Medicines & Healthcare products
Regulatory Agency

Medicines and Healthcare products Regulatory Agency Annual Report and Accounts 2014/15

CPRD NIBSC MHRA

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1.1 Chairman's Foreword

I write this foreword from the perspective of someone who joined the agency two-thirds of the way through the financial year, when I succeeded Professor Sir Gordon Duff, in December 2014. Sir Gordon stood down as Chairman following his appointment as Principal of St Hilda's College, Oxford in August 2014. I am very conscious of the debt that we owe to Sir Gordon and would like to pay tribute to his tremendous contribution to medicines regulation over the past twenty years, most recently as the agency's Chairman.

Sadly, three months into my appointment the agency lost one of its longest serving non-executive directors, Professor Barry Furr, who died suddenly on 27 February 2015. Professor Furr, who pioneered the development of cancer treatment medicines earlier in his career, was a much valued and highly respected member of the Board, whose experience and wisdom will be missed greatly.

Although I am new to the agency, I am not unfamiliar with its work or that of its predecessor, the Medicines Control Agency (MCA). As a former Chairman of the Committee on the Safety of Medicines (CSM), and later on, as Chairman of the National Institute for Clinical Excellence now called the National Institute for Health and Care Excellence (NICE), I have long held the agency in the highest regard.

Since becoming Chairman of the agency on 1 December, I have learned much about those aspects of the organisation's work with which my role as Chair of CSM and as Chairman of NICE did not bring me into contact. For example, during this fascinating period of induction I learned much about medical devices, the Clinical Practice Research Datalink (CPRD), the National Institute for Biological Standards and Control (NIBSC), the inspectorate, policy development, human resources, finance and procurement, among many other branches of the agency. This period learning has only reinforced the admiration I already had for the agency and its staff.

2014/15 has been a year of significant change for the agency. It continues to meet the strategic goals and direction of travel as set out in the agency's Corporate Plan (2013-2018), along with a range of unexpected developments. In particular, I have been very impressed with the agency's contribution to the fight against Ebola. As Dr Hudson has mentioned in his foreword to the Annual Report, the agency's response to Ebola illustrates the agency's strength in depth. In addition, I have been impressed with the continuing development of the CPRD. CPRD is a national and international asset that offers exciting opportunities for the safeguarding of public health through scientific innovation and research. Our aim is to ensure its development as a resource that harnesses advances of the digital age to the research quest for better health. 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 in individual and public health.

Looking ahead, I, and the members of the agency's Board, look forward to reading the report and findings of the Triennial Review, about which Dr Hudson has written in his foreword. I, too, look forward very much to working with Dr Hudson and his senior management team in 2015/16. That team leads a world-class organisation that is staffed by highly motivated and talented individuals committed to protecting public health; and the journey the agency will make will continue to be one of evolution and

growth in a rapidly changing international, political, scientific and technological landscape. For me, it is a privilege to serve as the agency's Chairman.

Professor Sir Michael Rawlins
Chairman

1.2 Chief Executive's Foreword

The year 2014/15 has once again been a very busy year marked by change, planned work, as well as unexpected developments, such as Ebola. The year also saw changes in Whitehall, as George Freeman, the Minister for Life Sciences, succeeded Earl Howe as our Minister, highlighting the continued importance attached by the Government to the Life Sciences agenda, in which the agency plays a key role. Throughout the year we have said farewell to colleagues, including six long serving members of Commission on Human Medicines (CHM). At the same time, we have welcomed new staff, e.g. newly appointed directors of Human Resources (HR) and CPRD, who took up their posts in January 2015. While it is sad to say farewell to former colleagues, it is also invigorating and exciting for the agency as it welcomes new staff.

In late 2014 we said farewell to Sir Gordon Duff, who stood down as chairman on 30 November, and was succeeded by Sir Michael Rawlins. Sir Gordon has worked closely with the agency and its predecessors for over twenty years, initially via the advisory committee structure in 1993 and then as Chair of CHM, and more recently as the agency's Chairman. I am very grateful to Sir Gordon for his enormous contribution to our work over so many years.

Sir Gordon's distinguished successor, Sir Michael Rawlins, came to the agency with a wealth of experience having been a consultant physician and clinical pharmacologist in Newcastle upon Tyne, chair of the CSM, and the founding Chairman of NICE and currently also chair of Biobank. Although Sir Michael has only been in post since December, the agency and the wider health landscape have already felt the positive impact and influence of his drive and energy.

The past year was marked by the launch of new initiatives, such as the Early Access to Medicines Scheme (EAMS), the progression of the Adaptive Pathways scheme, and the 'One-stop Shop' for advice on regenerative medicine, all of which are proving successful. The agency has now published a series of case studies highlighting the work of the innovation office. It also saw the publication of two major independent reviews of aspects of the agency's work: one on access to clinical advice and engagement with the clinical community, in relation to medical devices by Professor Terence Stephenson; the second a scientific review of NIBSC by Professor Sir Patrick Sissons of Cambridge University. Both reviews confirmed the agency's good work in these particular areas and sign-posted what measures needed to be taken in the future. One of the recommendations to come out of Stephenson Review led to the setting up of a Devices Expert Advisory Committee (DEAC) under its founding chair, Dr Peter Nightingale.

We continue to build links with other organisations in the UK for a common purpose, for example, with NHS England we have established shared networks of over 270 Medical Device Safety Officers (MDSO) and 360 Medicines Safety Officers (MSO) in larger healthcare organisations. These networks are being supported by national conferences, regional workshops, and monthly webinars. These promote improved patient safety by highlighting areas of good practice and issues of strategic importance, such as the delivery of integrated reporting and feedback systems.

At the same time, the agency has also been busy internationally with a range of work, including: a Good Manufacturing Practice (GMP) project of the International Coalition of Medicines Regulatory Authorities (ICMRA); the development of new biological standards; the coordination of medical device registries via the

International Medical Device Regulatory Forum (IMDRF), as well as building relationships globally. Most recently, we signed a confidentiality agreement with our Mexican counterpart. Indeed, recognising the international aspects of our work, our annual lecture this year was given by Dr Dan Hartman, Director of Integrated Development at the Gates Foundation. Dr Hartman spoke about the global health regulatory environment, where are we now, how can regulators in the developed world help and what can we learn.

We also marked two significant anniversaries in 2014: the 150th anniversary of the British Pharmacopeia (BP) and the 50th anniversary of the Yellow Card Scheme. Both anniversaries were marked with a series of symposia and events discussing future strategy and attracted much attention and praise from stakeholders. The 50th anniversary of the Yellow Card Scheme was an excellent opportunity to expand the scope of the scheme to include device incidents, counterfeits, and defective medicines.

One challenge that, understandably, was not on our radar a year ago was Ebola. Since the outbreak and spread of this terrible disease earlier in the year in West Africa, the agency has been extremely active as part of the UK's and the international community's efforts to combat Ebola. This is work that has involved staff across the agency to whom I would like to express my heartfelt gratitude for their hard work. The way the agency has responded to Ebola illustrates the agency's 'strength indepth' and flexibility. These qualities have also been recognised across Government in the UK and beyond. In addition, there has been the usual mix of high profile medicine and device issues handled highly professionally by staff from throughout the agency, as well as progress in reviewing negotiating and taking forward various aspects of regulation. The agency has also fully contributed to other Government priorities such as dementia, anti-microbial Resistance (AMR) and the UK's strategy on children's and young people's health outcomes.

The past year has continued to show the success of the agency's merger with the National Institute of Biological Standards and Control (NIBSC). That union, together with the establishment of CPRD in 2012, continues to offer exciting opportunities for the safeguarding of public health, research and support for innovation. It has been good to see the development of new opportunities the agency now has, with the three centres working together, that many other regulators do not have. It has also been good to see the progress made by CPRD over the past year as it develops along the path set out in the business case, reinforcing the uniqueness of this international resource. The enlargement of the agency's functions and capabilities is central to the future strategic direction as mapped out in the Corporate Plan.

During the past five months the agency, as with other arms-length-bodies, has been subject to a Triennial Review. The Triennial Review has been considering the agency's function and form, as well as performance, capability, efficiency and governance. Such external reviews oblige organisations to think hard about their purpose and how they conduct their business. They are also an opportunity to re-evaluate oneself and to act on constructive feedback. This, the agency will do, when the Triennial Review's report and findings are published.

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.

Despite the ever changing and evolving environment in which we operate, we have many exciting opportunities ahead of us and 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

1.3 About the Medicines and Healthcare products Regulatory Agency

1.3.1 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.

1.3.2 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.

1.3.3 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.

1.3.4 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 NIBSC and CPRD to support innovation and contribute 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.

1.3.5 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)

Agency operational funding is structured as follows:

- **Medicines regulation** is funded entirely from fees. In setting its fees the agency takes account of full cost recovery rules as set out in HM Treasury's Managing Public Money.

- **Devices regulation** is primarily funded through a service level agreement with the DH.

- **NIBSC** derives approximately 60% of its non-capital revenue from fees charged for services, including the sale of biological standards, and from research funding. DH provides the remaining 40% to finance its important public health functions.

- **CPRD** is operated as a joint arrangement with DH's National Institute for Health Research with a 50:50 investment contribution and joint control.

Each of the agency's centres – MHRA, NIBSC and CPRD - operates with segmented accounts which highlight their respective trading positions, bearing their appropriate share of corporate services costs. The key principle is that the three centres do not cross-subsidise each other.

1.3.6 An overview of our centres

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

CPRD is a centre that anonymises healthcare records for data services, interventional and observational research. The aim is to improve public health; facilitate interventional studies through innovation and increase their efficiency; enable academic and industry research in the UK and globally, and support UK growth.

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

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 (OCABR) testing for biological medicines and is the home of the UK Stem Cell Bank.

1.3.7 Brief overview of how we regulate

The agency grants marketing authorisation for medicines through various routes to make medicines available. The 'national' procedure involves granting UK only valid licences while those granted via the decentralised procedure (DCP) route ensures companies can market their medicines in the UK and other named EU countries.

The agency also grants licences to companies who already have a national licence in one or more EU countries but want to market it in others through the mutual recognition procedure (MRP). Most new types of medicine are now licensed by the European Medicines Agency (EMA) through the Centralised procedure to ensure that they are available to patients and used in the same way across all the member states (MS).

The agency is the competent authority for medical devices in the UK; all medical devices placed on the market in the UK must comply with the Medical Devices Regulations in order to receive a CE mark. The regulations governing devices are different from those governing medicines in that independent notified bodies assess whether manufacturers have met the requirements set out in legislation before awarding a CE mark. Notified bodies must first be designated by the competent authority in their respective EU member state before they can carry out this role; the agency is the designating authority in the UK.

Manufacturers can apply to any notified body in the EU and once they have the necessary certification their products can be sold anywhere in the EU. Following an appropriate assessment, the notified body will issue relevant certification allowing manufacturers to put CE marks on their products and put them on the market in the EU. The legislation places obligations on manufacturers to ensure that their devices are safe and fit for their intended purpose before they are CE marked and placed on the market in any EU member state.

The agency's CPRD Centre provides 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, including the safety and effectiveness of medicines and devices, and the causes of diseases. The research outputs help develop new treatments and improve health for all.

The agency is responsible for developing and producing international standards in use around the world to assure the quality of biological medicines through NIBSC one of our Centres. NIBSC has responsibility for testing biological medicines; performing OCABR testing for biological medicines and is the home of the UK Stem Cell Bank.

1.4 Working together to deliver our objectives

Each year the agency produces a Business Plan identifying key strategic activities for the year ahead to support delivery of the five year Corporate Plan. The Business Plan splits out the activities for 2014/15 under five themes:

- Vision and scope of our role
- Bring innovation and new products speedily and safely to patients
- Strengthening surveillance
- Safe products and secure supply in globalised industries
- Achieving excellence – a well-run, efficient and effective organisation

Our overview of our key work and achievements over the year are presented below under these themes.

1.4.1 Vision and scope of our role

The Business Plan identified that the agency would seek to build capability and maintain its leading position across all regulatory areas. Alongside this the agency would target partnership work with others in the new health and care system to define our role both within the system and with patients and the public.

Taking a leading role in providing scientific and regulatory advice at the European level is a position the agency is familiar with and has maintained this year. 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 2014/15 the MHRA had 166 appointments as coordinator. This was the highest number of any member state and reflects the high regard in which the agency's scientific and regulatory expertise is held. At the national level 325 regulatory or scientific advice meetings were also held to give guidance to companies.

The type of advice described above is usually sought during the product development stage, further along in the process a company will look to obtain a Marketing Authorisation (MA) in order to launch their product; the MHRA has again performed strongly as a regulator of choice in this area. 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 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, the UK was awarded 31 Rapporteur/Co Rapporteurs during the 2014/15 reporting period. This acknowledges not only the widely respected knowledge of the MHRA and its assessment processes but also makes 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:

- Translarna (ataluren), the first medicine for the treatment of Duchenne muscular dystrophy (DMD), where the Messenger RNA (mRNA) contains a mutation causing premature stop codons or nonsense codons. Ataluren makes ribosomes less sensitive to premature stop codons (referred to as "read-through").
- Scenesse (afamelanotide), a non-selective agonist of melanocortin receptors that mimics the tanning process and is the first treatment licensed for erythropoietic protoporphyria, a rare genetic disease which causes intolerance to light.
- Holoclar (*ex-vivo* expanded autologous human corneal epithelial cells containing stem cells), an orphan medicine used for the treatment for severe limbal stem cell deficiency (LSCD) due to burns in the eye. This is the first recommendation worldwide of a therapy based on stem cells.

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). Over the course of this year the UK remained the preferred RMS responsible for leading on 195 (45%) of all procedures in which the UK was involved. This demonstrates that industry continues to recognise the value of the MHRA's science and assessment processes.

Following the grant of an MA continual surveillance of that medicines safety is undertaken; increasingly this surveillance is conducted at the European level.

In 2013 MHRA referred the safety of valproate containing medicines in pregnancy for consideration by the EMA's Pharmacovigilance Risk Assessment Committee (PRAC). To inform that review the CHM established a working group to evaluate valproate containing products in the light of a Europe-wide review of the risk of developmental disorders in children born to women who took valproate during pregnancy. The review completed in January 2015 and concluded that use of sodium valproate in pregnancy was associated with a risk of developmental problems of up to 40% in pre-school children exposed to valproate in the womb and that warnings on the use of valproate in women and girls should be strengthened. The warnings aim to ensure that patients are aware of the risk of valproate in pregnancy and that they only take valproate when clearly necessary. The MHRA has been working with both DH and clinical guideline bodies on UK implementation of the risk minimisation measures as a result of the review and with this in mind hosted a stakeholder event in March to discuss tools to facilitate discussions of risk between prescribers and patients.

This was one of a number of EU wide reviews of medicines safety led by the MHRA. Since the introduction of the new Pharmacovigilance legislation (July 2012) MHRA has played a leading role (Rapporteur or Co-Rapporteur) in 33% of all pharmacovigilance referrals (9 out of the 27 referrals considered by the PRAC).

If, as part of vigilance activities, it comes to light that the safety profile of a medicine which has been available without prescription has changed such that healthcare professional intervention is needed, then its status will be reviewed. Although this is not a common occurrence, there have been two such examples this year:

- Domperidone: a Europe-wide review of the risks and benefits of domperidone recommended restriction of the indication to nausea and vomiting, new

contraindications and warnings and a reduction in the dose and duration of treatment due to the increased risk of serious cardiac side effects. Following CHM advice in light of this review all Domperidone products were reclassified as Prescription Only Medicines (POMs)

- Oral diclofenac: A Europe-wide review of this anti-inflammatory drug identified a small but potentially important increased risk of serious cardiovascular events potentially associated with doses and durations of treatment applicable to pharmacy use; it was not considered that the pharmacy setting could be relied upon to adequately identify and exclude patients at risk of such events. As a result oral diclofenac products were restricted to POM.

This year the NIBSC centre has spearheaded the agency's drive to continue to be a key player in the area of biological medicine. Measurement standards for these medicines are critical for increasing global access by supporting the introduction of new high quality competitor products on the market and driving costs down. Currently the emergence, driven by patent expiry of 'biosimilar' versions of products with major clinical and economic importance, such as anti-cancer and anti-inflammatory monoclonal antibodies is a major theme. NIBSC is developing a new range of standards and reference materials to support this transition and has, through the World Health Organisation (WHO) initiated a strategic review of future global needs.

The NIBSC centre has also been successful in attracting external research funding, securing over £4 million this year. Projects include continued support for the UK Stem Cell Bank, and several internationally funded collaborative projects focused on development of innovative influenza vaccines and novel analytical methods for vaccine characterisation. NIBSC's world class expertise in polio vaccines has seen funding secured from the Bill and Melinda Gates Foundation to support the further development of vaccine candidates for use post eradication. Complementary vaccine strategies suitable for the production of recombinant virus-free polio virus vaccines are being developed as part of a collaboration funded by WHO in collaboration with the Universities of Leeds, Reading and Oxford. In addition, following its initiation last year, a major EU funded programme coordinated at NIBSC has begun to produce, characterise and distribute research and reference reagents for the poverty-related diseases TB, Malaria and HIV as well as Hepatitis B and C.

Another key focus for the agency this year has been the Ebola outbreak in West Africa, which has posed a significant challenge to healthcare systems across the globe. The agency responded accordingly as this specifically required reprioritisation of effort across the agency. During this period, four Clinical Trial Authorisation (CTA) applications were assessed by the MHRA, comprising a mix of first-in-human vaccines, a first-in-human antiviral and a further antiviral which had undergone phase 3 testing for a different indication. Assessment was prioritised to ensure that the applications were evaluated as rapidly as possible without compromising the rigour of the review. The MHRA also played a key part in the EMA taskforce on Ebola vaccines and was appointed to provide rapid scientific advice on any vaccine manufacturing or testing issue, supporting companies to develop vaccines as rapidly as possible.

As the outbreak grew it was recognised that reference standards were urgently needed to underpin consistent diagnosis of disease, and to provide comparable measurements of immunological responses to the virus. NIBSC has taken a global lead in standardisation activities strongly supported by WHO and DH. In close collaboration with Public Health England (PHE) NIBSC has made good progress with

assay development, acquisition of materials, and co-ordination of an international group of expert laboratories to test and agree on appropriate calibration methods and associated reference materials.

Whilst the Ebola outbreak presented an unexpected focus for the agency's time and resource support has continued this year for another key health public initiative. Following on from work last year the MHRA contributed to a UK government led workshop combining a number of regulators, clinical experts and patient representatives to discuss dementia. The workshop was used to consider how regulators from around the globe could create a supportive approach to the development of new medicines, in light of the high unmet medical need for dementia. The goal of this project is to overcome the current challenges in drug development and help drive towards the goal of a cure or disease modifying therapy for dementia by 2025.

The cross-Europe work to update the Medical Devices Directives has also continued this year with the MHRA working to ensure that the new legislation is both effective and proportionate. Extensive stakeholder consultation has been undertaken to help establish strong well-reasoned UK positions and the MHRA worked with colleagues across the community to develop detailed proposals on a large number of specific issues. It should be noted that much of the criticism levelled at the current system has been as much about management of the system as the legislation itself. With the UK having been founder members of both the Compliance and Enforcement Network (COEN) and Notified Bodies Operations Group (NBOG), the MHRA has been a leading player in establishing mechanisms aiming to improve the management of the system and enhancing efficiency through collaboration with EU partners.

Working within the current system the MHRA has been one of the leading authorities in supporting the design, development and roll-out of the notified body Joint Audit programme. Mandatory joint audits for all notified bodies are a legislative requirement with such audits conducted by a team including the designating authority, two other member states and officials from the European Commission (EC). The goal of such audits, supported by more comprehensive procedural guidance, has been to bring about greater consistency of both expectations and performance of notified bodies across the system. The effect has been substantial and will lead to significantly improved consistency and lowered risk of unsafe products finding their way to market.

The agency has continued to build partnerships across its centres during this year, with the CPRD centre benefitting from numerous external partnerships and collaborations. CPRD continues to engage in strong partnerships with the Health and Social Care Information Centre (HSCIC) which acts as a Trusted Third Party facilitating data linkage, NIHR Clinical Research Network that undertakes research activities on the ground working closely with General Practices, and academic research organisations. CPRD business development has continued this year and the centre is now working with 17 of the world's 20 biggest pharmaceutical companies whilst also increasing numbers of academic users. An increase in the number of protocols submitted for approval to the MHRA Independent Scientific Advisory Committee (ISAC), which grew a further 3.38% (245 protocols submitted) in 2014/15, a figure which has grown by 37% since 2011 further demonstrates this growth.

A significant piece of partnership work has been undertaken by the MHRA centre in conjunction with NHS England which has seen the launch of two new safety networks (one for medication safety officers and one for medical device safety

officers) which aim to simplify and increase both medication and medical device error reporting, improve data quality, maximise learning and identify key safety contacts to allow better communication between local and national levels. The two networks act as a forum for discussing potential and recognised safety issues, identifying trends and actions to improve the safe use of medicines and medical devices, much of which takes place via monthly webinars. Supporting these networks was a joint event held in January by the MHRA and NHS England which was well attended and positively reviewed.

Supporting patient involvement, the agency has developed a Patient Group Consultative Forum (PGCF); open to individual patients and carers and representatives from patient groups/charities. The forum provides a means for two-way dialogue between the agency and patients/patient groups, enabling patient groups to raise issues with the agency and for the agency to elicit feedback and information on patient experience to assist in the development of policy objectives and agency projects. A successful event for forum members was held in November 2014 to support the implementation of the Stephenson review, in particular how to improve patient reporting of adverse incidents with medical devices and improve the communications to patients when patient safety issues do arise.

The MHRA centre has also continued this year, in conjunction with DH's work around nicotine-containing-products (NCP) following the agreement at the European level of the new Tobacco Products Directive (TPD). Interest from companies in launching such products as medicines has continued this year and September saw a Marketing Authorisation granted to Kind Consumer Limited for Voke/Nicotine 0.45mg inhaler. Work will continue alongside DH into 2015/16 in this area.

1.4.2 Bringing innovation and new products speedily and safely to patients

In the Business Plan, the agency identified its desire to lead and contribute to innovation initiatives at the National, EU and global levels whilst developing its own in-house expertise in developing scientific areas. An objective for the CPRD centre to expand its reach and develop the service it provides was also identified.

One of the agency's key contributions to supporting innovation has been EAMS which was launched in April 2014. EAMS is a UK scheme which aims to give patients with life threatening or seriously debilitating conditions access to medicines (that do not yet hold a MA) when there is a clear unmet medical need. The scheme consists of a two-step evaluation process, the Promising Innovative Medicine (PIM) designation (which indicates that a product may be eligible for EAMS based on early clinical data) and EAMS scientific opinion. The scientific opinion describes the risks and benefits of the medicine and supports the prescriber and patient to make a decision on whether to use the medicine before its licence is approved**.** Since launching the scheme the MHRA has issued six PIM designations and one EAMS scientific opinion, the latter for pembrolizumab for the treatment of patients with advanced melanoma which was issued in March 2015.

EAMS is complementary to other ongoing initiatives to improve patient access in areas of unmet clinical need, with another such route being the EMA pilot project on adaptive pathways. Over 50 submissions have been received with promising candidates progressing through discussion meetings and into formal scientific advice. An MHRA representative continues to chair discussions with companies, seeking

agreement between stakeholders on levels of evidence needed for early and iterative decision making. The MHRA also has representation in the Innovative Medicines Initiative (IMI) Get Real project, which is looking at integrating real-world data to meet the needs of Health Technology Assessment bodies, earlier in the drug development process. Close involvement in these areas gives the agency a strong platform through which to support and drive innovation.

During 2014/15 a new scientific Division of Advanced Therapies was established at NIBSC to focus particularly on gene therapeutics and regenerative medicines, reflecting the rapidly growing importance of this innovative class of medicines, and the need for a thorough understanding of their critical characteristics. A Memorandum of Understanding (MoU) signed this year with University College London, will stimulate joint research collaboration and further teaching opportunities for the division. Developing standards for these products sits alongside the potential for the development of standards which will support new diagnostic technologies, such as next generation sequencing, that will underpin the emerging field of Precision Medicines. This year also saw the first meeting of NIBSC's reformed Scientific Advisory Committee. The Committee panel is of a high calibre and their input in taking forward recommendations from the 2013 Sissons Review has been very beneficial work which will continue into 2015/16.

The CPRD centre has continued to focus on expanding its reach, while also delivering innovative products and tools to its users. Increasing CPRD's coverage of the UK population significantly increases its capacity to support new research. Previously CPRD had only collected primary care data from one GP software source (Vision), however this year data from EMIS, the largest supplier of GP software in the UK has been added. This has increased CPRD's coverage of the UK population from 8% to 11%; a figure set to continuing rising over 2015/16.

Providing innovative tools to support CPRD users has been delivered via three key developments this year. Clinical trial facilitation has been enhanced through innovative tools that support interrogating CPRD data based on clinical criteria for study feasibility and protocol optimisation; serving to make trials more efficient and ensuring products and interventions are brought to patients quicker. The Trialviz tool provides fast feasibility and protocol optimisation outputs and its use (supported by CPRD researchers) is currently being rolled out widely. A Health Technology Assessment report published in July 2014 provided early evidence that using electronic healthcare records to understand the best available treatment for patients, from a range of possible options, is more efficient and less costly than the existing clinical trial process.

The second development has been the launch of a new modular based e-learning system. This cost effective and convenient training tool successfully translates complex statistical and pharmacoepidemiological concepts into pithy and attractive e-learning modules, to the benefit of CPRD users. Key to the success of the project was the cross functional team comprised of CPRD, the agency's Information Management Division (IMD) and a third party vendor, Digital Life Sciences. The project demonstrated how the agency can partner with a leading media company to deliver high specification e-Learning which meets the needs of its clients.

The third development was the launch of an updated version of the CPRD GOLD (GP On-Line Data) web interface, used to query and retrieve selections of CPRD data. With the aid of customer feedback this updated version was designed to deliver a more robust service and improve the process through which customers can obtain their data via a more efficient download mechanism. The customer applications have

also been upgraded to decrease the amount of time required to query data and an application added that contains all code dictionaries currently offered by CPRD.

The agency has taken the opportunity this year to build on previously established innovation initiatives including through the Innovation Office. The Innovation Office, launched in March 2013, offers free regulatory advice on both medicines and medical devices to developers of innovative products or those using innovative approaches (for example novel clinical trial designs or novel manufacturing operations). To date, 172 queries have been received via the web-based portal (approximately 60% of the queries related to medicines and 40% to medical devices). The role of the Innovation Office has expanded with the recent introduction of a “one-stop shop” for regulatory advice on ‘Regenerative Medicine’ (Advanced Therapies). The Human Tissue Authority (HTA), Human Fertilisation and Embryology Authority (HFEA), Health Research Authority (HRA) and the MHRA are co-operating to provide advice on Regenerative Medicines, using the MHRA’s Innovation Office web portal as the single entry point for such queries. To date, there have been four such ‘One-stop Shop’ queries. The MHRA has also worked with partners to deliver advice and guidance around innovation. June saw the fourth joint MHRA / Bioindustry Association conference, the theme was the regulation of healthcare innovation and the event provided updates on regulatory and scientific developments from senior experts at MHRA, NICE, European regulatory agencies, industry and research charities.

The agency supports patient choice and the availability of products, where it is safe to do so, from pharmacy or general retail outlets through the reclassification process. This year the MHRA, in agreement with the agency’s expert advisory body CHM, established a National Stakeholder Platform with a remit to consider strategic issues relating to reclassification. The CHM also recommended the involvement of external stakeholders earlier in the reclassification process. The stakeholder platform has been established and met for the first time in February; the presence of three patient representatives is something which has been particularly beneficial. In addition to this the Patient Group Consultative Forum has also met this year to discuss reclassification – this exercise was intended to give the group an overview of the process, but also to gather their insights into issues such as how patients and the public buy their medicines, what information they are looking for at the point of purchase, what sort of information would assist them if for example a product is newly reclassified. This has provided the agency with important intelligence in this area.

Keeping with the reclassification theme, the MHRA completed and announced the change in availability of Nexium Control 20mg Gastro-Resistant Tablets from a pharmacy (P) medicine to a general sales list (GSL) medicine. This medicine is used to treat (up to 14 days) reflux symptoms (e.g. heartburn and acid regurgitation) in adults.

In the medical devices arena the MHRA has seen an increase in requests for advice on software, particularly whether particular apps would constitute a medical device. The MHRA published guidance to assist innovators and developers in determining the classification of their product. However, the MHRA continues to tackle a long list of emerging issues in this area which will continue into 2015/16. Work with the Royal College of Physicians (RCP) on guidance for medical practitioners who are developing apps, with NHS England to ensure that their developing guidelines and processes are complemented by consideration of regulatory requirements and in contributing to the European shadow group supporting the International Medical Devices Forum (IMDRF) work stream which is producing harmonised global

guidance in this area are all areas in which the MHRA has been involved this year. The MHRA has also been looking at the regulatory status of sequencing devices and software used to translate sequencing data into information that may be used by clinicians or individuals. A cross-agency group is currently exploring this as part of a wider insight into genomics and the impact of emerging technologies on the work of the MHRA.

Throughout the year MHRA toxicologists have maintained their active involvement in projects with the National Centre for 3Rs (NC3Rs), some of which were highlighted in the government's delivery plan on its commitment to replace, reduce and refine the use of animals in research, published in 2014. These projects aim to reduce animal numbers, but also seek to replace animal use with *in vitro* alternatives. The results from a number of these projects are being used to influence international guidelines on animal testing. MHRA toxicologists are continuing to have dialogue with counterparts from China's Food and Drug Administration to discuss a number of initiatives that have the ultimate aim to reduce animal testing.

1.4.3 Strengthening surveillance

The Business Plan placed the overarching focus within this theme onto developing vigilance systems that take advantage of innovative methodology and technology to improve safety reporting and subsequent communications. This was to be undertaken in conjunction with working with others in the sector to ensure systems for the reporting of incidents are both relevant and accessible.

The MHRA centre plays a key role at the European level in coordinating and leading projects to develop European vigilance systems and harmonise standards to improve detection of issues. The MHRA has been coordinating a three year EU-wide pharmacovigilance project entitled Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) to help EU Member States meet the requirements of the updated pharmacovigilance legislation which came into effect in 2012. SCOPE gathers information and expertise on how regulators in member states run their national pharmacovigilance systems, using this information to develop and deliver guidance, training in key aspects of pharmacovigilance, and tools and templates to support best practice. The MHRA is leading topics in the work packages on Adverse Drug Reaction (ADR) collection, Signal management, Quality management systems, and Risk Communications.

The MHRA also led a consortium of organisations this year looking to build new ways of gathering information on suspected adverse drug reactions; this project came in response to the rapid adoption of smartphones, apps, and social media. The MHRA's involvement has been twofold: one has been the development of an application ('app') for healthcare professionals and the public to report suspected ADRs (a beta version was launched at the March 2015 event described below), the second is exploring the potential for publicly available social media data to be used for identifying potential drug safety issues. Work on both will continue into 2015/16.

This year has been a busy and productive one for the MHRA's Yellow Card Scheme, which has expanded its reach whilst marking a significant milestone in its 50th anniversary. A series of events were held showcasing the achievements of the Scheme in protecting public health whilst looking ahead to the future. The first event, in November, saw the Parliamentary Under Secretary of State for Life Sciences launch a new Yellow Card website which provides a single point of access to MHRA

incident systems. Patients and healthcare professionals can now report any incidents or problems associated with medical devices, defective medicines and counterfeit healthcare products as well as suspected adverse drug reactions via this new single reporting portal. A second event in December featured a keynote speech from the Chief Medical Officer, and the third event in March was used to discuss a road map for the Scheme into the future. The MHRA's Yellow Card Centres will be holding events within their respective regions into 2015/16.

The MHRA have been piloting a transparency and vigilance scheme which aims to give a healthcare professionals in specialist areas an early indication of adverse incident reports for particular devices and seeks their input based on their clinical experience. This contributes to a key recommendation from the Stephenson Review concerning clinical involvement into regulatory and safety decisions for devices. This scheme supplements the established reporting and vigilance mechanisms for devices.

The MHRA recognises the value of collecting Unique Device Identifiers (UDI) for implantable medical devices in patient electronic records in support of device post-market surveillance and patient tracking and tracing and has undertaken a feasibility study to look at recording implant UDIs in patient electronic records. The study has identified that considerable work will need to be done to encourage healthcare professionals to adapt their current data collection procedures and that significant changes will need to be made to hospital IT systems to allow UDI information to be systematically collected at the point of use. The MHRA is currently working with partners to encourage NHS Trusts to implement systems for UDI recording and to adapt national data recording and transfer systems so that UDI information can be centrally collated and analysed.

The NIBSC centre has been involved this year in a replacement WHO standard for measurement of Haemophilus influenza b polysaccharide, standards were also established for measurement of Hepatitis B surface antigen, anti-malaria (Plasmodium falciparum) antibodies, and Toxoplasmosis gondii. Diagnostic standards were established for measurement of Luteinizing hormone (reproductive potential) and C-peptide (early onset of Type I diabetes), and for haemostasis. International Standards were established to support measurements of Coagulation factor XIa, lupus anticoagulant, plasmin and ADAMST13 (von Willebrand factor-cleaving protease). Complementary standardisation projects, including development of new CE marked standards for clinical diagnosis of Varicella Zoster B, Hepatitis A and Haemophilus influenza b have also been progressed.

The CPRD centre's data has also featured in a number of drug safety and epidemiological research papers this year, a select few are highlighted below:

- A study led by London School of Hygiene & Tropical Medicine, published in The Lancet in August 2014, which showed that a higher body mass index (BMI) increases the risk of developing 10 of the most common cancers, and could be linked to more than 12,000 cases of cancer in the UK each year. In total the research generated over 285 pieces of media coverage.
- Researchers from the Universities of Nottingham and Keele assessed the burden of gout in the UK with CPRD data showing that one in forty people in the UK is affected, with highest prevalence in the North East and Wales; while the prevalence of gout rose by 64% between 1997 and 2012. However, in 2012, less than one in five patients was prescribed medication within six

months of their diagnosis, and only around one in four was on this treatment a year after their diagnosis. The paper was featured heavily in the popular media.

- In what was described as the Mega Hypertension Study, research from UCL Farr Institute (published in the Lancet in June 2014) looked into a linked cohort of 1.25 million patients and reported associations of blood pressure with a substantially wider range of incident cardiovascular diseases than seen before in the largest database ever produced on how blood pressure is related to cardiovascular disease.
- Finally, this past year two papers using CPRD data were shortlisted in the list of the final five to claim the prestigious BMJ UK Research Paper of the Year Award.

It is not only in the academic sector where CPRD data is making a big contribution. The influential consultation document on 'Suspected cancer' by NICE used a range of CPRD data. The resulting draft guidelines give clearer and updated information on the recognition of early signs and symptoms of over 200 different types of cancer and the criteria that warrant further investigations or referral to specialists.

1.4.4 Safe products and secure supply in globalised industries

Objectives identified in the Business Plan under this theme sought to bring about a convergence in standards and practice through collaboration with other regulators to combat counterfeiting and ensure a more secure supply. Ensuring the quality of products on the market, tackling the risk posed by the illegal supply of medicines and medical devices and developing new biological standards were also identified.

The MHRA inspectorate has continued this year to support the enhanced harmonisation of inspection expectations across Europe and the wider regulatory community. The Inspectorate has contributed to several international training events for regulators organised by the EMA, Pharmaceutical Inspection Co-operation Scheme (PIC/S), WHO and other international organisations. This work has been supplemented by chairing the newly formed PIC/S Good Clinical Practice & Good Pharmacovigilance Practice Working Group and the Organisation for Economic Co-operation and Development (OECD) Good Laboratory Practice Working Group along with active participation in a number of EMA and EC subgroups. These activities put the Inspectorate in a strong position to enhance harmonisation and also demonstrate the high regard with which the inspectorate is held by other regulators and international organisations.

Aside from this the inspectorate has also collaborated with industry and Cogent SSC (the national skills body for the science industries) to produce a Gold Standard role profile for Responsible Persons, supporting those in this important role to develop their skills and understanding further.

The inspection landscape has changed in recent years, in particular with the global shift in attention to inspection findings which concern data integrity. The MHRA has seized the initiative by publishing guidance for industry on data integrity definitions, which it is hoped will help overcome some of these issues. The inspectorate also delivered educational sessions in the form of three major symposia which were conducted over a total of six days, reaching over 1000 delegates. We have also inspected over 1800 companies during the year, 80 of which were overseas.

NIBSC's annual work relating to the seasonal influenza vaccines was particularly challenging this year with strain changes required for the vaccines for both hemispheres owing to the emergence of a new H3 variant. This placed significant pressure on both vaccine manufacturers and the Global Influenza Surveillance and Response system (GISRS), of which NIBSC is a key component, and underlined the importance of the twice yearly meetings that NIBSC hosts to bring the key players together and ensure that the vaccine response system works as smoothly as possible.

Joint work has been underway this year between the BP and NIBSC. This has looked at the possibility of developing monographs at an earlier stage in the lifecycle of a product and at the support for future monographs. Work on the characterisation of herbal medicines using genomic technology has been successful, delivering ahead of plan both reference materials and written standards. In the coming year the feasibility of the BP providing secondary biological reference standards will be explored as will the development of micrographs to aid the identification of herbal drugs.

As the Official Medicines Control Laboratory for the UK, NIBSC has continued to carry out Official Control of Batch Release as part of the European regulatory system. 143 different product licences (for UK, Europe and outside Europe) for Human Blood and Vaccine products were tested and release certificates issued. Notable this year was an increase in both the number of batches tested and the range of products covered.

Another emerging feature this year has been the increased need for testing of suspect biological products. Counterfeits have been a major global problem for non-biologics for many years, but with the huge rise in economic importance of biologics, and the increasing globalisation of production of these products this trend is expected to continue.

The NIBSC centre has also taken the opportunity to work with international colleagues this year and have undertaken four joint projects with the United States Pharmacopeia to support quality assurance of analytical methods for glycoprotein therapeutics such as erythropoietin, for therapeutic monoclonal antibodies, and for tetanus toxoid, and also to support measurement of prekallikrein activator, a contaminant in therapeutic albumin.

Earlier in this report the 50th anniversary of the Yellow Card was highlighted; that was not the only significant milestone reached this year, with BP celebrating 150 years since publication. A commemorative reception was held at the House of Lords which included speeches from Earl Howe (Parliamentary Under Secretary of State for Quality), Ms Helen Gordon (Chief Executive, Royal Pharmaceutical Society) and Sir Gordon Duff (then Chair of the Agency). This event provided an opportunity to reflect on the history and successes of BP and the challenges ahead. Earlier in the year a number of technical meetings took place: including a conference on "The Quality of Medicines – Future Evolution", the annual meeting of National Pharmacopoeial Authority Secretaries and the Third International Meeting of World Pharmacopoeias the latter two were both hosted by the MHRA. A number of bilateral meetings also took place to progress international collaboration activities with countries including China, India, Indonesia, Kazakhstan, Russia, the US and WHO.

The 2015 edition of Rules and Guidance for Pharmaceutical Manufacturers and Distributors (the "Orange Guide") and the Rules and Guidance for Pharmaceutical Distributors (the "Green Guide") have been updated to incorporate changes to the detailed European Community guidelines on Good Manufacturing

Practice (GMP) and the revised EU Guidelines on Good Distribution Practice (GDP). The MHRA took the opportunity to provide updates on areas such as the Innovation Office, the risk based inspections programme and guidance on registration requests for companies involved in the sourcing and supply of active substances to be used in the manufacture of licensed human medicines.

In terms of the agency's work in tackling the threat from illegal products, preparations have continued to implement parts of the Falsified Medicines Directive (FMD), specifically further measures to prevent the entry of falsified medicines into the legal supply chain. From July 2015 a website logo will be introduced to allow patients across the EU to identify legal suppliers of medicines "at a distance" to authenticate the legitimacy of the business and thereby also providing the public/patients with a degree of confidence in the product they, the end user, will receive. Consultation is underway and will continue into 2015/16 on the facilitation and operation of this EU common logo in the UK.

The second aspect is the requirement for a safety feature comprising a seal on the outer packaging on a medicine (to indicate whether the pack has been tampered with) and a unique identifier to be applied to certain categories of medicines. Further amending legislation is required for this track and trace element and the MHRA will continue to work with DH on this into 2015/16.

These initiatives will help the agency continue to tackle the issue of illegal products; however action has also been taken this year within the current regulatory framework. The MHRA Enforcement Group participated in Operation Pangea VII, a week-long international crackdown on the illegal trade in medicines. £8.6 million worth of counterfeit and unlicensed medicines were seized, including hauls of potentially harmful slimming pills and controlled drugs such as diazepam and anabolic steroids. The operation also targeted websites selling counterfeit and unlicensed medicines, resulting in their closure or suspension. In the UK alone, a total of 3.6 million doses of counterfeit and unlicensed medicines were seized, five arrests were made, and 1,891 websites were taken down. For the first time, the MHRA has also targeted YouTube accounts, removing 18,671 online videos from the platform, which were facilitating the sale and supply of unlicensed and counterfeit medicines.

In June 2014 the MHRA received notification from PHE that a number of cases of septicaemia in neonates had been identified at a number of London hospitals. The infection was identified as being associated with *Bacillus cereus* and a recall and Press Statement were issued. A full investigation was initiated with the incident isolated to a specific day; quick action taken by the Incident Management Team ensured that the risk was quickly minimised.

On the devices front concerns raised by patients who have experienced severe and debilitating complications associated with vaginal mesh implant surgery led the MHRA to conduct an extensive review of the available information on the safety of these devices. The review concluded that the benefits of the use of these devices continue to outweigh the risks. However as part of an EC taskforce in conjunction with the Netherlands, Denmark and Sweden a mandate has been supplied to the European Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) asking for a scientific opinion on 'the safety of surgical meshes used in urogynecological surgery'. The MHRA will continue to keep available information about the safety of these implants under close scrutiny and are collaborating closely with NHS England and the relevant professional clinical bodies. In addition to this the

MHRA is fully participating in a Scottish Independent Working Group looking at this issue.

Over the course of the year, the MHRA investigated 892 defective medicines reports and issued 17 drug alerts, while 16 Company led drug alerts were issued. There has been a consistent year on year reduction in the number of drug alerts issued over the past three years although the number of reports received has remained relatively consistent. The reduction can be explained in part by a number of cases where a recall would have been desirable but has not been possible due to product shortages. In 2014, the number of cases for which a Company Led Drug Alert was deemed appropriate exceeded the number of conventional Drug Alerts for the first time.

The past year has also seen an increase in the number of complex cases which have arisen from Good Manufacturing Practice (GMP) and Good Laboratory (GLP) inspections by both UK and EU Inspectors. A large number of Licences held by a number of Marketing Authorisation Holders may be impacted with potential for multiple recalls and in some cases suspension of affected Licences. For this type of case, close liaison with DH has been required to evaluate criticality of affected products and with EMA where centrally authorised products are involved.

In terms of medical devices vigilance during this year, the MHRA devices division received and investigated 14836 adverse incidents reports (12.5% increase in the last 3 years); issued 53 Medical Device Alerts (MDAs), oversaw 902 Field Safety Corrective actions (FSCAs) undertaken by manufacturers in the UK and issued 242 National Competent Authority Reports to inform other EU competent authorities of safety actions being undertaken within the EU. The number of FSCAs undertaken in the UK has varied between 800-1000 annually, however our revised monitoring policies have enabled a reduction in the number of MDAs issued by MHRA.

1.4.5 Achieving excellence – a well-run, efficient and effective organisation

The objectives under this theme centre on ensuring the agency operates in a financially sustainable way and continues to meet its financial targets, whilst identifying and implementing revised or new processes with the aim of increasing efficiency.

A key component of an effective and efficient organisation is how well the different areas within it work together. The enlargement of the agency in 2013 to create the three centres identified many potential benefits; this year the agency has carried on where it left off last year in taking advantage of these. Some excellent examples include the cross-agency collaboration to support the Ebola response, continued support of the introduction of new vaccines into the UK schedule, quality assurance of diagnostic devices, advanced therapies, biosimilars, blood or blood related products and BP Standards.

The agency has made some significant changes to its digital offer during the year. The agency's corporate website, which also incorporates content for the MHRA centre transitioned to the GOV.UK platform in January 2015. The transition was part of the government-wide initiative to ensure that all government departments and executive agencies publish their information on one single domain, to make it easier for citizens to access information about government services. In February the

agency's homepage was the 19th most visited on GOV.UK (out of 300+ government departments and executive agencies), serving to demonstrate the profile of the agency and the desire to access its content. Additionally a refreshed NIBSC website (which is exempt from the requirement to transition to GOV.UK) was launched this year (a key recommendation from the Sissons Review) and this was accompanied by the introduction of a regular e-newsletter and e-alerts for customers.

Another means of accessing agency information is via agency run events and conferences and the agency has continued to offer a range of these this year for which there is significant demand. This year has seen thirteen such events delivered with over 3850 delegates attending. These events provide the agency with a platform to offer advice and guidance but they also serve to deliver revenue and the programme this year generated just over £949,000. Several events this year were targeted towards the licensing process (both new applications and variations) with the aim of providing advice and guidance to applicants to get their applications right first time, to understand new procedures and ultimately to avoid delays in the licensing process. These particular events were attended by over 360 delegates who provided positive feedback.

Alongside offering guidance and advice to applicants the MHRA has also taking the opportunity to review the efficiency of its own processes to establish where improvements could be made. One example of this is the implementation this year of a pilot processing initiative designed to improve the efficiency in the review of multiple parallel variations. The pilot will continue until July 2015 during which time the MHRA will continue to receive feedback from companies about how the processes work for them, and what should happen post July.

The agency has also made changes this year at the Buckingham Palace Road (BPR) site in central London. Over the course of the year an accommodation programme has been underway to deliver financial savings and increased efficiency by reducing the floorspace the agency (mainly MHRA and CPRD centre staff are based at this site) occupies through re-modelling its layout. The changes were delivered over the course of January and February of 2015 and will deliver savings in rental and utility costs moving forward. During this period the delivery of the agency's services were not interrupted.

1.5 Contributing to the Secretary of State's health inequalities agenda

During 2014/15, the agency continued to support the Secretary of State in meeting his duty to reduce health inequalities across the health and care system.

We participated in key DH projects with a health inequalities focus, like the Children and Young People's Health Outcomes Strategy. Our focus has been on strengthening paediatric pharmacovigilance as well as increasing the number of age appropriate formulations for children available on the UK market in the context of European paediatric legislation.

We also contributed to regulatory discussions on dementia and antimicrobial resistance (AMR); developed standards to support regenerative medicines and tools to improve the diagnosis of disease; and worked with international partners to increase the reach and public health impact of our efforts.

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).

In addition, the agency continued to work to ensure that the Yellow Card scheme is accessible. It now includes reporting for medical device adverse incidents, is open for anyone to report an adverse incident, and continues to have basic information about the scheme translated into 12 languages, which are available at the reporting website. As a result of its paediatric pharmacovigilance strategy, the agency has modified its online Yellow Card form to make it easier to report suspected adverse reactions experienced by the woman or child associated with medicines taken during pregnancy and has also updated its guidance to healthcare professionals on reporting suspected adverse drug reactions in children. In all cases the intention is to maximise safety reporting from the 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.

1.6 Performance against targets 2014/15

No.	Area of work	Performance Target	Rating	Comments
PM1	**Medicines licensing – validation of applications**	a) For Type IB/II variations, 97% of scientific validation process completed within 14 days of case creation	**Green**	**Met** Nearly 100% (99.93%) validated within 14 days of case creation
		b) For new Marketing Authorisation applications, 97% of validation reports produced within 14 days of case creation.	**Green**	**Met** Nearly 100% (99.6%) of validation reports produced within 14 days
		c) 97% of Change of Ownership applications validated or Request For Information (RFI) issued within 42 days of receipt.	**Green**	**Met** 100% 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% 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	**Green**	**Met** • 99% DCP RMS in 70 days • Nearly 100% DCP CMS in 100 days • 100% MR in 50 days • 100% Centralised Rap/Co-Rap in 80 days
		c) The assessment of Type IB minor and Type II major variation applications in National and European (MR, centralised) procedures: 97% assessed within the designated time.	**Green**	**Met** • Type II – 98% assessed in 90 days • Type IB – 97% assessed 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** 100% of all authorisations within 30 days (with an average of 12 days for Phase 1 trials)

		b) Timescales for clinical investigation notifications for medical devices: maximum of 60 days with an overall average of 54 days or less	**Green**	**Met** 100% handled within 60 days (with an average of 45 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** 100% made available within 2 working days and 100% made available within 3 working days
		b) Medical Device Alerts will be issued: 95% within 10 days, 100% within 15 days	**Green**	**Met** 99% published within 10 days 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** 92% within 5 working days
PM5	**Publication of UK assessment reports for new Marketing Authorisations**	The publication of UK assessment reports for new Marketing Authorisations • 98% within 60 net calendar days of grant of new authorisations	**Green**	**Met** 99% (237 of 240) PARs completed within 60 days
PM6	**Standards and control**	a) Biologics standards supply - 93% of all materials supplied within 6 working days	**Red**	**Not Met** 87% of all materials supplied within 6 working days
		b) Batch release activity – 99% of all requested OCABR	**Green**	**Met**

		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		Batch release certificates issued: • 100% within 8 days for Plasma Pools • 100% within 10 days for Blood Products • 100% within 15 days for Haemostasis • 100% within 60 days for Vaccines
PM7	**CPRD activity**	a) To enable 280 research studies in 2014/15.	**Red**	**Not Met** 253 research studies enabled
		b) To double (8% to 16%) the population cover of primary care data within the CPRD system by the end of the financial year.	**Red**	**Not Met** Increased from 8% to 11%
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** 94% replied to within 20 working days
		b) Return responses to Parliamentary Questions (PQs) to DH 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** 87% answered on time with 0 rewrites. 96 PQs have been dealt with this year.
		c) Return Ministerial correspondence (POs) drafts to DH 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** 87% answered on time with no rewrites. 104 POs have been dealt with this year.
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.	**Green**	**Met**

Green = target met
Amber = target almost met (i.e. narrowly missed)
Red = target not met

1.6.1 Commentary on performance against targets 2014/15

Over the course of the year, the agency met 19 of its 22 targets.

The Biologics standards supply target (PM6a) was not met due to staff illness occurring at the same time as a major surge in demand for influenza standards during Quarter 1. Contingency plans were put in place to deal with the resource gap immediately thereafter and, consequently, our performance exceeded target during the latter half of the year.

CPRD enabled 253 research studies during 2014/15, rather than the 280 target set (PM7a). In Quarter 4, applications to ISAC for research protocol approval were lower than expected and, as a consequence, the number of studies enabled fell approximately 10% below the target for the year.

Lastly, CPRD increased the population cover of primary care data within its system from 8 to 11% but slower than anticipated negotiations with primary care software suppliers has impacted its ability to further increase the research dataset. A review of practice recruitment activities is planned for 2015/16, alongside a range of supporting activities.

1.7 Public Accountability

1.7.1 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 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 take into account developments at EU level, including the EMA's recently published policy on transparency.

1.7.2 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.

There was a slight increase in the number of FOIA requests handled, with 586 requests made to the agency during the year ending April 2015, and 566 answered, of which 344 were answered in full or in part.

The divisions responsible for pharmacovigilance (158), licensing of medicines (146), inspection/enforcement activities (137), and medical devices (80) accounted for the majority of requests.

The general public was the most frequent requester (233), with other significant requester groups being industry (217), the legal profession (43), and journalists (33). 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" could include requesters so affiliated, but who may not wish this to be known.

Requests for internal reviews doubled to 34, although just under half were generated by three individuals. The requests requiring review were as usual varied with no particular issues trending. There were four Information Commissioner investigations of agency decisions, three of which resulted in formal Decision Notices - all upholding the original decision.

1.7.3 Complaints

There were 18 administrative (i.e. customer service related) complaints made during 2014/15, of which two were escalated to the agency's Central Complaints Officer. There were no formal referrals to the Parliamentary & Health Service Ombudsman (PHSO) for investigation.

1.7.4 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 87% of PQs and 87% of POs being answered on time.

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, vaccines, hormone pregnancy tests, and anti-convulsant medicine.

1.7.5 Contracts

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.

1.8 Sustainability report

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.

The agency operates from two main sites at South Mimms (Hertfordshire) and BPR (London). Data presented here is for both sites individually, where held, alongside a total figure.

1.8.1 Greenhouse Gas (GHG) emissions performance

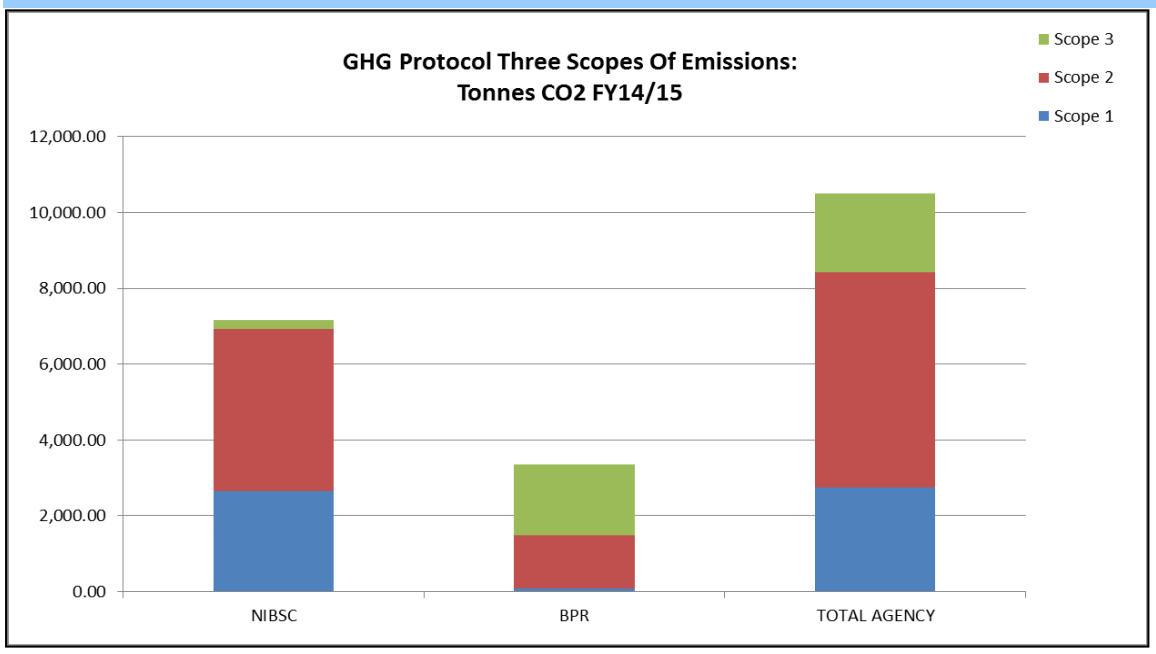
In 2013/14 the newly enlarged agency calculated its first carbon footprint, which stands as a baseline indicator for carbon emissions associated with the agency.

Greenhouse gas emissions financial and non-financial indicators:

GREENHOUSE GAS EMISSIONS		South Mimms	BPR	Total
GHG Emissions (tCO^2)	Total Gross Emissions	7,155	3,344	10,499
	Gross Gas Emissions	2,484	83	2,567
	Gross Electricity Emissions	4,271	1,395	5,666
	Gross Property Emissions	215	3	218
	Gross Transport Emissions	185	1,863	2,048
Energy Consumption ('000 kWh)	Gas Consumption	13,415	448	13,863
	Electricity Consumption	7,936	2,595	10,531
Financial Indicators (£k)	Expenditure on Energy*	1,293	343	1,636
	Expenditure on Transport	353	1,617	1,970

Notes: 1. Energy expenditure covers electricity only for BPR, as gas costs are consolidated in the service charge.

2. Transport data includes international air, rail, courier and air freight data.



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 figures 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[1] for the South Mimms site has been produced since 2009/10. The figure has fallen from a baseline figure of 8,633 TCO^2 in 2009/10 to 7,155 TCO^2 in 2014/15 representing a reduction of 17% over this period; a significant achievement.

Prior to 2013/14 carbon emission data was not collected for the BPR site; however data has now been compiled for two years with the Carbon Footprint being 3,630 TCO^2 in this first year and 3,344 TCO^2 in 2014/15.

An increase in the Government's conversion factor for electricity this year has increased the tonnes of carbon associated with this element of the Footprint for both sites; even though the electricity consumption has actually decreased at both sites. The increase reflects the Governments continuing emphasis on carbon associated with this energy source.

The two sites have very different impacts; BPR has a significant impact from business travel and South Mimms has a significant impact from energy consumption; this is due to the nature of the work and activities carried out at each site.

1.8.2 Gas and electricity consumption

Gas and electricity consumption have been collated for the BPR site from 2013/14. Following the recent consolidation of floors at this site in March 2015 it is anticipated that these figures will decline for future reporting periods by approximately a third. Both gas and electricity consumption at the South Mimms site have been collated since 2009/10 and both have 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 reduction of 12% in electricity consumption has been achieved; numerous factors have contributed to this such as the replacement of old equipment with energy efficient versions, staff switch off initiatives and maintenance improvements.

It is a mandatory requirement for the South Mimms site to be included in Phase II of the Carbon Reduction Commitment Scheme, which encourages organisations to reduce their carbon emissions. This obligation requires a payment on the number of tonnes of carbon produced from energy sources. It is estimated that the payments for this financial year will be in the region of £110k.

It should be noted that as a result of the significant savings made during the last four years on energy consumption, a considerable amount of budget has been saved on utility bills for electricity and gas. This totals £746k, over this period, on electric and gas expenditure as well as a corresponding reduction in carbon payments.

[1] Carbon Footprint calculations have followed the methodology set by Defra in the report: Environmental Reporting Guidelines: Including mandatory greenhouse gas emissions reporting guidance, June 2013 and UK Government conversion factors for Company Reporting 2014.

1.8.3 Waste management performance

Waste management financial and non-financial indicators:

WASTE		South Mimms	BPR
Non-Financial Indicators (Tonnes)	Total Waste	240	50
	Landfill Waste	30	0
	Recycled Waste	145	19
	Incinerated / Energy Recovery	65	31
Financial Indicators (£k)	Total Disposal Costs	88	3
	Landfill Costs	3	U/A
	Recycled Costs	10	U/A
	Incinerated Costs	75	U/A

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

Staff across the agency have been working to reduce the amount of waste produced. The agency previously operated a small satellite office at Welwyn Garden City which closed in April 2014; the relocation of the small number of staff from this office to the South Mimms site included the re-use of furniture and office items saving approximately £8k. The consolidation of floors at the BPR site has incorporated re-use of furniture and fittings, including lighting, carpets and meeting room furniture and fabrication. This is something that has been encouraged as part of the project process; any remaining furniture will be re-used by the next tenant.

At South Mimms work has been undertaken to tender the waste management in conjunction with LUPC (London Universities Purchasing Consortium). This is anticipated to reduce both costs and environmental impact, as well as to continually improve waste management practices on site.

The launch of Warp-It at South Mimms in October 2014 has brought substantial benefits and created behavioural change in the approach to waste. This is a resource re-use tool that allows staff to exchange work based items within the work place. It has produced significant savings and benefits including; £37k savings, 5.1 tonnes waste savings, 13 TCO^2. The success of this initiative led to a nomination for an Environmental Award in December 2014.

1.8.4 Finite resource consumption

Water consumption financial and non-financial indicators:

WATER		TOTAL
Non-Financial Indicators (M^3)	Water Consumption (Office Estate)	9,346
	Water Consumption (Other Estate)	35,667
Financial Indicators (£k)	Water Supply Costs (Office Estate)	U/A
	Water Supply Costs (Other Estate)	31

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

Water consumption has been collated for the BPR site from 2013/14. Following the consolidation of floors at this site in March 2015, these figures are anticipated to decline for future reporting periods by approximately a third in common with those for gas and electricity. 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 23% realised; against a target of a 10% reduction over a three year period. This has brought environmental benefits, cost savings and has aided a reduction in the Carbon Footprint.

1.8.5 Travel management update

There are high carbon emissions from business travel associated with the BPR site and initiatives are underway to help reduce this. The previously established car share scheme that has been in place at South Mimms for several years has now been extended to cover staff based at BPR, in order to promote car sharing across the sites. The use of video conference and teleconference equipment has been encouraged, making it easier for staff to communicate and attend meetings without the need to travel, helping to reduce the Carbon Footprint associated with business travel.

1.8.6 Future energy saving projects

A review has been undertaken at the South Mimms site to investigate larger scale energy saving projects, identifying several options that could have significant potential to make further energy savings onsite. Following the review two such projects have been progressed: replacement of single glazed windows with double glazed units and the installation of Solar PVs. Both are estimated to bring significant savings in energy consumption for the site; with the solar PVs contributing 5% of the current site electricity. This move to a renewable energy source has been welcomed by staff at the site and will bring environmental benefits, cost savings and a significant reduction in carbon emissions produce by energy consumption.

Dr Ian Hudson
Chief Executive and Accounting Officer
Medicines and Healthcare products Regulatory Agency
6 July 2015

2 Directors' Report

2.1 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 the 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.

2.1.1 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.

Sir Michael Rawlins, Chairman from 1 December 2014

Sir Michael was appointed Chairman of the Agency on 1 December 2014. He is a clinical pharmacologist and specialist in internal medicine. He was professor of clinical pharmacology in Newcastle, and physician at the Newcastle Hospitals, from 1999-2006.

Sir Michael was chairman of the Committee on Safety of Medicines (1992-1998), chairman of the Advisory Council on the Misuse of Drugs (1998-2008) and founding chairman of the NICE (1999-2013). He is recent past president of the Royal Society of Medicine (2012-2014).

Currently, Sir Michael is Chairman of UK Biobank, honorary professor at the London School of Hygiene and Tropical Medicine, and emeritus professor at the University of Newcastle upon Tyne.

Professor Sir Gordon Duff, Chairman until 30 November 2014

Sir Gordon, who was appointed as Chairman of the Agency on 1 January 2013, stood down on 30 November 2014. Sir Gordon left MHRA to become Principal of St Hilda's College, Oxford, to which he was appointed on 1 August 2014.

Sir Gordon was Chair of 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, AC DBE

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, who joined the Board in 2008, sadly passed away on 27 February 2015.

Professor Furr 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.

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

Martin Hindle

Martin is currently Chairman of East Midlands Academic Health Science Network and a Non-Executive Director of PHE. He is a member of the Council of Leicester University and the International Advisory Board of the University of Bradford Business School.

He has served as Chairman of University Hospitals of Leicester and as a Non-Executive Director of the Health Protection Agency (HPA), National Biologicals Standards Board and the National Blood Authority.

He has held a series of roles as Chair, CEO and executive board director in international pharmaceuticals and telecommunications. He has served on boards in the UK, USA, Japan, France and the Nordic region.

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

Professor Vincent Lawton, CBE

Professor Vincent Lawton 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 Research & Development (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 Association of the British Pharmaceutical Industry (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 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 NIHR 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 (HPA) 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

David is a clinical pharmacologist who has undertaken basic, translational and clinical research over the past 30 years in pursuit of developing safe and effective medicines for the treatment of hypertension and cardiovascular 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.

He is Honorary President of the European Society for Clinical Pharmacology & Therapeutics (EACPT), President-Elect of the British Pharmacological Society (BPS), and Vice-President, Clinical Division of the International Union of Basic and Clinical Pharmacology (IUPHAR). He has held the Chair of the Scottish Medicines Consortium, Presidency of the Scottish Society of Physicians and Vice-Presidency 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 Medical Devices Agency (MDA), he was involved in the merger with MCA 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 European Association for Cranio-Maxillo-Facial Surgery (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.

2.2 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 NIBSC and CPRD, directors from the agency's corporate divisions and a representative from DH Legal Services.

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

2.2.1 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 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 CHMP and was its vice-chairman from October 2012 to September 2013.

Vanessa Birchall-Scott

Vanessa Birchall-Scott joined the agency as Director of HR in January 2015. In her previous role Vanessa was the Strategic Head of HR for Virgin Care.
Vanessa holds a Master's degree in Human Resources, is a Fellow of the Chartered Institute of Personnel and Development and is also a qualified coach. Prior to joining Virgin Care she worked in a number of senior NHS roles, latterly as Director of Human Resources and Organisational Development for Surrey Primary Care Trust.

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.

Dr Stephen Inglis

Dr Stephen Inglis became Director of NIBSC 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 took up the post as the Director of Licensing Division in April 2014. He was formerly the acting and deputy director of the division.

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 EC 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 MCA in 1989, the predecessor organisation of MHRA. He 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 DH in 1990, including secondments to the Foreign Office and EC in Brussels.

While at 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 DH was as Head of European Affairs, where he was responsible for managing DH's EU business, as well as policy and finance for healthcare accessed by UK citizens elsewhere in the EU.

John Quinn

John Quinn joined the agency in February 2014 as Director of Information Management. He is responsible for delivering a new Information and Technology Strategy and supporting range of services.

John was previously Chief Knowledge Officer at the Department for Education, where he was led the delivery of the IT Strategy, Programme Management, and the award winning KM Programme, and was A foundation Delivery Partner of the G-Cloud programme

Prior to that, he was Director of Knowledge and Information at the Learning and Skills Council, where he led the delivery of the E-Communications Programme and Knowledge Management strategy.

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 Master's 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 PRAC and in the last five years has been closely involved in developing the European Risk Management strategy with other agencies.

Dr Janet Valentine

Dr Janet Valentine joined as head of CPRD in January 2015 having previously been the Head of Population Health and Informatics at the Medical Research Council (MRC), a post she held since 2008.

During her time at the MRC, Janet was responsible for strategy development and delivery of large multi-stakeholder initiatives in ageing, population health sciences and health informatics research.

Prior to that, Janet was the Deputy Chief Executive of the UK Clinical Research Collaboration (UKCRC). Janet's scientific background is in cancer research and she has worked at the National Cancer Research Institute, Breakthrough Breast Cancer and the Imperial Cancer Research Fund.

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 (ABHI) 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.

2.2.2 Former Members

Liz Booth

Liz Booth joined the agency as interim Director of Human Resources in April 2014 replacing the outgoing Rebecca Starling.

Liz's previous role was as an Associate Director at the Royal College of General Practitioners. Liz has a wide range of HR and change management experience and held previous roles as the Head of HR at the General Dental Council, HR Director/ Director of Projects at the National Society for the Prevention of Cruelty to Children (NSPCC) and HR Director at The Prince's Trust. Liz left the agency in February 2015.

Dr John Parkinson

Dr John Parkinson took up the post of Director of 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 stood down as Director of CPRD in June 2014.

2.3 Our Workforce

2.3.1 Office locations

The agency operates from two main sites. 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 and the British Pharmacopeia Commission Laboratory based at Teddington.

2.3.2 Staff resources

During the year an average of 1,200 permanent full-time equivalent staff were employed.

2.3.3 Recruitment

The Constitutional Reform and Governance Act 2010 require 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 provide further guidance. The agency recruits staff on the basis of these principles.

The Chairman and non-executive directors are appointed by the Secretary of State for Health and are on fixed term contracts. Other than the Chief Executive, the members of the CET (who are directors of a centre or division) hold appointments which are open-ended. Their appointment and that of the Chief Executive can be terminated with three months' notice on either side.

The agency continues to experience some difficulties recruiting for business critical roles when using traditional advertising. In addition with the slight upturn in the London economy some employees are leaving the agency as a result of better offers in the private sector.

In response to this an Employer Brand (EB) pilot is underway in an effort to be more effective at filling those roles which are traditionally hard-to-fill. This includes the use of social media such as LinkedIn and Twitter to promote careers at the agency. The two areas of focus this year have been the Inspectorate and Enforcement Division and NIBSC. This work will continue into 2015/16.

The agency recruited 151 staff during the calendar year 2014.

Calendar year 2014 - recruited by level	**Male**	**Female**
Executive Directors	0	2
Senior Civil Servants	3	0
Other Civil Service Staff	64	82
Total	**67**	**84**

2.3.4 Sickness Absence

The average annual sickness rate for the calendar year 2014 was 6.69 working days per full time equivalent employee.

The annual turnover for the agency was 14.4%.

During 2014/15 a procurement exercise was undertaken to identify a new Occupational Health provider and Imperial Occupational Health will take on this role in 2015. The intention is for this service to be more proactive.

2.3.5 Learning and development

The agency's learning and development (L&D) 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. This has now been extended to masterclasses and e-learning through the full integration of Civil Service Learning (CSL) into the overall Learning offering in 2014/15.

During 2014/15 the agency ran a total of 110 courses, with a total of 1007 attendances recorded. CSL was fully integrated into the L&D offering to staff this year and 13 sessions were run across BPR and NIBSC to help staff understand the many functions available to staff through this tool. 2279 e-learning events took place in 2014/15. This includes mandatory training for Responsible for information, unconscious bias and health and safety subjects. Staff have accessed many open courses and the L&D budget has funded 12 places at G7-SCS1 to attend the Management and Leadership programmes through CSL.

The number of training courses delivered in the agency have dropped slightly since the introduction of CSL, but not to the extent that we had anticipated. There was an increased focus on supporting managers in managing HR issues and performance management skills associated with appraisals. There was also an increase in Business specific, business delivered training with the introduction of the new procurement policy.

We have procured a new Leadership course through the CSL gateway application process. This is being delivered by the Oxford Group who know the agency objectives well. This is called the Scientific Leadership programme and two events will have been delivered in this reporting period. We are yet to receive the evaluation feedback on these from the Oxford Group.

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. 57 days training was delivered to 214 people across the agency to support these skills.

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.

2.3.5.1 Performance Management and Talent Development

A new Civil Service performance management approach was introduced in 2013/14 and learning from this has been applied to the approach for 2014/15, with the expectation of further review following this first full year experience. The Civil Service approach included ratings of staff performance and peer review processes alongside revised documentation. The agency remains committed to ensuring that the importance of this discussion is understood and the opportunity is taken to reflect on past performance in terms of the “what” and the “how” and to jointly agree objectives, whilst reflecting on development needs.

The performance assessment part of this approach links to the increasing importance of the talent management agenda within the agency and the intention to support staff with further work on career pathways and identification of opportunities both within and outside of the agency, whilst ensuring that succession plans are factored in for hard to fill to roles.

2.3.5.2 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.

2.3.5.3 Revalidation

During 2013 the agency developed 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 have a strengthened medical appraisal to assess their professional competence. The agency has continued to ensure it meets GMC requirements for revalidation.

2.3.5.4 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.

2.3.6 Employee Consultation

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 DH; 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 have taken on more of these duties.

The agency holds Industrial Relations Committee meetings quarterly and in 2014 a revised Industrial Relations Constitution was agreed and signed with greater emphasis on partnership. This included additional informal meetings set up to discuss ad hoc topics as required. Alongside this there are a number of joint initiatives with TU representatives to tackle particular workforce challenges, such as stress and wellbeing.

The HR team continue to provide ongoing training and support to managers in managing performance, conducting investigations and related report writing. This is in addition to offering Occupational Health support and mediation in the workplace where appropriate.

The agency actively encourages regular one-to-ones as well as team, divisional and all staff meetings; the intention is to involve members of staff both in the work of their team and the wider agency and to have a continuous open dialogue.

The agency holds a quarterly 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 (INsite) 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 INsite.

The agency measures staff engagement through the annual Civil Service People Survey held every October. In 2014, 65% of staff took part in the survey and the agency's engagement index score was 59%, unchanged from the previous year and equal to the Civil Service average. In response to the results, a corporate action plan is developed and in addition, divisions and centres also produce local action plans to address issues raised by staff in their part of the agency.

2.3.7 HR Information

Part implementation of an Oracle HR Information System several years ago has to date hampered the production of HR data and informatics. During 2014 it was decided to look at options for a new HRIS which would provide staff, managers and HR with a system which is more comprehensive and up to date. The intention is for this to included elements of self-service. This procurement exercise will conclude in 2015 and the intention is to implement in 2015/16.

2.3.8 Equality disclosures

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.
- Supports members of staff with disabilities through a formal reasonable adjustment policy.
- Operates a number of HR policies which support employees with caring responsibilities: these include flexible working arrangements
- Supports employees to access a wide range of learning and development opportunities as part of the Civil Service commitment of five days of training per year.
- Supports Civil Service development programmes to encourage under representation within the Civil Service.
- Uses staff survey data proactively to identify general concerns about bullying and harassment seeking early intervention through training and coaching.
- 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.
- to revisit the establishment of an Equality Working Group

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 to collect complete workforce data and to benchmark it.

At the end of the calendar year for 2014 the ethnic breakdown of the agency's workforce (%) was as follows:

Ethnic breakdown of the agency's workforce (%):

- White 61.6%
- BME 29.2%
- No data/prefer not to say 9.1%

2.4 Pension liabilities

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

2.5 Spend on Consultancy and Temporary staff

During 2014/15, expenditure on consultants was £48k (£26k in 2013/14).

The agency continues to employ temporary staff where it is of operational necessity. The agency temporary staff expenditure was £2,374k in 2014/15 (£1,761k in 2013/14).

2.6 Disclosure of relevant audit information

As far as the Directors are aware, there is no relevant audit information of which the agency's auditors are unaware. The Directors have taken all reasonable steps to make themselves aware of any relevant audit information and to establish that the agency's auditors are aware of that information.

2.7 Auditor service and cost

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 £98,400 for 2014/15 (2013/14, £90,000).

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

2.8 Our financial review

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. Income from trading activities in 2014/15 was £122.3m.

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 before interest and dividends for 2014/15 was £40.6m, compared to £28.7m in 2013/14. After finance costs and dividends of £14.0m, a net surplus of £27.0m arose in 2014/15 and has been transferred to reserves.

2014/15 has seen cash inflows from operating activities for the agency of £31.7m, compared to £39.6m in 2013/14. The cash inflow arose from trading activities and efficient working capital management.

2.9 Supplier payment performance

The agency is committed to the Better Payment Practice Code which requires the agency to pay all valid non-NHS invoices by the due date or within 30 days of receipt of goods or a valid invoice, whichever is later. 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 2014/15 - 82% of supplier bills were paid by the enlarged agency within five days and 100% within 30 days. This compares to 82% within five days and 100% within 30 days in 2013/14. No interest payments were made to suppliers under the Late Payment of Commercial Debts (Interest) Act 1998.

	2014/15			**2013/14**		
	Transactions	**Value (£000)**	**%**	**Transactions**	**Value (£000)**	**%**
0 - 5 days	23,222	34,357	82	23,400	35,054	82
6 - 10 days	2,533	23,739	8	2,065	22,822	8
11 - 30 days	1,566	16,121	8	1,716	9,349	8
Over 30 days	672	1,627	2	533	5,069	2
	27,993	**75,844**	**100**	27,714	72,794	100

2.10 Performance measures 2015/16

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

2015-16 Performance targets

No.	Activities	2015-16 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

No.	Activities	2015-16 Targets
		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% (fatal and serious only) 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
PM5	**Publication of UK assessment reports for new Marketing Authorisations**	Publish 98% of UK assessment reports 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 2015/16.
		b) To increase the population cover of primary care data within the CPRD system to 20% by the end of the financial year.
PM8	**Answering Freedom of Information requests, letters and Parliamentary Questions**	a) Respond to all requests under the Freedom of Information Act within 20 working days.
		b) Return responses to Parliamentary Questions (PQs) to DH 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 DH within 4 working days of receipt in at least 80% of cases with less than 5% returned to MHRA by the Department for rewriting.

2.11 Health and safety

The agency is committed to embedding health and safety across the organisation with the aim of reducing the risk of the agency's activities.

This section gives a brief overview of activities and initiatives that have been carried out in relation to health and safety along with plans for the future. Data presented

here is for both main agency sites at South Mimms and BPR and includes the smaller site at York where relevant; a total figure is also shown if required.

The health and safety governance structure at the agency consists of a single advisory team and the agency-wide Health and Safety Strategy Group (HSSG) with reporting mechanisms to both the CET and Agency Board. Work has continued over the year to harmonise several key health and safety policies across the organisation, including driving on business, immunisation and offsite working.

2.11.1 Training & Competence

Face to face training
At the South Mimms site specialist training is provided for laboratory workers, laboratory managers, and risk assessors. The training programme was delivered against plan for 2014/15 (figures can be found in the table below). The programme for 2015/16 has been agreed and issued.

Training	No of Delegates
Lab workers	53
Lab managers & supervisors	42
Risk assessors	20

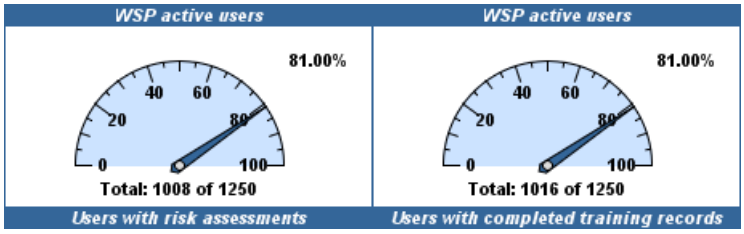
Driving Monitor
The driving Monitor programme was introduced this year. The data in this report is for MHRA and CPRD centre members of staff that have been registered on the Driving Monitor system. The NIBSC centre will be rolled out from July 2015.

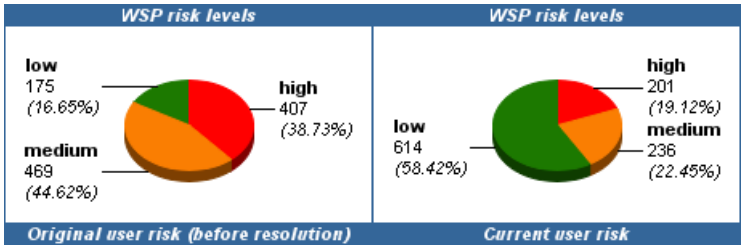
Good progress has been made towards the key performance indicator target of 95% of drivers assessed from the MHRA and CPRD centres.

Drivers risk	Percentage of drives	Number of drivers identified
High	1.7%	2
Medium	16.1%	19
Low	82.2%	97

Note: 690 members of staff registered on the system have been assessed as staff that do not drive on agency business.

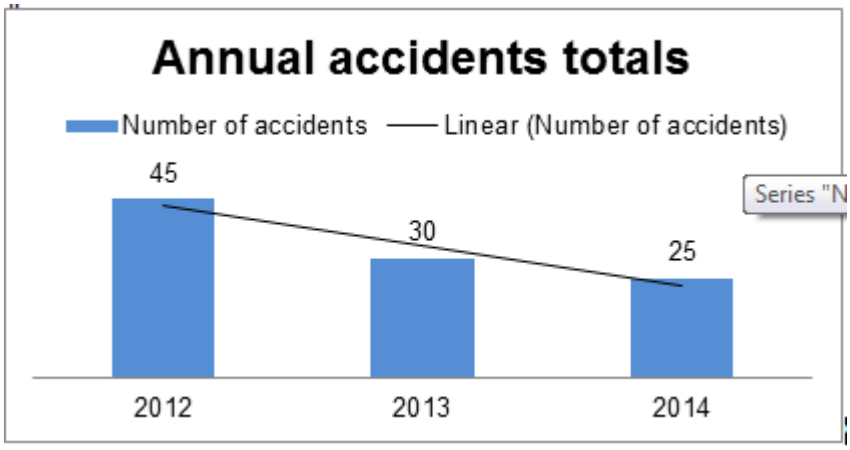
Cardinus
The Cardinus system was introduced in 2013/14 and provides Display Screen Equipment training modules and risk assessments which have been rolled out to all centres. Figures for 2014/15 can be found below.





Accident rates

Accident rates across the agency in 2014/15 showed a downward trend from previous years. Two reports were made under the Reporting of Injuries, Disease and Dangerous Incidents Reporting (RIDDOR) regulations. One report was for slip, trip and fall the other for a manual handling injury. The reports were made under RIDDOR as the members of staff were absent from work for more than seven days after the incidents.



The graph above shows the accident data since the merger in April 2013: with relevant information from both sites for 2012 before the merger.

2.11.2 Audits

The BPR site was audited against the BSI 18001 certification (BS OHSAS 18001 Occupational Health and Safety Management); no major non-compliances were identified.

The internal audit programmes for the South Mimms site were achieved to plan in 2014/15 with any the subsequent tracking of any actions that are identified.

2.11.3 Health and Safety interventions

The scope of activities undertaken at the South Mimms site, and the broad range of biological agents held means that the Biological Agents Unit of the HSE assigns its highest inherent hazard score, prompting regular inspections as set out in an annual intervention plan.

This year one inspection was undertaken that covered three topics, with three corresponding scores recorded of ‘Fully compliant’, ‘Broadly Compliant’ and ‘Poor’.

Two further inspections have been held for which the official outcomes have not yet been issued. The Intervention Plan for the 2015-2017 period has been agreed.

Recommendations from inspections are routinely incorporated into the action plans.

2.12 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 4).

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.
Lack of NIBSC resources to support required work.	Income generation strategy and five year financial model aimed at sustainability.
Financial instability at NIBSC resulting from loss of influenza standards income.	Evaluation of alternative potency tests. Continue to build alternative revenue streams.

2.13 Directors statement with respect to conflict of interest

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

2.14 HM Treasury 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.

2.15 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.

2.16 Disclosure of serious untoward incidents

2.16.1 Details of incidents involving data loss or confidentiality breaches

Sensitive personal data were mistakenly sent to 2 recipients who are both agency employees and was investigated. The data did not get transmitted further than those involved and the breach was contained within the organisation with exposure limited to a very small audience. Agency papers were left on the public transport and email containing sensitive commercial information sent to the wrong e-mail address in error.

An inspection report was also sent to the wrong e-mail address in error. All breaches were investigated and managed within the MHRA, and were not reported to the Information Commissioners Office (ICO).

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.

2.17 Fraud

The agency, in line with the Civil Service Code, has a zero tolerance policy of fraud and has in place procedures covering (a) anti-fraud policy, (b) internal whistle-blowing policy, and (c) dealing with staff conflicts of interest. Each year the agency's staff are required to complete e-learning via the Civil Service Learning's "Responsible for Information" training course, which includes a module on fraud.

The DH has established an anti-fraud unit which aims to establish clear lines of accountability between DH and their Arms Length Bodies within the Health Group (of which the agency is one) and having a collaborative approach between these organisations.

Our internal anti-fraud unit is working closely with them including sharing best practice and, in some cases, having the option to refer onward.

Dr Ian Hudson
Chief Executive and Accounting Officer
Medicines and Healthcare products Regulatory Agency
6 July 2015

3 Remuneration report

3.1 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.

3.2 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 (CET 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.

3.3 Remuneration (including salary) and pension entitlements

The section below provides details of the remuneration and pension interests of the most senior management (i.e. CET and Agency Board members) of the agency. CET members' salary and bonus awards were decided by a pay committee whose members were Dr Ian Hudson, Professor Vincent Lawton, CBE (Non-Executive Director) and Simon Claydon (Department of Health (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.

The disclosures in these tables are subject to audit by the Comptroller and Auditor General.

3.4 CET remuneration, bonus and benefits table

2014/15	Salary £'000	Performance pay and bonuses £'000	Pension related benefits £000	Total £000
Dr Stephen Inglis Director of NIBSC	170 – 175	Nil	52.5 – 55.0	220 – 225
Dr June Raine, CBE Director of Vigilance & Risk Management of Medicines	125 – 130	10 – 15	20.0 – 22.5	155 – 160
Mr Peter Commins Chief Operating Officer	135 – 140	10 – 15	60.0 – 62.5	205 – 210
Dr Ian Hudson Chief Executive	145 – 150	Nil	87.5 – 90.0	230 – 235
Mr Gerald Heddell Director of Inspection, Enforcement and Standards	100 – 105	10 – 15	55.0 – 57.5	165 – 170
Mr John Wilkinson, OBE Director of Devices	115 – 120	Nil	42.5 – 45.0	160 – 165
Dr John Parkinson[1] Director CPRD	15 – 20	Nil	N/A	15 – 20
Ms Rachel Bosworth Director of Communications	95 – 100	Nil	17.5 – 20.0	115 – 120
Mr Jonathan Mogford Director of Policy	95 – 100	Nil	40.0 – 42.5	135 – 140
Dr Siu Ping Lam Director of Licensing	115 – 120	Nil	52.5 – 55.0	160 – 165
Mr John Quinn Chief Information Officer	95 – 100	Nil	102.5 – 105.0	195 – 200
Ms Elizabeth Booth[2]** Interim Director of Human Resources	90 – 95	Nil	N/A	90 – 95
Ms Vanessa Birchall-Scott[3] Director of Human Resources	15 – 20	Nil	5.0 – 7.5	20 – 25
Dr Janet Valentine[4] Director of CPRD	20 – 25	Nil	7.5 – 10.0	25 – 30

Band of the highest paid directors total remuneration	170 – 175
Median total	39,007
Remuneration ratio	4.4

***** CET members receive no 'benefits in kind'.

**In addition to remuneration paid, an amount of £50-55k was paid to the recruitment agency for services provided.

2013/14	Salary	Performance	Pension related	Total

[1] Mr John Parkinson retired from the MHRA on 6th June 2014. The full year equivalent is £100-105k.
[2] Ms Elizabeth Booth was appointed interim Director of Human Resources on 1 April 2014 and left on 28th January 2015.
[3] Ms Vanessa Birchall-Scott was appointed on 19th January 2015. The full year equivalent is £90-95k.
[4] Dr Janet Valentine was appointed on 2nd January 2015. The full year equivalent is £90-95k.

	£'000	pay and bonuses £'000	benefits £000	£000
Dr Stephen Inglis Director of NIBSC[1]	170 – 175	Nil	67.5 – 70.0*	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 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

CET members receive no 'benefits in kind'.
* This figure was not available last year

[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.

3.5 Agency Board remuneration, bonus and benefits table

2014/15	Salary £'000	Benefits in kind (taxable) to nearest £100*	Total £000
Professor Sir Michael Rawlins Chairman[1]	20 – 25	-	20 – 25
Professor Sir Gordon Duff Chairman[2]	40 – 45	1,900	40 – 45
Professor Vincent Lawton, CBE Non Executive Director	10 – 15	-	10 – 15
Professor Barrington Furr, OBE Non Executive Director	5 – 10	500	5 – 10
Mr John Williams, CBE Non Executive Director	5 – 10	700	5 – 10
Mr Martin Hindle Non Executive Director	5 – 10	700	5 – 10
Ms Deborah Oakley Non Executive Director	5 – 10	-	5 – 10
Professor Dame Valerie Beral Non Executive Director	5 – 10	-	5 – 10
Professor Sir Alexander Markham Non Executive Director	5 – 10	800	5 – 10
Professor David Webb Non Executive Director	5 – 10	1,700	5 – 10

*Includes £2,100 for 2013/14. Prof Sir Gordon Duff £1,800, Prof Barrington Furr £100 (passed away 27 February 2015), Mr Martin Hindle £100 and Mr John Williams £100.

Agency Board – Remuneration, bonus and benefits table 2013/14			
Professor Sir Gordon Duff Chairman	60 – 65	800	60 – 65
Professor Vincent Lawton, CBE Non Executive Director	10 – 15	-	10 – 15
Dr Shelley Dolan Non Executive Director[3]	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[4]	0 – 5	-	0 – 5
Ms Deborah Oakley Non Executive Director	5 – 10	-	5 – 10
Professor Dame Valerie Beral Non Executive Director[5]	0 – 5	-	0 – 5
Professor Sir Alexander Markham Non Executive Director[5]	0 – 5	600	0 – 5
Professor David Webb Non Executive Director[5]	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 Michael Rawlins was appointed Chairman with effect from 1 December 2014.
[2] Professor Sir Gordon Duff left the Agency Board on 30th November 2014.
[3] Miss Shelley Dolan and Professor Angus Mackay OBE left the Agency Board on 31st May 2013.
[4] Sir Alan Langlands left the Agency Board on 30th September 2013.
[5] Professor Dame Valerie Beral, Professor Sir Alexander Markham & Professor David Webb were appointed Non-Executive Director with effect from 1st September 2013.

3.6 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 and other 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 2014/15 relate to performance in 2013/14 and the comparative awards reported in 2013/14 relate to performance in 2012/13.

3.7 Pay multiples

The banded remuneration of the highest paid director in the agency in the financial year 2014/15 was £170-175k (2013/14, £170-175k). This was 4.4 times (2013/14, 4.5) the median remuneration of the workforce, which was £39,007 (2013/14, £38,298).

No employee received remuneration in excess of the highest paid director in 2014/15 (2013/14, 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.

3.8 Pension benefits table

Neither the Chairman, nor Agency Board directors have any pension entitlement arising from their service with the agency.

The following table provides details of the pension entitlements of CET Directors:

	Real increase in pension and related lump sum at 60 Bands of £2,500	Total accrued pension at age 60 at 31 March 2015 and related lump sum Bands of £5,000	Cash Equivalent Transfer Value at 1 April 2014 * To nearest £1,000	Cash Equivalent Transfer Value at 31 March 2015 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	50 – 55 plus lump sum of 90 – 95	900	996	72	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 140 – 145	1,018	1,041	20	31
Mr Peter Commins Chief Operating Officer	2.5 – 5.0	80 – 85	1,385	1,510	53	33
Dr Ian Hudson Chief Executive	5.0 – 7.5	50 – 55	776	896	75	35
Mr Gerald Heddell Director of Inspection, Enforcement and Standards	2.5 – 5.0	20 - 25	324	378	48	25
Mr John Wilkinson, OBE Director of Devices	2.5 – 5.0	5 – 10	87	133	31	28
Ms Rachel Bosworth Director of Communications	0.0 – 2.5 plus lump sum of 2.5 – 5.0	20 – 25 plus lump sum of 65 – 70	374	410	14	23
Mr Jonathan Mogford Director of Policy	0.0 – 2.5 plus lump sum of 5.0 – 7.5	30 – 35 plus lump sum of 90 – 95	480	538	31	23
Dr Siu Ping Lam Director of Licensing	2.5 – 5.0 plus lump sum of 7.5 – 10.0	35 – 40 plus lump sum of 115 – 120	705	790	48	28
Mr John Quinn Chief Information Officer	2.5 – 5.0 plus lump sum of 12.5 – 15.0	25 – 30 plus lump sum of 75 – 80	293	376	65	23
Ms Vanessa Birchall-Scott Director of Human Resources	0.0 – 2.5	0.0 – 2.5	0	5	4	5
Dr Janet Valentine Director of CPRD	0.0 – 2.5	0.0 – 2.5	0	6	4	6

* 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.

Mr John Parkinson opted out of the PCSPC on 31 March 2014

3.9 Cash Equivalent Transfer Value (CETV)

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.

3.10 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
6 July 2015

4 Governance statement

4.1 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.

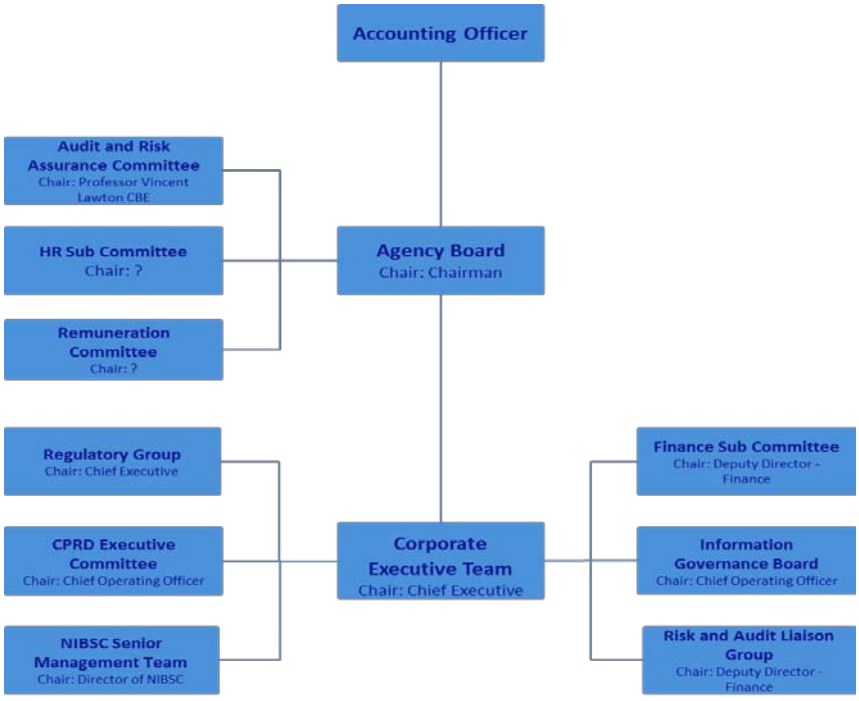
In discharging this overall responsibility, the agency is responsible for putting in place proper arrangements for the governance of its affairs and facilitating the effective exercise of its functions which include arrangements for the management of risk.

4.2 Governance structure

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 following structures and processes are designed to ensure accountability and give the agency a framework for risk management:

- The Agency Board (AB) is made up of the Chairman and eight non-executive directors and is primarily responsible for advising on the strategic development of the agency and ensuring that targets set out in our Business Plan and endorsed by ministers are met.
- The agency's Chief Executive is responsible for service delivery and resources.
- The Corporate Executive Team (CET) consisting of the Agency's executive directors, takes overall responsibility for day-to-day management, strategic decision-making, line management, and all financial, policy, operational and resource management issues.



4.3 Effectiveness of the Corporate 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 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 Framework Document is currently in the process of being updated and is expected to be finalised in the near future.

4.3.1 The Agency Board

The Agency Board (AB) is responsible for the monitoring of the implementation of ministers' objectives for the strategic direction of the agency, taking into account the perspective(s) of its stakeholders, and advising Ministers and the agency accordingly.

The AB normally meets once a month and approves:

- 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 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.

Non-executive members are appointed by the Secretary of State following open competition and do not represent any specific customer, sectoral or stakeholder interests.

4.3.2 Attendance

Member	Agency Board	Agency Board away day
Professor Sir Gordon Duff[1]	5 (5)	1 (1)
Professor Sir Michael Rawlins[2]	3 (3)	1 (1)
Professor Dame Valerie Beral	5 (8)	2 (2)
Professor Barrington Furr, OBE[3]	5 (7)	2 (2)
Mr Martin Hindle	8 (8)	2 (2)
Professor Vincent Lawton, CBE	7 (8)	2 (2)
Professor Sir Alex Markham	6 (8)	2 (2)
Ms Deborah Oakley	5 (6)	2 (2)
Professor David Webb	6 (8)	2 (2)
Mr John Williams, CBE	8 (8)	2 (2)

[1] Professor Sir Gordon Duff stood down as Chairman on 30 November 2014.
[2] Professor Sir Michael Rawlins was appointed on 1 December 2014.
[3] Professor Barrington Furr, OBE, passed away on 27 February 2015.

Following the appointment of the new Chairman in December 2014, future meetings were rescheduled. As a result, some members were not able to attend certain meetings. The maximum number of meetings held during the year that each member could attend and allowing for the reschedule is shown in brackets.

In addition, the Chief Operating Officer (7/8) and myself as Chief Executive usually (8/8) attend all meetings. Also the Director of Communications (6/8) and Director of Policy (4/8) normally attend. Other senior executives, including the Director of NIBSC, the Director of Licensing, The Director of VRMM, the Interim Director of HR and the Chief Information Officer have also attended in relation to specific topics.

4.3.3 Role of the Chairman

The Chairman is directly accountable to ministers for the performance of the agency and its decisions and meets the Secretary of State at an annual accountability meeting at least once a year to discuss the agency's strategy and performance.

The Chairman is responsible for providing leadership to the Agency Board and to the agency itself, for enabling all AB members to make a full contribution to the Board's affairs and for ensuring that the AB acts as a team for the benefit of the agency and its stakeholders. The Chairman will also annually review the performance of me as the Chief Executive in the undertaking of my responsibilities.

The role of the Chairman, together with the AB, is to advise on and monitor:

- The implementation of strategies to ensure the regulatory systems are effective and robust
- The implementation of strategies for increasing public knowledge and understanding about the safe use of medicines and medical devices.
- The steps taken by the agency to carry out its statutory responsibilities, while remaining within budget; using available resources efficiently and effectively.
- The service provided to manufacturers, to health and social care professionals and to the general public.
- The steps taken by the agency to protect the interests of the public.

4.3.4 Effectiveness of the Agency Board

In 2014/15 the Board undertook the first stage of a three stage effectiveness evaluation process in line with guidance issued by the Cabinet office for the Board to undertake an assessment of its own effectiveness.

The review involved a discussion on the purpose and usefulness of the evaluation and was followed up with completion of the NAO produced evaluation questionnaire.

The results of the evaluation questionnaire pointed to two arears of concern. These were:

- The Board has a clear set of objectives that are independent of those for organisation.
- The Board realistically assess its performance against its objectives at regular intervals and at year-end

Further work will be undertaken during the year to address the issues raised.

4.3.5 Conflict of Interest

Potential conflicts of interest are managed by all AB 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.

4.3.6 Declaration of interests

The Agency Board Register of Interests can be found on the agency website at the following location:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/435607/MHRA_Non-Executive_Directors_register_of_interest.pdf

4.4 Audit and Risk Assurance Committee

The Audit and Risk Assurance Committee (ARAC) consists of four non-executive Directors. It is a sub-committee of the Agency Board and reports independently to the Accounting Officer and the Agency Board on: the adequacy of the agency's governance arrangements, assurance and the risk management framework and the associated control environment; the agency's financial and non-financial performance to the extent that it affects the agency's exposure to risk and weakens the control environment; oversight of the financial reporting process; Conflict of Interests, Health & Safety and Regulatory Fraud. At the request of ARAC, work was done during the year to list external regulatory fraud risks facing the agency and the controls and mitigations in place. This was discussed at two quarterly meetings and it was agreed that these risks will be under constant review and updates will be provided to ARAC every six months. The ARAC also discussed and agreed the annual internal audit plan as well as updates on progress of CPRD.

It has sight of the corporate risk register at each of its meetings. ARAC 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. ARAC provides advice on the implications of the internal audit reviews and monitors progress against the plan to tackle identified weaknesses to ensure that there is a continuous improvement of the system of internal control.

On an annual basis, ARAC provides a formal and independent assurance on the adequacy of the risk management framework and associated control environment to the Accounting Officer. Informally, a regular dialogue is maintained between the Chair of the ARAC and the Accounting Officer. The ARAC Chair provides a synopsis of the work of the committee to the Agency Board after each quarterly meeting and includes updates on the internal audit reviews and the corporate risk register.

4.4.1 Attendance

Member	ARAC
Professor Vincent Lawton, CBE	4 (4)
Professor Barrington Furr, OBE[1]	2 (3)
Ms Deborah Oakley	4 (4)
Professor David Webb	1 (1)
Routine Attendees:	
Chief Executive	4 (4)
Chief Operating Officer	3 (4)
Deputy Director - Finance	3 (3)
Head of Internal Audit	4 (4)
Representative from the External Auditor	4 (4)
Representative from the Department of Health	4 (4)
Corporate Risk Manager (secretarial support)	4 (4)

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

[1] Professor Barrington Furr, OBE, passed away on 27 February 2015.

4.5 Remuneration Committee

The Remuneration Committee is a subcommittee of the AB and its role is to provide a formal and transparent process for determining executive remuneration in line with civil service pay guidance. The Remuneration Committee will make recommendations about the total individual remuneration package for each member of the CET, including bonus payments where applicable. The review of any proposed severance arrangements for CET members would also fall within their remit.

The membership of the Remuneration Committee consists of three non-executive members of the Agency Board; the Chair of the Board is not eligible for membership. The Director of Human Resources, the Chair of the Board and me as Chief Executive will also be required to attend.

The Remuneration Committee meets in person or by tele-conference on an annual basis. The Chair of the Committee provides a confidential oral report of the meeting to the AB.

4.6 HR Sub-Committee

The HR Sub-Committee (HRC) is a subcommittee of the Agency Board and its role is to advise and challenge the CET on strategic matters such as People Strategy, Workforce Planning, Succession Planning and Organisational Design. In the performance of these duties the HR Sub-Committee will also fulfil the role of a nominations and governance committee.

The membership of the HRC consists of three non-executive members of the Agency Board appointed by the Chairman. The HRC is also routinely attended by the Chief Operating Officer, the Director of Human Resources, the Deputy Director of Human Resources and a HR Business Partner.

Meetings are held as necessary to coincide with the requirements of the agency's work plans and people related activity, they may be called by either the Chair, the COO or the Director of Human Resources. The HRC met once in 2014/15.

4.7 The Corporate Executive Team

The Corporate Executive Team (CET) is the highest executive decision-making body of the agency. The CET comprises me as 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 Chief Operating Officer is the senior executive with responsibility over Finance.

The regular programme of business includes monthly reports of performance and operational risk from the next level of management, finance reports and quarterly 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 and to ensure the agency exercises proper stewardship of public funds, including compliance with principles laid out in Managing Public Money. The CET members have no significant interests to disclose which may conflict with their responsibilities. The Remuneration Report (sections 3.4 and 3.5 of this report) gives details of the remuneration paid to the members of the AB and CET.

4.7.1 Attendance

Member	CET
Dr Ian Hudson	12 (12)
Ms Vanessa Birchall-Scott	2 (2)
Ms Elizabeth Booth	5 (7)
Ms Rachel Bosworth	12 (12)
Mr Peter Commins	12 (12)
Mr Gerald Heddell	10 (12)
Dr Stephen Inglis	11 (12)
Dr Siu Ping Lam	12 (12)
Mr Jonathan Mogford	11 (12)
Mr John Parkinson	2 (2)
Mr John Quinn	10 (12)
Dr June Raine, CBE	11 (12)
Dr Janet Valentine	3 (3)
Mr John Wilkinson, OBE	11 (12)

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

4.7.2 Conflict of Interest

The CET members have no significant interests to disclose which may conflict with their responsibilities.

4.8 Regulatory Group

The Regulatory Group is the executive decision-making body within the MHRA Centre. The Regulatory group meets once a month and the membership consists of: me as the Chief Executive; the directors of: Devices; Licensing, Inspection, Standards & Enforcement; Vigilance & Risk Management of Medicines and the directors or deputies from: Policy, Communications, Information Management; Finance and Procurement and Human Resources.

The primary responsibilities of the Regulatory Group are:

- To provide a steer on strategic regulatory issues
- To provide direction on regulatory aspects of Corporate and Business plans
- To oversee:
  - Existing and emerging regulatory projects
  - Opportunities to shape the EU and international agenda
  - Cross-Agency interactions with trade associations on regulatory matters
- To monitor the financial position of, and legal, operation and reputational risks to, the regulatory centre

The Regulatory Group reports quarterly on governance to the CET and minutes of the Regulatory Group meeting are provided monthly to the CET along with a current issues register.

4.9 NIBSC Senior Management Team

The NIBSC SMT is the executive decision-making body within the NIBSC Centre; it meets monthly and is responsible for:

- Developing and reviewing all aspects of NIBSC-specific strategy;
- Agreeing annual objectives for approval by the agency CEO;
- Monitoring and reviewing progress against objectives;
- Receiving reports and recommendations from Programme Boards and SMT subgroups;
- Decision making on NIBSC-specific issues;
- Overseeing all aspects of NIBSC specific governance, including compliance with H&S, HTA, Home Office legislation and quality assurance of NIBSC functions.

The NIBSC SMT consists of the NIBSC director, deputy director and heads of all divisions. The SMT is also attended routinely by representatives from Communications, Finance, HR and IMD of the agency.

4.10 CPRD Executive Committee

The CPRD Executive Committee (CEC) is the executive decision-making body within the CPRD Centre. It is responsible for the overall direction and management of CPRD and ensuring that progress is appropriately maintained.

A Memorandum of Understanding (MoU) is in place between the agency and DH Research and Development Directorate (RDD) for the joint operation of CPRD. A formal agreement sets out the activities, governance arrangements, financial

contributions and the sharing of outputs. This was further enhanced with the status change of DH participation at the CPRD Executive Committee to enjoy equal voting rights. Both parties to the arrangement have joint rights and will accordingly enjoy the benefits and share the costs on a 50/50 basis.

The CEC membership is made up of the deputy director of Research Information and Intelligence from DH, the agency's Chief Operating Officer, IMD director, CPRD director, director of Policy, director of Communications, CPRD senior managers and the Chair of the CPRD external advisory group.

Primary responsibilities are to ensure that:

- strategic direction is developed in co-ordination with the Corporate Executive Team, Agency Board and the CPRD Expert Advisory Group and that during the years 0-5 is as set out in the Business Case/ and the Government's 'The Plan for Growth';
- the CPRD KPIs are met and benefits are realised;
- principles of good corporate governance are followed and that CPRD meets all governance requirements required of its operation;
- CPRD is well managed financially and resources are managed effectively;
- the quality of CPRD's work is kept under regular review;
- there are effective communications with key stakeholders and that external communications are of a consistently high quality and are joined up with NIHR and DH.

The CEC reports, and provides governance assurance, on the operations of CPRD to the CET, AB, NIHR and external governance bodies.

4.11 Finance sub committee

The CET established a Finance Sub-Committee (FSC) which consists of a senior representative from each Division of the agency and chaired by the Deputy Director of Finance to consider the agency's financial reporting and governance in detail on its behalf, with the key points being presented at every CET meeting by the Chair of the FSC.

The FSC has a governance role in all matters financial and provides assurance to the CET that it is supporting the Accounting Officer in the execution of their responsibilities. Although local financial information is also provided to each Division and to the CPRD Executive Committee, the NIBSC Senior Management Team, and the Regulatory Group for their regular consideration, the FSC's remit covers the whole agency.

Finance staff provide regular financial reports for the members of the FSC to consider. These usually include (but are not limited to):

- Monthly management accounts, including the income and expenditure position;
- A forecast of the income and expenditure for the year;
- Income Risk Assessment;
- Statement of Financial Position;
- Cash Forecast.

FSC members also consider other Finance papers such as the annual Strategic Financial Choices and Budget papers in order to provide additional insight and comments that aid financial governance.

4.12 Risk and Audit Liaison Group

The Risk and Audit Liaison Group (RALG) consists of a senior representative from each Division of the agency. It is chaired by the Deputy Director of Finance. Alternate members attend in cases of absence of the main members. The Divisional representatives are the central contacts at the Divisions for the co-ordination of all Divisional risks and audit issues.

The RALG provides a forum for divisional and corporate risk management and audit issues to be discussed and monitored by senior Divisional representatives.

The RALG submits its minutes to the CET and ARAC on a regular basis.

4.13 Information Management Governance Board

The Information Management Governance Board (IMGB) is accountable to the CET with a remit to steer all aspects of the agency's overall IT strategy. This includes proposing the annual IT budget and IT strategy to CET, monitoring IT projects and approving new IT projects following by submission of business cases from relevant areas.

4.14 Data quality to support the CET and AB needs

4.14.1 Financial Data

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.

With a few exceptions, Finance monthly reports are discussed at the monthly 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.

4.14.2 Operational Data

Information Governance audit reviews of Sentinel Data Quality were conducted in each of the last three years to ensure the data quality in the Sentinel was fit for purpose (Sentinel is the agency's database for licensing information). A rating of 'substantial' was issued by the internal auditors in 2013/14. In addition they reported on their positive observations, in particular the effort around behavioural shift and ongoing focus on personal responsibility for information governance. I am content that the improvements imbedded continue to operate effectively and have increased the integrity of Sentinel data.

4.15 Risk

4.15.1 Capacity to handle risk and change

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.

4.15.2 Assessment of risk

In February 2015, the agency undertook a review of potential external regulatory and financial fraud. Following discussions at local business unit level by senior managers, which included a Peer Review, a list of potential external regulatory and financial fraud risks was presented to and discussed by the CET and ARAC. The agency's assessment was that awareness of risks and mitigations to manage them were appropriate.

At 31 March 2015, the agency's corporate risk register identified three principal risks. These were:

- The agency fails to meet its statutory and other public health roles due to reduced funding;
- NIBSC financial instability from sudden loss of influenza standards income plus impact of any future enforced changes in Terms and Conditions, including pension transfers;

- Lack of NIBSC resources to support required work and pressures of resource constraints resulting in drop in quality of key functions.

Other risks include the failure of the agency to identify a financially sustainable regulatory role; the failure to prevent fake medicinal products and devices reaching the public through the legitimate supply chain; and 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 recent addition to the corporate risk register is the issue on transparency and clinical trials and the consequent reputational risk to the agency. An Information Management Assessment has been undertaken and a report presented to CET. A cross agency group is to review and prioritise findings with a view to present a project plan.

The mitigations for these risks are discussed in section 2.12. The corporate risk register is reviewed quarterly by the CET and updated as appropriate. Each corporate risk is vested in a specific CET member(s), who owns and monitors the particular risk. The corporate risk register is also subject to quarterly review by ARAC. 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 RALG.

The cross-agency RALG, formed to strengthen the agency's risk management system, held four meetings during the year to 31 March 2015. 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 CET.

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.

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. The agency's statutory duties include:

- operating a system of licensing, classification, monitoring and enforcement to ensure that medicines for human use, sold or supplied in the UK, are of an acceptable standard;
- ensuring compliance with statutory obligations relating to the investigation of medicines in clinical trials and assessing notifications or proposals for clinical trials from manufacturers of medical devices;
- discharging statutory obligations, including those of the UK's EU competent authority, for medical devices and contributing to developing the safety and performance standards that support this work;
- operating and contributing to systems at both UK and EU level of post-marketing surveillance for medicines and medical devices, taking action to safeguard public health;
- ensuring compliance, in the UK, with statutory obligations relating to the manufacture, distribution, sale, labelling, advertising and promotion of medicines;

- devising and drawing up standards for the purity and potency of biological substances and designing appropriate test procedures;
- preparing, approving, holding and distributing standard preparations of biological substances;
- providing, or arranging for, the provision of laboratory testing facilities for the testing of biological substances, carrying out such tests, examining records of manufacture and quality control and reporting on the results;
- carrying out, or arranging for the carrying out, of research in connection with biological standards and control function;

In relation to the Macpherson report, the agency does not use any quality assuring analytical models for its day to day work at this time. However, should the need arise, the agency can draw on DH models.

4.15.3 Information risk

As part of the wider Information and Technology Strategy, MHRA is paying particular attention to developing our Information Management. As part of this process, all staff are required to annually complete mandatory Information Security training entitled "Handling Information" on the Civil Service Learning portal and required to achieve a pass on the final test as a way of demonstrating learning. MHRA also undertake an annual assessment around compliance against HMG Security Policy Framework, and provide returns to DH.

We have revised and bolstered data classification exercises across the organisation with the purpose of capturing richer information around our information assets in order that we can apply optimised safeguards and exploit the value of our data better both internally and with partners. We have initiated a programme of work that will address Information Assurance, Information Security and IT Security to support our current and strategic commitments for greater governance and risk management particularly around Cyber Security.

4.15.4 Internal audit

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.

Nine assurance based reviews have been performed during the year of which two were rated as substantial, five as moderate and two as limited.

The key themes from these reviews were as follows:

- The review of key operational processes, such as contract management and policy performance indicators resulted in moderate ratings, but a limited rating for CPRD KPIs. These areas evidence some area of improvements on prior year findings but have highlighted the need for management to continue to address all the recommendations in full to enhance the adequacy and effectiveness of controls;
- The review of key financial processes identified a strong control environment with both phases reported as substantial; and

- The reviews of IT and information related processes identified a number of weaknesses in internal control with a limited report issued in IT cyber security due to a lack of overall strategy, governance, reporting and visibility of third party suppliers. The review of IT Strategy recognised the direction of travel and management's long-term plans, resulting in a moderate report.

Management actions have been agreed and implementation programmes are in place in response to all recommendations made in the nine internal audit reports.

4.15.5 Opinion of the Head of Internal Audit

The Internal Audit annual report gave an overall 'moderate' opinion which is the second highest rating achievable and concluded that the 'MHRA has had adequate and effective systems of control, governance and risk management in place for the reporting year 2014/15'.

The cases where Internal Audit identified the need for control enhancements were not deemed significant in the context of the overall control environment. Where enhancements were proposed, corrective action has been agreed and subsequent delivery is monitored closely with quarterly updates provided to ARAC. For the Cyber Security review, the following 'high' recommendations have been made and accepted by management:

- implementation of a formalised cyber security policy framework to include policies, procedures and guidelines in line with industry good practice;
- information assets register should be reviewed and updated on a regular basis including information identification, classification and ownership of each information asset should be formally defined;
- network security arrangements should be reviewed and controls should be put in place on the basis of the agency's cyber risk appetite.

Action against weakness identified has contributed to the overall assurance reported within this governance statement.

4.15.6 Certificates of assurance

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 2015 with Divisional Directors confirming compliance with all agency SOPs and policies.

The agency has not delegated any of its statutory functions to other organisations.

4.16 Effectiveness of internal control framework

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, ARAC and CET and a plan to address weaknesses and ensure continuous improvement of the system is in place.

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;

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 2014/15.

4.17 Update on 2013/14 significant governance issues

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. HR carried out an investigation and discovered major data, systems and processing errors. The Information Commissioner's Office (ICO) was notified and no further action was taken.

Since that time, HR have been working to correct the systems and processing issues. An external review into the data issues was carried out and an action plan agreed and implemented. The actions from this have now been carried out with a data cleanse exercise almost complete. In order to sustain improved data quality and processing, it is necessary to implement a new and integrated HR and payroll solution. This will reduce the manual input required from both HR and payroll and

reduce potential for errors. The agency is currently going through a procurement exercise with the aim of introducing the new solution during 2015/16.

4.17.1 Summary of Governance Framework

The systems for corporate governance, risk management, internal control and assurance are monitored by the Agency Board, ARAC and CET, and have been in existence throughout the year to 31 March 2015 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.

4.18 Accounting Officers 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.

The agency has adhered to the requirements on publishing information on any highly paid and/or senior off payroll appointments and that DH has received accurate data and disclosures to this end.

I am satisfied, based on the advice given to me by the Head of Internal Audit, the Agency Board, ARAC and the CET, 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
6 July 2015

5 Financial Statements

5.1 Statement of accounting officer'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.

5.2 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 2015 under the Government Trading Funds Act 1973. The financial statements comprise: the Statement of Comprehensive Income, Statement of Financial Position, Statement of Cash Flows, Statement of Changes in Taxpayers' Equity; and the related notes. These financial statements have been prepared under the accounting policies set out within them. I have also audited the information in the Remuneration Report that is described in that report as having 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 2015 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 there under.

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** **14 July 2015**
Comptroller and Auditor General

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

5.3 Statement of comprehensive income for year ended 31 March 2015

	NOTE	2014/15		2013/14	
		£000	**£000**	£000	£000
Income					
Trading income	3.1				
Income from trading activities		**122,287**		112,963	
Income from Department of Health		***30,480**		28,850	
Total trading income			**152,767**		141,813
Other income	3.2		**9,493**		8,985
Total Income			**162,260**		150,798
Expenditure					
Staff costs	6	**(70,941)**		(70,169)	
Operating costs	8	**(50,681)**		(51,939)	
Total Expenditure			**(121,622)**		(122,108)
Operating surplus			**40,638**		28,690
Finance income	9		**427**		403
Finance costs	9		**(48)**		(51)
Surplus for the financial year			**41,017**		29,042
Dividend payable			**(14,044)**		(12,878)
Sub total			**26,973**		16,164
Transfers under absorption accounting			**-**		104,664
Retained surplus for the year			**26,973**		120,828
Other comprehensive income/(loss)					
Other (loss)	10		**(812)**		(21)
Other comprehensive income/(loss) for the year			**(812)**		(21)
Total comprehensive income for the year			**26,161**		120,807

*Includes £9.0m (2013/14 £7.0m) of capital funding recognised as income in line with FReM.

The notes on pages 90 to 119 form part of these accounts.

5.4 Statement of financial position as at 31 March 2015

	NOTE	31 March 2015		31 March 2014	
		£000	£000	£000	£000
Non-current assets					
Property, plant and equipment	11	**96,726**		100,748	
Intangible assets	12	**19,471**		20,817	
Total non-current assets			**116,197**		121,565
Current assets					
Inventories	14	**6,827**		6,756	
Trade and other receivables	15	**22,235**		24,916	
Cash and cash equivalents	16	**192,534**		168,385	
Total current assets			**221,596**		200,057
Total assets			**337,793**		321,622
Current liabilities					
Trade and other payables	17	**(45,282)**		(51,066)	
Other liabilities	18	**(33,552)**		(35,576)	
Provisions	19	**(350)**		(678)	
Total current liabilities			**(79,184)**		(87,320)
Total assets less current liabilities			**258,609**		234,302
Non-current liabilities					
Other liabilities	18	**(4,122)**		(5,905)	
Provisions	19	**(2,236)**		(2,189)	
Borrowings	20	**(1,328)**		(1,328)	
Total non-current liabilities			**(7,686)**		(9,422)
Assets less liabilities			**250,923**		224,880
Taxpayers' equity:					
Public dividend capital			**1,329**		1,329
Reserves					
Revaluation reserve			**61,879**		62,311
General reserve			**42,470**		42,156
Income and expenditure reserve			**954**		954
Retained earnings			**144,291**		118,130
Total equity			**250,923**		224,880

Dr Ian Hudson
Chief Executive and Accounting Officer
Medicines and Healthcare Products Regulatory Agency
6 July 2015

The notes on pages 90 to 119 form part of these accounts.

5.5 Statement of cash flows for the year ended 31 March 2015

	NOTE	2014/15 £000	2014/15 £000	2013/14 £000	2013/14 £000
Cash flows from operating activities					
Operating surplus		**40,638**		28,690	
Interest paid	9	**(48)**		(51)	
Other losses	10	**(812)**		(21)	
Depreciation and amortisation		**10,876**		10,667	
Disposal of assets		**2,446**		17	
Impairment and reversals		**59**		257	
Realised (gain)/loss on non current assets	11	**-**		(485)	
Realised gain on inventories	14	**120**		124	
(Increase) in inventories	14	**(71)**		(6,756)	
Decrease/(Increase) in trade and other receivables	15	**2,680**		(12,596)	
(Decrease)/Increase in trade and other payables	17	**(5,785)**		19,734	
(Decrease)/Increase in other liabilities	18	**(3,807)**		12,376	
(Decrease)/Increase in provisions	19	**(281)**		465	
Dividend payable		**(14,044)**		(12,878)	
DH share of CPRD		**(280)**		-	
Net cash inflow from operating activities			**31,691**		39,543
Cash flows from investing activities					
Interest received	9	**427**		403	
Purchase of property, plant and equipment	11	**(466)**		(460)	
Purchase of intangible assets	12	**(7,503)**		(13,738)	
Net cash (outflow) from investing activities			**(7,542)**		(13,795)
Cash flows from financing activities			**-**		-
Net increase in cash and cash equivalents in the financial year	16		**24,149**		25,748
Transfers under absorption accounting	16		**-**		7,963
Cash and cash equivalents at the beginning of the financial year	16		**168,385**		134,674
Cash and cash equivalents at the end of the financial year	16		**192,534**		168,385

The notes on pages 90 to 119 form part of these accounts.

5.6 Statement of changes in taxpayers equity for the year ended 31 March 2015

	PDC[1]	Retained earnings	Reval. reserve[2]	General reserve	I & E[3] reserve	Total
	£000	£000	£000	£000	£000	£000
Balance at 31 March 2013	1,329	101,987	155	-	954	104,425
Changes in taxpayers' equity for 2014/15						
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 non current assets	-	-	(485)	-	-	(485)
Impairment and reversals	-	-	257	-	-	257
Realised gain on inventories – biological standards	-	-	(124)	-	-	(124)
Transfers	-		100	(100)	-	-
Sub total	-	-	(252)	(100)	-	(352)
Balance at 31 March 2014	**1,329**	**118,130**	**62,311**	**42,156**	**954**	**224,880**
Changes in taxpayers' equity for 2014/15						
Surplus for the year	**-**	**26,973**	**-**	**-**	**-**	**26,973**
Other losses	**-**	**(812)**	**-**	**-**	**-**	**(812)**
Retained surplus for the year	**-**	**26,161**	**-**	**-**	**-**	**26,161**
Other changes						
Net gain on revaluation of non current assets	**-**	**-**	**2**	**-**	**-**	**2**
Realised gain on inventories – biological standards	**-**	**-**	**(120)**	**-**	**-**	**(120)**
Transfers	**-**	**-**	**(314)**	**314**	**-**	**-**
Sub total	**-**	**26,161**	**(432)**	**314**	**-**	**26,043**
Balance at 31 March 2015	**1,329**	**144,291**	**61,879**	**42,470**	**954**	**250,923**

The notes on pages 90 to 119 form part of these accounts.

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

5.7 Notes to the Accounts

5.7.1 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 2014/15 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 2014/15. The application of the Standards as revised would not have a material impact on the accounts for 2014/15, were they applied in that year:

- IFRS 13 – Fair Value Measurement – Effective date 1 January 2013 (EU adopted).
- IAS 36 – Impairment of assets – Effective date 1 January 2014 (EU adopted).

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.

All other non-current 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. Land and buildings are regularly 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.

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 90 years
Laptops and associated applications	3 years
Plant and equipment	5 to 25 years
Vehicles	3 - 7 years
Fixtures and fittings	Up to 20 years
Computer systems	5 -10 years
Office refurbishment costs	10 - 15 years

During the annual asset verification exercise, 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 Statement of Comprehensive Income. 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

Statement of Comprehensive Income 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 the life of the assets. 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 required to bring the asset into a usable state. 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	15 years	831
Risk Based Inspection	5 years	1,307
Pharmacovigilance	8 years	443

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

By their nature losses and special payments 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. Losses and special payments are disclosed in note 24.

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 Statement of Comprehensive Income.

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 2014/15 (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. 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.

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. The agency also recovers part of its input VAT proportionate to its business activities in relation to total income. 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 arrangement and complies with IFRS11. 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 parties to the joint arrangement. Details of the joint venture are in note 4 CPRD joint arrangement memorandum account.

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 2013/14 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 OPERATING SEGMENTS

The Agency's income is derived from three centres related to its regulatory function in achieving its objectives of protecting, promoting and improving public health. These are:

The Clinical Practice Research Datalink (CPRD) is the 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.

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

	2014/15			
	CPRD* £000	**NIBSC £000**	**Regulator £000**	**Total £000**
Income from external customers	**3,878**	**19,858**	**98,551**	**122,287**
Income from DH	**-**	**21,380**	**9,100**	**30,480**
Total income**	**3,878**	**41,238**	**107,651**	**152,767**
Direct costs	**(3,205)**	**(32,970)**	**(44,709)**	**(80,884)**
Indirect costs	**(757)**	**(2,813)**	**(37,168)**	**(40,738)**
Total expenditure	**(3,962)**	**(35,783)**	**(81,877)**	**(121,622)**
Segment operating surplus/(deficit)	**(84)**	**5,455**	**25,774**	**31,145**

* represents MHRA's 50% share of joint arrangement

** Excludes Other income £9.5m (see note 3.2)

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.

	2013/14			
	CPRD £000	NIBSC £000	Regulator £000	Total £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

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.
- British Pharmacopoeia income is recognised as and when earned.
- Miscellaneous income: This is non-statutory income recognised as and when earned.
- Revenue grants from the Department of Health for the provision of services 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

	2014/15 £000	2013/14 £000
Income from fee charging activities*	**149,255**	138,194
Miscellaneous income	**3,512**	3,619
Total trading income	**152,767**	141,813

*Includes £10.5M (2013/14, £9.3M) 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 £9.5M from the Department of Health to offset the additional costs of dividend (£4.0M) and depreciation (£5.5M), resulting from the transfer of the National Institute for Biological Standards and Control to the agency on 1 April 2013.

4 CLINICAL PRACTICE RESEARCH DATALINK

Joint arrangement memorandum account

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

50% of the agency share of income and expenditure and non-current assets, currents assets and current liabilities are reflected in the agency accounts.

Income and expenditure*

	2014/15 £000	2013/14 £000
Revenue	**7,756**	7,904
Expenditure	**(7,924)**	(6,342)
Operating (deficit)/surplus	**(168)**	1,562

Statement of financial position

	2014/15 £000	2013/14 £000
Non-Current assets		
Intangible assets*	**7,032**	-
Current assets		
Trade and other receivables	**1,914**	-
Cash and cash equivalents	**10,163**	17,689
Current liabilities		
Trade and other payables	**(291)**	-
Other liabilities	**(1,297)**	-
DH contribution to joint arrangement	**(16,127)**	(16,127)
Assets less liabilities	**1,394**	1,562
Equity		
Surplus b/f	**1,562**	-
Surplus for the year	**(168)**	1,562
Total equity	**1,394**	1,562

*intangible assets represent the net book value of CPRD assets at 31 March 2015 and includes purchases made in 2013/14. For 2013/14, these were shown as assets under construction in the agency accounts. No restatement is being made and all movements are shown in 2014/15 as detailed below. See Note 11.

Statement of cash flows

	2014/15		2013/14	
	£000	**£000**	£000	£000
Cash flows from operating activities				
Operating surplus	**(168)**		1,562	
Depreciation and amortisation	**505**		-	
Disposals	**-**		-	
Impairment and reversals	**58**		-	
Increase in trade and other payables	**291**		-	
(Increase) in trade and other receivables	**(1,914)**			
Increase in other liabilities	**1,297**		-	
Net cash inflow from operating activities		**69**		1,562
Cash flows from investing activities				
Purchase of intangible assets	**(7,595)**		-	
Net cash (outflow) from investing activities		**(7,595)**		-
Cash flows from financing activities		**-**		8,000
Net increase in cash and cash equivalents in the financial year		**(7,526)**		9,562
Cash and cash equivalents at the beginning of the financial year		**17,689**		8,127
Cash and cash equivalents at the end of the financial year		**10,163**		17,689

Intangible assets

	2014/15	2013/14
	£000	£000
Cost	**-**	-
At 1 April 2014	**3,008**	-
Additions	**4,587**	-
Disposals	**(78)**	-
Reversals	**(58)**	-
At 31 March 2015	**7,459**	-
Amortisation		
At 1 April 2014	**82**	
Disposals	**(78)**	
Charged during the year	**423**	
At 31 March 2015	**427**	**-**
		-
Net Book Value at 31 March 2015	**7,032**	**-**

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. 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. 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.

	2014/15		
Charging activity	**Income £000**	**Expenditure £000**	**Surplus £000**
Licensing	**46,237**	**(32,845)**	**13,392**
Inspections	**9,137**	**(7,875)**	**1,262**
Vigilance, Risk Management and Enforcement	**32,443**	**(27,461)**	**4,982**
British Pharmacopoeia	**3,333**	**(2,696)**	**637**
Devices	**9,559**	**(8,204)**	**1,355**
Clinical Trials	**3,430**	**(2,720)**	**710**
Total Regulator	**104,139**	**(81,801)**	**22,338**
CPRD	**7,756**	**(7,924)**	**(168)**
Less: DH share of joint arrangement	**(3,878)**	**3,962**	**84**
	3,878	**(3,962)**	**(84)**
NIBSC	**41,238**	**(35,783)**	**5,455**
Total	**149,255**	**(121,546)**	**27,709**

	2013/14		
Charging activity	Income £000	Expenditure £000	Surplus £000
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 arrangement	(3,952)	3,170	(782)
	3,952	(3,172)	780
NIBSC	35,945	(33,150)	2,795
Total	138,194	(121,991)	16,203

*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

	2014/15 Total £000	2014/15 Permanently Employed £000	2014/15 Other £000	2013/14 Total £000
Wages and salaries	**56,156**	**53,782**	**2,374**	55,480
Social security costs	**4,927**	**4,927**	**-**	5,009
Other pension contributions	**9,882**	**9,882**	**-**	9,865
Sub-total	**70,965**	**68,591**	**2,374**	70,354
Less recoveries in respect of outward secondment	**(24)**	**(24)**	**-**	(185)
Total staff costs	**70,941**	**68,567**	**2,374**	70,169

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:

	2014/15 Total	2014/15 Permanently Employed	2014/15 Other	2013/14 Total	2013/14 Permanently Employed	2013/14 Other
Chairman	**1**	**1**	**-**	1	1	-
Executive Directors	**11**	**11**	**-**	11	11	-
Senior Civil Servants	**110**	**107**	**3**	127	126	1
Other Civil Service staff	**1,078**	**922**	**156**	1,075	975	100
Total	**1,200**	**1,041**	**159**	1,214	1,113	101

6.3 Reporting of civil service and other compensation schemes

6.3.1 Exit packages

There were no exit packages in 2014/15.

	2013/14 Total number of exit packages by cost band
< £10,000	-
£ 10,000 - £25,000	1
£ 25,000 - £50,000	2
£ 50,000 - £ 100,000	1
£100,000 - £150,000	-
£150,000 - £200,000	-
Total number of exit packages	**4**
Total resource cost	**£171,589**

Redundancy and other departure costs were 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 £Nil (2013/14, £172k) are included in wages and salaries and shown on the exit package table.

6.4 Off-payroll engagements

6.4.1 For all off-payroll engagements as at 31 March 2015, for more than £220 per day and that last longer than six months:

	Number
Number of existing engagements as at 31 March 2015	3
Of which, the number that have existed:	
for less than one year at the time of reporting	1
for between one and two years at the time of reporting	2
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	

6.4.2 For all new off-payroll engagements between 1 April 2014 and 31 March 2015, 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 2014 and 31 March 2015	2
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	2
Number for whom assurance has been requested	2
Of which:	
assurance has been received	2
assurance has not been received	
engagements terminated as a result of assurance not being received	

MHRA defines board member and/or senior officials with significant financial responsibility as members of the Corporate Executive Team; hence these individuals are disclosed in the Remuneration Report in section 3. There was one arrangement in 2014/15 in which a board member was involved in an off-payroll arrangement, however this individual was not deemed to have significant financial responsibility.

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 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).

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

For 2014/15, employees contributions were payable to the PCSPS at one of six rates in the range 1.5% to 8.85% of pensionable pay, 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 the costs are actually incurred, and reflect past experience of the scheme.

The employee contribution rates for PCSPS are as follows:

Full time pay range	Classic scheme	Classic plus, Premium and Nuvos schemes
Up to £15,000	1.50%	3.50%
£15,001 to £21,000	3.00%	5.00%
£21,001 to £30,000	4.48%	6.48%
£30,001 to £50,000	5.27%	7.27%
£50,001 to £60,000	6.06%	8.06%
£60,001 and above	6.85%	8.85%

Increases to employee contributions will apply from 1 April 2015. 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: http://www.civilservicepensionscheme.org.uk/

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 participating 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 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".

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.

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

The employee contribution rates for NHS pensions are as follows:

	2014/15 Annual pensionable pay banding	2014/15 Employee Contribution
Tier 1	Up to £15,431.99	5.0%
Tier 2	£15,432.00 to £21,387.99	5.6%
Tier 3	£21,388.00 to £26,823.99	7.1%
Tier 4	£26,824.00 to £49,472.99	9.3%
Tier 5	£49,473.00 to £70,630.99	12.5%
Tier 6	£70,631.00 to £111,376.99	13.5%
Tier 7	£111,377 and over	14.5%

The Government Financial Reporting Manual 2014/15 (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 2014/15, employers' contributions for the agency employees of £9,881,677 with a further £4,076 respect of staff on secondment were payable to the PCSPS and NHSPS (£9,865,807 in 2013/14 and a further £31,579 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 2013/14) for PCSPS and 14 per cent (14 percent in 2013/14) for NHSPC , 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 £204,476 (£229,452 in 2013/14) 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 2013/14). Employers can also match employee contributions up to a limit of 3 per cent of pensionable pay. In addition, employer contributions of £6,273 (£4,573 in 2013/14), 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 £5,128. No contributions were prepaid at that date.

There were no cases of retirement on ill-health grounds during 2014/15 (2013/14, Nil). No additional pension liabilities were accrued.

7. 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 £14.044M (2013/14 £12.878M).

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.

8. EXPENDITURE

Operating costs

	2014/15 £000	2013/14 £000
Computing	**11,918**	11,402
Depreciation and amortisation	**10,876**	10,667
Other accommodation costs	**5,345**	5,558
Rentals under operating leases (see note 13 below)	**4,499**	4,535
Supplies and services	**3,697**	3,125
Contracted-out administration services	**3,481**	2,657
Medicines testing and laboratory expenses	**2,531**	2,716
Laboratory consumables and services	**2,478**	2,175
Loss on disposal	**2,446**	17
Travel and subsistence	**2,334**	2,381
Legal Services	**1,427**	1,323
Other administration costs	**1,294**	1,315
Inventories consumed	**1,177**	90
Printing, stationery and distribution	**1,156**	871
Contracted-out personnel and payroll services	**797**	628
Training	**765**	791
Telecommunications	**747**	767
Committee costs	**737**	739
Marketing	**264**	201
Pharmacovigilance database and other costs	**176**	246
Auditors remuneration - audit fee	**98**	90
Impairment and reversals	**59**	257
Release of unutilised provision/increase in provisions	**(78)**	487
Other (gains)/losses	**(163)**	63
VAT refund	**(1,664)**	-
Net (decrease)/increase in debt and credit note provision	**(1,994)**	2,008
DH share of joint arrangement	**(3,722)**	(3,170)
Total operating costs	**50,681**	51,939

9. FINANCE INCOME AND COSTS

	2014/15 £000	2013/14 £000
Finance income		
Interest received from Government Banking Service	**427**	403
	427	403
Finance costs		
Interest paid	**(48)**	(51)
Net cash inflow from returns on investments and servicing of Finance	**379**	352

10. OTHER GAINS AND LOSSES

	2014/15 £000	2013/14 £000
(Loss) on foreign exchange	**(812)**	(21)
Total	**(812)**	(21)

11. PROPERTY, PLANT AND EQUIPMENT

2014/15	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 2014	86,464	9,101	20,728	13,887	130,180
Additions	-	36	69	361	466
Reclassification*	-	1,773	-	-	1,773
Transfers	2,043	1,174	1,849	20	5,086
Revaluation	-	-	405	(342)	63
Disposals	-	(6,021)	(1,235)	(4,548)	(11,804)
At March 2015	**88,507**	**6,063**	**21,816**	**9,378**	**125,764**
Depreciation					
At 1 April 2014	3,473	7,933	12,846	5,180	29,432
Reclassification	-	1,014	-	-	1,014
Charged during the year	3,600	887	1,662	1,744	7,893
Revaluation	-	-	244	(183)	61
Disposals	-	(6,016)	(1,205)	(2,141)	(9,362)
Depreciation at 31 March 2015	**7,073**	**3,818**	**13,547**	**4,600**	**29,038**
Net book value at 31 March 2015	**81,434**	**2,245**	**8,269**	**4,778**	**96,726**
Net book value at 31 March 2014	82,991	1,168	7,882	8,707	100,748
Asset financing:					
Owned					
Net book value at 31 March 2015	**81,434**	**2,245**	**8,269**	**4,778**	**96,726**

*Reclassification of assets

During the year 2014/15, assets previously classified as computer systems with a total net book value of £759,000 were reclassified to computer and telecom 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

12. INTANGIBLE ASSETS

2014/15	Computer systems £000	AUC~ £000	Software licences £000	Total £000
Cost or Valuation				
At 1 April 2014	34,017	10,980	4,916	49,913
Additions	1,005	8,002	-	9,007
DH share of CPRD*	(48)	(1,448)	(8)	(1,504)
Transfers	3,676	(8,847)	85	(5,086)
Reclassification	(1,773)	(87)	87	(1,773)
Disposals	(12,858)	-	(264)	(13,122)
Reversals	-	(59)	-	(59)
At 31 March 2015	**24,019**	**8,541**	**4,816**	**37,376**
Amortisation				
At 1 April 2014	26,202	-	2,894	29,096
Charged during the year	2,308	-	675	2,983
DH share of CPRD*	(40)	-	(2)	(42)
Reclassification	(1,014)	-	-	(1,014)
Disposals	(12,858)	-	(260)	(13,118)
Amortisation at 31 March 2015	**14,598**	**-**	**3,307**	**17,905**
Net book value at 31 March 2015	**9,421**	**8,541**	**1,509**	**19,471**
Net book value at 31 March 2014	7,815	10,980	2,022	20,817
Asset financing:				
Owned				
Net book value at 31 March 2015	**9,421**	**8,541**	**1,509**	**19,471**

~ Assets Under Construction

Assets under construction include items that will transfer to other asset categories when construction is complete, including those within Property Plant and Equipment.

*Relates to additions in 2013/14 when these were shown as assets under construction in the agency accounts.

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 2014/15 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.

13. LEASES

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 2014/15 £000**	**Land and buildings 2014/15 £000**	Others 2013/14 £000	Land and buildings 2013/14 £000
Minimum lease payments	**15**	**4,499**	95	4,535
Total	**15**	**4,499**	95	4,535

Total future minimum lease payments				
Payable:				
Within one year	**-**	**2,900**	-	4,399
Within two to five years	**-**	**11,200**	-	17,578
Over five years	**-**	**4,667**	-	11,719
Total	**-**	**18,767**	-	33,696

Finance Leases

The agency had no finance leases in 2014/15.

14. INVENTORIES

	31 March 2015 £000	31 March 2014 £000
Raw materials	**-**	10
Biological standards	**6,775**	6,611
Laboratory consumables and other stores	**52**	135
Total	**6,827**	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 2015 was £120k.

15. TRADE AND OTHER RECEIVABLES

	31 March 2015 £000	31 March 2014 £000
Amounts falling due within one year:		
Due from the Department of Health (see below)	**9,500**	9,080
Other trade receivables	**5,774**	9,448
Other receivables	**1,863**	249
Accrued income	**3,114**	4,023
Prepayments	**1,490**	1,424
	21,741	24,224
Amounts falling due after more than one year:		
Prepayments	**494**	692
Total	**22,235**	24,916

Other trade receivables are shown net of a provision for bad debts of £1.4m (31 March 2014 £3.5m) and credit notes of £0.3m (31 March 2014 £1.1m).

Intra government balances

	31 March 2015 £000	31 March 2014 £000
Balances with other central government bodies	**11,152**	9,165
Balances with local authorities	**2**	55
Balances with NHS Trusts	**2,067**	2,129
Balances with Public Corporations and Trading Funds	**25**	-
Subtotal	**13,246**	11,349
Balances with bodies external to government	**8,989**	13,567
Total	**22,235**	24,916

Amount Due from the Department of Health consists of:

	31 March 2015 £000	31 March 2014 £000
Other trade receivables	**7**	95
DH Funding for NIBSC*	**9,493**	8,985
Total	**9,500**	9,080

* see Note 3.2

Provision for bad debt

	31 March 2015 £000	31 March 2014 £000
Bad debt provision	**1,356**	3,458
Total	**1,356**	3,458

16. CASH AND CASH EQUIVALENTS

	31 March 2015 £000	31 March 2014 £000
Balance at 1 April 2014	**168,385**	134,674
Transfers under absorption accounting	**-**	7,963
Net change in year	**24,149**	25,748
Balance at 31 March 2015	**192,534**	168,385
Made up of		
Government Banking Service	**192,534**	168,385
Cash and cash equivalents*	**192,534**	168,385

* includes £10.2m held on behalf of CPRD joint venture

17. TRADE AND OTHER PAYABLES

Amounts falling due within one year:	31 March 2015 £000	31 March 2014 £000
Due to Department of Health (see below)	**14,366**	13,328
Payments received on account	**14,036**	17,519
Taxation and other social security costs	**2,648**	2,669
Other trade payables	**4,774**	4,201
Other payables	**2**	2,177
Accruals	**9,456**	11,172
Total	**45,282**	51,066

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

Amount Due to the Department of Health consists of:

	31 March 2015 £000	31 March 2014 £000
Payment on account	**6**	6
Accruals	**316**	444
Dividend payable*	**14,044**	12,878
Total	**14,366**	13,328

Intra government balances

	31 March 2015 £000	31 March 2014 £000
Balances with other central government bodies	**21,786**	22,942
Balances with local authorities	**7**	16
Balances with NHS Trusts	**368**	465
Balances with Public Corporations and Trading Funds	**-**	5
Subtotal	**22,161**	23,428
Balances with bodies external to government	**23,121**	27,638
Total	**45,282**	51,066

18. OTHER LIABILITIES

	Current		Non-Current	
	31 March 2015	31 March 2014	**31 March 2015**	31 March 2014
	£000	£000	£000	£000
Deferred revenue:				
Licence fees - applications and variations	**14,082**	10,331	**3,521**	3,443
Other fees	**6,325**	8,336	**601**	3,443
Others:				
DH Contribution to CPRD joint arrangement	***13,145**	*16,909	**-**	-
Total	**33,552**	35,576	**4,122**	5,905

*includes 50% DH share of CPRD joint arrangement surplus (see Note 4)

Intra government balances

	31 March 2015	31 March 2014
	£000	£000
Balances with other central government bodies	**13,145**	16,909
Balances with local authorities	**-**	-
Balances with NHS Trusts	**-**	-
Balances with Public Corporations and Trading Funds	**-**	-
Subtotal	**13,145**	16,909
Balances with bodies external to government	**24,529**	18,667
Total	**37,674**	35,576

19. PROVISIONS

	Current		Non-Current	
	31 March 2015	31 March 2014	**31 March 2015**	31 March 2014
	£000	£000	**£000**	£000
Early retirement	**-**	16	**-**	-
Other provisions	**350**	662	**2,236**	2,189
Total	**350**	678	**2,236**	2,189

Movement in provisions

	Early retirement	Other provisions	**Total**
	£000	£000	**£000**
At 1 April 2014	16	2,851	**2,867**
Arising during the year	-	15	**15**
Used during the year	(2)	(4)	**(6)**
Provision not required written back	(14)	(320)	**(334)**
Unwinding of provision	-	44	**44**
At 31 March 2015	-	2,586	**2,586**
Expected timing of cash flows:			
Between 1 April 2015 and 31 March 2016	-	350	**350**
Between 1 April 2016 and 31 March 2019	-	-	**-**
Beyond 2019	-	2,236	**2,236**
Total	-	2,586	**2,586**

Other provisions are in respect of:

- dilapidations for the headquarters building and is the current estimated cost for reinstating the structure of the building as required by the lease discounted at the Treasury discounted rate of minus 1.05% (medium term);
- dilapidation and onerous contract provision for the Welwyn Garden Office. This is expected to be settled in March 2016 and has been discounted at minus 1.5% (short term).

20. BORROWINGS

	Non-Current	
	31 March 2015	31 March 2014
	£000	£000
Loans from Department of Health	**1,328**	1,328
Total	**1,328**	1,328

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

	Total 2014/15	**Less than one year**	**Between one and five years**	**More than five years**	**Total 2013/14**
	£000	**£000**	**£000**	**£000**	**£000**
Fixed interest rate					
3.50%	**1,328**	-	-	1,328	1,328
At 31 March 2015	**1,328**	**-**	**-**	**1,328**	1,328
At 31 March 2014	**-**	-	-	1,328	1,328

21. CONTINGENT LIABILITIES

The Department of Health has agreed that it will meet the costs of any liabilities arising from legal claims in respect of regulatory 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.

22. CAPITAL COMMITMENTS

Contracts entered into not provided for in the accounts

	Intangible 31 March 2015	**Tangible 31 March 2015**	Intangible 31 March 2014	Tangible 31 March 2014
	£000	**£000**	£000	£000
Contracted	**1,929**	**1,893**	1,054	-
Total	**1,929**	**1,893**	1,054	-

23. 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.

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

2014/15	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	**4,733**	**35,262**	**14,366**	**9,500**
HMRC	**4,219**	**1,331**	**1,599**	**1,644**
Department for Work and Pensions	**247**	**4**	**42**	**-**
Treasury Solicitors	**820**	**-**	**35**	**-**
BIS	**7,100**	**-**	**4,222**	**-**
Various NHS Trust	**130**	**1,753**	**368**	**2,067**
Other government bodies	**189**	**276**	**1,521**	**34**
Local Authorities	**1,486**	**2**	**7**	**2**
Educational Bodies	**1,591**	**2,664**	**249**	**264**
As at 31 March 2015	**20,515**	**41,292**	**22,409**	**13,511**
2013/14				
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

During 2014/15, none of the Board members, members of the key management staff or other related parties had undertaken any material transactions with the agency. Details of compensation for key management staff are disclosed in the remuneration report.

24. 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 (2013/14: nil).

Losses may relate to cash and stores losses, exchange rate fluctuations, 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.

Exchange rate losses of £812k were incurred during the year.

As part of its three year savings plan, the agency relinquished one floor of office accommodation at its Buckingham Palace Road headquarters. This resulted in a write off of £2,405k, being the undepreciated element of the fit-out costs. There were no other material losses or special payments during the year (2013/14: £nil).

25. 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.

	2014/15 £000	2013/14 £000
Government Banking Service*	**192,534**	168,385
Total	**192,534**	168,385

* Includes £13k Proceeds of Crime which is the Agency's share of confiscated monies resulting from successful prosecutions and £52k 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 (2013/14:£1.328M). This resulted in interest payable of £0.048M (2013/14: £0.051M) out of total expenditure of £121.6M (2013/14: £122.1M)

Currency risk

The level of currency risk is determined by the level of income generated by activity undertaken on behalf of the EMA. For 2014/15 this was £10.482M (Euro 14.488M) (2013/14: £9.272M; Euro 11.221M). This represents 6.5% (2013/14: 6.9%) 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.

26. 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.

6 HM Treasury Direction

6.1 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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