Medicines and Healthcare Products Regulatory Agency

Medicines and Healthcare Products Regulatory Agency Annual Report and Accounts 2013/14

CPRD NIBSC MHRA

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Chairman's foreword

When I wrote the foreword to last year's annual report, I did so as someone who had been in post for three months, with the difficult task of replacing an exceptional predecessor, Sir Alasdair Breckenridge. This time, I write with the perspective of having seen through a full business year. The financial year 2013/14 was certainly one of change and challenge, needing detailed reflection and careful planning for continued success in discharging the agency's duty to the UK public.

The financial year began with the MHRA merger with the National Institute for Biological Standards and Control (NIBSC), one of the country's world-leading Institutes. This merger, combined with the development of the Clinical Practice Research Datalink (CPRD), will transform what we can do together. The agency's union with NIBSC offers unprecedented opportunities for biomedical research and support of innovation in biological medicines, a field of ever-growing importance to individual and public health.

In May, I was sorry to lose two of the Board's longest-serving members: Professor Angus Mackay and Dr Shelley Dolan, who each brought a wealth of expertise and wisdom to the Board's deliberations. Their retirements were followed in September by the departure of Sir Alan Langlands, who had to step down from the Board in order to meet his new commitments as Vice Chancellor of the University of Leeds. Thankfully, the loss of such outstanding members was made good by the appointment in September of three world-renowned replacements; the epidemiologist, Professor Dame Valerie Beral; the molecular geneticist, Professor Sir Alex Markham; and the clinical pharmacologist, Professor David Webb.

Also in September we bade farewell to Sir Kent Woods, who retired as chief executive having led the MHRA since January 2004. Sir Kent's wise leadership and strategic insight assured his appreciation and admiration within the agency, among regulators across the globe, and throughout the wider public health community.

Although I was sorry to see Sir Kent leave, I looked forward to working with his successor, Dr Ian Hudson, whom I knew professionally from my work on the Commission on Human Medicines when Dr Hudson was director of licensing. I can report that the transition from Sir Kent to Dr Hudson has worked seamlessly, thanks to both. Since taking up his new role, Dr Hudson has greatly impressed the Board, our Ministers and our stakeholders in the UK and overseas. Dr Hudson's appointment has been a great success, and I am confident he will lead the agency to continued high performance during the challenging times ahead.

We have been fortunate this year in receiving wise guidance from two commissioned reports, those of Sir Patrick Sissons on NIBSC and of Professor Terrence Stephenson on the regulation of Devices. The guidance in these reports from panels of experts will set us fair for the future and will help us continue to be alert and agile to anticipate and meet the demands of a changing world.

Sadly, this will be my last foreword to the agency's annual report because I shall leave towards the end of 2014 to become Principal of St Hilda's College, Oxford. I will be sorry to leave the agency, an organisation I have known as Board Chairman,

and earlier as Chairman of both the Commission on Human Medicines and the Committee on the Safety of Medicines. The agency is a world-class organisation peopled by superb and talented individuals committed to protecting the public health. It has been a privilege to have such a long and close association with it.

Professor Sir Gordon Duff
Chairman

Chief Executive's foreword

This is my first foreword since taking up the post of chief executive last September and I would like to start by thanking Sir Kent Woods, whom I succeeded, for his leadership over the previous 10 years. I am pleased our links with Sir Kent will continue through his chairmanship of the European Medicines Agency's Management Board. The agency is now considerably larger and more diverse in its responsibilities compared to when it was first formed. It is also operating in an ever more complex environment, with a rapidly changing nature of the products and internationalisation of the industries we regulate together with a changing healthcare environment nationally.

The financial year began on 1 April 2013 with the MHRA's merger with the world-renowned National Institute for Biological Standards and Control (NIBSC). This union, together with the establishment of the Clinical Practice Research Datalink (CPRD) in 2012, has created exciting opportunities for the safeguarding of public health through scientific innovation and research. That the merger went so smoothly was due to the hard work and dedication of staff in the joint MHRA/NIBSC merger project groups, to whom I pay tribute. As with CPRD, MHRA's union with NIBSC offers unprecedented opportunities for scientific research, support and innovation in the field of biological medicines, a field of growing importance as the agency enters its second decade. Having the three centres of NIBSC, CPRD and MHRA regulatory all within the same agency puts us in a unique position to be able to meet the challenges of the future.

April 2013 also saw the launch of the agency's Corporate Plan 2013-18, which set out our strategic direction for the next five years. It is a dynamic document, which will be regularly reviewed to check that we continue to head in the right direction. It creates a structure for our work and will inform our annual business, divisional and team plans.

Throughout the year, the agency has also been fully engaged in the revision of the Clinical Trials Directive, the Medical Devices Regulations, the development of legislation on Pharmacovigilance Fees, and in the implementation of the new Pharmacovigilance legislation and the Falsified Medicines Directive. Additionally, during the financial year, the agency was a source of expert policy advice on nicotine containing products, including electronic cigarettes.

Much of the work of the agency is within the context of the EU network, where we continue to be a leading contributor in all aspects of the work of the network. We are leading the SCOPE project, which aims to strengthen the pharmacovigilance capacity across the EU. Beyond the EU, we continue to strengthen our ties with regulatory counterparts including those of the United States, China, India, Japan and Australia. Indeed, Dr Margaret Hamburg, Commissioner of the United States. Food and Drug Administration, visited us in March 2014 and gave the agency's 2014 Annual Lecture. The subject of Dr Hamburg's lecture "Globalisation of medicines, the regulators response" was very timely, as throughout the financial year, we have been working with other regulators on a number of quality issues relating to manufacture outside the EU. Moreover, following the annual global summit of medicines regulators in December, we agreed to lead a strand of work on Good Manufacturing Practice for the newly established International Coalition of Medicines Regulatory Authorities (ICMRA). Also, in June 2013, we again took a leading role in the highly successful Pangea VI initiative against the internet sale of counterfeit and substandard medicines and devices; 99 countries participated.

During the course of the last year, we have increasingly recognised that the changing world in which we operate means that we have to refashion our business and adapt ourselves to meet the needs of a 21st century regulator. In November, the Agency Board and Corporate Executive Team agreed a way forward that would allow the agency to re-balance and refocus itself over the next three years. Our five year corporate plan and annual business plan set out our direction of travel over this period, and highlight the priority areas we need to focus on and develop or change. There are many exciting opportunities ahead of us as we take forward this plan, however part of this programme includes achieving financial savings particularly within the regulatory centre of the agency. These will be achieved through a combination of headcount reduction of 125 posts (reversing much of the growth of the previous five years), as well as looking for other non-pay savings. I am grateful to our staff who are both excited by the opportunities ahead of us, and also understand the realities of the need to make savings over the next three years.

Following the merger with NIBSC and the heightened interest in medical devices in 2012/13, two independent reviews of aspects of the agency's work were conducted: one was a scientific review of NIBSC, while the second report was on the MHRA's access to clinical advice in the devices sector. Both reviews were carried out by panels of renowned experts, whose reports were presented in February 2014. The agency will respond to the reports' content and findings by the summer.

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 agency's first decade and has been the key to its success. I would also like to pay tribute to the work of the many independent experts whose deliberations help inform MHRA's regulatory decisions.

As I conclude this foreword, I would like to congratulate our chairman, Sir Gordon Duff, on his recent appointment as Principal of St. Hilda's College, Oxford. While we are delighted for St Hilda's, we are also sorry that the appointment will oblige Sir Gordon to stand down as Chairman later in the year. Sir Gordon has worked closely with, or more recently as part of the agency for over 20 years, initially via the advisory committee structure in 1993 and then as Chair of the Commission on Human Medicines, and more recently as Chairman of the agency, and I would like to take this opportunity to thank Sir Gordon for his enormous contribution to our work over so many years.

It has been a privilege to take on the post of chief executive. Despite the sobering realities of continued austerity and of an ever changing and evolving environment in which we operate, we have many exciting opportunities ahead of us. I am confident we will meet the challenges we face and the agency will continue to remain one of the leading regulatory agencies in the world.

Dr Ian Hudson
Chief Executive

2 About the Medicines and Healthcare Products Regulatory Agency

2.1 *Who we are*

The Medicines and Healthcare Products Regulatory Agency is an executive agency of the Department of Health (DH) and operates as a government trading fund. The Secretary of State for Health determines the policy and financial framework within which the agency operates, but is not involved in the day-to-day management.

2.2 *Mission*

The agency's mission is to protect and improve the health of millions of people every day through the effective regulation of medicines and medical devices, underpinned by science and research.

2.3 *Aims*

The agency's aims are to:

- Ensure that medicines, medical devices and blood components for transfusion meet applicable standards of safety, quality, efficacy and effectiveness;
- Ensure that the supply chain for medicines, medical devices and blood components is safer and more secure;
- Promote international standardisation and harmonisation to assure the efficacy and safety of biological medicines;
- Promote increased understanding of the risks and benefits of medicines, medical devices and blood components, leading to safer and more effective use;
- Promote and support innovation, research and development beneficial to public health;
- Influence the shape and operation of the UK, EU and international regulatory frameworks in which we operate, to achieve risk-proportionate and effective public health protection;
- Achieve national and international recognition of the excellence of our work in protecting and promoting public health, thereby contributing to the success of the UK economy.

2.4 *Objectives*

The agency's strategic objectives are to:

- Enhance the understanding of the role of regulation; building partnerships and making best use of available data to provide information about the performance of medicines and devices to influence clinical practice in the interests of patients;

- Realise the full benefits of the National Institute of Biological Standards and Controls (NIBSC) and the Clinical Practice Research Datalink (CPRD); influence thinking and regulation in the EU and globally to support access to beneficial innovative products whilst contributing to the government life sciences and growth agendas;
- Strengthen systems that collect and use information about the performance of medicines and medical devices;
- Work with UK, EU and global partners to address the challenges posed by increasingly globalised medicines and devices industries - not least to combat counterfeiting and ensure a more secure supply chain; and
- Regulate effectively and proportionately; utilising a skilled and motivated workforce to deliver organisational efficiency and value for money.

2.5 *Composition*

The agency is comprised of three centres:

- Medicines and Healthcare products Regulatory Agency (MHRA)
- Clinical Practice Research Datalink (CPRD)
- National Institute for Biological Standards and Control (NIBSC)

Information on the responsibilities and activities for each can be found in their dedicated sections later in this report.

2.6 *2013/14 – A year of consolidation for the new organisation*

2013/14 has been an exciting year of change and consolidation for the newly enlarged agency, merging the functions of the Clinical Practice Research Datalink (CPRD) and the National Institute for Biological Standards and Control (NIBSC) alongside the medicines and medical devices regulatory functions (MHRA).

This new, three centre organisation combines expertise in regulation and biological standards with the provision of data for public health research, all as part of an organisation with a strong global reputation and level of influence. The focus this year has been to embed the three centres into one agency and to begin realising the benefits from this enlargement to secure the future capability of the agency. Some examples are provided below of how the three centres have worked together to deliver key public health gains.

One way in which the benefits of the merger have already been realised has been through the creation of cross-agency groups which bring together expertise focused on key product areas - vaccines, biosimilars and advanced therapies - to respond to emerging issues, shape effective regulation and facilitate innovative product development. Notable outcomes include the introduction and review of risk management plans for three new vaccines for influenza, shingles and rotavirus which have been added into the UK vaccination schedule, with the aim of offering protection from these serious conditions. These groups have aided the UK government's commitment to leading the world in regenerative medicines, and have played a key role in assessing the potential benefits and risks from availability of new, less costly, versions of important biologics.

This year has seen continued collaboration between the MHRA regulatory centre and CPRD over the pertussis vaccine which was added to the UK immunisation schedule in October 2012. An epidemiological study using data from the CPRD has been underway since the vaccine was added to the schedule to actively monitor its safety in pregnancy; over half a million pregnant women have now been vaccinated across the UK with no safety concerns being identified and with good evidence of effectiveness. This represents the first controlled evidence of the safety of maternal pertussis immunisation, and has supported the government's decision to continue the programme. The World Health Organisation (WHO) and many countries across the world are currently considering similar recommendations making the data from this study of global relevance.

The opportunity for CPRD data to be exploited to bolster patient safety surveillance is currently being explored. Supporting medicines surveillance is a combined Yellow Card (a surveillance system for medicines) and CPRD approach to improve the way signal detection and evaluation takes place, a key way in which emerging safety issues are identified. In terms of medical device surveillance the agency has been working with NHS England to establish pilot sites in English hospitals to introduce a mechanism through which implantable devices can be electronically recorded in a patient's NHS record. This linkage will allow benefit/risk assessments to be made and will improve performance surveillance of these types of device.

The agency is in a strong position to support the delivery of a number of key government health priorities. This year a new scientific Division of Advanced Therapies has been established at NIBSC and will focus on supporting the development of gene and cell therapies (including regenerative medicines). This

division will identify and meet the needs for standardisation within the field, ensuring an internal capability to analyse and test cell and gene therapy products in the event of incidents and emergencies whilst also contributing to the cross government regenerative medicines group.

The Prime Ministers' Dementia Challenge campaign, launched in March 2012, is designed to make a real difference to the lives of people with dementia and their families and carers, building on progress made through the National Dementia Strategy. As part of the campaign an international Dementia Steering Group in which the agency participates has been established, focusing on the target of making the UK a world leader in dementia care and research. The agency contributes in a number of ways, including providing advice to those developing innovative medicines, responding to emerging science through, for example acceptance of novel biomarkers, agreeing new trial designs or endpoints designed to demonstrate the safety and efficacy of new products, and through the operation of CPRD which is a valuable tool for use in Dementia research.

The Department of Health's Children and Young People's Health Outcomes Strategy has been underway since 2012 and the agency has supported the strategy this year in several ways. A key focus has been on increasing the reports the Yellow Card scheme receives describing reactions to medicines experienced by children and young people to improve the identification of possible drug safety issues. This includes work that is on-going to update advice on the reporting of adverse drug reactions (ADRs) in children, including following off-label prescribing.

Updates have also been made to the online reporting form to allow for easier reporting of adverse reactions suspected to be associated with drug exposure in pregnancy. During the year the opportunity was taken to partner with Royal Colleges and other professional bodies, NHS organisations and some parent and patient organisations to raise awareness of the Yellow Card scheme.

Other areas of work being taken forward to deliver on the commitments made in response to the strategy are around promoting submission of reports on medication errors, strengthening both paediatric signal detection and signal evaluation within Europe, contributing to work seeking to strengthen the European guideline on paediatric pharmacovigilance and to update guidance on excipients including those with paediatric-specific issues. The agency has led on a number of these safety reviews.

2.7 *Overview of the regulator, Medicines and Healthcare products Regulatory Agency (MHRA)*

The MHRA regulatory centre is responsible for:

- Assessing the safety, quality and efficacy of medicines, and authorising their sale and supply in the UK
- Carrying out post-marketing surveillance of medicines and medical devices, monitoring adverse reactions and taking action to safeguard public health
- Testing medicines to identify and address quality defects, monitoring the safety and quality of imported medicines, investigating internet sales and counterfeit medicines
- Ensuring compliance with UK and European standards through inspection and enforcement
- Managing the British Pharmacopoeia (BP)
- Overseeing the UK bodies that audit medical device manufacturers, operating a compliance system for medical devices, and contributing to the development of standards for medical devices
- Providing expert scientific, technical and regulatory advice on medicines and medical devices
- Regulating clinical trials of medicines and medical devices
- Promoting good practice in the safe use of medicines and medical devices, and providing information to help inform treatment choices

Key highlights

The regulation, approval and surveillance of medicines and medical devices is increasingly coordinated at the European level and is important that the MHRA is able to contribute to and influence this work. The licensing of new medicines is one such area which is increasingly coordinated across Europe.

The Centralised procedure forms part of the European medicines licensing system and results in a single European Marketing Authorisation and subsequent direct access to the single community market. As part of this procedure an application is made to the European Medicines Agency (EMA) and a rapporteur, and if relevant a co-rapporteur, are appointed to lead the scientific evaluation. The appointment of the rapporteur/co-rapporteur is made on the basis of objective criteria designed to ensure the provision of objective scientific opinions and the use of the best and available expertise in the relevant scientific area.

The MHRA continued this year to have the highest number of rapporteur/co-rapporteur appointments in Europe, acknowledging not only the widely respected knowledge of the MHRA and its assessment processes but also making a real difference to treatment options for a range of conditions. Some examples from this work include the coming to market of the following new medicines:

- Remsima (infliximab), the first biosimilar monoclonal antibody to be licensed in Europe, addressing a number of scientific challenges. Remsima, a copy of Remicade (infliximab) is licensed to treat a wide range of inflammatory diseases. There is considerable interest in biosimilar products and as such this assessment decision has been subject to close scrutiny from other companies that are developing other biosimilar medicines. Importantly, as

these drugs are very expensive, less costly biosimilars will allow more patients to be treated.

- Maci (autologous cultured chondrocytes),a tissue-engineered advanced therapy product which consists of patient's own cartilage cells on a collagen membrane for the repair of knee cartilage.
- Orphacol (cholic acid) for use in the treatment of inborn errors in primary bile acid synthesis in infants, children and adolescents aged one month to 18 years, and adults. This is the first regulatory approved treatment in Europe for this genetic condition. Without treatment these children have very poor quality of life and eventually develop liver failure, which in most cases requires liver transplantation.
- Lojuxta (lomitapide) which is a novel lipid-lowering agent. It is first in class for high-risk patients with homozygous familial hypercholesterolaemia.

The Decentralised procedure is the other principal route to market across multiple member states. Through this procedure the company applying for the authorisation has, in the vast majority of cases, the choice of which member state they would like to lead the assessment – designated by them as the Reference Member State (RMS) (other states in which the applicant wishes the authorisation to be recognised are called Concerned Member States). Over the course of this year the UK remained the preferred RMS responsible for leading on 48% of all procedures in which the UK were involved. This demonstrates that industry recognises the value of the MHRA's science and assessment processes, something which the MHRA is keen to build on in the coming year.

During different stages of the research and development period of a medicinal product, companies may seek regulatory or scientific advice to assist with their product development, safety testing and/ or clinical trial design. Scientific advice may be requested from the EMA or nationally from MHRA. In the case of the former, a member state will be appointed the coordinator by the Committee for Medicinal Products for Human Use (CHMP) Scientific Advice Working Party to provide scientific advice and in 2013/14 the MHRA had the highest number of appointments as the scientific advice coordinator. For the same year, the MHRA also held 321 regulatory or scientific advice meetings nationally to give guidance to companies.

Once medicines are licensed continual surveillance of their safety is undertaken, which in some cases leads to Europe-wide reviews. Over the course of the year the MHRA has acted as rapporteur or co-rapporteur for over 20% of such reviews, leading these on behalf of the European Pharmacovigilance Risk Assessment Committee (PRAC) which the MHRA chairs.

The MHRA has been involved in the reviewing many medicines and medical devices over the past year. Some examples include: the MHRA led a review of combined hormonal contraceptives and venous thromboembolism which confirmed that these products are safe and effective and has resulted in updated advice for healthcare professionals and women to help inform prescribing decisions. A review of the safety of codeine for pain relief in children was also undertaken; this led to restrictions in its use in children under 12 and those susceptible to respiratory problems. On the advice of the Commission on Human Medicines (CHM), MHRA suspended the use of hydroxyethyl starch (HES) products, which were used to replace lost blood volume, pending the outcome of a Europe wide review of data which suggested an increased risk of renal injury and death associated with the use of these products. The review subsequently concluded that the balance of benefits and risks remains favourable in a restricted patient population with patients being closely monitored.

At the European level the MHRA is coordinating a project entitled 'Strengthening Collaborations for Operating Pharmacovigilance in Europe' (SCOPE), designed to support regulators in member states in meeting the requirements of the EU pharmacovigilance legislation. Work packages within SCOPE examine specific topics to develop guidance documents, practical tools and training packages for member states to help improve the operation of their pharmacovigilance systems, and ultimately improve patient safety. In addition, this year, as part of the PROTECT project (funded by the European Innovative Medicine Initiative) the MHRA led a work package focusing on the detection of duplicate adverse drug reaction reports resulting from multiple reporting. The findings from this were published in the peer reviewed journal 'Drug Safety'.

Ongoing surveillance activities which the MHRA undertakes also relate to the inspection of premises involved in all aspects of medicines supply, both in the UK and abroad. During 2013/14 the MHRA's inspectorate conducted 140 overseas inspections (34 of these on behalf of the EMA). Over the course of the year a number of data integrity issues at a number of manufacturing sites have come to light, which included some Indian manufacturing sites involving companies of significant size that produce significant volumes of generic medicines destined for the supply chain in the UK and elsewhere. Appropriate regulatory action was been taken in each case, with the MHRA coordinating the continued availability of essential medicines manufactured at these sites with the Department of Health, whilst recalling those medicines which did not meet sufficient standards. Issues such as this do not just affect the UK and it is this recognition of the increasing coordination, networks and sharing of information both in Europe and internationally that have led the inspectorate to pursue a programme of targeted training and cooperation designed to strengthen domestic and international compliance with Good Practice requirements.

Highlights from this year include:

- Collaboration with the World Health Organisation (WHO), United States Food and Drug Administration (USFDA) and the Central Drugs Standard Control Organization (CDSCO) to provide training for Good Manufacturing Practice inspectors in India.
- Working with the EMA to train EU Good Clinical Practice bioequivalence inspectors.
- Intensification of links with key international regulators including the USA, Japan, China and India with the goal to develop further collaborative working arrangements.

Over the course of the year the MHRA investigated 917 defective medicines reports, and issued a total of 27 drug alerts. An example of one such issue came in December 2013 and involved a patient level recall for Jext (adrenaline) pre-filled pens, due to a potential problem with delivery of the dosage following activation of the auto-injector. This recall required collaboration between MHRA divisions and two marketing authorisation holders to ensure sufficient alternative medicines were available before Jext was withdrawn from the UK, thus maintaining supply of a critical medicine and protecting patients.

During the year the MHRA devices division received and investigated 13,927 adverse incident reports, oversaw 889 Field Safety Corrective actions undertaken by manufacturers in the UK, and issued 877 Medical Device Alerts.

The MHRA has maintained its commitment to tackle the illegal online supply of falsified or unlicensed medicines and medical devices including through Operation Pangea. The annual operation, coordinated by INTERPOL, resulted in 3.7 million doses of unlicensed medicines seized in the UK alone (worth approximately £12.2 million) over the course of the one week operation in June 2013. During the year warnings were also issued to dentists about unapproved dental curing lights and other dental devices being sold online and to consumers about unlicensed herbal medicines and tanning injections.

Enforcement is a critical way in which the MHRA can continue to protect the public from illegal and dangerous medicines. With this in mind the MHRA provides secretariat support to meetings of the Heads of Medicines Agencies (HMA) Working Group of Enforcement Officers (WGEO); the aim is to increase collaboration on enforcement across the EU. The group pursues greater sharing of knowledge, skills and experience regarding enforcement activity in support of legislation in place to ensure safe supply chains and protection to patients. The MHRA is are also co-chair for the European region of the World Health Organisation (WHO) Substandard Spurious Falsely-labelled Falsified Counterfeit medical products (SSFFC) – a WHO global initiative.

Collaborating and working with European counterparts is also a strategy which the devices division of the MHRA have followed this year. The MHRA has led a task force seeking to improve the level of collaboration across member states with the European Commission to support the regulation and safety of medical devices. Keeping with this theme, the MHRA has also contributed to an initiative to enhance cooperation around medical device vigilance including the development of monthly conference calls and plans to accelerate the development of a single European portal for submission of adverse incident reports. The MHRA was Co-chair of the Compliance and Enforcement working group, led the medical device trending task force, the cardiac ablation medical device specific vigilance guidance task force and led on a project introducing new EU legislation concerned with stronger auditing requirements for bodies which issue certification to medical devices across the EU.

These activities reflect the commitment of the MHRA to bring products safely to market which are in an advanced stage of development whilst ensuring the safety of established medicines and their supply to patients. Despite this focus, the MHRA likewise takes a strong interest in the next generation of medicines and medical devices and in its support of the government's life sciences agenda launched an Innovation Office in March 2013. The office aims to support those involved in innovative products by offering advice and assistance on the regulatory requirements to bring such products to market. Over the course of the year around 50 queries were received, covering both medicines and medical devices, with around 20% leading to meetings with MHRA assessors to discuss the products and issues in greater detail.

The focus on innovative medicines in particular continues with the UK Early Access to Medicines Scheme (EAMS) which was announced by the Secretary of State on 14 March 2014 and will be launched in April 2014. The scheme's objectives are to provide for the availability of medicines for life threatening and seriously debilitating conditions where there is an unmet medical need, in advance of the approval of the marketing authorisation (product licence). In addition, the launch by the EMA of an adaptive licensing pilot in March 2014 was the result of significant active engagement by MHRA, who formed part of a discussion group that drafted the launch documentation. Moving forward, the MHRA is contributing to wider government work to make the EMA pilot a success, dependent on companies coming forward with products.

During the year the MHRA established a pilot patient group consultative forum in recognition of the benefits that enhanced interaction with patient groups, particularly in accessing their views to inform strategies and projects would bring. One such group, the Commission on Human Medicines Patient and Public Expert Advisory Group provides the MHRA with expert advice on interactions with patients and the public. Achievements this year have included providing advice on information to patients regarding new drug driving regulations and recommendations to the CHM on how patients can be more involved in licensing decisions: which will be piloted during 2014/15. At the individual patient level the delivery of the Yellow Card strategy (seeking to strengthen the reporting of suspected adverse drug reactions, both by number and quality of reports) is tied to patient reporting, which is a key part of the scheme. In order to raise awareness and promote reporting amongst patients the MHRA has partnered with a number of parent and patient organisations over the course of the year and has publicised the need for reporting of ADRs in children.

Other points of note this year include a significant milestone for the British Pharmacopoeia (BP), which in 2014 celebrates its 150th year of being in print. To recognise and celebrate this event the MHRA will host the National Pharmacopoeial Authority meeting and the WHO's 3rd International meeting of World Pharmacopoeias in April 2014 alongside developing new branding and a comprehensive communication strategy for the BP.

The devices division has been the focus of an independent review conducted by Professor Terence Stephenson, Chairman of the Academy of Medical Royal Colleges. The subject of the review was the MHRA's access to clinical advice and its engagement with the clinical community. The recommendations of this report will be a key element in the shaping of the division's strategy for clinical engagement over 2014/15.

Looking ahead there have been a number of legislative changes at the European level, the effect of which will be seen in the coming years. In December 2012 the European Commission proposed a revised Tobacco Products Directive (TPD), the MHRA were involved in the continual negotiations around this, with the Directive approved by the Council of Ministers in March 2014. The revised Directive requires electronic cigarettes to be regulated either as medicinal products, if they make a medicinal claim, while those that do not make a claim will not be regulated as medicines.

Agreement was reached on two further pieces of legislation:

- The EU Clinical Trials Regulation at the end of 2013, revising and simplifying the current regime for authorising clinical trials.
- The fee system for EU pharmacovigilance work, ensuring that the new EU pharmacovigilance legislation can now be fully implemented.

Negotiations are continuing on strengthening the EU legislative framework for medical devices through improved pre-market assessment by notified bodies, coupled with strengthened vigilance and post-market surveillance to ensure safety of devices whilst encouraging innovation.

This year the MHRA has continued to respond to the changing landscape whilst protecting and enhancing public health. A number of initiatives which have started or progressed this year give the MHRA an excellent foundation to continue to build on in 2014/15.

2.8 *Overview of Clinical Practice Research Datalink (CPRD)*

CPRD is the English NHS observational data and interventional research service providing anonymised NHS primary care data on millions of people in England, held in electronic health records, to help answer clinical research questions about a population. CPRD has the ability to provide linked data with a range of other data sources, such as disease registries, to build a more complete picture of a patient's journey of care from cradle to grave. The research outputs help develop new treatments and improve health for all.

CPRD is jointly funded by the agency and the NHS National Institute for Health Research (NIHR).

Key highlights

2013/14 has been a busy year for CPRD with progress made in a number of areas despite some challenges; challenges associated with changes to the NHS and the desire to get a national system approach to uses of data and of the mechanism whereby people can object to the use of their anonymised data.

A notable positive has been the continued growth witnessed in research studies enabled by CPRD data, an upward trend which is expected to continue into 2014/15. From these studies a number of papers have been published which demonstrate the positive public health impact that CPRD's data is able to provide. For example the power of CPRD to enable better Biological sample collection and contribute towards increased knowledge in the area of Pharmacovigilance was shown by O'Meara H et al[*]. Another example comes from a paper by Vasilakis-Scaramozza et al[†] looking at the widely used Selective Serotonin Re-uptake Inhibitors and demonstrated no association with a statistically increased risk of congenital abnormalities.

Over the course of the year CPRD has been showcased at 12 major international meetings which have led to the establishment of a number of research projects, with continuing discussions centred on developing many more. Some notable successes from this are work for the Sanger Institute and an expanded customer base including some of the biggest companies in the biotechnology and devices sectors.

CPRD Trialviz, a trial feasibility tool, was launched this year, utilising Primary Care data and, at the request of the National Institute for Health Research (NIHR), rapidly incorporated hospital data (Hospital Episode Statistics). Trialviz has been widely acclaimed as a global first in its ability to dramatically improve feasibility of a study to find and recruit patients and to help optimise the trial protocol. NIHR has access to the system and both parties work together to meet the needs of clinical trial

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Pharmacotherapy. 2013 Jun 6. [Epub ahead of print]
PMID: 23744675.

sponsors. Building on this CPRD, intends to develop other clinical trial enabling software, leading to additional launches in 2014/15 as the profile of CPRD as an enabler of efficient clinical trials grows, something which has been witnessed this year through increasing requests for demonstrations of the system.

Additionally in this area CPRD completed two pilot studies of randomisation at “Point of Care”; these low risk studies give indications of how this low cost methodology could be adopted on a wider basis in future.

The changes in the healthcare landscape over the past year have impacted on CPRD’s potential to grow as originally forecasted, particularly in relation to increasing the numbers of Primary Care practices joining the system. Despite this, the open data agenda and the focus on health services research within the care.data plans demonstrate how Real World Data (RWD) is having a far greater influence in ensuring that all parts of the care delivery system are operating to ensure best patient outcomes – something which CPRD is uniquely positioned to support.

CPRD has continued to work closely and develop relationships with various healthcare and commercial organisations, for example close working relationships have been developed with the Medical Research Council (MRC) and the Farr Institute with the aim of maximising the research potential and thus public health gains which can be made. One output from this has been the launch of the pilot version of the new Breast Implant registry. This web based registry will enable research related to benefit/ risk and the tracking of patients. CPRD will pilot the registry through its early life to ensure it is self-funding, sustainable and is collecting information on as many NHS and private implants as possible.

Competition within the sector has increased as other countries develop their own research data systems. However, CPRD remains confident about its approach and its offer as each of the other systems seen to date lacks one or a number of the following factors - no national health identifier making linkage difficult, no single healthcare system, small population, homogeneity of the population, lack of publications on data validity. Thus CPRD, through combining all these features, retains its unique offer in the research arena.

2.9 *Overview of National Institute for Biological Standards and Control (NIBSC)*

NIBSC is responsible for developing and producing over 90% of the international standards in use around the world to assure the quality of biological medicines. Alongside this, NIBSC is the UK's Official Medicines Control Laboratory (OMCL), responsible for testing biological medicines within the framework of the EU whilst also performing Official Control Authority Batch Release testing for biological medicines and is the home of the UK Stem Cell Bank.

Key highlights

2013/14 has been an important and successful year for NIBSC. The hard work undertaken preparing for the merger with MHRA paid off handsomely and the transition was achieved smoothly in April 2013.

2013/14 has seen NIBSC produce a new scientific strategy to cover the next ten years, an exercise which identified a number of key areas in which investment is required in order to address important emerging areas of technology and product development. One important outcome has been the development of a new scientific Division of Advanced Therapies, concentrating on supporting the development of gene and cell therapies (including regenerative medicines). Other key areas for investment which have been identified and are being addressed include support for the use of new technologies such as deep sequencing to analyse and characterise biological medicines.

The UK Stem Cell Bank's progress was peer reviewed as part of an application to the Medical Research Council for the next phase of funding, with the application receiving a very high score and the subsequent awarding of funding for the next three years. This represents a strong endorsement of the work done over the past five years to support development of the emerging field of stem cell therapy and regenerative medicine. Over the course of the year NIBSC has also been successful in attracting competitive external research funding of £3.3m from a range of UK, European and US sources.

NIBSC has continued to play a key role internationally with 1497 batches of medicines independently tested and approved for release on to the European market, 8 new WHO international standards established, and a series of new CE marked standards and reference materials developed to support improved clinical diagnosis. At the European level NIBSC has continued to play a key role as the UK's Official Medicines Control Laboratory.

Alongside routine batch release work, preparations for the possible adoption into the UK vaccine programme of Bexsero, a new vaccine against Meningococcus B, has been a major focus. This is a complex and challenging product from a testing perspective but good progress has been made and the first batches were approved for marketing in Europe.

A range of new and replacement standards and reference materials were developed and approved through WHO's Expert Committee for Biological Standardisation. These include materials to improve the potency measurement of important vaccines (such as polio) and therapeutic products used in the treatment of cancers and inflammatory conditions, products to support tests for disease-causing agents for

diagnosis or proof of blood safety (such as Hepatitis A and B) and materials to support diagnosis of allergenic reactions (e.g. serum IgE).

NIBSC has maintained its critical support to the global seasonal influenza vaccination campaign through provision of candidate strains for vaccine manufacture and reagents for their quality assurance. As one of four Essential Regulatory Laboratories, operating within the WHO Global influenza Surveillance and Response Network, NIBSC also played a key role in the global response to threat posed by influenza H7N9 in May 2013, through provision of safe vaccine manufacturing strains.

NIBSC also made an important contribution to the global polio eradication initiative. Work has continued to evaluate candidate vaccine strains recently developed at NIBSC to support safe polio vaccine manufacture post eradication. These strains continue to show considerable promise and form part of NIBSC's larger involvement in this initiative including the intention by WHO to spread the production of polio vaccines throughout the world, the containment of strains post-eradication and NIBSC's heavy involvement in maintaining the quality of the surveillance programme which is essential at the current stage of eradication.

NIBSC's achievements over the past five years and its forward plans were tested this year through a major independent scientific review carried out by Sir Patrick Sissons and an external panel of experts during November and December 2013. The review made several recommendations which are being taken forward, but overall the outcome was a ringing endorsement both of the importance and the quality of NIBSC's scientific work.

This year the agency became the target of a number of animal rights protests, both at the NIBSC site in South Mimms and the BPR site in London. While unwelcome, responding to the threat of disruption provided a good opportunity to test the agency's business continuity plans and also to highlight through local media, the external website and internal staff communications the importance of the agency's work. This also gave the agency the opportunity to showcase the world leading efforts that have been underway at NIBSC and across other parts of the agency over many years to reduce the need for animal testing through development and approval of innovative medicines testing methods.

2.10 *Contributing to the Secretary of State's health inequalities agenda*

The agency is in a position to influence and support the Secretary of State in meeting his duty to reduce health inequalities and we welcome the opportunity to do so.

Following clinical trials the licensing for use of a medicine takes account of factors such as sex, age and race, particularly if any of these populations is a specific target for benefits or poses specific risks. Examples include the effects of a product on children, on the elderly, on those who are pregnant or on those from different ethnicities (such information will be included within the Summary of Product Characteristics).

This sits alongside the active role the agency has played in specific Department of Health projects with a health inequalities focus, including the paediatric strategy and the Children and Young People's Health Outcomes Strategy. The latter seeks to increase the number of age appropriate formulations for children available on the UK market in the context of the European paediatric legislation.

The agency has worked to ensure that the Yellow Card scheme is accessible and one of the ways this has been realised is through the translation of basic information about the scheme into 12 languages, which are available at the reporting website. The agency has also focused on encouraging paediatric Yellow Card reports as part of a wider paediatric strategy. In both cases the intention is to maximise safety reporting from these different population groups.

It is vital that the information patients receive and access about their medicines is of a high standard to help address health inequalities and empower patient choice. The agency continues to work with providers of medicines information to improve the quality and the accessibility of the information: making it accessible at the right time and in the right format for patients.

Through the Early Access Scheme and the work underway on adaptive licensing (discussed elsewhere in this report), the agency is also actively making changes to enable patients to get access to products as soon as safely possible.

NIBSC has secured new research funding as part of the 'European Research Infrastructures for Poverty Related Diseases' grant. This collaborative programme led by NIBSC, involves institutes from 10 countries and aims to speed up the development of new tools to combat a range of blood borne viruses.

The agency aims to increase the use of CRPD to support public health research internationally, which may include analysing health outcomes for different groups.

3 Strategic Report

3.1 *Performance against targets 2013/14*

Target	Evidence and measures	Rating	Comments
PM1 Medicines licensing – validation of applications	a) 100% of Type IA variations validated within 30 days of receipt.	Red	Not met 96% validated within 30 days of receipt.
	b) 98% of Type IB/II variations validated within 14 days of receipt.	Red	Not met 89% validated within 14 days of receipt.
	c) For new Marketing Authorisation applications, 100% of validation reports produced within 14 days.	Green	Met 100% of validation reports produced within 14 days.
	d) 98% of Change of Ownership applications granted within 42 days of receipt	Red	Not met 92% granted within 42 days of receipt.
PM2 Medicines licensing – assessment of applications	a) The assessment of applications for new Marketing Authorisations for UK only: 97% 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 99% DCP RMS in 70 days 99% DCP CMS in 100 days 100% MR in 50 days 100% Centralised Rapportuer/Co-Rapporteur 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 – 98% in 90 days Type IB – 97% in 30 days
PM3 Assessment of clinical trials and investigations	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 11.8 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 47 days.
PM4 Capturing and analysing adverse event reports – making reports available, issuing alerts and acting on signals	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 and nearly 100% available within 3 working days.
	b) Medical Device Alerts will be issued: 95% within 10 days, 100% within 15 days	Green	Met 96% published within 10 days and 100% published within 15 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 94% within 5 working days
PM5 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 net calendar days of grant of new authorisations 98% within 40 net calendar days of grant of the major variation	Green	Met 99% PARs completed 100% updates of PARs with major non-safety variations of clinical importance
PM6 Standards and control	a) Biologics standards supply - 93% of all materials supplied within 6 working days	Green	Met 95% of all materials supplied within 6 working days.
	b) Batch release activity - Completion of all requested OCABR and non-EU testing within agreed timelines: Time taken to issue Batch	Red	Part met/part almost met Batch release certificates: Over 99% certificates

	Release Certificate after last item received from the manufacturer should be no more than 10 days for Blood Products and 60 days for Vaccines.		issued within 10 days for Blood Products 100% certificates issued within 60 days for Vaccines
PM7 NIBSC research activity	a) >80 papers and scientific review articles authored in calendar year 2013.	Red	Not met 71 papers and scientific review articles authored.
	b) Over £2.5 million in externally awarded research grant/contract funding utilised in the financial year 2013/14.	Green	Met £3.3m annual outturn of externally awarded research grant/contract funding utilised.
PM8 Answering Freedom of Information requests, letters and Parliamentary Questions	a) 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.	Green	Met 96% replied to within 20 working days.
	b) Return responses to Parliamentary Questions (PQs) to the Department of Health by noon on the date specified in at least 80% of cases with less than 5% returned to MHRA by the Department for rewriting.	Green	Met 92% answered on time with a 2% rewrite rate. 103 PQs have been dealt with this year.
	c) Return Ministerial correspondence (POs) drafts to the Department of Health within 4 working days of receipt in at least 80% of cases with less than 5% returned to MHRA by the Department for rewriting.	Green	Met 88% answered on time with no rewrites.
PM9 Finance – income and expenditure position	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

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

3.1 *Commentary*

Over the course of the year the agency has met 18 of its 23 targets.

The targets which were not met relating to the validation of applications (PM1) were caused by a combination of staff absence and higher than anticipated application volumes, particularly during the summer and Christmas periods. The MHRA (the centre which these targets sit within) is looking at the introduction of new technology to increase efficiency in this area, alongside the introduction of new leave policies to maintain appropriate staffing levels during holiday periods. Whilst these targets were missed the performance figures demonstrate a continuation of improvement in these areas over the last two years, with great strides made and backlogs significantly reduced.

The target at PM6b (relating to batch release activity at NIBSC) has only narrowly been missed. Overall performance on certificates issued within 10 days for Blood Products was just over 99%. The other part of this target, certificates issued within 60 days for Vaccines, is on 100% (and therefore has been met).

The target at PM7a was not met this year. This target will not be measured next year (see section 9.1 of this document) and instead will be measured as part of the metrics being introduced in 2014/15.

3.2 *Statutory Basis*

The agency is a government trading fund that was established by the Medicines and Healthcare Products Regulatory Agency Trading Fund Order 2003 (SI 2003/1076), made under the Government Trading Funds Act 1973.

The trading fund order was amended in 2005 and further amended in 2014 by The Medicines and Healthcare Products Regulatory Agency Trading Fund (Appropriation of Additional Assets and Liabilities) Order 2014 to facilitate the transfer of the National Institute for Biological Standards and Control (NIBSC) in to the agency.

The agency's funding is structured as follows:

- All income for medicines regulation is derived from fees. In setting fees the agency takes account of full cost recovery rules as set out in HM Treasury's Managing Public Money.
- The majority of the income for devices regulation is received through a service level agreement with the Department of Health.
- Approximately 60% of NIBSC's revenue is derived from the fees charged for services, including the sale of biological standards, and from research funding. The Department of Health provides the remaining 40% to finance NIBSC's important public health functions.
- CPRD is operated as a joint venture with the Department of Health's National Institute for Health Research funded equally by the two parties to the joint venture.

Each of our centres operates with segmented accounts which highlight their respective trading positions, bearing their appropriate share of corporate services. The key principle is that the three centres do not cross-subsidise each other.

3.3 *The entity's employees*

Office locations

The agency operates from two main sites. Buckingham Palace Road (BPR) in London serves as the agency's headquarters at which the majority of MHRA, CPRD and corporate division staff are based. The site at South Mimms, Hertfordshire, is the base for NIBSC staff and some corporate division staff.

The agency also has significantly smaller office space in York, Welwyn Garden City and the British Pharmacopeia Commission Laboratory based at Teddington. The decision to close the Welwyn Garden City Office was taken during the financial year with the offices to be vacated during 2014, relocating the activity to the South Mimms site.

Staff resources

During the year an average of 1,214 permanent full-time equivalent staff were employed.

Recruitment

The agency recruits staff on the basis of fair and open competition, as well as selection on merit, in accordance with the Civil Service Code.

The main challenge to filling posts has come from recent changes in government legislation. This has led to an increased demand for particular types of roles across industry, such as Pharmacovigilance inspectors, which are required by pharmaceutical companies, who are able to offer salaries in line or above the market rate. These salaries are often offered with competitive benefits packages, which the agency cannot compete with. The approach of the recruitment team at the agency has been to source from Europe where salaries are often lower, but skill sets and standards are comparable, this is proving a positive approach. Recruitment has also been undertaken in Australia.

The agency recruited 139 staff during 2013/14

2013/14 - recruited by level	**Male**	**Female**
Executive Directors	1	1
Senior Civil Servants	3	2
Other Civil Service Staff	57	75
Total	**61**	**78**

Trade Unions

The agency has a framework agreement in place with recognised trade unions.

The Cabinet Office Facility Time Framework requires that Civil Servants who are accredited trade union representatives are required to spend at least 50% of their time delivering their Civil Service role and facility time costs should not represent more than 0.1% of the pay bill.

The agency is compliant with the Cabinet Office Facility Time Framework.

Prior to 1 April 2014 there were four full time accredited trade union representatives at the Department of Health; these were partly funded by the agency and contributed to agency business. However, in line with the new Facility Time arrangements, local trade union representatives at the agency are taking on more of these duties.

The agency holds established Industrial Relations Committee meetings quarterly; with additional formal meetings set up to discuss ad hoc topics as required.

Learning and development

The agency'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 and are met through appropriate means, including taking part in projects, coaching and shadowing, as well as traditional training courses.

During 2013/14 the agency ran a total of 131 training courses, with a total of 1032 attendances recorded. Towards the end of 2013/14 the agency transitioned to using Civil Service Learning (CSL) as the main provider for learning and development activity. This means that for the majority of training courses staff now attend open courses with other civil servants, enabling the sharing of ideas and experiences. As a result figures for internal training events and attendances are expected to fall during 2014/15 as staff will attend the open courses.

On 1 October 2013 the new civil service Performance Management system was introduced, as a result training sessions on the new system were run for both managers and staff in the agency. 36 training sessions were provided for 311 staff, giving a total of 158 days of training time.

Three more Management and Leadership Ignite programmes were run during the year, with 69 members of staff attending these programmes, taking the total number of managers who have completed the programme to 221. Over 80% of attendees continue to report that the programme met their objectives.

As part of the agency's programme of building management capability, a Performance Conversations programme of bite-size training was introduced for managers, including topics such as managing discipline and grievance, having return to work discussions, managing the probationary period and giving effective feedback in 1:1 meetings.

Coaching has continued to be made available to both managers and staff as required, and there is now a cross-government mentoring scheme available through CSL.

Continuing Professional Development (CPD)

The agency organises a number of events to support the continuing professional development of its staff. This includes supporting external training and qualifications, and professional subscriptions. There is an internal CPD lecture programme covering a variety of subject areas, alongside internal events and seminars such as lunch and learn sessions where external speakers are invited to give a presentation regarding a specific topic. The agency has links with Kings College London and a number of

other academic institutions, which enable access for example to courses and seminars run by such institutions.

Revalidation

During 2013 the agency developed its own guidance and training to ensure that medically qualified staff that it employs met the requirements of the General Medical Council (GMC) revalidation process. In addition to their line management appraisal, medically qualified staff had a strengthened medical appraisal to assess their professional competence in 2013. In preparation for this the agency developed extensive guidance and delivered training and workshops for both managers and staff. During 2014 the intention is to strengthen this process further to ensure all revalidation requirements continue to be met. Over the course of the year 16 medically qualified staff were revalidated.

Investors in people

The MHRA was awarded Investors in People (IIP) Bronze level accreditation for the second time in November 2012, which puts the agency in the top 16% of IIP accredited organisations. During 2013 work in people management and development which is aligned to the IIP Standard has continued with the next assessment scheduled for November 2015.

3.4 *Environmental matters*

Sustainable Development

The agency is committed to embedding sustainable development principles across the organisation with the aim of reducing the environmental impact of the agency's activities.

This section gives a brief overview of activities and initiatives that have been carried out in relation to sustainable development[‡] along with plans for the future. The agency operates from two main sites at South Mimms (Hertfordshire) and Buckingham Palace Road (BPR) (London). Data presented here is for both sites individually, where held, alongside a total figure.

Greenhouse Gas (GHG) emissions performance

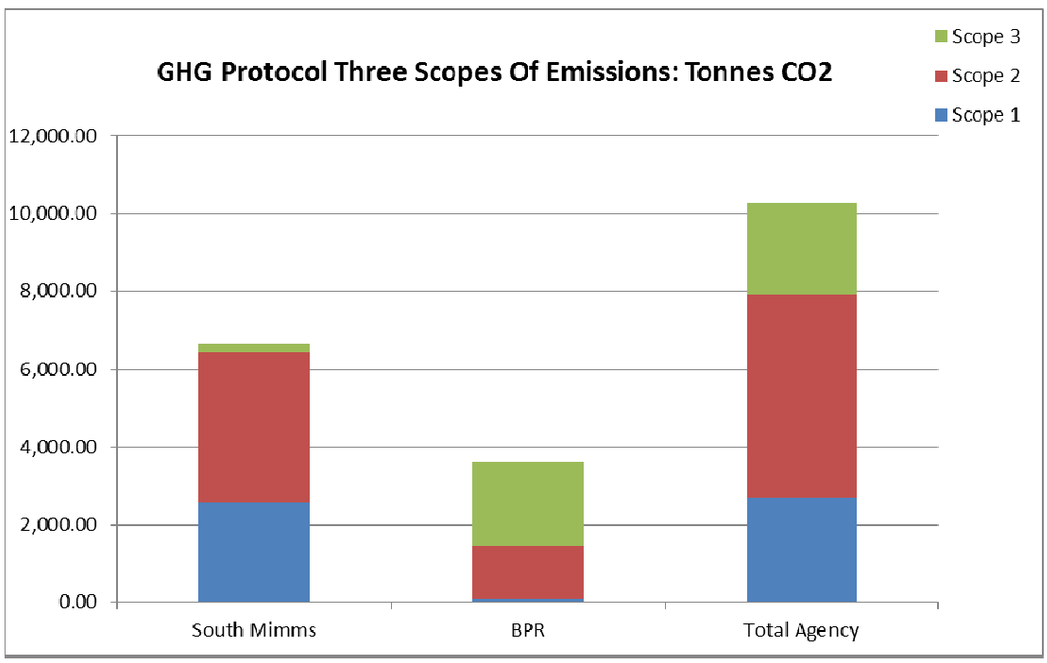
Following the enlargement of the organisation at the start of the year the agency has undertaken a considerable amount of work to establish its carbon footprint (for the agency this includes utility consumption, water supply, waste production, process emissions, employee business travel and movement of goods with the total figure shown in bold in the table below) which will serve as a baseline indicator and foundation from which to measure improvements.

The table below shows Greenhouse Gas Emissions for the baseline year 2013/14, including financial and non-financial indicators.

[‡] Following guidance provided by HM Treasury Public Sector Annual Reports: Sustainability Reporting Guidance 2013/14

GREENHOUSE GAS EMISSIONS		South Mimms	BPR	Total
GHG Emissions (tCO^2)	Total Gross Emissions	6,667	3,630	**10,297**
	Gross Gas Emissions	2,463	89	2,552
	Gross Electricity Emissions	3,875	1,372	5,247
	Gross Property Emissions	141	3	144
	Gross Transport Emissions	186	2,165	2,351
Energy Consumption ('000 kWh)	Gas Consumption	13,386	487	13,873
	Electricity Consumption	8,014	2,838	10,852
Financial Indicators (£k)	Expenditure on Energy	1,281	318*	1,599
	Expenditure on Transport	377	1,548	1,925

Notes:
1. * Expenditure on energy includes electricity only for BPR, as gas costs are consolidated into the service charge.
2. The data forms the first set of information available for the new organisation and so represents the baseline year, this data set will be added to each financial year to build on this.
3. Travel data includes international air and rail data. Transport includes courier and air freight data.
4. Carbon Reduction Commitment expenditure and the purchase of carbon credits is not relevant for this reporting year.

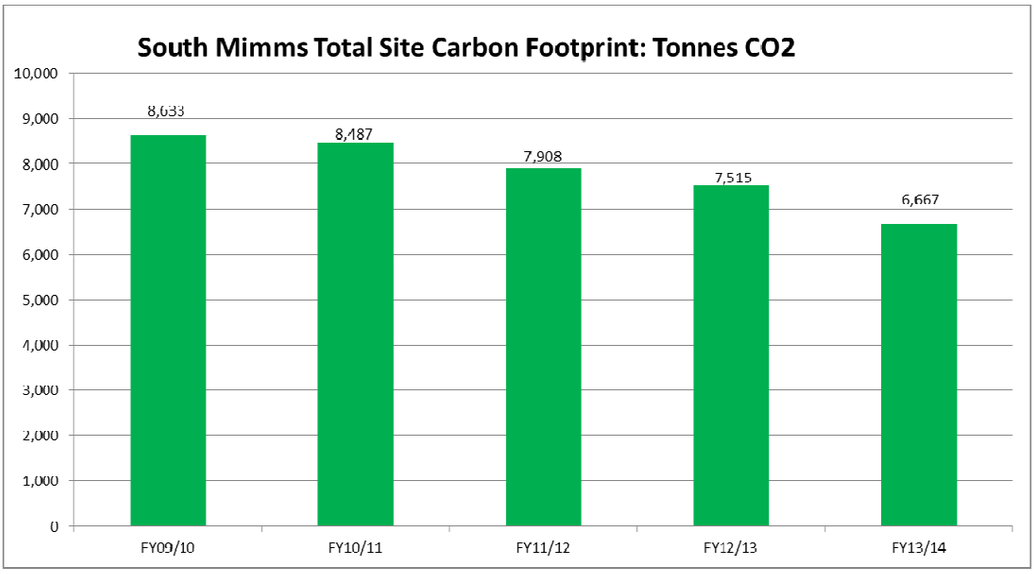


The GHG Protocol provides an international accounting framework for GHG emissions and divides these into 3 Scopes. The above graph shows the breakdown of these for the agency by giving the figure for the South Mimms and BPR sites, and the combined agency total. The scope types are as follows:

- Scope 1 emissions cover sources controlled by the agency and include gas consumption, fuel oil usage and fugitive emissions
- Scope 2 emissions cover electricity purchases
- Scope 3 covers all other emissions and is considered an optional reporting category, but has been calculated for the agency (this includes business activity such as water supply, waste usage, employee travel and movement of goods).

The Carbon Footprint[§] of the South Mimms site has been produced and recorded since 2009/10. The figure has fallen from 8,633 in 2009/10 to 6,667 in 2013/14 (both figures in tonnes CO^2) representing a reduction of 23% over this period, which is a significant achievement.

Prior to 2013/14 carbon emission data was not collected for the BPR site; however data has been compiled for this first year representing a significant step forward in understanding the impact on the environment of the entire new organisation. This exercise has established that the two sites have a very different impact from the emissions produced; with the BPR site having a significant impact from business travel and the South Mimms site having a significant impact from energy consumption.



Gas and electricity consumption

This is the first year that gas and electricity consumption have been collated for the BPR site, these figures will serve as a comparison to build on next year. Both gas and electricity consumption at the South Mimms site have been collected for the previous five years and have both shown significant reductions. A 20% reduction in gas consumption has been achieved, aided by the replacement of older boilers with more energy efficient versions. A total reduction at the site of 11% in electricity consumption has been recorded; numerous factors have contributed to this such as the replacement of old transformers, staff awareness initiatives and maintenance improvements.

[§] *Carbon Footprint calculations have followed the methodology set by Defra in the report: 2013 government GHG Conversion Factors for Company Reporting; Methodology Paper for Emission Factors, July 2013.*

Waste management performance

Waste management financial and non-financial indicators:

WASTE		South Mimms	BPR
Non-Financial Indicators (Tonnes)	Total Waste	235.63	97.46
	Landfill Waste	24.88	1.67
	Recycled Waste	136.35	32.21
	Incinerated / Energy Recovery	74.40	63.58
Financial Indicators (£k)	Total Disposal Costs	82	3
	Landfill Costs	2	U/A
	Recycled Costs	8	U/A
	Incinerated Costs	72	U/A

Note:

1. The breakdown of specific waste costs are unavailable (U/A) for BPR, as this is built into the service charge.

At the BPR site work has been undertaken to raise awareness and improve recycling habits, in particular the importance of segregating waste to avoid contamination.

At the South Mimms site rates of recycling have increased following both staff awareness initiatives and good management practices; with 58% of waste now being recycled, and a corresponding 85% reduction in waste sent to landfill over the last four years.

Finite resource consumption

Water consumption financial and non-financial indicators

WATER		TOTAL
Non-Financial Indicators (M3)	Water Consumption (Office Estate)	8,283
	Water Consumption (Other Estate)	33,779
Financial Indicators (£k)	Water Supply Costs (Office Estate)	U/A
	Water Supply Costs (Other Estate)	31

Notes: 1. The indicators cover data for sites at NIBSC and BPR, which are the two main MHRA sites.

2. The breakdown of specific water costs are unavailable (U/A) for BPR, as this is built into the service charge.

This is the first year water usage has been collated for the BPR site, and in common with the gas and electricity consumption figures this data will be serve as a comparison to build on year on year. Due to the nature of the work carried out at the South Mimms site water consumption is high. However, good progress has been made with savings of 27% realised this year (against a target of a 10% reduction over a three year period) this has largely been achieved through the replacement of older on-site equipment such as autoclaves and equipment washing machines with more efficient newer models.

Biodiversity and the natural environment

The South Mimms site has a staff allotment which is worked on at lunchtimes. The allotment helps biodiversity at the site and increases the types of plants grown and wildlife present. The site also installed a commercial food composter to allow canteen waste to be converted to compost; this saves on food waste disposal costs and represents a more environmentally friendly option.

Sustainable procurement

2013/14 saw the launch of a new resource reuse system called “Warp-It” at the South Mimms site. This system aims to initiate the re-use of business items between staff on a site. The system has proved to be very successful with savings of over £15,000 in the first half year period resulting from savings in the purchase cost and savings in disposal costs. It is anticipated that this system will be extended to the BPR site during 2014/15.

Staff engagement

Sustainable Development Working Groups (SDWG) have worked on a number of initiatives across both agency sites during the year, examples include:

- BPR: in February staff were encouraged to take part in cycle safety events organised by the local Business Improvement District, helping to raise awareness of this greener option for business travel.
- South Mimms: “Switch offs” (of lights and electrical equipment) and staff awareness initiatives have continued this year and typical savings of 10% have been achieved in energy consumption.

Future plans

The agency has registered for the Carbon Reduction Commitment Energy Efficiency Scheme which is now in its second phase. It is a mandatory scheme for qualifying organisations and requires the purchase of carbon credits to cover the total amount of carbon emissions produced each year. For the South Mimms site this is in the region of £100k pa and is another significant reason to target electricity and gas consumption. It also carries a rigorous mandatory (substantial) reporting requirement to provide site data to the government.

Work will continue into 2014/15 at both sites to explore and develop proposals, for example determining if renewables and the generation of onsite power would be a viable option at the South Mimms site.

The agency is committed to reducing the impact the organisation has on the environment and aims to bring further savings in energy consumption, water usage and waste volumes; and will endeavour to continue to embed sustainable development into the organisation.

Dr Ian Hudson
Chief Executive and Accounting Officer
Medicines and Healthcare Products Regulatory Agency
8 July 2014

4 Directors Report

4.1 *Financial performance*

The agency has produced a sustainable financial performance, despite the challenging business and economic conditions in the UK and globally which affects the agency's core markets for its services. As a government trading fund, the agency is funded mostly by income from its fees. Fee income in 2013/14 was £113.0m

The agency is required by a HM Treasury Minute (reproduced in section 16 of this document) for the five-year period from 1 April 2013 to 31 March 2018 to achieve a return, averaged over the period as a whole, of at least 3.5% in the form of an operating surplus on ordinary activities before interest (payable and receivable) and dividends expressed as a percentage of average capital employed. Capital employed consists of the all the agency's capital and reserves.

The operating surplus for the enlarged agency before interest and dividends for 2013/14 was £28.7m, compared to £12.2m for the agency as it was structured in 2012/13 before the merger with the National Institute for Biological Standards and Control. After finance costs and dividends of £12.9m, a net surplus of £16.2m arose in 2013/14 and has been transferred to reserves.

2013/14 has seen cash inflows from operating activities for the enlarged agency of £39.6m, compared to £24.7m in 2012/13 for the agency before the merger. The cash inflow arose from trading activities and efficient working capital management.

4.2 *Spend on consultancy and temporary staff*

During 2013/14, expenditure on consultants was £26k (£Nil in 2012/13).

The agency continues to employ temporary staff where it is of operational necessity. The agency temporary staff expenditure was £1,761k in 2013/14 (£1,617k in 2012/13).

4.3 *Supplier payment performance*

The agency is committed to the Better Payment Practice Code. The agency's policy is to attempt to pay all suppliers within five days of receipt of a valid invoice. The agency's systems recorded invoice date, rather than the date of receipt, so payment will have been faster than the recorded statistics.

In 2013/14 - 82% of supplier bills were paid by the enlarged agency within five days and 100% within 30 days. This compares to 94% within five days and 100% within 30 days in 2012/13. 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	23,400	35,054	82	15,230	26,882	94
6 - 10 days	2,065	22,822	8	770	16,033	4
11 - 30 days	1,716	9,349	8	237	1,196	2
Over 30 days	533	5,069	2	-	-	-
	27,714	**72,794***	**100**	**16,245**	**44,119**	**100**

* includes payments made for purchase of non- current assets (£14.2m) and 2012/13 dividend (£3.5m).

4.4 *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.

4.5 *Going concern basis*

Based on normal business planning and control procedures, the Agency Board has reasonable expectation that the agency 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.

4.6 *Pension liabilities*

These are covered in note 1.8.2 and 6.5 of the accounts.

4.7 *Exit Packages and Severance Payments*

These are covered in note 6.3 of the accounts.

4.8 *Off Payroll Engagements*

These are covered in note 6.4 of the accounts.

4.9 *Disclosure of relevant audit information*

As far as the Chief Executive is aware, there is no relevant audit information of which the agency'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 agency's auditors are aware of that information.

4.10 *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 agency trading fund under section 4(6) of the Government Trading Funds Act 1973. The auditor's remuneration payable is £90,000 for 2013/14. This compares to £80,000 for 2012/13.

On the 1st April 2013 the agency joined the Health Group Internal Audit operated by the Department of Health. The internal audit function provides an independent review of the systems and workings supporting the performance indicators reported in the annual accounts.

4.11 *Diversity and inclusion*

The agency values its diverse workforce and seeks to promote diversity and inclusion across the organisation and its activities.

- The agency operates a monitored system of fair and open recruitment, including a guaranteed interview scheme for people with disabilities
- The agency encourages all staff to access its wide range of excellent staff development opportunities
- The agency supports members of staff with disabilities through a formal reasonable adjustment policy.
- The agency uses staff survey data proactively to identify general concerns about bullying and harassment seeking early intervention through training and coaching.
- The agency has a 'Bullying and Harassment Policy' in place to ensure employees are aware of the behaviour expected of them and how the agency will tackle any issues raised, either formally or informally, where the policy has been contravened.

Historically the ethnic make-up of the agency's workforce has been broadly in keeping with the demographic of the agency's central London Head Office location. The merger with NIBSC, based in Hertfordshire has changed the expected demographic and there is some work to do during 2014/15 to collect complete workforce data and to benchmark it.

At the end of the year the ethnic breakdown of the agency's workforce (%) was as follows:

- White 61.1%
- BME 28.3%
- No data/ prefer not to say 10.6%

4.12 *Sickness absence*

The average annual sickness rate was 6.1 working days per full time equivalent employee (the Civil Service average is 6.4).

4.13 *Internal communications and employee engagement*

The agency actively encourages regular contact between managers and staff to involve members of staff both in the work of their team and the wider agency. Such contact includes regular one to one meetings between line managers and their staff, as well as team, divisional and all staff meetings; the latter being open to all members of staff and held twice a year at both BPR and South Mimms.

The agency holds a bi-annual conference for its managers alongside separate sessions in which the chief executive can discuss and consult with his senior leaders on the future direction of the agency.

Information is shared with staff in a number of ways such as by email, through the agency's intranet pages with updates on topical issues and on a monthly basis by means of a team brief. The team brief gives staff the opportunity to discuss and feedback on topics within their division. This feedback is collated centrally, with responses published on the agency's intranet.

The agency measures staff engagement through the annual Civil Service People Survey held every October. In 2013, 71% of staff took part in the survey and the agency's engagement index score was 59%, 2% down when compared to the previous year and 1% higher than the Civil Service average. In response to the results, each division produces an action plan to address issues raised by staff in that division.

During 2012, the agency developed an employee communications and engagement strategy. This outlines a number of initiatives to ensure that the organisation is a good place to work and aims to engage staff further with the agency's work – the challenges and opportunities it brings, and the role they play in it. The strategy will be refreshed during the course of 2014/15.

4.14 *Health and safety*

The merger with NIBSC in April 2013 altered the health and safety risk profile for the agency significantly. In order to fulfil its remit NIBSC must work with potentially hazardous materials, including human pathogens and radioactive substances. Other risks that need to be managed include exposure to noise, machinery, manual handling, ergonomic problems, stress, slips, trips and falls. Recognising this and the added risk from major organisational change related to the merger, an independent health and safety audit of NIBSC was commissioned. The audit, which was completed in April 2013, found much evidence to demonstrate that NIBSC takes health and safety matters seriously and devotes a significant amount of time and effort to managing its health and safety risks. The audit also reported that there is an impressive team of committed and competent staff who are able to guide NIBSC with the development and implementation of its health and safety arrangements and that there is good health and safety leadership at NIBSC. The audit concluded that whilst accidents do happen, the number of cases and root causes suggest that

management of risk is fundamentally sound and that there are good arrangements in place to learn lessons from incidents that arise and to implement steps to prevent recurrence. The audit made a number of recommendations for further strengthening health and safety arrangements, which formed the basis of an action plan for 2013/14, and these actions have been largely completed.

The nature of NIBSC's work is considered by the Health and Safety Executive (HSE) to place it in a high risk category, which entails regular HSE inspections and intervention plans. During 2013/14 four areas of NIBSC work were inspected. Three were found to be fully compliant with expectations and one broadly compliant. Recommendations from these inspections have been incorporated into actions plans for the coming year, and a further round of inspections has been agreed for 2015-16.

The increased overall risk profile for the agency has also been reflected in changes to the health and safety governance structure. A single advisory team has been established covering the whole agency, a new agency-wide strategy group has been established to drive improvement where judged necessary, and reporting mechanisms have been strengthened to both the Corporate Executive Team and the Agency Board. Work has been carried out over the year to harmonise several key health and safety policies across the organisation, including driving on business, immunisation and offsite working, and the BPR site has recently achieved a BSI 18001 certification on Occupational Health and Safety. A refresh of the content and the location of health and safety topics have made them far simpler for staff to locate on the agency's intranet pages and the agency has also been undertaking the Chartered Institute of Environmental Health (CIEH) health and safety training for its managers who are based at the BPR site, a programme of work approved by the Corporate Executive Team. Accident rates across the agency in 2013/14 showed a downward trend from previous years, and no reports were made under the Reporting of Injuries, Disease and Dangerous Incidents Reporting (RIDDOR) regulations.

4.15 *Data protection*

During the year there were no incidents that resulted in the loss of personal, or protectively marked agency data by employees.

All agency employees and 3rd party suppliers are required to undergo the annual 'Responsible for Information' training as mandated by the Cabinet Office on how to identify and protect information.

The CPRD operates under very strict governance and has achieved the highest level of governance compliance related to ethical uses and the issues around privacy and confidentiality. It achieves this by working with "effectively anonymised" coded data and its operation in this respect is fully Caldicott 2 complaint.

As well as the anonymised coded data, CPRD (General Practice Research Database (GPRD) until 2012) had been downloading text that was used in some detailed, fully anonymised, research projects to enhance significantly the potential value of the research output. CPRD was made aware of a need to change the way it anonymised the text and ensure fair processing and as a consequence is now not loading any new text to its research information system, pending developments that will ensure any future system meets all the legal and governance requirements.

See section 13.14 for further information on significant governance issues this year.

4.16 *Risks and uncertainties at 31 March 2014*

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

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

Further information on the agency approach to managing its strategic risks can be found in the Annual Governance statement (section 14).

Risks	Mitigating factors and actions
Financial risk: Failure to meet statutory and public health roles due to reduced funding.	• Changes in work practices to increase efficiency. • Alternative funding fees paper presented to HM Treasury.
CPRD fails to meet its Key Performance Indicators.	• KPI's are monitored by CPRD senior management team during its fortnightly meetings.
A lack of clarity on the part of the Health and Social Care Information Centre may lead to confusion about responsibilities.	• Close scrutiny of the roles of CPRD and HSCIC undertaken by CPRD senior management team.
The poor quality and lack of proper security control of staff data.	• Data cleansing exercise being undertaken.

4.17 *Directors statement with respect to conflict of interest*

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

Dr Ian Hudson
Chief Executive and Accounting Officer
Medicines and Healthcare Products Regulatory Agency
8 July 2014

5 Better regulation

Better regulation is an important government agenda, aiming to minimise bureaucracy for businesses and front-line staff in the public sector and delivering better public services.

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

- Theme 1 - Life Sciences and Growth - captures the work that the agency and stakeholders are undertaking to identify whether earlier access to medicines is viable considering both potential risks and benefits. It also explores how we can continue to make the UK an attractive environment for clinical trials;
- Theme 2 - EU/International Regulation - captures the issues arising from the development of EU law that the agency needs to influence to ensure the right outcomes, or that are transposed into UK law;
- Theme 3 - Regulatory Policy Development – covers the work undertaken by the Policy division to develop and support regulatory policy;
- Theme 4 - Burden Reduction/Simplification - covers the work which is planned to reduce burdens or simplify regulation; and
- Theme 5 – Regulatory Strategy – the work undertaken to support the Programme and set its strategic direction.

2013/14 has been a busy year for EU negotiations, with the agency leading for government on three negotiations and playing a major part in a fourth. There was an agreement on the EU Clinical Trials Regulation at the end of 2013, revising and simplifying the current regime for authorising clinical trials in line with government objectives to make the EU a more attractive place to conduct trials; this is expected to enter into force in mid-2016. An agreement was reached on the fee system for EU pharmacovigilance work, ensuring that the new EU pharmacovigilance legislation can now be fully implemented.

The revision of the Tobacco Products Directive was also agreed, introducing EU-wide rules from 2016 for the regulation of nicotine-containing products (NCPs), like e-cigarettes, either as medicines or under a stand-alone regime. The agency continues to encourage companies to license NCPs as medicines.

All three pieces of EU legislation are going through the final stages of approval before becoming law. Finally, negotiations are continuing on strengthening the EU legislative framework for medical devices through improved pre-market assessment by notified bodies, coupled with strengthened vigilance and post-market surveillance to ensure safety of devices whilst encouraging innovation.

There has been strong and constructive agency input into government work on life sciences and innovation. The agency-chaired Expert Group on Innovation in the Regulation of Healthcare published its report after 18 months of wide-ranging discussions. One of the areas of discussion was around early access, and the government announced a scheme in March 2014, to be launched in April. The early access scheme is designed to allow earlier patient access to promising new medicines to treat life threatening or seriously debilitating conditions before these are

licensed. It includes a Promising Innovative Medicine designation to identify promising candidates for the scheme early on in the drug development process. The other major area for discussion was on “adaptive licensing”. The group concluded that adaptive licensing was aimed at more proactive use of existing flexibilities in the EU medicines framework. The agency has been a leading player in a discussion group on adaptive licensing set up by the European Medicines Agency, working towards a pilot at EU level on adaptive licensing.

The agency was also involved in leading a regulatory workstream of an on-going project under the Ministerial Industry Strategy Group on pharmaceutical manufacture in the UK. This concluded that international work on globalised harmonisation of inspections was seen as the priority area for industry.

The agency has, at the request of the Parliamentary Under Secretary of State for Health, established the Herbal Working Group to provide recommendations to the government on how to solve the complex area of herbal practitioner regulation and the associated access to unlicensed herbal medicinal products. The first meeting of the group took place on 30 January 2014; the group is scheduled to deliver its recommendations in 2015.

As part of the work to reduce the burden on industry, the agency has actively participated in the cross government Red Tape Challenge. The agency’s Red Tape Challenge sought suggestions from stakeholders on how to simplify processes and reduce bureaucracy. Building on the 2012 consolidation of legislation this year two business process changes were introduced: (“do and tell” notification for parallel importers and the Coordinated, Composite Collection “CCC” approach for assessing multiple changes to the same marketing authorisation.) Industry figures collected through Business Engagement Assessments under the Accountability for Regulator Impact put these savings at £29m per annum for businesses.

The Medicines Industry Liaison Group (MLG), previously established to facilitate the Agency’s work with industry on, in particular, monitoring the Red Tape Challenge implementation, continued to meet on a quarterly basis and assist in the generation of burden reduction measures and prioritisation whilst maintaining effective relationships between the agency and industry stakeholders.

The agency is also transitioning to the gov.uk website whilst at the same time working to review and subsequently reduce the amount of guidance it publishes. This will deliver a better and more targeted service to the agency’s customers with the added benefit of locating all government services in a single digital location.

The agency is currently in the process of developing and finalising the next burden reduction strategy which will detail the programme for future burden reduction measures that will be taken forward within the next financial year. These measures will be agreed and prioritised to ensure the agency obtains the best value for its resource deployment.

6 Transparency

The government is committed to transparency in the area of clinical trials and believes it is important for patients, researchers and the NHS and can be achieved through ensuring trial registration and outcome publication.

The government supports the European Commission's proposal for greater transparency under the new Clinical Trials Regulation which provides a clear legal basis for public access to an EU database including all trial documentation and summaries of the results of all clinical trials conducted in the EU. In addition, where a trial is used to support a Marketing Authorisation application, the Clinical Study Report must be submitted by the applicant within 30 days of the authorisation (rejection or withdrawal).

The agency is engaged in a programme of work to take stock of the current position, in relation to information the agency receives, and its holdings; and to form a position, in line with DH and wider government objectives, on future and retrospective release of information. This will contribute to a work stream feeding into development of the European Medicine Agency's policy of disclosure, which is currently the subject of legal action.

6.1 *Freedom of Information*

The agency continues to make information available routinely on its website, and by disclosure under the Freedom of Information Act (FOIA). Successful or partly successful requests are listed each month in summary form on the website, with the original, anonymised, request and subsequent agency disclosure available on demand.

The year saw a significant increase in the number of FOIA requests handled, with 573 (+27%) requests made to the agency during the year ending April 2014, and 566 (+27%) answered, of which 401 (+21%) were answered in full or in part.

The divisions responsible for medicines inspection/enforcement activities (28%), licensing of medicines (25%), pharmacovigilance (25%) and medical devices (10%) accounted for the majority of requests. Industry was the most frequent requester (41%), with other significant requester groups being the public (34%), journalists (5%) and the legal profession (7%). It should be noted that as the Act does not require a requester to state whether or not they are representing a particular group or organisation, that the category "public" may contain requesters so affiliated, but who do not wish this to be known.

Requests for internal reviews increased from six to seventeen. The requests requiring review were varied, although the issues of breast implants and Nicotine Replacement Therapies featured on more than one occasion. There were three Information Commissioner investigations of agency decisions resulting in Decision Notices - all upholding the original decision - and there were no new Tribunal cases during this year.

6.2 *Parliamentary Questions*

The agency 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 Agency exceeded its targets of meeting its PQ and PO deadlines 80% of the time, with 92% of PQs and 88% of POs being answered on time (an increase in performance of 2% and 3% respectively).

In addition to regular areas of interest – typically relating to the safety of medicines and devices, clinical trials etc – there were also questions concerning topical matters such as early access to medicines, electronic-cigarettes, and animal testing.

6.3 *Contractual arrangements*

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

The contract for travel and hotel bookings is with Hogg Robinson. The contract for scientific analysis work is with LGC Limited.

7 External Communications

Effective communication is a critical requirement in ensuring the agency achieves the aims and strategic objectives, as set out in the Corporate Plan 2013-2018. The agency has a communications strategy in place which recognises the diverse messages which the agency delivers, the diverse audience which these messages need to reach and the different means of delivery.

The agency‘s media relations team works to build and maintain relationships with the media sector, recognising that they are not only an audience, but also a channel through which agency messages reach other audiences.

The agency uses events and conferences to update primarily industry but other stakeholders too about changes in regulations and procedures affecting a wide range of areas from manufacturing and distribution through to advertising. These events are well attended, receive positive feedback and help to build and sustain strong relationships. These events also provide an important source of income for the agency which was in the region of £600,000 in 2013/14.

In common with other government departments the agency strives to offer as much information as possible through its website as part of the digital by default agenda and has been working to migrate content to the GOV.UK website to which the agency will transition in 2014/15.

7.1 *Enquiries received via customer services*

In terms of providing information on a reactive basis one of the ways in which individuals or organisations can submit enquiries to the agency is by contacting the customer services team.

During the past year customer services dealt with 23,000 telephone calls and 26,000 emails from the full range of agency stakeholders - including members of the public. This is the first year that emails received have been higher than telephone queries, showing a change in customer preferences. Enquiries received through either channel are dealt with immediately wherever possible. The team uses various resources, their own knowledge and the website to answer enquiries, with enquiries transferred elsewhere in the agency when appropriate.

The team works 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 agency is responsive to the information customer’s request.
The quality of the telephone service is measured by a mystery shopping service, whilst an email feedback area captures customer feedback on the service they have received.

The team received full accreditation from Customer First following an assessment in January 2014 which tested the performance across three key categories: building customer relationships, maximising market awareness and developing people.

7.2 *Public and stakeholder engagement*

One of the sub-strategies of the communications strategy is patient, public and stakeholder engagement which has been in place since October 2012 and outlines the agency's commitment to engage with a wide range of stakeholders including patients and the public.

The agency believes that openness and transparency are critical to building trust and confidence; as such agendas and papers from the Patient, Public Engagement Expert Advisory Group are available without restrictions on our website. An example of the type of work carried out as part of the strategy are meetings between patients and the agency to discuss adverse reactions to medical products with the aim of listening to the concerns of the patient and providing detailed responses to address any concerns and to explain the regulatory process. Meetings with a selection of patient groups take place twice a year to consider and discuss areas of interest during the medicines licensing process.

Significant progress on this agenda has been achieved this year. Notable successes include the approval by the Commission on Human Medicines (CHM) of a pilot project to involve patients in licensing decisions. The proposal for this was developed by a Task and Finish group of the Patient and Public Expert Advisory Group. On the patient side, mention has already been made of the development of a pilot patient group consultative forum. This year has seen a programme of stakeholder engagement with healthcare professionals which has been used to inform the development of the paediatric Yellow Card project. The agency also completed its first audit to assess external stakeholder's perceptions of the agency; the findings from this work will inform a number of strategic projects over the course of 2014/15. The agency has worked in partnership with NHS England and has led an extensive programme of stakeholder engagement to inform the development of the joint project to increase reporting of adverse incidents with medical devices and medication errors. The agency's e-newsletter for external stakeholders is now issued monthly and there has been greater support and involvement across the agency to encourage high quality engagement with patients and the public to respond to emerging issues and to support project development.

8 The future

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

The Corporate Plan sets out the external challenges and opportunities facing the agency 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 agency'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 agency 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 on the statutory duty to earn a 3.5% return on the agency's assets;
- The competitive position of the agency's 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 agency'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 devices regulation, as it becomes an increasingly collective and networked activity between national agencies;
- The cost recovery basis of the regulatory functions, with fees seeking just to 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; and
- The challenge of regulating two industries – medicines and devices – with highly globalised supply chains.

8.1 *Performance measures 2014/15*

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

No.	Activities	2014-15 Targets
PM1	Medicines licensing – validation of applications	a) For Type IB/II variations, 97% of scientific validation process completed within 14 days of case creation
		b) For new Marketing Authorisation applications, 97% of validation reports produced within 14 days of case creation.
		c) 97% of Change of Ownership applications validated or Request For Information (RFI) issued within 42 days of receipt.
PM2	Medicines licensing – assessment of applications	a) The assessment of applications for new Marketing Authorisations for UK only: 97% assessed in 150 days
		b) The assessment of applications for new Marketing Authorisations in European (MR, DC & Centralised) procedures: 97% assessed within the designated time
		c) The assessment of Type IB minor and Type II major variation applications in National and European (MR, centralised) procedures: 97% assessed within the designated time.
PM3	Assessment of clinical trials and investigations	a) The assessment of applications for clinical trials of medicines in the UK: 98% in 30 days (all trial phases) and an average time of 14 days (Phase I trials)
		b) Timescales for clinical investigation notifications for medical devices: maximum of 60 days with an overall average of 54 days or less
PM4	Capturing and analysing adverse event reports –making reports available, issuing alerts and acting on signals	a) Maximum timescales between receipt of reports and making them available for evaluation and analysis: For fatal and serious device adverse incidents: 95% within 2 working days and 100% within 3 working days
		b) Medical Device Alerts will be issued: 95% within 10 days, 100% within 15 days
		c) For fatal UK adverse drug reactions: 90% within 24 hours, 100% within 72 hours
		d) For serious UK adverse drug reactions: 95% within 72 hours, 100% within 5 days
		e) Ensure all UK potential signals (relating to medicines) from whatever source are acted on promptly: 85% initially evaluated within 5 working days

No.	Activities	2014-15 Targets
PM5	Publication of UK assessment reports for new Marketing Authorisations	Publish 98% of UK assessment reports for new Marketing Authorisations within 60 net calendar days of grant of new Authorisations
PM6	Standards and control	a) Biologics standards supply - 93% of all materials supplied within 6 working days
		b) Batch release activity – 99% of all requested OCABR and non-EU testing completed within agreed timelines: 8 days for Plasma Pools 10 days for Parenterals 15 days for Haemostasis 60 days for vaccines
PM7	CPRD activity	a) To enable 280 research studies in 2014/15.
		b) To double (8% to 16%) the population cover of primary care data within the CPRD system by the end of the financial year.
PM8	Answering Freedom of Information requests, letters and Parliamentary Questions	a) 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.
		b) Return responses to Parliamentary Questions (PQs) to the Department of Health by noon on the date specified in at least 80% of cases with less than 5% returned to MHRA by the Department for rewriting.
		c) Return Ministerial correspondence (POs) drafts to the Department of Health within 4 working days of receipt in at least 80% of cases with less than 5% returned to MHRA by the Department for rewriting.
PM9	Finance – income and expenditure position	Achieve an income and expenditure surplus during 2014-15, and as a minimum, exceed a 3.5% per annum return on capital employed.

9 Agency Board

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

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

In particular this includes:

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

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

The Board, 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 executive. 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 Corporate Executive Team (CET) directors and their staff, and of the expert advisory committees.

The Board members use their experience and expertise and meet these responsibilities by:

- meeting on a regular basis
- attending sub-committees e.g. Audit and Risk Assurance Committee
- considering strategy papers from the CET and other agency staff as necessary
- attending occasional agency events including all staff meetings, agency annual lectures and informal briefing meetings with executive staff where necessary.

9.1 *Board member biographies*

The Board 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

[*] The Board carried a vacancy following Sir Alan Langlands' resignation in September 2013.

re-appointment for a further three year term. AB members come from a variety of medical, scientific, legal, administrative and political backgrounds.

Professor Sir Gordon Duff

Sir Gordon took up his 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.

Professor Dame Valerie Beral

Dame Valerie studied medicine at Sydney University, Australia. After a few years of clinical work in Australia, New Guinea and the UK, she spent almost 20 years at the London School of Hygiene & Tropical Medicine working in the Department of Epidemiology.

In 1988 she became the Director of the Cancer Epidemiology Unit in Oxford. Major focuses of her research include the role of reproductive, hormonal and infectious agents in cancer.

She is Principal Investigator for the Million Women Study and leads the international collaborations on breast, ovarian and endometrial cancer.

Professor Barrington Furr, OBE

Professor Furr 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

Mr Hindle 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 East Midlands Academic Health Sciences Network and non-executive director of Public Health England (PHE).

He 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 Chairman of University Hospitals of Leicester NHS Trust, a Non-executive Director of the Health Protection Agency, National Blood Authority, and the National Biological Standards Board.

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

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 Year's Honours list for services to the pharmaceutical industry.

Professor Sir Alex Markham

Professor Markham has made contributions to medical science in various fields and is accredited in pathology and internal medicine. His commercial experience includes the worldwide development of DNA Fingerprinting for forensic and medico-legal applications which was recognised by the Queen's Award for Technological Achievement in 1990.

A Fellow of the Academy of Medical Sciences, Professor Markham has previously served as a Board Director of the International Union against Cancer (UICC), as Chairman of the National Cancer Research Institute (NCRI) in the UK , and has been a member of the UK Clinical Research Collaboration Board and the National Institute of Health Research Advisory Board. He was a member of the Government's Cancer Reform Strategy Advisory Board, and chaired its Clinical Outcomes Group.

Professor Markham was Chief Executive of Cancer Research UK for 4 years from May 2003-2007, when he returned to academic work at Leeds University. He received a knighthood in the 2008 New Year's Honours for services to medicine.

Deborah Oakley

Ms Oakley'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. She was a board member of the Health Protection Agency from 2009 until it's abolition in 2013. She chaired the Biological Medicines Technical Committee. She also served on the board of NHS Camden from 2007 to 2011 where she chaired the audit committee.

Professor David Webb

Professor Webb is a Clinical Pharmacologist who undertakes basic, translational and clinical research in pursuit of developing safe and effective medicines for the treatment of hypertension and chronic kidney disease.

He holds the Christison Chair of Therapeutics and Clinical Pharmacology at the University of Edinburgh, and is a consultant physician and toxicologist at the Royal Infirmary of Edinburgh, running Edinburgh's Hypertension Excellence Centre. In addition, having created Edinburgh's Centre for Cardiovascular Science, he now directs a Scottish Translational Medicine and Therapeutics Initiative funded by the Wellcome Trust.

He is Honorary President of the European Society for Clinical Pharmacology & Therapeutics and President-Elect of the British Pharmacological Society and has been the Chair of the Scottish Medicines Consortium, President of the Scottish Society of Physicians and Vice-President of the Royal College of Physicians of Edinburgh.

John Williams, CBE

Previously a Consultant Surgeon, specialising in Oral and Maxillofacial Surgery, Mr Williams was Dean of the Faculty of Dental Surgery of the Royal College of Surgeons of England and Vice Chairman of the Academy of Medical Royal Colleges as well as Vice President of the Royal College of Surgeons.

Appointed as the inaugural Chairman of the Committee on Safety of Devices of the MDA, he was involved in the merger with Medicines to form MHRA, transferring there with the amalgamation.

Formerly President of the British, European and International Associations of his speciality, he served for 10 years as Secretary General of the EACMFS before being elected President of that organisation. His particular surgical interests were in facial injuries, where he was author of a major reference work and Malignant Disease of the cranio-facial region.

He was honoured by the appointment as CBE in 1999 for services to patients and the surgical and dental professions.

9.2 *Former members*

Sir Alan Langlands

At the time of his departure from the Board, Sir Alan was the serving 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.

Sir Alan resigned from the Board in September 2013 to take up the post of vice-chancellor at the University of Leeds.

Dr Shelley Dolan

Dr 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 she was appointed to the Clinical Advisory Group for Healthcare for London.

She resigned from the board in May 2013 having served two terms.

Professor Angus Mackay, OBE

Professor Mackay, 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.

Professor MacKay left the board in May 2013.

10 Corporate Executive Team

The Corporate Executive Team (CET) is the highest executive decision-making body of the agency. The CET is chaired by agency's Chief Executive Dr Ian Hudson and comprises the directors of each of the MHRA's operating divisions, the directors of the National Institute for Biological Standards and Control (NIBSC) and Clinical Practice Research Datalink (CPRD), directors from the agency's corporate divisions 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.

10.1 *The team*

Dr Ian Hudson

Dr Hudson became Chief Executive of the Medicines and Healthcare Products Regulatory Agency in September 2013.

He is a physician who practised as a paediatrician for a number of years, before working in the pharmaceutical industry in clinical research and development between 1989 and 2001, when he joined the former MCA (Medicines Control Agency) as Director of the Licensing division.

Before being appointed as chief executive, Dr Hudson was the MHRA's Licensing Director, responsible for the majority of its medicines licensing activities. He was also the UK delegate to the Committee for Human Medicinal Products (CHMP) and was its vice-chairman from October 2012 to September 2013.

Rachel Bosworth

Rachel Bosworth took up the post of Director of Communications in 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 in 2006. Peter joined the Agency 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 London health authorities and the Court Service, an executive agency managing the criminal and civil justice systems in England and Wales. He has also been a non-executive

Director of Harrow Primary Care Trust and a Director and trustee of London Lighthouse, an independent sector HIV/AIDS service provider.

Gerald Heddell

Gerald Heddell took up the post as Director of the Inspection, Enforcement and Standards (IE&S) division in 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.

Stephen Inglis

Stephen Inglis became Director of the National Institute for Biological Standards and Control in 2002.

He joined NIBSC following 10 years' experience in the biotechnology industry developing vaccines and immunotherapeutics, latterly as Research Director of Cantab Pharmaceuticals. From 1980-1990 he was a Lecturer in the Department of Pathology at Cambridge University specialising in research on the molecular biology of RNA viruses.

He trained initially in biochemistry at Aberdeen University and gained a Ph.D. in molecular virology from Cambridge University in 1978. He has served on a number of national advisory bodies including the Joint Committee for Vaccine and Immunisation, the Joint Professional Advisory Committee to the UK Blood Services, and the Scientific Pandemic Influenza Committee.

Dr Siu Ping Lam

Dr Siu Ping Lam joined the CET in September as Acting Director of Licensing division when Dr Hudson moved into the role of chief executive.

He has over 24 years' experience in medicines regulation. During this time he has shaped many changes in European Directives for Pharmaceuticals, set up the Traditional Herbal Medicines Registration scheme, the Homoeopathic Medicines Registration scheme and the Medicine/Device combination consultation operation. He was UK delegate to a number of European Commission Working Parties.

He gained his first degree in Pharmacy from the University of London, qualified as a pharmacist and practised in community and hospital pharmacies. He gained a PhD in Pharmaceutical Chemistry at King's College London (KCL) as a Croucher Scholar and, before joining the Medicines Control Agency (MCA) in 1989, the predecessor organisation of MHRA, was a Maplethorpe Fellow at King's (KCL) with research interests in drug metabolism and pharmacokinetics. Siu Ping is a Fellow of the Royal Pharmaceutical Society of Great Britain.

Jonathan Mogford

Jonathan Mogford joined the MHRA from the Department of Environment, Food and Rural Affairs (DEFRA) where he was heading up its 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.

John Quinn

John joined the agency in February as Chief Information Officer (CIO).

John was previously Head of Business Solutions at the Department of Education, where he led the delivery of the IT strategy, project and programme management and knowledge management.

He has worked primarily in the education sector at the Learning and Skills Council and Department of Children, School and Families since joining the Civil Service in 1994.

Dr June Raine, CBE

Dr June Raine, Director of Vigilance and Risk Management of Medicines division (VRMM), 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.

10.2 *Former members*

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.

Sir Kent retired in September 2013.

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.

Alison left the agency in November 2013.

Geoff Le Fevre

Geoff Le Fevre joined the MCA (Medicines Control Agency) in March 2002 as Head of Human Resources (HR) 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.

Geoff retired on 8 July 2013.

Rebecca Starling

Rebecca Starling took up the post of Director of HR on 23 September 2013, Rebecca was previously the Assistant Director of HR at the University of Cambridge.

She has also held a number of HR roles in a range of public and private sector organisations including the Serious Organised Crime Agency, PA Consulting Group, DWP Job Centre Plus, Foreign and Commonwealth Office and BP.

Rebecca left the agency in March 2014.

Joanna Billan

Joanna Billan was acting Director of HR from July until September 2013 to cover the transition until Rebecca Starling joined. Joanna had served as Deputy HR Director for the preceding 6 years.

Prior to this Joanna had a number of roles both in the public and private sector working across a number of spectrums within HR, including strategy and organisation change, employee relations, leadership and development. Joanna is an accredited coach and a chartered member of the Chartered Institute of Personnel and Development (CIPD).

Joanna left the agency in February 2014

11 Remuneration report

11.1 *Remuneration policy*

It is the aim of the Medicines and Healthcare Products Regulatory Agency 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.

11.2 *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.

Other than the Chief Executive, 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.

11.3 *Remuneration (including salary) and pension entitlements*

The section below provide details of the remuneration and pension interests of the most senior management (i.e. Corporate Executive Team and Agency Board members) of the agency. Corporate Executive Team members' salary and bonus awards were decided by a pay committee whose members were Professor Sir Kent Woods, Professor Vincent Lawton, CBE (Non-Executive Director) and Simon Claydon (DH HR Deputy Director).Dr Ian Hudson 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.

11.4 *CET remuneration, bonus and benefits table*

2013/14	Salary £'000	Performance pay and bonuses £'000	Pension related benefits £000	Total £000
Dr Stephen Inglis Director of NIBSC[1]	170 – 175	Nil	Not available**	170 – 175
Dr June Raine, CBE Director of Vigilance & Risk Management of Medicines	125 – 130	10 – 15	10.0 – 12.5	145 – 150
Mr Peter Commins Chief Operating Officer	125 – 130	Nil	27.5 – 30.0	150 – 155
Dr Ian Hudson Chief Executive[2]	135 – 140	Nil	37.5 – 40.0	170 – 175
Mr Gerald Heddell Director of Inspection, Enforcement and Standards	105 – 110	10 – 15	27.5 – 30.0	140 – 145
Mr John Wilkinson, OBE Director of Devices	115 – 120	Nil	45.0 – 47.5	155 – 160
Dr John Parkinson Director CPRD	100 – 105	Nil	2.5 – 5.0	100 – 105
Professor Sir Kent Woods Chief Executive[3]	60 – 65	Nil	N/A	60 – 65
Ms Rachel Bosworth Director of Communications	95 – 100	Nil	12.5 – 15.0	105 – 110
Mr Jonathan Mogford Director of Policy	90 – 95	Nil	37.5 – 40.0	125 – 130
Mrs Alison Davis Director of Information Management[4]	60 – 65	Nil	15.0 – 17.5	75 – 80
Dr Siu Ping Lam Acting Director of Licensing[5]	60 – 65	Nil	35.0 – 37.5	95 – 100
Mr Geoff LeFevre Director of Human Resources[6]	25 – 30	5 – 10	(7.5 – 10.0)	20 – 25
Ms Rebecca Starling Director of Human Resources[7]	45 – 50	Nil	(2.5 – 5.0)	40 – 45
Mr John Quinn Chief Information Officer[8]	15 – 20	Nil	17.5 – 20.0	30 – 35
Mrs Joanna Billan Acting Director of Human Resources[9]	10 – 15	Nil	5.0 – 7.5	15 – 20

Band of the highest paid directors total remuneration	170 – 175
Median total	38,298
Remuneration ratio	4.5

***** Corporate Executive Team members receive no 'benefits in kind'.
** NHS Pensions have not been able to provide this information.

[1] Dr Stephen Inglis joined the CET following the merger with NIBSC on 1st April 2013.
[2] Dr Ian Hudson was appointed Chief Executive with effect from 21st September 2013, prior to this date his title was Director of Licensing. The full year equivalent is 145-150.
[3] The agency received from University of Leicester invoices with a total of £41,173.10 relating to April & May 2013. From 1st June to his leaving date of 20th September 2013 Professor Sir Kent Woods was paid through the agency payroll.
[4] Mrs Alison Davis left the MHRA on 1st November 2013.
[5] Dr Siu Ping Lam was appointed as Acting Director of Licensing with effect from 21st September 2013. The full year equivalent is 100-115.
[6] Mr Geoff LeFevre retired from the agency on 8th July 2013.
[7] Ms Rebecca Starling was appointed as Director of Human Resources with effect from 23rd September 2013 and left on 21st March 2014.
[8] Mr John Quinn was appointed Chief Information Officer with effect from 1st February 2014. The full year equivalent is 90-95.
[9] Mrs Joanna Billan was Acting Director of Human Resources from 8th July 2013 to 30th September 2013.

2012/13	Salary £'000	Performance pay and bonuses £'000	Pension related benefits £000	Total £000
Professor Sir Kent Woods Chief Executive	190 – 195	Nil	N/A	190 – 195
Mr Peter Commins Chief Operating Officer	125 – 130	5 – 10	80.0 – 82.5	210 – 215
Dr Ian Hudson Licensing Director	125 – 130	5 – 10	57.5 – 60.0	185 – 190
Dr June Raine, CBE Director of Vigilance & Risk Management of Medicines	120 – 125	Nil	7.5 – 10.0	125 – 130
Mr John Wilkinson, OBE Director of Devices	110 – 115	Nil	45.0 – 47.5	155 – 160
Dr John Parkinson Director CPRD	100 – 105	5 – 10	80.0 – 82.5	185 – 190
Mr Gerald Heddell Director of Inspection, Enforcement and Standards	105 – 110	Nil	40.0 – 42.5	145 – 150
Ms Rachel Bosworth Director of Communications	95 – 100	Nil	25.0 – 27.5	120 – 125
Mrs Alison Davis Director of Information Management	95 – 100	Nil	35.0 – 37.5	130 – 135
Mr Geoff LeFevre Director of Human Resources	90 – 95	Nil	10.0 – 12.5	100 – 105
Mr Jonathan Mogford Director of Policy	85 – 90	Nil	7.5 – 10.0	90 – 95

Band of the highest paid directors total remuneration	190 – 195
Median total	38,134
Remuneration ratio	5.05

11.5 *Agency Board remuneration, bonus and benefits table*

2013/14	Salary £'000	Benefits in kind (taxable) to nearest £100	Total £000
Professor Sir Gordon Duff Chairman[1]	60 – 65	800	60 – 65
Professor Vincent Lawton, CBE Non Executive Director	10 – 15	-	10 – 15
Dr Shelley Dolan Non Executive Director[2]	0 – 5	-	0 – 5
Professor Barrington Furr, OBE Non Executive Director	5 – 10	700	5 – 10
Professor Angus Mackay, OBE Non Executive Director	0 – 5	2,100	0 – 5
Mr John Williams, CBE Non Executive Director	5 – 10	900	5 – 10
Mr Martin Hindle Non Executive Director	5 – 10	1,100	5 – 10
Sir Alan Langlands Non Executive Director[3]	0 – 5	-	0 – 5
Ms Deborah Oakley Non Executive Director	5 – 10	-	5 – 10
Professor Dame Valerie Beral[4] Non Executive Director	0 – 5	-	0 – 5
Professor Sir Alexander Markham[4] Non Executive Director	0 – 5	600	0 – 5
Professor David Webb[4] Non Executive Director	0 – 5	-	0 – 5

Agency Board – Remuneration, bonus and benefits table 2012/13			
Professor Sir Gordon Duff Chairman	15 – 20	1,000	15 – 20
Professor Vincent Lawton, CBE Non Executive Director	10 – 15	-	10 – 15
Dr Shelley Dolan Non Executive Director	5 – 10	-	5 – 10
Professor Barrington Furr, OBE Non Executive Director	5 – 10	1,400	5 – 10
Professor Angus Mackay, OBE Non Executive Director	5 – 10	6,300	10 – 15
Mr John Williams, CBE Non Executive Director	5 – 10	800	5 – 10
Mr Martin Hindle Non Executive Director	0 – 5	200	0 – 5
Sir Alan Langlands Non Executive Director	0 – 5	-	0 – 5
Ms Deborah Oakley Non Executive Director	0 – 5	-	0 – 5

*Agency Board members received no performance pay, bonus or any pension related benefits

With the exceptions of Professor Sir Gordon Duff and Professor Vincent Lawton, CBE all Non Executive Directors full year equivalent salaries are in the range £5 – 10 thousand pounds.

[1] Professor Sir Gordon Duff commenced his role as Chairman on 1st January 2013
[2] Miss Shelley Dolan and Professor Angus Mackay OBE left the Agency Board on 31st May 2013
[3] Sir Alan Langlands left the Agency Board on 30th September 2013.
[4] Professor Dame Valerie Beral, Professor Sir Alexander Markham and Professor David Webb were appointed Non-Executive Director with effect from 1st September 2013.

11.6 *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 Agency and thus recorded in these accounts.

Benefits: The Agency'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 Agency.

Bonus: Bonus awards are based on performance levels attained and are made as part of the appraisal process. The awards reported in 2013/14 relate to performance in 2012/13 and the comparative awards reported in 2012/13 relate to performance in 2011/12.

11.7 *Pay multiples*

The banded remuneration of the highest paid director in the Agency in the financial year 2013/14 was £170-175k (2012/13, £190-195k). This was 4.5 times (2012/13, 5.05) the median remuneration of the workforce, which was £38,298 (2012/13, £38,134).

No employee received remuneration in excess of the highest paid director in 2013/14 (2012/13, 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.

11.8 *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:

	Real increase in pension and related lump sum at 60 Bands of £2,500	Total accrued pension at age 60 at 31 March 2014 and related lump sum Bands of £5,000	Cash Equivalent Transfer Value at 1 April 2013 * To nearest £1,000	Cash Equivalent Transfer Value at 31 March 2014 To nearest £1,000	Real increase in Cash Equivalent Transfer Value To nearest £1,000	Employers Contribution to stakeholder pension To nearest £1,000
Dr Stephen Inglis Director of NIBSC	2.5 – 5.0 plus lump sum of 0.0 – 2.5	45 – 50 plus lump sum of 85 – 90	802	820	80	20
Dr June Raine, CBE Director of Vigilance & Risk Management of Medicines	0.0 – 2.5 plus lump sum of 2.5 – 5.0	45 – 50 plus lump sum of 135 – 140	990	1,019	11	31
Mr Peter Commins Chief Operating Officer	0.0 – 2.5 plus lump sum of 0.0 – 2.5	75 – 80	1,285	1,394	24	31
Dr Ian Hudson Chief Executive	2.5 – 5.0 plus lump sum of 0.0 – 2.5	45 – 50	693	776	32	32
Mr Gerald Heddell Director of Inspection, Enforcement and Standards	0.0 – 2.5 plus lump sum of 0.0 – 2.5	15 – 20	290	324	25	26
Mr John Wilkinson, OBE Director of Devices	2.5 – 5.0 plus lump sum of 0.0 – 2.5	5 – 10	46	90	32	28
Dr John Parkinson Director CPRD	0.0 – 2.5 plus lump sum of 0.0 – 2.5	65 – 70	1,251	1,266	2	25
Ms Rachel Bosworth Director of Communications	0.0 – 2.5 plus lump sum of 2.5 – 5.0	20 – 25 plus lump sum of 60 – 65	339	374	9	23
Mr Jonathan Mogford Director of Policy	0.0 – 2.5 plus lump sum of 5.0 – 7.5	25 – 30 plus lump sum of 80 – 85	426	484	27	22
Mrs Alison Davis Director of Information Management	0.0 – 2.5 plus lump sum of 0.0 – 2.5	10 – 15	186	212	13	14
Dr Siu Ping Lam Acting Director of Licensing	0.0 – 2.5 plus lump sum of 5.0 – 7.5	35 – 40 plus lump sum of 105 – 110	640	702	31	15
Mr Geoff LeFevre Director of Human Resources	0.0 – 2.5 plus lump sum of 0.0 – 2.5	20 – 25 plus lump sum of 70 – 75	512	510	3	6
Ms Rebecca Starling Director of Human Resources	0.0 – 2.5 plus lump sum of 0.0 – 2.5	0 – 5	8	8	(4)	11
Mrs Joanna Billan Acting Director of Human Resources	0.0 – 2.5 plus lump sum of 0.0 – 2.5	15 – 20 plus lump sum of 55 – 60	289	299	8	3
Mr John Quinn Chief Information Officer	0.0 – 2.5 plus lump sum of 2.5 – 5.0	20 – 25 plus lump sum of 60 – 65	279	293	12	4

* 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

11.9 *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 member 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 worked out in accordance with The Occupational Pension Schemes (Transfer Values) (Amendment) Regulations 2008 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.

11.10 *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.

Dr Ian Hudson
Chief Executive and Accounting Officer
Medicines and Healthcare Products Regulatory Agency
8 July 2014

12 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 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 agency 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 Medicines and Healthcare Products Regulatory Agency 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 agency's assets, are set out in the chapter under Accounting Officers' in Managing Public Money, published by HM Treasury.

13 Governance Statement

13.1 *Introduction*

The Department of Health (DH) has appointed me as Chief Executive of the Medicines and Healthcare Products Regulatory Agency and HM Treasury have appointed me Accounting Officer for the Medicines and Healthcare products Regulatory Agency Trading Fund. As Accounting Officer, I have responsibility for maintaining a sound system of internal control that supports the achievement of the agency's policies, aims and objectives, whilst safeguarding the public funds and agency assets for which I am personally responsible, in accordance with the responsibilities assigned to me in the documents *Corporate Governance in Central Government Departments* and *Managing Public Money*.

This statement sets out the stewardship and control framework at the agency and the risks to agency performance. It explains how I have discharged my responsibility, as Accounting Officer, to manage and control the agency's resources in 2013/14. I took over stewardship of the Agency on 21st September 2013 after the retirement of my predecessor, Professor Sir Kent Woods. As part of my CEO induction programme, I attended a range of training courses. These have included media training, training as a Caldicott Guardian, and training for Senior Responsible Officer for the Regulation of Investigatory Powers Act (RIPA) and Public Accountability for new Accounting Officers. I also attended a training course on preparing to appear before a Parliament Select Committee.

13.1 *Scope of responsibility*

The agency 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 efficiently, effectively and economically.

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

13.2 *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 on-going 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.

13.3 *The agency's governance framework*

Corporate Governance is the way in which organisations are directed and controlled, and good governance is vital to effective financial and risk management. HM Treasury's *Managing Public Money* and *Financial Reporting Manual* require that I provide a statement on how I have discharged my responsibility to manage and control the agency's resources for which I am responsible during the year.

The agency 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 agency 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 agency has a Board, an Audit and Risk Assurance 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.

The agency's responsibilities and risk profile changed when the National Institute for Biological Standards and Control (NIBSC), previously part of the Health Protection Agency (HPA), became part of the agency on 1st April 2013. To prepare for the transfer of function, various work streams had been set up over the previous year to ensure a seamless integration. I can report that the systems and controls put in place delivered the objective of ensuring NIBSC carried on with business as usual when control transferred to the agency.

13.4 *The Agency Board*

The Agency Board consists of the agency Chairman and eight non-executive Directors. In addition senior executives attend as appropriate, including me in my role of Chief Executive. 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, a discussion has been initiated to consider the most appropriate way forward taking into account the nature of the agency's two-tier hierarchy of the CET with responsibility for the strategy, operational management and service delivery and the Agency Board whose role is to monitor the agency's strategic direction.

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 agency

responsibilities. Members also declare their interest in any items being discussed at Board meetings. Where potential conflicts of interests are identified, Board Members take no part in any discussions and are not involved in any decisions that relate to those matters.

13.5 *The Audit and Risk Assurance Committee*

The Audit and Risk Assurance 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; and 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 Audit and Risk Assurance 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 Agency's progress in implementing audit recommendations. The Committee is chaired by Professor Vincent Lawton, CBE.

The following persons routinely attend all Committee meetings:

- Me as 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.

13.6 *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 corporate 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 (section 11 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 agency for the year ended 31 March 2014 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 *Corporate Governance in Central Government Departments: Code of good practice 2011* in so far as it is relevant to us.

13.7 *Data quality to support the Corporate Executive Team (CET) and Agency Board's (AB) needs*

The CET and AB receive reports at its meetings to support its discussions. All reports comply with a prescribed layout to ensure that the CET and AB are able to focus on the key issues and the decisions that are required.

All finance papers are discussed at the monthly Finance Sub Committee (FSC) prior to submission to the CET and AB and any resource or financial implications are highlighted.

The CET or AB has not raised any concerns about the quality of the information it receives.

13.8 *Agency Board and Audit and Risk Assurance Committee 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 Audit and Risk Assurance Committee.

Member	Agency Board	Agency Board away day	Audit and Risk Assurance Committee
Professor Sir Gordon Duff	10 (10)	2 (2)	-
Professor Dame Valerie Beral	6 (8)	-	-
Professor Barrington Furr, OBE	8 (10)	2 (2)	3 (4)
Mr Martin Hindle	10 (10)	2 (2)	-
Professor Vincent Lawton, CBE	9 (10)	2 (2)	4 (4)
Professor Sir Alex Markham	6 (7)	1 (1)	-
Ms Deborah Oakley	9 (10)	2 (2)	4 (4)
Professor David Webb	7 (7)	1 (1)	-
Mr John Williams, CBE	10 (10)	2 (2)	-
Dr Ian Hudson	7 (7)	1 (1)	3

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 agency website at the following location:

http://www.mhra.gov.uk/Aboutus/Ourstructure/AgencyBoard/AgencyBoardmembers/index.htm

13.9 *The risk, control and assurance framework*

The agency follows HM Treasury guidance with the aim of managing risk to a reasonable level rather than to eliminate all risk of achieving policies, aims or objectives.

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 agency's Intranet. Information about corporate governance and risk management is also included in the induction pack for new staff.

A corporate risk manager who oversees the risk management process and provides specialist advice is responsible for the continuous improvement in the agency'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 Audit and Risk Assurance Committee and the Corporate Executive Team, and have been in existence throughout the year to 31 March 2014 and up to the date of approval of the annual report and accounts.

13.10 *Risk Management*

An internal audit is commissioned annually to review various aspects of the agency's corporate governance and risk management systems in order to ensure continuous improvement by identifying new areas where best practice could be adopted. The internal audit annual report gave an overall 'satisfactory' opinion which is the second highest rating achievable.

On the 1st April 2013 the agency joined the Health Group Internal Audit operated by the Department of Health. Following a tender, PwC were awarded the three year contract. The corporate risk register is used by Internal Audit to inform the annual audit plan.

At 31 March 2014, the agency's corporate risk register identified four red risks. These were:

- The agency fails to meet its statutory and other public health roles due to reduced funding;
- CPRD fails to meet its Key Performance Indicators (KPIs);
- A lack of clarity on the part of the Health and Social Care Information Centre may lead to confusion about responsibilities;
- The poor quality and lack of proper security control of staff data.

Other risks included the failure to prevent fake medicinal products and devices reaching the public through the legitimate supply chain as well as the failure to communicate public health safety messages on use of medicines and medical devices leading to the agency's reputation and public confidence being damaged. A more recent addition to the corporate risk register is the issue on transparency and clinical trials and the consequent reputational risk to the agency. A plan is being formulated to mitigate this risk and ensure the policy is aligned with the European Medicines Agency's forthcoming plans.

The mitigations for these risks are discussed in section 4.15. 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 quarterly review by the Audit and Risk and Assurance Committee. In addition any risks that are considered by divisional management to be of a corporate nature are communicated to the agency's corporate risk manager or through the Divisional representative at the quarterly meetings of the Risk and Assurance Liaison Group (RALG).

The cross-Agency RALG, formed to strengthen the agency's risk management system, held four meetings during the year to 31 March 2014. It is a forum where Divisional risks and audit issues are discussed and monitored by senior representatives from all Divisions of the agency. If appropriate, remedial action is recommended to the Corporate Executive Team.

Divisional risk registers maintained at operational level record the divisional risks identified and the actions taken to mitigate those risks in a similar manner as for the corporate risk register. These are dynamic working documents which are updated regularly in order to ensure that the risk registers reflect the opportunities and the threats that may arise during the daily course of business operations.

Divisional Directors in accordance with their duty of accountability are required to complete an annual assurance statement. The assurance statement is a live document and was updated as appropriate. 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 members and senior management team of the agency:

- are clear about the legislative requirements associated with each of the statutory functions for which their division 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 2014.

In line with recommendations in the Harris Review, where relevant and appropriate, the agency has carried out its functions in line with the statutory duties placed on the Secretary of State by the Health and Social Care Act 2012, and this includes the health inequalities duty. In addition I can confirm that in line with recommendations in the Harris Review an appropriate QA framework is in place and is used for all business critical models.

13.11 *Health and Safety*

The agency commissioned an independent health and safety legal compliance audit of NIBSC. The audit commenced in February and concluded in April 2013 and was undertaken by an independent external organisation. NIBSC undertakes independent testing of biological medicines, such as viral and bacterial vaccines, human blood products, hormones and other biotherapeutic medicines. This work creates the potential for staff to be exposed to a broad range of health and safety risks. Other risks for staff are associated with the use of radioactive substances and exposure to noise, machinery, manual handling, ergonomic problems, stress, slips, trips and falls.

The audit was undertaken during a period of change to NIBSC's health and safety arrangements due to the uncoupling from the HPA and joining the agency, changes to the remit of staff and work underway to take forward Health and Safety Executive recommendations in relation to risk assessment. Some of the arrangements at NIBSC meet legal requirements, some go beyond legal requirements and some do not currently meet legal requirements.

The audit found much evidence to demonstrate that: NIBSC takes health and safety matters seriously; it devotes a significant amount of time and effort to improving its health and safety arrangements; NIBSC could do more to acknowledge achievement of planned health and safety objectives; this, coupled with better planning and strategic focus, would help to restore health and safety to a more positive footing. The audit also found that: there is an impressive team of committed and competent staff who are able to guide the Institute with the development and implementation of its health and safety arrangements; there is good health and safety leadership at NIBSC. The audit concluded that whilst harm to staff and others does arise (e.g incidents relating to cuts to hands, cold burn from dry ice, coffee burn to wrist and slipping) the number of cases and root causes do not indicate that the management of risk is fundamentally failing and that there are good arrangements in place to learn lessons from incidents that arise and to implement steps to prevent recurrence.

13.12 *Pensions Assurance*

As an employer with staff entitled to membership of the NHS Pension Scheme following the integration of NIBSC into the agency, control measures are in place to ensure all employer obligations contained within the Scheme regulations are complied with. This includes ensuring that deductions from salary, employer's contributions and payments in to the Scheme are in accordance with the Scheme

rules, and that member Pension Scheme records are accurately updated in accordance with the timescales detailed in the Regulations.

13.13 *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 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 her annual report;

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 Audit and Risk Assurance 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 Governance Statement. The conclusion of the review is that the agency's overall governance and internal control structures have been appropriate for the agency's business and working satisfactorily throughout 2013/14.

13.14 *Significant governance issues*

The agency's internal audit coverage, as detailed above, provides good assurance of the effectiveness of the agency's system of internal control.

Six reviews performed during the year had assurance rated as 'Satisfactory'. These were Sentinel Data Quality review (Information Governance), Payroll Controls, Accounts Receivable review, NIBSC Income review, MHRA wide Governance review and Review of CPRD.

A review of NIBSC business continuity plan, the objective of which was to assess how well NIBSC is able to respond to and recover from an incident affecting delivery of core business services and systems, identified four significant issues with the potential for high risk impact. These included the provision of additional staff support; initiating a review process with communication to all divisional heads; arranging training for divisional heads to help them understand business continuity as well as disaster recovery planning; and, ensuring the NIBSC business continuity plan aligns with agency's business continuity plan. A Counter Fraud and Money Laundering review identified fraud risks and recommended action to mitigate these risks. These reports were specifically brought to my attention. They have also been discussed at the Audit and Risk Assurance Committee meetings during the year. Management action to rectify weaknesses identified has been agreed and a programme of implementation is in place.

In December 2013, the agency's pension provider's Annual Benefit Statements (ABS) were sent to staff home addresses whereas previously all pensions statements were distributed to work locations. In early January 2014 it was brought to the attention of the Agency's HR division that some staff had not received their ABS. HR investigated why this was the case, realised that a data loss had occurred and uncovered that there was major data, systems and processing errors including old / incorrect home address data which caused the ABSs to not be received by a significant number of agency staff.

A major project was initiated to understand the reasons for the data loss, and to identify data, systems, and reporting errors. This phase is nearing completion and activity is now underway to map existing and future processes so that stronger procedures are in place with built-in controls, verification checks and training for staff administering the process. A data cleansing exercise will also be undertaken.

The risk of any further data loss is being contained by a ban on the use of staff home addresses for communications to staff. A report was made to the Information Commissioner's Office and we have received notification that no further action will be undertaken.

There were no other significant security incidents, including data security, 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.

13.15 *Accounting Officer's comment*

Management has taken the time to consider the implications of the findings of internal audit reviews and associated risks prior to agreeing the implementation of recommendations. As Accounting Officer, I note that the audits undertaken 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 improvements which have been identified in some areas.

I am satisfied, based on the advice given to me by the Head of Internal Audit, the Agency Board, the Audit and Risk Assurance Committee, the Corporate Executive

Team and discussions with my predecessor, that on balance there are adequate and effective risk management, corporate governance and internal control systems to manage the achievement of the agency's objectives.

Dr Ian Hudson
Chief Executive and Accounting Officer
Medicines and Healthcare Products Regulatory Agency
8 July 2014

14 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 Agency (MHRA) for the year ended 31 March 2014 under the Government Trading Funds Act 1973. The financial statements comprise: the Statement of Comprehensive Income, Statement of Financial Position, Statement of Cash Flows, and Statement of Changes in Equity; and the related notes. These financial statements have been prepared under the accounting policies set out within them. I have also audited the information in the Remuneration Report that is described in that report as having been audited.

Respective responsibilities of the Board, 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 and to identify any information that is apparently materially incorrect based on, or materially inconsistent with, the knowledge acquired by me in the course of performing the audit. 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 2014 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 Strategic Report and Directors Report sections 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.

Sir Amyas C E Morse **Date 15 July 2014**
Comptroller and Auditor General

National Audit Office
157-197 Buckingham Palace Road
Victoria
London
SW1W 9SP

15 Accounts

STATEMENT OF COMPREHENSIVE INCOME for the year ended 31 March 2014

	NOTE	**2013/14**		2012/13	
		£000	**£000**	£000	£000
Income					
Trading income	3.1				
Income from trading activities		**112,963**		99,584	
Income from Department of Health		***28,850**		9,231	
Total trading income			**141,813**		108,815
Other income	3.2		**8,985**		-
Total Income			**150,798**		108,815
Expenditure					
Staff costs	6.1	**(70,169)**		(54,680)	
Operating costs	7.1	**(51,939)**		(41,928)	
Total Expenditure			**(122,108)**		(96,608)
Operating surplus			**28,690**		12,207
Finance income	8		**403**		340
Finance costs	8		**(51)**		(46)
Surplus for the financial year			**29,042**		12,501
Dividend payable			**(12,878)**		(3,494)
Sub total			**16,164**		9,007
Transfers under absorption accounting			**104,664**		-
Retained surplus for the year			**120,828**		9,007
Other comprehensive income/(loss)					
Other (loss)/gain	9		**(21)**		7
Other comprehensive income for the year			**(21)**		7
Total comprehensive income for the year			**120,807**		9,014

*Includes £7.0m of capital funding recognised as income in line with FReM.

The notes on pages 84 to116 form part of these accounts.

STATEMENT OF FINANCIAL POSITION as at 31 March 2014

	NOTE	31 March 2014		31 March 2013	
		£000	£000	£000	£000
Non-current assets					
Property, plant and equipment	10	**100,748**		12,269	
Intangible assets	11	**20,817**		9,329	
Total non-current assets			**121,565**		21,598
Current assets					
Inventories	12	**6,756**		-	
Trade and other receivables	13	**24,916**		12,320	
Cash and cash equivalents	14	**168,385**		134,674	
Total current assets			**200,057**		146,994
Total assets			**321,622**		168,592
Current liabilities					
Trade and other payables	15	**(51,066)**		(31,332)	
Provisions	17	**(678)**		(137)	
Other liabilities	18	**(35,576)**		(24,472)	
Total current liabilities			**(87,320)**		(55,941)
Total assets less current liabilities			**234,302**		112,651
Non-current liabilities					
Borrowings	16	**(1,328)**		(1,328)	
Provisions	17	**(2,189)**		(2,265)	
Other liabilities	18	**(5,905)**		(4,633)	
Total non-current liabilities			**(9,422)**		(8,226)
Assets less liabilities			**224,880**		104,425
Taxpayers' equity:					
Public dividend capital			**1,329**		1,329
Reserves					
Revaluation reserve			**62,311**		155
General reserve			**42,156**		-
Income and expenditure reserve			**954**		954
Retained earnings			**118,130**		101,987
Total equity			**224,880**		104,425

Dr Ian Hudson
Chief Executive and Accounting Officer
Medicines and Healthcare Products Regulatory Agency
8 July 2014

The notes on pages 84 to 116 form part of these accounts.

STATEMENT OF CASH FLOWS for the year ended 31 March 2014

	NOTE	2013/14 £000	2013/14 £000	2012/13 £000	2012/13 £000
Cash flows from operating activities					
Operating surplus		**28,690**		12,207	
Interest paid	8	**(51)**		(46)	
(Loss)/Gain on foreign exchange	9	**(21)**		7	
Depreciation and amortisation		**10,667**		7,266	
Disposals of assets		**17**		39	
Impairment and reversals		**257**		76	
Realised loss on property, plant and equipment	10	**(485)**		-	
Realised gain on inventories	11	**124**		-	
(Increase) in inventories	12	**(6,756)**		-	
(Increase)/Decrease in trade and other receivables	13	**(12,596)**		9,371	
Increase in trade and other payables	15	**19,734**		695	
Increase/(Decrease) in provisions	17	**465**		(901)	
Increase/(Decrease) in deferred revenue	18	**12,376**		(526)	
Dividend payable		**(12,878)**		(3,494)	
Net cash inflow from operating activities			**39,543**		24,694
Cash flows from investing activities					
Interest received	8	**403**		340	
Purchase of property, plant and equipment	10	**(460)**		(440)	
Purchase of intangible assets	11	**(13,738)**		(4,799)	
Net cash (outflow) from investing activities			**(13,795)**		(4,899)
Cash flows from financing activities			**-**		-
Net increase in cash and cash equivalents in the financial year	14		**25,748**		19,795
Transfers under absorption accounting	14		**7,963**		-
Cash and cash equivalents at the beginning of the financial year	14		**134,674**		114,879
Cash and cash equivalents at the end of the financial year	14		**168,385**		134,674

The notes on pages 84 to 116 form part of these accounts.

STATEMENT OF CHANGES IN TAXPAYERS' EQUITY
for the year ended 31 March 2014

	PDC[1] £000	Retained earnings £000	Reval. reserve[2] £000	General reserve	I & E [3] reserve £000	Total £000
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**
Changes in taxpayers' equity for 2013/14						
Transfers under absorption accounting	**-**	**-**	**62,408**	**42,256**	**-**	**104,664**
Surplus for the year	**-**	**16,164**	**-**	**-**	**-**	**16,164**
Other losses	**-**	**(21)**	**-**	**-**	**-**	**(21)**
Retained surplus for the year	**-**	**16,143**	**62,408**	**42,256**	**-**	**120,807**
Other changes						
Net loss on revaluation of property, plant and equipment	**-**	**-**	**(485)**	**-**	**-**	**(485)**
Impairment and reversals	**-**	**-**	**257**	**-**	**-**	**257**
Realised gain on inventories – biological standards	**-**	**-**	**(124)**	**-**	**-**	**(124)**
Transfers between revaluation reserve and general reserve in respect of changes in indexation of assets	**-**		**100**	**(100)**	**-**	**-**
Sub total	**-**	**-**	**(252)**	**(100)**	**-**	**(352)**
Balance at 31 March 2014	**1,329**	**118,130**	**62,311**	**42,156**	**954**	**224,880**

The notes on pages 84 to 116 form part of these accounts.

[1] Public Dividend Capital
[2] Revaluation Reserve
[3] Income and Expenditure Reserve

15.2 *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 2013/14 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 2013/14. The application of the Standards as revised would not have a material impact on the accounts for 2013/14, were they applied in that year:

- 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).
- IAS 27 Separate Financial Statements - Effective date 1 January 2013 (EU adoption from 1 January 2014).
- IAS 28 Investments in 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 Critical accounting judgements and estimates

The preparation of the financial statements requires the use of estimates and assumptions. Although we base judgements and estimates on our best knowledge of current events and actions, actual results may differ from our assumptions. The most significant estimates and areas of management judgement made in the accounts relate to:

- **Measurement of the accrual for employee leave liability**

We use an employee by employee breakdown of actual leave balance and average salary for the grade to calculate our liability. The principal uncertainty is in respect of when the leave balance will be used. In the absence of information on the timing of staff members' future use of their leave, we neither discount the liability nor include any forecast of future salary increases.

1.4 Non-Current Assets

1.4.1 Property, Plant & Equipment

Property, 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.

NIBSC assets are revalued annually using Office of National Statistics cost indices. These indices reflect the upward or downward movements in valuation of these assets and are broadly consistent with fair values. The fair value of freehold land and buildings is determined by an independent valuation carried out every five years in accordance with guidance issued by the Royal Institute of Chartered Surveyors. A valuation took place at 31 March 2013. Valuation is on an open market (existing use) basis except for buildings of a specialised nature, where a market value is not readily obtainable, which are valued on a depreciated replacement cost basis. In the years when no valuation occurs, land and buildings are reviewed to ensure that carrying amounts are not materially different from those that would be determined at the end of the reporting period, and in the third year following each quinquennial valuation; an independent verification exercise is carried out.

The difference between the carrying value, net of accumulated depreciation, of property, plant and equipment at the date of the statement of financial position and the net book value at historic cost is credited (in the case of a surplus) or debited (in the case of a deficit) to the revaluation reserve.

Impairment losses, where identified, are charged against the revaluation reserve balance attributable to the asset concerned. If the loss exceeds this balance, the excess is taken to the statement of comprehensive income.

1.4.2 Depreciation, amortisation and impairments

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

Freehold buildings	Up to 80 years
Laptops and associated applications	3 years
Plant and equipment	5 to 20 years
Vehicles	7 years
Fixtures and fittings	Up to 20 years
Computer systems	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 has 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.

1.4.3 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	3 -10 years
Sentinel architecture costs	15 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	£639
Risk Based Inspection	60 months	£1,434
Pharmacovigilance	94 months	£554

Sentinel architecture is the suite of Sentinel applications used by the MHRA centre e.g. Product Licensing Case Folder.

Pharmacovigilance: is the database for collecting, monitoring, researching, assessing and evaluating information from healthcare providers and patients on the adverse effects of medicines, biological products, herbals and traditional medicines.

Risk based Inspection (RBI): is a Risk Data Repository to house intelligence information and processing of this information via a statistical model (algorithm) to improve inspection planning

1.4.4 Inventories

Inventories are valued at the lower of cost, or net current replacement cost if materially different, and net realisable value. For inventories held for resale, net

realisable value is based on estimated selling price less further costs expected to be incurred to completion. Work in progress is valued at cost, less the cost of work invoiced on incomplete contracts and less foreseeable losses. Cost means direct cost plus production overheads. Where necessary, provision is made for obsolete, slow moving and defective inventories in accordance with IAS 2.

1.4.5 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.

1.5 Cash

Cash represents cash held with the Government Banking Service.

1.6 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.

1.7 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 Statement of Comprehensive Income 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 the actual outstanding leave for all staff and the year on year movement is charged to the Income Statement.

1.8.2 Pensions

We operate two different pension arrangements.

- The Principal Civil Service Pension Scheme (PCSPS)
- The National Health Service Pension Scheme (NHSPS)

Although each is an unfunded scheme, they each receive contributions, partly from participating employees and partly from the agency. Details of each scheme are included in the notes to the financial statements (note 6). Each scheme is multi-employer, and the scheme administrators prepare separate accounts which are subject to audit and regular actuarial review. Because of this, the Government Financial Reporting Manual 2013/14 (FReM) requires the pension schemes to be treated as defined contribution schemes within these financial statements. The amount charged to operating costs is the employer's contributions payable for the year.

In certain circumstances, employees taking early retirement are entitled to an enhanced lump sum and ongoing pension. The agency is responsible for meeting the additional cost of the lump sum, the full cost of the pension until normal retirement age and the enhanced element of the pension thereafter. Payment is made in full for all early retirees from the NHS pension scheme in the year of retirement; for all other pension schemes, provision is made for the estimated future cost of early retirements at the time when the employee retires. Further details are provided within note 6.

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 Statement of comprehensive income as incurred.

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.

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 agency from the date of early retirement until age 60, when the Principal Civil Service Pension Scheme (PCSPS) or the National Health Service Pension Scheme (NHSPS) assumes the

liability. Provisions for early departure costs are discounted at the pensions rate (currently 1.80 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 and Welwyn Garden City office as required by the lease.

An onerous contract provision has also been made for the Welwyn Garden City office.

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 English NHS observational data and interventional research service, with a 50:50 investment contribution by the Department of Health (DH) and the Medicines and Healthcare Products Regulatory Agency, the timing of that investment is to be managed to ensure an equal sharing of risk. Total investment is expected to be £60M over the life of the project with the agency as the operator. This project is accounted for as a joint venture and complies with IAS 31. Any surplus / deficit generated are to be shared equally. To supplement the original business case, a Memorandum of Understanding was agreed between the agency and DH that as of 1 April 2013 all income / expenditure and assets / liabilities are to be split evenly between the joint venturers. However, in its first year as the CPRD infrastructure was being put in place, only incremental costs were attributed to the joint venture. Details of the joint venture are in note 3.3 CPRD joint venture memorandum account. In 2013/14, the Department of Health paid £8.0M towards this project.

CPRD services are designed to maximise the way anonymised NHS clinical data can be linked to enable many types of observational research and deliver research outputs that are beneficial to improving and safeguarding public health.

1.15 National Institute for Biological Standards and Control (NIBSC)

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 alongside the Clinical Practice Research Datalink (CPRD) and the MHRA Regulator. All staff and total assets of £111,756,000 plus total liabilities of £7,092,000 were transferred to the agency on that date. This has been incorporated in the agency financial statements under absorption accounting in line with guidance from DH with a net value of £104,664,000.

1.16 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.

1.17 Corporation tax

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

2 Financial Duty

The agency's financial duty is set out in full in a HM Treasury minute dated 24 March 2014, which is reproduced after the notes to the accounts.

The requirement is that the agency 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 £12.878M (2012/13 £3.494M).

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 Income

Income from trading activities represents invoiced amounts and accrued amounts deferred to future periods 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. Income is recognised according to type of income stream. The agency has the following income streams:

- Applications for marketing authorisations and subsequent variations: A number of processes have been assigned to determine the stage of work completed. This determines the income to recognise and to defer.
- Service fees: These are invoiced annually early in the financial year and cover vigilance and risk management of medicines and enforcement. Income is recognised based on amounts collected in the financial year.
- Inspections: Fees are for pre-inspection preparation, travelling time, reporting of inspections and resolving issues. It also incorporates activities such as evaluation of compliance assessment report and other support functions and directly related overheads. 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.
- Applications for clinical trials authorisations and variations: Income 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 receivable from governmental and non-government bodies for the purchase of specific capital assets are recognised as income as they are received provided no conditions are attached. Where there are conditions attached to the grant, the income is transferred to deferred income until those conditions are met.

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

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

3.1 Trading income

	2013/14 £000	2012/13 £000
Income from fee charging activities*	**138,194**	106,731
Miscellaneous income	**3,619**	2,084
Total trading income	**141,813**	108,815

*Includes £9.3M (2012/13, £7.3M) 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.

3.2 Other income

The Trading Fund received financial assistance in the form of additional funding of £9.0M from the Department of Health to offset the additional costs of dividend (£3.8M) and depreciation (£5.2M), resulting from the transfer of the National Institute for Biological Standards and Control to the agency on 1 April 2013.

3.3 CPRD Joint venture memorandum account

Income and expenditure*

	2013/14 £000	2012/13 £000
Revenue	**7,904**	7,760
Expenditure	**(6,342)**	(5,357)
Operating surplus	**1,562**	2,403

*50% agency share reflected in agency accounts.

Statement of financial position

	2013/14 £000	2012/13 £000
Current assets		
Cash and cash equivalents	**17,689**	8,127
Current liabilities		
DH contribution to joint venture	**(16,127)**	(8,127)
Assets less liabilities	**1,562**	-
Equity		
Surplus b/f	**-**	-
Surplus for the year	**1,562**	-
Total equity	**1,562**	-

Cash and cash equivalents

	Total £000	2013/14 £000	2012/13 £000
DH contribution	**16,400**	**8,000**	8,400
Revenue	**7,904**	**7,904**	-
Expenditure	**(6,342)**	**(6,342)**	-
Incremental cost*	**(273)**	**-**	(273)
Total	**17,689**	**9,562**	8,127

***first year of joint venture, only additional incremental costs of developing CPRD attributed to joint venture (see Note 1.14)

4 Segmental information

In accordance with IFRS 8, we have identified four key factors to distinguish our reportable operating segments. These are:

- that the reportable operating segment engages in activities from which we earn revenues and incur expenses;
- that the reportable operating segment's financial results are regularly reviewed by the chief operating decision makers to make decisions about allocating resources to the segment and assess its performance;
- that the reportable operating segment has discrete financial information;
- that the reportable operating segment provides a distinct service to its customers.

We consider our chief operating decision maker to be our Corporate Executive Team (CET). The segmental information below is based on information presented to the CET. The CET reviews financial information based on three reportable segments:

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.

The National Institute for Biological Standards and Control (NIBSC) is a global leader in the standardisation and control of biological medicines. As part of the agency it is a world leader in supporting science and research and the regulation of medicines and medical devices, strengthening the support provided to the UK medicine's industry.

MHRA regulatory centre: The regulator is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe.

	2013/14			
	CPRD*	**NIBSC**	**Regulator**	**Total**
	£000	**£000**	**£000**	**£000**
Income from external customers	**3,952**	**17,415**	**91,596**	**112,963**
Income from DH	**-**	**18,530**	**10,320**	**28,850**
Total income	**3,952**	**35,945**	**101,916**	**141,813**
Direct costs	**(2,534)**	**(30,406)**	**(48,284)**	**(81,224)**
Indirect costs	**(638)**	**(2,744)**	**(37,502)**	**(40,884)**
Total expenditure	**(3,172)**	**(33,150)**	**(85,786)**	**(122,108)**
Segment surplus/(deficit)	**780**	**2,795**	**16,130**	**19,705**

* represents MHRA's 50% share of joint venture

We do not recognise revenue for goods or services provided by one segment to another. Transactions of this sort are accounted for in segmental information produced for management reports but are excluded on consolidation of financial statements.

	2012/13			
	CPRD £000	NIBSC £000	Regulator £000	Total £000
Income from external customers	7,760	-	91,824	99,584
Income from DH	-	-	9,231	9,231
Total income	7,760	-	101,055	108,815
Direct costs	(4,382)		(50,255)	(54,637)
Indirect costs	(975)		(40,996)	(41,971)
Total expenditure	(5,357)	-	(91,251)	(96,608)
Segment surplus/(deficit)	2,403	-	9,804	12,207

5 Fees and charges

Treasury guidance on fees and charges is applied when setting fee levels for the agency. 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 agency has complied with the cost allocation and charging requirements as set out in HM Treasury's guidance.

		2013/14	
Charging activity	**£000 Income**	**£000 Expenditure**	**£000 Surplus/ (Deficit)**
Licensing	**40,192**	**(34,192)**	**6,000**
Inspections	**10,183**	**(8,020)**	**2,163**
Vigilance, Risk Management and Enforcement	**30,965**	**(29,665)**	**1,300**
British Pharmacopoeia	**2,851**	**(2,747)**	**104**
Devices	**10,768**	**(8,124)**	**2,644**
Clinical Trials	**3,338**	**(2,921)**	**417**
Total Regulator	**98,297**	**(85,669)**	**12,628**
CPRD	**7,904**	**(6,342)**	**1,562**
Less: DH share of joint venture	**(3,952)**	**3,170**	**(782)**
	3,952	**(3,172)**	**780**
NIBSC	**35,945**	**(33,150)**	**2,795**
Total	**138,194**	**(121,991)**	**16,203**

		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

*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

	2013/14			2012/13
	Total	**Permanently Employed**	**Other**	Total
	£000	**£000**	**£000**	£000
Wages and salaries	**55,480**	**53,728**	**1,752**	42,759
Social security costs	**5,009**	**5,005**	**4**	3,893
Other pension contributions	**9,865**	**9,860**	**5**	8,142
Sub-total	**70,354**	**68,593**	**1,761**	54,794
Less recoveries in respect of outward secondment	**(185)**	**(185)**	**-**	(114)
Total staff costs	**70,169**	**68,408**	**1,761**	54,680

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:

	2013/14			2012/13		
	Total	**Permanently Employed**	**Other**	Total	Permanently Employed	Other
Chairman	**1**	**1**	**-**	1	1	-
Executive Directors	**11**	**11**	**-**	11	10	1
Senior Civil Servants	**127**	**126**	**1**	106	106	-
Other Civil Service staff	**1,075**	**975**	**100**	818	721	97
Total	**1,214**	**1,113**	**101**	936	838	98

6.3 Reporting of civil service and other compensation schemes

6.3.1 Exit packages

		2013/14		**2012/13**
	Number of compulsory redundancies	**Number of other departures agreed**	**Total number of exit packages by cost band**	Total number of exit packages by cost band
< £10,000	-	-	-	-
£ 10,000 - £25,000	-	1	1	2
£ 25,000 - £50,000	-	2	2	2
£ 50,000 - £ 100,000	-	1	1	-
£100,000 - £150,000	-	-	-	-
£150,000 - £200,000	-	-	-	-
Total number of exit packages	**-**	**4**	**4**	**4**
Total resource cost	**-**	**£171,589**	**£171,589**	**£102,192**

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 £172k (2012/13, £102k) are included in wages and salaries and shown on the exit package table.

6.3.2 Non-compulsory departures

	Agreements Number	Total value of agreements £000
Voluntary redundancies including early retirement contractual costs	**4**	**172**
Mutually agreed resignations contractual costs	**-**	**-**
Early retirements in the efficiency of the service contractual costs	**-**	**-**
Contractual payments in lieu of notice	**-**	**-**
Exit payments following Employment Tribunals or court orders	**-**	**-**
Non-contractual payments requiring HMT approval*	**-**	**-**
Total	**4**	**172**

6.4 Off-payroll engagements

6.4.1 For all off-payroll engagements as of 31 March 2014, for more than £220 per day and that last longer than six months:

	Number
Number of existing engagements as of 31 March 2014	3
Of which, the number that have existed:	
for less than one year at the time of reporting	3
for between one and two years at the time of reporting	-
for between 2 and 3 years at the time of reporting	-
for between 3 and 4 years at the time of reporting	-
for 4 or more years at the time of reporting	-

Confirmation that all existing off-payroll engagements have at some point been subject to a risk based assessment as to whether assurance is required that the individual is paying the right amount of tax and, where necessary, that assurance has been sought.

6.4.2 For all new off-payroll engagements between 1 April 2013 and 31 March 2014, for more than £220 per day and that last longer than six months:

	Number
Number of new engagements, or those that reached six months in duration, between 1 April 2013 and 31 March 2014	1
Number of new engagements which include contractual clauses giving the Agency the right to request assurance in relation to income tax and National Insurance obligations	-
Number for whom assurance has been requested	1
Of which:	
assurance has been received	1
assurance has not been received	-
engagements terminated as a result of assurance not being received	-

6.5 Pensions

Pension scheme participation

Past and present employees of the agency are covered by the provisions of the Principal Civil Service Pension Schemes (PCSPS). Employees who have transferred from the Health Protection Agency (HPA) have retained their membership of the NHS Pension Scheme.

The Principal Civil Service Pension Scheme (PCSPS).

The PCSPS is a defined benefit scheme 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 agency recognises the contributions payable for the year.

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.

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 6.25% of pensionable earnings for classic and 3.5% and 8.25% for premium, classic plus and nuvos. Increases to employee contributions will apply from 1 April 2014. 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 their 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.

The NHS Pension Scheme (NHSPS)

Past and present employees of NIBSC are covered by the provisions of the NHS Pensions Scheme. Details of the benefits payable under these provisions can be found on the NHS Pensions website at www.nhsbsa.nhs.uk/pensions The scheme is an unfunded, defined benefit scheme that covers NHS employers, GP practices and other bodies, allowed under the direction of the Secretary of State, in England and Wales. The scheme is not designed to be run in a way that would enable NHS bodies to identify their share of the underlying scheme assets and liabilities. Therefore, the scheme is accounted for as if it were a defined contribution scheme: the cost to the NHS Body of participating in the scheme is taken as equal to the contributions payable to the scheme for the accounting period.

In order that the defined benefit obligations recognised in the financial statements do not differ materially from those that would be determined at the reporting date by a formal actuarial valuation, the FReM requires that "the period between formal valuations shall be four years, with approximate assessments in intervening years". An outline of these follows:

a) Accounting valuation

A valuation of the scheme liability is carried out annually by the scheme actuary as at the end of the reporting period. This utilises an actuarial assessment for the previous accounting period in conjunction with updated membership and financial data for the current reporting period, and are accepted as providing suitably robust figures for financial reporting purposes. The valuation of the scheme liability as at 31 March 2014 is based on valuation data as 31 March 2013, updated to 31 March 2014 with summary global member and accounting data. In undertaking this actuarial assessment, the methodology prescribed in IAS 19, relevant FReM interpretations, and the discount rate prescribed by HM Treasury have also been used.

The latest assessment of the liabilities of the scheme is contained in the scheme actuary report, which forms part of the annual NHS Pension Scheme (England and Wales) Pension Accounts, published annually. These accounts can be viewed on the NHS Pensions website. Copies can also be obtained from The Stationery Office.

b) Full actuarial (funding) valuation

The purpose of this valuation is to assess the level of liability in respect of the benefits due under the scheme (taking into account its recent demographic experience), and to recommend the contribution rates.

The last published actuarial valuation undertaken for the NHS Pension Scheme was completed for the year ending 31 March 2004. Consequently, a formal actuarial valuation would have been due for the year ending 31 March 2008. However, formal actuarial valuations for unfunded public service schemes were suspended by HM Treasury on value for money grounds while consideration is given to recent changes to public service pensions, and while future scheme terms are developed as part of the reforms to public service pension provision due in 2015.

The Scheme Regulations were changed to allow contribution rates to be set by the Secretary of State for Health, with the consent of HM Treasury, and consideration of the advice of the Scheme Actuary and appropriate employee and employer representatives as deemed appropriate.

c) Scheme provisions

The NHS Pension Scheme provided defined benefits, which are summarised below. This list is an illustrative guide only, and is not intended to detail all the benefits

provided by the Scheme or the specific conditions that must be met before these benefits can be obtained:

The Scheme is a “final salary” scheme. Annual pensions are normally based on 1/80th for the 1995 section and of the best of the last three years pensionable pay for each year of service, and 1/60th for the 2008 section of reckonable pay per year of membership. Members who are practitioners as defined by the Scheme Regulations have their annual pensions based upon total pensionable earnings over the relevant pensionable service.

With effect from 1 April 2008 members can choose to give up some of their annual pension for an additional tax free lump sum, up to a maximum amount permitted under HMRC rules. This new provision is known as “pension commutation”.

Annual increases are applied to pension payments at rates defined by the Pensions (Increase) Act 1971, and are based on changes in retail prices in the twelve months ending 30 September in the previous calendar year. From 2011/12 the Consumer Price Index (CPI) has been used and replaced the Retail Prices Index (RPI).

Early payment of a pension, with enhancement, is available to members of the scheme who are permanently incapable of fulfilling their duties effectively through illness or infirmity. A death gratuity of twice final year’s pensionable pay for death in service, and five times their annual pension for death after retirement is payable.

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 employer.

Members can purchase additional service in the NHS Scheme and contribute to money purchase AVC’s run by the Scheme’s approved providers or by other Free Standing Additional Voluntary Contributions (FSAVC) providers.

	2013/14 Annual pensionable pay banding	2013/14 Employee Contribution
Tier 1	Up to £15,431.99	5.0%
Tier 2	£15,432.00 to £21,387.99	5.3%
Tier 3	£21,388.00 to £26,823.99	6.8%
Tier 4	£26,824.00 to £49,472.99	9.0%
Tier 5	£49,473.00 to £70,630.99	11.3%
Tier 6	£70,631.00 to £111,376.99	12.3%
Tier 7	£111,377 and over	13.3%

Contributions for new members of the NHS Pension Scheme are based on their pensionable pay at the time of joining the Scheme.

The Government Financial Reporting Manual 2013/14 (FReM) requires the scheme to be accounted for as defined contribution in nature.

Employer contributions

The agency has accounted for its employer contributions to these schemes as if there were defined contribution schemes.

For 2013/14, employers’ contributions for the agency employees of £9,865,807 with a further £31,579 respect of staff on secondment were payable to the PCSPS and NHSPS (£8,115,131 in 2012/13 and a further £19,203 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 2012/13), 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 £229,452 (£213,803 in 2012/13) 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 2012/13). Employers can also match employee contributions up to a limit of 3 per cent of pensionable pay. In addition, employer contributions of £4,573 (£3,493 in 2012/13), 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 £5,320. No contributions were prepaid at that date.

There were no cases of retirement on ill-health grounds during 2013/14 (2012/13, One case). No additional pension liabilities were accrued.

7. Expenditure

7.1 Operating costs

	2013/14 £000	2012/13 £000
Computing	**11,402**	11,324
Depreciation and amortisation	**10,667**	7,266
Other accommodation costs	**5,558**	6,027
Rentals under operating leases (see 7.2 below)	**4,535**	1,666
Supplies and services	**3,125**	-
Medicines testing and laboratory expenses	**2,716**	2,657
Contracted-out administration services	**2,657**	2,560
Travel and subsistence	**2,381**	2,442
Laboratory consumables and services	**2,175**	-
Net increase in debt and credit note provision	**2,008**	1,348
Legal Services	**1,323**	1,305
Other administration costs	**1,315**	1,124
Printing, stationery and distribution	**871**	444
Training	**791**	924
Telecommunications	**767**	683
Committee costs	**739**	787
Contracted-out personnel and payroll services	**628**	623
Release of unutilised provision/increase in provisions	**487**	217
Impairment and reversals	**257**	-
Pharmacovigilance database and other costs	**246**	299
Marketing	**201**	113
Inventories consumed	**90**	-
Auditors remuneration - audit fee	**90**	80
Other losses	**63**	-
Loss on disposal	**17**	39
DH share of joint venture	**(3,170)**	-
Total operating costs	**51,939**	41,928

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 2013/14 £000**	**Land and buildings 2013/14 £000**	Others 2012/13 £000	Land and buildings 2012/13 £000
Minimum lease payments	**95**	**4,535**	74	1,666
Total	**95**	**4,535**	74	1,666

Total future minimum lease payments				
Payable:				
Within one year	**-**	**4,399**	48	4,530
Within two to five years	**-**	**17,578**	-	18,058
Over five years	**-**	**11,719**	-	16,473
Total	**-**	**33,696**	48	39,061

7.3 Finance Leases

The agency had no finance leases in 2013/14.

8 Finance income and costs

	2013/14 £000	2012/13 £000
Finance income		
Interest received from Government Banking Service	**403**	340
	403	340
Finance costs		
Interest paid	**(51)**	(46)
Net cash inflow from returns on investments and servicing of Finance	**352**	294

9 Other gains and losses

	2013/14 £000	2012/13 £000
(Loss)/Gain on foreign exchange	**(21)**	7
Total	**(21)**	7

10 Property, plant and equipment

2013/14	Land and building £000	Computer and telecom equipment £000	Plant and equipment £000	Fittings, furniture and office equipment £000	Total £000
Cost or valuation					
At 1 April 2013	-	8,430	1,518	13,792	23,740
Transfers under absorption accounting	83,866	-	19,010	101	102,977
Additions	-	402	58	-	460
Reclassification	-	-	(54)	-	(54)
Transfers	2,598	269	1,424	-	4,291
Revaluation	-	-	(1,140)	(6)	(1,146)
Disposals	-	-	(88)	-	(88)
At 31 March 2014	**86,464**	**9,101**	**20,728**	**13,887**	**130,180**
Depreciation					
At 1 April 2013	-	6,756	1,083	3,632	11,471
Transfers under absorption accounting	-	-	11,024	22	11,046
Reclassification	-	-	(54)	-	(54)
Charged during the year	3,473	1,177	1,524	1,527	7,701
Revaluation	-	-	(660)	(1)	(661)
Disposals	-	-	(71)	-	(71)
Depreciation at 31 March 2014	**3,473**	**7,933**	**12,846**	**5,180**	**29,432**
Net book value at 31 March 2014	**82,991**	**1,168**	**7,882**	**8,707**	**100,748**
Net book value at 31 March 2013	-	1,674	435	10,160	12,269
Asset financing: **Owned**					
Net book value at 31 March 2014	**82,991**	**1,168**	**7,882**	**8,707**	**100,748**

Assets held at nil net book value

Within the asset register, NIBSC assets with a cost of £7,550,000 are held at nil net book value. The assets are being used beyond their expected useful life. The Government Financial Reporting Manual 2013/14 requires a revaluation to the end of the useful economic life. As these assets currently have a life that is beyond that anticipated, they have economic value and are capable of use, therefore, management will review the asset position as part of ongoing activity to ensure that where an asset is approaching its end of depreciated life the value in life is re-assessed and appropriate adjustments made.

Reclassification of assets

During the year 2013/14, assets previously classified as plant and equipment with a total net book value of £54,000 were reclassified to computer systems.

2012/13	Computer and telecom equipment £000	Plant, equipment and vehicles £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

11 Intangible assets

2013/14	Computer systems £000	AUC~ £000	Software licences £000	Total £000
Cost or Valuation				
At 1 April 2013	28,887	2,523	2,417	33,827
Transfers under absorption accounting*	1,497	3,771	1,346	6,614
Additions	1,169	11,571	1,017	13,757
Reclassification	54	-	-	54
Transfers*	2,430	(6,885)	164	(4,291)
Disposals	(20)	-	(28)	(48)
At 31 March 2014	**34,017**	**10,980**	**4,916**	**49,913**
Amortisation				
At 1 April 2013	23,139	-	1,359	24,498
Transfers under absorption accounting	727	-	899	1,626
Reclassification	54	-	-	54
Charged during the year	2,302	-	664	2,966
Disposals	(20)	-	(28)	(48)
Amortisation at 31 March 2014	**26,202**	**-**	**2,894**	**29,096**
Net book value at 31 March 2014	**7,815**	**10,980**	**2,022**	**20,817**
Net book value at 31 March 2013	5,748	2,523	1,058	9,329
Asset financing:				
Owned				
Net book value at 31 March 2014	**7,815**	**10,980**	**2,022**	**20,817**

~ Assets Under Construction

* In producing the Health Protection Agency's closing balances at 31 March 2013, the NIBSC AUC figure was understated by £1,424k. This has been corrected by the Medicines and Healthcare products Regulatory Agency in 2013/14 by an adjustment on the 'Transfers under absorption accounting' and Transfers figure. Although the overall net total is unaffected it does affect the 'transfer under absorption accounting' figure disclosed elsewhere in these accounts.

2012/13	Computer systems £000	AUC £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)
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

12 Inventories

	31 March 2014 £000	31 March 2013 £000
Raw materials	**10**	-
Biological standards	**6,611**	-
Laboratory consumables and other stores	**135**	-
Total	**6,756**	-

When first recorded in the NIBSC balance sheet at 31 March 2010 an unrealised gain of £3,958,000 was credited to the revaluation reserve. A portion of the reserve relating to these inventories held at 31 March 2010 and distributed during the year is credited as a realised gain to operating costs. The amount thus realised in 2014 was £124,000.

13 Trade and other receivable

	31 March 2014	31 March 2013
Amounts falling due within one year:	**£000**	£000
Due from the Department of Health (see 13.2 below)	**9,080**	1,054
Other trade receivables	**9,448**	6,272
Other receivables	**249**	233
Accrued income	**4,023**	2,781
Prepayments	**1,424**	1,655
	24,224	11,995
Amounts falling due after more than one year:		
Prepayments	**692**	325
Total	**24,916**	12,320

Other trade receivables are shown net of a provision for bad debts of £3.5m (31 March 2013 £4.5m) and credit notes of £1.1m (31 March 2013 £4.7m).

13.1 Intra government balances

	31 March 2014 £000	31 March 2013 £000
Balances with other central government bodies	**9,165**	3,162
Balances with local authorities	**55**	49
Balances with NHS Trusts	**2,129**	2,046
Balances with Public Corporations and Trading Funds	**-**	1
Subtotal	**11,349**	5,258
Balances with bodies external to government	**13,567**	7,062
Total	**24,916**	12,320

13.2 Amount Due from the Department of Health consists of:

	31 March 2014 £000	31 March 2013 £000
Other trade receivables	**95**	-
DH Funding for NIBSC*	**8,985**	-
Value Added Tax	**-**	1,054
Total	**9,080**	1,054

* see Note 3.2

13.3 Provision for bad debt

	31 March 2014 £000	31 March 2013 £000
Bad debt provision	**3,458**	4,515
Total	**3,458**	4,515

14 Cash and cash equivalents

	31 March 2014 £000	31 March 2013 £000
Balance at 1 April	**134,674**	114,879
Transfers under absorption accounting	**7,963**	-
Net change in year	**25,748**	19,795
Balance at 31 March 2014	**168,385**	134,674
Made up of		
Government Banking Service	**168,385**	134,473
Commercial banks and cash in hand	**-**	201
Cash and cash equivalents*	**168,385**	134,674

* includes £17.7m held on behalf of CPRD joint venture

15 Trade and other payables

Amounts falling due within one year:	31 March 2014 £000	31 March 2013 £000
Due to Department of Health (see 15.1 below)	**13,328**	213
Payments received on account	**17,519**	13,720
Taxation and other social security costs	**2,669**	2,050
Other trade payables	**4,201**	3,323
Other payables	**2,177**	-
Accruals	**11,172**	12,026
Total	**51,066**	31,332

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

15.1 Amount Due to the Department of Health consists of:

	31 March 2014 £000	31 March 2013 £000
Other trade payables	**-**	82
Payment on account	**6**	-
Accruals	**444**	131
Dividend payable*	**12,878**	-
Total	**13,328**	213

* see Note 3.2

15.2 Intra government balances

	31 March 2014 £000	31 March 2013 £000
Balances with other central government bodies	**22,942**	12,170
Balances with local authorities	**16**	4
Balances with NHS Trusts	**465**	362
Balances with Public Corporations and Trading Funds	**5**	-
Subtotal	**23,428**	12,536
Balances with bodies external to government	**27,638**	22,290
Total	**51,066**	34,826

16 Borrowings

	Non-Current	
	31 March 2014 £000	31 March 2013 £000
Loans from Department of Health	**1,328**	1,328
Total	**1,328**	1,328

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

	Total 2013/14 £000	Less than one year £000	Between one and five years £000	More than five years £000	Total 2012/13 £000
Fixed interest rate					
3.50%	**1,328**	-	-	1,328	1,328
At 31 March 2014	**1,328**	**-**	**-**	**1,328**	1,328
At 31 March 2013	**-**	-	-	1,328	1,328

17 Provisions for liabilities and charges

	Current		Non-Current	
	31 March 2014 £000	31 March 2013 £000	**31 March 2014 £000**	31 March 2013 £000
Early retirement	**16**	16	**-**	17
Other provisions	**662**	121	**2,189**	2,248
Total	**678**	137	**2,189**	2,265

Movement in provisions

	Early retirement £000	Other provisions £000	**Total £000**
At 1 April 2013	33	2,369	**2,402**
Arising during the year	-	559	**559**
Used during the year	(17)	-	**(17)**
Unwinding of provision	-	(77)	**(77)**
At 31 March 2014	16	2,851	**2,867**

Expected timing of cash flows:			
Between 1 April 2014 and 31 March 2015	16	662	**678**
Between 1 April 2015 and 31 March 2018	-	-	**-**
Beyond 2018	-	2,189	**2,189**
Total	16	2,851	**2,867**

The provision for early retirement and voluntary severance is to cover the agency's estimated liability for pensions in respect of early retirements. They have been discounted using the Treasury discounted rate of 1.80%.

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 0.65% (medium term);
- dilapidation and onerous contract provision for the Welwyn Garden Office. This is expected to be settled in 2014/15 and has not been discounted.
- Committee member's tax and NI liability expected to be settled in 2014/15.

18 Other Liabilities

	Current		Non-Current	
	31 March 2014 £000	31 March 2013 £000	**31 March 2014 £000**	31 March 2013 £000
Deferred revenue:				
Licence fees - applications and variations	**10,331**	10,116	**3,443**	3,372
Other fees	**8,336**	2,737	**3,443**	40
Government grant	**-**	-	**-**	1,221
Others:				
DH Contribution to CPRD joint venture	***16,909**	8,125	**-**	-
Dividend payable	**-**	3,494		
Total	**35,576**	24,472	**5,905**	4,633

*includes 50% DH share of CPRD joint venture surplus (see Note 3.3)

19 Contingent liabilities

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

20 Capital commitments

Contracts entered into not provided for in the accounts

	Intangible 31 March 2014 £000	**Tangible 31 March 2014 £000**	Intangible 31 March 2013 £000	Tangible 31 March 2013 £000
Contracted	**1,054**	**-**	205	944
Total	**1,054**	**-**	205	944

21 Related party transactions

The agency 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 agency 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 agency 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 (£565,458);
- The University of Leicester for the secondment of the agency's Chief Executive (£41,173);
- BIS for accommodation costs (£8,218,323).

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

2013/14	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	**3,978**	**42,672**	**13,328**	**9,080**
HMRC	**350**	**1,932**	**3,467**	**-**
Department for Work and Pensions	**565**	**3**	**174**	**-**
BIS	**8,218**	**-**	**4,252**	**1**
Various NHS Trust	**113**	**1,747**	**465**	**2,129**
Other government bodies	**277**	**509**	**1,725**	**85**
Local Authorities	**(102)**	**4**	**16**	**55**
Educational Bodies	**928**	**2,849**	**455**	**855**
As at 31 March 2014	**14,327**	**49,716**	**23,882**	**12,205**
2012/13				
Department of Health	3,625	19,744	3,707	1,072
Various NHS Trusts	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

During 2013/14, none of the Board members, members of the key management staff or other related parties had undertaken any material transactions with the agency.

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 (2012/13: 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 (2012/13: £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 agency'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 agency'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 agency'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.

	2013/14 £000	2012/13 £000
Government Banking Service*	**168,385**	134,473
Commercial banks and cash in hand	**-**	201
Total	**168,385**	134,674

* Includes £243k Proceeds of Crime which is the Agency's share of confiscated monies resulting from successful prosecutions and £55k Enforcement cash which is confiscated monies held pending a court decision.

Interest rate risk

The agency 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 (2012/13:£1.328M). This resulted in interest payable of £0.051M (2012/13: £0.046M) out of total expenditure of £122.1M (2012/13: £96.6M)

Currency risk

The level of currency risk is determined by the level of income generated by activity undertaken on behalf of the EMA. For 2013/14 this was £9.272M (Euro 11.221M) (2012/13: £7.266M; Euro 8.584M). This represents 6.9% (2012/13: 6.7%) 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 agency's policy is to maintain a strong capital structure consistent with its size. The agency's objective when managing capital is to safeguard its ability to continue as a going concern.

24 Events after the reporting period

The agency's Trading Fund accounts are laid before the Houses of Parliament by the Department of Health. IAS10 requires the Agency 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.

16 HM Treasury minute dated 24 February 2014

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 2013 to 31 March 2018 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 27 March 2008.

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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