Safeguarding public health

Medicines and Healthcare products Regulatory Agency

Annual Report and Accounts 2012/13

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1 Chairman's & Chief Executive's Foreword

Chief Executive's Foreword

As I write this foreword, I reflect not only on the last financial year but also on the past decade, as I will retire in 2013. Since its inception in 2003 the Agency has grown in response to a widening range of responsibilities placed upon it. That expansion of tasks and capability has continued in 2012/13.

The financial year began with the launch of the Clinical Practice Research Datalink (CPRD) jointly funded by the NHS National Institute for Health Research and ourselves. Formed from the merger of the General Practice Research Database (already established in MHRA) and the Department of Health's Research Capability Programme, CPRD is a health data resource of international significance. Its wealth of anonymised NHS clinical and public health information will help us to better understand the use and outcomes of treatments in routine care. It will also be of value to researchers in many health-related disciplines.

During the year there was an unprecedented level of interest in implantable medical devices. This was triggered by two rather different problems. The first concerned the improper use of unauthorised filler in a make of breast implant (PIP) widely used in cosmetic surgery. The second arose from evidence of accelerated wear in certain types of artificial hip joints with a metal-on-metal bearing surface. In each case the Agency worked closely with national experts and with the professional associations to communicate information and guidance to clinicians and users as investigations took place. Evidence was presented both to Commons Select Committee hearings and to the media. Detailed reviews and recommendations have now been published in the Keogh report on cosmetic surgery and Earl Howe's review of the handling of the PIP incident. These will inform the current negotiation of the revision of the EU Medical Devices Directives.

The Agency has also been fully engaged in the revision of the Clinical Trials Directive and in the implementation of the new Pharmacovigilance legislation and the Falsified Medicines Directive. Beyond the EU, we have strengthened our ties with regulatory counterparts including those of the United States, China, India, Japan and Australia. In October the MHRA took a leading role in the highly successful Pangea V initiative against the internet sale of counterfeit and substandard medicines and devices. Over 100 countries participated with more than £6.5 million worth of counterfeit and unlicensed medicines seized. Our work in combating counterfeit medicines was also recognised by the Partnership for Safe Medicines who honoured us with a Guardian Award demonstrating outstanding leadership in the fight to stop counterfeit medicines.

In August, the Human Medicines Regulations 2012 came into force. This was the culmination of a three-year project by the Agency to consolidate and review the Medicines Act 1968 and over 200 statutory instruments. It represents a major contribution to regulatory simplification in the domain of pharmaceuticals.

Another notable example of improved, streamlined regulation is our initiative to speed up the application process for making more medicines available where it is safe to do so – moving medicines from prescription-only to over-the-counter. This process could cut the time from application to decision by three months or more.

Innovation is a key theme for us and I'm delighted that we have now launched an 'Innovation Office' to help organisations developing novel medicinal products and devices to navigate the

regulatory processes and to bring them to market. We always aim to be an innovating regulator and this has been exemplified this year by our 'Good Clinical Practice Guide'. This was written and produced by the Agency and is the only such publication by a regulatory authority within Europe, providing valuable and practical guidance on GCP.

Our online account management facility, iRIS, which allows our customers once registered to view their current and historical account details online had a 31% increase this year in the number of customer subscribers. The service was also shortlisted for the Change Management Award at The Civil Service Awards.

In December we bade farewell to the Agency's founding chairman, Sir Alasdair Breckenridge. He had made an outstanding contribution to the building of the Agency and at a personal level I greatly valued his advice and support. It is a pleasure to welcome his successor, Sir Gordon Duff, who brings a wealth of experience from his years as chairman of the Commission on Human Medicines and of the National Biological Standards Board.

The Agency continues to respond to scientific and technological developments by its merger with the internationally renowned National Institute for Biological Standards and Control (NIBSC) on 1 April 2013. I should like to pay tribute to staff from both organisations who have contributed to the merger project groups with enthusiasm and commitment. We are already beginning to reap the benefits of the merger, which has been implemented in shadow form during 2012/13.

The Agency's achievements over the past year would not have been possible without the expertise and dedication of its staff. That high level of commitment has been a constant theme of the Agency throughout the past decade and has been the key to its success. It has been a privilege to lead the Agency over the past decade. I have every confidence that it has the 'strength in depth' to meet the challenges that the future will bring, as it works to ensure that patients gain maximum benefit at minimum risk from medicines and medical devices.

Professor Sir Kent Woods
Chief Executive

Chairman's Foreword

The year began with the MHRA in a reflective and expectant mood as it approached its tenth anniversary and prepared for the merger with NIBSC and a change of Chairman and Chief Executive.

I write this foreword from the perspective of someone who joined MHRA half-way through the financial year, when I succeeded the founding chairman, Sir Alasdair Breckenridge. I'm very conscious of the debt that each of us owes to Sir Alasdair, and of the hard task that falls to me in replacing his strategic leadership. Although I am new to MHRA, I am not unfamiliar with its work or that of its predecessor, the Medicines Control Agency. As the former Chairman of the Commission on Human Medicines (CHM), and its predecessor, the Committee on the Safety of Medicines (CSM), I have long held the Agency in the highest regard.

Since becoming Chairman of MHRA on 1 January, I have learned much about aspects of the organisation's work with which my role as Chair of CHM didn't bring me into contact. This has been a fascinating period of learning, and has reinforced the admiration I already had for the MHRA and its staff.

2012/13 has been a year of unprecedented change for the Agency with the creation of the Clinical Practice Research Datalink (CPRD) and the intensive efforts to prepare for the MHRA's merger with the world-renowned National Institute for Biological Standards and Control (NIBSC) on 1 April 2013. As with CPRD, the MHRA's union with NIBSC offers new opportunities for scientific research, support and innovation in the field of biological medicines, a field of growing importance as MHRA enters its second decade.

I am pleased that the Agency will take forward important work on the Government's Life Sciences and Growth agenda, notably as this relates to regulatory innovation and improving the UK's attractiveness as a base for clinical trial activity.

Regulating proportionately to reduce regulatory burden where it is safe to do so will also be a key theme, as will working collaboratively with those we regulate, providing clear guidance and advice and facilitating compliance with regulatory requirements where possible.

Continuing to be a leading regulator in Europe and beyond will be ever more important as we seek to influence and shape a convergence of high standards which will lead to improved health protection.

In December, my distinguished predecessor, Sir Alasdair, retired after nearly ten years at the helm of MHRA's Board. During that time, Sir Alasdair oversaw the expansion of MHRA's roles and its development into one of the world's leading regulators. I am very grateful to Sir Alasdair for what he achieved and for the rich legacy he has left us. I am most honoured that I should have been chosen to be his successor.

As I write this foreword, I know that Sir Kent Woods, MHRA's founding Chief Executive, will retire soon. Much of MHRA's success over the past decade is due to Sir Kent's strong and wise leadership, deft managerial skills and intellectual prowess, which have won him well-deserved admiration among regulators across the globe, as well as within the wider public health community. Again, I would like to use the opportunity of this foreword to pay a warm personal tribute to Sir Kent for forging a national regulatory agency of world standing.

Although I will be very sorry to see Sir Kent leave, I look forward to working with his successor as MHRA prepares for its second decade. For as Sir Kent mentioned in his foreword to the Annual Report, MHRA's journey will continue to be one of evolution and growth in a rapidly-changing international, political, scientific and technological landscape.

We must be alert and agile to anticipate, and meet, the demands of a changing world so that we can protect and improve the health of millions through science, research and effective regulation

Professor Sir Gordon Duff
Chairman

2 MHRA at a glance

2.1 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.

2.2 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.

2.3 Aims

The MHRA's aims are:

- **protecting public health** through regulation, with acceptable benefit-risk profiles for medicines and medical 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.

2.4 Objectives

The MHRA'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**.

2.5 Activities

The MHRA'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 Clinical Practice Research Datalink (CPRD) 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
- providing the public and professions with authoritative information to enable informed dialogue on treatment choices.

2.6 Operational highlights

- The Agency introduced a novel computer system in conjunction with Oracle Life Sciences and Accenture to deliver a better risk-based inspection programme. Once populated with sufficient data the software will help ensure that sites of highest risk are targeted and those with good compliance histories are inspected less frequently
- The Agency collaborated globally with other regulators to help raise world standards in providing safe medicines. Initiatives such as Operation Pangea (tackling the sale of medicines sold illegally over the internet, involving 100 countries resulting in 4.1million doses of medicines being seized globally in the week-long operation in October 2012) and the rollout of an updated Falsified Medical Products Strategy have been instrumental in reducing the threat of fake products reaching the UK market
- The Agency's new 'Grey Guide' is the first publication of its kind by a regulator giving practical examples of how companies can comply with legislation governing clinical trials. The theme of risk adaptation runs throughout the book in line with Government policies on innovation
- The newly-introduced Pharmacovigilance Regulation requires European Member States to make available all Summary of Product Characteristics (SPCs) and Patient Information Leaflets (PILs) for authorised medicinal products they hold. This has been a major undertaking for the Agency and by March 2013 over 17,000 SPC and corresponding PILs have been published on the MHRA website
- As part of the UK Government's industrial strategy for life sciences, the Agency launched an Innovation Office to help support research and ensure that regulation does not stifle innovation. The Innovation Office will also help companies, SMEs, academics and individuals, who have developed a novel medicine or medical device, or a distinctly novel approach to the development or manufacture of a product, in their regulation
- Over the past year the MHRA has been involved in a number of cases affecting a range of medicinal products where the continued supply presented a significant challenge against the delicate balance of risk/benefits. For example, due to microbial contamination at the manufacturing plant, the supply of Immucyst for the treatment of bladder cancer was interrupted. In response the Agency worked with various manufacturers, other global regulators and Department of Health colleagues to secure an alternative supply in a timely manner. In the case of Cetero Research facilities, for example, information received

following inspection indicated that the bio-analytical data were found to be unreliable such that a range of medicinal products with data generated from the facilities were suspended at the European level affecting a number of markets. To assist companies to resolve potential supply issues, Licensing Division processed some 250 requests for expedited variations to maintain supply, often within 72 hours

- Over the year the number of adverse incidents involving medical devices rose 26% while the Agency was dealing with the several high-profile public health issues arising out of the PIP breast implant scandal and accumulating evidence around the performance of metal-on-metal hip implants. This took place against a backdrop of consultation and negotiations on the revision of European medical devices legislation
- One of the most notable events for 2012 was the implementation of the new EU pharmacovigilance legislation and the creation of the new Pharmacovigilance Risk Assessment Committee (PRAC), chaired by the UK. Furthermore the UK was appointed to lead an EU-wide project to enable Member States to operate effectively to the standards required in the new pharmacovigilance legislation. This is a Joint Action project and forms part of the European Commission's 2013 Health Programme
- The public health-focussed work on the regulation of nicotine containing products as medicines has progressed, and a review of the scientific and market research by the Commission on Human Medicine's (CHM's) has been completed. A Government announcement on the final decision on the regulation of these products as medicines will be made in Spring 2013. In February 2013 the MHRA signed a national pledge along with wider Government and other organisations to do everything possible to improve the care that children and young people receive. To deliver on these commitments the Agency will be taking forward a strategy to improve paediatric pharmacovigilance
- The work of the EU Platform on Access to Medicines on good governance of non-prescription medicines, jointly chaired by the UK and the European Commission, was completed and the recommendations were agreed in April 2013. The task this year is to steer implementation of the recommendations which aim to optimise access to non-prescription medicines
- Work was undertaken to ensure that we realise the potential public health benefits offered by the MHRA-NIBSC merger and we have been exploring how best to make optimal use of the expertise and the existing and expanding data sources that we have available to us. In particular a Strategic Working Group on vaccines risk management has been established – the 'Vaccination and Immunisation Safety - Integrated Operations Network' ('VISION'). The remit of the VISION network is to provide a forum to co-ordinate cross-organisational activities in post-authorisation risk management and risk-benefit evaluation of vaccines
- Our online account management facility, iRIS, which allows our customers once registered to view their current and historical account details online had a 31% increase this year in the n umber of customer subscribers. The service was also shortlisted for the Change Management Award at The Civil Service Awards.

2.7 Key financials

Overall, both income and expenditure were lower than in 2012/13. However, the MHRA reported a surplus of £9.0m in 2012/13, down £8.1m from 2011/12.

2.8 Legislative, regulatory, operational and external environment

This has been another year of substantial change in the MHRA's external operating environment. Key internal changes have included the development of the Clinical Practice Research Datalink (CPRD) and preparing for the MHRA's enlargement to include the National Institute for Biological Standards and Control (NIBSC). Externally, the general financial climate and changes to the amount, and the MHRA's share, of EU regulatory work contributed to tougher operating conditions last year.

CPRD was launched on 1 April 2012, linking GP data from the previous General Practice Research Database (GPRD) to hospital data, providing a comprehensive system for research. Throughout 2012/13, CPRD has been in a development phase, recruiting staff and developing its capability, products and services.

In the latter part of 2012/13, a Programme Board oversaw preparations for NIBSC to join the MHRA on 1 April 2013. Two projects focussed on particular aspects of the merger: 'Realising the benefits' and 'Creating the new organisation'. These identified work to get the best out of the synergies and added capability and capacity from the MHRA enlargement.

On the EU side, the focus this year has been on the implementation of the Pharmacovigilance Directive and the Falsified Medicines Directive. The new pharmacovigilance legislation significantly strengthened the post-marketing surveillance for medicines across the EU. The falsified medicines legislation introduced stricter rules ensuring that medicines are acceptably safe and that the trade in medicines is rigorously controlled. Furthermore, the European Commission (EC) published two important proposals for the review of the Clinical Trials Directive and Medical Devices Regulations which the MHRA is leading on behalf of the UK Government. The MHRA has actively worked with the EC, members of the European Parliament, other Member States, various industry groups and research organisations to influence the development of these proposals to ensure UK needs are met and safeguard public health in the UK.

The medicines and medical devices industries operate globally, and the regulatory frameworks that govern them increasingly evolve at EU and 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 benefit from their own knowledge and expertise to protect UK public health. In 2012/13 this activity included continued engagement with key regulators and the main source countries China and India. In India, supplier of about one quarter of all medicines on the UK market, the MHRA strengthened its visibility considerably by organising a number of events focused on engagement with industry and regulators. In China the MHRA strengthened its relation with the Chinese State Food and Drugs Administration through a bilateral meeting between the two heads of agencies. The MHRA also signed agreements with Brazil, Taiwan and Kosovo allowing for the exchange of regulatory information which can help authorities make regulatory decisions.

3 Performance against targets 2012/13

Target	Evidence and Measures		Comments
PM1 Medicines Licensing time targets	a) The assessment of applications for new Marketing Authorisations for UK only: 98% assessed in 150 days	**Green**	Met 100% in 150 days
	b) The assessment of applications for new Marketing Authorisations in European (MR, DC & centralised) procedures: 97% assessed within the designated time	**Green**	Met • 100% DCP RMS in 70 days • 100% DCP CMS in 100 days • 100% MR in 50 days • 100% Centralised Rap/Co-Rap in 80 days
	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.	**Green**	Met • Type II 97% in 90 days • Type IB 97% in 30 days •
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)	**Green**	Met Almost 100% of all authorisations within 30 days. Average of 12 days for Phase 1 trials.
	b) Timescales for clinical investigation notifications for medical devices: maximum of 60 days with an overall average of 54 days or less	**Green**	Met 100% handled within 60 days with an average of 47days.
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	**Green**	Met Nearly 100% made available within 2 working days (4,842 out of a total of 4,870 fatal and serious incidents reports) and 100% available within 3 working days.
	c) For fatal UK adverse drug reactions: 90% within 24 hours, 100% within 72 hours	**Green**	Met • 100% within 24 hours • 100% within 72 hours

	d) For serious UK adverse drug reactions: 95% within 72 hours, 100% within 5 days	**Green**	Met • 100% 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	**Green**	Met 92% 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.	**Green**	Met 93% replied to within statutory time limits (20 working days - up to 40 for cases considering public interest arguments). In this year a total of: • 483 FOI requests were received • 7 internal reviews were completed • 0 ICO review was completed (None for 2012/13) • 2 1st tier tribunals are underway • 1 upper tier tribunal is underway
	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	**Green**	Met • 100% PARs completed • 100% updates of PARs with major non-safety variations of clinical importance
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	a) Meet DH deadlines for responses to Parliamentary Questions (PQs) in at least 80% of the cases, with less than 10% rewrite rate.	**Green**	Met 92 PQs were answered with this year with 91% answered on time and no rewrites
	b) Meet Ministerial correspondence deadlines (POs) in at least 80% of cases with less than 10% rewrite rate.	**Green**	Met 130 POs were answered this year with 86% answered on time and a 1% rewrite rate (1 PO).

MHRA Parliamentary and Ministerial business	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 2013.	**Green**	**Achieved in Quarter 2**
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.	**Green**	Met
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, with an average of 85% returned evaluation assessments.	**Green/ Red**	Part met/Part not met 87% average score for courses, and an average of 68% returned evaluation assessments (190 out of 311 evaluation assessments).
	b) Ensure that at least 85% of staff who complete 3 month evaluation information are able to put their learning in to practice within the following 3 months, with an average of 70% of returned evaluation assessments.	**Red/ Amber**	Part not met/Part almost met 44% of 3 month evaluation assessments (94 out of 212 evaluation assessments) were returned and 81% of delegates were able to put their learning into practice within the following 3 months.
	c) Implement IiP continuous learning action plan to achieve bronze level standard in the December 2012 IiP assessment.	**Green**	Achieved in Quarter 3
	d) Implement a successful transfer of the NIBSC's function from HPA to the MHRA with minimal disruption to business.	**Green**	Met
	e) Develop and introduce revised management and leadership programme to increase leadership capability by end of 2013.	**Green**	On track

Green = target met
Amber = target almost met (ie: narrowly missed)
Red = target not met

4 People

4.1 Employee engagement

Employee involvement and well-being

Regular contact between managers and staff is actively encouraged to involve everybody in the work of their team and the MHRA. This includes regular one to one meetings between line managers and their staff, as well as unit, divisional and all staff meetings open to everyone and held twice a year.

Information is shared with staff in a number of ways including by email and the MHRA's intranet page. 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 and the feedback is collated centrally with responses made available on INsite - the MHRA's intranet.

There is also regular consultation and negotiation with trade union representatives with a number of regular and ad hoc meetings held throughout the year.

The MHRA measures how engaged its staff are by means of the annual Civil Service People Survey held every October. In 2012, almost 75% of staff took part in the survey and our engagement index score increased to 61%, 3% higher compared to last year and 3% higher than the Civil Service average. In response to the results, each division produces an action plan to address issues raised by staff at a local level.

During 2012, the MHRA has developed an employee communications and engagement strategy. This outlines a number of initiatives to ensure that the organisation is a good place to work. It also aims to help staff be engaged with the MHRA's work – the challenges and opportunities it brings, and the role they play in it.

4.2 Staff resources

During the year an average of 936 permanent full-time equivalent staff were employed.

4.3 Recruitment

The MHRA recruits staff on the basis of fair and open competition, as well as 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.

The MHRA recruited 150 staff during 2012/13.

	MALE	**FEMALE**
Executive Directors	0	0
Senior Civil Servants	6	6
Other Civil Service Staff	55	83
TOTAL	**61**	**89**

55 people from ethnic minority groups were recruited. 32% of the MHRA's staff are from ethnic minority groups and 2% 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 42 times for appointments over the period of 12 months.

E-recruitment

The MHRA has implemented e-recruitment and is using a civil service package. This should enable the MHRA to deliver improvements for the applicant and manager.

4.4 Spend on consultancy and temporary staff

During 2012/13, expenditure on consultants was £Nil (£Nil in 2011/12).

The MHRA continues to employ temporary staff where it is of operational necessity. The MHRA temporary staff expenditure was £1,617k in 2012/13 (£960k in 2011/12).

4.5 Diversity and inclusion policy

People with disabilities

In relation to employees with disabilities, the MHRA complies with the equal opportunities legislation and provides special facilities where necessary such as interpreters or specialist equipment.

Equality and diversity

The MHRA complies with equal opportunities legislation and provides special facilities where necessary. The MHRA has a cross-agency diversity focus group that checks 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.

The MHRA is committed to providing equal opportunities to all staff. Our aim is to ensure that 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 MHRA abides by the statutory regulations regarding discrimination.

4.6 Sickness absence

During the year, 1.7% of available working days were recorded as sickness absence. This is an improvement on last year which showed 2.0% of working days were lost.

4.7 Learning and development

The MHRA's learning and development strategy actively promotes the development of staff by offering a suite of corporate and specific training. Individual needs are set out in personal development plans. These are met through appropriate means, including taking part in projects, coaching and shadowing, as well as traditional training courses.

The MHRA ran 111 training courses, with over 82% of attendees saying the course met their objectives during 2012/13.

During 2012/13 the MHRA launched a new management and leadership programme built specifically around the requirements of the MHRA to improve leadership capability. The programme gives managers a greater context of the environment they are operating in to help them learn more about the challenges facing the organisation. It is supported by the corporate executive team, line managers and internal MHRA coaches to cement learning.

To date, 152 managers have completed the programme with over 80% of attendees saying the course met their objectives. Further long term analysis is being carried out to measure the impact on performance,

The MHRA also ran its first ever leadership and change conference in March 2013 covering the new organisation's vision, values and corporate plan. The conference was open to all MHRA and NIBSC managers and was delivered by the corporate executive team. Over 250 managers attended and their feedback was excellent. Further events are planned.

4.8 Continuing Professional Development (CPD)

The MHRA organises a number of events to support the continuing professional development of its staff. This includes supporting external training and qualifications, and professional subscriptions. It also organises internal events and seminars such as lunch and learn sessions where external speakers are invited to give a presentation regarding a specific topic.

4.9 Revalidation

The MHRA has developed its own guidance and training to ensure that medically qualified staff that it employs meet the requirements of the new General Medical Council (GMC) revalidation process. During 2013, in addition to their line management appraisal, all medically qualified staff will have a strengthened medical appraisal to assess their professional competence. In preparation for this the MHRA has developed extensive guidance and delivered training and workshops for both managers and staff.

5 Finance

5.1 Financial review

The MHRA has produced a sustainable performance, despite the challenging business and economic conditions in the UK and globally. As a trading fund, the MHRA is funded by income from its fees. Fee income in 2012/13 was £99.6m, which was slightly lower compared to £107.0m in 2011/12. This reflects a reduction of 7% and is the result of a reduction in fees and simplification of the fee structure.

The operating surplus before interest for 2012/13 was £12.2m, compared to £20.2m in 2011/12. After finance costs and public dividend capital of £3.5m, a net surplus of £9.0m arose and was transferred to reserves.

2012/13 has seen cash inflows from operating activities of £24.7m, compared to £30.5m in 2011/12. The cash inflow was from trading activities and efficient working capital management.

5.2 Supplier payment performance

The MHRA is committed to the Better Payment Practice Code. The MHRA's policy is to attempt 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.

In 2012/13 - 94% of supplier bills were paid within five days and 100% within 30 days. This compares to 90% within five days and 100% within 30 days in 2011/12. No interest payments were made to suppliers under the Late Payment of Commercial Debts (Interest) Act 1998.

	Transactions	**Value (£000)**	**%**	**Transactions**	**Value (£000)**	**%**
0 - 5 days	15,230	26,882	94	11,129	41,195	90
6 - 10 days	770	16,033	4	1,113	4,120	9
11 - 30 days	237	1,196	2	124	458	1
Over 30 days	8	8	0	-	-	-
	16,245	**44,119**	**100**	**12,366**	**45,733**	**100**

5.3 HM Treasury accounts direction

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

5.4 Going concern basis

Based on normal business planning and control procedures, the MHRA 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.

5.5 Pension liabilities

These are covered in notes 6.5 and 16 of the accounts.

5.6 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.

5.7 Audit services and costs

The Comptroller and Auditor General (C&AG) is head of the National Audit Office (NAO) 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 £80,000 for 2012/13. This compares to £87,000 for 2011/12. The internal audit function has been provided by PricewaterhouseCoopers (PwC) who have been appointed by the MHRA under a non-statutory letter of engagement to provide an independent review of the systems and workings supporting the performance indicators reported in the annual accounts.

6 Better regulation

Better regulation is a key part of the government's agenda to help reduce regulatory burdens where it is safe to do so, and in so doing deliver better public services.

The MHRA's Regulatory Programme helps prioritise initiatives in collaboration with industry, focuses effort on minimising regulatory burdens and allows the MHRA to react quickly and appropriately to changing circumstances. The programme is split into five themes:

- new/EU regulation - this captures issues arising from the development of EU law that the MHRA needs to influence to ensure the right outcomes, or that we transpose into UK law.
- life sciences and growth – this captures the work that the MHRA and stakeholders are undertaking to identify whether earlier access to medicines is viable, considering both potential risks and benefits. It also explores how the MHRA can continue to make the UK an attractive environment for clinical trials.
- professional/product interface – this explores whether the MHRA has the right balance between the roles of medicines legislation and professional regulation.
- burden reduction/simplification – this covers the work the MHRA plans to undertake to reduce burdens or simplify regulation.
- regulatory strategy – this is the work the MHRA undertakes to support the Regulatory Programme and set its strategic direction.

As part of the work to reduce regulatory burdens, the MHRA delivered a critical project in 2012 to simplify and consolidate UK medicines legislation. Most of the Medicines Act of 1968 and over 200 statutory instruments were replaced with one set of Regulations - the Human Medicines Regulations 2012, which came into force on 14 August 2012.

The MHRA's Red Tape Challenge sought suggestions from stakeholders on how to simplify processes and reduce bureaucracy. The wide variety of responses the MHRA received from individuals and organisations amounted to around 260 proposals relating to legislation, process and guidance. These proposals included expanding electronic communications, reviewing guidance and forms, and simplifying fees. Some of the proposals were taken forward in 2012/13 and the focus for the year ahead is to take forward projects to deliver the remaining high priority proposals, liaising with stakeholders.

The MHRA has established a Medicines Industry Liaison Group (MILG) to facilitate working with industry, particularly monitoring the Red Tape Challenge implementation and discussing recommendations on regulatory reform. This group was established as part of the Better Regulation of Medicines Initiative (BROMI). Since 2005, BROMI has taken forward a wide range of initiatives aiming to deliver proportionate, risk-based, targeted and cost effective medicines regulation to free up industry to focus on the development of new products. During 2012/13, BROMI workstreams included patient information, authorisation and pharmacovigilance. More recent workstreams have focused on the reclassification of medicines and regulatory communications. This approach has also informed how changes to the European pharmacovigilance legislation are implemented in the UK and across Europe.

Another key burden reduction initiative was the implementation of new innovative software to analyse risk data and target inspection activity. As a result, inspections will be better prioritised, helping to target its activity to the areas of greatest risk and will ultimately protect public health. This risk-based approach will help reduce the overall administrative and economic burden on

companies and organisations who are regulated by the MHRA and who demonstrate a high level of compliance.

7 Transparency

The government supports transparency in the publication of clinical trial results. The MHRA is engaged in negotiations on the proposed EU Clinical Trials Regulation. This has a strong focus on transparency in relation to publishing the results of all clinical trials at pan-European level.

The government is discussing with stakeholders about the publication of clinical trial data and is mindful of the need for a proper balance between data transparency and the legitimate concerns of industry.

7.1 Freedom of information

Through the Freedom of Information Act (FOIA), the MHRA continues to routinely make available on its website volumes of information and via disclosure under the Act. Successful or partly successful requests are regularly listed in summary form on the website, with the full disclosure available on demand.

449 FOIA requests were made to the MHRA during 2012/13 and 444 were answered, of which 331 were answered in full or in part. The majority of requests related to outcomes of the MHRA's inspection and enforcement activities relating to medicines and devices, the licensing status and other information for medicines, and post-market safety monitoring for medicines and devices. The majority of requests came from industry and the public, with good representation from journalism and the legal profession as well.

Requests for internal reviews decreased from 21 to 6. This reflects the increased emphasis on supplying detailed explanation at the initial request stage, even when the MHRA is unable to provide some or all of the requested information. There were no Information Commissioner investigations on MHRA decisions resulting in Decision Notices, or Information Tribunal decisions, during this year.

7.2 Parliamentary Questions

The MHRA is accountable to ministers and parliament. Part of this accountability is discharged in answering Parliamentary Questions (PQs) and replying to Ministerial correspondence such as Private Office (PO) cases. The MHRA exceeded its targets of meeting its PQ and PO deadlines 80% of the time, with 90% of PQs and 85% of PO cases being answered on time. The MHRA target for PQ and PO cases being returned for correction or amendment (called ‘rewrites’) is 10% or less of the total completed. This was exceeded with only one PO being returned during the year.

In addition to regular questions – for example, relating to the safety of existing medicines and devices, or to clinical trials – there were also questions concerning topical matters such as early access to medicines, the Traditional Herbal Remedies Product Directive and its implications for herbal remedies, electronic cigarettes, and implanted medical devices such as hip replacements and breast implants.

7.3 Enquiries via customer services

One of the ways industry or members of the public can ask for information we hold is by contacting our customer services team.

During the past year the team dealt with 25,000 telephone calls and 21,000 emails from the full range of MHRA stakeholders - including members of the public.

Both telephone enquiries and emails are dealt with immediately wherever possible. The team uses various resources, their own knowledge and the website to answer enquiries. Calls and emails are transferred elsewhere in the MHRA when appropriate.

The team work closely with the operating divisions and the press office to ensure lines to take and associated information on key topics are available and updated, ensuring the MHRA is responsive to the information our customers request.

The quality of service the customer services team provides is measured by a mystery shopping service. It also has an email feedback area to capture customer comments and resolve any outstanding issues.

7.4 Public and stakeholder engagement

One of the sub-strategies of the communications strategy is patient, public and stakeholder engagement.

This outlines our commitment to engage with a wide range of stakeholders including patients and the public. It was approved by the Corporate Executive Team in October 2012.

Openness and transparency is critical to building trust and confidence in who we are and what we do. Agendas and papers from the Patient, Public Engagement Expert Advisory Group are now available without restrictions on our website as part of our commitment to openness and transparency.

Examples of work undertaken include brokering meetings between patients who experienced adverse reactions to medical products and MHRA staff. The aim is to listen to the concerns of the patient, provide detailed responses to questions and concerns with empathy and increase knowledge and understanding of the regulatory process.

Meetings with a selection of patient groups take place twice a year and consider and discuss areas of interest during the medicines licensing process. An extensive programme of stakeholder engagement, including with patient groups, was undertaken to inform the development of the MHRA’s five year Corporate Plan.

The MHRA recently launched a stakeholder newsletter which serves as a 'window' to our website offering stakeholders an 'at-a-glance' insight into current activities and information.

7.5 Contractual arrangements

Accenture provide an outsourced IT contract to the MHRA covering information technology infrastructure support, applications development and maintenance services essential to the MHRA's business. In March 2013, the MHRA signed a contract with Accenture to cover the continuing development and maintenance of its bespoke applications. The contract is for a minimum period of three years, with optional rolling one year extensions to a maximum of seven years. The committed contract expenditure is approximately £7.5million. This contract was approved by the Cabinet Office.

The MHRA had a contract with FCm Travel Solutions until the end of June 2012 for travel, and with Expotel for hotel bookings. The contract for travel and hotel bookings from July 2012 is with Hogg Robinson. The contract for management and leadership courses is with the Oxford Group and scientific analysis work is with LGC Limited.

8 Corporate social responsibility

8.1 Social, community and environmental issues

Our landlords at Buckingham Palace Road (BPR) office, Business Innovation & Skills (BIS), provide services and encourage behaviour that meets sustainability requirements. This includes recycling, energy efficiency and other facilities. The MHRA performance is not monitored separately.

The MHRA considers environmental and sustainability issues when procuring goods and services. In particular, our policy and practice of using virtual servers is energy efficient. Staff are encouraged to travel on MHRA business in the most sustainable and cost-effective way. 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.

The MHRA's initiative to send invoices/credit notes electronically to its customers gathered pace during the year with a total of 1,126 customers now signed up. Of 56,617 invoices/credit notes sent out, 33,809 (59%) were sent electronically.

8.2 Sustainability

The MHRA has developed a Sustainable Development (SD) Action Plan for 2011/13 which includes an SD Terms of Reference. In order to deliver this plan the MHRA has created a Sustainable Development Working Group (SDWG). The MHRA's aim to reduce its carbon footprint is set out in the action plan and it also focuses on areas such as energy management, sustainable procurement, recycling and water usage.

The SDWG has worked hard to deliver and embed good sustainability practices into the ways of working at the MHRA. This group meets every two months and includes the tenants of BPR. This group recently helped to promote 'Earth Hour' which took place in March 2013.

The SDWG is made up of a number of working groups to focus on specific topics:

- sustainability targets, monitoring and reporting
- staff engagement and publicity;
- energy use (electronic equipment)
- waste management and recycling.

This group also works with Business Innovation & Skills (BIS) 151 Estates Management who play an important role in the government's vision to significantly reduce the impact we have on our environment, cutting our waste, bringing down water usage and making our procurement more sustainable. The MHRA also reports on energy consumption annually via the Property Benchmarking Service (e-PIMS). The MHRA expects to see significant reductions on energy and water consumption, including less paper usage as the MHRA works towards the central government target.

Some obligations of the new MHRA organisation will change from 1st April 2013 as a result of the MHRA/NIBSC merger. This merger will mean that the obligation for reporting energy and water consumption and waste volumes will significantly lessen because of the multi-status nature of the

MHRA. To help the MHRA adopt these requirements, several recommendations have been tabled to the Corporate Executive Team which centred on the 'Carbon Reduction Commitment Energy Efficiency Scheme (CRCs)', 'Greening Government Commitment Reporting (GGCs)', 'Annual Reporting', 'Display Energy Certificates' (DECs), electronic Property Mapping Systems (e-PIMS)' and 'Total Carbon Footprint'.

For the future CRC commitments, the MHRA will be exempt from these reporting requirements because it does not own its own building and is therefore classed as a tenant in 151 BPR. NIBSC will be exempt from CRC in 2013/14 because it has left a qualifying organisation (HPA) and joined a non-qualifying organisation. However NIBSC will re-register on the CRC scheme in 2013/14 and so begin its CRC tax liabilities again from April 2014.

For the future GGC commitments the MHRA will be exempt from these reporting requirements because it is a Trading Fund. NIBSC is currently required to report to the Department of Health, but because it has now merged with the MHRA this data will not be required to be submitted. However it has been decided in a paper to the CET that as a joint organisation it will still continue to record and collect all SD data. This collected data will continue to feed into the MHRA annual reports as required for Her Majesty's Treasury (HMT). The MHRA DECs will still continue to be displayed annually and a new Total Carbon Footprint will be produced for the new MHRA organisation.

8.3 Risks and uncertainties at 31 March 2013

These are the main risks the MHRA faces that, should they occur, would have the greatest material effect on the functioning of the MHRA as a whole.

By considering such risks the MHRA can assess the continuing viability of its strategy and business plan against changes in circumstance, and to make adjustments when necessary. This does not mean it expects the risks to materialise – instead it indicates that these are areas of risk which it needs to be aware of and to consider how to respond in order to perform its role effectively.

Further information on the MHRA approach to managing its strategic risks can be found in the Annual Governance statement on page 47.

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. • Consideration of time recording to manage resources for remunerated and unremunerated activities.
Fragility and inadequacy of spreadsheets used to track large volumes of centralised work: Excel not robust enough and has limited functionality.	• Data backed up frequently. • Business case for IT solution to be considered.

8.4 Data protection

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

All employees are required to undergo annual training on how to protect information

8.5 Health and safety

The MHRA has recently achieved an BSI 18001 accreditation on Occupational Health and Safety.

Health and safety topics are now much simpler to locate on the MHRA's intranet. The MHRA has also been undertaking the Chartered Institute of Environmental Health (CIEH) health and safety training for its managers which has been approved by the CET.

9 The future

9.1 Future developments

The merger with NIBSC and the launch of CPRD will strengthen the MHRA's capacity and capability. The strategic direction set out in the MHRA's Corporate Plan 2013-18 will ensure that the whole organisation achieves the full benefit from its enlargement, securing its future capability with the new generation of biological products and in building its capacity to use clinical data and information.

The Corporate Plan also sets out the external challenges and opportunities facing the MHRA over the next five years. In particular, the future operating environment will be much more challenging, notably in relation to the economic climate and the MHRA's share of European work. Further increases over the next five years in the amount of regulatory activity conducted within the EU network rather than at purely member state level should improve the overall efficiency of the regulatory system, but at some risk to the financial income of individual agencies.

A number of factors will create challenges for the MHRA as a Trading Fund:

- being a 'three centre' organisation with quite distinct but complementary functions and types of income. These centres will operate within their respective financial constraints and collectively deliver our statutory duty to earn a 3.5% return on our assets
- the competitive position of our regulatory functions in relation to other national agencies. This will continue to affect volumes of remunerated activity, but with an increasing proportion of medicines-related regulatory income being derived from activity on behalf of the EU network. These EU fees are not cost-based, are not within the MHRA's control and are designed to satisfy the UK's needs within the wider EU community
- the expectation of greater efficiency in the delivery of medicines and medical devices regulation, as it becomes an increasingly collective and networked activity between national agencies
- the cost recovery basis of our regulatory functions, with fees seeking to just cover the associated costs incurred. Any fee reduction from lower volumes of work, lower fee levels or changes in the functions delivered would require immediate and proportionate reductions in costs and reprioritisation of effort
- the challenge of regulating two industries – medicines and medical devices – with highly globalised supply chains.

9.2 Performance measures 2013/14

In order to deliver its core responsibilities in the most effective and efficient way, the MHRA will work to the following targets:

Activities	Targets
Medicines licensing – validation of applications	• 100% of Type IA variations validated within 30 days of receipt. • 98% of Type IB/II variations validated within 14 days of receipt. • For new Marketing Authorisation applications, 100% of validation reports produced within 14 days. • 98% of Change of Ownership applications granted within 42 days of receipt
Medicines licensing – assessment of applications	• The assessment of applications for new Marketing Authorisations for UK only: 97% assessed in 150 days. • The assessment of applications for new Marketing Authorisations in European (Mutual Recognition (MR), Dentralised (DC) and centralised) procedures: 97% assessed within the designated time. • The assessment of Type IB minor and Type II major variation applications in National and European (MR, centralised) procedures: 97% assessed within the designated time.
Assessment of clinical trials and investigations	• 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).
	• Timescales for clinical investigation notifications for medical devices: maximum of 60 days with an overall average of 54 days or less.
Capturing and analysing adverse event reports – making reports available, issuing alerts and acting on signals	• Maximum timescales between receipt of reports and making them available for evaluation and analysis: For fatal and serious device adverse incidents: 95% within two working days and 100% within three working days. • Medical Device Alerts will be issued: 95% within 10 days, 100% within 15 days
	• For fatal UK adverse drug reactions: 90% within 24 hours, 100% within 72 hours • For serious UK adverse drug reactions: 95% within 72 hours, 100% within five days. • Ensure all UK potential signals (relating to medicines) from whatever source are acted on promptly: 85% initially evaluated within five working days.
Publication of UK assessment reports for new Marketing Authorisations	• 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 and 98% within 40 days of grant of the major variation.
Standards and control	• Biologics standards supply - 93% of all materials supplied within six working days. • Batch release activity - completion of all requested Official Control Authority Batch Release (OCABR) and non-EU testing within agreed timelines; time taken to issue Batch Release Certificate after last item received from the manufacturer should be no more than 10 days for blood products and 60 days for vaccines.
NIBSC research activity	• >80 papers and scientific review articles authored in the calendar year 2013. • Over £2.5 million in externally awarded research grant/contract funding utilised in the financial year 2013/2014.
Answering Freedom of Information requests, letters and Parliamentary Questions	• In working towards achieving 100% compliance, ensure that at least 92% of requests under the Freedom of Information Act are replied to within 20 working days. • Return responses to Parliamentary Questions (PQs) to the Department of Health by noon on the date specified with less than 5% returned to MHRA by the Department for rewriting. • Return ministerial correspondence (POs) drafts to the Department of Health within four working days of receipt in at least 80% of cases with less than 5% returned to MHRA by the Department for rewriting.
Finance – income and expenditure position	• Achieve an income and expenditure surplus during 2013/14 and, as a minimum, exceed a 3.5% per annum return on capital employed, without cross-subsidising between MHRA, NIBSC and CPRD.

10 Agency Board

10.1 The Board

The MHRA Agency Board (AB) is primarily responsible for advising on the strategic development of the MHRA and ensuring that targets set out in its Business Plan, and endorsed by ministers, are met.

The MHRA AB is responsible for monitoring the implementation of ministers' objectives for the strategic direction of the MHRA, taking into account the perspectives of its stakeholders, and advising ministers and the MHRA accordingly.

In particular this includes:

- the MHRA's corporate governance and financial management
- the MHRA's business strategy and corporate objectives
- the Agency's five year corporate plan and annual business plan
- the MHRA's key financial and performance targets
- the content of the MHRA's annual report
- the MHRA 's internal and external communications management and quality.

The AB monitors the effective, efficient and economic delivery of the MHRA's objectives. It ensures that it fulfils its core objectives and complies with all statutory and administrative requirements for the use of MHRA funds and the maintenance of the highest standards of corporate governance and public accountability.

The AB, as a whole, does not exercise any line management or executive functions, nor does it have a legal or constitutional role or any liability in respect of decisions of the Corporate Executive Team (CET). It does not determine the details of regulatory policy, nor does it have any involvement in any regulatory decisions affecting medicines or medical devices. These are the responsibility of the Chief Executive, working through CET directors and their staff, and of the expert advisory committees.

The AB use their experience and expertise and meet these responsibilities by:

- meeting on a regular basis
- attending sub-committees e.g. Risk and Audit Committee
- considering strategy papers from the CET and other MHRA staff as necessary
- attending occasional MHRA events including All Staff meetings, MHRA Annual Lectures and informal briefing meetings with executive staff where necessary.

Board member biographies

The AB currently consists of nine members who are initially appointed by the Secretary of State for Health for a three year term of office. There is the possibility of re-appointment for a further

three year term. The MHRA's Board members come from a variety of medical, scientific, legal, administrative and political backgrounds.

Professor Sir Gordon Duff

Sir Gordon Duff took up the post as Chairman of the MHRA on 1 January 2013.

Sir Gordon was Chair of the Commission of Human Medicines (CHM) until December 2012. He was also Chair of the National Emergency Quality Panel and Chair of the Scientific Pandemic Influenza Committee.

Since 1991, Sir Gordon has been Lord Florey Professor of Molecular Medicine at the University of Sheffield. From 2000–2009, Sir Gordon was Chairman of the National Biological Standards Board and has been co-chair of the Scientific Advisory Group for Emergencies since 2009.

He was knighted in 2007 for services to public health.

Shelley Dolan

Shelley Dolan was appointed Chief Nurse at the Royal Marsden NHS Foundation Trust in June 2007, having previously been Nurse Consultant Cancer: Critical Care.

Shelley has a wealth of clinical experience involving the use of a wide range of medical devices, medicines and clinical research trials.

She is the Director of Infection Prevention and Control at the Royal Marsden and is involved in a research programme concentrating on the early identification of sepsis in the person with cancer.

Shelley is also the chair of the Royal Marsden Local Research Ethics Committee. In 2007 Shelley was appointed to the Clinical Advisory Group for Healthcare for London.

Professor Barrington Furr, OBE

Professor Barrington Furr OBE has worked in ICI's legacy companies Zeneca and AstraZeneca for over 33 years, from which he retired in 2005. In 1997, Professor Furr was appointed Senior Vice-President of Therapeutic Research for Zeneca, a department of over 600 staff in both the UK and US, responsible for drug development in cardiovascular and metabolic diseases, infection cancer and musculoskeletal disease (UK), and neuroscience and respiratory diseases (US).

Following Zeneca's merger with Astra in 1999, he was appointed Chief Scientist and Head of Project Evaluation for AstraZeneca Pharmaceuticals and a year later was made head of AstraZeneca's research centre in Bangalore, which is committed to developing world medicine.

He is now retired, but consulting within the pharmaceutical industry and is a non-executive director of Genus, the world's leading livestock genetics company. He is a William Pitt fellow at Pembroke College, Cambridge. During his career, Professor Furr has been honoured for his commitment to drug discovery and in 1996, he was awarded the Jubilee Medal of the Society for Endocrinology. He was also made an OBE in the Millennium Honours for services to cancer drug discovery.

Martin Hindle

Martin has held a series of senior roles, as Chairman, CEO and executive board director in the international pharmaceutical and telecoms sectors. He has been a member of boards in the UK, USA, Japan, France and the Nordic region.

He is currently the Chairman of University Hospitals of Leicester NHS Trust, Chairman of East Midlands Academic Health Sciences Network, a non-executive director of Public Health England (PHE) and a non-executive director of the Medicines and Healthcare products Regulatory Agency.

Martin is a member of the Council of University of Leicester and a member of the Advisory Board for the University of Bradford Business School.

He has previously served as a Non-Executive Director of the Health Protection Agency, National Blood Authority, and the National Biological Standards Board.

Martin holds an honours degree in Pharmacy and an MSc in Industrial Administration. He is also a Member of the Royal Pharmaceutical Society.

Sir Alan Langlands

Sir Alan Langlands is the current Chief Executive of the Higher Education Funding Council for England, the Chair of the Health Foundation, and UK higher education lead for the Office of Strategic Coordination of Health Research. He was formerly Principal and Vice Chancellor of the University of Dundee from 2000 to 2009, as well as Chair of the UK Biobank Ltd from 2004 to 2012, and Chief Executive of NHS England from 1994 to 2000.

Professor Vincent Lawton, CBE

Professor Vincent Lawton CBE was Managing Director and Vice President Europe of Merck Sharp & Dohme UK (MSD) Ltd with whom he worked for 26 years in senior positions across Europe and North America. Professor Lawton joined MSD in 1980 as Human Resources Director in Europe. In the United States he worked in the R&D and commercial areas. He worked in the Marketing Department in MSD Canada, launching a new treatment for urinary tract infection (UTI), achieving market leadership.

In 1987, he was the Pharmaceutical Division Director for MSD in Spain, where he successfully launched a number of major new products and helped to drive the company's considerable success in the Spanish market. Professor Lawton's last position was Managing Director of MSD UK and Vice President in Europe, where he made many personal achievements, including significant business growth between 1991 and 2006.

He served on the Board of Management of the ABPI for 15 years. He was a founder member of Pharmaceutical Industry Competitiveness Task Force (PICTF), co-chairing the Clinical Research in the NHS Task force with Sir John Pattison and latterly with Professor Sally Davies. He was also a founder member of Ministerial Industry Strategy Group (MISG). During 2004 and 2006 he was President of the Association of the British Pharmaceutical Industry (ABPI) and was appointed CBE in the 2006 New Years Honours list for services to the pharmaceutical industry.

Professor Angus Mackay, OBE

Professor Angus Mackay, OBE, was Mental Health Service Director / Consultant Psychiatrist at the Argyll and Bute Hospital. He is qualified in medicine and pharmacology and is a member of various Scottish, UK and European bodies concerned with medicines regulation. Until recently, he was also Chairman of the Health Technology Board for Scotland (HTBS), a body established by the Scottish Parliament to advise the NHS in Scotland on the clinical and cost effectiveness of new and existing health technologies, including medicines and medical devices and was a member of the Committee on Safety of Medicines for 17 years.

Deborah Oakley

Deborah's career has been in the Financial Services Industry. She worked for twenty years at Newton Investment Management as a senior fund manager and company director specialising in smaller pension schemes, charities and private clients. She now works at Veritas Investment Management, looking after private client portfolios. She combines this with her public service positions.

In addition to the MHRA she is a non-executive director of the Royal Free London NHS Foundation Trust where she chairs the audit committee. Deborah was a board member of the Health Protection Agency from 2009 until it's abolition in 2013. She chaired the Biological Medicines Technical Committee. Deborah also served on the board of NHS Camden from 2007 to 2011 where she chaired the audit committee.

John Williams, CBE

John Williams, CBE, was recently re-appointed a member to the Agency Board. A consultant surgeon specialising in oral and maxillofacial surgery, he was president of both the British and European associations as well as the International Association of Oral and Maxillofacial Surgery.

He has also previously been appointed as the chairman of the Committee on the Safety of Devices.

10.2 Directors statement with respect to conflict of interest

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

11 Corporate Executive Team

The Corporate Executive Team (CET) is the highest executive decision-making body of the MHRA. The CET is chaired by MHRA Chief Executive Professor Sir Kent Woods and comprises the directors of each of the MHRA's divisions, the directors of the National Institute for Biological Standards and Control (NIBSC) and Clinical Practice Research Datalink (CPRD), and a representative from the Department of Health (DH) Legal Services.

The CET devolves certain areas of its business to sub-committees, each chaired by a designated director.

11.1 The team

Professor Sir Kent Woods

Professor Sir Kent Woods qualified in medicine from Cambridge in 1972, followed by higher clinical training in Birmingham and epidemiological training at Harvard School of Public Health. In 1984 he was appointed Senior Lecturer in Clinical Pharmacology at Leicester University, where he now holds a personal chair in therapeutics. His clinical and research interests have been in coronary heart disease. He was Regional Director of R&D, NHS Executive Trent, from 1995-1999 before becoming Director of the NHS Health Technology Assessment programme. Sir Kent took up the post of Chief Executive at the MHRA in January 2004.

Rachel Bosworth

Rachel Bosworth took up the post of Director of Communications on 20 June 2011.

Rachel joined the MHRA from the East of England Development Agency (EEDA) where she was the Executive Director of Communications and Deputy Chief Executive. Rachel has extensive experience in communications, marketing and external relations in the public and private sectors, including setting up and leading Peterborough City Council's corporate communications and marketing department, and managing public affairs and media relations in the rail industry.

Rachel is a qualified journalist, a member of the Chartered Institute of Public Relations and holds an MBA with Distinction from Loughborough University.

Peter Commins

Peter Commins took up the post of Chief Operating Officer on 29 August 2006. Peter joined the MHRA from the Royal Free teaching hospital where he was Finance Director for four years. Prior to this he held positions as Finance Director of two health authorities and an executive agency. He has also been a Non-Executive Director and Audit Committee Chairman of Harrow Primary Care Trust.

Alison Davis

Alison took up the post of Director of the Information Management Division of the MHRA in January 2006. She graduated in chemistry and initially worked as a pharmaceutical research chemist before moving into the IT field in 1986. Since then, Alison has held a variety of IT posts with Glaxo, DuPont and DuPont Pharmaceuticals. Immediately before joining the MHRA, she was based in Paris, as Director of IM for the Europe, Middle East and Africa region of Bristol-Myers Squibb's Worldwide Medicines Division.

In addition to delivering IT solutions for the MHRA, Alison has been active in working collaboratively with colleagues from other EU National Competent Authorities, in particular as part of the Heads of Medicines Agencies' Telematics Support Group.

Gerald Heddell

Gerald Heddell took up the post as Director of the Inspection, Enforcement and Standards (I&S) Division on 4 January 2005.

Gerald is a microbiologist who is a Chartered Biologist and a member of the Society of Biology and the Royal Society of Chemistry. Since leaving the NHS in 1978, he has worked in a succession of progressively senior roles in manufacturing and quality assurance for The Wellcome Foundation, Glaxo Wellcome and GlaxoSmithKline. Gerald has experience in most aspects of pharmaceutical manufacture and control.

Dr Ian Hudson

Dr Ian Hudson is a physician who has practiced as a paediatrician for a number of years. He was formerly a research fellow at the University of Glasgow. He joined SmithKline Beecham in 1989 where he held various appointments in clinical research and development.

He joined the MCA (Medicines Control Agency) in January 2001 as Director of the Licensing Division. He is the CHMP (Committee for Human Medicinal Products) delegate for the UK.

Geoff Le Fevre

Geoff Le Fevre joined the MCA (Medicines Control Agency) in March 2002 as Head of Human Resources and was appointed to the role of Director of Human Resources in April 2004. A qualified human resources practitioner, he is a Chartered Fellow of the Chartered Institute of Personnel and Development.

Geoff has wide ranging human resource and personnel management experience gained in the public and private sectors and his previous employers include Police Information Technology Organisation, Gold Group International Limited, English Heritage and Sealink.

Jonathan Mogford

Jonathan Mogford joined the MHRA from the Department of Environment, Food and Rural Affairs (DEFRA) where he was heading up their work on climate change mitigation and land use.

Jonathan has also held a wide variety of policy posts since joining the Department of Health (DH) in 1990, including secondments to the Foreign Office and the European Commission in Brussels.

While at the DH he also worked as Private Secretary to the Secretary of State for Health and headed policy teams responsible for pharmaceutical industry policy and private sector provision of healthcare services for NHS patients.

Jonathan's most recent post in the Department of Health was as Head of European Affairs, where he was responsible for managing the DH's EU business, as well as policy and finance for healthcare accessed by UK citizens elsewhere in the EU.

Dr John Parkinson

Dr John Parkinson took up the post of Director, Clinical Practice Research Datalink (CPRD), in 2012, having run the General Practice Research Database (GPRD) for the MHRA since 2005. He was also seconded to the Research Capability Programme which came together with GPRD to form the new enlarged observational and interventional data research system.

He gained his PhD in Biochemistry from the University of Liverpool and has worked for, and as a consultant to, the pharmaceutical and wider healthcare industries. Before joining the MHRA he worked as Client Services Director at the University of Dundee on the Tayside Record Linkage system.

Dr June Raine, CBE

Dr June Raine, Director of Vigilance and Risk Management of Medicines Division, trained in general medicine in Oxford after completing a Masters degree in pharmacology. Her interest in drug safety led to a career in medicines regulation.

June has worked on a wide range of topics from paracetamol toxicity to paediatric medicines, patient information to proactive pharmacovigilance. She chairs the European Pharmacovigilance Risk Assessment Committee (PRAC), and in the last five years has been closely involved in developing the European Risk Management strategy with other agencies

John Wilkinson, OBE

John Wilkinson took up the post of Director of Devices on 6 February 2012. He joined the MHRA from Eucomed, the European medical technology industry association, where he was Chief Executive.

His earlier experience included the role of Director General of the Association of British Healthcare Industries and a number of roles in the medical devices industry, both in the UK and the USA, with Becton Dickinson and the BOC Group.

John holds a first degree in Zoology from the University of Aberdeen and an MBA from the University of Warwick.

11.2 Directors statement with respect to conflict of interest

All Corporate Executive Team members have confirmed that they have no significant outside interest that conflict with their MHRA responsibilities.

12 Remuneration report

12.1 Remuneration policy

The MHRA's policy is to maintain levels of remuneration such as to attract, motivate and retain executives of a high calibre who can effectively contribute to the successful development of the business.

12.2 Service contracts

The Constitutional Reform and Governance Act 2010 requires Civil Service appointments to be made on merit on the basis of fair and open competition. The Recruitment Principles published by the Civil Service Commission specify the circumstances when appointments may be made otherwise.

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 non executive directors are appointed by the Secretary of State for Health and are on fixed term contracts.

12.3 Remuneration (including 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 MHRA. Corporate Executive Team members' salary and bonus awards were decided by a pay committee whose members are Professor Sir Kent Woods, Professor Vincent Lawton, CBE (Non-Executive Director) and Simon Claydon (DH HR Deputy Director). Professor Sir Kent Woods', Professor Sir Alasdair Breckenridge's and Professor Sir Gordon Duff's salary and bonus awards are set by a DH Pay Committee in accordance with the Department's senior salaries review processes. Remuneration for non executive directors is determined by DH in accordance with the Departmental review process.

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.

12.4 CET remuneration, bonus and benefits table

Corporate Executive Team–Remuneration	2012/13		2011/12	
	Salary £000	Bonus* £000	Salary £000	Bonus* £000
Professor Sir Kent Woods Chief Executive [1]	190 - 195	Nil	190 - 195	5 - 10
Mr Peter Commins Chief Operating Officer	125 - 130	5 - 10	125 - 130	5 - 10
Dr Ian Hudson Licensing Director	115 - 120	5 - 10	115 - 120	Nil
Dr June Raine, CBE Director of Vigilance & Risk Management of Medicines	120 - 125	Nil	120 - 125	Nil
Mr John Wilkinson, OBE Director of Devices[2]	110 - 115	Nil	15 - 20	N/A
Dr John Parkinson Director CPRD[3]	100 - 105	5 - 10	N/A	N/A
Mr Gerald Heddell Director of Inspection, Enforcement and Standards	105 - 110	Nil	105 - 110	Nil
Ms Rachel Bosworth Director of Communications[4]	95 - 100	Nil	70 - 75	N/A
Mrs Alison Davis Director of Information Management	95 - 100	Nil	95 - 100	5 - 10
Mr Geoff LeFevre Director of Human Resources	90 - 95	Nil	90 - 95	Nil
Dr Susanne Ludgate[5] Clinical Director - Devices	70 - 75	5 - 10	90 - 95	Nil
Mr Jonathan Mogford Director of Policy	85 - 90	Nil	85 - 90	Nil
Mrs Diane Leakey Acting Director of Communications[6]	N/A	N/A	15 - 20	N/A
Mr Simon Gregor Director of Communications[7]	N/A	N/A	5 - 10	Nil
Band of the highest paid director's total remuneration	190 - 195		200 - 205	
Median total	38,134		38,694	
Remuneration ratio	5.05		5.23	

*Bonus comprises of non-consolidated performance related pay awards.
Corporate Executive Team members receive no 'Benefits in kind'

[1] The Chief Executive is on secondment to the MHRA from the University of Leicester commencing 1 January 2004 and ending on 31 May 2013. During 2012/13 the MHRA paid a total of £247,064 (2011/12 £256,835) 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 John Wilkinson commenced his appointment as Director of Devices on 6th February 2012.
[3] Dr John Parkinson became a CET member on 1st April 2013 following the launch of CPRD.
[4] Ms Rachel Bosworth commenced her appointment as Director of Communications on 20th June 2011.
[5] Dr Susanne Ludgate resigned from the Agency with effect from 31st December 2012.
[6] Mrs Diane Leakey was acting Director of Communications to 30th June 2011.
[7] Mr Simon Gregor resigned from the Agency with effect from 19th April 2011.

12.5 Agency Board remuneration, bonus and benefits table

Agency Board – Remuneration	2012/13			2011/12		
	Salary £000	Bonus* £000	Benefit in kind †	Salary £000	Bonus* £000	Benefit in kind †
Professor Sir Alasdair Breckenridge, CBE Chairman[7]	65 - 70	Nil	-	90 - 95	5 - 10	-
Professor Sir Gordon Duff Chairman[8]	15 - 20	N/A	-	N/A	N/A	N/A
Professor Vincent Lawton, CBE Non Executive Director	10 - 15	N/A	-	10 - 15	N/A	-
Dr Shelley Dolan Non Executive Director	5 - 10	N/A	-	5 - 10	N/A	-
Professor Barrington Furr, OBE Non Executive Director	5 - 10	N/A	1,300	5 - 10	N/A	1,300
Professor Angus Mackay, OBE Non Executive Director	5 - 10	N/A	4,200	5 - 10	N/A	6,800
Mr John Williams, CBE Non Executive Director	5 - 10	N/A	100	5 - 10	N/A	600
Ms Lisa Arnold Non Executive Director[9]	0 - 5	N/A	-	5 - 10	N/A	-
Mr Michael Fox Non Executive Director	0 - 5	N/A	-	5 - 10	N/A	100
Mr Martin Hindle Non Executive Director[10]	0 - 5	N/A	-	N/A	N/A	N/A
Sir Alan Langlands Non Executive Director	0 - 5	N/A	-	N/A	N/A	N/A
Sir John Lilleyman Non Executive Director[11]	0 - 5	N/A	200	5 - 10	N/A	1,000
Ms Deborah Oakley Non Executive Director	0 - 5	N/A	-	N/A	N/A	N/A

*Bonus comprises of non-consolidated performance related pay awards.
†Benefits in kind are disclosed to the nearest £100.

[7] Professor Sir Alasdair Breckenridge left the Agency on 31st December 2012.
[8] Professor Sir Gordon Duff was appointed Chairman with effect from 1st January 2013.
[9] Ms Lisa Arnold and Mr Michael Fox left the Agency Board at the end of their terms on 31st August 2012.
[10] Mr Martin Hindle, Sir Alan Langlands and Ms Deborah Oakley were appointed to the Agency Board for three years commencing 1st September 2012.
[11] Sir John Lilleyman retired from the Agency Board with effect from 31st July 2012.

12.6 Disclosure of remuneration (including salary), bonus and benefits information

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 MHRA and thus recorded in these accounts.

Benefits: The MHRA's non-executive directors necessarily incur travelling and other expenses to attend Agency Board meetings. The "benefits in kind" relate solely to these expenses. The tax liability arising thereon is met by the MHRA.

Bonus: Bonus awards are based on performance levels attained and are made as part of the appraisal process. The awards reported in 2012/13 relate to performance in 2011/12 and the comparative awards reported in 2011/12 relate to performance in 2010/11.

12.7 Pay multiples

The banded remuneration of the highest paid director in the MHRA in the financial year 2012/13 was £190-£195k (2011/12, £200-205k). This was 5.05 times (2011/12, 5.23) the median remuneration of the workforce, which was £38,134 (2011/12, £38,694).

No employee received remuneration in excess of the highest paid director in 2012/13 (2011/12, 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.

12.8 Pension benefits table

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:

Pension Benefits £000	Accrued pension at pension age as at 31/3/13 and related lump sum	Real increase in pension and related lump sum at pension age	CETV at 31/3/13	CETV at 31/3/12*	Real increase in CETV
Mr Peter Commins Chief Operating Officer	75 - 80	2.5 - 5.0	1,285	1,151	67
Dr June Raine, CBE Director of Vigilance & Risk Management of Medicines	40 - 45 plus lump sum of 125 - 130	0.0 - 2.5 plus lump sum of 0.0 - 2.5	990	927	10
Dr Ian Hudson Licensing Director	40 - 45	2.5 - 5.0	693	606	48
Mr Gerald Heddell Director of Inspection, Enforcement and Standards	15 - 20	0.0 - 2.5	290	248	36
Mrs Alison Davis Director of Information Management	10 - 15	0.0 - 2.5	186	148	25
Dr Susanne Ludgate Clinical Director – Devices to 31.12.12	40 - 45 plus lump sum of 125 - 130	0.0 - 2.5 plus lump sum of 0.0 - 2.5	905	886	1
Mr Geoff LeFevre Director of Human Resources	20 - 25 plus lump sum of 70 - 75	0.0 - 2.5 plus lump sum of 0.0 - 2.5	512	497	10
Mr Jonathan Mogford Director of Policy	25 - 30 plus lump sum of 75 - 80	0.0 - 2.5 plus lump sum of 0.0 - 2.5	429	399	6
Ms Rachel Bosworth Director of Communications	15 - 20 plus lump sum of 45 - 50	0.0 - 2.5 plus lump sum of 2.5 - 5.0	279	244	19
Mr John Wilkinson, OBE Director of Devices	0 - 5	2.5 - 5.0	46	6	32
Dr John Parkinson Director CPRD	65 - 70	2.5 - 5.0	1,251	1,168	76

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

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

12.9 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 Pensions Increase legislation. Members joining from October 2002 may opt for either the appropriate defined benefit arrangement or a 'money purchase' stakeholder pension with an employer contribution (**partnership** pension account).

Employee contributions are salary-related and range between 1.5% and 3.9% of pensionable earnings for **classic** and 3.5% and 5.9% for **premium**, **classic plus** and **nuvos**. Increases to employee contributions will apply from 1 April 2013. 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 initial pension is payable on retirement. For **premium**, benefits accrue at the rate of 1/60th of final pensionable earnings for each year of service. Unlike **classic**, there is no automatic lump sum. **Classic plus** is essentially a hybrid with benefits for service before 1 October 2002 calculated broadly as per **classic** and benefits for service from October 2002 worked out as in **premium**. In **nuvos** a member builds up a pension based on his pensionable earnings during their period of scheme membership. At the end of the scheme year (31 March) the member's earned pension account is credited with 2.3% of their pensionable earnings in that scheme year and the accrued pension is uprated in line with Pensions Increase legislation. In all cases members may opt to give up (commute) pension for a lump sum up to the limits set by the Finance Act 2004.

The **partnership** pension account is a stakeholder pension arrangement. The employer makes a basic contribution of between 3% and 12.5% (depending on the age of the member) into a stakeholder pension product chosen by the employee from a panel of three providers. The employee does not have to contribute, but where they do make contributions, the employer will match these up to a limit of 3% of pensionable salary (in addition to the employer's basic contribution). Employers also contribute a further 0.8% of pensionable salary to cover the cost of centrally-provided risk benefit cover (death in service and ill health retirement).

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

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

12.10 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.

12.11 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
1 July 2013

13 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.

14 Annual Governance Statement

14.1 Introduction

This statement sets out the stewardship and control framework at the MHRA and the risks to MHRA performance. It explains how I have discharged my responsibility, as Accounting Officer, to manage and control the MHRA's resources in 2012/13.

14.2 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.

14.3 The purpose of the governance framework

The governance framework comprises the systems and processes, culture and values, by which the Agency is directed and controlled and the activities through which it accounts to and 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 and assurance 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.

14.4 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, assurance and risk management systems to ensure that the highest standards of integrity, accountability and operational capability are maintained.

14.5 The Agency Board

The Agency Board consists of me as the Chief Executive, 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. No evaluation of the effectiveness of the Board was undertaken during the year. However, it is intended to have this undertaken during 2013/14 in line with guidance issued by Cabinet Office.

Potential conflicts of interest are managed by all Board members declaring in a register of interests any company directorships and other significant interests held by them or their close family and friends which may conflict with their MHRA responsibilities. The register is available for inspection.

Members also declare their interest in any items being discussed at Board meetings. The Chair decides whether there is a conflict of interest and whether they should remain involved in the discussion.

14.6 The Risk and Audit Committee

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, assurance and 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 Risk and Audit Committee reviewed the strategic risks at each meeting, approved or noted (as appropriate) updated policies, took reports of audit findings from external and internal auditors and reviewed the MHRA's progress in implementing audit recommendations. The Committee is chaired by Professor Vincent Lawton, CBE.

The following persons routinely attend all Committee meetings:
- The Accounting Officer
- The Chief Operating Officer
- The Deputy Director of Finance
- The Head of Internal Audit
- A representative from the External Auditor
- A representative from the Department of Health.

14.7 The Corporate Executive Team

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 regular programme of business includes monthly reports of performance and operational risk from the next level of management, finance reports and reviews of the strategic risk register. The CET receives monthly finance reports containing clear consistent and comparable performance information to drive improvements. 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 39 to 45 of this report gives details of the remuneration paid to the members of the Agency Board and Corporate Executive Team.

The governance framework has been in place in the Medicines and Healthcare products Regulatory Agency for the year ended 31 March 2013 and up to the date of approval of the annual report and accounts.

Taking all the above factors into account I am satisfied that the governance framework complies with the **Corporate Governance in Central Government Departments: Code of good practice 2011** in so far as it is relevant to us.

14.8 Agency Board meeting attendance and Register of Interests

The attendance of the Agency Board Non-Executive Directors at the Agency Board meetings, the Agency Board Away day, and the Risk and Audit Committee,

Member	Agency Board	Agency Board awayday	Risk and Audit Committee
Professor Vincent Lawton, CBE	8 (9)	2 (2)	4 (4)
Dr Shelley Dolan	7 (9)	1 (2)	-
Professor Barrington Furr, OBE	9 (9)	1 (2)	3 (4)
Professor Angus Mackay, OBE	7 (9)	2 (2)	-
Mr John Williams, CBE	8 (9)	2 (2)	-
Ms Lisa Arnold	2 (3)	1 (1)	
Mr Michael Fox	3 (3)	- (1)	2 (2)
Mr Martin Hindle	6 (6)	1 (1)	-
Sir Alan Langlands	6 (6)	1 (1)	-
Sir John Lilleyman	1 (3)	- (1)	-
Ms Deborah Oakley	5 (6)	1 (1)	2 (2)

The maximum number of meeting held during the year that each member could attend is shown in brackets.

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

14.9 The risk, control and assurance 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, internal control and assurance 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 2013.

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.

At 31 March 2013, the Agency's corporate risk register identified three red risks. These were:

- Failure to manage an orderly succession for the Chief Executive
- A reduction in the Agency's pharmacovigilance income; and
- Effect on the Agency of HM Treasury's proposed 5 % cut in fees as part of the current Spending Review process.

The 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 Agency' corporate risk manager or through the Divisional representative at the quarterly meetings of the Risk and Audit Liaison Group (RALG).

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 2013. It is a forum where Divisional risk and audit issues are discussed and monitored by senior representatives from all Divisions of the MHRA. 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 assurance statement. The assurance statement has been redesigned in accordance with the DH assurance mapping proposals. It not only confirms that effective systems of internal control have been in place within their areas of responsibility, throughout the particular period under review but also provides for a high level overview of the core functions of the organisation. This includes assurances that that members and senior management team of the MHRA:

- are clear about the legislative requirements associated with each of the statutory functions for which your organisation is responsible, and specifically any restrictions on delegation of those functions;
- are ensuring that the necessary capability and capacity to undertake those functions is being put in place in the organisation; and
- will explicitly ensure the organisation has the statutory power to take on a statutory function on behalf of another person or body, before the organisation takes on any such function (if asked to do so)

All such accountability statements have been received for the year to 31 March 2013.

There were no significant security incidents, including data security, during the year ended 31 March 2013.

14.10 Review of effectiveness

The Agency has responsibility for conducting, at least annually, a review of the effectiveness of its governance and assurance 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 and assurance 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.

In addition to the above, we are required to comment on the following issues in this statement:

- We support the Government's 'Transparency Agenda', which seeks to make more government data available and accessible to the public. We already publish a great deal of information on our website and we specifically publish expenditure and staff data at http://www.mhra.gov.uk/Aboutus/TransparencyData/index.htm

- Following a central Government request for all public bodies to review the tax arrangements for how they pay their public sector appointees (including Board members), senior staff and other individuals paid on an individual basis, I confirm that all relevant payments are made through the payroll. The Agency has four exceptions to this rule and in all cases assurances have been obtained to confirm the tax and NI obligations are being met.

As Accounting Officer, I have responsibility for reviewing the effectiveness of the governance framework. My review of the effectiveness of the governance and assurance 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 and Assurance 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 2012/13.

14.11 Significant governance issues

The review, as detailed above, provides good assurance of the effectiveness of the Agency's system of internal control. There were no significant issues. The annual internal audit report highlighted that while there is a generally sound system of internal control in place, there were some medium risk findings in specific areas for management to address. One of these medium risks was subsequently upgraded to high risk. These were highlighted in three reports classed as medium risk and included: weaknesses around Performance indicators and Measures where

some targets were not appropriately defined. This has since been addressed in the Target Setting audit review that followed; the Core Business Process audit review revealed a need for improvement in effectiveness of operations, and the payroll audit review also revealed a need for improvement in effectiveness of operations and control design. The Annual Follow Up audit review of the Core Business Processes resulted in one risk rating previously classed as a medium being increased to a high risk. Issues identified were immediately addressed and control measures have been further strengthened. These recommendations and their implementation have all been monitored. .

Three further reviews performed during the year were low risk rated. These were Information Governance, Business Expansion and Regulation of Herbal Medicines. One particular area of good practice identified by the internal auditors during the Information Governance review where clear evidence emerged to demonstrate that senior management at MHRA have achieved a remarkable behavioural shift in the attitudes of staff towards their own personal responsibility regarding data integrity and accuracy.

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 is in place.

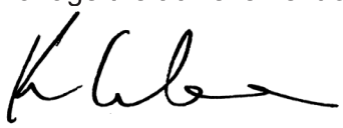
The Agency has again had to deal with strategic issues relating to effective medicines, medical devices and a changing organisation. There are covered in more detail in the Chairman and Chief Executive's review. Other risks and uncertainties including information governance and income risk are detailed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

There have been no governance issues identified during the year that are considered significant in relation to the Agency's overall governance and assurance 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.

14.12 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 MHRA's objectives.



Professor Sir Kent Woods
Chief Executive and Accounting Officer
Medicines and Healthcare products Regulatory Agency
1 July 2013

15 Audit certificate

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 2013 under the Government Trading Funds Act 1973. The financial statements comprise: the Statement of Comprehensive Income, Statement of Financial Position, Statement of Cash Flows, Statement of Changes in Taxpayer's 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 2013 and of its surplus 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 Finance section of the Annual Report 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

Date 4 July 2013

16 Accounts

STATEMENT OF COMPREHENSIVE INCOME for the year ended 31 March 2013

	NOTE	**2012/13**		2011/12	
		£000	**£000**	£000	£000
Revenue					
Revenue from trading activities		**99,584**		107,030	
Revenue from Department of Health		**9,231**		10,217	
Total Revenue	3		**108,815**		117,247
Expenditure					
Staff costs	6	**(54,680)**		(55,061)	
Operating costs	7	**(41,928)**		(41,947)	
Total Expenditure			**(96,608)**		(97,008)
Operating surplus			**12,207**		20,239
Finance income	8		**340**		271
Finance costs	8		**(46)**		(201)
Surplus for the financial year			**12,501**		20,309
Dividend payable			**(3,494)**		(3,094)
Retained surplus for the year			**9,007**		17,215
Other comprehensive income/(loss)					
Other gains/(losses)	9		**7**		(86)
Total comprehensive income for the year			**9,014**		17,129

The notes on pages 60 to 83 form part of these accounts.

STATEMENT OF FINANCIAL POSITION as at 31 March 2013

	NOTE	31 March 2013		31 March 2012	
		£000	£000	£000	£000
Non-current assets					
Plant and equipment	10	**12,269**		15,235	
Intangible assets	11	**9,329**		8,505	
Total non-current assets			**21,598**		23,740
Current assets					
Trade and other receivables	12	**12,320**		21,691	
Cash and cash equivalents	13	**134,674**		114,879	
Total current assets			**146,994**		136,570
Total assets			**168,592**		160,310
Current liabilities					
Trade and other payables	14	**(31,332)**		(31,545)	
Provisions	16	**(137)**		(1,242)	
Other liabilities	17	**(24,472)**		(23,564)	
Total current liabilities			**(55,941)**		(56,351)
Total assets less current liabilities			**112,651**		103,959
Non-current liabilities					
Borrowings	15	**(1,328)**		(1,328)	
Provisions	16	**(2,265)**		(2,061)	
Other liabilities	17	**(4,633)**		(5,159)	
Total non-current liabilities			**(8,226)**		(8,548)
Assets less liabilities			**104,425**		95,411
Taxpayers' equity:					
Public dividend capital			**1,329**		1,329
Reserves					
Revaluation reserve			**155**		155
Income and expenditure reserve			**954**		954
Retained earnings			**101,987**		92,973
Total equity			**104,425**		95,411

Professor Sir Kent Woods
Chief Executive and Accounting Officer
Medicines and Healthcare products Regulatory Agency
1 July 2013

The notes on pages 60 to 83 form part of these accounts.

STATEMENT OF CASH FLOWS for the year ended 31 March 2013

	NOTE	2012/13 £000	2012/13 £000	2011/12 £000	2011/12 £000
Cash flows from operating activities					
Operating surplus		**12,207**		20,239	
Interest paid	8	**(46)**		(201)	
Gain/(Loss) on foreign exchange	9	**7**		(86)	
Depreciation and amortisation		**7,266**		7,326	
Disposals of assets		**39**		479	
Impairment and reversals		**76**		2,429	
(Decrease) in deferred revenue		**(526)**		(2,166)	
Decrease/(Increase) in trade and other receivables	12	**9,371**		(3,074)	
Increase in trade and other payables		**695**		5,404	
(Decrease)/Increase in provisions	16	**(901)**		3,240	
Dividend paid	17	**(3,494)**		(3,094)	
Net cash inflow from operating activities			**24,694**		30,496
Cash flows from investing activities					
Interest received	8	**340**		271	
Purchase of plant and equipment	10	**(440)**		(1,277)	
Purchase of intangible assets	11	**(4,799)**		(2,128)	
Net cash outflow from investing activities			**(4,899)**		(3,134)
Cash flows from financing activities			**-**		-
Net increase in cash and cash equivalents in the financial year	13		**19,795**		27,362
Cash and cash equivalents at the beginning of the financial year	13		**114,879**		87,517
Cash and cash equivalents at the end of the financial year	13		**134,674**		114,879

The notes on pages 60 to 83 form part of these accounts.

STATEMENT OF CHANGES IN TAXPAYERS' EQUITY
for the year ended 31 March 2013

	Public dividend capital (PDC)	Retained earnings	Revaluation reserve	Income & expenditure reserve	Total
	£000	£000	£000	£000	£000
Balance at 31 March 2011	1,329	75,844	155	954	78,282
Changes in taxpayers' equity for 2011-12					
Total comprehensive income for the year	-	17,129	-	-	17,129
Balance at 31 March 2012	1,329	92,973	155	954	95,411
Changes in taxpayers' equity for 2012-13					
Total comprehensive income for the year	**-**	**9,014**	**-**	**-**	**9,014**
Balance at 31 March 2013	**1,329**	**101,987**	**155**	**954**	**104,425**

The notes on pages 60 to 83 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 2012/13 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 Accounting standards that have been issued but have not yet been adopted.

The Treasury FReM does not require the following Standards and Interpretations to be applied in 2012/13. The application of the Standards as revised would not have a material impact on the accounts for 2012/13, were they applied in that year:

- *IFRS 9 Financial Instruments* - Effective date 1 January 2015 (not yet EU adopted)
- *IFRS 10 Consolidated Financial Statements* - Effective date 1 January 2013 (EU adoption from 1 January 2014)
- *IFRS 11 Joint Arrangements* - Effective date 1 January 2013 (EU adoption from 1 January 2014).
- *IFRS 12 Disclosure of Interests in Other Entities* - Effective date 1 January 2013 (EU adoption from 1 January 2014).
- *IFRS 13 Fair Value Measurement* - Effective date 1 January 2013 (not yet EU adopted)
- *IAS 1 Presentation of financial statements (Other comprehensive income) - a*mendment to improve disclosures to users of the accounts. This is effective for 2013/14.
- *IAS 19 Post employment benefits (Pensions)* - amendment to improve the recognition and disclosure requirements for defined benefit plans and modify the accounting for termination benefits. The new requirements are effective for 2013/14.
- *IAS 16 Property, plant and equipment* - amendment providing clarification on classification, effective 2013/14.
- *IAS 28 Associates and joint ventures* - Effective date 1 January 2013 (EU adoption from 1 January 2014)

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	£826
Product Licensing	96 months	£272
Pharmacovigilance	94 months	£665

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 in commercial bank accounts.

1.5 Losses and Special Payments

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

1.6 Revenue

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

- Applications and variations: A number of processes have been assigned to determine the stage of work completed. This determines the revenue to recognise and to defer.
- Service fees: These are invoiced annually early in the financial year.
- Inspections: Income is recognised on completion of all the inspection processes.
- EMA (European Medicines Agency): Income from EMA work is recognised on completion of predetermined stages, where there is a contract in place or payment is received.
- Clinical trials: Revenue is recognised as and when earned.
- Miscellaneous income: This is non statutory income recognised as and when earned.
- Government grants are grants from the Department of Health for the provision of services. Revenue grants are treated as income. Capital grants, conditional on developing assets, 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. An amount equal to the depreciation charge on the asset is released from deferred income to offset the expenditure.

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 as well as the Department of Health’s terms and conditions and other procedures governing implementation of the SCS pay, 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 2012/13, 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 minus 1.0 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 2.35 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.

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 Clinical Practice Research Datalink (CPRD)

The Clinical Practice Research Datalink (CPRD) is the new English NHS observational data and interventional research service, jointly funded by the Department of Health and the Medicines and Healthcare products Regulatory Agency (MHRA).

In 2012/13, the Department of Health paid £7.0m towards this project. This contribution to the joint venture has subsequently partly been offset by the DH share of expenditure to date of £274k.

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 Corporation tax

As a trading fund, MHRA is not liable for Corporation 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 £3.494M (2011/12 £3.094M).

The Agency planned 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

	2012/13 £000	2011/12 £000
Income from fee charging activities*	**106,731**	**114,114**
Other income	**2,084**	**3,133**
Total revenue	**108,815**	**117,247**

*Includes £7.3m (2011/12, £7.8m) 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.

		2012/13	
Charging activity	**£000 Income**	**£000 Expenditure**	**£000 Surplus/ (Deficit)**
Licensing	**42,926**	**(38,600)**	**4,326**
Inspections	**9,585**	**(8,281)**	**1,304**
Vigilance, Risk Management and Enforcement	**30,712**	**(29,125)**	**1,587**
CPRD	**7,760**	**(5,357)**	**2,403**
British Pharmacopoeia	**2,850**	**(2,662)**	**188**
Devices	**9,615**	**(9,406)**	**209**
Clinical Trials	**3,283**	**(3,033)**	**250**
Total	**106,731**	**(96,464)**	**10,267**

	2011/12		
Charging activity	£000 Income	£000 Expenditure	£000 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

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

	Total	2012/13 Permanently Employed	Other	2011/12 Total
	£000	£000	£000	£000
Wages and salaries	**42,759**	**40,945**	**1,814**	43,126
Social security costs	**3,893**	**3,870**	**23**	3,866
Other pension contributions	**8,142**	**8,111**	**31**	8,117
Sub-total	**54,794**	**52,926**	**1,868**	55,109
Less recoveries in respect of outward secondment	**(114)**	**(114)**	**-**	(48)
Total staff costs	**54,680**	**52,812**	**1,868**	55,061

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:

	Total	2012/13 Permanently Employed	Other	Total	2011/12 Permanently Employed	Other
Chairman	**1**	**1**	**-**	1	1	-
Executive Directors	**11**	**10**	**1**	10	9	1
Senior Civil Servants	**106**	**106**	**-**	109	109	-
Other Civil Service staff	**818**	**721**	**97**	791	748	43
	936	**838**	**98**	911	867	44

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

	2012/13` Number of compulsory redundancies	Number of other departures agreed	Total number of exit packages by cost band	2011/12 Total number of exit packages by cost band
< £10,000	-	-	-	5
£ 10,000 - £25,000	-	2	2	6
£ 25,000 - £50,000	-	2	2	10
£ 50,000 - £ 100,000	-	-	-	2
£100,000 - £150,000	-	-	-	1
£150,000 - £200,000	-	-	-	1
Total number of exit packages	**-**	**4**	**4**	**25**
Total resource cost	**-**	**£102,192**	**£102,192**	**£907,015**

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 £102k (2011/12, £907k) are included in wages and salaries and shown on the exit package table. A further £174k was accrued in 2011/12 for 4 departures in 2012/13.

6.4 Off-payroll engagements

The MHRA had two off-payroll engagements that were in place as of 31 January 2012, costing over £58,200 per annum.

No. in place on 31 January 2012	2
Of which:	
No. that have since come onto the MHRA's payroll	-
Of which:	
No. that have since been renegotiated/re-engaged to include contractual clauses allowing the MHRA to seek assurance as to their tax obligations	2
No. that have not been successfully renegotiated and therefore continue without contractual clauses allowing the MHRA to seek assurance as to their tax obligations	-
No. that have come to an end	-
Total	2

The MHRA started two new off-payroll engagements between 23 August 2012 and 31 March 2013. This was for more than £220 per day and lasted more than six months.

No. of new engagements	2
Of which:	
No. of new engagements which include contractual clauses giving the MHRA the right to request assurance in relation to income tax and national insurance obligations	2
Of which:	
No. for whom assurance has been accepted and received	2
No. for whom assurance has been accepted and not received	-
No. that have been terminated as a result of assurance not being received	-
Total	2

6.5 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 2012/13, employers' contributions for MHRA employees of £8,115,131 with a further £19,203 respect of staff on secondment were payable to the PCSPS (£8,098,884 in 2011/12 and a further £7,234 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 2011/12), 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 £213,803 (£234,492 in 2011/12) 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 2011/12). Employers can also match employee contributions up to a limit of 3 per cent of pensionable pay. In addition, employer contributions of £3,493 (£3,284 in 2011/12), 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 £4,501. No contributions were prepaid at that date.

There were no cases of retirement on ill-health grounds during 2012/13 (2011/12, One case). No additional pension liabilities were accrued.

7. Expenditure

7.1 Operating costs

	2012/13 £000	2011/12 £000
Computing	**11,324**	10,161
Depreciation and amortisation	**7,266**	7,326
Other accommodation costs	**6,027**	7,163
Medicines testing and laboratory expenses	**2,657**	2,229
Contracted-out administration services	**2,560**	1,563
Travel and subsistence	**2,442**	2,010
Rentals under operating leases (see 7.2 below)	**1,666**	201
Net increase in debt and credit note provision	**1,348**	1,193
Legal Services	**1,305**	1,576
Other administration costs	**1,124**	1,478
Training	**924**	768
Committee costs	**787**	701
Telecommunications	**683**	795
Contracted-out personnel and payroll services	**623**	364
Printing, stationery and distribution	**444**	306
Pharmacovigilance database and other costs	**299**	228
Increase in provisions	**217**	3,240
Marketing	**113**	79
Auditors remuneration - audit fee	**80**	87
Loss on disposal	**39**	479
Total operating costs	**41,928**	41,947

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

Payments recognised as an expense	**Others 2012/13 £000**	**Land and buildings 2012/13 £000**	Others 2011/12 £000	Land and buildings 2011/12 £000
Minimum lease payments	**74**	**1,666**	76	201
Total	**74**	**1,666**	76	201

Total future minimum lease payments	**2012/13 £000**	**2012/13 £000**	2011/12 £000	2011/12 £000
Payable:				
Within one year	**48**	**4,530**	64	1,647
Within two to five years	**-**	**18,058**	28	17,995
Over five years	**-**	**16,473**	-	20,907
Total	**48**	**39,061**	92	40,549

7.3 Finance Leases

The Agency had no finance leases in 2012/13.

8 Finance income and costs

	2012/13 £000	2011/12 £000
Finance income		
Interest received from Government Banking Service	**340**	271
	340	271
Finance costs		
Interest paid	**(46)**	(201)
Net cash inflow from returns on investments and servicing of Finance	**294**	70

9 Other gains and losses

	2012/13 £000	2011/12 £000
Gain/(Loss) on foreign exchange	**7**	(86)
Total	**7**	(86)

10 Plant and equipment

2012/13	Computer and telecom equipment £000	Laboratory equipment £000	Fittings furniture and office equipment £000	Total £000
Cost or valuation				
At 1 April 2012	8,190	1,416	13,553	23,159
Additions	333	102	5	440
Transfers	-	-	234	234
Disposals	(93)	-	-	(93)
At 31 March 2013	**8,430**	**1,518**	**13,792**	**23,740**
Depreciation				
At 1 April 2012	4,856	925	2,143	7,924
Charged during the year	1,955	158	1,489	3,602
Disposals	(55)	-	-	(55)
Depreciation at 31 March 2013	**6,756**	**1,083**	**3,632**	**11,471**
Net book value at 31 March 2013	**1,674**	**435**	**10,160**	**12,269**
Net book value at 31 March 2012	3,334	491	11,410	15,235
Asset financing:				
Owned				
Net book value at 31 March 2013	**1,674**	**435**	**10,160**	**12,269**

2011/12	Computer and telecom equipment £000	Laboratory equipment £000	Fittings furniture and office equipment £000	Total £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, a spreadsheet error led to the misallocation of sums in the fittings, furniture and office equipment category, although the overall net figure was unaffected. This adjustment corrects the misallocation in the balances.

11 Intangible assets

2012/13	Computer Systems £000	Assets under Construction £000	Software Licences £000	Total £000
Cost or Valuation				
At 1 April 2012	26,421	2,085	1,894	30,400
Additions	2,035	2,523	241	4,799
Transfers	1,483	(2,009)	292	(234)
Disposals	(1,052)	-	(10)	(1,062)
Reversals	-	(76)	-	(76)
At 31 March 2013	**28,887**	**2,523**	**2,417**	**33,827**
Amortisation				
At 1 April 2012	20,870	-	1,025	21,895
Charged during the year	3,321	-	343	3,664
Disposals	(1,052)	-	(9)	(1,061)
Amortisation at 31 March 2013	**23,139**	**-**	**1,359**	**24,498**
Net book value at 31 March 2013	**5,748**	**2,523**	**1,058**	**9,329**
Net book value at 31 March 2012	5,551	2,085	869	8,505
Asset financing:				
Owned				
Net book value at 31 March 2013	**5,748**	**2,523**	**1,058**	**9,329**

2011/12	Computer Systems £000	Assets under Construction £000	Software Licences £000	Total £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
Disposals	(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

12 Trade and other receivables

Amounts falling due within one year:	31 March 2013 £000	31 March 2012 £000
Due from the Department of Health (see 12.1 below)	**1,054**	755
Other trade receivables	**6,272**	16,388
Other receivables	**233**	253
Accrued income	**2,781**	1,845
Prepayments	**1,655**	2,450
	11,995	21,691
Amounts falling due after more than one year: Prepayments	**325**	-
Total	***12,320**	*21,691

*Intra government balance disclosed in note 21

Other trade receivables are shown net of a provision for bad debts of £4.5m (31 March 2012 £4.7m) and credit notes of £4.7m (31 March 2012 £7.9m).

12.1 Amount Due from the Department of Health consists of:

	31 March 2013 £000	31 March 2012 £000
Other trade receivables	**-**	11
Value Added Tax	**1,054**	744
Total	**1,054**	755

12.2 Provision for bad debt

	31 March 2013 £000	31 March 2012 £000
Bad debt provision	**4,515**	4,676
Total	**4,515**	4,676

13 Cash and cash equivalents

	31 March 2013 £000	31 March 2012 £000
Balance at 1 April	**114,879**	87,517
Net change in year	**19,795**	27,362
Balance at 31 March	**134,674**	114,879
Made up of		
Government Banking Service	**134,473**	114,392
Commercial banks and cash in hand	**201**	487
Cash and cash equivalents	**134,674**	114,879

14 Trade and other payables

Amounts falling due within one year:	Current		Non-Current	
	31 March 2013 £000	31 March 2012 £000	**31 March 2013 £000**	31 March 2012 £000
Due to Department of Health (see 14.1 below)	**213**	50	**-**	-
Payments received on account	**13,720**	17,483	**-**	-
Taxation and other social security costs	**2,050**	1,979	**-**	-
Other trade payables	**3,323**	2,697	**-**	-
Other payables	**-**	15	**-**	-
Accruals	**12,026**	9,321	**-**	-
Total	***31,332**	*31,545	**-**	-

*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 2013 £000	31 March 2012 £000	**31 March 2013 £000**	31 March 2012 £000
Other trade payables	**82**	50	**-**	-
Accruals	**131**	-	**-**	-
Total	**213**	50	**-**	-

15 Borrowings

	Current		Non-Current	
	31 March 2013 £000	31 March 2012 £000	**31 March 2013 £000**	31 March 2012 £000
Loans from Department of Health	**-**	-	**1,328**	1,328
Total	**-**	-	**1,328**	1,328

16 Provisions

	Current		Non-Current	
	31 March 2013 £000	31 March 2012 £000	**31 March 2013 £000**	31 March 2012 £000
Early retirement	**16**	16	**17**	**30**
Other provisions	**121**	1,226	**2,248**	**2,031**
Total	**137**	1,242	**2,265**	**2,061**

	Early retirement £000	Other provisions £000	**Total £000**
At 1 April 2012	46	3,257	**3,303**
Arising during the year	-	-	**-**
Used during the year	(17)	(1,105)	**(1,122)**
Unwinding of provision	4	217	**221**
At 31 March 2013	33	2,369	**2,402**

Expected timing of cash flows:			
Between 1 April 2013 and 31 March 2014	16	121	**137**
Between 1 April 2014 and 31 March 2017	17	-	**17**
Beyond 2017	-	2,248	**2,248**
Total	33	2,369	**2,402**

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 2.35%.

Other provisions 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 minus 1.0%;
- unpaid tax and national insurance on travel and subsistence payments pending final settlement with HMRC.

17 Other Liabilities

	Current		Non-Current	
	31 March 2013	31 March 2012	**31 March 2013**	31 March 2012
	£000	£000	£000	£000
Deferred revenue:				
Licence fees - applications and variations	**10,116**	15,664	**3,372**	3,923
Other fees	**2,737**	3,406	**40**	84
Government grant	**-**	-	**1,221**	1,152
Others:				
Contribution to CPRD joint venture	**8,125**	1,400	**-**	-
Dividend Payable	**3,494**	3,094	**-**	-
Total	**24,472**	23,564	**4,633**	5,159

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

	Total 2012/13	**Less than one year**	**Between one and five years**	**More than five years**	**Total 2011/12**
	£000	**£000**	**£000**	**£000**	**£000**
Fixed interest rate					
3.50%	**1,328**	-	-	1,328	1,328
At 31 March 2013	**1,328**	**-**	**-**	**1,328**	1,328
At 31 March 2012	**-**	-	-	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 31 March 2013	**Tangible 31 March 2013**	Intangible 31 March 2012	Tangible 31 March 2011
	£000	**£000**	£000	£000
Contracted	**205**	**944**	1,853	174
Total	**205**	**944**	1,853	174

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 (£973,875);
- The University of Leicester for the secondment of the Agency's Chief Executive (£247,064);
- BIS for accommodation costs (£5,225,140).

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

2012/13	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	**3,625**	**19,744**	**3,707**	**1,072**
Various NHS Trust	**103**	**1,660**	**362**	**2,046**
Department for Work and Pensions	**974**	**1**	**-**	**2**
BIS	**5,225**	**-**	**-**	**-**
Other government bodies	**1,229**	**404**	**4,969**	**2,088**
Local Authorities	**35**	**4**	**4**	**49**
Educational Bodies	**370**	**1,588**	**1**	**465**
As at 31 March 2013	**11,561**	**23,401**	**9,043**	**5,722**
2011/12				
Department of Health	3,096	14,195	3,144	755
Various NHS Trusts	153	1,498	299	761
Department for Work and Pensions	2,150	-	-	-
Other government bodies	238	198	3,624	175
Local Authorities	(333)	4	-	-
Educational Bodies	438	1,177	-	384
As at 31 March 2012	5,742	17,072	7,067	2,075

During 2012/13, 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

2012/13	Debtors: Amounts falling due within one year £000	Debtors: Amounts falling due after more than one year £000	Creditors: Amounts falling due within one year £000	Creditors: Amounts falling due after more than one year £000
Balances With Other Central Government Bodies	**3,162**	**-**	**8,676**	**-**
Balances With Local Authorities	**49**	**-**	**4**	**-**
Balances with NHS Trusts	**2,046**	**-**	**362**	**-**
Balances with Public Corporations and Trading Funds	**1**	**-**	**-**	**-**
Subtotal	**5,258**	**-**	**9,042**	**-**
Balances with Bodies External to Government	**7,062**	**-**	**22,290**	**-**
As at 31 March 2013	**12,320**	**-**	**31,332**	**-**
2011/12				
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	**-**

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 (2011/12: 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 (2011/12: £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.

	2012/13 £000	2011/12 £000
Government Banking Service*	**134,473**	114,392
Commercial banks and cash in hand	**201**	487
Total	**134,674**	114,879

* Includes £229k Proceeds of Crime which is the Agency's share of confiscated monies resulting from successful prosecutions and £97k 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 (2011/12:£1.328M). This resulted in interest payable of £0.046M (2011/12: £0.046M) out of total expenditure of £96.6M (2011/12: £97.0M)

Currency risk

The level of currency risk is determined by the level of income generated by activity undertaken on behalf of the EMA. For 2012/13 this was £7.266M (Euro 8.584M) (2011/12: £7.782M; Euro 9.306M). This represents 6.7% (2011/12: 6.6%) 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

- On 1 April 2013 the National Institute for Biological Standards and Control (NIBSC), up until then part of the Health Protection Agency (HPA), officially became a new 'centre' of the Medicines and Healthcare products Regulatory Agency (MHRA) alongside the Clinical Practice Research Datalink (CPRD) and the MHRA Regulator.

- The following balances were transferred to MHRA as part of the transfer: Non current assets £95.5m (made up of property, plant and equipment and intangible assets) current assets £15.8m (made up of inventories, trade and other receivables and cash) together with liabilities of £7.1m (made up of trade and other payables).

- MHRA and NIBSC worked together to establish systems and management arrangements for the transfer without any destabilisation of functions or services. Implementation of the transition has been taking place throughout 2012/13 as appropriate to business requirements.

- The Department of Health has announced the appointment of Dr Ian Hudson, currently MHRA Director of Licensing, as Chief Executive of the Medicines and Healthcare Products Regulatory. He will take up the post in September when Professor Sir Kent Woods steps down.

- 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.

17 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.

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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