Medicines & Healthcare products
Regulatory Agency

Medicines and Healthcare products Regulatory Agency Annual Report and Accounts 2015/16



CPRD NIBSC MHRA

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Any enquiries regarding this publication should be sent to us at
Medicines and Healthcare Products Regulatory Agency
151 Buckingham Palace Road
London
SW1W 9SZ
Telephone (weekdays: 9:00 – 17:00): 020 3080 6000
Email: info@mhra.gsi.gov.uk

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Chairman's Foreword

When I wrote the foreword to last year's Annual Report, I did so after having been in post for five months. As I write this foreword I have now served as Chairman for over eighteen months allowing me to become more familiar with the breadth of the Agency's roles and responsibilities as well as to meet many of the staff within each of its three centres including the Clinical Practice Research Datalink (CPRD), the Regulator Centre, and The National Institute for Biological Standards and Control (NIBSC). I have also had the opportunity to represent the Agency overseas.

The Agency's staff do an outstanding job and are more than capable of meeting unexpected challenges such as responding to the Ebola and Zika outbreaks. The Agency's response to these international public health emergencies illustrates the Agency's strength in depth. Indeed, the very high regard in which the Agency is held was echoed by Dr Margaret Chan, Director General of the World Health Organisation, when she gave the MHRA Annual Lecture on 1 March 2016.

I have also been impressed by the development of the CPRD and the exciting opportunities it offers for safeguarding of public health through scientific innovation and research. Our aim is to ensure its development harnesses the advances of the digital age to the quest for better health. As with CPRD, NIBSC offers unprecedented opportunities for scientific research, support and innovation in the field of biological medicines, which is a field of growing importance for public health.

The Board has also continued to evolve over the past year. In September 2015, in line with one of the recommendations in the Triennial Review, we became a unitary Board. In the same month, we were joined by four new members (Dr Barbara Bannister, Professor Bruce Campbell, Mr Matthew Campbell-Hill, and Mr Stephen Lightfoot). In February 2016, the Board started to hold some of its meetings in public, which are now a permanent feature of the calendar. Also in February, Martin Hindle, non-executive director, was appointed Deputy Chairman. The appointment has allowed for greater flexibility in the operation of the Board.

Furthermore, during the year, I, along with Dr Hudson, Chief Executive, have met with the Presidents of the Royal Medical Colleges and have begun a series of meetings with the Chief Medical Officers, Chief Pharmaceutical Officers and other officials in the Devolved Administrations. This is something we will develop further in 2016/17.

Looking ahead, I, and the members of the Board, look forward to working with Dr Hudson and his senior management team in 2016/17. The team leads a world-class organisation, 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. We will work closely with the government to consider the implications of the result of the referendum on the UK's membership of the European Union, working to secure positive outcomes whilst maintaining our focus on ensuring the efficacy and safety of all medicines and devices within the UK. And for me, it continues to be a massive privilege to be the Agency's Chairman.

Sir Michael Rawlins
Chairman

Chief Executive's perspective on performance of the organisation

This is the third foreword to the Annual Report I have written since I was appointed as Chief Executive in September 2013 and during that time it has been my privilege to lead an Agency whose work touches the lives of nearly everyone across the UK. That work makes a major contribution to safeguarding public health across the UK and beyond.

The MHRA is now considerably larger and more diverse in its responsibilities compared to when it was first formed. It is also operating in an ever more complex environment with the rapidly changing nature of the products and globalisation of the industries we regulate together with a changing healthcare environment nationally.

2015/16 has once again been another very busy year marked by change, planned work, and responding to unexpected developments. A year ago, when the Agency was heavily engaged in supporting the fight against Ebola, no one could have foreseen the impact the Zika virus would have on global public health. The MHRA is part of the global coalition responding to the outbreak.

Throughout the year we have said farewell to Board members, staff colleagues, and members of expert advisory committees. This is a feature of any successful organisation that goes through a process of renewal. At the same time, we have welcomed new staff and new Board members. Dr Christian Schneider joined the Agency as Director-designate of the National Institute for Biological Standards and Control (NIBSC) on 1 January and went on to succeed Dr Stephen Inglis as director on 1 April 2016. I am indebted to Dr Inglis for the very significant contribution he made to NIBSC, the Agency and public health more widely. The past year saw the publication of the Department of Health's Triennial Review reports on the Agency, the Commission on Human Medicines (CHM) and the British Pharmacopoeia Commission (BPC). The Reviews considered the bodies' function and form, as well as performance, capability, efficiency and governance.

The overarching message for the agency and its statutory committees that came out of the reviews was that the Agency, CHM and the BPC perform very well, although there are some challenges, and areas to develop which the Agency is addressing. The Reviews' positive findings are a tribute to the hard work and dedication of the Agency's staff and experts who serve on our advisory committees.

During the second half of the year, work began on refreshing the Agency's five-year Corporate Plan, which had reached its mid-life point. The public consultation on Corporate Plan proved reassuring as it confirmed that the Corporate Plan is very much fit for purpose however we need to adjust the emphasis a little in light of the changes in our environment since the plan was first prepared in 2013. The Corporate Plan is a dynamic document, which will be regularly reviewed to check that we continue to head in the right direction.

In July 2015, a Yellow Card smartphone app was launched by our minister, George Freeman, allowing patients, carers and healthcare workers to report adverse reactions to medications, as well as enabling them to set up alerts for news on particular drugs and find out how many Yellow Cards have been submitted for a given medicine.

During the past year a key focus has been our support for innovation, whether nationally or through our participation in the EU regulatory networks. Work continues on a range of initiatives, such as our Innovation Office, the Earlier Access to

Medicines Scheme, the Adaptive Pathways Scheme, and the 'One stop Shop' for advice on regenerative medicine, all of which are proving successful.

The Agency has also been busy internationally, in Europe and beyond, with a range of work, including a Good Manufacturing Practice (GMP) project of the International Coalition of Medicines Regulatory Authorities (ICMRA), development of new biological standards, as well as building relationships globally. In October, the Agency signed a Memorandum of Understanding with the Central Drugs Standards Control Organisation (CDSCO) of India. The agreement will increase collaboration between the two countries in the area of medicines and medical devices. All of this has been on top of the large amount of routine work which members of staff handle all the time.

In addition, there has been a range 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. Devices work has been assisted greatly by the newly established Devices Expert Advisory Committee (DEAC).

The Clinical Practice Research Datalink (CPRD), which was established in 2012 continues to offer exciting opportunities for the safeguarding of public health, research and support for innovation. It has also been good to see the significant progress made by CPRD over the past year as it develops, reinforcing the uniqueness of this international resource.

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 since it was established in 2003. Additionally, I would like to pay tribute to the work of the many independent experts whose deliberations help inform MHRA's regulatory decisions.

I was greatly encouraged that the staff response rate to the annual Civil Service People Survey in October 2015 was 71%, which was 6% higher than in the previous year. The Agency's overall engagement index score was 63%, which was 4% higher than the previous year, higher than the Civil Service average and places us in the upper quartile of all Civil Service organisations. The Agency attaches great importance to the views of its staff and has a programme of work at divisional and Agency level to act on the feedback from the staff survey. This is in addition to the Agency's extensive programme of training and development.

Following the result of the referendum on the UK's membership of the European Union, our focus continues to be on our public health role. We will continue to work to the highest levels of excellence and quality, working with and supporting our customers, partners and stakeholders to protect health and improve lives. Working closely with government we will consider the implications for the work of the Agency moving forward and to secure positive outcomes. Despite continued challenges and the ever changing and evolving environment in which we operate, there are many exciting opportunities ahead of us. I am confident we will meet these challenges and we will continue to remain one of the leading regulatory agencies for medicines, devices, biological standards and use of healthcare data for research in the world.

Ian Hudson
Chief Executive

1.1 Overview

Purpose and activities of the Medicines and Healthcare products Regulatory Agency

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.

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.

Aims

The Agency's aims are to:

- Ensure that medicines meet applicable standards of safety, quality and efficacy. That blood components for transfusion meet applicable standards of safety and quality and that medical devices meet applicable standards of safety and performance;
- 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.

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.

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** provides services for observational and interventional research, with a 50:50 investment contribution by the National Institute for Health Research (NIHR) and the Agency.

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.

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 the UK's preeminent research service providing access to anonymised NHS data for research. CPRD observational and interventional services are designed to maximise the way anonymised NHS clinical data can be used to improve and safeguard public health.

CPRD has a 50:50 investment contribution by NIHR and the Agency.

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.

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).

All medical devices placed on the market in the UK have to comply with two sets of device-specific legislation; the European Union laws (Medical Devices Directives and Regulations) and the UK laws (Medical Devices Regulations). The Agency is the designated and competent authority in the UK for assessing whether manufacturers and their medical devices meet the requirements set out in legislation.

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 across the UK, held in electronic health records, to help answer clinical

research questions about a population, including the safety and effectiveness of medicines and devices.

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.

Review of the year

The Agency has a five year Corporate Plan (2013-2018), and each year a Business Plan is developed to identify the objectives and activities for the year ahead which will contribute to meeting the Corporate Plan objectives. The information in this section reflects the five Corporate Plan (and thus Business Plan) themes.

Vision and scope of our role

This year our objectives within this theme were to contribute to major forward-thinking strategic exercises for both medicines and devices. We also set out our ambition to continue strengthening collaboration with partners across the health and social care network and to develop our scientific strength in biologics.

- We play a leading role in protecting public health not only in the UK but across Europe by leading European Union (EU) wide safety reviews. We have led over a third of these since new legislation was introduced in 2012. This year we led reviews concerning:
  - Pneumonia associated with inhaled corticosteroids used in chronic obstructive pulmonary disease (COPD).
  - Cardiovascular risk associated with high dose ibuprofen.
  - Risk of neurodevelopmental disorders in children whose mothers took valproate in pregnancy.

- The high regard in which our scientific expertise is held is reflected in the amount of European work which we have led this year relating to the licensing of medicines. We have:
  - Acted as rapporteur or co-rapporteur in 20 centralised procedures which concluded with the granting of a Marketing Authorisation.
  - Been appointed Reference Member States (RMS) in 43% of procedures instigated this year in which the applicant has sought a UK licence.
  - Held 319 regulatory or scientific advice meetings this year, using our expertise to support applicants in overcoming a range of issues.
  - Led 96 European Scientific advice meetings, helping us shape regulation and approvals across Europe.

- Working in collaboration with others in our sector including academia, health and social network partners and other regulators both in the UK and worldwide help us broaden our influence and deliver positive outcomes. This year:
  - CPRD signed a Memorandum Of Understanding (MOU) with the National Institute for Health Research (NIHR) Clinical Research Network. CPRD is collaborating with HSCIC and PHE on a DH led Health Data Finder, a web portal which helps to navigate the UK health data landscape.
  - NIBSC signed an updated MOU with the Chinese National Institute for Food and Drug Control (NIFDC) (we worked with them to produce our first jointly developed WHO International Standard for vaccines against EV71) and we established a second formal partnership with Imperial College.
  - We signed a MOU with India relating to our medicines regulatory work.
  - We maintained external Quinquennial Reviews of NIBSC's scientific divisions overseen by the independent Scientific Advisory Committee.

- The rapid spread of viruses can have devastating impacts and we want to be at the forefront of global responses to the threat they pose. This year our work on Ebola and Zika are two examples where we have responded in such a way. This year we:
  - Delivered interim standards for viral diagnosis and measuring antibody responses against the Ebola virus which were endorsed by the WHO's Expert Committee for Biological Standardisation.
  - Started developing standards for measuring antibodies against Zika virus following the health emergency in South America.
  - Have continued our work to support the eradication of poliovirus.

- The quality of our research work was again demonstrated this year with NIBSC attracting substantial amounts of competitively won external research funding from a variety of sources with 16 awards made.

- Over the course of this year:
  - CPRD's customer base grew 12% with data services provided to more than 70 unique clients based within the UK and internationally.
  - The US National Cancer Institute became a new CPRD customer, joining the US Food and Drug Administration as a regular user of CPRD data.
  - CPRD added 4 million patients to the database bringing the total patient lives on the database to 21 million.

- The emergence of biosimilar versions of biological medicines promises to increase global access to medicines for a wide range of important diseases, bringing benefits to patients worldwide. However, the availability of standards to allow quality comparisons to be made is crucial as new manufacturers emerge around the world. This year we:
  - Initiated projects to develop the first international standards for the monoclonal antibody products Infliximab and Rituximab; work is already well advanced.
  - Launched a global initiative, working with a group of key international organisations, on harmonised international standardisation.

- This year we have, in line with many scientific organisations that work with animals, elected to increase transparency of our activities to enhance public understanding of the importance of our in vivo work and its contribution to public health.

- This year we welcomed Dr Margaret Chan, Director General of the World Health Organisation to our annual lecture. This event was very well attended and set an Agency record for social media engagement with just under 3 million unique views.

- This year we published a mid-point 'refresh' and update to our Corporate Plan which brought together a review and refocus of our strategic priorities to the end of March 2018 in light of the new challenges and opportunities facing the Agency.

Spotlight on…..

The Independent Scientific Advisory Committee (ISAC) reviews research applications for use of CPRD data for observational studies. During 2015/16 ISAC approved 225

new research studies. To improve transparency and increase understanding of the important public health research that CPRD data support, a summary of all ISAC research protocols approved prospectively from July 2015 is now published on the CPRD website.

Bringing innovation and new products speedily and safely to patients

In the Business Plan we identified our desire to contribute to the Government's growth and innovation agenda, ensure the effective implementation of new EU legislation, increase uptake of CPRD services and continuing to ensure safe access to a range of products for self-medication.

- We see a very important part of our role in supporting access to innovative new medicines. This year we engaged in the Accelerated Access Review (AAR), a government priority due to report in 2016 which included:
  - Working with external auditors to analyse the independent review of the ''Early Access to Medicines Scheme'' (EAMS) and work on "Getting ahead of the curve", which focuses on the role of regulatory flexibilities such as conditional marketing approval and the new European Priority Medicines (PRIME) designation in accelerating access to medicines.
  - Looking to the year ahead we will support the AAR, including any recommendations about working in partnership with other UK partners to encourage speedy, safe adoption of transformative innovation through strengthened joint working.

- Our Innovation Office has continued to provide a single point of access to expert regulatory information, advice and guidance which supports organisations of all backgrounds and sizes. This year:
  - The Innovation Office received 122 enquiries (making a total of 283 queries since its introduction).
  - Supported industry, academia and SME's in a range of innovative activities including the development of induced pluripotent stem cells (IPS) for use in new therapeutic products and the manufacture of mammalian cell culture.
  - We continued to house the Regulatory Advice Service for Regenerative Medicine, which responds to queries about regenerative medicine; forming a single point of access to free, joined-up regulatory information, advice and guidance from four independent and expert UK-based agencies – the Health Research Authority (HRA), Human Fertilisation and Embryology Authority (HFEA), Human Tissue Authority (HTA), and ourselves.

The work of the Innovation Office demonstrates our a commitment to ensure that the UK remains one of the best places in the world to develop life sciences projects, protecting health and improving lives both in the UK and worldwide.

- We have played a key role in work on key EU negotiations and implementation relating to four important pieces of legislation. We have:
  - Played an active role in making and drafting proposals relating to the revised **medical devices legislation**. We have focused on addressing the regulatory concerns, whilst considering the practicalities of implementation and ensuring proposals are proportionate. Within the current framework we have worked across the Competent Authorities Network to ensure existing legislation is managed to ensure consistency of application of the legislation while enhancing collaboration between member states.
  - Continued preparations for implementing the new **Clinical Trials Regulation**, which aims to make the EU a more attractive and safer place for the conduct of clinical research. The Regulation also increases transparency via Public access to all data documents submitted to support authorisation of trials conducted in the EU (unless there is a clear case for confidentiality); and public consultation on all revisions to harmonised standards around such trials.

- Implemented the new Distance Selling Logo registration scheme in July 2015. This introduced a logo for websites selling medicines, helping consumers identify legally-operating websites; 313 websites registered this year. Further communications about this initiative, part of the **EU Falsified Medicines Directive,** are planned for 2016/17.
- We worked closely with the European Commission (EC) to implement a Europe-wide notification scheme for electronic cigarettes and refill containers sold as consumer products as part of the revised **Tobacco Products Directive**. The Directive will help consumers make informed choices about such products and increases our contribution to public health in this important area.

- The Agency continued leading the Innovative Medicines Initiative WEB-RADR project launched in 2014. The three year project reached a number of key milestones:
  - Minister George Freeman launched the first iteration of the Yellow Card Scheme mobile app in July 2015; it has been downloaded over 2300 times.
  - Following stakeholder research an enhanced app was delivered in March 2016.

- We have invited stakeholders to contribute to work on emerging innovative issues this year including Next Generation Sequencing and an event which identified the need for European medical device human factors guidance, which is being taken forward.

- We established a stakeholder platform on the Reclassification of Medicines in 2014 which considers strategic issues related to moving medicines from prescription only control to non-prescription availability. This year we published the first year's work of this platform, an initiative we believe will enable more medicines to be made available without prescription, supporting patients in accessing medicines for self-medication.
  - In terms of reclassification this year: the emergency hormonal contraceptive, ellaOne (ulipristal acetate 30mg) became available in the UK from pharmacies without prescription for women of childbearing age.

- We have continued to develop CPRD's observational and interventional services:
  - For the first time CPRD has provided services to facilitate recruitment of over 160 patients into intervention studies.
  - Developed an integrated IT platform to support real world data clinical trials in a primary care setting. The platform increases the likelihood of recruiting patients on time and to target increasing efficiency and reducing study costs.
  - Two new datasets, the Diagnostic Imaging Dataset (DIDS) and Hospital Episode Statistics Accident and Emergency data (HES A&E) have been added to the set of routinely linked data available for research.
  - Made available anonymised primary care data from GP practices using EMIS GP software to researchers for the first time. By year end, one third of all contributing GP practices were using EMIS software.

- Through NIBSC we have continued to build new scientific capabilities to deal with innovative areas of medicines development, putting us in a strong position for the years to come. This year we have:
  - Significantly invested in Next Generation Sequencing (NGS) and associated bioinformatics.

- Strengthened our Advanced Therapies Division by enhancing the capability to analyse biologics through spectroscopy, expanding our monoclonal antibody team and increasing our programme to develop reference materials to support genetic testing.

Spotlight on….

Our Early Access to Medicines Scheme (EAMS) supports access to innovative medicines for patients with life threatening or seriously debilitating conditions 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 (describes the risks and benefits and supports the prescriber and patient in making a decision on using the medicine). This year the MHRA has issued 7 PIM designations and 8 EAMS scientific opinions. Of these Scientific Opinons granted this year Osimertinib, Nivolumab and Sacubitril/valsartan have all gone on to receive a marketing authorisation.
In March 2015, the first scientific opinion was granted to pembrolizumab for the treatment of patients with advanced melanoma; this medicine was subsequently licensed in EU and has been the subject of The National Institute for Health and Care Excellence (NICE) technology appraisal guidance. This has benefited more than 500 UK patients by way of earlier access to this much needed treatment.

Strengthening surveillance

The Business Plan identified the clinical input into the management of devices, the strengthening of vigilance work (working with partners) and leading the development of incident reporting systems as key activities for this year.

- This year we continued working with the Department of Health on the introduction of GS1 (which includes the Unique Device Identifiers) and PEPPOL standards for medical devices. The aim is to integrate this information, which ultimately links individual products to patients, into the reporting of incidents and into European recall and field safety action systems, so improving market surveillance and crisis management.

- As well as holding the chair of the Executive Group of the European medical devices competent authorities group (CAMD), we are the lead authority in a bid for a substantial Joint Action which is designed to enhance collaboration across member states in the area of market surveillance. The programme is designed to develop tools and training to ensure a harmonised approach and maximise the benefits of collaborative working in order to enhance patient safety and efficient supervision of the regulatory system.

- We have continued 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.
  - We have continued this year to lead topics in the work packages on Adverse Drug Reaction (ADR) collection, Signal management, Quality management systems, and Risk Communications.
  - The first Stakeholder Event for SCOPE partners and consortium members was held this year, with updates provided on progress achieved across the eight Work Packages.

- Last year we celebrated the 50th anniversary of the Yellow Card Scheme and held events to mark this milestone and look to the future. We held additional events this year, through the regional Yellow Card Centres which supplemented the work last year in developing a roadmap for the Scheme. This identifies four themes:
  - improving patient safety through systematic and cultural change
  - embedding Yellow Card into the healthcare system
  - making the best scientific use of Yellow Card data
  - Yellow Card Scheme sustainability into the future through collaboration

- We recognise the value of collaborative partnerships to strengthen and embed reporting of suspected ADRs, particularly with Royal Colleges and professional bodies. We continued to focus on such partnerships this year, with an emphasis on reporting in children and young people. To support this we continued our joint partnership with the Royal College of Paediatrics and Child Health (RCPCH) and three separate strands of project work; through the MedsIQ initiative, the Paediatric Care Online UK (PCO UK) project, and the Personal Child Health Record (the ‘red book’). All three now contain sustainable information and champion reporting to the Yellow Card Scheme.

- We launched the new Yellow Card website in November 2014 enabling a single point of access to our incident reporting systems under the Yellow Card brand. The number of reports increased by 19% for all incidents received online compared to the numbers received through the separate reporting systems in the previous year. In addition:
  - General promotion, electronic integration into clinical IT systems, and the work of Yellow Card Centres have all contributed to a 26% increase in Adverse Drug Reactions (ADRs) received by the Yellow Card Scheme.
  - The total number of suspected ADR reports received this year was 40,663 with significant increases in reporting from both healthcare professionals and members of the public.

- This year we investigated 1019 defective medicines reports, issued 13 drug alerts and supported 12 company led drug alerts.

- We received and investigated 17615 adverse incidents reports (26.5% increase in the last 3 years); issued 30 Medical Device Alerts (MDAs), oversaw 839 Field Safety Notices (FSNs) issued by manufacturers in the UK and 231 National Competent Authority Reports to inform other EU competent authorities of safety actions being undertaken within the EU.

- We received and assessed 2470 SABRE reports relating to blood.

- Influenza can pose a significant risk and each year we play a critical role in the global vaccine response against both seasonal and pandemic influenza. This year we:
  - Responded to challenging circumstances with two strain changes recommended by WHO and pressure on potency standard production with one of three global suppliers unavailable.
  - Played a key role in international discussions on how to increase the speed and resilience of vaccines supplies optimally tailored to circulating strains.

- Papers and publications which we ourselves publish or which utilise our data help to demonstrate the importance of the research we undertake and the research we facilitate. This year:
  - A record 183 publications arose from research using CPRD data.
  - Ten pieces of new or revised NICE guidance cited findings from research utilising CPRD data were published.
  - NIBSC published a total of 104 papers.

- This year CPRD data has been used in a number of important studies demonstrating the benefit and importance to public health that CPRD data brings. This year:
  - A collaborative study between CPRD, Public Health England and the University of Bristol provided the first national data on mortality rates for people with intellectual disability. This found that half of such deaths can be classified as avoidable and a PHE factsheet is now under development.
  - A CPRD-led study, requested by the EMA and funded by Novartis, assessed the safety outcomes of vildagliptin, bringing together data and analysis from five European databases. The results showed no suggestion of an increased risk of incident congestive heart failure compared to other non-insulin antidiabetic drugs.

- CPRD has collaborated with GSK on two safety studies in young women immunised with the HPV-vaccine. This demonstrated no evidence of an increased risk of spontaneous abortion or other adverse pregnancy outcomes in women inadvertently vaccinated around gestation; no evidence of an increased risk of autoimmune diseases overall in vaccinated women, however there may be an increased risk of Graves' and Hashimoto's diseases.
- A study led by CPRD (funded by Astellas) compared new users of topical tacrolimus and topical pimecrolimus with users of moderate- to high-potency topical corticosteroids. The low incidence of lymphoma and cutaneous T-cell lymphoma found in this study indicated that the public health impact of the excess risk of exposure to topical tacrolimus and topical pimecrolimus would be low.
- CPRD researchers contributed to the Department of Health Chief Medical Officer (CMO) Annual Report for 2014. The 2014 report was published in autumn 2015 and focused on Women's Health in England. CPRD provided information on current trends in select issues affecting women's health including maternal mental health and psychotropic prescribing in pregnancy; trends in post natal examinations at 6-8 weeks; and trends in the diagnosis of type 2 diabetes, chronic kidney disease or hypertension up to 12 months post-partum among women who were first diagnosed with diabetes or hypertension during pregnancy.
- An EPID Research led study, requested by the EMA and funded by Takeda, assessed the risk of bladder cancer in relation to antidiabetic drug, pioglitazone exposure. This study showed that pioglitazone did not increase the risk of bladder cancer in terms of exposure, duration of use or cumulative dose.
- A study lead by Oxon Epidemiology and London School of Hygiene and Tropical Medicine (LSHTM) studied the association between BMI and Dementia. The results demonstrated patients who were either middle-aged or old age had an increased risk of dementia if they were underweight which was contradictory to the general consensus at the time. The findings of the study resulted in extensive media coverage.

Spotlight on….

Supporting the previously launched Medication Safety Officer (MSO) and Medical Device Safety Officer (MDSO) networks we provided in conjunction with NHS England a new collaborative discussion forum to replace the Patient Safety Direct website. 383 MSOs and 304 MDSOs were within the two networks in England as of March 2016 and 200 safety officers attended the second joint event held by MHRA and NHS England in February 2016 showing the strong support the networks have attracted.

On the medical devices side we have seen an increase in the number of adverse incident reports for medical devices (17,615 in 2015/16 versus 14,836 in 2014/15) since launching the network. And we have undertaken early development work on direct medical device adverse incident reporting to us from local risk management systems.

A recent report from the University Hospital of Southampton NHS Foundation Trust found that the introduction of MDSO e-reporting has resulted in improved reporting across all types of incident. Through this the Trust identified "hot spots" including

stock shortages, the need for equipment replacement, systematic device failures and user training for infusion pumps.
The Trust introduced additional training for infusion pump users with immediate success, with no further incidents seen.

This example demonstrates how the introduction of the MDSO network and the strong encouragement we have given to report all incidents has led to improvements. We will continue to encourage greater reporting of adverse incidents from medical device users, as this data provides important information about emerging issues with products and, therefore, impacts directly on public health.

Safe products and secure supply in globalised industries

Activities identified in the Business Plan under this theme included ongoing collaboration with international agencies to harmonise regulatory standards, whilst continuing to promote the safe purchasing of medicines and devices.

- The sale of unlicensed medicines and non-compliant medical devices from unregulated sources poses significant risks to patients who purchase such products. This year we again participated in Operation Pangea VIII tackling this illegal online trade. As part of this operation:
  - 6.2 million doses of falsified and unlicensed medicines were seized in the UK.
  - 15,487 counterfeit and non-compliant medical devices seized.
  - 1,380 websites were taken down.
  - 326 social media videos were removed

- We have worked on several worldwide initiatives to help protect the supply chain:
  - NIBSC expertise has been important for the analysis of counterfeit biological medicines, identifying Pegfilgrastim, Rituximab and Trastuzumab following seizures by our enforcement group.
  - We are establishing a global communications programme on the risks of fake medicines and medical devices, working with the World Health Organisation (WHO).

- Our Inspectorate continues to play an important role worldwide, working with other regulatory bodies and industry organisations. This year we:
  - Conducted 1700 inspections, including 100 overseas.
  - Launched an external Inspectorate blog which has over 3,500 subscribers, and had the fourth most subscribers of all government blogs. It has achieved nearly 100,000 unique page views since launching in June.
  - Hosted 2000 delegates at symposia covering all aspects of inspections.
  - Led work on the development of Data Integrity Definitions and Guidance for Industry working alongside other global regulators.
  - Led and supported a number of training events organised by the Pharmaceutical Inspection Co-operation Scheme (PIC/S), WHO and the EMA. We also chair a number of the PIC/S working groups and expert circles
  - Supporting global public health we tested samples for WHO as part of their response to the hospitalisation of over 400 patients in the Democratic Republic of Congo after they received a substandard medicine.
  - Have progressed the International Coalition of Medicines Regulatory Agencies (ICMRA) Good Manufacturing Practice (GMP) project
  - We will be the chairman of PIC/S in 2016/17.

- We have reviewed the safety of a number of medicines this year both in their current licensed indications and with a view to making changes to those indications to ensure ongoing safety for patients. This year we:
  - Reviewed infant Paracetamol licences, updating their posology following recommendations made in conjunction with the new national programme to immunise infants with meningococcal group B vaccine.
  - Sought CHM advice on the safety of human papillomavirus (HPV) vaccine and subsequently led a European review which resulted in a European consensus conclusion that the evidence does not support a causal

association between HPV vaccines and postural orthostatic tachycardia syndrome (POTS) or complex regional pain syndrome (CRPS).
  - Continued work we began in 2014 reviewing the scientific evidence on exposure in pregnancy to hormone pregnancy tests (which were used in the UK until the late 1970's). The review is ongoing and will also consider what lessons can be learned for improving existing regulatory systems in relation to medicines used in pregnancy and whether the findings have any implications for currently licensed medicines.
  - Undertook a review of the risks and benefits of Alteplase in the treatment of acute ischaemic stroke, seeking expert advice from an ad hoc CHM Expert Working Group. The benefit-risk balance is positive in this indication with all assessment reports, data considered by the Group and minutes of meetings published on our website.

- We have continued work with our Expert Advisory Group to refine our advice on the management of patients who have received metal-on-metal hips in the light of emerging clinical evidence. Updated advice on patient monitoring will be published in mid-2016.

- Our product testing capability has been called upon in several instances to deal with potential supply issues, in particular to support the introduction into the UK of FluMist, the new childhood influenza vaccine, and to deal with a potential shortage of TB vaccine, helping support ongoing treatment for patients. We have also this year:
  - Established 13 new or replacement WHO International Standards and other important reference materials bringing our total catalogue items to 910. These include standards for measurement of Hepatitis C Virus, Meningococcal Serogroup A Polysaccharide, Diphtheria Toxoid, and Blood Coagulation Factor IX.
  - As part of the European Official Control Authority Batch Release scheme (OCABR) tested and issued release certificates for over 1580 batches of vaccines and blood-derived products.

Spotlight on:

In January 2016, we were made aware of results of tests carried out on a batch of St. John's Wort tablets registered under the traditional herbal registration (THR) scheme, showing the presence of toxic pyrrolizidine alkaloids above the daily intake limit that the Committee on Herbal Medicinal Products (HMPC) consider might be acceptable. Pyrrolizidine alkaloids are not found in St. John's Wort itself. The contamination was identified as being likely to be from accidental collection of local weeds during harvesting; which led to requests from the Agency to other THR holders of St John's Wort medicines to provide assurances regarding levels of pyrrolizidine alkaloids in current batches. As a result, expert advice is being sought to help proactively manage the risk of pyrrolizidine alkaloid contamination in future.

In April 2015 a Dutch TV programme raised a safety concern that particles of glue could be injected into patients treated with Terumo hypodermic needles and alleged that 20% of needles could be impacted. These needles are widely used in the UK for a range of vaccination programmes, with 90,000 supplied via NHS Supply Chain in 2013/14.

We worked alongside other EU competent authorities and determined that 1% of needles were affected with toxicological tests confirming that the presence of

microscopic amounts of glue presented a negligible risk to patients and no adverse reports were received. This negligible risk was insignificant in comparison with the benefits of the needles continued use for a range of vaccination programmes including rabies, MMR, HPV, shingles and Hib.

This is an excellent example of a collaborative effort between a number of EU authorities and a measured response to a potential interruption to vaccination programmes in the UK, based on a reasoned consideration of the risks involved, supported by toxicological expertise from the UK and the Netherlands. The direct benefit to patients in the UK was the continued availability of the Neolus needles prevented any interruption to the numerous vaccination programmes).

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, continuing the regulatory excellence programme, whilst strengthening the reputation of the Agency with external stakeholders and recruiting and developing people with the right skills to deliver our objectives.

- This year we finalised the procurement of a new, Agency wide e-business software solution. This cloud based system includes core HR functionality as well as Recruitment, Learning and Development, Talent Management and Performance Management. A phased rollout of this system is planned for this year and is expected to bring numerous benefits and efficiencies via changed processes.

- We have focused this year on developing our social media offer. We recognise the growing use of this channel and it gives us an additional way to reach our stakeholders. This has included:
  - The introduction of verified Twitter feeds to signify the authenticity of our content.
  - The launch of our employer brand project to promote the Agency as an employer of choice, using media and social media such as LinkedIn and Twitter
  - Hosting a live Twitter Q&A session about the role of a Pharmaceutical Assessor. This session, the first of its kind for the Agency, attracted a wide range of questions and interest and gave us the opportunity to engage directly. The increases in engagement rate and impressions (17.8k versus an average of 2.3k) demonstrated the interest shown in the session.

- The new BP website (www.pharmacopoeia.com), launched in August 2015, incorporates the functionality of both the old websites, includes new features and improved search capabilities and has been favourably received by users.

- We continue to use a range of means to engage with and support our stakeholders, and our events programme helps us do this. This year we organised and delivered a record number of 29 events and exhibitions, including joint events with key partners.

- Our British Pharmacopoeia (BP) Secretariat has been working with NIBSC in the areas of Herbal and Biological Medicines. This year the new Appendix (XI V) detailing a general method for DNA-Based Identification Techniques for Herbal Drugs, was published in the BP 2016. This serves two purposes, firstly to confirm the suitability of the DNA extraction technique used, and secondly, to confirm the suitability of the PCR chemistry and system used.

- The Department of Health carried out a Triennial Review of the British Pharmacopoeia Commission which confirmed that the functions of the BP Commission were still required and that the Commission should be retained as an Advisory Non-Departmental Public Body. A number of recommendations were made regarding tendering for the next publication contract, appointments to the BP Commission and use and scope of the BP website.

- Over the past year the Agency has significantly enhanced its horizon scanning capability. A cross Agency team is now producing regular reports on emerging areas of devices and medicines development that may pose regulatory challenges, with resources allocated accordingly. Specific areas identified for immediate attention have included advanced therapies, genomics for diagnosis, manipulation of the gut microbiome and gene editing.

- Seeking to build on our strong patient safety and vigilance capabilities we launched an initiative this year to pursue a common excellence model for patient safety and vigilance for both medicines and devices. This involves three project areas with proposals for each under development:
  - Incident reporting and signal detection.
  - Risk-benefit assessment.
  - Improving delivery, targeting and audit of safety messages and risk communications.

- Each year we produce an Agency action plan to build on any areas for development which our people have told us about in the annual Civil Service People Survey. This year we received positive results which showed:
  - An increase in the response rate to 71%, this is 6 points up on the previous year.
  - 62% of staff were positive the Agency keeps them informed about matters that affect them, a significant 4% increase.
- These improved results show the value of our employee engagement programme, which this year featured:
  - Two successful managers' conferences.
  - Two series of all-staff meetings.
  - Workshops on improving the customer service we provide, attended by around 200 staff.
  - Workshops as part of the refresh of the Agency's Corporate Plan 2013-18.

- This year we have continued our efficiency programme, making the best use of our limited resources. Alongside this we have taken a lead in digital devices and technology with a focus on using digital technologies to deliver cost-effective and smart services across the Agency that put the user first.

Contributing to the Secretary of State's health inequalities agenda

During 2015/16, 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, for example 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 with such information included within the Summary of Product Characteristics.

We have continued to work to ensure that the Yellow Card scheme is accessible. Anyone can report an adverse incident, and basic information about the scheme has been translated into 12 languages and is 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 continued work on 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, TB and malaria. In addition, as part of the global efforts to eradicate Polio, NIBSC scientists are developing novel attenuated and non-replicating vaccines through programmes of research funded by the WHO and Bill and Melinda Gates Foundation.

CPRD has been used to study health inequalities between different groups, most recently in a study undertaken by the CPRD Observational Research Team into differences in mortality in patients with learning difficulties and the general

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

Key issues and risks facing the agency in delivering its objectives

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 Governance statement (section 2.4).

Risks	Mitigating factors and actions
Threat to agency stemming from the EU referendum.	With the outcome of the referendum result now known, there are significant implications for the agency. The CET have created an agency team to consider what the referendum result means for the agency, and make concrete plans for the future.
Failure to meet statutory and public health roles due to reduced funding.	Changes in work practices to increase efficiency. Alternative funding for Devices through fees: planning for implementation is ongoing.
Financial instability at NIBSC resulting from loss of influenza standards income.	Evaluation of alternative potency tests. Continue to build alternative revenue streams.
Failure to prevent falsified medical products reaching the public via the illegitimate supply chain.	Continue internet monitoring and public awareness campaigns.

1.2 Performance Analysis

How the Agency measures performance

Performance against targets 2015/16

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	**Met**	Met - 100% validated within 14 days of case creation
		b) For new Marketing Authorisation applications, 97% of validation reports produced within 14 days of case creation	**Met**	Met - Nearly 100% (99.8%) 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	**Met**	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	**Met**	Met - 98% in 150 days
		b) The assessment of applications for new Marketing Authorisations in European (MR, DC & centralised) procedures: 97% assessed within the designated time	**Nearly Met**	Nearly met - 96% DCP RMS in 70 days
			Met	Met - 100% DCP CMS in 100 days
			Met	Met - 100% MR in 50 days
			Met	Met - 100% Centralised Rap/Co-Rap in 80 days
		c) The assessment of Type IB minor and Type II major variation applications in	**Met**	Met - 97% Type II in 90 days

		National and European (MR, centralised) procedures: 97% assessed within the designated time	**Met**	Met - 97% Type IB 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)	**Met**	Met - 100% of all authorisations within 30 days
			Met	Met - 12.7 days average 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	**Met**	Met - 100% handled within 60 days
			Met	Met - 100% average 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	**Met**	Met - 99% made available within 2 working days
			Met	Met - 100% available within 3 working days
		b) Medical Device Alerts will be issued: 95% within 10 days, 100% within 15 days	**Met**	Met - 100% published within 10 days
			Met	Met - 100% published within 15 days
		c) For fatal UK adverse drug reactions: 90% within 24 hours, 100% within 72 hours	**Met**	Met - 100% within 24 hours
			Met	Met - 100% within 72 hours
		d) For serious UK adverse drug reactions: 95% within 72 hours, 100% within 5 days	**Met**	Met - 100% within 72 hours
			Met	Met - 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	**Met**	Met - 93% 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	**Met**	Met - 98% within 60 days
PM6	**Standards and control**	a) Biologics standards supply - 93% of all materials supplied within 6 working days	**Met**	Met - 93% 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	**Met**	Met - 100% within 8 days for Plasma Pools
			Met	Met - 100% within 10 days for Parentals
			Met	Met - 100% within 15 days for Haemostasis
			Met	Met - 100% within 60 days for vaccines
PM7	**CPRD activity**	a) To enable 280 research studies in 2015/16.	**Target not met**	229 studies were enabled. Shortfall may be in part due to HSCIC delays in data linkage during 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.	**Target not met**	Target not reached as achieving data flows from all 3 major GP software providers has taken longer than anticipated.
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 (or within permitted extension).	**Nearly Met**	Nearly met - 99.7% answered within 20 working days.
		b) Return responses to Parliamentary Questions (PQs) to the Department of Health by noon on the date specified in at least 80% of cases with less than 5% returned to MHRA by the Department for rewriting.	**Met**	Met - 91% answered on time
			Met	Met - 0% returned for rewriting
		c) Return Ministerial correspondence (POs) drafts to the Department of Health within 4 working days of receipt in at least 80% of cases with less than 5% returned to MHRA by the Department for rewriting.	**Met**	Met - 98% answered on time
			Met	Met - 0% returned for rewriting

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

Performance measures 2016/17

No.	Activities	2016-17 Targets
PM1	**Medicines licensing – validation of applications**	a) For Type IB[1] and Type II[2] variations, 97% of scientific validation process completed within 14 days of case creation
		b) For new Marketing Authorisation applications, 97% of validation reports produced within 14 days of case creation.
		c) 97% of Change of Ownership applications validated or Request For Information (RFI) issued within 42 days of receipt.
PM2	**Medicines licensing – assessment of applications**	a) The assessment of applications for new Marketing Authorisations for UK only: 97% assessed in 150 days
		b) The assessment of applications for new Marketing Authorisations in European (MR, DC & centralised) procedures: 97% assessed within the designated time
		c) The assessment of Type IB minor and Type II major variation applications in National and European (MR, centralised) procedures: 97% assessed within the designated time.
PM3	**Assessment of clinical trials and investigations**	a) The assessment of applications for clinical trials of medicines in the UK: 98% in 30 days (all trial phases) and an average time of 14 days (Phase I trials)
		b) Timescales for clinical investigation notifications for medical devices: maximum of 60 days with an overall average of 54 days or less
PM4	**Capturing and analysing adverse event reports – making reports available, issuing alerts and acting on signals**	a) Maximum timescales between receipt of reports and making them available for evaluation and analysis: For fatal and serious device adverse incidents: 95% within 2 working days and 100% (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**	Publish 98% of UK assessment reports within 60 net calendar days of grant of new authorisations

[1] Type IB variations are minor changes to a market authorisation unlikely to have a significant impact on the quality, safety or efficacy of the medicinal product concerned which are neither a Type IA or Type II change, as defined in Commission Regulation EC 1234/2008.

[2] Type II variations are major changes to a market authorisation as defined in Commission Regulation EC 1234/2008, which may have a significant impact on the quality, safety or efficacy of the medicinal product concerned.

No.	Activities	2016-17 Targets
	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 official control authority batch release (OCABR) and non-EU testing completed within agreed timelines: • 10 days for Plasma Pools • 10 days for Parenterals • 15 days for Haemostasis • 60 days for vaccines
PM7	**CPRD activity**	a) Support 260 new observational research studies in 2016/17
		b) drive the increase of CPRD GP coverage from 600 to 1000 GP practices
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 (or within permitted extension).
		b) Return responses to Parliamentary Questions (PQs) to the DH by noon on the date specified in at least 90% of cases with less than 5% returned to MHRA by the Department for rewriting.
		c) Return Ministerial correspondence (PO's) drafts to the DH within 4 working days of receipt in at least90% of cases with less than 5% returned to MHRA by the Department for rewriting.
PM9	**Summary Evaluation Report reviews – TSE**	a) In relation to Medical Devices utilising starting materials for which a TSE certificate of suitability is available – An opinion must be provided within 4 weeks from the date in which the Notified Body informed the MHRA
		b) In relation to Medical Devices utilising starting materials for which a TSE certificate of suitability is not available – An opinion must be provided within 12 weeks from the date in which the Notified Body informed the MHRA
		c) For Summary Evaluation reports received from other Member States – responses must be provided within the required timeframe to ensure timely response back to the Notified Body.

Financial Review

The Agency has continued to produce a sustainable financial performance, despite the challenging business and economic conditions in the UK which have resulted in reduced government funding for its Devices and NIBSC operations. As a government trading fund, the Agency is funded mostly by income from its fees. Income from trading activities in 2015/16 was £124.3m.

The Agency is required by a HM Treasury Minute (reproduced on page 107 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 for 2015/16 was £24.8m, compared to £39.8m in 2014/15. After finance costs and dividends of £3.2m, a net surplus of £20.8m arose in 2015/16 and has been transferred to reserves.

2015/16 has seen cash inflows from operating activities for the Agency of £30.5m, compared to £45.8m in 2014/15. The cash inflow arose from trading activities and efficient working capital management.

Sustainability report

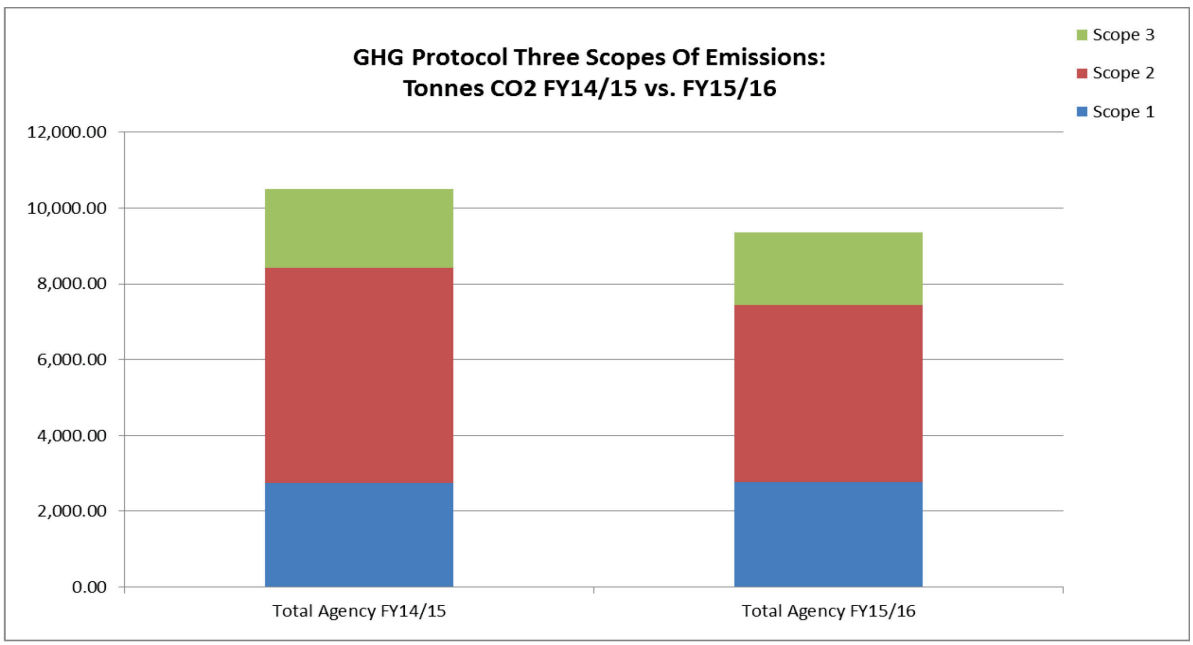
Greenhouse Gas (GHG) emissions performance

The Carbon Footprint for the sites at South Mimms and Buckingham Palace Road (BPR) have been produced individually and then combined to give an overall Carbon Footprint for the Agency. Several factors have impacted on the emissions data over the year, details of which are summarised below.

Greenhouse gas emissions financial and non-financial indicators				
Greenhouse Gas Emissions		**South Mimms**	**BPR**	**Total**
GHG Emissions (tCO^2)	Total Gross Emissions	6,804	2,545	9,349
	Gross Gas Emissions	2,483	44	2,527
	Gross Electricity Emissions	3,896	776	4,672
	Gross Property Emissions	267	2	269
	Gross Transport Emissions	157	1,723	1,880
Energy Consumption ('000 kWh)	Gas Consumption	13,467	238	13,705
	Electricity Consumption	7,790	1,551	9,341
Financial Indicators (£k)	Expenditure on Energy*	1,307	166	1,473
	Expenditure on Transport	344	1,515	1,859

Notes: 1. Expenditure on energy includes electricity only for BPR; gas is consolidated in the service charge.

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



The GHG Protocol provides an international accounting framework for GHG emissions and divides these into 3 Scopes. The graph above provides a 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 the first year to 6,804 TCO^2 this year, representing a reduction of 21% 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. The Carbon Footprint was 3,630 TCO^2 in the first year and 2,545 TCO^2 this year. The reduction seen of approximately one third of emissions is in direct relation to the floor consolidation project (the three rented floors at BPR were reduced to two), undertaken by the Facilities Manager at BPR in March 2015.

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.

Gas and electricity consumption

Gas and electricity consumption have been collated for the BPR site from 2013/14. The floor consolidation project has meant that this year attributable utility consumption has been greatly reduced. This has also given a reduction of £176k in electricity costs.

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 14% in electricity consumption has been achieved; numerous factors have contributed to this such as the replacement of old equipment with energy efficient versions, ‘switch off’ initiatives and maintenance improvements.

There is a mandatory requirement for the South Mimms site to be included in Phase II of the Carbon Reduction Commitment Scheme (a 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 circa £107k.

However due to the significant savings made during the last five years on energy consumption, a considerable amount of energy budget has been saved on utility bills for electricity and gas. This has been calculated as a total of £965k, over this period,

[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 2015.*

on electric and gas expenditure as well as a corresponding reduction in carbon tax payments.

Waste management performance

At South Mimms work has been undertaken to tender waste management in conjunction with LUPC (London Universities Purchasing Consortium); this joint approach with other Government organisations gained efficiencies from the collaboration. The new supplier is now in place and zero landfill has also been achieved this year.

The launch of Warp-It at South Mimms has brought substantial benefits and created behaviour change in the approach to waste. Warp-It is a resource re-uses system that allows staff to exchange work based items within the Institute. It has produced significant savings as shown below and there have been many associated benefits.

Savings associated with resource re-use		
Re-use Savings		**Total**
Re-use of resources	Total Savings £	99,372
	Total savings $KgCO^2$ Emissions	30,351
	Total Savings Waste Reduction Kg	11,007

Significant improvements have been made in terms of re-use of resources in efforts to not only reduce waste volumes but also reduce costs associated with purchasing new items. In particular re-use of furniture has been a big initiative across both sites. The Environment and Energy Manager has been working with Project Engineers to identify furniture requirements and sourced these as free issue from other Government organisations. This has saved £60k to date as a result of not purchasing new furniture.

The floor consolidation project at BPR incorporated the re-use of furniture and fittings whenever possible; including lighting, carpets and meeting room furniture and fabrication. This is something that has been encouraged as part of the project process; with any remaining furniture being re-used by the next tenant.

Finite resource consumption

Water consumption financial and non-financial indicators		
Water		**Total**
Non-Financial Indicators (M^3)	Water Consumption (BPR)	5,507
	Water Consumption (South Mimms)	28,229
Financial Indicators (£k)	Water Supply Costs (BPR)	U/A
	Water Supply Costs (South Mimms)	23
Notes: 1. Water costs are unavailable (U/A) for BPR, as these are built into the service charge. 2. BPR is mainly office consumption and NIBSC is mainly laboratory consumption.		

Water consumption has been collated for the BPR site from 2013/14. Following the recent floor consolidation at BPR these figures have declined significantly; reduction of utilities was one of the considerations for undertaking this project.

Due to the nature of the work carried out, the South Mimms site has been a relatively high water consumer. However, very good progress has been made to reduce this, with savings of 44 % realised. This has brought both environmental benefits to this finite resource and costs savings, as well as aiding a reduction in the Carbon Footprint.

Travel management update

High carbon emissions from BPR are a result of business travel, which accounts for over two thirds of total emissions attributable to this source. Initiatives are underway to help reduce this such as the previously established car-share scheme that has been in place at South Mimms for several years which 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 across the Agency has been encouraged, with new facilities installed this year which make it easier for staff to communicate and attend meetings without the need to travel. The use of this technology has enabled many meetings to be undertaken in a more environmentally friendly manner and thus help to reduce the Carbon Footprint associated with business travel.

Large scale energy saving projects

A specific opportunities assessment was carried out for the South Mimms site by the Environment and Energy Manager to investigate larger scale energy saving projects. Solar PV was identified as the most beneficial for the site to further reduce energy consumption.

The Solar PV project commenced towards the end of this year following an extensive tender process. The project included installation of 1,490 solar panels on seven south-facing roofs.

The site will consume all of the electricity produced and this will equate to approximately 10% of overall consumption. Estimates over the lifecycle of the project suggest it will bring savings of £2.7m; including FITs (Feed in Tariffs) from the Government, offsetting grid electricity and carbon tax abatement.

This first significant move into renewable energy has been welcomed by staff at the site and will bring numerous benefits including environmental, cost savings and a significant reduction in carbon emissions; as well as adding to the security of electricity supply.

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. Data presented here is for the whole of the Agency.

Responsibility for health and safety lies with the Agency's Chief Executive, cascading down through the Corporate Executive Team to Centre and Divisional management. The Health & Safety Strategy Group (HSSG) continue to develop and drive health & safety (H&S) initiatives across the Agency. This is supported by the Main Safety Committees and Sub-Committees.

Work has been carried out to improve risk assessments, overseas travel safety, accident reporting and developing cross Agency policies and procedures.

Training & Competence

NIBSC specialist training has been provided for laboratory workers, laboratory managers, risk assessors and authorisers. The following training was delivered during this reporting period:

Course	Total
Laboratory Managers H&S	9
Laboratory Workers H&S	22
Radiation Refresher Training	16
Practical Manual Handling	9
Risk Assessor / Risk Authoriser	7
Lab Modules 1,2 & 3	50
	113

The following Agency wide Civil Service Learning modules have been completed:

Course	Total
Basic Fire Safety Awareness	310
Health & Safety Awareness for all Staff	163
Health & Safety Awareness for Managers	41
Manual Handling	186
	700

Driving Monitor

Driver risk ratings are based on a risk assessment which combines driver history with an on-line assessment. Drivers deemed as 'high risk' receive additional training. The following data covers the whole Agency.

Centre	Risk Rating	Number of Drivers (%)
NIBSC	High	0.95
	Medium	4.7
MHRA / CPRD	High	0.95
	Medium	5.2

A total of 92.1% of staff have registered with Driving Monitor, with 82.3% of staff stating that they do not drive on Agency business.

Cardinus

Agency staff (81%) have completed the Display Screen Equipment (DSE) via the on-line Cardinus system. The 294 staff with 'high risk' DSE assessments are being assisted to resolve their DSE Issues with the assistance of Occupational Health.

Accident Data Trends

There have been no Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) reportable accidents / incidents during this reporting period.

NIBSC

There has been an increase in reporting, especially within the last six months. This is largely attributed to access issues for Safety Organiser being resolved and increased awareness.

MHRA & CPRD

The accidents reported are all minor and all apart from one have occurred at the Buckingham Palace Road (BPR) office.

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 programme for NIBSC was completed for 2015/16. No major actions were identified and all other audit actions have been closed.

HSE Interventions / Investigations at NIBSC 2015-2016

The scope of activities undertaken at NIBSC, 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.

There have been three planned intervention inspections which were all scored as ‘Broadly Compliant’. The HSE also acknowledged that NIBSC had demonstrated continued progress with improving health and safety performance.

Recommendations from inspections are routinely incorporated into the action plans.

Dr Ian Hudson
Chief Executive and Accounting Officer
Medicines and Healthcare products Regulatory Agency
5 July 2016

2 Accountability Report

2.1 Corporate Governance Report

2.2 Directors' Report

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.

Following recommendations in the triennial review a change was made in the composition of the board. These are detailed on page 50.

The Chairman

Sir Michael Rawlins

Sir Michael 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.

Biographies of new Board Appointments

Dr Barbara Bannister

Dr Barbara Bannister is a specialist in infectious and tropical diseases, who has previously served on the Commission on Human Medicines (CHM). She was awarded MBE for services to public health in 2013.

Although now retired from clinical practice, she remains an honorary consultant at the Royal Free Hospital and is an advisor on military medicine to the Ministry of Defence.

Professor Bruce Campbell

Professor Bruce Campbell is a consultant vascular surgeon at the Royal Devon and Exeter Hospital and an Honorary Professor at the University of Exeter Medical School.

Professor Campbell served on the Topic Selection Panel for the MHRA's Technical Forums from 2008-13 and was a member of the Independent Review Group for the MHRA in 2013-14. Professor Campbell has chaired the National Institute for Health and Care Excellence (NICE) Advisory Committees on Interventional Procedures since 2002 and on Medical Technologies since 2009.

Matthew Campbell-Hill

Matthew Campbell-Hill is a technology and media consultant with a special interest in emerging technologies and public engagement. He is a member of the National Information Board, and trustee and director of Cornwall Mobility.

Mr Campbell-Hill has been a standing member on multiple medical technology committees NICE since 2009, and across medical Royal Colleges. He is also a wheelchair fencing athlete for GB, captaining the men's sabre team to two World Cup medals since 2012, and is a part time broadcast journalist for the BBC.

Stephen Lightfoot

Stephen Lightfoot, currently Deputy Chair of Sussex Community NHS Foundation Trust and Director of Gainsborough Property Development UK Limited, also has wide-ranging experience of the medicines and medical devices industries.

Previous positions include serving as General Manager of GE Healthcare's global medical diagnostics division, Managing Director of Daiichi Sankyo's UK pharmaceutical business and Commercial Director of Schering Healthcare's UK pharmaceutical business.

Chief Executive

Dr Ian Hudson

Dr Hudson 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.

Chief Operating Officer

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.

Other Board members are: Prof Dame Valerie Beral, Mr Martin Hindle, Prof Sir Alex Markham, Ms Deborah Oakley and Prof David Bebb.

Biographies of all board and CET members can be found at:

https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

Conflict of interests

Potential conflicts of interest are managed by all Board members declaring in a register of interests any company directorships and other significant interests held by them or their close family and friends which may conflict with their Agency responsibilities. Members also declare their interest in any items being discussed at

Board meetings. Where potential conflicts of interests are identified, Board Members take no part in any discussions and are not involved in any decisions that relate to those matters.

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

Declaration of Interests

The 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

Incidents reported to the Information Commissioner's Office

There have been no personal data related incidents formally reported to the Information Commissioner's Office in 2015/16.

2.3 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, changes in taxpayers equity 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
- confirm that, as far as he is aware, there is no relevant audit information of which the entity's auditors are unaware, and the Accounting Officer has taken all the steps that he ought to have taken to make himself aware of any relevant audit information and to establish that the entity's auditors are aware of that information
- confirm that the annual report and accounts as a whole is fair, balanced and understandable and that he takes personal responsibility for the annual report and accounts and the judgments required for determining that it is fair, balanced and understandable.

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.

2.4 Governance Statement

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.

Governance Structure

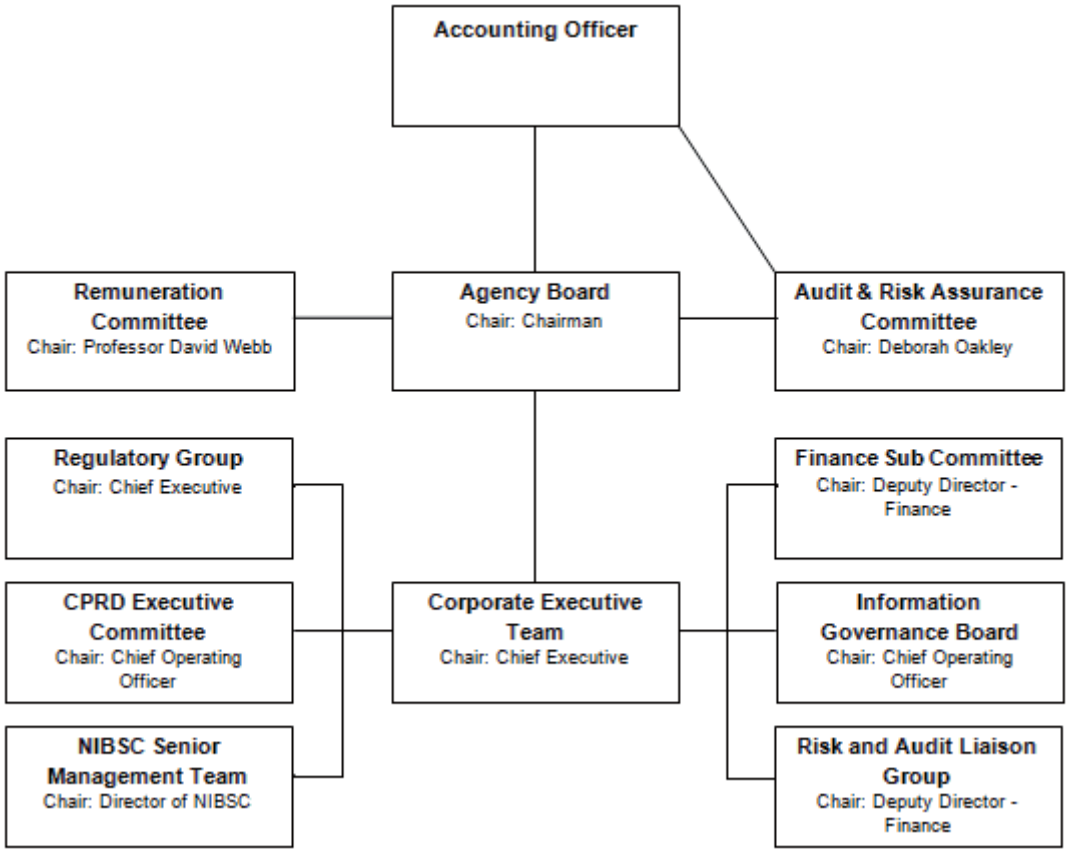
The Agency is an executive agency of the Department of Health and operates as a government trading fund. The Agency came into existence on 1 April 2003.

At the beginning of the reporting period; the following structures and processes were in place to ensure accountability and give the Agency a framework for risk management:

- The Agency Board (AB) made up of the Chairman and non-executive directors and 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 Corporate Executive Team (CET) consisting of the Agency's divisional directors takes overall responsibility for day-to-day management, strategic decision-making, line management, and all financial, policy, operational and resource management issues.

During the reporting period; a change in Governance structure from separate Non Executive and Executive Boards to a unitary Board was agreed and this structure was effective from 18 September 2015. The Board now consists of the Chairman, nine Non-Executive Directors, me as the Chief Executive (and Accounting Officer) and the Chief Operating Officer. This change was in response to a recommendation arising from the Triennial Review.

As the Agency's Chief Executive, I am responsible for service delivery and resources.



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 which was updated in March 2016.

The Board

The responsibilities of the Agency's board, known as the Board, are set out in the Agency's framework document and are set out on page 45.

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

interests. Conflicts of interests are declared at the start of each meeting and where appropriate members refrain from discussions

Following on from recommendations in the Triennial Review, there was a change in the Governance structure in the Agency. The separate Non-Executive and Executive Boards became a unitary Board from 18 September 2015 with the Chief Operating Officer and Chief Executive part of new and enlarged Board.

Board Attendance

	Board	Board Away Day
Professor Sir Michael Rawlins	10 (10)	1 (1)
Dr Barbara Bannister, MBE[1]	5 (6)	1 (1)
Professor Dame Valerie Beral	8 (10)	0 (1)
Professor Bruce Campbell[1]	6 (6)	1 (1)
Mr Matthew Campbell-Hill[1]	6 (6)	0 (1)
Mr Martin Hindle	9 (10)	1 (1)
Professor Vincent Lawton, CBE[2]	4 (4)	N/A
Mr Stephen Lightfoot[1]	6 (6)	1 (1)
Professor Sir Alex Markham	9 (10)	1 (1)
Ms Deborah Oakley	9 (10)	1 (1)
Professor David Webb	10 (10)	1 (1)
Mr John Williams, CBE[3]	4 (4)	N/A
Dr Ian Hudson	10 (10)	1 (1)
Mr Peter Commins	10 (10)	1 (1)

[1] Dr Barbara Bannister, Professor Bruce Campbell, Mr Matthew Campbell-Hill and Mr Stephen Lightfoot were appointed with effect from 1st September 2015.
[2] Professor Vincent Lawton appointment term ended on 20 July 2015.
[3] Mr John Williams appointment term ended on 31 August 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 Director of Communications (10/12) and Director of Policy (11/12) normally attend. Other senior executives, including the Director of NIBSC, the Director of Licensing, the Director of VRMM, the Director of HR and the Chief Information Officer have also attended in relation to specific topics

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 Board and to the Agency itself, for enabling all Board members to make a full contribution to the Board's affairs and for ensuring that the Board 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 Board, 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.

Effectiveness of the 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.

As part of their 2015/16 audit work plan, the internal auditors commenced work in January 2016 to review the Board's effectiveness. A Terms of Reference was agreed by the Board at its April 2016 meeting and fieldwork commenced in June 2016. A formal report is expected in July 2016.

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 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. The ARAC also discussed and agreed the annual internal audit plan as well as updates on progress of CPRD. In addition, ARAC asked for and received updates on the implementation of the IT cyber security recommendations at its quarterly meetings.

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 Board after each quarterly meeting and includes updates on the internal audit reviews and the corporate risk register.

ARAC Attendance

Member	ARAC
Ms Deborah Oakley[1]	4 (4)
Professor Vincent Lawton, CBE[2]	1 (1)
Mr Martin Hindle[3]	3 (3)
Mr Stephen Lightfoot[3]	2 (3)
Professor Sir Alex Markham[3]	3 (3)
Professor David Webb[4]	1 (1)
Routine Attendees:	
Chief Executive	4 (4)
Chief Operating Officer	4 (4)
Deputy Director - Finance	4 (4)
Head of Internal Audit	4 (4)
Representative from the External Auditor	4 (4)
Representative from the Department of Health	2 (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] Ms Deborah Oakley has been ARAC Chair since September 2015.

[2] Professor Vincent Lawton stepped down as ARAC Chair and left the committee on 20 July 2015.

[3] Mr Martin Hindle, Mr Stephen Lightfoot and Professor Sir Alex Markham became ARAC members on 18 September 2015.

[4] Professor David Webb stepped down from ARAC on 18 September 2015.

Remuneration Committee

The Remuneration Committee is a subcommittee of the Board 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 four non-executive members of the Board; the Chair of the Board is not eligible for membership. The Director of Human Resources 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 Board.

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 (section 2.5 of this report) gives details of the remuneration paid to the members of the Board and CET.

CET Attendance

	CET
Dr Ian Hudson	11 (12)
Ms Vanessa Birchall-Scott	11 (12)
Ms Rachel Bosworth	10 (12)
Mr Peter Commins	11 (12)
Mr Gerald Heddell	11 (12)
Dr Stephen Inglis	9 (12)
Dr Siu Ping Lam	12 (12)
Mr Jonathan Mogford	7 (12)
Mr John Quinn	9 (12)
Dr June Raine, CBE	9 (12)
Dr Janet Valentine	9 (12)
Mr John Wilkinson, OBE	10 (12)

Data Quality to Support the Needs of the Board

Financial Data

The CET and Board receive reports at its meetings to support its discussions. All reports comply with a prescribed layout to ensure that the CET and Board 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 Finance Sub Committee prior to submission to the CET and Board and any resource or financial implications are highlighted.

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

Operational Data

MHRA have put in new processes, policies and governance to support the operational management of information. This includes the establishment of a new Information Asset Owner network; new Information Security capability and operational reporting; and an Information Asset Board with stakeholder responsible for the full information lifecycle. We also have in place a number of projects to improve data and information handling through the information and records Management Programme, Business Intelligence Programme, the Cyber and information Security project, and are developing business cases to replace Devices Lotus notes systems, Sentinel and CRPD systems. These programmes will be delivered to an underpinning information architecture which will improve quality, lifecycle management and use.

Risk

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.

Assessment of Risk

At 31 March 2016, 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;
- Failure to prevent falsified medical products reaching the public via the illegitimate supply chain.

Other risks include the failure to keep up with world class expertise and NIBSC facilities resulting in the failure to respond to business pressures and competition; that IMD does not have the capability or capacity to deliver the Agency's IT Strategy; 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 risk of delayed implementation of the e-cigarettes aspects of the Tobacco Products Directive.

The mitigations for these risks are discussed on page 30. 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 Risk and Audit Liaison Group (RALG).

The cross-agency RALG, formed to strengthen the Agency's risk management system, held four meetings during the year to 31 March 2016. 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.

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.

The Information Security and Assurance programme, consists of a series of mini projects primarily delivering:

- hierarchical policies, procedures, guidelines and the mechanisms to achieve compliance;

- Culturally embed information security into all of our activities as second nature through education and engagement;
- Visible and recorded executive oversight, support and sponsorship;
- Decision making Steering group of stakeholders in senior leadership across all divisions;
- Alignment to ISO27001.

Effectiveness of whistleblowing arrangements

The Agency published a new internal Whistleblowing Policy and Procedure, Guidance for Managers and Frequently Asked Questions documents in January 2016 based on a best practice policy created by Civil Service Employee Policy. The new policy and accompanying documents have been publicised to managers and all staff. In addition, a Non-Executive Whistleblowing Champion was appointed to provide oversight and assurance to the whistleblowing policy and procedure and challenge the Agency, as appropriate, to ensure that internal mechanisms are working effectively to support staff in raising concerns, appropriate action is being taken, and any lessons are being learned. The Agency has two Nominated Officers under the Civil Service Code to whom staff can speak if they have a whistleblowing concern and are uncertain how to address it.

During the year, there were two internal whistleblowing cases raised by staff. Both cases were investigated and a written report provided to the complainant. Neither case was upheld. The individuals were informed of their right to raise their concerns with the Civil Service Commission, but have not chosen to do so.

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.

The key themes from these reviews were as follows:

- Key financial risks that relate to how MHRA funds are utilised (the value for money question);
- Key risk areas that may impact efficiency of MHRA operations, effectiveness of internal controls and efficacy of strategy (delivery of the MHRA's strategic/corporate plan objectives);
- The key theme's which have been identified by the HGIAS as areas of risk across the health group where further added value and sharing of best practice can be gained. These are Information Flows, Cultures and Behaviours and Risk Management;
- Key and significant projects or initiatives that require assurances; and
- Focus on assurance work, along with some advisory work where required.

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

Internal Audit reviews

- The review of end to end payroll process and data flows resulted in a limited rating and highlighted significant weaknesses in the framework of governance, risk management and control. The report recommended a review of standing data amendments on a monthly basis as well as strengthened controls to ensure that payroll reports are reviewed to identify payments to staff members who left in the previous month;
- The review of IT strategy and key financial processes which concentrated on the end to end NIBSC income process both reported moderate assurance and the need for management to continue to enhance the adequacy and effectiveness of controls;
- The review of Licensing Division's fraud controls resulted in a moderate assurance and found that the licensing application process is underpinned by robust and detailed reviews of data by industry specialists and subject matter experts based on product/device type;
- The reviews of handling of adverse events and reactions, CPRD KPIs and Agency KPIs all resulted in a substantial assurance;
- The Business Continuity Planning review resulted in a moderate assurance;
- The TSO contract review resulted in a limited assurance. The review recommended the development of an appropriate framework for the application of discounts as well as a governance process to monitor contractor's compliance with framework discounts;
- The review of service management in the Licensing Division resulted in a moderate assurance. Recommendations for improvement included a proposal to develop a training plan for staff within the service management team; review of SOPs on a regular basis; review of the IT system capabilities and creation of a feature to monitor and track all key service level targets.

The reviews noted on good practice as follows:

- within the VRMM division where a monthly quality assurance process takes place and in the Devices division where data checks are performed on a weekly basis with daily data cleanses to ensure there are no input errors;
- that the process behind the generation of MHRA's IT strategy has been comprehensive and robust;
- high level management engagement throughout the governance process with appropriate escalation within CPRD;

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

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 adequate and effective systems of control, governance and risk management in place'. 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.

The following 'high' recommendations have been made and accepted by management:

- Management should undertake a review to ensure all staff have completed annual declarations of interest (Licensing division fraud controls review);
- A monthly process should be agreed with HR to identify any leavers and remove their access rights from the system (NIBSC income review);
- A report of all changes to standing data should be produced from the payroll system and reviewed on a monthly basis (HR payroll process and data flows);

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

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 2016 with Divisional Directors confirming compliance with all Agency SOPs and policies.

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

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 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 2015/16.

Summary of Governance Framework

The systems for corporate governance, risk management, internal control and assurance are monitored by the Board, ARAC and CET, and have been in existence throughout the year to 31 March 2016 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.

Accounting Officer's Comment

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

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 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.

2.5 Remuneration and staff report

Remuneration report

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.

Service contracts

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 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.

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 Board members) of the Agency. CET members' salary and bonus awards were decided by the Remuneration Committee; Professor Vincent Lawton, CBE (Non-Executive Director and Chair of the Committee), Deborah Oakley and Martin Hindle (Non-Executive Directors). Dr Ian Hudson and Professor Sir Michael Rawlin'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 (pages 64 to 69) are subject to audit by the Comptroller and Auditor General.

CET remuneration, bonus and benefits table

2015/16	Salary £000	Performance pay and bonuses £000	Pension related benfits £000	Total £000
Dr Stephen Inglis Director of NIBSC	170 - 175	Nil	N/A	170 - 1 75
Dr Ian Hudson Chief Executive	150 - 155	10 - 15	62.5 - 65.0	220 - 225
Mr Peter Commins Chief Operating Officer	135 - 140	Nil	57.5 - 60.0	190 - 195
Dr June Raine, CBE Director of Vigilance & Risk Management of Medicines	125 - 130	10 - 15	32.5 - 35.0	165 - 170
Mr Gerald Heddell Director of Inspection. Enforcement and Standards	85 - 90	Nil	32.5 - 35.0	115 - 120
Mr John Wilkinson, OBE Director of Devices	115 - 120	10 - 15	42.5 - 45.0	165 - 170
Ms Rachel Bosworth Director of Communications	95 - 100	10 - 15	22.5 - 25.0	125 - 130
Mr Jonathan Mogford Director of Policy	95 - 100	Nil	35.0 - 37.5	130 - 140
Dr Siu Ping Lam Director of Licensing	115 - 120	Nil	55.0 - 57.5	170 - 175
Mr John Quinn Chief Information Officer	95 - 100	Nil	2.5 - 5.0	95 - 100
Ms Vanessa Birchall-Scott Director of Human Resources	90 -95	Nil	55.0 - 57.5	145 - 150
Dr Janet Valentine Director of CPRD	90 - 95	Nil	55.0 - 57.5	145 - 150

Band of the highest paid directors total remuneration	170 - 175
Median total	38,973
Remuneration ratio	4.4
Range of staff remuneration	7 - 175

* CET members receive no ‘benefits in kind’.

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	200 - 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 of 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.

[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.

Board remuneration, bonus and benefits table

2015/16	Salary £000	Benefits in kind (taxable) to nearest £100*	Total £000
Professor Sir Michael Rawlins Chairman	60 - 65	-	60 - 65
Dr Barbara Bannister, MBE[1] Non Executive Director	0 - 5	-	0 - 5
Professor Dame Valerie Beral Non Executive Director	5 - 10	-	5 - 10
Professor Bruce Campbell[1] Non Executive Director	0 - 5	-	0 - 5
Mr Matthew Campbell-Hill[1] Non Executive Director	0 - 5	3,200	5 - 10
Mr Martin Hindle Non Executive Director	5 - 10	700	5 - 10
Professor Vincent Lawton, CBE[2] Non Executive Director	0 - 5	-	0 - 5
Mr Stephen Lightfoot[1] Non Executive Director	0 - 5	200	5 - 10
Professor Sir Alex Markham Non Executive Director	5 - 10	1,200	5 - 10
Ms Deborah Oakley Non Executive Director	10 - 15	-	10 - 15
Professor David Webb Non Executive Director	5 - 10	900	5 - 10
Mr John Williams, CBE[3] Non Executive Director	0 - 5	700	0 - 5

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

[1] Dr Barbara Bannister, Professor Bruce Campbell, Mr Matthew Campbell-Hill and Mr Stephen Lightfoot were appointed with effect from 1st September 2015.
[2] Professor Vincent Lawton appointment term ended on 20 July 2015.
[3] Mr John Williams appointment term ended on 31 August 2015.

Following a change in governance effective from 18 September 2015, Dr Ian Hudson and Mr Peter Commins joined the Board. Their salary details are included in the CET table in this report.

2014/15	Salary £000	Benefits in kind (taxable) to the nearest £100	Total £000
Professor Sir Michael Rawlins[1] Chairman	20 - 25	-	20 - 25
Professor Sir Gordon Duff[2] Chairman	40 - 45	1,900	40 - 45
Professor Vincent Lawton, CBE Non Executive Director	10 - 15	-	10 - 15
Professor Barrington Furr, OBE[3] 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 Alex Markham Non Executive Director	5 - 10	800	5 - 10
Professor David Webb Non Executive Director	5 - 10	1,700	5 - 10

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

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

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 2015/16 relate to performance in 2014/15 and the comparative awards reported in 2014/15 relate to performance in 2013/14.

Fair pay disclosure

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 banded remuneration of the highest paid director in the Agency in the financial year 2015/16 was £170-175k (2014/15, £170-175k). This was 4.4 times (2014/15, 4.4) the median remuneration of the workforce, which was £38,973 (2014/15, £39,007). No employee received remuneration in excess of the highest paid director in 2015/16 (2014/15, none).

The range of staff remuneration was £7-175k (2014/15, £7-175k).

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

Pension benefits table

Neither the Chairman, nor 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 2016 and related lump sum Bands of £5,000	Cash Equivalent Transfer Value at 1 April 2015 To nearest £1,000	Cash equivalent Transfer Value at 31 March 2016 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	-	-	-	-	-	-
Dr Ian Hudson Chief Executive	2.5 - 5.0 plus Nil lump sum	50 - 55	896	1,031	59	37
Mr Peter Commins Chief Operating Officer	2.5 - 5.0 plus Nil lump sum	85 - 90 plus Nil lump sum	1,510	1,681	57	34
Dr June Raine, CBE Director of Vigilance & Risk Management of Medicines	0.0 - 2.5 plus lump sum of 5.0 - 7.5	45 - 50 plus lump sum of 145 -150	1,041	1,053	31	31
Mr Gerald Heddell Director of Inspection, Enforcement and Standards	0.0 - 2.5 plus Nil lump sum	20 - 25 plus Nil lump sum	378	392	25	21
Mr John Wilkinson, OBE Director of Devices	2.5 - 5.0 plus Nil lump sum	10 - 15 plus Nil lump sum	133	188	33	29
Ms Rachel Bosworth Director of Communications	0.0 - 2.5 plus lump sum of 2.5 - 5.0	20 - 25 plus lump sum of 70 - 75	410	467	20	24
Mr Jonathan Mogford Director of Policy	0.0 - 2.5 plus lump sum of 5.0 - 7.5	30 - 35 plus lump sum of 95 - 100	538	617	30	24
Dr Siu Ping Lam Director of Licensing	0.0 - 2.5 plus lump sum of 5.0 - 7.5	40 - 45 plus lump sum of 120 -125	791	883	30	29
Mr John Quinn Chief Information Officier	0.0 - 2.5 plus lump sum of 0.0 - 2.5	25 - 30 plus lump sum of 75 - 80	376	437	18	23
Ms Vanessa Birchall-Scott Director of Human Resources	0.0 - 2.5 plus Nil lump sum	0 - 5 plus Nil lump sum	5	32	19	23
Dr Janet Valentine Director of CPRD	2.5 - 5.0 plus Nil lump sum	0 - 5 plus Nil lump sum	6	62	19	23

* Dr Stephen Inglis opted out of the pension scheme on 1 April 2015.

Cash Equivalent Transfer Values

A Cash Equivalent Transfer Value (CETV) is the actuarially assessed capitalised value of the pension scheme benefits accrued by a member at a particular point in time. The benefits valued are the member's accrued benefits and any contingent spouse's pension payable from the scheme. A CETV is a payment made by a pension scheme or arrangement to secure pension benefits in another pension scheme or arrangement when the member leaves a scheme and chooses to transfer the benefits accrued in their former scheme. The pension figures shown relate to the benefits that the individual has accrued as a consequence of their total membership

of the pension scheme, not just their service in a senior capacity to which disclosure applies.

The figures include the value of any pension benefit in another scheme or arrangement which the member has transferred to the Civil Service pension arrangements. They also include any additional pension benefit accrued to the member as a result of their buying additional pension benefits at their own cost. CETVs are worked out in accordance with The Occupational Pension Schemes (Transfer Values) (Amendment) Regulations 2008 and do not take account of any actual or potential reduction to benefits resulting from Lifetime Allowance Tax which may be due when pension benefits are taken.

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.

Staff report

Staff costs

	Total	2015/16 Permanently Employed	Other	2014/15 Total
	£000	£000	£000	£000
Wages and salaries	**55,898**	**53,956**	**1,942**	56,156
Social security costs	**4,952**	**4,952**	**-**	4,927
Other pension contributions	**11,168**	**11,168**	**-**	9,882
Sub-total	**72,018**	**70,076**	**1,942**	70,965
Less recoveries in respect of outward secondment	**(92)**	**(92)**	**-**	(24)
Total staff costs	**71,926**	**69,984**	**1,942**	70,941

Staff resources

During the year an average of 1,216 permanent full-time equivalent staff were employed.

	Total	2015/16 Permanently Employed	Other
Chairman	**1**	**1**	**-**
Chief Executive/Directors	**11**	**11**	**-**
Senior Civil Servants	**115**	**111**	**4**
Other Civil Service Staff	**1,089**	**902**	**187**
Total	**1,216**	**1,025**	**191**

	Total	2014/15 Permanently Employed	Other
Chairman	1	1	
Executive Directors	11	11	
Senior Civil Servants	110	107	3
Other Civil Service Staff	1,078	922	156
Total	1,200	1,041	159

Staff composition – gender analysis

	Male	Female
Chief Executive/Directors	8	5
Senior Civil Servants	60	55
Other Civil Service Staff	465	624
Total	533	684

Staff composition – ethnic breakdown

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

- White 62.6%
- BME 29.7%
- No data/prefer not to say 7.7%

Sickness absence

The average annual sickness rate for the calendar year 2015 was 6.6 working days per full time equivalent employee.

The annual turnover for the Agency was 12.2%.

Staff policies

The Constitutional Reform and Governance Act 2010 requires Civil Service appointments to be made on merit on the basis of fair and open competition (with the Recruitment Principles published by the Civil Service Commission providing further guidance). We follow these principles and recruit all staff on the basis of them. This year we have reviewed recruitment processes and guidance for managers with specific reference to the guaranteed interview scheme for people with disabilities and the introduction of an anonymous application process. We make reasonable adjustments for people with disabilities in order that they can participate fully in our recruitment processes for example with accessible interview locations etc.

Our learning and development strategy actively promotes the development of all staff, including the offer of training courses as part of a commitment to 5 development days per year per staff member. In terms of individual development needs, these are recorded in Personal Development Plans which employees agree and review with their line manager. These requirements are met through a range of approaches and wherever possible we provide training on site (either at NIBSC or BPR) to facilitate accessibility.

Alongside this we have a commitment to promoting and achieving equality and diversity. This year we have committed to an Equality and Diversity pledge and objectives which span business, staff and facilities, with objectives which are measurable. We have also initiated Equality Impact Assessments for all activities, including policies, procedures, communications, services, staff restructures and workplace facilities. We support members of staff with disabilities through occupational health referrals, a confidential employee assistance programme and a formal reasonable adjustment policy.

We have also increasingly been seeking to ensure that representation on internal people related groups, such as the People Survey Focus Group and the Equality and Diversity Group include recognised trade union representation within a cross section of representatives from across the Agency. There is recognition that trade union representatives can significantly contribute to issues of common interest and in addition to more formal groups they should be engaged with initiatives such as those relating to health & wellbeing.

Spend on consultancy and temporary staff

During 2015/16, expenditure on consultants was £28k (£48k in 2014/15).

The Agency continues to employ temporary staff where it is of operational necessity. The Agency temporary staff expenditure was £1,944k in 2015/16 (£2,374k in 2014/15).

Reporting of civil service and other compensation schemes (subject to audit)

Exit packages (subject to audit)

Cost band	Total Number of exit packages by cost band
< £10,000	-
£ 10,000 - £ 25,000	2
£ 25,000 - £ 50,000	2
£ 50,000 - £100,000	-
£100,000 - £150,000	-
£150,000 - £200,000	-
Total number of exit packages	**4**
Total resource cost	**£104,993**

All departures were as a result of voluntary redundancies.

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 £104k (2014/15, £Nil) are included in wages and salaries and shown on the exit package table.

Off Payroll engagements

There were no off payroll engagements at 31 March 2016.

For all new off-payroll engagements, or those that reached six months in duration, between 1 April 2015 and 31 March 2016, for more than £220 per day and that last for longer than six months

	Number
Number of new engagements, or those that reached six months in duration, between 1 April 2015 and 31 March 2016	3
No. of the above which include contractual clauses giving the agency the right to request assurance in relation to income tax and National Insurance obligations	3
Number for whom assurance has been requested	3
Of which:	
No. for whom assurance has been received	3
No. for whom assurance has not been received	-
No. that have been terminated as a result of assurance not being received	-

All three transferred to payroll and assurance in relation to income tax and NI obligations continues to be provided in the form of pay slips. The engagements above did not include any board members or senior officials with significant financial responsibility.

2.6 Parliamentary accountability and audit report

This section is subject to audit.

1. 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.

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.

2. 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.

	2015/16		
	Income	Expenditure	Surplus
Charging activity	**£000**	**£000**	**£000**
Licensing	**47,667**	**(36,352)**	**11,315**
Inspections	**8,204**	**(8,743)**	**(539)**
Vigilance, Risk Management and Enforcement	**30,529**	**(34,347)**	**(3,818)**
British Pharmacopoeia	**3,481**	**(2,767)**	**714**
Devices	**9,809**	**(9,555)**	**254**
Clinical Trials	**3,757**	**(2,936)**	**821**
Total Regulator	**103,447**	**(94,700)**	**8,747**
CPRD	**9,562**	**(9,208)**	**354**
Less: DH share of joint arrangement	**(4,781)**	**4,604**	**(177)**
	4,781	**(4,604)**	**177**
NIBSC	**41,318**	**(38,675)**	**2,643**
Total	**149,546**	**(137,979)**	**11,567**

	2014/15		
	Income	Expenditure	Surplus
Charging activity	£000	£000	£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

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

3. 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 £300k in total, and those individually that exceed £300k. There were no special payments in excess of £300k during the year (2014/15: 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 £127k were incurred during the year.

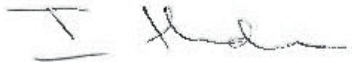
The Agency has been informed by its landlord, BIS the leaseholder of the office accommodation at Buckingham Place Road (BPR) of its intention to relinquish the leasehold of the building by the end of 2017/18. In line with this, the Agency has reduced the remaining life of the fit out costs of BPR to December 2017. This has resulted in additional depreciation of £1.0m being recognised in 2015/16.

During the year, the Agency undertook a full review of assets, lives and values and concluded that due to changing requirements during the year, it would be prudent to impair certain capital expenditure. Accordingly, £2.4m relating the Business Intelligence asset and £0.3m relating to CPRD software development has been expensed in 2015/16.

There were no other material losses or special payments during the year (2014/15: £nil).

4. ANY OTHER SIGNIFICANT PAYMENTS

There were none.



Dr Ian Hudson
Chief Executive and Accounting Officer
Medicines and Healthcare products Regulatory Agency
5 July 2016

2.7 The certificate and report of the Comptroller and Auditor General to the House of Commons

I certify that I have audited the financial statements of the Medicines and Healthcare products Regulatory Agency for the year ended 31 March 2016 under the 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 and Staff Report and the Parliamentary Accountability disclosures that is described in that report as having been audited.

Respective responsibilities of the Accounting Officer 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 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 Medicines and Healthcare products Regulatory Agency's circumstances and have been consistently applied and adequately disclosed; the reasonableness of significant accounting estimates made by the Medicines and Healthcare products Regulatory Agency; 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 the Medicines and Healthcare products Regulatory Agency's affairs as at 31 March 2016 and of the net deficit for the year then ended; and

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

In my opinion:

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

- the information given in the Performance Report and Accountability disclosures 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 and Accountability disclosures 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
Comptroller and Auditor General
National Audit Office
157-197 Buckingham Palace Road
Victoria
London
SW1W 9SP

Date 13 July 2016

3 Financial Statements

STATEMENT OF COMPREHENSIVE INCOME for the year ended 31 March 2016

	NOTE	2015/16		2014/15	
		£000	**£000**	£000	£000
Income					
Trading Income	3.1				
Income from trading activities		**124,344**		122,287	
Income from Department of Health*		**28,619**		30,480	
Total Trading Income			**152,963**		152,767
Other income	3.2		**10,182**		9,493
Total income			**163,145**		162,260
Expenditure					
Staff costs	6	**(71,926)**		(70,941)	
Operating costs	7	**(66,373)**		(51,493)	
Total Expenditure			**(138,299)**		(122,434)
Operating Surplus			**24,846**		39,826
Finance income	8		**569**		427
Finance costs	8		**(47)**		(48)
Surplus for the financial year			**25,368**		40,205
Other comprehensive income					
Realised gain on inventories - biological standards			**(104)**		-
Net gain on revaluation of property, plant and equipment			**16,322**		-
Total comprehensive income for the year			**41,586**		40,205

*Includes £7.0m (2014/15 £9.0m) of capital funding recognised as income in line with FReM.

The notes on pages 84 to 107 form part of these accounts.

STATEMENT OF FINANCIAL POSITION as at 31 March 2016

	NOTE	2015/16		2014/15	
		£000	**£000**	£000	£000
Non-current assets					
Property, plant and equipment	9	**113,998**		96,726	
Intangible assets	10	**11,799**		19,471	
Total non-current assets			**125,797**		116,197
Current assets					
Inventories	12	**6,289**		6,827	
Trade and other receivables	13	**23,852**		22,235	
Cash and cash equivalents	14	**211,428**		192,534	
Total current assets			**241,569**		221,596
Total assets			**367,366**		337,793
Current liabilities					
Trade and other payables	15	**(145,775)**		(45,282)	
Other liabilities	16	**(30,675)**		(33,552)	
Provisions	17	**(992)**		(350)	
Total current liabilities			**(177,442)**		(79,184)
Total assets less current liabilities			**189,924**		258,609
Non-current liabilities					
Other liabilities	16	**(7,360)**		(4,122)	
Provisions	17	**(2,120)**		(2,236)	
Borrowings	18	**(1,328)**		(1,328)	
Total non-current liabilities			**(10,808)**		(7,686)
Assets less liabilities			**179,116**		250,923
Taxpayers equity					
Public dividend capital			**1,329**		1,329
Reserves					
Revaluation reserve			**78,097**		61,879
General reserve			**42,470**		42,470
Income and expenditure reserve			**954**		954
Retained earnings			**56,266**		144,291
Total equity			**179,116**		250,923

Dr Ian Hudson
Chief Executive and Accounting Officer
Medicines and Healthcare Products Regulatory Agency
5 July 2016

The notes on pages 85 to 107 form part of these accounts.

STATEMENT OF CASH FLOWS for the year ended 31 March 2016

	NOTE	2015/16		2014/15	
		£000	£000	£000	£000
Cash flows from Operating activities					
Operating surplus		**24,846**		39,826	
Depreciation and amortisation		**11,396**		10,876	
Disposal of assets		**8**		2,446	
Impairment and reversals		**2,697**		59	
Realised gain on inventories	12	**104**		120	
Decrease/(Increase) in inventories	12	**538**		(71)	
(Increase)/Decrease in trade and other receivables	13	**(11,110)**		2,680	
Increase/(Decrease)in trade and other payables	15	**1,144**		(5,785)	
(Decrease) in other liabilities	16	**361**		(3,807)	
Increase/(Decrease) in provisions	17	**526**		(281)	
DH share of CPRD		**-**		(280)	
Net cash inflow from operating activities			**30,510**		45,783
Cash flows from investing activities					
Purchase of property, plant & equipment	9	**(4,749)**		(466)	
Purchase of intangible assets	10	**(2,838)**		(7,503)	
Net cash (outflow) from investing activities			**(7,587)**		(7,969)
Cash flows from financing activities					
Interest received	8		**569**		427
Interest paid	8		**(47)**		(48)
Dividend paid			**(4,551)**		(14,044)
Net cash (outflow) from financing			**(4,029)**		(13,665)
Net increase in cash and cash equivalents in the financial year	14		**18,894**		24,149
Cash and cash equivalents at the beginning of the financial year	14		**192,534**		168,385
Cash and cash equivalents at the end of the financial year	14		**211,428**		192,534

The notes on pages 85 to 107 form part of these accounts.

STATEMENT OF CHANGES IN TAXPAYERS' EQUITY
for the year ended 31 March 2016

	PDC[1]	Retained earnings	Reval. reserve[2]	General reserve	I & E reserve[3]	Total
	£000	£000	£000	£000	£000	£000
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	-	40,205	-	-	-	40,205
Dividend payable	-	(14,044)	-	-	-	(14,044)
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	-	-	(432)	314	-	(118)
Balance at 31 March 2015	**1,329**	**144,291**	**61,879**	**42,470**	**954**	**250,923**
Changes in taxpayers equity for 2015/16						
Surplus for the year	-	25,368	-	-	-	25,368
Other changes						
Net gain on revaluation of non-current assets	-	-	16,322	-	-	16,322
Realised gain on inventories - biological standards	-	-	(104)	-	-	(104)
Dividend payable	-	(113,393)	-	-	-	(113,393)
Sub total	-	(113,393)	16,218	-	-	(97,175)
Balance at 31 March 2016	**1,329**	**56,266**	**78,097**	**42,470**	**954**	**179,116**

The notes on pages 85 to 107 form part of these accounts

Key
1 Public Dividend Capital represents taxpayers' equity in the agency.
2 Revaluation Reserve
3 Income and Expenditure Reserve is a one off capital grant from the Department of Health and represents taxpayer's equity in the agency.

NOTES TO THE ACCOUNTS

1 ACCOUNTING POLICIES

1.1. General

1.1.1. Compliance with government accounting requirements

The financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) as adaped and interpreted by the 2015/16 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 2015/16. The application of the Standards as revised would not have a material impact on the accounts for 2015/16, were they applied in that year:

- IFRS 9 Financial Instruments: Effective date 1 January 2018.
- IFRS 14 Regulatory Deferral Accounts: Not yet EU endorsed.
- IFRS 15 Revenue from contracts with customers: Effective 1 January 2017

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.

- **Provision for potential refund of grants costs**

A follow up review of overhead cost recovered on grant funded projects is currently being undertaken to ensure they have been recovered in line with prescribed guidance. This is expected to result in recovered costs being disallowed and having to be refunded.

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 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 line with FReM, an independent desktop valuation has been carried out at year end.

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 to 7 years
Fixtures and fittings	Up to 20 years
Computer systems	5 to 10 years
Office refurbishment costs	10 to 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 to 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)
CPRD architecture	8 years	5,923
Sentinel architecture	15 years	623
Risk Based Inspection	5 years	697
Pharmacovigilance	8 years	332

CPRD architecture is the application developed to manage the collection of patient's data including features to manipulate data as required for clinical trials.

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. 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. 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.

1.6. 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 National Institute for Health Research and the 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 arrangement 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.

1.7. Income

Income from trading activities represents invoiced amounts 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.
- NIBSC standards income is recognised as and when earned.
- NIBSC research grants, income is recognised in line with expenditure incurred at pre-determined stages.
- 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.

1.8. Inventories

Inventories are valued at the lower of cost or 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.

1.9. 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.

1.10. 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. 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 by the National Institute for Health Research 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 segments 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.

	2015/16			
	CPRD*	NIBSC	Regulator	Total
	£000	£000	£000	£000
Income from external customers	4,781	21,799	97,764	124,344
Income from DH	-	19,519	9,100	28,619
Total income	4,781	41,318	106,864	152,963
Direct costs	(4,083)	(36,123)	(58,948)	(99,154)
Indirect costs	(522)	(2,552)	(35,891)	(38,965)
Total expenditure	(4,605)	(38,675)	(94,839)	(138,119)
Segment operating surplus	176	2,643	12,025	14,844

* represents MHRA's 50% share of joint arrangement

** Excludes Other income £10.2m (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.

	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

3. INCOME

3.1. Trading income

	2015/16	2014/15
	£000	£000
Income from fee charging activities*	**149,547**	149,255
Miscellaneous income	**3,416**	3,512
Total Trading Income	**152,963**	152,767

*Includes £10.4M (2014/15, £10.5M) 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 £10.2M (£9.5M in 2014/15) from the Department of Health to offset the additional costs of dividend £4.6M (£4.0M in 2014/15) and depreciation £5.6M (£5.5M in 2014/15), 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

	2015/16	2014/15
	£000	£000
Revenue	**9,562**	7,756
Expenditure		(7,924)
Operating expenditure	**(6,550)**	-
Staff costs	**(2,658)**	-
Operating surplus/(deficit)	**354**	(168)

Statement of financial position

	2015/16	2014/15
	£000	£000
Non-current assets		
Tangible assets	**34**	-
Intangible assets	**7,336**	7,032
Current assets		
Trade and other receivables	**1,638**	1,914
Cash and cash equivalents	**12,567**	10,163
Current liabilities		
Trade and other payables	**(969)**	(291)
Other liabilities	**(2,731)**	(1,297)
DH contribution to joint arrangement	**(16,127)**	(16,127)
Assets less liabilities	**1,748**	1,394
Equity		
Surplus b/f	**1,394**	1,562
Operating Surplus/(Deficit) for the year	**354**	(168)
Total Equity	**1,748**	1,394

Statement of cash flows

	2015/16		2014/15	
	£000	**£000**	£000	£000
Cash flow from operating activities				
Operating deficit	**354**		(168)	
Depreciation and amortisation	**856**		505	
Impairment and reversals	**484**		58	
Increase in trade and other payables	**678**		291	
Decrease/(Increase) in trade and other receivables	**276**		(1,914)	
Increase in other liabilities	**1,434**		1,297	
Net cash inflow from operating activities		**4,082**		69
Cash flows from investing activities				
Purchase of intangible assets	**(1,682)**		(7,595)	
Net cash (outflow) from investing activities		**(1,682)**		(7,595)
Cash flows from financing activities		**-**		-
Net increase/(decrease) in cash and cash equivalents in the financial year		**2,400**		(7,526)
Cash and cash equivalents at the beginning of the financial year		**10,163**		17,689
Cash and cash equivalents at the end of the financial year		**12,563**		10,163

Intangible assets

	2015/16 £000	2014/15 £000
Cost		
At 1 April	**7,459**	3,008
Additions	**1,678**	4,587
Impairment*	**(495)**	-
Disposals	**-**	(78)
Reversals	**-**	(58)
At 31 March	**8,642**	7,459
Amortisation		
At 1 April	**427**	82
Disposals	**-**	(78)
Impairment	**(11)**	-
Charged during the year	**856**	423
At 31 March	**1,272**	427
Net Book Value at 31 March	**7,370**	7,032

*Dataline software consultancy fees previously capitalised.

5. 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 £13.393M (2014/15 £14.044M) of which £10.182M is reimbursed by DH leaving a net figure of £3.211M.

At the request of the Department of Health, the agency has agreed to pay a special dividend of £100M for 2015/16.

The agency planned its fee strategy so as to achieve a return averaged over the period 1 April 2013 to 31 March 2018 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.

6. STAFF COSTS

Staff costs

	2015/16 Total	2014/15 Total
	£000	£000
Wages and salaries	**55,898**	56,156
Social security costs	**4,952**	4,927
Other pension contributions	**11,168**	9,882
Sub-total	**72,018**	70,965
Less recoveries in respect of outward secondment	**(92)**	(24)
Total staff costs	**71,926**	70,941
See staff report page 71		

7. OPERATING COSTS

	2015/16	2014/15
	£000	£000
Computing	**22,699**	11,918
Depreciation and amortisation	**11,396**	10,876
Accommodation	**6,409**	5,345
Medicines testing and laboratory expenses	**4,637**	2,531
Supplies and services	**3,777**	3,697
Travel and subsistence	**2,293**	2,334
Other operating costs	**15,162**	14,792
Total operating costs	**66,373**	51,493

Other operatings costs include:	**£000**	£000
Operating leases	**2,920**	4,499
Contracted out services	**2,947**	4,278
Audit fees	**108**	98

8. FINANCE INCOME AND COSTS

	2015/16	2014/15
	£000	£000
Finance income		
Interest received from Government Banking Service	**569**	427
	569	**427**
Finance costs		
Interest paid	**(47)**	(48)
Net cash inflow from returns on investments and servicing of Finance	**522**	**379**

9. PROPERTY, PLANT AND EQUIPMENT

2015/16	AUC £000	Land and buildings £000	Computer and telecom equipment £000	Plant and equipment £000	Fittings, furniture and office equipment £000	Total £000
Cost or valuation						
At 1 April 2015		88,507	6,063	21,816	9,378	125,764
Additions	4,582	-	108	59	-	4,749
Reclassification	4,334	-	-	-	-	4,334
Transfers	(7,815)	5,386	186	2,243	-	0
Revaluation	-	16,222	-	127	38	16,387
Reversal	-	-	-	-	(60)	(60)
Elimination of accumulated depreciation	-	(10,991)	-	-	-	(10,991)
Disposals	-	-	-	(1,245)	-	(1,245)
At 31 March 2016	**1,101**	**99,124**	**6,357**	**23,000**	**9,356**	**138,938**
Depreciation						
At 1 April 2015	-	7,073	3,818	13,547	4,600	29,038
Charged during the year	-	3,918	792	1,521	1,797	8,028
Revaluation	-	-	-	78	24	102
Elimination of accumulated depreciation	-	(10,991)	-	-	-	(10,991)
Disposals	-	-	-	(1,237)	-	(1,237)
At 31 March 2016	**-**	**-**	**4,610**	**13,909**	**6,421**	**24,940**
Net book value at 31 March 2016	**1,101**	**99,124**	**1,747**	**9,091**	**2,935**	**113,998**
Net book value at 31 March 2015	-	81,434	2,245	8,269	4,778	96,726
Asset financing:						
Owned						
Net book value at 31 March 2016	**1,101**	**99,124**	**1,747**	**9,091**	**2,935**	**113,998**

~ 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.

Land and buildings

A professional valuation of land and buildings was carried out on 31 March 2016 which resulted in a net revaluation of £10,991k. In line with International Accounting Standard 16, accumulated depreciation has been eliminated against the carrying amount of the asset with the net amount restated to equal the revalued amount.

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 31 March 2015	88,507	6,063	21,816	9,378	125,764
Depreciation					
At 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)
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 £642,000 were reclassified to computer and telecom equipment.

10. INTANGIBLE ASSETS

2015/16	Computer systems £000	AUC~ £000	Software Licences £000	Total £000
Cost or valuation				
At April 2015	24,019	8,541	4,816	37,376
Additions	113	2,520	-	2,633
Transfers	1,143	(1,560)	417	0
Reclassification	(2)	(4,334)	-	(4,336)
Disposals	-	-	(61)	(61)
Impairment	(247)	(2,359)	-	(2,606)
At 31 March 2016	25,026	2,808	5,172	33,006
Amortisation				
At April 2015	14,598	-	3,307	17,905
Charged during the year	2,747	-	621	3,368
Reclassification	-	-	-	-
Disposals	-	-	(61)	(61)
Impairment	(5)	-	-	(5)
Amortisation at 31 March 2016	17,340	-	3,867	21,207
Net book value at 31 March 2016	7,686	2,808	1,305	11,799
Net book value at 31 March 2015	9,421	8,541	1,509	19,471
Asset financing:				
Owned				
Net book value at 31 March 2016	7,686	2,808	1,305	11,799

~ 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.

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)
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.

11. LEASES

Operating leases

All costs of operating leases are charged to the Statement of comprehensive income as incurred.

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 2015/16 £000**	**Land and buildings 2015/16 £000**	Others 2014/15 £000	Land and buildings 2014/15 £000
Minimum lease payments	**-**	**2,920**	15	4,499
Total	**-**	**2,920**	15	4,499

Total future minimum lease payments				
Payable:				
Within one year	**-**	**2,800**	-	2,900
Within two to five years	**-**	**2,100**	-	11,200
Over five years	**-**	**-**	-	4,667
Total	**-**	**4,900**	-	18,767

Finance Leases

The agency had no finance leases in 2015/16.

12. INVENTORIES

	31 March 2016 £000	31 March 2015 £000
Biological standards	**6,232**	6,775
Laboratory consumables and other stores	**57**	52
	6,289	6,827

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 2015-16 was £104k (£120k in 2014/15).

13. TRADE AND OTHER RECEIVABLES

	31 March 2016 £000	31 March 2015 £000
Amounts falling due within one year:		
Due from the Department of Health (see 13.1 below)	**10,182**	9,500
Other trade receivables	**5,695**	5,774
Other receivables	**1,256**	1,863
Accrued income	**3,966**	3,114
Prepayments	**2,423**	1,490
	23,522	21,741
Amounts falling due after more than one year:		
Prepayments	**330**	494
Total	**23,852**	22,235

Other trade receivables are shown net of a provision for bad debts of £0.8m (31 March 2015 £1.4m) and credit notes of £0.2m (31 March 2015 £0.3m).

13.1. Amount Due from the Department of Health consists of:

	31 March 2016 £000	31 March 2015 £000
Other trade receivables	**-**	7
DH Funding for NIBSC*	**10,182**	9,493
Total	**10,182**	9,500

* see Note 3.2

13.2. Provision for bad debt

	31 March 2016 £000	31 March 2015 £000
Bad debt provision	**848**	1,356
Total	**848**	1,356

14. CASH AND CASH EQUIVALENTS

	31 March 2016 £000	31 March 2015 £000
Balance at 1 April	**192,534**	168,385
Net change in year	**18,894**	24,149
Balance at 31st March	**211,428**	192,534
Made up of:		
Government Banking Service	**211,428**	192,534
Cash and cash equivalents*	**211,428**	192,534

* includes £9.4m held on behalf of CPRD joint venture

15. TRADE AND OTHER PAYABLES

	31 March 2016 £000	31 March 2015 £000
Amounts falling due within one year:		
Due to the Department of Health (see 15.1 below)	**113,693**	14,366
Payments received on account	**14,762**	14,036
Taxation and social security costs	**2,780**	2,648
Other trade payables	**3,064**	4,774
Other payables	**105**	2
Accruals	**11,371**	9,456
Total	**145,775**	45,282
Amounts falling due after more than one year:		
There are no creditors falling due after one year		

15.1. Amount Due to the Department of Health consists of:

	31 March 2016 £000	31 March 2015 £000
Payment on account	**-**	6
Accruals	**301**	316
Special dividend*	**100,000**	-
Dividend payable	**13,392**	14,044
Total	**113,693**	14,366

* see note 5

16. OTHER LIABILITIES

	Current		Non-Current	
	31 March 2016	31 March 2015	**31 March 2016**	31 March 2015
	£000	£000	**£000**	£000
Deferred revenue:				
Licence fees - applications and variations	**14,237**	14,082	**4,496**	3,521
Other fees	**2,254**	6,325	**2,864**	601
Others:				
DH Contribution to CPRD joint arrangement*	**14,184**	13,145	**-**	-
Total	**30,675**	33,552	**7,360**	4,122

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

17. PROVISIONS

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 as required by the lease discounted at the Treasury discounted rate of minus 1.55% (short term)

	Current		Non-current	
	31 March 2016	31 March 2015	**31 March 2016**	31 March 2015
	£000	£000	**£000**	£000
Dilapidations	**992**	350	**2,120**	2,236
Total	**992**	350	**2,120**	2,236

Movement in provisions

	Dilapidations	**Total**
	£000	**£000**
At 1 April 2015	2,586	**2,586**
Arising during the year	922	**952**
Used during the year	(306)	**(306)**
Provision not required written back	(20)	**(20)**
Unwinding of provision	(70)	**(70)**
At 31 March 2016	3,112	**3,142**
Expected timing of cash flows:		
Between 1 April 2016 and 31 March 2017	992	**1,022**
Between 1 April 2017 and 31 March 2020	2,120	**2,120**
Beyond 2020	-	**-**
Total	3,112	**3,142**

18. BORROWINGS

	Non-current	
	31 March 2016	31 March 2015
	£000	£000
Loan 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 loan is as follows:

	Total 2015/16	**Less than one year**	**Between one and five years**	**More than five years**	**Total 2014/15**
	£000	**£000**	**£000**	**£000**	**£000**
Fixed interest rate					
3.50%	**1,328**	**-**	**-**	**1,328**	1,328
At 31 March 2016	**1,328**	**-**	**-**	**1,328**	1,328
At 31 March 2015				1,328	1,328

19. CAPITAL COMMITMENTS

Contracts entered into not provided for in the accounts

	Intangible 31 March 2016	**Tangible 31 March 2016**	Intangible 31 March 2015	Tangible 31 March 2015
	£000	**£000**	£000	£000
Contracted	**5,143**	**3,398**	1,929	1,893
Total	**5,143**	**3,398**	1,929	1,893

20. 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.

2015/16	Payments to Related Party £000	Receipts from Related Party £000	Amounts owed to Related Party £000	Amounts due from Related Party £000
Department of Health	**5,449**	**31,311**	**113,693**	**10,182**
HMRC	**1,004**	**2,384**	**1,622**	**1,043**
Department for Work and Pensions	**77**	**-**	**-**	**-**
BIS	**7,691**	**-**	**2,327**	**-**
Various NHS Trusts	**185**	**1,840**	**322**	**281**
Other government bodies	**1,126**	**198**	**765**	**19**
Local Authorities	**1,559**	**1**	**-**	**747**
Educational Bodies	**1,323**	**2,217**	**117**	**446**
As at 31 March 2016	**18,414**	**37,951**	**118,846**	**12,718**
2014/15				
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 Trusts	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

During 2015/16, none of the Board members, members of the key management staff or other related parties had undertaken any material transactions with the agency or with other organisations that the Board members, members of the key management staff may hold positions in. Details of compensation for key management staff are disclosed in the remuneration report.

21. 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 and Euros. Euro balances are converted at the exchange rate prevailing at the end of the year.

	2015/16	2014/15
	£000	£000
Government Banking Service*	**211,428**	192,534
Total	**211,428**	192,534

* Includes £102k Proceeds of Crime which is the Agency's share of confiscated monies resulting from successful prosecutions and £51k 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 of 3.5%, held throughout the year was £1.328M (2014/15:£1.328M). This resulted in interest payable of £0.047M (2014/15: £0.048M) out of total expenditure of £138.3M (2014/15: £122.4M).

Currency risk

The level of currency risk is determined by the level of income generated by activity undertaken on behalf of the EMA. For 2015/16 this was £10.347M (Euro 13.167M) (2014/15: £10.482M; Euro 14.488M). This represents 6.4% (2014/15: 6.5%) 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.

22. EVENTS AFTER THE REPORTING PERIOD

The result of the referendum held on 23 June was in favour of the UK leaving the European Union. This is a non-adjusting event. A reasonable estimate of the financial effect of this event cannot be made.

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.

The Accounting Officer authorised these financial statements for issue on 5 July 2016.

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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