Safeguarding public health

MHRA

Medicines and Healthcare products Regulatory Agency

Annual Report and Accounts 2011/12

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CONTENTS

Chairman and Chief Executive's Review

The MHRA's role is to safeguard public health, through the effective regulation of medicines and medical devices. We continue to play a crucial role in protecting, promoting and improving public health, delivering this to the highest standards.

Between now and April 2013, the Agency will take on substantial additional functions and grow in size by over a third. This will be a major strand of work in the forthcoming year which builds on and complements our strengths.

The health landscape in which we operate is changing, and will continue to change, but our role in safeguarding public health remains critical.

This introduction to the 2011/12 annual report sets out some of our key activities over the year, and highlights some of the issues we have handled, as well as giving a flavour of our many significant achievements.

Effective medicines

Our licensing division has continued to make major contributions within the European Regulatory Network as a leading assessment Member State in the area of centralised applications as well as a major player in the decentralised application process in Europe. Similarly, we made significant contributions to assist the innovation of medicines as a leading coordinator in the network, providing scientific advice to companies during the research and development phase prior to submission of application.

In September, the first ever children's medicine to hold a new paediatric use marketing authorisation (PUMA) was granted by the European Commission. The medicine, Buccolam, is now specifically licensed for children aged three months to 18 years to treat severe convulsions and epileptic seizures. The news was a landmark for the MHRA's continuing campaign to improve the quality, safety and efficacy of children's medicines available in the UK. We have been advocating the increased availability of specific children-only medicines for several years in recognition that many adult medicines are offered to children in reduced doses.

During the year, we also announced updated recommended doses for children's liquid medicines containing paracetamol to ensure children get the most effective amount, and to support giving it to them in the best way. The updated dosing has a larger number of narrower age bands and defines a single dose per age band. The change is to ensure children get the most optimal dose of paracetamol suitable for their age, making it easier for parents and carers to know exactly how much paracetamol they should give their children.

We had to issue a recall of all batches of Nurofen Plus from the market, because of reports of packs containing Seroquel tablets. This recall led to the police opening an investigation and sentencing is expected in 2012. The MHRA Enforcement Group, the Defective Medicines Reporting Centre and our Inspectorate continue to support the police with their enquiries.

The reporting of adverse reactions is a critical part of our intelligence gathering on the effects of medicines and medical devices. For medicines, we received a total of 25,872 UK spontaneous suspected Adverse Drug Reaction Reports. 13,221 reports (51 per cent) of these were received directly from healthcare professionals and members of the public. Of the direct Yellow Cards 56 per cent were received electronically. This is important because electronic reporting is easier and quicker and gives us information into our database more rapidly, meaning that critical safety information is available for our scientists to evaluate more quickly.

We developed a user-friendly Yellow Card website for health professionals and patients, working with suppliers of software that health professionals use in their day-to-day work. This resulted in the approval of the electronic Yellow Card as a standard for inclusion in the GP System of Choice programme, giving all GPs in England the ability to send us important adverse reaction information directly from their clinical systems. A pilot in 2011 showed a near doubling of reports from general practice.

Our work to reduce illegal activity relating to medicines continued throughout the year. We played a key role in Operation Pangea IV, the largest internet-targeting enforcement action of its kind, with 80 countries participating in this year's event. Over £5million worth of counterfeit and illegal medicines were seized across the globe as part of a week-long international crackdown on the illicit internet trade in pharmaceuticals. Fifty-five people were arrested, or placed under investigation, worldwide; 13,500 illegal online pharmacy websites were shut down; and more than 45,000 packages were inspected by regulators and customs officials. Around 2.5 million doses of unlicensed and counterfeit pills were seized.

The last year also saw the culmination of a case known as Operation Singapore which involved combating the infiltration of counterfeit medicine into the UK legitimate supply chain during a five-month period in 2007. More than two million doses of fake life-saving drugs were imported into the UK and, although more than half of these were seized by the MHRA, almost 900,000 doses reached pharmacies and patients. We carried out an immediate recall of Zyprexa, Plavix and Casodex and, as a result, a further 196,000 doses were recovered. The investigation involved 13 countries and after a four-month court case, the principal offender was convicted of conspiracy to defraud and sentenced to eight years in prison.

Over 100 deaths and numerous critically ill patients were reported in Lahore, following the administration of suspect medicines. Our laboratory supported the Punjab Health Authority by testing a number of implicated samples. Within one day of receiving the samples, we identified the presence of the anti-malarial pyrimethamine in what purported to be isosobide mononitrate. As an overdose of pyrimethamine would result in the reported symptoms, appropriate life saving treatment was initiated for surviving victims without delay. MHRA's analysis of samples provided critical support to the continuing investigations by the Pakistan Authorities.

Medical devices

There was an unprecedented level of interest in medical devices in the latter part of the year, as we managed the UK's response to the PIP Silicone Gel Breast Implants issue.

In March 2010 the French regulatory agency discovered that unauthorised silicone filler was being used for PIP breast implants. We and other regulators around the world immediately issued alerts to stop their use.

The key question was, what potential health risk did the non-authorised filler represent? All brands of breast implants tend to fail over time, and by ten years after implantation at least one in ten will have ruptured and need replacement. The intense public debate was wide-ranging and often misinformed, either through genuine lack of understanding or through conflicting interests.

There are, however, important questions to be asked both about the actual risk posed by the unauthorised implants and about the post-market surveillance system for implantable medical devices in the EU. Work is urgently in hand on both. The second question is particularly timely because the Medical Devices Directive is currently being reviewed, and lessons learned from this incident should be fed into that revision process. Questions are also being asked about how the cosmetic surgery industry is overseen, and its follow-up responsibilities to patients. We now have a substantial data collecting initiative in place to determine the exact rate of rupture and an extensive toxicology programme looking at safety aspects of the filler material in order to address these questions.

We also issued updated advice about the management and monitoring of patients with metal on metal hip implants and in particular radiological investigation and monitoring of blood iron levels. The advice about the management and monitoring of patients with metal on metal hip implants comes from the Expert Advisory Group that we have set up that will continue to look at all further scientific evidence and offer advice as necessary.

Legislation

The MHRA is currently undertaking a major piece of work to consolidate and review UK medicines legislation. The current body of UK medicines legislation comprises the Medicines Act 1968 and approximately 200 statutory instruments. This important project is consolidating the existing legislation into one set of regulations, so simplifying and clarifying the way provisions are drafted. It is also identifying proposals for substantive policy changes to the current regulatory framework (where there is flexibility to do so under EU legislation) to ensure the legislative framework remains fit for purpose. Our current timetable is for the consolidated legislation to come into force in July 2012.

The UK adopted the EU Falsified Medicines Directive in July 2011 and the MHRA has started to adopt the new regulations. This process will result in changes to the current legislation from mid 2012.

We have also been working closely with the European Commission on reviewing the legislative framework for medical devices, which is expected to be published in the second half of 2012. The intention of the review is to update, rather than overhaul, the current legislative framework. There are, however, areas that need to be addressed, such as ensuring that all Notified Bodies - responsible for pre-market assessment of medium- and high-risk devices - across Europe operate to a consistently high standard. In a hugely innovative market where technology is rapidly developing, the requirements for manufacturers to undertake appropriate pre-market clinical investigations, and to ensure appropriate clinical follow-up once devices have been placed on the market, need to be strengthened. The challenge remains the imperative to balance supporting the rapid entry to the market of potentially life changing or life saving devices, with ensuring that patient safety is adequately safeguarded.

We have made a significant contribution to EU discussions on the forthcoming review of the Clinical Trials Directive, which we expect to be published in the second quarter of 2012. In particular, we have promoted inclusion of a risk adapted approach to the regulation of clinical trials involving medicines, based on a pilot scheme that we have developed and implemented.

Communication

Effective communication is critical to our role and is a major contributor to the achievement of our responsibilities for safeguarding and improving public health.

One of the highlights of the year was our Annual Lecture, with Professor David Spiegelhalter giving an excellent presentation on the subject of risk communication. He focused on conveying the benefits and harms of treatments, the uncertainty of risk and how we can understand better levels of risk. His insight into how personal responses to risk information are dominated by a number of factors, including emotion and personality, personal experiences and cultural attitudes, was fascinating and thought-provoking.

We have considerably increased our use of digital communications, with the launch of a new home page for our website, aimed at making it easier to navigate the site and find information more quickly. In November, our efforts were acknowledged by an award for excellence in digital communications that recognised that the engagement rate for the MHRA's email alerting service is one of the highest in the world. In January 2012, we launched the MHRA press Twitter feed, which now has over 1000 followers.

We have worked extensively with the media, both proactively and providing comment and information on a range of issues, from implants to counterfeit medicines, and medicines safety to policy issues.

We continue to inform consumers proactively about herbal medicines, promoting the Traditional Herbal Registration (THR) scheme to inform and safeguard patients. The THR certification mark indicates that a herbal medicine has been registered with the MHRA and meets required standards relating to its quality, safety, evidence of traditional use and other criteria as set out under the Traditional Herbal Medicinal Products Directive (THMPD).

Changing organisation

As the wider health landscape changes, the MHRA is developing and changing too. In January, we took over responsibility for the Central Alerting System (CAS) for the Department of Health. CAS is an IT system that facilitates provision of email alerts to contact points in NHS organisations. During the next 18 months, we will be undertaking a full review of CAS, including consulting with CAS users and recipients about possible future use of and improvements to the system.

We have also been preparing for two exciting new developments which will extend the range and breadth of the MHRA's responsibilities over the next year.

In March 2012, we launched the Clinical Practice Research Datalink (CPRD), the new English NHS observational data and interventional research service. CPRD is jointly funded by the NHS National Institute for Health Research (NIHR) and the MHRA, and builds on the strengths of our own General Practice Research Database (GPRD) and the Research Capability Programme from the Department of Health. CPRD services are designed to maximise the way anonymised NHS clinical data can be linked to enable many types of observational research and deliver research outputs that are beneficial to improving and safeguarding public health.

This exciting development gives us capabilities in regulatory science unmatched anywhere else in the world. It gives us the best possible opportunity to make well informed risk-benefit judgments on the products we regulate, and also strengthens our ability to support innovation in areas of unmet medical need.

During 2012/13, we will also be preparing actively to welcome the National Institute for Biological Standards and Control (NIBSC) into the MHRA. NIBSC is a global centre of excellence for biological medicines, setting standards worldwide and assuring the quality of biological medicines. NIBSC and the MHRA already work closely together as we are both leading sources of scientific and regulatory advice to industry.

Going forward, our aim is to take the maximum advantage of the possibilities created by these new functions within a single organisation. The 'new MHRA' will be larger, broader in scope and with an even wider range of external relationships than we have already. Our focus as a leading national regulator will continue to be on excellence and innovation. Our continued aim is to ensure medicines and medical devices are fit for purpose, with an appropriate balance between risks and benefits.

Professor Sir Alasdair Breckenridge
Chairman

Professor Sir Kent Woods
Chief Executive

Performance Against Targets 2011/2012

TARGET	EVIDENCE AND MEASURES	RED/ AMBER/ GREEN STATUS	COMMENTS
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	**Green**	Target met. 94% assessed in 100 days 100% assessed in 150 days
	The assessment of applications for new Marketing Authorisations in European (MR, DC & centralised) procedures: • 97% assessed within the designated time	**Green**	Target met. MRP 100% assessed in 50 days DCP RMS: 99% in 100 days DCP CMS: 100% in 70 days Centralised: 100% in 80 days
	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.	**Green/ Red**	Target partially met. Target met for IB assessments: 97% in designated time. Target met for Type II assessments for non-safety variations: 98 % in designated time. However, overall Type II assessments target missed due to processing of old variations resulting in 92% met in designated time. For application received since 1st April 2011, the target has been fully met.

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)	**Green**	2011/12 performance: 99.8% of all authorisations within 30 days Average of 12.4 days for Phase I trials.
	Timescales for clinical investigation notifications for medical devices: • Maximum of 60 days with an overall average of 54 days or less	**Green**	All assessed within 60 days with an average of 48 days.
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	**Green**	All adverse incident reports involving death or serious injury were available on AITS (Adverse Incident Tracking System) within 3 days of the report's receipt by the MHRA.
	Publish Medical Device Alerts (MDAs) within 55 working days of senior management agreement to issue a 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 and association Field Safety Notice will be issued in 10 days. • Targets: 95% within 10 days; 100% within 15 days	**Green**	As there were two in-year changes in the target, a note is attached explaining the measurement of success in meeting the target.

PM3 Timescales for capturing and analysing adverse event reports (cont'd)	For fatal UK adverse drug reactions: 90% within 24 hours, 100% within 72 hours	**Green**	100% within 24 hours achieved
	For serious UK adverse drug reactions: 95% within 72 hours, 100% within 5 days	**Green**	100% within 72 hours achieved
	Ensure all UK potential signals (relating to medicines) from whatever source are acted on promptly: • 80% initially evaluated within 5 working days	**Green**	97% within 5 working days 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	**Green**	End of year figure: 92.7%
	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	**Green** **Green**	486 Public Assessment Reports have been completed since April: 100% were published within the 60 day target. 49 Public Assessment Reports have been updated for major non-safety variations of clinical significant, 100% were published within the 40 day target.

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 the cases, with less than 10% rewrite rate. Meet Ministerial correspondence deadlines in at least 80% of cases with less than 10% rewrite rate.	**Green**	PQs answered on time were 87.5% with a rewrite rate of 1.46%. POs answered on time were 84%.
	Gain Ministerial agreement by the end of the year for a strategy and action plan for the Agency reflecting the new regulatory excellence programme.	**Green**	Will be fully discharged as soon as we have shared the Agency business plan for 2012/13 (which includes our proposals for the regulatory programme) with Ministers. In November last year shared with Ministers both the successes we have had on making regulatory improvements together with our plans for the future, which included reference to the development of a regulatory programme.
PM6 Finance target	Achieve an income and expenditure surplus during 2011/12, and as a minimum, exceed a 3.5% per annum return on capital employed.	**Green**	The MHRA has delivered an income and expenditure surplus for 2011/12 and exceeded the objective of 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 an average 75% overall for courses, to demonstrate they are successful and meeting the Agency's needs.	**Green**	Overall, our evaluation scores for the period show a success ration of 90%
	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.	**Green**	We continue to send course evaluations after 6 weeks (IT training), 3 months (soft skills) and 6 months (M&L). For this period the evaluation scores show that 89% are putting new learning into practice.
	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.	**Green**	A new learning plan for April 2012-March 2013 has been designed based on the needs identified by each division and the Agency as a whole. This is in line with the requirements of the IiP Standard.

Note on the Publication of Medical Device Alerts (PM3)

The target in force at the start of 2011/12, i.e. 18 days for the publication of Immediate Medical Device Alerts and 55 days for Medical Device Alerts was superseded by a tighter timescale for all alerts with effect from 1 May 2011. At the same time a new category of Medical Device Alert was introduced – the coversheet MDA, which was associated with a manufacturer's Field Safety Notice. The new targets were 10 working days for a Medical Device Alert and 6 working days for a coversheet MDA. The target was set at 95% of all MDAs published to be within the specified timescales.

From 1 January 2012 the coversheet MDA was discontinued and all Medical Device Alerts now have a target of 10 working days for publication.

Despite the much reduced timescales for the publication of MDAs during 2011/12 the Devices Division achieved all but one of these on time.

A summary for each quarter of 2011/12 is given in the table below:

Quarter	Immediate MDA	MDA	Coversheet MDA	"10 day" MDA
Q1	3	22*	17	n/a
Q2	n/a	n/a	12	12
Q3	n/a	n/a	9	7
Q4	n/a	n/a	n/a	15

*One of these failed to meet the 10 day target, but was completed within 15 days. This represents 97% within the target timescale.

Performance Measures 2012 - 2013

TARGET 2011-12	EVIDENCE AND MEASURES
PM1 Medicines Licensing time targets	a) The assessment of applications for new Marketing Authorisations for UK only: • 98% assessed in 150 days
	b) The assessment of applications for new Marketing Authorisations in European (MR, DC centralised) procedures: • 97% assessed within the designated time
	c) 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	a) The assessment of applications for clinical trials of medicines in the UK: • 98% in 30 days (all trial phases) and an average time of 14 days (Phase I trials)
	b) 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	a) Maximum timescales between receipt of reports and making them available for evaluation and analysis: • For fatal and serious device adverse incidents: 95% within 2 working days and 100% within 3 working days
	b) Medical Device Alerts will be issued: • 95% within 10 days, 100% within 15 days
	c) For fatal UK adverse drug reactions: 90% within 24 hours, 100% within 72 hours
	d) For serious UK adverse drug reactions: 95% within 72 hours, 100% within 5 days
	e) Ensure all UK potential signals (relating to medicines) from whatever source are acted on promptly: • 85% initially evaluated within 5 working days

PM4 Transparency of decision-making in the Agency and accountability to the public	a) 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
	b) 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	a) Meet DH deadlines for responses to Parliamentary Questions in at least 80% of the cases, with less than 5% rewrite rate Since we are now at less than 2% and should be seeking continuous improvement b) Meet Ministerial correspondence deadlines in at least 80% of cases with less than 10% rewrite rate
	c) Gain Ministerial agreement by the end of the year for a strategy and action plan for the Agency reflecting the new regulatory excellence programme by end of 2013
PM6 Finance target	Achieve an income and expenditure surplus during 2012/13, 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	a) Achieve evaluation scores of an average 85% overall for courses, to demonstrate they are successful and meeting the Agency's needs
	b) Ensure that at least 85% of staff who complete 3 month evaluation information are able to put their learning into practice within the following 3 months, with an average of 70% of returned evaluation assessments
	c) Implement IiP continuous learning action plan to achieve bronze level standard in the December 2012 IiP assessment
	d) Implement a successful transfer of the NIBSC's function from the HPA to the MHRA with minimal disruption to business
	e) Develop and introduce revised management and leadership programme to increase leadership capability by end of 2013

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 the focus this year has been on work necessary to the successful implementation of the two new directives on Pharmacovigilance (which come into force in July 2012) and Falsified Medicines (coming into force on 2 January 2013) and on working with the Commission to ensure that the forthcoming review of the Clinical Trials Directive will meet UK needs.

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 2011/12 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.

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.

We worked with the wider Department of Health, the Devolved Administrations and the Health Professions Council (HPC) on proposals for introducing a requirement to be registered with the HPC for practitioners who wish to supply unlicensed herbal medicines following an individual patient consultation. The proposals will use a derogation in European medicines legislation under which registered practitioners, on the basis of a designation as an authorised healthcare professional will be able to commission the manufacture of an unlicensed herbal medicine to meet the needs of their individual patient. We expect there will be a public consultation on the proposals in the near future.

There was intensive discussion with pharmacy interests about their concerns over the risk of prosecution for breach of section 64 of the Medicines Act 1968 (supply of a medicine not of the nature or quality demanded by the purchaser) where an inadvertent error has been made in the dispensing of a medicine. A possible legislative amendment was identified for consideration in the Health and Social Care Bill - extending the possibility of a defendant being able to mount a defence that they had exercised all due diligence to avoid committing the offence. There was not, however, sufficient measure of agreement on this approach and the issue will be further considered in the MHRA's planned review of sanctions and penalties in medicines legislation.

7. Future developments

An issue of growing significance is the concern about use of unlicensed medicines or licensed medicines outside their authorised indications ("off label" use) in situations where a suitable licensed medicine is available. Longstanding professional guidance is clear that, when prescribing, healthcare professionals should first look to use a licensed medicine within its authorised indications; and only if such a medicine is not available should use of a licensed medicine off label be considered; and only if neither of these is possible should prescribing of an unlicensed medicine be considered. Concerns have been raised about reports of supply of medicines in response to the practice of prescribing unlicensed and off label medicines in preference to licensed medicines within their authorised indications in order to make cost effective use of health service resources rather than to meet the needs of individual patients. A recent judgement of the European Court of Justice confirms the MHRA’s longstanding understanding of the legal position that manufacturers and importers should not supply an unlicensed medicine in a situation where a suitable licensed product is available.

The MHRA is currently in discussion with the wider Department of Health and NICE as there are difficult issues as to how Ministers can balance their responsibilities both to uphold the medicines licensing system and to promote cost effective use of resources in the health service.

8. Better regulation

There is an ambitious agenda of regulatory reform, exploring ways of reducing regulatory burdens where this is safe to do so

As outlined in the Annual Report for 2010/2011, and building on the Arms Length Bodies report, the Agency has continued to make strong progress on our commitment to further embed good regulatory practice, ensuring that regulation is proportionate, accountable, consistent, transparent and targeted, within the culture of the MHRA. This has been exemplified in the work of the Regulatory Excellence programme, which has looked at opportunities to simplify regulation while continuing to deliver our public health outcomes.

A key deliverable of the programme, a project designed to consolidate and simplify medicines legislation, has gone out to public consultation and the Agency remains on track to deliver the new regulations in the summer of 2012. The programme has also included the MHRA's participation in the Red Tape Challenge (RTC), which started towards the end of the reporting period. The Agency looks forward to analysing comments and ideas on how it can make further regulatory improvements. Both the consolidation and participation in the RTC are in addition to existing regulatory improvement initiatives, such as the Better Regulation of Medicines Initiative and a risk-based approach to inspection.

The Agency is also taking forward key commitments designed to improve the UK environment for pharmaceutical innovation, as set out in the Government's Plan for Growth (published in March 2011) and the Life Sciences Strategy (published in December 2011).

9. Performance Outcomes

A key undertaking of the MHRA Corporate Plan (2010 - 2015) is to supplement the established performance (output) targets of the organisation with a new range of outcome indicators. Whereas output measurement is concerned with the "how much" questions, outcome measurement is concerned with effectiveness and the "so what" questions. Outcomes evaluation seeks to determine what has actually changed in the lives of our stakeholders as a result of our endeavours. The Agency recognised that this was a challenging programme and that outcome measures need to be taken over the longer term. However, we undertook to report annually on progress against the measures, and in November we published our first annual review on outcome measures:
http://www.mhra.gov.uk/home/groups/comms-ic/documents/publication/con134858.pdf
which covered a variety of outcome projects against seven outcome themes:

- *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.*

Looking ahead, we have identified a need to move the work to a more prospective approach in which the desired outcomes are identified at the start of MHRA's considerations of its possible interventions on any particular issue, and are then followed through.

Following discussions on progress in outcomes measurement within the Agency outcomes group, it was suggested that for 2012/13 the following five outcome themes are employed:

(1) The timely, proportionate and effective response to public health risks
(2) Enable better medicines and devices to be available to patients
(3) Safer and more effective use of medicines and devices based on the latest information
(4) More targeted regulation, managing risk and public health benefit
(5) Confidence in the work we do and satisfaction in the service we offer

It was agreed that these five themes embrace the most productive activities of the original seven themes while also focusing efforts on those outcomes that are most important to the Agency and its stakeholders. A number of work streams for each outcome theme have been proposed, as have a series of metrics for each theme and we will report on these in due course.

10. 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.

11. Financial Review

Agency Financial Position

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

Income and Expenditure

The total income for the year at £117.2m was 3.5% lower than 2010/11 income (£121.4m). This is mainly as a result of a decrease in licences (£7.3m) and inspections income (£0.5m) partly offset by an increase in vigilance, risk management and enforcement income (£4.3m).

Total costs for 2011/12 at £97.0m were 7.2% higher than the level of £90.5m in 2010/11. Staff numbers decreased from 974 to 911. Total staff costs at £55.1m remained at the same level as last year (2010/11, £55m), however these included termination costs of £0.9m (2010/11, £47k). Other operating costs increased by 14.2% from £35.5m to £41.9m. The annual depreciation charge increased by £0.9m to £7.3m.

The operating surplus for 2011/12 was £20.2m, compared to £30.9m in 2010/11. For 2012/13 there is a planned operating surplus of £1.5m.

After charging a dividend on public capital of £3.1m (2010/11 £2.3m), the net surplus in 2011/12 was £17.1m, giving a retained surplus carried forward into 2012/13 of £92.9m.

Assets and liabilities

At 31 March 2012, the Agency had Plant and equipment assets of £15.2m (31 March 2011: £19.2m).

Intangible assets were £8.5m (31 March 2011: £11.4m). Net current assets were £81.8m (31 March 2011: £76.9m). After allowing for deferred revenue of £25.6m (31 March 2011: £27.8m) and long-term creditors and provisions of £3.4m (31 March 2011: £1.4m), the total net assets were £95.4m (31 March 2011: £78.2m).

12. Staff resources

During the year an average of 911 permanent full-time equivalent staff were employed.

Recruitment

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

53 Staff were recruited during 2011-2012:

	MALE	FEMALE
Executive Directors	1	1
Senior Civil Servants	0	0
Other Civil Service Staff	24	27
TOTAL	**25**	**28**

13 people from ethnic minority groups were recruited. 31 per cent of the MHRA's staff are from ethnic minority groups and 1 per cent have a disability as defined under the Equality Act 2010.

The permitted exceptions to the principles of fair and open competition and selection on merit were used 8 times for appointments over the period of 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, 2.0% of available working days were recorded as sickness absence. This is an improvement on last year which showed 3.1% of working days were lost. During the year we

have increased training in sickness absence and we have also introduced self referral for Occupational Health.

Employee involvement and wellbeing

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

The MHRA had a successful move of Headquarters building in 2010. Following this move two project groups were established during the year to ensure that the move was successful in its objectives and that the benefits of the move had been fully realised. These Groups are made up Divisional representatives with the outcomes from the Group being shared with staff on the Agency's intranet.

Staff are updated on topical issues on a monthly basis by a team brief. As part of this process, staff get an opportunity to discuss the topics within their Division, the feedback is collated centrally and then responses made available on Insite, the Agency's intranet.

There is also regular consultation and negotiation with trade union representatives.

The MHRA measures how engaged its staff are by means of an annual People Survey held each October. There is a senior-level appreciation that engaged staff are likely to be more productive and view the organisation as a good place to work.

In 2011, 78% of staff took part in the survey and our engagement index score of 58% was two percent higher than the Civil Service average. In response to the results, the senior leadership team designed a corporate action plan to bring about improvements to the way the Agency leads and manages change. A statistical analysis tells us this is thought to be the organisation's key driver of engagement. For the first time ever, operational divisions were also asked to develop their own action plans to address issues raised by staff at a local level.

The MHRA Health and Safety policy sets out our responsibilities in the Standard Operating Procedures. With the appointment of a Health and Safety Manager it is the MHRA's intention to continue to improve H&S standards and seek certification to BS18001 OHSAS.

Learning and development

The MHRA actively promotes the development of staff by offering a full suite of corporate and specific training. Individual needs are set out in personal development plans and are met through appropriate means, including participation in projects and shadowing.

13. Equality and diversity

MHRA complies with equal opportunities legislation and provides special facilities where necessary. The MHRA has a cross-Agency Diversity Focus Group which meets regularly during the year to check progress in relation to the MHRA Diversity Strategy. 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 together with mandatory training which was rolled out during the year.

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.

14. Events after the reporting period

None.

15. Directors' statement with respect to conflict of interest

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

16. Supplier payment performance

The MHRA is committed to the Better Payment Practice Code and the commitment to speed-up payments. The Agency's policy is to pay all suppliers within five days of receipt of a valid invoice. The MHRA's systems recorded invoice date, rather than the date of receipt, so payment will have been faster than the recorded statistics.

Over the year, 90 per cent of supplier bills were paid within five days and 100 per cent within 30 days (in 2010/11 81 per cent within 5 days and 100 per cent within 30 days). No interest payments were made to suppliers under the Late Payment of Commercial Debts (Interest) Act 1998.

	2011/12			2010/11		
	Transactions	**Value (£000)**	**%**	**Transactions**	**Value (£000)**	**%**
0 - 5 days	11,129	41,195	90	8,671	47,503	81
6 - 10 days	1,113	4,120	9	1,467	7,690	14
11 – 30 days	124	458	1	511	2,568	5
Over 30 days	0	0	-	23	116	-
	12,366	**45,773**	**100**	**10,672**	**57,877**	**100**

17. Consultants and contingent labour

Central Government controls on spending on consultancy were introduced during 2010-11 in addition to those already in existence within the Agency. During the year, the expenditure on consultants was £Nil (£35k in 2010/11)

We continue to employ temporary staff where it is of operational necessity. Agency staff expenditure was £960k in 2011/12 (£574k in 2010/11).

18. Risks and uncertainties at 31 March 2012

Risks	Mitigating factors and actions
Income Risk: As a government trading fund the MHRA's income stream is dependant on demand for its services.	• Constant monitoring and analysis of income streams. • Production of monthly risk assessment reports on income.
Information Risk: Lack of confidence in the Agency's ability to rely on electronic data to inform decision making and to provide accurate information on medicinal products, due to the quality of historical data and the introduction of new errors in the *Sentinel* system.	• Auditing carried out on the *Sentinel* system to review samples of critical documents for errors. • SOPs are in place for all Divisions that use *Sentinel*; the Agency is Quality Certified to ISO 9000 standard. There is a full in-house programme of business training in the use of *Sentinel*, including data assurance. • Specific project team set up to review and cleanse Sentinel data. • Mechanisms for internal and external stakeholders to report errors in the data to a dedicated Data Cleansing team for remediation and feedback to managers.
Loss of key staff Risk: As a people based organisation the MHRA relies on the knowledge and experience of its staff and risks losing the knowledge and experience should they leave the organisation.	• Competitive pension and non financial employment package including career development opportunities in place to attract and retain staff. • Regular surveys of staff including full survey of all staff, Investors in People assessment and exit interviews to track and identify trends.

19. 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.

20. Risk management

The Agency's risk management and internal control systems are the responsibility of the Corporate Executive Team, which is assisted by the Agency Board and the Risk and Audit Committee in a monitoring role. The Corporate Executive Team 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.

21. 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.

22. Social, community and environmental issues

At the end of last year the Agency achieved a bronze rating following the refurbishment of its new building under the SKA scheme. This well recognised scheme is the environmental performance of fit-out projects for office buildings in the UK.

The MHRA has developed a Sustainable Development Action Plan for 2011-13 and a new sustainable development working group (SDWG) was re-launched this year and will assist with achieving the targets. The Action Plan sets out the organisation's aims to reduce our carbon footprint in areas such as energy management, sustainable procurement, recycling and water usage. Good progress has been made in all these areas. This group helps promote engagement of staff in some national events/awareness weeks, such as 'Climate Week 12-18th March', 'Walk to Work Week 14-18th May' and 'Recycle Week 18-24th June 2012'.

The Agency has used substantially less paper this year for individual guidance documents, resulting in less related waste as we seek to use technology to reduce all forms of office waste. One such plan is to disseminate our guidance electronically rather than in paper form.

During 2011/12 the Agency started the migration to send electronic invoices / credit notes etc. to its customers. Since November 2011 9,674 invoices and credit notes (65%) were sent electronically, saving paper and envelopes as well as postage.

Since moving to our new offices at 151 Buckingham Palace Road (BPR) Business Innovation and Skills (BIS) provide services and encourage behaviour that meets sustainability requirements. This includes recycling, energy efficiency and other facilities.

We are now able to monitor and measure energy, utilities and water usage and we receive monthly environmental reports and data on energy and water usage; once the Building Management System (BMS) is fully commissioned then reductions can be achieved through limiting main plant operating times.

This year a food waste trial was offered as a pilot study only to the second floor of 151 BPR. The trial is to end shortly and following some successful early feedback results it may be possible to extend this trial to all floors.

Our main parent department, the Department of Health (DH) exceeded the 10% Carbon Reduction Target between May 2010 and May 2011 and the MHRA fed into this reduction with various initiatives including the move to 151 Buckingham Palace Road (BPR) and the associated reduction in the number of printers and personal computers. As part of the Greening Government Commitments, the DH and MHRA will continue to implement initiatives in order to meet the 25% carbon reduction target by 2014/15.

The MHRA is a member of the Cycle to Work scheme, which provides tax efficient incentives for employees to use cycles to travel to work.

Pension liabilities

These are covered in notes 6.4 and 16.1 to the accounts.

23. 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 to make himself aware of any relevant audit information and to establish that the MHRA's auditors are aware of that information.

24. 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 £87,000 for the year ended 31 March 2012 (£96,000 for the year ended 31 March 2011). 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.

25. 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/.

26. Personal data security incidents

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

27. Freedom of information

The Freedom of Information Act has continues to be a valuable component in the MHRA's commitment to, and demonstration of, openness and transparency, contributing to the broader

transparency agenda across central government. 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. 2011 saw another busy year for requests arriving at the Agency with 498 having been made. As usual the majority of requests came from industry and members of the public, with journalism and the legal profession also being well represented. Requests for Internal reviews increased again in 2011 from 18 to 21 indicating that awareness of information rights continues to grow, as does the confidence to challenge the decisions of public authorities. The number of Information Commissioner investigations of Agency decisions fell from 6 to 3.

28. Launch of the Clinical Practice Research Datalink

In March 2011, the Government launched its 'Plan for Growth' which details steps needed to enable the British economy to become more internationally competitive. As part of this initiative the Government pledged to build a consensus on using e-health record data to create a unique position for the UK in health research.

On 31 October 2011, the Department of Health's National Institute for Health Research (NIHR) in partnership with the Medicines and Healthcare products Regulatory Agency (MHRA) announced the creation of a new Clinical Practice Research Datalink service (CPRD), which became fully established on 1 April 2012.

CPRD will subsume the General Practice Research Database (GPRD) into its operations.

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 (Corporate Executive Team 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 Corporate Executive Team 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. Corporate Executive Team and Agency Board members) of the Agency. Corporate Executive Team members salary and bonus awards were decided by a Pay Committee whose members are Professor Sir Kent Woods, Lisa Arnold (Non-Executive Director) and Simon Claydon (DH HR Deputy 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.

Reporting bodies are required to disclose the relationship between the remuneration of the highest-paid director in their organisation and the median remuneration of the organisation's workforce.

Pay multiples

The banded remuneration of the highest-paid director in the MHRA in the financial year 2011/12 was £200-205k (2010/11, £200-205k). This was 5.23 times (2010/11, 5.37) the median remuneration of the workforce, which was £38,694 (2010-11, £37,681).

No employee received remuneration in excess of the highest paid director in 2011/12 (2010/11, none).

Total remuneration includes salary, non-consolidated performance-related pay, benefits-in-kind as well as severance payments. It does not include employer pension contributions and the cash equivalent transfer value of pensions.

Remuneration

Corporate Executive team	2011/12 Salary £000	2011/12 Non consolidated performance related pay awards £000	2011/12 Benefits in kind (to nearest £100)	2010/11 Salary £000	2010/11 Non consolidated performance related pay awards £000	2010/11 Benefits in kind (to nearest £100)
Professor Sir Kent Woods Chief Executive [1]	190 - 195	5 - 10	-	190 - 195	5 - 10	-
Mr Peter Commins Chief Operating Officer[2]	125 - 130	5 - 10	-	125 - 130	5 - 10	-
Dr June Raine, CBE Director of Vigilance & Risk Management of Medicines	120 - 125	0 - 5	-	120 - 125	0 - 5	-
Dr Ian Hudson Licensing Director	115 - 120	0 - 5	-	115 - 120	5 - 10	-
Mr Gerald Heddell Director of Inspection, Enforcement and Standards	105 - 110	0 - 5	-	105 - 110	0 - 5	-
Mrs Alison Davis Director of Information Management	95 - 100	5 - 10	-	95 - 100	0 - 5	-
Dr Susanne Ludgate Clinical Director Devices	90 - 95	0 - 5	-	90 - 95	0 - 5	-
Mr Geoff LeFevre Director of Human Resources	90 - 95	0 - 5	-	90 - 95	0 - 5	-
Mr Jonathan Mogford Director of Policy	85 - 90	0 - 5	-	85 - 90	0 - 5	-
Ms Rachel Bosworth Director of Communications[3]	70 - 75	0 - 5	-	N/A	N/A	-
Mrs Diane Leakey Acting Director of Communications[4]	15 - 20	N/A	-	30 - 35	N/A	-
Mr John Wilkinson, OBE Director of Devices[5]	15 - 20	N/A	-	N/A	N/A	-
Mr Simon Gregor Director of Communications[4]	5 - 10	0 - 5	-	90 - 95	0 - 5	-

[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 2011/12 the MHRA paid a total of £256,835 (2010/11 £255,326) 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 Peter Commins was acting Director of Devices until 5th February 2012 in addition to his duties as Chief Operating Officer.

[3] Ms Rachel Bosworth commenced her appointment as Director of Communications on 20th June 2011. The full year equivalent is £95k - £100k.

[4] Mrs Diane Leakey was acting Director of Communications from 18th October 2010 to 30th June 2011. Mr Simon Gregor went on long term sick leave on 18th October 2010 and resigned with effect from 19th April 2011.

[5] Mr John Wilkinson, OBE commenced his appointment as Director of Devices on 6th February 2012. The full year equivalent is £115 - £120k.

Agency Board	2011/12 Salary £000	2011/12 Non consolidated performance related pay awards £000	2011/12 Benefits in kind (to nearest £100)*	2010/11 Salary £000	2010/11 Non consolidated performance related pay awards £000	2010/11 Benefits in kind (to nearest £100)*
Professor Sir Alasdair Breckenridge, CBE Chairman	90 - 95	5 - 10	-	90 - 95	5 - 10	-
Professor Vincent Lawton, CBE Non Executive Director[6]	10 - 15	N/A	-	5 - 10	N/A	-
Ms Lisa Arnold Non Executive Director[7]	5 - 10	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	100	5 - 10	N/A	100
Professor Barrington Furr, OBE Non Executive Director	5 - 10	N/A	1,300	5 - 10	N/A	700
Sir John Lilleyman Non Executive Director	5 - 10	N/A	1,000	5 - 10	N/A	1,000
Professor Angus Mackay, OBE Non Executive Director	5 - 10	N/A	6,800	5 - 10	N/A	5,200
Mr John Williams, CBE Non Executive Director	5 - 10	N/A	600	5 - 10	N/A	600

*The Agency's Non-Executive Directors necessarily incur travelling and other expenses to attend Agency meetings. The "benefits in kind" relate solely to these expenses. The tax liability arising thereon is met by the MHRA and is shown in the table above as a benefit in kind.

Salary: 'Salary' includes gross salary; reserved rights to London weighting or London allowances; and any other allowance to the extent that it is subject to UK taxation. This presentation is based on payments made by the Agency and thus recorded in these accounts.

Non consolidated performance related pay awards: Non consolidated performance related pay awards are based on performance levels attained and are made as part of the appraisal process. The awards reported in 2011/12 relate to performance in 2010/11 and the comparative awards reported in 2010/11 relate to performance in 2009/10.

Benefits in kind: The monetary value of benefits in kind covers any benefits provided by the Agency and treated by HM Revenue and Customs as a taxable emolument. The estimated monetary value of benefits in kind which relate solely to the provision of interest free loans for the purchase of season tickets for home to office travel is not included.

[6] Professor Vincent Lawton, CBE was appointed chair of the Risk & Audit Committee with effect from 1st September 2011.
[7] Ms Lisa Arnold resigned as Chair of the Risk & Audit Committee with effect from 31st August 2011.

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 Corporate Executive Team Directors:

	Accrued pension at pension age as at 31/3/12 and related lump sum	Real increase in pension and related lump sum at pension age	CETV at 31/3/12	* CETV at 31/3/11	Real increase in CETV
	£000	£000	£000	£000	£000
Mr Peter Commins Chief Operating Officer	65 - 70	0.0 - 2.5	**1,116**	**1,014**	14
Dr June Raine, CBE Director of Vigilance & Risk Management of Medicines	40 - 45 plus lump sum of 120 - 125	(0.0 - 2.5) plus lump sum of (0.0 - 2.5)	**927**	**866**	(13)
Dr Ian Hudson Licensing Director	30 - 35	0.0 - 2.5	**522**	**479**	(1)
Mr Gerald Heddell Director of Inspection and Standards	10 - 15	0.0 - 2.5	**229**	**203**	16
Mrs Alison Davis Director of Information Management	10 - 15	0.0 - 2.5	**144**	**111**	19
Dr Susanne Ludgate Clinical Director – Devices	40 - 45 plus lump sum of 125 - 130	(0.0 - 2.5) plus lump sum of (2.5 - 5.0)	**903**	**894**	(21)
Mr Geoff LeFevre Director of Human Resources	20 - 25 plus lump sum of 65 - 70	0.0 - 2.5 plus lump sum of 0.0 - 2.5	**497**	**481**	(1)
Mr Jonathan Mogford Director of Policy	20 - 25 plus lump sum of 70 - 75	(0.0 - 2.5) plus lump sum of (0.0 - 2.5)	**399**	**370**	(2)
Ms Rachel Bosworth Director of Communications From 20.06.2011	10 - 15 plus lump sum of 40 - 45	0.0 - 2.5 plus lump sum of 5.0 - 7.5	**280**	**233**	39
Mrs Diane Leakey Acting Director of Communications To 30.06.2011	30 - 35 plus lump sum of 95 - 100	0.0 - 2.5 plus lump sum of 0.0 - 2.5	**648**	**587**	14
Mr John Wilkinson, OBE Director of Devices from 06.02.2012	0 - 5	0.0 - 2.5	**5**	**0**	4
Mr Simon Gregor Director of Communications to 19.04.2011	20 - 25	0.0 - 2.5	**200**	**199**	0

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

The disclosures in the tables on pages 29 to 31 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
21 June 2012

Statement of Agency's and Chief Executive's Responsibilities

Under Section 4(6)(a) of the Government Trading Funds Act 1973, HM Treasury has directed the Medicines and Healthcare products Regulatory Agency (MHRA) to prepare for each financial year a statement of accounts in the form and on the basis set out in the Accounts Direction. The accounts are prepared on an accruals basis and must give a true and fair view of the state of affairs of the MHRA and of its income and expenditure, recognised gains and losses and cash flows for the financial year.

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

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

HM Treasury has appointed the Chief Executive of the MHRA as Accounting Officer of the Agency. The responsibilities of an Accounting Officer, including responsibility for the propriety and regularity of the public finances for which the Accounting Officer is answerable, for keeping proper records and for safeguarding the MHRA's assets, are set out in the chapter under *Accounting Officers* in *Managing Public Money*, published by HM Treasury.

Annual Governance Statement

Scope of responsibility

The MHRA is responsible for ensuring that its business is conducted in accordance with the law and proper standards, and that public money is safeguarded and properly accounted for, and used economically, efficiently and effectively.

In discharging this overall responsibility, the MHRA is responsible for putting in place proper arrangements for the governance of its affairs, facilitating the effective exercise of its functions, and which include arrangements for the management of risk.

The purpose of the governance framework

The governance framework comprises the systems and processes, and culture and values, by which the Agency is directed and controlled and the activities through which it accounts to, engages with the public. It enables the Agency to monitor the achievement of its strategic objectives and to consider whether those objectives have led to the delivery of appropriate, cost-effective services.

The Agency's system of internal control is a significant part of that framework and is designed to manage risk to a reasonable level. It cannot eliminate all risk of failure to achieve policies, aims and objectives and 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 governance framework has been in place in the Medicines and Healthcare products Regulatory Agency for the year ended 31 March 2012 and up to the date of approval of the annual report and accounts, and accords with Treasury guidance.

The MHRA's governance framework

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, agrees high level performance targets and approves its corporate and business plans, 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. The MHRA has an Agency Board, a Risk and Audit Committee and a Corporate Executive Team. 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 Board receives regular reports from subcommittees. Board papers are generally distributed in good time and minutes and matters arising are dealt with at each meeting.

The Board plays a full part in developing Strategic and Business Plans and exercises a monitoring role throughout the year.

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 adequacy of the Agency's governance arrangements, including the risk management framework and the associated control environment, the Agency's financial and non-financial performance to the extent that it affects the Agency's exposure to risk and weakens the control environment, oversight of the financial reporting process and scrutiny of the treasury management strategy and policies. It has sight of the corporate risk register at each of its meetings. The Committee is chaired by Professor Vincent Lawton, CBE.

The Corporate Executive Team comprises me as the Chief Executive, the Chief Operating Officer and the other Divisional Directors, who take executive responsibility for the strategy, operational management and service delivery of the Agency, including risk management. The Corporate Executive Team receive regular updates on key performance indicators. This focuses on progress against the business plan, performance against budget and key performance indicators, as well as key risks on the delivery of objectives. Meetings are held with specific directors to address issues which emerge from these reports. As the Accounting Officer, I also have responsibility for the Agency's resources. The Team members have no significant interests to disclose which may conflict with their responsibilities. The Remuneration Report on pages 28 to 33 of this report gives details of the remuneration paid to the members of the Agency Board and Corporate Executive Team.

Taking all the above factors into account I am satisfied that the governance structure complies with the Code of Practice for Corporate Governance in Central Government Departments in so far as it is relevant to us.

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

The risk and control framework

Risk management is embedded at every level in the business by encouraging empowerment and delegation so that risks can be managed proactively by those with local knowledge and experience, who are held accountable for the effective management of those risks.

The objective is to identify and evaluate a risk, determine an appropriate response and actively manage the response to ensure the Agency's exposure is limited to an acceptable level.

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 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 Corporate Executive Team, and have been in existence throughout the year to 31 March 2012.

The Corporate Executive Team is 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 internal audit annual report gave an overall 'satisfactory' opinion which is the second highest rating achievable.

The Agency's corporate risk register is reviewed quarterly by the Corporate Executive Team and updated as appropriate. Each corporate risk is vested in a specific CET 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 and Audit Liaison Group, formed to strengthen the Agency's risk management system, held four meetings during the year to 31 March 2012. 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 Corporate Executive Team.

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 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 2012.

Review of effectiveness

The Agency has responsibility for conducting, at least annually, a review of the effectiveness of its governance framework including the system of internal control. The review of effectiveness is

informed by the work of the Divisional Directors within the Agency who have responsibility for the development and maintenance of the governance environment, the Head of Internal Audit's annual report, and by comments made by the external auditors.

The process that has been applied in maintaining and reviewing the effectiveness of the governance framework includes the following:

- the Agency's internal management processes, such as performance monitoring and reporting; the staff performance appraisal framework; monitoring of policies, such as the corporate health and safety policies; and the corporate budget challenge process;

- an annual self assessment of the adequacy of the governance arrangements in divisions completed by each divisional director;

- the Agency's internal audit coverage, which is planned using a risk based approach. The outcome from the internal audit coverage helps form the Head of Internal Audit's opinion on the overall adequacy of the Agency's internal control framework, which is reported in his annual report;

- Investors in People assessments and accreditation;

- the work of the Risk and Audit Committee, which reviews the outcomes from the annual audit plan and the annual report of the Head of Internal Audit.

As Accounting Officer, I have responsibility for reviewing the effectiveness of the governance framework. My review of the effectiveness of the governance framework is informed by the work of the internal auditors and the Divisional Directors within the Agency who have responsibility for the development and maintenance of the governance environment, 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 governance environment by the Agency Board, the Risk and Audit Committee and the Corporate Executive Team, and a plan to address weaknesses and ensure continuous improvement of the system is in place.

I have considered the evidence provided with regards to the production of the Annual Governance Statement. The conclusion of the review is that the MHRA's overall governance and internal control structures have been appropriate for the MHRA's business and working satisfactorily throughout 2011-12.

Significant governance issues

The review, as detailed above, provides good assurance of the effectiveness of the Agency's system of internal control. The annual internal audit report highlighted that while there is a generally sound system of internal control in place, there were some significant findings in specific areas for management to address. These were highlighted in three reports classed as high rated and included: weaknesses around the use of Government Procurement Cards although there were no instances of misuse identified; that Government accreditation requirements on controls on the implementation of Oracle iReceivables had not been properly followed although there were no issues identified in the operation of Oracle iReceivables; and a review of Information

Governance noted weaknesses around the clarity of responsibility in relation to the cause and correction or errors. Five further reviews performed during the year were medium rated.

The annual report also identified areas of good practice. These included the Health and Safety review, where processes and systems implemented by management were seen to be innovative and effective. It also noted that the approach to the set up of a new business stream in the Business Expansion review was broadly well approached, with good collaboration from relevant parties.

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 by October 2012.

The Agency has also had to deal with strategic issues relating to effective medicines, medical devices and a changing organisation. There are covered in more detail in the Chairman and Chief Executive's review. Other risks and uncertainties including information governance and income risk are detailed in the Management Commentary

There have been no other governance issues identified during the year that are considered significant in relation to the Agency's overall governance framework. Specific opportunities for improvement in governance and internal controls identified as part of the assurance processes detailed above have been addressed or are included in action plans for the relevant managers.

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 Corporate Executive Team, 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
21 June 2012

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 Authority (MHRA) for the year ended 31 March 2012 under the Government Trading Funds Act 1973. The financial statements comprise: the Income Statement, Statement of Financial Position, Statement of Cash Flows, Statement of Changes in 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 been audited.

Respective responsibilities of the Chief Executive and auditor

As explained more fully in the Statement of Accounting Officer's Responsibilities, the Chief Executive as Accounting Officer is 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 MHRA's circumstances and have been consistently applied and adequately disclosed; the reasonableness of significant accounting estimates made by MHRA; and the overall presentation of the financial statements. In addition I read all the financial and non-financial information in the Annual Report 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.

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

Opinion on regularity

In my opinion, in all material respects the expenditure and income recorded in the financial statements have been applied to the purposes intended by Parliament and the financial transactions recorded in the financial statements 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 MHRA's affairs as at 31 March 2012 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 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 returns adequate for my audit have not been received from branches not visited by my staff; or
- the financial statements and the part of the Remuneration Report to be audited are not in agreement with the accounting records and returns; or
- I have not received all of the information and explanations I require for my audit; or
- the Governance Statement 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 9SP

2 July 2012

ACCOUNTS

STATEMENT OF COMPREHENSIVE INCOME for the year ended 31 March 2012

	NOTE	**2011/12**		2010/11	
		£000	**£000**	£000	£000
Revenue					
Revenue from trading activities		**107,030**		110,479	
Revenue from Department of Health		**10,217**		10,908	
Total Revenue	3		**117,247**		121,387
Expenditure					
Staff costs	6	**(55,061)**		(54,981)	
Operating costs	7	**(41,947)**		(35,496)	
Total Expenditure			**(97,008)**		(90,477)
Operating surplus			**20,239**		30,910
Finance income	8		**271**		223
Finance costs	8		**(201)**		(46)
Surplus for the financial year			**20,309**		31,087
Dividend payable			**(3,094)**		(2,271)
Retained surplus for the year			**17,215**		28,816
Other comprehensive income/(loss)					
Other (losses)/gains	9		**(86)**		48
Total comprehensive income for the year			**17,129**		28,864

The notes on pages 46 to 68 form part of these accounts.

STATEMENT OF FINANCIAL POSITION as at 31 March 2012

	NOTE	**31 March 2012**		31 March 2011	
		£000	**£000**	£000	£000
				Restated*	Restated*
Non-current assets					
Plant and equipment	10	**15,235**		19,187	
Intangible assets	11	**8,505**		11,382	
Total non-current assets			**23,740**		30,569
Current assets					
Trade and other receivables	12	**21,691**		18,617	
Cash and cash equivalents	13	**114,879**		87,517	
Total current assets			**136,570**		106,134
Total assets			**160,310**		136,703
Current liabilities					
Trade and other payables	14	**(31,545)**		(26,964)	
Provisions	16	**(1,242)**		(18)	
Other liabilities	17	**(23,564)**		(22,813)	
Total current liabilities			**(56,351)**		(49,795)
Total assets less current liabilities			**103,959**		86,908
Non-current liabilities					
Borrowings	15	**(1,328)**		(1,328)	
Provisions	16	**(2,061)**		(45)	
Other liabilities	17	**(5,159)**		(7,253)	
Total non-current liabilities			**(8,548)**		(8,626)
Assets less liabilities			**95,411**		78,282
Taxpayers' equity:					
Public dividend capital			**1,329**		1,329
Reserves					
Revaluation reserve			**155**		155
Income and expenditure reserve			**954**		954
Retained earnings			**92,973**		75,844
Total equity			**95,411**		78,282

* Restated:

1. Change in accounting policy on treatment of government grants to comply with HM Treasury changes in Financial Reporting Manual. Government grant moved from reserves to other liabilities (see note 16.2).
2. Other liabilities reclassified into current and non current.

Professor Sir Kent Woods
Chief Executive and Accounting Officer
21 June 2012

The notes on pages 46 to 68 form part of these accounts.

STATEMENT OF CASH FLOWS for the year ended 31 March 2012

		2011/12		2010/11	
	NOTE	**£000**	**£000**	£000	£000
				Restated*	Restated*
Cash flows from operating activities					
Operating surplus		**20,239**		30,910	
Interest paid	8	**(201)**		(46)	
(Loss)/Gain on foreign exchange	9	**(86)**		48	
Depreciation and amortisation		**7,326**		6,907	
Disposals of assets		**479**		-	
Impairment and reversals		**2,429**		-	
(Decrease) in deferred revenue		**(2,166)**		(3,811)	
(Increase) in trade and other receivables	12	**(3,074)**		(1,219)	
Increase in trade and other payables		**5,404**		7,231	
Increase/(Decrease) in provisions	16	**3,240**		(11,454)	
Dividend paid	17	**(3,094)**		(2,271)	
Net cash inflow from operating activities			**30,496**		26,295
Cash flows from investing activities					
Interest received	8	**271**		223	
Purchase of plant and equipment	10	**(1,277)**		(17,130)	
Purchase of intangible assets	11	**(2,128)**		(1,256)	
Net cash outflow from investing activities			**(3,134)**		(18,163)
Cash flows from financing activities			**-**		-
Net increase in cash and cash equivalents in the financial year	13		**27,362**		8,132
Cash and cash equivalents at the beginning of the financial year	13		**87,517**		79,385
Cash and cash equivalents at the end of the financial year	13		**114,879**		87,517

* Restated: Change in accounting policy on treatment of government grants to comply with HM Treasury changes in Financial Reporting Manual. Government grant moved from reserves to other liabilities (see note 16.2).

The notes on pages 46 to 68 form part of these accounts.

STATEMENT OF CHANGES IN TAXPAYERS' EQUITY for the year ended 31 March 2012

	Public dividend capital (PDC)	Retained earnings	Revaluation reserve	Income & expenditure reserve	Total
	£000	£000	£000	£000	£000
Balance at 31 March 2010 (restated *)	1,329	46,980	155	954	49,418
Changes in taxpayers' equity for 2010-11					
Total comprehensive income for the year	-	28,864	-	-	28,864
Balance at 31 March 2011 (restated *)	1,329	75,844	155	954	78,282
Changes in taxpayers' equity for 2011-12					
Total comprehensive income for the year	**-**	**17129**	**-**	**-**	**17,129**
Balance at 31 March 2012	**1,329**	**92,973**	**155**	**954**	**95,411**

The notes on pages 46 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 accordance with International Financial Reporting Standards (IFRS) as adapted and interpreted by the 2011/12 Government Financial Reporting Manual (FReM) issued by HM Treasury. The accounting policies contained in the FReM comply with IFRS as adapted or interpreted for the public sector context. Where the FReM permits a choice of accounting policy, the accounting policy that is judged to be 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.

1.1.2 IFRS's, amendments and interpretations in issue but not yet effective, or adopted:

IAS 8, accounting policies, changes in accounting estimates and errors, require disclosures in respect of new IFRS's, amendments and interpretations that are, or will be applicable after the accounting period. There are a number of IFRS's, amendments and interpretations issued by the International Accounting Standards Board that are effective for financial statements after this accounting period. The following have not been adopted early by the MHRA.

- *IAS 1 'Presentation of Financial Statements'* Amendment to the existing standard to improve disclosures to users of the accounts. The effective date is for accounting periods beginning on, or after 1 June 2012.IAS 12 'Income Taxes' – Amendment
- *IAS 19 'Post employment benefits'* The amendments will improve the recognition and disclosure requirements for defined benefit plans and modify the accounting for termination benefits. The new requirements are effective for accounting periods beginning on or after 1 January 2013. IFRS 7 'Financial Instruments: Disclosures' – Amendment
- *IFRS 9 'Financial Instruments'* A new standard intended to replace IAS39. The effective date is for accounting periods beginning on, or after 1 January 2015.IFRS 10 'Consolidated Financial Statements' – New
- *IFRS13 'Fair value Measurement'* IFRS 13 applies when other IFRS's require or permit fair value measurements. The new requirements are effective for accounting periods beginning on, or after 1 January 2013.

None of these new or amended standards and interpretations are likely to be applicable or are anticipated to have future material impact on the financial statements of the

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

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 valued at modified historic cost except where current cost adjustments are immaterial. 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

Plant & Equipment 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, 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 cost 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.

Intangible assets in the course of construction are carried at cost, less any impairment loss. Cost includes professional fees. 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	£1,670
Product licensing	96 months	£575
Pharmacovigilance	94 months	£1,366

Sentinel architecture is the suite of Sentinel 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.

1.3.4 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.

1.4 Cash

Cash represents cash held with the Government Banking Service and foreign currency held 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, where there is a contract in place.
- 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 Corporate Executive Team, 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

1.8.1 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 2011/12, with the current pay freeze, the provision already created was deemed to be sufficient and no further adjustment was made.

1.8.2 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.

1.8.3 Termination benefits

The Agency accrues for termination benefits at the point at which the employee has accepted the offer made by the Agency. Termination benefits include lump sum payments and payments in lieu of notice.

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

A provision is recognised when the Agency has a legal or constructive obligation as a result of a past event, it is probable that an outflow of economic benefits will be required to settle the obligation and a reliable estimate can be made of the amount of the obligation. If the effect is material, expected future cash flows are discounted using the real rate set by HM Treasury (currently 2.2 per cent).

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 for early departure costs are discounted at the pensions rate (currently 2.8 per cent). Where discounting is used, the increase in the provision due to unwinding the discount is recognised as a staff cost.

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.

Provision has been made for dilapidations of the headquarters building as required by the lease and for unpaid PAYE tax and national insurance on committee members' travel and subsistence payments.

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 Grants

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 treated as deferred income initially 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 income statement and each year, an amount equal to the depreciation charge on the asset is released from deferred income to 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 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 £3.094M (2010/11 £2.271M).

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

	2011/12	2010/11
	£000	£000
Income from fee charging activities*	**114,114**	117,573
Other income	**3,133**	3,814
Total revenue	**117,247**	121,387

*Includes £7.8m (2010/11, £6.9m) EU Income from European Medicines Agency (EMA): EMA income relates to assessments of medicines, scientific advice provided and inspections undertaken on behalf of the European Medicines Agency.

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

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 MHRA operates as a single reportable operating segment as defined within the scope of IFRS 8 (Segmental Reporting) under paragraph 12 (aggregation criteria). The MHRA's activities are inter-related and contiguous, the objective is to protect, promote and improve public health.

The MHRA charges fees for its business activities. There is no cross-charging between divisions in relation to back-office functions or overheads.

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.

Fees are set to recover the full cost incurred by the Agency. The MHRA has complied with the cost allocation and charging requirements as set out in HM Treasury's guidance.

	2011/12		
	£000	**£000**	**£000**
Charging activity	**Income**	**Expenditure**	**Surplus/ (Deficit)**
Licensing	**48,701**	**(38,135)**	**10,566**
Inspections	**9,795**	**(8,419)**	**1,376**
Vigilance, Risk Management and Enforcement	**33,036**	**(30,033)**	**3,003**
GPRD	**5,927**	**(4,390)**	**1,537**
British Pharmacopoeia	**2,656**	**(2,465)**	**191**
Devices	**10,679**	**(9,904)**	**775**
Clinical Trials	**3,320**	**(3,004)**	**316**
Total	**114,114**	**(96,350)**	**17,764**

	2010/11		
	£000	£000	£000
Charging activity	Income	Expenditure	Surplus/ (Deficit)
Licensing	55,956	(35,858)	20,098
Inspections	10,321	(8,748)	1,573
Vigilance, Risk Management and Enforcement	28,699	(25,811)	2,888
GPRD	5,750	(3,657)	2,093
British Pharmacopoeia	2,553	(2,651)	(98)
Devices	11,245	(9,580)	1,665
Clinical Trials	3,049	(2,619)	430
Total	117,573	(88,924)	28,649

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

6 Staff costs and numbers

6.1 Staff costs

	2011/12			2010/11
	Total	**Permanently Employed**	**Other**	Total
	£000	**£000**	**£000**	£000
Wages and salaries	**43,126**	**41,964**	**1,162**	42,928
Social security costs	**3,866**	**3,842**	**24**	3,783
Other pension contributions	**8,117**	**8,086**	**31**	8,355
Sub-total	**55,109**	**53,892**	**1,217**	55,066
Less recoveries in respect of outward secondment	**(48)**	**(48)**	**-**	(85)
Total staff costs	**55,061**	**53,844**	**1,217**	54,981

Details of the remuneration of the Corporate Executive Team and Agency Board's remuneration is set out in the Remuneration Report

6.2 Staff numbers

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

	2011/12			2010/11		
	Total	**Permanently Employed**	**Other**	Total	Permanently Employed	Other
Chairman	1	1	-	1	1	-
Executive Directors	10	9	1	10	9	1
Senior Civil Servants	109	109	-	109	108	1
Other Civil Service staff	791	748	43	854	795	59
	911	867	44	974	913	61

6.3 Reporting of civil service and other compensation schemes – exit packages

	`			**2010/11**
	Number of compulsory redundancies	**Number of other departures agreed**	**Total number of exit packages by cost band**	Total number of exit packages by cost band
< £10,000	1	4	5	-
£ 10,000 - £25,000	1	5	6	-
£ 25,000 - £50,000	2	8	10	1
£ 50,000 - £ 100,000	-	2	2	-
£100,000 - £150,000	-	1	1	-
£150,000 - £200,000	-	1	1	-
Total number of exit packages	**4**	**21**	**25**	**1**
Total resource cost	**£86,673**	**£820,342**	**£907,015**	**£47,331**

Redundancy and other departure costs have been paid in accordance with the provisions of the Civil Service Compensation Scheme, a statutory scheme made under the Superannuation Act 1972. Exit costs are accounted in full in the year in which the departure was agreed as binding. Where the department has agreed early retirements, the additional costs are met by the Agency and not the Civil Service pension scheme. Ill health retirement costs are met by the pension scheme and are not included in the table.

Termination benefits of £907k (2010/11, £47k) are included in wages and salaries and shown on the exit package table.

6.4 Pensions

The PCSPS is an unfunded multi-employer defined benefit scheme. 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 2011/12, employers' contributions for MHRA employees of £8,098,834 with a further £7,234 respect of staff on secondment were payable to the PCSPS (£8,311,346 in 2010/11 and a further £13,795 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 2010/11), 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, a stakeholder pension with an employer contribution. Employers' contributions of £234,492 (£176,580 in 2010/11) 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 2010/11). Employers can also match employee contributions up to a limit of 3 per cent of pensionable pay. In addition, employer contributions of £3,284 (£3,566 in 2010/11), 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 £4,635. No contributions were prepaid at that date.

There was one case of retirement on ill-health grounds during 2011/12 (2010/11, nil). No additional pension liabilities were accrued.

7. Expenditure

7.1 Operating costs

	2011/12	2010/11
	£000	£000
Computing	**10,161**	10,644
Depreciation and amortisation	**7,326**	6,907
Other accommodation costs	**7,163**	3,524
Increase in provisions/Release of unutilised provision	**3,240**	(3,275)
Medicines testing and laboratory expenses	**2,229**	2,203
Travel and subsistence	**2,010**	2,110
Legal Services	**1,576**	1,625
Contracted-out administration services	**1,563**	1,535
Other administration costs	**1,478**	1,386
Net increase in debt and credit note provision	**1,193**	184
Telecommunications	**795**	1,104
Training	**768**	745
Committee costs	**701**	650
Loss on disposal	**479**	-
Contracted-out personnel and payroll services	**364**	179
Printing, stationery and distribution	**306**	666
Pharmacovigilance database and other costs	**228**	224
Rentals under operating leases (see 7.2 below)	**201**	2,878
Auditors remuneration - audit fee	**87**	96
Marketing	**79**	81
Consultancy	**-**	35
Tax & NI	**-**	1,995
Total operating costs	**41,947**	35,496

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	**2011/12**	**2011/12**	2010/11	2010/11
	£000	**£000**	£000	£000
Minimum lease payments	**76**	**201**	84	2,878
	76	**201**	84	2,878

Total future minimum lease payments	**2011/12**	**2011/12**	2010/11	2010/11
	£000	**£000**	£000	£000
Payable:				
Within one year	**64**	**1,647**	63	182
Within two to five years	**28**	**17,995**	26	15,070
Over five years	**-**	**20,907**	-	25,402
Total	**92**	**40,549**	89	40,654

Total future sub-lease payments expected to be received: £170k (2010/11: £172k)

7.3 Finance Leases

The Agency had no finance leases in 2011/12.

8 Finance income and costs

	2011/12	2010/11
	£000	£000
Finance income		
Interest received from Government Banking Service	**271**	223
	271	223
Finance costs		
Interest paid	**(201)**	(46)
Net cash inflow from returns on investments and servicing of Finance	**70**	177

9 Other gains and losses

	2011/12	2010/11
	£000	£000
(Loss)/Gain on foreign exchange	**(86)**	48
	(86)	48

10 Plant and equipment

2011-12	Computer and telecom equipment	Laboratory equipment	Fittings furniture and office equipment	Total
	£000	£000	£000	£000
Cost or valuation				
At 1 April 2011	8,264	1,778	15,209	25,251
Additions	122	107	1,048	1,277
Disposals	(196)	(469)	(33)	(698)
Reversals	-	-	(1,806)	(1,806)
Adjustment (note)	-	-	(865)	(865)
At 31 March 2012	**8,190**	**1,416**	**13,553**	**23,159**
Depreciation				
At 1 April 2011	3,059	1,258	1,747	6,064
Charged during the year	1,993	136	1,288	3,417
Disposals	(196)	(469)	(27)	(692)
Adjustment (note)	-	-	(865)	(865)
Depreciation at 31 March 2012	**4,856**	**925**	**2,143**	**7,924**
Net book value at 31 March 2012	**3,334**	**491**	**11,410**	**15,235**
Net book value at 31 March 2011	5,205	520	13,462	19,187
Asset financing:				
Owned				
Net book value at 31 March 2012	**3,334**	**491**	**11,410**	**15,235**

Note: In producing the closing balances at 31 March 2011, an excel spreadsheet problem led to the misallocation of sums in the fittings furniture and office equipment, although the overall net figure was unaffected. This adjustment corrects the misallocation in the balances.

2010-11	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

2011-12	Computer Systems	Assets under Construction	Software Licences	Total
	£000	£000	£000	£000
Cost or Valuation				
At 1 April 2011	30,465	1,206	1,850	33,521
Additions	431	1,502	195	2,128
Disposals	(4,475)	-	(151)	(4,626)
Reversals	-	(623)	-	(623)
At 31 March 2012	**26,421**	**2,085**	**1,894**	**30,400**
Amortisation				
At 1 April 2011	21,280	-	859	22,139
Charged during the year	3,592	-	317	3,909
1Disposals	(4,002)	-	(151)	(4,153)
Amortisation at 31 March 2012	**20,870**	**-**	**1,025**	**21,895**
Net book value at 31 March 2012	**5,551**	**2,085**	**869**	**8,505**
Net book value at 31 March 2011	9,185	1,206	991	11,382
Asset financing:				
Owned				
Net book value at 31 March 2012	**5,551**	**2,085**	**869**	**8,505**

2010-11	Computer Systems	Assets under Construction	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**

12 Trade and other receivables

	31 March 2012	31 March 2011
Amounts falling due within one year:	**£000**	£000
Due from the Department of Health (see 12.1 below)	**755**	361
Other trade receivables	**16,388**	13,575
Other receivables	**253**	264
Accrued income	**1,845**	1,833
Prepayments	**2,450**	2,584
	***21,691**	*18,617

*Intra government balance disclosed in note 21

Amounts falling due after more than one year:
There are no debtors falling due after more than one year.

Other trade receivables are shown net of a provision for bad debts of £4.7M (31 March 2011 £5.9M) and credit notes of £7.9m (31 March 2011 £5.6m).

12.1 Amount Due from the Department of Health consists of:

	31 March 2012	31 March 2011
	£000	£000
Other trade receivables	**11**	361
Value Added Tax	**744**	-
	755	361

12.2 Provision for bad debt

	31 March 2012	31 March 2011
	£000	£000
Bad debt provision	**4,676**	5,899
	4,676	5,899

13 Cash and cash equivalents

	31 March 2012	31 March 2011
	£000	£000
Balance at 1 April	**87,517**	79,385
Net change in year	**27,362**	8,132
Balance at 31 March	**114,879**	87,517

Made up of		
Government Banking Service	**487**	244
Commercial banks and cash in hand	**114,392**	87,273
Cash and cash equivalents	**114,879**	87,517

14 Trade and other payables

	Current		Non-Current	
Amounts falling due within one year:	**31 March 2012**	31 March 2011	**31 March 2012**	31 March 2011
	£000	£000	**£000**	£000
Due to Department of Health (see 14.1 below)	**50**	311	**-**	-
Payments received on account	**17,483**	13,487	**-**	-
Taxation and other social security costs	**1,979**	2,041	**-**	-
Other trade payables	**2,697**	2,201	**-**	-
Other payables	**15**	1	**-**	-
Accruals	**9,321**	8,923	**-**	-
	***31,545**	* 26,964	**-**	-

*Intra government balance disclosed in note 21

Amounts falling due after more than one year:

There are no creditors falling due after one year.

14.1 Amount Due to the Department of Health consists of:

	Current		Non-Current	
	31 March 2012	31 March 2011	**31 March 2012**	31 March 2011
	£000	£000	**£000**	£000
Value Added Tax	**-**	288	**-**	-
Other trade payables	**50**	-	**-**	-
Accruals	**-**	23	**-**	-
	50	311	**-**	-

15 Borrowings

	Current		Non-Current	
	31 March 2012	31 March 2011	**31 March 2012**	31 March 2011
	£000	£000	**£000**	£000
Loans from Department of Health	**-**	-	**1,328**	1,328
	-	-	**1,328**	1,328

16 Provisions

	Current		Non-Current	
	31 March 2012	31 March 2011	**31 March 2012**	31 March 2011
	£000	£000	**£000**	£000
Early retirement	**16**	18	**30**	45
Other provisions	**1,226**	-	**2,031**	-
	1,242	18	**2,061**	45

	Early retirement	Other provisions	**Total**
	£000	£000	**£000**
At 1 April 2011	63	-	**63**
Arising during the year	-	3,257	**3,257**
Used during the year	(18)	-	**(18)**
Unwinding of provision	1	-	**1**
At 31 March 2012	46	3,257	**3,303**
Expected timing of cash flows:			
Between 1 April 2012 and 31 March 2013	16	1,226	**1,242**
Between 1 April 2013 and 31 March 2015	30	-	**30**
Beyond 2015	-	2,031	**2,031**
Total	46	3,257	**3,303**

The provision for early retirement and voluntary severance is to cover the MHRA's estimated liability for pensions in respect of early retirements. They have been discounted using the Treasury discounted rate of 2.8%.

Other provisions established during the year are in respect of:

- dilapidations for the headquarters building and is the current estimated cost for reinstating the structure of the building as required by the lease discounted at the Treasury discounted rate of 2.2%;
- a further provision in lieu of unpaid PAYE tax and national insurance on committee members travel and subsistence payments has been created pending settlement with HMRC; these have not been discounted as payment is expected to be made within the next twelve months.

17 Other Liabilities

	Current		Non-Current	
	31 March 2012	31 March 2011	**31 March 2012**	31 March 2011
	£000	£000	£000	£000
Deferred revenue:		Restated*		Restated*
Licence fees - applications and variations (note 1)	**15,664**	18,591	**3,923**	4,656
Other fees (note 1)	**3,406**	1,836	**84**	1,644
Government grant (note 2)	**1,400**	115	**1,152**	953
Dividend Payable	**3,094**	2,271	**-**	-
Total	**23,564**	22,813	**5,159**	7,253

* Restated:
Note 1: Other liabilities reclassified into current and non current.

Note 2: Change in accounting policy on treatment of government grants to comply with HM Treasury changes in Financial Reporting Manual. Government grant moved from reserves to other liabilities (see note 16.2).

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

	Total 2011/12	**Less than one year**	**Between one and five years**	**More than five years**	**Total 2010/11**
	£000	**£000**	**£000**	**£000**	**£000**
Fixed interest rate					
3.50%	**1,328**	-	-	1,328	1,328
At 31 March 2012	**1,328**	**-**	**-**	**1,328**	
At 31 March 2011	**-**	-	-	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 2012	**31 March 2012**	31 March 2012	31 March 2011
	£000	**£000**	£000	£000
Contracted	**1,853**	**174**	1,018	751
	1,853	**174**	1,018	751

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 (£2,149,991);
- The University of Leicester for the secondment of the Agency's Chief Executive (£256,835);

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

2011-12	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	3,096	12,484	-	11
Various NHS Trust	153	1,498	-	761
Department for Work and Pensions	2,150	-	-	-
Other government bodies	238	198	4	175
Local Authorities	(333)	4	-	-
Educational Bodies	438	1,177	-	384
As at 31 March 2012	**5,742**	**15,361**	**4**	**1,331**
2010-11				
Department of Health	2,579	11,127	-	361
Various NHS Trusts	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

During 2011/12, 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

2011-12	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	3,004	-	6,768	-
Balances With Local Authorities	-	-	-	-
Balances with NHS Trusts	2,356	-	299	-
Balances with Public Corporations and Trading Funds	6	-	-	-
Subtotal	5,366	-	7,067	-
Balances with Bodies External to Government	16,325	-	24,478	-
As at 31 March 2012	**21,691**	**-**	**31,545**	**-**
2010-11				
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	-

22 Losses and special payments

Managing Public Money requires a statement showing losses and payments by value and by type to be shown where they exceed £250k in total, and those individually that exceed £250k.

There were no special payments in excess of £250k during the year (2010/11: nil).

Losses may relate to cash and stores losses, bookkeeping losses, losses arising from failure to make adequate charge for use of public property or services, fruitless payments and claims abandoned as well as frauds. Special payments may relate to extra contractual, extra statutory and ex gratia payments and compensation.

There were no other material losses or special payments during the year (2010/11: £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.

	2011/12	2010/11
	£000	£000
Government Banking Service	487	244
Commercial banks and cash in hand*	114,392	87,273
	114,879	87,517

* Includes £392k Proceeds of Crime which is the Agency's share of confiscated monies resulting from successful prosecutions and £95k Enforcement cash 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 (2010/11:£1.328M). This resulted in interest payable of £0.046M (2010/11: £0.046M) out of total expenditure in excess of £97M (2010/11: £91M)

Currency risk

The level of currency risk is determined by the level of income generated by activity undertaken on behalf of the EMA. For 2011/12 this was £7.782M (Euro 9.306M) (2010/11: £6.929M; Euro 7.881M). This represents 6.6% (2010/11: 5.6%) of the total gross income for the year. The Agency is potentially exposed to significant falls in the value of this currency; however, the risk is mitigated by the regular transfer of funds to the sterling accounts of the Agency leaving minimal 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.

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