and analysis: • For fatal and serious device adverse incidents: 100% within 3 working days
		• Publish medical device alerts within 55[1] working days of senior management agreement to issue an MDA • Immediate action MDAs within 18 working days of senior management agreement **From 1 May 2011:** • Medical Device Alerts associated with a manufacturer's Field Safety Notice will be issued within 6 days • A Medical Device Alert without an associated Field Safety Notice will be issued in 10 days • Targets: 95% within 10 days, 100% within 15 days
		• For fatal UK adverse drug reactions: 90% within 24 hours, 100% within 72 hours
		• For serious UK adverse drug reactions: 95% within 72 hours, 100% within 5 days
		• Ensure all UK potential signals (relating to medicines) from whatever source are acted on promptly: • 80% initially evaluated within 5 working days

[1] These KPIs will change from 1 May 2012

PM4	Transparency of decision-making in the Agency and accountability to the public	• In working towards achieving 100% compliance, ensure that at least 90% of requests under the Freedom of Information Act are replied to within 20 working days
		The publication of UK assessment reports for new Marketing Authorisations and major non-safety variations of clinical importance: • 98% within 60 days of grant of new authorisations • 98% within 40 days of grant of the major variation.
PM5	Ensure excellent service to Ministers by securing the quality and effectiveness of MHRA's policy responsibilities across Government and by the management and quality assurance of MHRA Parliamentary and Ministerial business.	• Meet DH deadlines for responses to Parliamentary Questions in at least 80% of the cases, with less than 10% rewrite rate • Meet Ministerial correspondence deadlines in at least 80% of cases with less than 10% rewrite rate • Gain Ministerial agreement by the end of the year for a strategy and action plan for the Agency reflecting the new regulatory excellence programme
PM6	Finance target	• Achieve an income and expenditure surplus during 2011/2012, and as a minimum, exceed a 3.5% per annum return on capital employed
PM7	The recruitment, development and retention of a workforce of the necessary size, motivation and skill to undertake the objectives of the Agency.	• Achieve evaluation scores of at least an overall average of 75% for courses, to demonstrate they are successful and meeting the Agency's needs
		• Ensure that at least 80% of staff who complete 3 month evaluation information are able to put their learning into practice within the following 3 months
		• To maintain and review on an annual basis (March 2012) a continuous learning action plan designed to maximise the development opportunities identified by the Agency's IIP reports

Management Commentary

1. Description of the business

The Medicines and Healthcare products Regulatory Agency 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;
- **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;
- 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. Legislative, regulatory, operational and external environment

The Agency's Corporate Plan 2010 - 2015 (available on the MHRA website at http://www.mhra.gov.uk/home/groups/es-policy/documents/publication/con088244.pdf gives details of the legal, regulatory, operational and external environment, including key relationships with stakeholders.

This has been a year of very substantial change in the external operating environment of the Agency. On the EU side, two very significant pieces of new EU legislation been agreed, to strengthen pharmacovigilance and to improve defences against falsified medicines. In the UK, the new Government has signalled an ambitious agenda of regulatory reform, looking to reduce regulatory burdens where this is safe to do so and to bear down on new regulation. The Agency has in place a major project to simplify Medicines Legislation. This, together with work that has progressed on the Better Regulation of Medicines Initiative (BROMI) and risk-based inspection, provides a baseline for a programme of Regulatory Excellence that the Agency has established to respond to the new Government's regulatory agenda.

The pharmaceutical and medical devices industries operate globally and the regulatory frameworks that govern them increasingly evolve at the international level. Most importantly, medicines and medical devices used in the treatment of patients here in the UK increasingly come from countries outside the EU. The MHRA, therefore, has a very direct interest in pursuing international work to ensure the safety and integrity of those products, in order to safeguard health in the UK. Building and maintaining strong relationships with other international regulators is therefore essential in order to share information and to benefit from other regulators' knowledge and expertise in order to protect UK health. In 2010/11 this activity included collaboration agreements with Japan and New Zealand, a Memorandum of Understanding (MOU) between the MHRA and the Chinese State Food and Drugs Administration (SFDA), and a MOU between the British and Chinese Pharmacopoeias.

The 5th Global Summit of Heads of Medicines Regulatory Agencies, organised by the MHRA, included representatives from 19 countries across the globe, as well as the World Health Organisation (WHO), the European Commission, and the European Medicines Agency (EMA). Key issues for discussion included lessons learned from the H1N1 pandemic, substandard medicines, regulatory science and research, risk:benefit communication and global regulatory collaboration.

During the year the Agency actively worked with our European partners, the EU Commission and various industry groups to influence the future development of the devices regulatory regime. In addition, the Agency has worked hard to improve the consistency in which the various device Directives are interpreted and implemented throughout the EU and to improve the level and effect of cooperation between the various National Regulatory Authorities.

The MHRA fully endorses the concepts behind the "3Rs" (of replacement, reduction and refinement) regarding animal experimentation and whenever possible encourages companies to adopt methods that encompass this philosophy. Indeed, regarding nonclinical studies, companies are expected to comply with the ICH (the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use) M3(R2) guideline "Non-clinical safety studies for the conduct of human clinical trials and marketing authorisation for pharmaceuticals", Section 1.1 "Objectives of the Guideline" that makes the following statement: "This guidance should facilitate the timely conduct of clinical trials, reduce the use of animals in accordance with the 3R (reduce/refine/replace) principles and reduce the use of other drug development resources. Although not discussed in this guidance, consideration should be given to use of new *in vitro* alternative methods for safety evaluation. These methods, if validated and accepted by all ICH regulatory authorities, can be used to replace current standard methods".

Toxicologists from the MHRA regularly attend meetings and workshops organised by the National Centre for the Replacement, Reduction and Refinement of Animals in Research (NC3Rs). MHRA is also represented on the Inter-Departmental Group on the 3Rs.

7. Future developments

The creation of a statutory register for practitioners supplying unlicensed herbal medicines by the Health Professions Council (HPC) should open the way to use a derogation in European medicines legislation to create national arrangements under which registered practitioners, on the basis of a designation as an authorised healthcare professional, will be able to commission unlicensed herbal medicines to meet the special needs of their individual patients.

8. Performance Outcomes

The Agency's Business Plan for 2010/2011 identified seven areas in which it intended to pursue some level of outcome measurement:

- The timely, proportionate and effective response to public health risks;
- Reduce threat to health from counterfeit medicines and devices;
- Enable better medicines to be available for patients;
- Help health services to treat patients more cost effectively;
- Safer and more effective use of medicines and devices based on latest information;
- Better informed patients; and
- More targeted regulation based on risk and public health benefit.

It was accepted that this was an ambitious start to outcome measurement and that it is a new and developing direction for the Agency which will be reviewed during the course of the next year. In the first year the Agency did not expect to have much to report by way of results and anticipated that much of the year would be spent identifying streams of work and setting baseline data which would enable future measurement of success or otherwise in these areas.

However, the Agency has made some progress and has definite outcomes to report, including two case studies, which will be published on the MHRA's website in the very near future.

9. HM Treasury accounts direction

The accounts have been prepared in accordance with accounts direction given by HM Treasury, in accordance with section 4(6)(a) of the Government Trading Funds Act 1973.

10. 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 20013, 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 £121.4m was 7.7% higher than 2009/10 income (£112.7m). This is mainly as a result of an increase in licences and applications income (£4.8m) and service fee income (£2.4m).

Total costs for 2010/11 at £90.5m were 8.7% lower than the level of £99.1m in 2009/10. Staff numbers increased from 972 to 974 and total staff costs increased by 3% from £53.4m to £54.9m, whilst other operating costs decreased by 22.3% from £45.8m to £35.5m. The annual depreciation charge increased by £0.8m to £6.9m as a result of the investments in new assets.

The operating surplus for 2010/11 was £30.9m, compared to £13.6m in 2009/10. For 2011/12 there is a planned operating surplus of £15.0m, based on both reduced revenues and operating costs. There has been no fee increase since April 2010.

After charging a public capital dividend amount of £2.3m (2009/10 £1.6m), the net surplus in 2010/11 was £28.9m, leaving a retained surplus carried forward into 2011/12 of £75.8m.

Assets and liabilities

At 31 March 2011, the Agency had tangible fixed assets of £19.2m, an increase of £15.2m in the year. This was due to the capital investment in the Agency's new head office as well the upgrade to laptop computers from PCs to accommodate new working practices.

Intangible assets were £3.7m lower at £11.4m. Net current assets were £4.6m higher at £76.9m. After allowing for deferred revenue of £26.7m (31 March 2010: £31.3m) and long-term creditors and provisions of £1.4m (31 March 2010 £9.7m), the total net assets were £79.4m (31 March 2010: £50.4m).

Staff resources

During the year an average of 974 permanent full-time equivalent staff were employed.

The MHRA had a reduced programme of recruitment during the year as a result of restrictions placed on external recruitment by the Government. Its recruitment practices are in accordance with the Civil Service Commissioners Code.

The Agency has maintained and developed its knowledge capability through continuous improvement and career development which is built on the individual, specialist and corporate needs of staff. Continuing Professional Development (CPD) is actively supported across all professions. Leadership capability is maintained and improved through a programme of management and leadership training.

Recruitment

MHRA recruits staff on the basis of fair and open competition and selection on merit, in accordance with the recruitment code laid down by the Civil Service Commissioners. Systems are subject to internal and external checks. Where necessary permitted exceptions are applied.

22 staff were recruited during 2010-11:

	MALE	FEMALE
Executive Directors	0	0
Senior Civil Servants	1	1
Other Civil Service Staff	8	12
TOTAL	**9**	**13**

Seven people from ethnic minority groups were recruited. 34 per cent of the MHRA's staff are from ethnic minority groups and 1 per cent have a disability as defined under the Disability Discrimination Act 1995.

The permitted exceptions to the principles of fair and open competition and selection on merit were used 13 times for appointments over 12 months.

People with disabilities

In relation to employees with disabilities, MHRA complies with the equal opportunities legislation and provides special facilities where necessary.

Sickness absence

During the year, 3.1 per cent of available working days were recorded as sickness absence.

Employee involvement

Regular contact between managers and staff is actively encouraged to involve everybody in the work of their team and the Agency including one to one, unit, divisional and all-Agency staff meetings.

The MHRA was successful in achieving the Investors in People Bronze Standard in July. To be awarded the Bronze Standard the agency had to achieve an additional 26 evidence requirements.

The agency exceeded this by achieving 36 evidence requirements and the Bronze Award places the Agency in the top 3% of IiP organisations.

The Agency moved its headquarters during the year and staff were involved in the design of the working and environmental arrangements including selection of furniture, neighbourhood protocols etc. A post relocation evaluation is being undertaken and staff have been encouraged to share their experiences. Regular communication to staff was maintained through the Agency intranet site, Insite. There is also regular consultation and negotiation with trade union representatives.

11. Equality and diversity

MHRA complies with equal opportunities legislation and provides special facilities where necessary. The MHRA set up a cross-Agency Diversity Focus Group in 2010 and this group ran a diversity survey across the Agency. The group used the information from the survey to develop a diversity strategy which was launched in January 2011. The vision of the strategy is to create a culture of inclusion and fairness where all skills, abilities, experience and contributions are valued and recognised. An improvement action plan has also been introduced.

The MHRA is committed to providing equal opportunities to all staff. Our aim is to ensure that all staff are aware that any form of discrimination against people because of gender, marital status, race, age, sexual orientation, religion, disability, part time or fixed time working, is prohibited within the MHRA and to ensure that the Agency abides by the statutory regulations regarding discrimination.

12. Events after the reporting period

None.

13. Directors' statement with respect to conflict of interest

All Executive and Agency Board members have confirmed that they have no significant outside interests that conflict with their MHRA responsibilities.

14. Supplier payment performance

The MHRA is committed to the Better Payment Practice Code and the commitment to speed-up payments. Following the introduction of a new payment target by the Department for Business Innovation and Skills in July 2010, the Agency's policy from August 2010 is to pay all suppliers within five days of receipt of a valid invoice (previously 10 days). The MHRA's systems recorded invoice date, rather than the date of receipt, so payment will have been faster than the recorded statistics. No interest payments were made to suppliers under the Late Payment of Commercial Debts (Interest) Act 1998.

Using the Civil Service standard measure, during 2010/11 MHRA paid 81 per cent of supplier bills within five days and 100 per cent within 30 days (in 2009/10 63 per cent within 5 days and 99 per cent within 30 days).

	2010/11			2009/10		
	Transactions	**Value (£000)**	**%**	**Transactions**	**Value (£000)**	**%**
0 - 5 days	8,671	47,503	81	7,020	30,454	63
6 - 10 days	1,467	7,690	14	2,672	12,447	24
11 - 30 days	511	2.568	5	1,360	5,930	12
Over 30 days	23	116	-	41	159	1
	10,672	**57,877**	**100**	**11,093**	**48,990**	**100**

15. 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. Additional contracts are for: travel, with FCm Travel Solutions; hotel bookings, with Expotel; management and leadership courses, with the Oxford Group; and scientific analysis work, with LGC Limited.

16. 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 is responsible for the detailed identification, monitoring and review of the Agency's corporate risks. These 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.

17. 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.

18. Sustainable development

The Agency moved its main London office from Vauxhall to new premises based in Victoria between October and November 2010. The Agency required contractors to undertake the refurbishment of the new building to obtain a good rating under the Ska scheme, which is an environmental labelling method designed to rate and compare the environmental performance of fit-out projects for office buildings in the UK. At time of publication, the Agency had not yet

received the rating achieved for this project but it was expected that it would achieve at least a bronze level.

Within the new premises, the Agency has taken the opportunity to make significant changes to the working environment with a view to improving sustainability performance and reducing costs. These changes include:

- Reduced physical space with hot-desking arrangements for all staff;
- Open-plan working for all including the Chairman and Chief Executive;
- No individual waste bins – there are central waste bins which encourage more recycling;
- All staff now have laptops and are encouraged to take these to meetings rather than print-off papers;
- No desktop PCs – docking stations are less power-hungry. The initial estimate of energy savings from the move to laptops is around 74 per cent equivalent to around 83 tonnes of CO_2 emission per annum;
- 12 desktop printers compared to 324 in the old building. Initial estimates of energy savings from this change is around 90 per cent equivalent to around 88 tonnes of CO_2 emission per annum ;
- 25 central printing stations for over 800 staff, all of which are default set to double-sided printing;
- Movement activated lighting in all meeting rooms;
- No individual electrical equipment is allowed (such as heaters, kettles, etc.).

All redundant desktop PCs, old laptops and printers were donated to Remploy.

The Agency expects to see significant reductions in power usage, paper and water as a result of these changes. In the meantime, the Agency is revising its Sustainable Development Plan for the next two years in line with the new ways of working. The Agency will be working towards central government targets for sustainability and the revised plan will show this. The move to the new premises has given the opportunity to better measure usage of power and water – these data were not available in the previous premises and so meaningful targets could not be set.

19. Pension liabilities

These are covered in notes 6.3 and 16 to the accounts.

20. Disclosure of relevant audit information

As far as the Chief Executive is aware, there is no relevant audit information of which the MHRA's auditors are unaware. The Chief Executive has taken all reasonable steps he ought to have taken to make himself aware of any relevant audit information and to establish that the MHRA's auditors are aware of that information.

21. Audit services and costs

The Comptroller and Auditor General (C&AG) is head of the National Audit Office and is appointed as the external auditor of the MHRA trading fund under section 4(6) of the Government Trading Funds Act 1973. The auditor's remuneration payable is £96,000 for the year ended 31 March 2011 (£98,000 for the year ended 31 March 2010). The internal audit function has been provided by PriceWaterhouseCoopers who have been appointed by MHRA under a non-statutory

letter of engagement to provide an independent review of the systems and workings supporting performance indicators reported in the annual accounts.

22. 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/.

23. Personal data security incidents

During the year there were no incidents that resulted in the loss of personal data by MHRA employees.

24. Freedom of information

The Freedom of Information Act has now been in place for five years and is a valuable component in the MHRA's commitment to, and demonstration of, openness and transparency. The Agency routinely makes available large volumes of information on its website, and information disclosed under the Act is published proactively in cases of special interest. Other successful or partly successful requests are regularly listed in summary form on the website, with the full disclosure available on demand. 2010 saw yet another increase in the number of requests arriving at the Agency from 516 to 534, making it the busiest year so far for FOIA requests. As before the majority of requests came from industry and members of the public, although journalism and the legal profession were also well represented. Requests for Internal reviews increased again in 2010 from 8 to 18, as did the number of Information Commissioner investigations of Agency decisions. The Agency also had another successful outcome in only the second Information Tribunal consideration of an Agency decision.

Remuneration Report

Service Contracts

Civil service appointments are made in accordance with the Civil Service Commissioners' Recruitment Principles. The Principles require 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. Their appointment can be terminated with three months' notice on either side. Early termination, other than for misconduct, would result in the individual receiving compensation as set out in the Civil Service Compensation Scheme. The Chief Executive's appointment can be terminated with three months' notice on either side.

Further information about the work of the Civil Service Commissioners can be found at http://civilservicecommission.independent.gov.uk/

The Chairman and the Agency Board Directors are appointed by the Appointments Commission and are on fixed term contracts.

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 by a Pay Committee whose members are Professor Sir Kent Woods, Lisa Arnold (Non-Executive Director) and Harbhajan Singh Brar (DH HR Director). Professor Sir Kent Woods', Professor Sir Alasdair Breckenridge's and Non Executive Directors' salary and bonus awards are set by DH through the Department's senior salaries review processes.

Remuneration

Executive Board – Salaries - £000	2010/11		2009/10	
	Salary	Bonus	Salary	Bonus
Professor Sir Kent Woods - Chief Executive [1]	190 - 195	5 - 10	190 - 195	0 - 5
Mr Peter Commins - Chief Operating Officer	125 - 130	5 - 10	125 - 130	10 - 15
Dr June Raine, CBE - Director of Vigilance & Risk Management of Medicines	120 - 125	0 - 5	120 - 125	10 - 15
Dr Ian Hudson - Licensing Director	115 - 120	5 - 10	115 - 120	10 - 15
Mr Gerald Heddell - Director of Inspection, Enforcement and Standards	105 - 110	0 - 5	105 - 110	10 - 15
Mrs Alison Davis - Director of Information Management	95 - 100	0 - 5	95 - 100	5 - 10
Dr Susanne Ludgate - Clinical Director - Devices	90 - 95	0 - 5	90 - 95	5 - 10
Mr Geoff LeFevre - Director of Human Resources	90 - 95	0 - 5	90 - 95	5 - 10
Mr Jonathan Mogford - Director of Policy [2]	85 - 90	0 - 5	5 - 10	0 - 5
Mr Simon Gregor - Director of Communications [3]	90 - 95	0 - 5	90 - 95	5 - 10
Mrs Diane Leakey - Acting Director of Communications [3]	30 - 35	N/A	N/A	N/A
Mr Clive Bray - Director of Device Technology & Safety [4]	40 – 45	0 - 5	95 - 100	5 - 10
Agency Board – Salaries - £000	**2010/11**		**2009/10**	
	Salary	Bonus	Salary	Bonus
Professor Sir Alasdair Breckenridge, CBE - Chairman	90 - 95	5 - 10	90 - 95	10 - 15
Ms Lisa Arnold - Non Executive Director	10 - 15	N/A	10 - 15	N/A
Dr Shelley Dolan - Non Executive Director	5 - 10	N/A	5 - 10	N/A
Mr Michael Fox - Non Executive Director	5 - 10	N/A	5 - 10	N/A
Professor Barrington Furr, OBE - Non Executive Director	5 - 10	N/A	5 - 10	N/A
Professor Vincent Lawton, CBE - Non Executive Director	5 - 10	N/A	5 - 10	N/A
Sir John Lilleyman - Non Executive Director [5]	5 - 10	N/A	0 - 5	N/A
Professor Angus Mackay, OBE - Non Executive Director	5 - 10	N/A	5 - 10	N/A
Mr John Williams, CBE - Non Executive Director [6]	5 - 10	N/A	0 - 5	N/A

Salary

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

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

[1] The Chief Executive is on secondment to the Agency from the University of Leicester commencing 1 January 2004 and ending on 31 May 2013. During 2010/11 the MHRA paid a total of £255,326 (2009/10 £243,801) 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] Mr Jonathan Mogford was appointed as Director of Policy on 1 March 2010.

[3] Mr Simon Gregor went on long term sick leave on 18 October 2010. Mrs Diane Leakey has been Acting Director of Communications since 18 October 2010. Mr Simon Gregor resigned from the Agency with effect from 19 April 2011.

[4] Mr Clive Bray resigned with effect from 31 August 2010. His position is temporarily covered by Mr Peter Commins and Dr Susanne Ludgate.

[5] Sir John Lilleyman was appointed as non-executive Director on 1 September 2009.

[6] Mr John Williams was appointed as non-executive Director on 1 September 2009.

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 31/3/11 and related lump sum	Real increase in pension and related lump sum at pension age	* CETV at 31/3/11	* CETV at 31/3/10	Real increase in CETV
	£000	£000	£000	£000	£000
Mr Peter Commins Chief Operating Officer	60 - 65	0.0 - 2.5	**978**	**904**	(2)
Dr June Raine, CBE Director of Vigilance & Risk Management of Medicines	35 - 40 plus lump sum of 115 - 120	0.0 - 2.5 plus lump sum of 0.0 - 2.5	**881**	**811**	6
Dr Ian Hudson Licensing Director	30 - 35	0.0 - 2.5	**459**	**410**	9
Mr Gerald Heddell Director of Inspection and Standards	10 - 15	0.0 - 2.5	**204**	**173**	24
Mrs Alison Davis Director of Information Management	5 - 10	0.0 - 2.5	**101**	**77**	15
Dr Susanne Ludgate Clinical Director – Devices	40 - 45 plus lump sum of 120 - 125	(0.0 - 2.5) plus lump sum of (0.0 - 2.5)	**901**	**882**	(2)
Mr Geoff LeFevre Director of Human Resources	20 - 25 plus lump sum of 60 - 65	0.0 - 2.5 plus lump sum of 0.0 - 2.5	**482**	**460**	10
Mr Jonathan Mogford Director of Policy	20 - 25 plus lump sum of 65 - 70	2.5 - 5.0 plus lump sum of 10.0 - 12.5	**341**	**268**	48
Mr Simon Gregor Director of Communications	20 - 25	0.0 - 2.5	**158**	**139**	4
Mrs Diane Leakey Acting Director of Communications from 18.10.2010	30 - 35 plus lump sum of 90 - 95	0.0 - 2.5 plus lump sum of 5.0 - 7.5	**584**	**543**	38
Mr Clive Bray Director of Devices Technology & Safety to 31.08.2010	40 - 45 plus lump sum of 135 - 140	(0.0 - 2.5) plus lump sum of (0.0 - 2.5)	**1,016**	**1,007**	(2)

* 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.

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 per cent of pensionable earnings for **classic** and 3.5 per cent 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 per cent 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 per cent and 12.5 per cent (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 per cent of pensionable salary (in addition to the employer's basic contribution). Employers also contribute a further 0.8 per cent 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 Sir Kent Woods
Chief Executive and Accounting Officer
Medicines and Healthcare products Regulatory Agency
6 July 2011

Statement of the Agency's and Chief Executive's Responsibilities

Under 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

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. 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 2011.

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 2011, 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 2011 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 manager is responsible for the continuous improvement in the MHRA's risk management policies and procedures. The manager also provides support and advice on risk management issues where required.

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 2011.

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

An internal audit is commissioned annually to review various aspects of the Agency's corporate governance and risk management systems in order to ensure continuous improvement by identifying new areas where best practice could be adopted. The auditors noted that the fact that there was only one recommendation relating to pharmacovigilance in the Benchmarking of European Medicines Agencies (BEMA) review reflected a strong control environment in place. The relationship between the Agency and the pharmaceutical industry in the handling of ADR reports was acknowledged as being of good practice. The annual Follow Up audit of all previous recommendations acknowledged the Agency's good practice of self assessment framework, whereby audit stakeholders are required to confirm centrally that all recommendations agreed within internal audit reports are completed or status of implementation is reported to the Risk and Audit Committee.

The risk and control framework

Our management of risk is embedded in planning and delivery through:

- the business planning process with risk registers,
- policies and standard operating procedures across the whole Agency.

The consideration of risk includes 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 and business efficiency manager 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 to strengthen the Agency's risk management system, held four meetings during the year to 31 March 2011. 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 2011.

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.

Data protection and information assurance

The MHRA has in place various robust and specific arrangements to ensure information security, including data protection, information security and information risk policies, which apply to all staff. Other arrangements include secure and confidential storage of information and encrypted removable equipment such as USB memory sticks for key staff. The MHRA has a secure data wiping and hardware disposal process for all obsolete and decommissioned computer equipment. The MHRA has confidential disposal arrangements in place.

The IMD Director holds the role of Senior Information Risk Owner (SIRO). This is one of the requirements to strengthen controls around information security set out in the report of the Data Handling Review, which was carried out in 2008 for the Cabinet Office. The SIRO makes an annual report of compliance with the requirements for protecting information and an assessment of information risk management to the Department of Health and to me in my role as the MHRA's Accounting Officer.

The MHRA does not routinely store sensitive personal data in medical records as part of its general functions. Where other sensitive personal information is held it is not usual for it to be transferred on portable media and it is closely controlled within the systems that process it. Board-level responsibility for the management of information risk rests with the SIRO. All significant information risks are included in the divisional risk register and reported to the Risk and Audit Liaison Group and the Risk and Audit Committee. Staff have been reminded of what to be alert for in the handling of sensitive personal data as defined by the Department of Health and relevant training will be provided for key personnel as required. All staff have been required to complete Level 1 Information Assurance training, as provided by the National School of Government.

There have been no Serious Untoward Incidents involving sensitive personal data in the past year and the overarching information risk is considered low.

The Agency has formal governance processes, as part of the corporate governance, which support maintaining information assurance while enabling delivery of its business needs. Further work will be undertaken to strengthen our long-term IT strategy to support our information governance standards and to reflect future needs of the Agency.

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 eight non-executive directors. The Agency Board had regular meetings during the year to 31 March 2011, 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 me as Accounting Officer and to 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 2011. The main agenda items were the corporate risk register, the 2009/10 NAO Final Annual Management letter, the NAO 2010/11 Interim Audit Report, various Internal Audit progress reports for 2010/11, the Audit Recommendations Tracker for monitoring the implementation of audit recommendations, the Benchmarking of European Medicines Agency (BEMA) audit, the MHRA quality management system and the NAO's ALB Summary Management Letter as well as the Internal Audit plan for 2010/11. These reviews in aggregate played a significant part in the Risk and Audit Committee's advice to me as 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 myself as Chief Executive and the Heads of Divisions, also convened regularly during the year to 31 March 2011, to undertake their executive responsibility for the strategy, operational management, corporate risk management and service delivery of the Agency. As the Accounting Officer, I am 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 2011 was provided by PricewaterhouseCoopers (PwC) under a three-year contract, which commenced on 1 April 2008. The PwC appointment was made under an Office of Government Commerce (OGC) Framework Agreement. It has been extended by mutual agreement by one year to 31 March 2012.

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 2010/11 was designed to focus mainly on the on the adequacy of controls around required areas, such as governance, as well as the operational areas assessed as presenting higher risk to the Agency. The Internal Audit Plan was themed around three core systems and processes:

- Risk management and corporate governance
- Financial risks and controls
- Business processes

In total eight reviews were conducted. The internal audits on Income Model, Banking Internal Controls, Business Continuity Management, Pharmacovigilance and the annual Follow Up reviews received moderate assurances. Two others on Proactive Anti Fraud Work and Information Governance received limited assurances while the review on KPIs was not subject to an assurance rating. The Proactive Anti Fraud Work audit contained two high risk weaknesses relating to non compliance with the Agency's Standard Operating Procedures. These non-compliances related to the use of Government Procurement Cards where insufficient review of expenses by authorised signatories was identified together with instances of no receipts being provided. The one high risk finding arising from the Information Governance audit was largely procedural and expected to be corrected through the continuing work undertaken by the data cleansing team. From the year's audit as a whole, all the internal audit recommendations (with the exception of 3 items categorised as low which were rejected), were accepted by management, A programme of implementation has been agreed with anticipated completion during the current year 2011/12 commenced.

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 operational areas.

Significant internal control issues

The internal audit reports on Proactive Anti Fraud Work and Information Governance 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 2011/12 commenced.

Accounting Officer's comment

On the basis of management comments provided, management has taken the time to consider the implications of the findings and associated risks prior to agreeing the implementation of recommendations. As Accounting Officer, I note that the audits undertaken do identify a number of areas where there are some control weaknesses and areas which require attention; these are in the process of being addressed by managers. I welcome the recommendations made and acknowledge the need for some areas of improvement which have been identified.

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 Sir Kent Woods
Chief Executive and Accounting Officer
Medicines and Healthcare products Regulatory Agency
6 July 2011

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 2011 under the Government Trading Funds Act 1973. These comprise the Income statement, the Statement of Financial Position, the Statement of Cash flows, Statement of Changes in taxpayers equity 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

As explained more fully in the Statement of the Agency and Chief Executive's responsibilities**,** the Agency and Chief Executive are responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view. My responsibility is to audit, certify and report on the financial statements in accordance with the Government Trading Funds Act 1973. I conducted my audit in accordance with International Standards on Auditing (UK and Ireland). Those standards require me and my staff to comply with the Auditing Practices Board's Ethical Standards for Auditors.

Scope of the audit of the financial statements

An audit involves obtaining evidence about the amounts and disclosures in the financial statements sufficient to give reasonable assurance that the financial statements are free from material misstatement, whether caused by fraud or error. This includes an assessment of: whether the accounting policies are appropriate to the Agency's circumstances and have been consistently applied and adequately disclosed; the reasonableness of significant accounting estimates made by the Agency; and the overall presentation of the financial statements. In addition I read all the financial and non-financial information in the Chairman and Chief Executive's Review, Corporate Governance and Management Commentary to identify material inconsistencies with the audited financial statements. If I become aware of any apparent material misstatements or inconsistencies I consider the implications for my certificate.

In addition, I am required to obtain evidence sufficient to give reasonable assurance that the expenditure and income reported in the financial statements have been applied to the purposes intended by Parliament and the financial transactions conform to the authorities which govern them.

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.

Opinion on Financial Statements

In my opinion:

- the financial statements give a true and fair view of the state of Agency's affairs as at 31 March 2011 and of its profit for the year then ended; and

- the financial statements have been properly prepared in accordance with the Government Trading Funds Act 1973 and HM Treasury directions issued thereunder.

Opinion on other matters

- In my opinion:

- the part of the Remuneration Report to be audited has been properly prepared in accordance with HM Treasury directions made under the Government Trading Funds Act 1973; and

- the information given in the Chairman and Chief Executive's Review, Corporate Governance and the Management Commentary for the financial year for which the financial statements are prepared is consistent with the financial statements.

Matters on which I report by exception

I have nothing to report in respect of the following matters which I report to you if, in my opinion:

- adequate accounting records have not been kept; or

- the financial statements are not in agreement with the accounting records or returns; or

- I have not received all of the information and explanations I require for my audit; or

- the Statement on Internal Control does not reflect compliance with HM Treasury's guidance.

Report

I have no observations to make on these financial statements.

Amyas C E Morse
Comptroller and Auditor General
National Audit Office
157 - 197 Buckingham Palace Road
Victoria
London
SW1W 9SS

7 July 2011

Accounts

INCOME STATEMENT for the year ended 31 March 2011

	NOTE	**2010/11**		2009/10	
		£000	**£000**	£000	£000
Revenue				Restated	Restated
Revenue from trading activities	3	**110,479**		101,186	
Revenue from Department of Health	3	**10,908**		11,504	
Total Revenue			**121,387**		112,690
Expenditure					
Staff costs	6	**(54,981)**		(53,373)	
Operating costs	7	**(35,496)**		(45,750)	
Total Expenditure			**(90,477)**		(99,123)
Operating surplus			**30,910**		13,567
Finance income	8		**223**		147
Finance costs	8		**(46)**		(64)
Other gains	9		**48**		4
Surplus for the financial year			**31,135**		13,654
Dividend payable			**(2,271)**		(1,583)
Retained surplus for the year			**28,864**		12,071

The notes on pages 48 to 68 form part of these accounts.

STATEMENT OF FINANCIAL POSITION as at 31 March 2011

	NOTE	**31 March 2011**		31 March 2010	
		£000	**£000**	£000	£000
Non-current assets					
Plant and equipment	10	**19,187**		3,963	
Intangible assets	11	**11,382**		15,127	
Total non-current assets			**30,569**		19,090
Current assets					
Trade and other receivables	12	**18,617**		17,398	
Cash and cash equivalents	13	**87,517**		79,385	
Total current assets			**106,134**		96,783
Total assets			**136,703**		115,873
Current liabilities					
Trade and other payables	14	**(26,964)**		(19,733)	
Provisions	16	**(18)**		(3,163)	
Other liabilities	17	**(2,271)**		(1,583)	
Total current liabilities			**(29,253)**		(24,479)
Total assets less current liabilities			**107,450**		91,394
Non-current liabilities					
Borrowings	15	**(1,328)**		(1,328)	
Provisions	16	**(45)**		(8,354)	
Other liabilities	17	**(26,727)**		(31,341)	
Total non-current liabilities			**(28,100)**		(41,023)
Assets less liabilities			**79,350**		50,371
Taxpayers' equity:					
Public dividend capital			**1,329**		1,329
Reserves					
Revaluation reserve			**155**		155
Income and expenditure reserve			**954**		954
Government grant reserve			**1,068**		953
Retained earnings			**75,844**		46,980
Total equity			**79,350**		50,371

Professor Sir Kent Woods
Chief Executive and Accounting Officer
Medicines and Healthcare products Regulatory Agency
6 July 2011

The notes on pages 48 to 68 form part of these accounts.

STATEMENT OF CASH FLOWS for the year ended 31 March 2011

		2010/11		2009/10	
	NOTE	**£000**	**£000**	£000	£000
Cash flows from operating activities					
Operating surplus			**30,910**		13,567
Impairments and reversals		**-**		865	
Interest paid	8	**(46)**		(64)	
Gain on foreign exchange	9	**48**		4	
Transfer from government grant reserve		**300**		500	
Depreciation and amortisation	11	**6,722**		5,968	
(Decrease) in deferred revenue		**(4,614)**		(1,007)	
(Increase)/Decrease in trade and other receivables	12	**(1,219)**		26	
Increase in trade and other payables		**7,919**		5,167	
(Decrease)/Increase in provisions	16	**(11,454)**		7,724	
Dividend paid	17	**(2,271)**		(1,583)	
Net cash inflow from operating activities			**26,295**		31,167
Cash flows from investing activities					
Interest received	8	**223**		147	
Purchase of plant and equipment	10	**(17,130)**		(1,247)	
Purchase of intangible assets	11	**(1,256)**		(2,121)	
Net cash outflow from investing activities			**(18,163)**		(3,221)
Net cash inflow before financing			**8,132**		27,946
Net increase in cash and cash equivalents	13		**8,132**		27,946
Cash and cash equivalents at the beginning of the financial year	13		**79,385**		51,439
Cash and cash equivalents at the end of the financial year	13		**87,517**		79,385

The notes on pages 48 to 68 form part of these accounts.

STATEMENT OF CHANGES IN TAXPAYERS' EQUITY

	Public dividend capital (PDC)	Retained earnings	Revaluation reserve	Gov't grant reserve	Income & expenditure reserve	Total
	£000	£000	£000	£000	£000	£000
Balance at 31 March 2009	**1,329**	**34,909**	**168**	**587**	**954**	**37,947**
Changes in taxpayers' equity for 2009-10						
Surplus for the year	-	12,071	-	-	-	**12,071**
Receipt of government grant	-	-	-	500	-	**500**
Depreciation of government grant	-	-	-	(134)	-	**(134)**
Indexation	-	-	(13)	-	-	**(13)**
Balance at 31 March 2010	**1,329**	**46,980**	**155**	**953**	**954**	**50,371**
Changes in taxpayers' equity for 2010-11						
Surplus for the year	**-**	**28,864**	**-**	**-**	**-**	**28,864**
Receipt of government grant	**-**	**-**	**-**	**300**	**-**	**300**
Depreciation of government grant	**-**	**-**	**-**	**(185)**	**-**	**(185)**
Indexation	**-**	**-**	**-**	**-**	**-**	**-**
Balance at 31 March 2011	**1,329**	**75,844**	**155**	**1,068**	**954**	**79,350**

The notes on pages 48 to 68 form part of these accounts

NOTES TO THE ACCOUNTS

1 Accounting Policies

1.1 General

1.1.1 Compliance with government accounting requirements

The financial statements have been prepared in compliance with the Government Trading Funds Act (1973) and in accordance with the 2010/11 Government IFRS based Financial Reporting Manual (FReM) issued by HM Treasury. The accounting policies contained in the FReM apply International Financial Reporting Standards as adapted or interpreted for the public sector context. Where the FReM permits a choice of accounting policy, the accounting policy which is judged to be the most appropriate to the particular circumstances of the Medicines and Healthcare products Regulatory Agency for the purpose of giving a true and fair view has been selected.

The particular policies adopted by the Medicines and Healthcare products Regulatory Agency are described below. They have been applied consistently in dealing with items that are considered material to the accounts.

1.2 Accounting convention

The Accounts have been prepared under the historical cost convention, modified to allow for the revaluation of non-current assets (excluding IT equipment and assets under the course of construction), at their value to the business by reference to their current costs.

1.3 Non-Current Assets

1.3.1 Plant & Equipment

Capitalisation

Plant & Equipment are capitalised provided they:

- individually have a cost equal to or greater than £5,000; or
- collectively have a cost of at least £5,000.

Computer and telecom equipment are stated in the Statement of Financial Position at cost less subsequent accumulated depreciation and any impairment in value. This carrying amount is broadly consistent with fair value due to the short economic life of these assets.

Laboratory equipment, fittings, furniture and office equipment are revalued annually using Office of National Statistics cost indices. These indices reflect the upward or downward movements in valuation of these assets and are broadly consistent with fair values.

Increases arising on revaluation are taken to the Revaluation Reserve except when it reverses a revaluation decrease for the same asset previously recognised in the Income Statement, in which case it is credited to the Income Statement to the extent of the decrease previously charged there. A revaluation decrease is charged to the Revaluation Reserve to the extent that there is a balance on the reserve for the asset and, thereafter, to the Income Statement.

1.3.2 Depreciation, amortisation and impairments

Assets under construction are not depreciated. Otherwise, depreciation and amortisation are charged on a straight line over the estimated useful life of the asset as follows:

Laptops and associated applications	3 years
Laboratory Equipment	5 -10 years
Computer servers, Software, Office equipment, Furniture, Fixtures and Fittings	5 -10 years
Office refurbishment costs	10 years

At each Statement of Financial Position date, the Agency checks whether there is any indication that any of its tangible or intangible non-current assets have suffered an impairment loss. If there is indication of an impairment loss, the recoverable amount of the asset is estimated to determine whether there has been a loss and, if so, its amount.

If there has been an impairment loss, the asset is written down to its recoverable amount, with the loss charged to the Revaluation Reserve to the extent that there is a balance on the reserve for the asset and, thereafter, to the Income Statement. Where an impairment loss subsequently reverses, the carrying amount of the asset is increased to the revised estimate of the recoverable amount but capped at the amount that would have been determined had there been no initial impairment loss. The reversal of the impairment loss is credited to the Income Statement to the extent of the decrease previously charged there and thereafter to the revaluation reserve.

1.3.3 Intangible Assets

Intangible assets are capitalised provided they:

- individually have a cost equal to or greater than £5,000; or
- collectively have a cost of at least £5,000.

Intangible assets acquired are initially recognised at fair value and amortised over a period not exceeding ten years. Following initial recognition, they are carried at cost less accumulated depreciation and any impairment in value.

Assets in the course of construction are carried at cost, less any impairment loss. Cost includes professional fees. Assets are revalued and depreciation commences the month after they are brought into use.

The useful lives of intangible assets are assessed to be either finite or indefinite. The Agency holds no assets with indefinite life. The estimated useful lives are:

Computer software	5 -10 years
Sentinel architecture costs	10 years
Sentinel software	Remaining life of the Sentinel architecture

Intangibles include the following assets developed in house:

Description	Amortisation period	Carrying value (£000)
Sentinel architecture	120 months	£2,478
Product licensing	96 months	£1,208
Pharmacovigilance	94 months	£2,267

Sentinel architecture is the hardware infrastructure (servers, storage, network, printers, scanners) that hosts the Sentinel suite of applications used by the MHRA e.g. Product Licensing Case Folder.

The Product Licensing System is the database used to record Product Licence information data and to manage the workflow for new Product Licences and changes to existing Product Licences.

1.4 Cash
Cash represents cash held with the Government Banking Service and foreign currency held in commercial bank accounts.

1.5 Losses and Special Payments
Losses and special payments are items that Parliament would not have contemplated when it passed legislation. By their nature they are items that ideally should not arise. They are therefore subject to special control procedures compared with the generality of payments. They are divided into different categories, which govern the way each individual case is handled and are charged to the relevant functional headings on a cash basis.

1.6 Revenue
Revenue from trading activities represents the invoiced amount and accrued amounts to be invoiced. Revenue is determined by reference to the value of work carried out to the statement of financial position date. Revenue is recognised according to type of income stream. The Agency has the following income streams:

- Applications and variations: A number of processes have been assigned to determine the stage of work completed. This determines the revenue to recognise and to defer.
- Service fees: These are invoiced annually early in the financial year.
- Inspections: Income is recognised on completion of all the inspection processes.
- EMA (European Medicines Agency): Income from EMA work is recognised on completion of predetermined stages.
- Clinical trials: Revenue is recognised as and when earned.
- Miscellaneous income: This is non statutory income recognised as and when earned.

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

Interest revenue is recognised in the income statement and represents interest earned.

1.7 Foreign currencies
The Agency's functional currency and presentational currency is sterling. Transactions denominated in a foreign currency are translated into sterling at the exchange rate ruling on the dates of the transactions. At the end of the reporting period, monetary items denominated in foreign currencies are retranslated at the spot exchange rate on 31 March. Resulting exchange gains and losses for either of these are recognised in the Income Statement in the period in which they arise.

1.8 Employee Benefits
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

Short-term employee benefits
Salaries, wages and employment-related payments are recognised in the period in which the service is received from employees. The cost of leave earned but not taken by employees at the

end of the period is recognised in the financial statements. The calculated cost is based on a weighted sample covering all grades of staff and the year on year movement is charged to the Income Statement. For 2010/11, with the current pay freeze, the provision already created was deemed to be sufficient and no further adjustment was made.

Retirement benefit costs
Past and present employees of the Agency are covered by the provisions of the Principal Civil Service Pension Schemes (PCSPS) which are defined benefit schemes or a "money purchase" stakeholder pension scheme. The defined benefit scheme is unfunded and non-contributory except in respect of dependants' benefits. The Agency recognises the expected cost of these elements on a systematic and rational basis over the period during which it benefits from employees' service by payment to the PCSPS of amounts calculated on an accruing basis. Liability for payment of future benefits is a charge on the PCSPS. In respect of the defined contribution schemes, the MHRA recognises the contributions payable for the year.

1.9 Leases
All costs of operating leases are charged to the Income Statement as incurred.

Lease incentives are recognised initially as a liability and subsequently as a reduction of rentals on a straight-line basis over the lease term.

There were no finance leases.

1.10 Provisions for liabilities and charges
Full provision is made in the accounts for all future liabilities in respect of payments to employees who have retired early. Payments are due from the MHRA from the date of early retirement until age 60, when the Principal Civil Service Pension Scheme (PCSPS) assumes the liability. Provisions are recognised where the MHRA considers that there is a present obligation arising from a past event and that there is a probable outflow of economic benefit to settle the provision. Where a provision is measured using the cash flows estimated to settle the obligation, its carrying amount is the present value of those cash flows using HM Treasury's discount rate of 3.2 % in real terms.

The provision for bad debts and credit notes 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.

1.11 Contingent Liabilities
A contingent liability is a possible obligation that arises from past events and whose existence will be confirmed only by the occurrence or non-occurrence of one or more uncertain future events not wholly within the control of the Agency, or a present obligation that is not recognised because it is not probable that a payment will be required to settle the obligation or the amount of the obligation cannot be measured sufficiently reliably. A contingent liability is disclosed unless the possibility of a payment is remote.

1.12 Value Added Tax
Most of the activities of the Agency are outside the scope of VAT and, in general, output tax does not apply and input taxes on some purchases are recoverable. Irrecoverable VAT is charged to the relevant expenditure category or included in the capitalised purchase cost of non-current assets. Where output tax is charged or input VAT is recoverable, the amounts are stated net of VAT.

1.13 Public Dividend Capital (PDC)

Public dividend capital represents taxpayers' equity in the Agency. PDC is recorded at the value received. As PDC is issued under legislation rather than under contract, it is not treated as an equity financial instrument.

1.14 Government Grant Reserve

Government grants are grants from the Department of Health for the provision of services. Revenue grants are treated as deferred income initially and credited to income to match the expenditure to which they relate. Capital grants are credited to the government grant reserve and released to operating revenue over the life of the asset in a manner consistent with the depreciation and impairment charges for that asset. Assets purchased from government grants are valued, depreciated and impaired as described above for purchased assets. Gains and losses on revaluations and impairments are taken to the government grant reserve and, each year, an amount equal to the depreciation charge on the asset is released from the government grant reserve to the offset the expenditure.

1.15 Income and Expenditure Reserve

Income and Expenditure Reserve is a one off capital grant from the Department of Health and represents taxpayer's equity in the Agency.

1.16 Development Expenditure

Development expenditure is assessed and capitalised if it meets all of the following criteria:

- An asset is created that can be identified;
- It is probable that the asset created will generate future economic benefits; and
- The development cost of the asset can be measured reliably.

Capitalised development costs are amortised over their expected economic lives. Where no internally generated intangible asset can be recognised, development expenditure is recognised as an expense in the financial year in which it is incurred.

1.17 Current and deferred tax

As a trading fund, MHRA is not liable for Corporation Tax or Deferred Tax.

2 Financial Duty

The MHRA's financial duty is 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 requirement is that the MHRA should be managed so that its revenue:

a) consists primarily 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 a surplus on ordinary activities before interest and dividends equivalent to at least 3.5% return on average capital employed.

Net asset values are shown in the Statement of Financial Position. 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. The dividend payable is £2.271M (2009/10 £1.583M).

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.

3 Revenue

	2010/11		2009/10	
	£000	**£000**	£000	£000
			Restated*	Restated*
Licences and inspections income	**68,886**		64,088	
Service fee income recognised during the year	**29,143**		26,726	
Income from miscellaneous activities	**12,450**		10,372	
Trading Income		**110,479**		101,186
Income from Department of Health		**10,908**		11,504
		121,387		112,690

	2010/11		2009/10	
	£000	**£000**	£000	£000
Licences and inspections				
Applications	**35,192**		30,329	
Clinical trials	**2,476**		2,661	
EMA*	**6,929**		6,871	
Inspections	**9,535**		9,443	
Variations	**13,193**		13,103	
Others	**1,561**		1,681	
		68,886		64,088
Service fees		**29,143**		26,726
Miscellaneous income				
British Pharmacopoeia	**2,553**		2,286	
GPRD	**5,749**		5,277	
RAMA XL	**1,082**		992	
Seminar and twinning	**756**		702	
Others	**2,310**		1,115	
		12,450		10,372
Trading Income		**110,479**		101,186
Department of Health		**10,908**		11,504
Total Revenue		**121,387**		112,690

*Restated to reclassify bad debts previously classed as reduction to income.

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

*EU Income: EMA income relates to assessments of medicines, scientific advice provided and inspections undertaken on behalf of the European Medicines Agency.

4 Segmental information

The Agency's income is derived from its regulatory function in achieving its objectives of protecting, promoting and improving public health. The Agency has therefore determined that reporting the overall financial position is more appropriate as it is this that drives the Agency's decision making.

5 Fees and charges

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.

The Agency's income is derived from its regulatory function in achieving its objectives of protecting, promoting and improving public health.

Principal activities are as follows:

Devices: Operating vigilance and other systems for reporting, investigating and monitoring adverse reactions to medicines, adverse incidents involving medical devices and blood products and taking any necessary action to safeguard public health

Medicines: Responsible for assessing the safety, quality and efficacy of medicines and authorising their sale or supply in the UK for human use.

	Devices		Medicines		Total	
	2010/11	2009/10	**2010/11**	2009/10	**2010/11**	2009/10
	£000	£000	**£000**	£000	**£000**	£000
Operating Income	**11,266**	12,021	**110,121**	100,669	**121,387**	112,690
Operating Expenditure	**(9,602)**	(12,043)	**(80,875)**	(87,080)	**(90,477)**	(99,123)
Operating surplus / (deficit)	**1,664**	(22)	**29,246**	13,589	**30,910**	13,567

The table above is for the purposes of providing information on fees and charges, not IFRS 8 purposes.

6 Staff costs and numbers

6.1 Staff costs

	2010/11			2009/10
	Total	**Permanently Employed**	**Other**	Total Restated*
	£000	**£000**	**£000**	£000
Wages and salaries	42,873	42,106	767	41,845
Social security costs	3,783	3,761	22	3,663
Other pension contributions	8,355	8,324	31	8,047
Early retirement and redundancy	55	55	-	16
Sub-total	55,033	54,246	820	53,571
Less recoveries in respect of outward secondment	(85)	(85)	-	(198)
Total staff costs	**54,981**	**54,161**	**820**	53,373

***** Restated to reclassify secondment costs

6.2 Staff numbers

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

	2010/11			2009/10		
	Total	**Permanently Employed**	**Other**	Total	Permanently Employed	Other
Chairman	1	1	-	1	-	1
Executive Directors	10	9	1	10	10	0
Senior Civil Servants	109	108	1	103	99	4
Other Civil service staff	854	795	59	858	769	89
	974	913	61	972	878	94

6.3 Pensions

The PCSPS is an unfunded multi-employer defined benefit scheme, but the Agency is unable to identify its share of the underlying assets and liabilities. A full actuarial valuation was carried out at 31 March 2007. Details can be found in the resource accounts of the Cabinet Office: Civil Superannuation (*www.civilservice-pensions.gov.uk*).

The employees of the Agency are civil servants to whom the conditions of the Superannuation Acts 1965 and 1972 and subsequent amendments apply. Employees are eligible to join the PCSPS.

For early retirements, other than those due to ill-health, the additional pension liabilities are not funded by the scheme. The full amount of the liability for the additional costs is charged to the Income Statement at the time the Agency commits itself to the retirement, regardless of the method of payment.

For 2010/11, employers' contributions for MHRA employees of £8,311,346 with a further £13,795 respect of staff on secondment were payable to the PCSPS (£7,994,582 in 2009/10 and a further £27,695 in respect of staff on secondment) at one of four rates in the range 16.7 per cent to 24.3 per cent of pensionable pay (16.7 per cent to 24.3 per cent in 2009/10), based on salary bands. The scheme's actuary reviews employer contributions every four years, following a full scheme valuation. The contribution rates reflect benefits as they are accrued, not when costs are actually incurred, and reflect past experience of the scheme.

Employees can opt to open a partnership pension account, which is a stakeholder pension with an employer contribution. Employers' contributions of £176,580 (£166,205 in 2009/10) were paid to one or more of a panel of three appointed stakeholder pension providers. Employer contributions are age related and range from 3 per cent to 12.5 per cent of pensionable pay (3 per cent to 12.5 per cent in 2009/10). Employers can also match employee contributions up to a limit of 3 per cent of pensionable pay. In addition, employer contributions of £3,566 (£2,940 in 2009/10), 0.8 per cent of pensionable pay, were payable to the PCSPS to cover the cost of the future provision of lump sum benefits on death in service and ill-health retirement of these employees.

Contributions due to the partnership pension providers at the reporting period date were £20,036. No contributions were prepaid at that date.

There was one case of retirement on ill-health grounds during 2010/11. No additional pension liabilities were accrued.

7. Expenditure

7.1 Operating costs

	2010/11	2009/10
	£000	£000
		Restated*
Computing	**10,634**	8,958
Depreciation and amortisation	**6,907**	6,102
Other accommodation costs	**3,524**	3,934
Rentals under operating leases (see 7.2 below)	**2,878**	4,284
Medicines testing and laboratory expenses	**2,203**	2,099
Travel and subsistence	**2,110**	2,457
Tax & NI	**1,995**	-
Legal Services	**1,625**	1,244
Contracted-out administration services	**1,535**	1,355
Other administration costs	**1,307**	1,426
Telecommunication	**1,104**	1,001
Training	**745**	1,145
Printing, stationery and distribution	**666**	577
Committee costs	**650**	912
Pharmacovigilance database and other costs	**224**	237
Contracted-out personnel and payroll services	**179**	584
Bad debts	**184**	150
Consultancy	**124**	340
Auditors remuneration - audit fee	**96**	104
Marketing	**81**	270
Release of unutilised provision/Increase in provisions	**(3,275)**	7,706
Impairment of furniture and fittings	**-**	865
Total operating costs	**35,496**	45,750

*Restated to reclassify bad debts previously classed as reduction to income

7.2 Operating leases

The operating lease rental payments represent rent payable by the Agency for its properties and equipment under non-cancellable operating lease agreements. Most of the agreements are renewable at the end of the lease period at market rate and contain no rental escalation clauses. The Agency does not have an option to purchase the leased asset at the expiry of the lease period and no arrangements have been entered into for contingent rental payments.

As lessee

	Others	**Land and buildings**	**Others**	**Land and buildings**
Payments recognised as an expense	2010/11	2010/11	2009/10	2009/10
	£000	£000	£000	£000
Minimum lease payments	**84**	**2,878**	62	4,222
	84	**2,878**	62	4,222

Total future minimum lease payments	2010/11	2010/11	2009/10	2009/10
		£000	£000	£000
Payable:				
Within one year	**63**	**182**	43	4,187
Within two to five years	**26**	**15,070**	19	3,561
Over five years	**-**	**25,402**	-	127
Total	**89**	**40,654**	62	7,875

Total future sub-lease payments expected to be received: £172k (2009/10: £176k)

7.3 Finance Leases

The Agency had no finance leases in 2010/11.

8 Finance income and costs

	2010/11	2009/10
	£000	£000
Finance income		
Interest received from HM Paymaster General	**-**	147
Interest received from Government Banking Service	**223**	-
	223	147
Finance costs		
Interest on loans	**(46)**	(64)
Net cash inflow from returns on investments and servicing of Finance	**177**	83

9 Other gains and losses

	2010/11	2009/10
	£000	£000
Gain on foreign exchange	**48**	4
	48	4

10 Plant and equipment

	Computer and telecom equipment	Laboratory equipment	Fittings furniture and office equipment	Total
	£000	£000	£000	£000
Cost or valuation				
At 1 April 2010	**5,194**	**1,479**	**430**	**7,103**
Additions	2,652	300	14,176	17,128
Transfers	288	-	162	450
Reclassification*	130	(1)	441	570
At 31 March 2011	**8,264**	**1,778**	**15,209**	**25,251**
Depreciation				
At 1 April 2010	**1,928**	**1,092**	**120**	**3,140**
Reclassification*	(436)	-	432	(4)
Charged during the year	1,567	166	1,195	2,928
Depreciation at 31 March 2011	**3,059**	**1,258**	**1,747**	**6,064**
Net book value at 31 March 2011	**5,205**	**520**	**13,462**	**19,187**
Net book value at 31 March 2010	**3,266**	**387**	**310**	**3,963**
Asset financing:				
Owned				
Net book value at 31 March 2011	**5,205**	**520**	**13,462**	**19,187**

11 Intangible assets

	Computer Systems	Assets under Contruction	Software Licences	Total
	£000	£000	£000	£000
Cost or Valuation				
At 1 April 2010	**30,458**	**1,318**	**1,076**	**32,852**
Additions	182	338	736	1,256
Transfers	-	(450)	-	(450)
Reclassification*	(175)	-	38	(137)
At 31 March 2011	**30,465**	**1,206**	**1,850**	**33,521**
Amortisation				
At 1 April 2010	**17,090**	**-**	**635**	**17,725**
Reclassification*	436	-	(1)	435
Charged during the year	3,754	-	225	3,979
Amortisation at 31 March 2011	**21,280**	**-**	**859**	**22,139**
Net book value at 31 March 2011	**9,185**	**1,206**	**991**	**11,382**
Net book value at 31 March 2010	13,368	1,318	441	**15,127**
Asset financing:				
Owned				
Net book value at 31 March 2011	**9,185**	**1,206**	**991**	**11,382**

* Reclassification of assets to appropriate categories. This reclassification does not affect net book values.

12 Trade and other receivables

	31 March 2011	31 March 2010
	£000	£000
Due from the Department of Health (see 12.1 below)	**361**	510
Other trade receivables	**13,575**	12,121
Other receivables	**264**	256
Accrued income	**1,833**	2,256
Prepayments	**2,584**	2,255
	*** 18,617**	* 17,398

*Intra government balance disclosed in note 21

Other trade receivables are shown net of a provision for bad debts of £5.9M (31 March 2010 £5.7M) and credit notes of £5.6m (31 March 2010 £4.6m).

12.1 Amount Due from the Department of Health consists of:

	31 March 2011	31 March 2010
	£000	£000
Other trade receivables	**361**	2
Value Added Tax	**-**	508
	361	510

12.2 Provision for bad debt

	31 March 2011	31 March 2010
	£000	£000
Bad debt provision	**5,899**	5,714
	5,899	5,714

13 Cash and cash equivalents

	31 March 2011	31 March 2010
	£000	£000
Balance at 1 April	**79,385**	51,439
Net change in year	**8,132**	27,946
Balance at 31 March	**87,517**	79,385
Made up of		
Cash with Office of Paymaster General	**-**	68,579
Commercial banks and cash in hand	**87,517**	10,806
Cash and cash equivalents	**87,517**	79,385

14 Trade and other payables

	Current		Non-Current	
	31 March 2011	31 March 2010	**31 March 2011**	31 March 2010
	£000	£000	**£000**	£000
Due to Department of Health (see 14.1 below)	**311**	-	**-**	-
Payments received on account	**13,487**	11,757	**-**	-
Taxation and other social security costs	**2,041**	-	**-**	-
Other trade payables	**2,201**	2,307	**-**	-
Other payables	**1**	1	**-**	-
Accruals	**8,923**	5,668	**-**	-
	*** 26,964**	* 19,733	**-**	-

*****Intra government balance disclosed in note 21

14.1 Amount Due to the Department of Health consists of:

	Current		Non-Current	
	31 March 2011	31 March 2010	**31 March 2011**	31 March 2010
	£000	£000	**£000**	£000
Value Added Tax	**288**	-	**-**	-
Accruals	**23**	-	**-**	-
	311	-	**-**	-

15 Borrowings

	Current		Non-Current	
	31 March 2011	31 March 2010	**31 March 2011**	31 March 2010
	£000	£000	**£000**	£000
Loans from Department of Health	**-**	-	**1,328**	1,328
	-	-	**1,328**	1,328

16 Provisions

Provisions for liabilities and charges

	Current		Non-Current	
	31 March 2011	31 March 2010	**31 March 2011**	31 March 2010
	£000	£000	**£000**	£000
Early retirement	**18**	46	**45**	58
Other provisions	**-**	3,117	**-**	8,296
	18	3,163	**45**	8,354

	Early retirement	Other provisions	**Total**
	£000	£000	**£000**
At 1 April 2010	104	11,413	**11,517**
Arising during the year	-	-	**-**
Used during the year	(48)	(8,138)	**(8,186)**
Unwinding discount	7	**-**	**7**
Provision not required written back	-	(3,275)	**(3,275)**
At 31 March 2011	63	-	**63**
Expected timing of cash flows:			
Between 1 April 2011 and 31 March 2012	18	-	**18**
Between 1 April 2012 and 31 March 2014	30	-	**30**
Beyond 1 April 2014	15	-	**15**
Total	63	-	**63**

The provision for early retirement and voluntary severance is to cover the MHRA's estimated liability for pensions in respect of early retirements. These are long term commitments dependent on the life expectancy of the pensioners.

Other provisions were in respect of building costs. Following successful conclusion of an agreement with the landlords on early surrender of Market Towers, resulting in a lower than expected payment, the balance of the provision was released.

17 Other Liabilities

	Current		Non-Current	
	31 March 2011	31 March 2010	**31 March 2011**	31 March 2010
	£000	£000	£000	£000
Deferred revenue:				
Licence fees (applications and variations)	-	-	**23,247**	28,697
Other fees	-	-	**3,480**	2,644
Dividend Payable	**2,271**	1,583	**-**	-
Total	**2,271**	1,583	**26,727**	31,341

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

	Total 2010/11	**Less than one year**	**Between one and five years**	**More than five years**	**Total 2009/10**
	£000	**£000**	**£000**	**£000**	**£000**
Fixed interest rate					
3.50%	**1,328**	-	-	1,328	1,328
At 31 March 2011	**1,328**	**-**	**-**	**1,328**	
At 31 March 2010	**1,328**	-	-	1,328	1,328

18 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.

19 Capital commitments

Contracts entered into not provided for in the accounts

	Intangible	**Tangible**	Intangible	Tangible
	31 March 2011	**31 March 2011**	31 March 2010	31 March 2010
	£000	**£000**	£000	£000
Contracted	**1,018**	**751**	2,941	-
	1,018	**751**	2,941	-

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 for Work and Pensions, primarily for the purchase of legal services from the DWP (£1,346,075);
- The University of Leicester for the secondment of the Agency's Chief Executive (£255,326);

The value of total transactions and balances outstanding at the end of the year are set out below.

	Payments to Related Party	Receipts From Related Party	Amounts Owed to Related Party	Amounts due from Related Party
	£000	**£000**	**£000**	**£000**
Department of Health	2,579	11,127	-	361
Various NHS Trust	165	1,897	-	841
Department for Work and Pensions	1,346	-	-	-
Other government bodies	743	261	30	25
Local Authorities	1,119	1	-	20
Educational Bodies	310	1,062	-	611
As at 31 March 2011	**6,262**	**14,348**	**30**	**1,858**
Department of Health	11,867	12,337	3	13
Various NHS Trusts	168	1,984	-	352
Department for Work and Pensions	1,234	-	-	-
Other government bodies	548	1,450	_	1
Local Authorities	2,520	-	-	21
Educational Bodies	383	790	-	426
As at 31 March 2010	**16,720**	**16,561**	**3**	**813**

During 2010/11, none of the Board members, members of the key management staff or other related parties had undertaken any material transactions with the MHRA.

21 Intra Government balances

	Debtors: Amounts falling due within one year	Debtors: Amounts falling due after more than one year	Creditors: Amounts falling due within one year	Creditors: Amounts falling due after more than one year
	£000	£000	£000	£000
Balances With Other Central Government Bodies	2,510	-	4,353	-
Balances With Local Authorities	229	-	-	-
Balances with NHS Trusts	2,438	-	269	-
Balances with Public Corporations and Trading Funds	18	-	-	-
Subtotal	5,195	-	4,622	-
Balances with Bodies External to Government	13,422	_	22,342	-
As at 31 March 2011	**18,617**	**-**	**26,964**	**-**
Balances With Other Central Government Bodies	535	-	613	-
Balances With Local Authorities	184	-	-	-
Balances with NHS Trusts	2,133	-	225	-
Balances with Public Corporations and Trading Funds	27	-	-	-
Subtotal	2,879	-	838	-
Balances with Bodies External to Government	14,519	-	18,895	-
As at 31 March 2010	17,398	-	19,733	-

22 Losses and special payments

There were no other material losses or special payments during the year (2009/10: £nil).

23 Financial Instruments

Financial risk management
International Financial Reporting Standard (IFRS) 7 requires disclosure of the role that financial instruments have had during the period in creating or changing the risks a body 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 IFRS mainly applies, the Agency is therefore exposed to little credit, liquidity or market risk.

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. This requires the Agency to ensure it has sufficient reserves of cash to enable it to undertake its statutory activities. The MHRA's objective is to ensure continuity of funding and flexibility. The Agency's operational cash flow is largely stable and predictable, reflecting the low risk profile. Cash flow forecasts are produced to assist management in identifying future liquidity requirements. The Agency is not therefore exposed to material liquidity risks.

The table below provides details of cash balances held at the end of the year. Balances held are denominated in Sterling, Euros and US dollars. Euro and US Dollar balances are converted at the exchange rate prevailing at the end of the year.

	2010/11	**2009/10**
	£000	**£000**
Paymaster	-	68,579
Commercial banks and cash in hand	**87,517**	10,806
	87,517	**79,385**

* Includes £350k Proceeds of Crime which is the Agency's share of confiscated monies resulting from successful prosecutions and £70k Enforcement which is confiscated monies held pending a court decision.

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 £1.328M (2009/10:£1.328M). This resulted in interest payable of £0.046M (2009/10: £0.064M) out of total expenditure in excess of £92M (2009/10: £99M)

Currency risk
The level of currency risk is determined by the level of income generated by activity undertaken on behalf of the EMA. For 2010/11 this was £6.929M (Euro 7.881M) (2009/10: £6.871M; Euro 7.698M). This represents 5.6% (2009/10: 6.8%) of the total gross income for the year. The Agency is potentially exposed to significant falls in the value of this currency; however, the risk is mitigated by the regular transfer of funds to the sterling accounts of the Agency leaving minimum balances in the Euro account.

Credit risk
Credit risk arises from cash and cash equivalents and accounts receivable. The Agency is not exposed to significant credit risk.

Capital risk management
The MHRA's policy is to maintain a strong capital structure consistent with its size. The MHRA's objective when managing capital is to safeguard its ability to continue as a going concern.

24 Events after the reporting period
MHRA's Trading Fund accounts are laid before the Houses of Parliament by the Department of Health.

IAS10 requires the MHRA to disclose the date on which the accounts are authorised for issue.

This is interpreted as the date of the Certificate and Report of the Comptroller and Auditor General.

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:

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

(ii) 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.

Published by TSO (The Stationery Office) and available from:

Online
www.tsoshop.co.uk

Mail, telephone, fax and email
TSO
PO Box 29, Norwich NR3 1GN
Telephone orders/general enquiries: 0870 600 5522
Order through the Parliamentary Hotline Lo-Call 0845 7 023474
Fax orders: 0870 600 5533
Email: customer.services@tso.co.uk
Textphone: 0870 240 3701

The Parliamentary Bookshop
12 Bridge Street, Parliament Square,
London SW1A 2JX
Telephone orders/general enquiries: 020 7219 3890
Fax orders: 020 7219 3866
Email: bookshop@parliament.uk
Internet: http://www.bookshop.parliament.uk

TSO@Blackwell and other accredited agents

Customers can also order publications from:
TSO Ireland
16 Arthur Street, Belfast BT1 4GD
Telephone orders/general enquiries: 028 9023 8451
Fax orders: 028 9023 5401

ISBN 978-0-10-297018-0

9 780102 970180