Medicines & Healthcare products
Regulatory Agency

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Annual Report and Accounts 2016/17



CPRD NIBSC MHRA

Medicines and Healthcare Products Regulatory Agency Annual Report and Accounts 2016/17

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Chairman's Foreword

As I write this foreword, now in my third year as Chairman, I continue to be immensely proud of my association with MHRA. It is a remarkable organisation, whose three centres (the Clinical Practice Research Datalink, MHRA regulator, and the National Institute for Biological Standards and Control) make it unique. The Agency is a truly world class regulator and centre for scientific research and innovation. That is a view I have heard so often across the UK and internationally.

As Dr Ian Hudson, Chief Executive, mentions in his foreword, the outcome of the referendum of 23 June 2016 will continue to feature in the thinking of our staff and stakeholders. The Agency acted very quickly to set up a task force to consider options and opportunities, and to work with our partners across Government as well as with our stakeholders. That process – to develop the Agency's strategic response to Brexit – continues. Meanwhile, the day-to-day work of the Agency, which is so vital to the protection of public health, continues as before. I and my fellow Board members take a deep interest in the work to develop the Agency's strategic response to Brexit, to ensure we get the best outcome for the protection of UK's public health for the UK.

Throughout the year I, along with Dr Hudson, have continued to meet with a wide range of stakeholders. These include our Ministers and senior officials from across Government, where we have fed into discussions on a range of issues, for example, the vitally importantly Life Sciences Strategy. Additionally, we have met with industry trade associations, the Presidents of the Royal Medical Colleges, the Chief Medical Officers, Chief Pharmaceutical Officers and other officials in the Devolved Administrations. This is something we will continue to do in 2017/18.

In September, I was sorry to lose Peter Commins, who, as Chief Operating Officer and Director of Finance, was one of the Board's executive directors. Peter brought a wealth of expertise and wisdom to the Board's discussions and gave invaluable service to the Agency over the previous decade prior to his retirement. Thankfully, Peter Commins' retirement was made good by the appointment of his successor, Jon Fundrey, who has come to the Agency following a distinguished career in the public and private sector.

Looking ahead I and the members of the Board, are conscious that the Agency faces a range of challenges in 2017/18. These include the relocation of the Agency's London offices to Canary Wharf, the roll-out of the Operational Transformation programme and, of course, Brexit, all on top of the "routine" work of the Agency regulating medicines and devices as well as developing our other services including Clinical Practice Research Datalink (CPRD). We are however very fortunate and privileged in having an Agency staffed by highly motivated and talented individuals committed to protecting the public health.

In conclusion, the Agency continues to perform well in addressing the public health challenges it faces as well as meeting a range of unexpected events, including international public health emergencies. But we must continue to be alert and agile to anticipate and meet the demands of an ever changing world.

Sir Michael Rawlins GBE
Chairman

Chief Executive's perspective on performance of the organisation

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

While 2016/17 has been another very busy year, there has been one subject that has been ever present in the minds of staff and the wide spectrum of our stakeholders: Brexit. Following the outcome of the EU referendum of 23 June 2016, we immediately set up a task force to feed in to central Government to look at a range of options and opportunities for the Agency as the UK prepares to leave the EU. That work has been and continues to be informed by working closely with our partners across Government and our stakeholders. At the same time, the Agency's day-to-day work, which is so vital to the safeguarding of public health in the UK and beyond, continues. As I write the foreword, we are still considering two main models for the post-Brexit regulation of medicines - one in which we continue to operate in partnership of some form with the EMA regulatory network; another in which we would be a standalone regulatory Agency, outside European procedures. Negotiations have not yet begun, but we will be prepared for any outcome and will retain protection of public health and patient safety as our guiding principles whatever the future model agreed.

During the past year, we continued to work on a range of activities to support innovation, including our innovation office, the Early Access to Medicines Scheme (EAMS), the 'One stop Shop' for advice on regenerative medicine, our support for manufacturing, as well as our contribution to EU schemes, including PRIME (Priority Medicines) and Adaptive Pathways. In October, the independent Accelerated Access Review was published, which set out recommendations to speed up access to innovative healthcare and technologies and to improve efficiency and outcomes for NHS patients. We contributed significantly to the review, and will play a key part in taking the recommendations forward.

Internationally, the Agency continues to be very active. In October, the Agency was elected to chair the International Coalition of Medicines Regulatory Authorities (ICMRA). At the same time, the Agency is developing its portfolio of formal ties with other regulators. In October, we signed a Memorandum of Understanding (MoU) with the Swiss regulator, Swissmedic, in November, NIBSC signed a MoU with the National Institute of Food and Drug Safety of the Republic of Korea; in December, we signed a MoU with Macedonia; and in March 2017, NIBSC signed an agreement with China's National Institute for Food and Drug Control.

Throughout the year, the Agency has worked very closely with our European counterparts through a wide range of committees and working groups at the European Medicines Agency and within the Heads of Medicines Agencies' network, as well as at a bilateral level. Additionally, the Agency has led work on the EU's Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) Joint Action. This project is now drawing to a close, with many excellent deliverables, including a successful Adverse Drug Reaction Reporting (ADR) campaign in November 2016 in which 22 countries participated. Also, during the past year, the Agency launched a notification scheme and introduced Yellow Card safety reporting for electronic cigarette products. By the end of March 2017, we had received over 36,000 notifications under the scheme.

During 2016/17, NIBSC developed a large number of new and replacement biological standards, including the first Ebola antigen standard; and standards sales have continued to be strong across many areas. Control testing also continues to increase. Also, in January,

NIBSC published work on a new method to produce a stable replica of poliovirus that could enable safer production of vaccines.

The Clinical Practice Research Datalink (CPRD) has continued to make good progress, working with GP software providers to increase coverage of the population enabling more linkages of data, and developing the clinical trial offering.

We have also made a significant contribution to the fight against fake medicines and medical devices. In June, over £15.8 million of counterfeit and unlicensed medicines and medical devices were seized as part of the annual Operation Pangea. More recently, as part of our 'Fake Meds' campaign, the television series 'Coronation Street' featured storylines with our input highlighting the dangers of buying slimming pills over the internet.

There have been a range of high profile medicine and device issues that have been handled highly professionally, as well as progress in taking forward various aspects of regulation. Indeed, during 2016/17 work concluded on the implementation of three key EU regulations: the revised Clinical Trials Regulations, the Falsified Medicines Directive, and the Medical Devices and in-vitro diagnostics (IVD) Regulations.

We have also made considerable progress with other key areas of work in 2016/17, which will feature significantly in the next 12 months. These include the relocation of the Agency's London offices in Victoria to Canary Wharf in the late spring of 2018, and our ambitious operational transformation programme, which will deliver a major business transformation to ensure we retain our position as a world-leading regulator using state-of-the-art digital technology.

Early in the year, we concluded the refresh of our Corporate Plan. The process and the feedback that was received, both internally and from our Board and external stakeholders, was reassuring and very helpful. The Agency's achievements over the past year would not have been possible without the expertise and dedication of our staff. That high level of commitment has been a constant theme of the Agency since it was established in 2003. In particular, I was very pleased to see that our response rate to the annual Civil Service People Survey in October 2016, along with our engagement score has increased from last year, placing us in the top quartile across the Civil Service. This is something I am keen to build on, recognising that there is still more to do to address the concerns that were raised in the responses.

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

Throughout the year we have said farewell to a number of staff and members of the Agency's expert advisory committees, as well as welcomed new colleagues. On 1 April, Dr Christian Schneider, formerly of the Danish Health and Medicines Authority, succeeded Dr Stephen Inglis CBE as Director of NIBSC, on his retirement after a long and distinguished career. In September, Peter Commins also retired as Chief Operating Officer and Director of Finance after a decade of distinguished service to the Agency, to be succeeded by Jon Fundrey, who joined us from the Department for Work and Pensions.

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

Our Board

Left to right-standing: Jon Fundrey, Professor Sir Alex Markham, Dr Barbara Bannister, Dr Ian Hudson, Stephen Lightfoot, Professor Bruce Campbell, Professor David Webb, Deborah Oakley

Seated: Dame Valerie Beral, Professor Sir Michael Rawlins, Martin Hindle, Matthew Campbell-Hill

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 safe and 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 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.

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 authorisations 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.

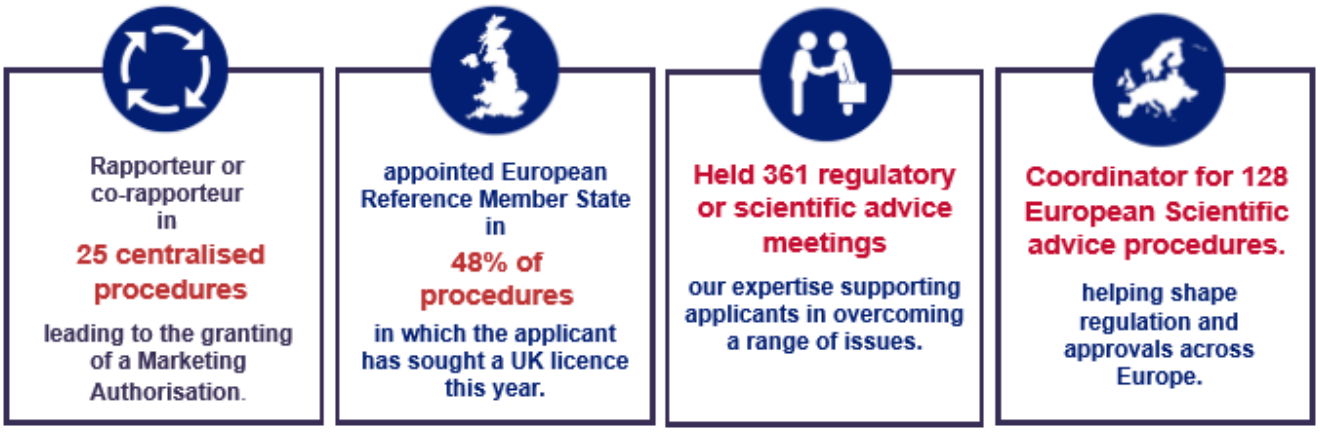
Review of the year

The Agency has a five year Corporate Plan (2013-2018), updated with a Corporate Plan Refresh in April 2016. 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, scope and partnerships

This year our objectives within this theme were to maximise the Agency's public health impact both within the UK public health and healthcare systems and through our active engagement with European and global regulatory networks. In particular, there is a renewed focus on establishing strong, effective and purposeful partnerships.

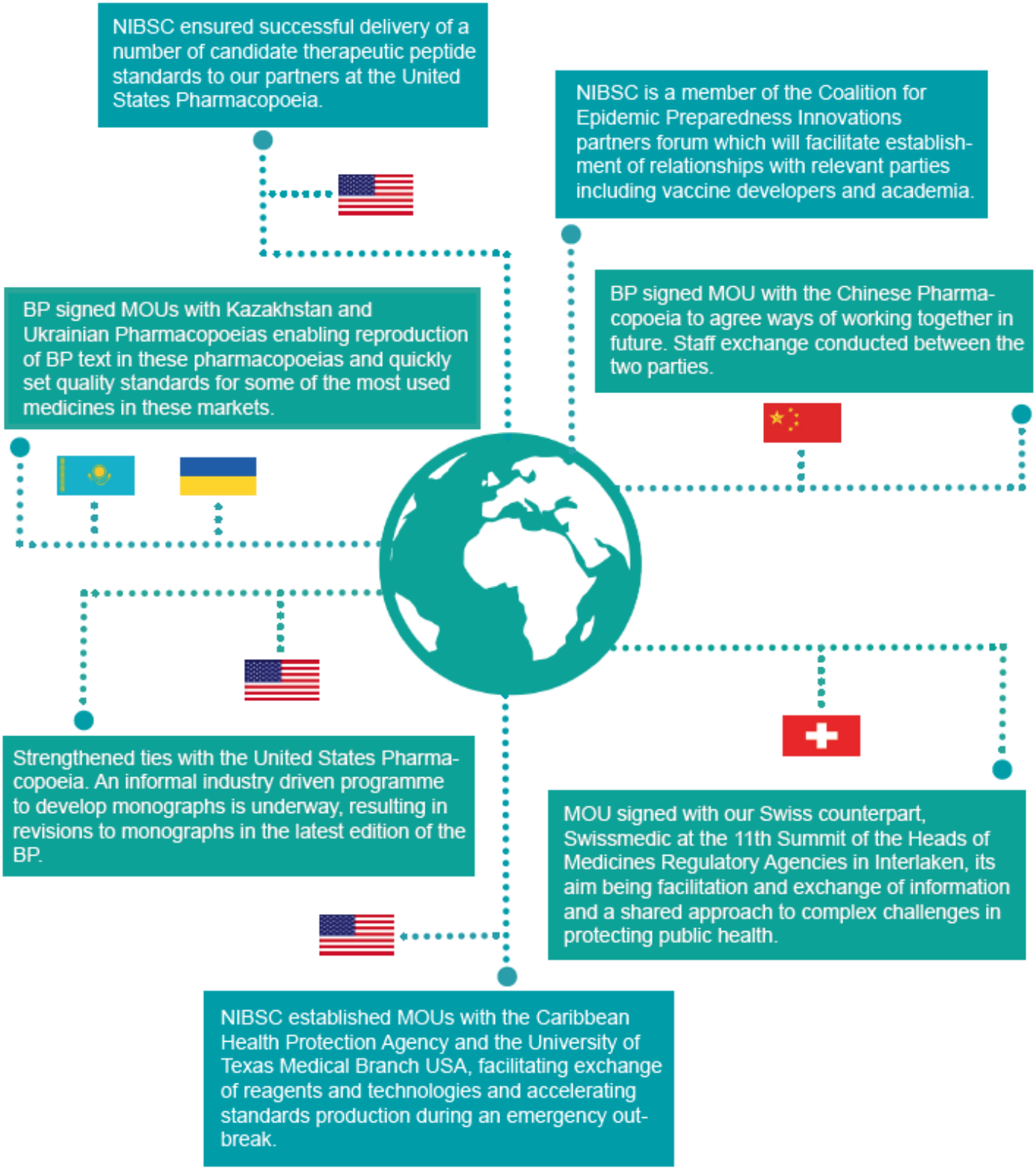
- The high regard in which our scientific expertise is held is reflected in the amount of European work which we have led this year relating to the licensing of medicines:



- 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:
  - The British Pharmacopoeia has been very active internationally. Memoranda of understanding (MOU) have been signed with other National Pharmacopoeia Authorities (NPAs).
  - The BP has continued its support to the global pharmaceutical industry by means of numerous presentations at events in India, China, US and Europe. This shows the BP to be progressive and innovative which is ensuring that the BP is the international partner of choice for industry and NPAs alike.
  - NIBSC is growing academic collaborations, with two students in the Engineering and Physical Sciences Research Council's Centre for Doctoral Training (at University College London and Imperial), and a studentship approved in the new Hubs on formulation for bioprocessing and for Stratified Medicines.
  - We maintained external Quinquennial Reviews of NIBSC's Advanced Therapies and Biotherapeutics Divisions, overseen by the independent Scientific Advisory Committee. Recommendations for the Biotherapeutics Division included the possible creation of an Industry Forum with wide representation from the biopharmaceutical sector, which would provide an opportunity to consider the generic issues and challenges faced by industry in the field of biotherapeutics. As part of NIBSC's investment programme, and following up recommendations from a previous QQR for the Bacteriology Division, research fellows were recruited in October 2016 to develop

research and standardisation programmes in the areas of microbiome research and prospective vaccines against group A and group B strep diseases.

This year:



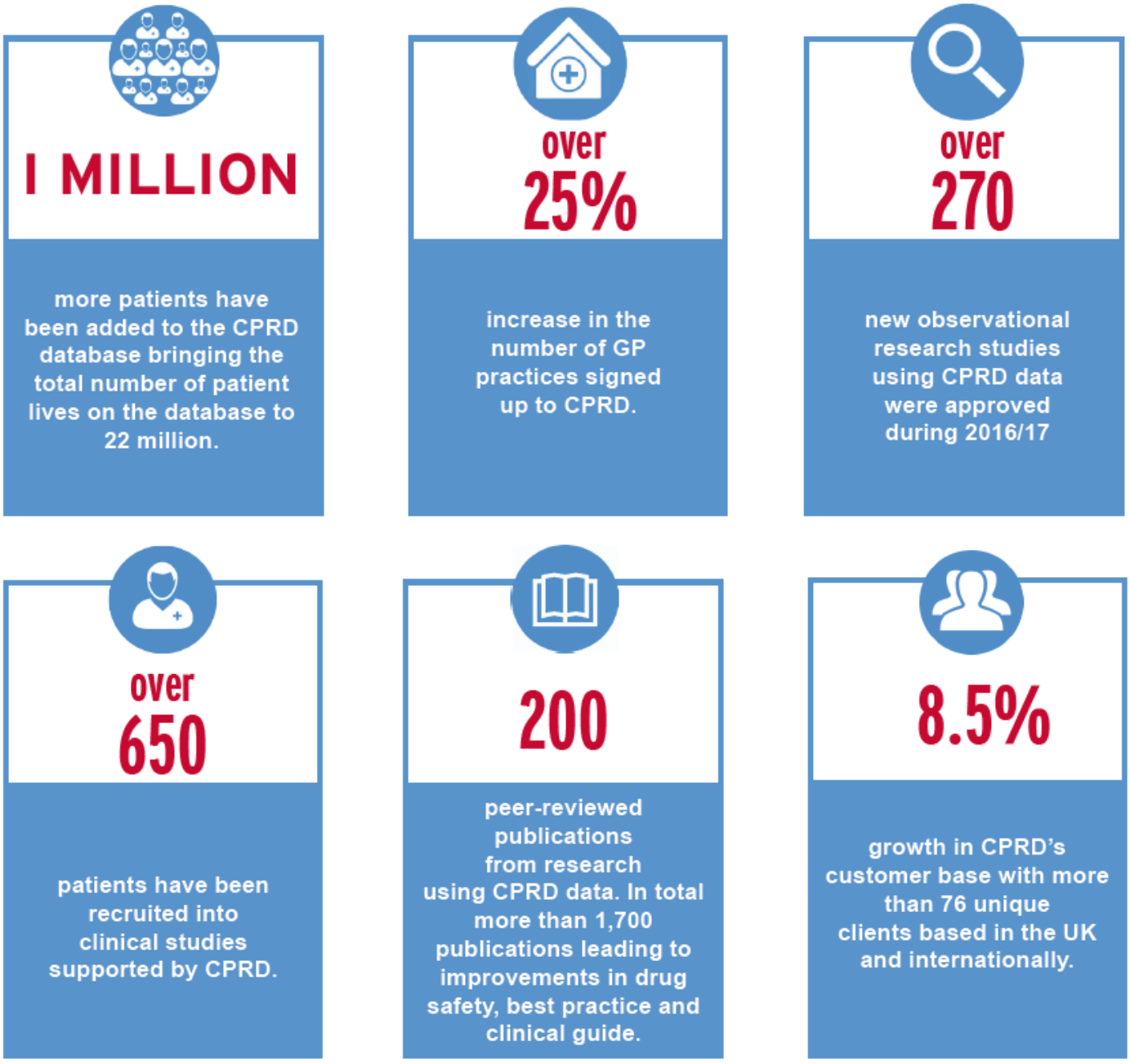
- The rapid spread of viruses can have devastating impacts and we want to be at the forefront of global responses to the threat they pose. This year we have:

  - Completed collaborative studies for EBOLA antibody, Nucleic Acid Testing (NAT) and antigen standards for WHO.
  - Launched an International collaborative study for a Zika virus antibody standard.
  - Developed platform technologies by which we can produce synthetic NAT standards for high containment viruses and thereby enable shipment of such standards around the globe without biosafety concerns and to enable their deployment in low and middle-income countries.
  - Received a grant from Innovate UK to investigate how serological reference reagents produced for Middle East Respiratory Syndrome, Ebola and Zika can be used in animal models of infection to assign protective antibody titres so that they can be related and applied to human vaccine studies.
  - Been investigating the picornavirus enterovirus 71 (EV71), which has recently been implicated in epidemics of severe neurological disease in children in the Asia-Pacific region. In collaboration with Leeds University a Medical Research Council (MRC) grant has been awarded to the Division of Virology at NIBSC for the development of stable immunogenic EV71 Virus-like particles (VLPs) with the aim of generating safe EV71 vaccines.
  - Continued our work to support the eradication of poliovirus: There has been further development of stably attenuated Polio virus for the safe production of inactivated vaccines. Related strains suitable for use as live attenuated vaccines are also in an advanced stage. The design and characterisation of these new vaccine strains have been developed in NIBSC's Virology Division and have received considerable global media coverage due to their significance at this critical stage of global Polio eradication.
    With grant funding support from the WHO Polio Research Committee and in collaboration with the University of Leeds, Oxford, Reading, IAH Pirbright and the John Innes Centre, advances in the area of Polio vaccine production have focused on the development of immunogenic Polio VLPs, Scientists at NIBSC have successfully generated genetically thermostabilised immunogenic Poliovirus empty capsids. This work was recently published in PloS Pathogens Jan; 13 (1):e1006117. A VLP patent has been filed.
    A Gates funded grant in collaboration with Imperial College London focused on the environmental surveillance for human enterovirus. There are also PATH-Gates grants to: Perform clinical assessment of new oral poliovirus type 2 vaccine in a transgenic mouse neurovirulence model, and to develop International standards and in vitro/vivo potency assays of Sabin inactivated poliovirus.

- In the UK Vi polysaccharide vaccines are regarded as travellers' vaccines but these vaccines are poorly protective in children and cannot be used to protect the young in typhoid endemic areas. A number of developing country manufacturers are developing Vi-conjugate vaccines to overcome this problem.
  - NIBSC has been working to develop polysaccharide and serum standards to support conjugate vaccine development and evaluation. The aim is that these standards will be endorsed by WHO's Expert Committee on Biological Standardisation (ECBS) later in 2017.
  - Work on the serology standard is in collaboration with the Oxford Vaccine Group and partly funded by the Bill & Melinda Gates Foundation.

- The quality of our research work was again demonstrated this year with NIBSC attracting research funding from a variety of sources including the WHO Polio Research Committee, MRC and PATH-Gates.

- Over the course of this year, CPRD has continued to grow its data and services with significant increases in the number of GP practices agreeing to contribute anonymised patient data for use in vital public health research studies:



Spotlight on…

An MHRA consultation on the strategy for pharmacopoeial public quality standards for biological medicines was commissioned to better understand the future needs for biological quality standards from our stakeholders across the globe. It was led by the British Pharmacopoeia, NIBSC and Licensing Division.

Biological medicines have worldwide importance. Their quality is assured by a regulatory framework which includes compliance to public quality standards. Documentary and physical standards work together to ensure that biological medicines are of acceptable quality for use by the patient. The consultation was published in January 2017 and it is expected that the outcomes of the consultation will be published in Q3/4 2017.

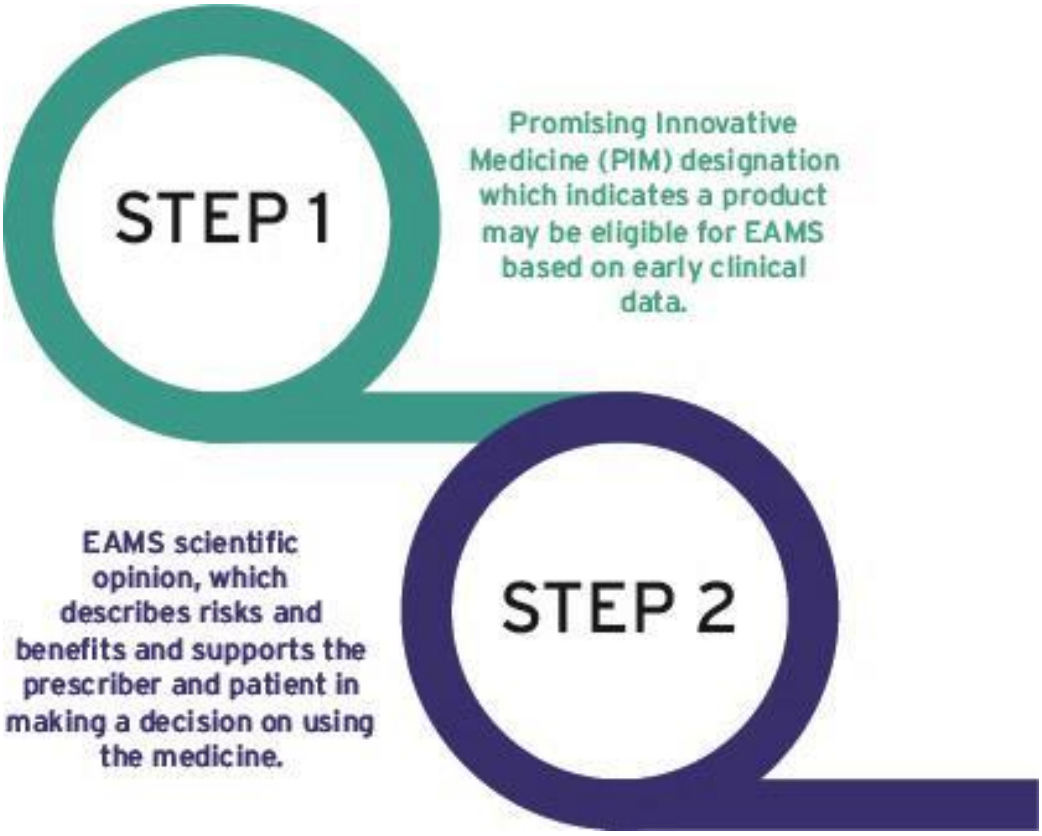
https://www.gov.uk/government/consultations/strategy-for-pharmacopoeial-public-quality-standards-for-biological-medicines

Enabling innovation

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.

- This year we were closely involved in the Accelerated Access Review which was published in October 2016. The Review set out 18 recommendations to speed up access to innovative healthcare and technologies and to improve efficiency and outcomes for NHS patients. The Agency contributed significantly to the Review, and will play a key part in taking the recommendations forward.

- 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:



This year the MHRA has issued 17 PIM designations and 4 EAMS scientific opinions. Of these Scientific Opinons granted this year Nivolumab and Venetoclax have gone on to receive a marketing authorisation.

- 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. Our work demonstrates our 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. This year:

- The Innovation Office received 129 enquiries, making a total of 416 queries since its introduction.
- Nine case studies highlighting the work of the Innovation Office have been published on the MHRA website. The most recent describes the regulatory advice given to Queen's University Belfast about their novel hydrogel-forming microarray patches. Since its publication in July 2016 this case study has been viewed 831 times, 741 being unique page views.
- We continued to house the Regulatory Advice Service for Regenerative Medicine (RASRM), 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, Human Fertilisation and Embryology Authority, Human Tissue Authority, and ourselves.
  We undertook a survey of customers and stakeholders that had used the RASRM in order to understand their experience of the service. Results indicate high satisfaction with the service, with a number of respondents providing contact details so that we could get in touch about developing endorsements of the service.

- The MHRA has maintained a heavy commitment to working with fellow authorities in Europe. As well as playing leading roles in several working groups, the Agency also holds the chair of the European Competent Authorities network, Competent Authorities for Medical Devices (CAMD) Executive Group and is lead authority for a 1.4 million Euro Joint Action targeted at improving market surveillance processes and practice across the system. We have played a key role in work on key EU negotiations and implementation relating to four important pieces of legislation.

- We continued to play an active role in the proposals for the revised **medical devices legislation.** We focused on addressing regulatory concerns, whilst considering the practicalities of implementation. We worked across the Competent Authorities Network, ensuring consistency of application of the existing legislation and enhancing collaboration between member states.
- We signed a Protocol with the General Pharmaceutical Council on the Distance Selling Logo. Additionally, a facility to accept payments using "Worldpay" on application for a logo registration was also made available. This initiative is part of the EU **Falsified Medicines Directive.**
- The implementation of the **Tobacco Products Directive** on 20 May 2016 provided MHRA with a new responsibility as the Competent Authority to establish a notification scheme for electronic cigarettes and refill containers. When the regulations were first announced, we were told that they would affect UK e-cigarette businesses, but the UK has received thousands more notifications than any other member state and the Agency is now regarded positively by key stakeholders across the industry as having been inclusive and pragmatic in our approach to implementation. We are currently processing information about products on the UK market and listing them on our website. Our focus is on safety in use and we have added a new entry point to our Yellow Card reporting portal to accept reports about safety and health effects of these products.
- We are implementing the **Clinical Trials Regulation** and working closely with ethics services colleagues across the UK to develop a stronger, more seamless system and provide a faster and more efficient process from the authorisation of a clinical trial application to commencement of the trial in research centres.

- The Agency continued leading the Innovative Medicines Initiative WEB-RADR Project, established to evaluate the implications of mobile technologies and social media for pharmacovigilance. The project has:

    - Delivered a mobile app reporting platform, which in addition to its roll out in the UK, Netherlands and Croatia is now being developed to support pharmacovigilance activities in Burkina Faso and Zambia in collaboration with the World Health Organisation.
    - Conducted Ground-breaking research into the value of social media data, highlighting a number of specific areas of value for further exploration.
    - Policy recommendations are being developed that will propose a framework for future use of mobile technologies and social media, based on the scientific research conducted.

- We have continued to develop CPRD's observational and interventional services:

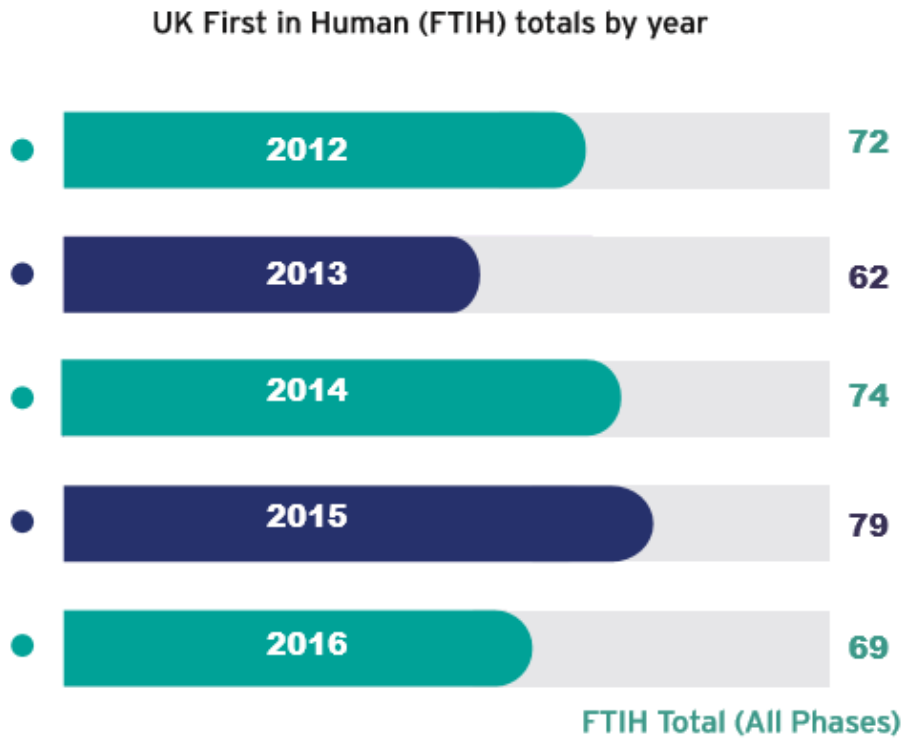
    - CPRD has developed a highly innovative clinical trials platform that supports real world post-marketing clinical trials in a primary care setting. The platform integrates patient recruitment; electronic health data collection via direct data capture from the patient record and patient-reported outcomes; and trial management functions.
    - Patient recruitment is underway for the first pragmatic post-authorisation clinical trial supported by CPRD services.
    - The number of GP practices signing up to CPRD has continued to rise each month over the course of the year.
    - CPRD has released 2 new routinely linked datasets since March 2016 making a total of 8 routinely linked datasets available for research, updated on a quarterly schedule.

- Through NIBSC we have continued to build new scientific capabilities in innovative areas of medicines development. This year we have:

    - Established a dedicated in-house Next Generation Sequencing (NGS) facility. NGS has enabled Antibody epitope mapping. Further developments will allow modelling evolutionary pathways of influenza viral escape from nanobodies specific to pandemic influenza. NGS is also used for high-throughput antibody repertoire sequencing and bioinformatics analysis.
    - Secured funding for a significant upgrade to the Nuclear Magnetic Resonance (NMR) facility.
    - Installed two new triple quadrupole mass spectrometers, supporting studies on physico-chemical value assignment to biological standards.
    - Through the UK Stem Cell Bank at NIBSC 'Regulator ready' stem cell lines are now available for clinical development.

Spotlight on…

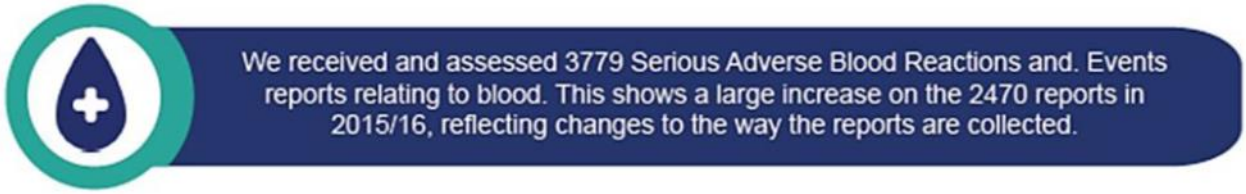
First-in-human clinical trials: MHRA Clinical Trial Unit (CTU) assessors have significantly contributed to the update of the guideline on strategies to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products, which address the increasing complexity of protocols for first-in-human clinical trials. This update reflects the evolution of practices in the last ten years and takes into account the lessons learnt from first-in-human clinical trial in France. This will be presented to the European Commission in May 2017 prior to adoption in June 2017.



Vigilance

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.

- We have continued coordinating the EU-wide pharmacovigilance project entitled Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE). The SCOPE Joint Action was set up to help medicines regulators strengthen national pharmacovigilance systems and build capacity for pharmacovigilance in Europe. SCOPE has gathered information and expertise on how regulators in Member States run their national pharmacovigilance systems. Using this information, a variety of tools have been developed including guidance documents, pharmacovigilance training materials such as e-learning and other tools to support best practice and develop internal business processes. The reports and training materials from the SCOPE Joint Action are available on the SCOPE website.



- 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:

  - In our role as a WHO Essential Regulatory laboratory, NIBSC hosted two International meetings with representatives from the International Federation of Pharmaceutical Manufacturers, developing country vaccine manufacturers and the WHO Global Influenza Surveillance and Response system laboratories to review current data regarding the circulation of seasonal influenza, pandemic threats and more broadly the resilience of global vaccine production.
  - We produced three new seasonal candidate vaccine viruses that are listed on the WHO website and available to vaccine manufacturers. We also constructed two new

pandemic viruses produced by reverse genetics which have passed safety testing and are also available.
  - We established the potency assay for Live Attenuated Influenza Vaccine with expected completion of a formal Technical transfer in 2017.
  - Work on current grants/contracts is continuing.

- Work of the Influenza virus team now includes the development of serological materials to act as references for Respiratory Syncytial virus (RSV) for virus neutralisation assays to evaluate immune responses in human vaccine trials. This new area of work is in response to the rapid development of Next Generation RSV vaccines.

- 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:

  - NIBSC published a total of 74 papers.
  - Studies using CPRD data were included in international guidelines including: European guidelines from the European League Against Rheumatism for the management of cardiovascular risk in patients with rheumatoid arthritis and. US guidelines from the Agency for Healthcare Research and Quality on medication for diabetes.
  - CPRD conducted a systematic review of National Institute for Health and Care Excellence guidance documents to identify the use of CPRD real-world evidence. It showed that 25 guidance documents referenced a total of 43 CPRD studies, all published since 2007.
  - Research using CPRD data was presented by researchers from 10 different countries across the UK, Europe and North America at the annual International Conference on Pharmacoepidemiology.
  - The CPRD bibliography has been updated and a total of 1,700 peer-reviewed articles have been published using CPRD data since the inception of the database.

- 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:

  - CPRD data was used in a multinational pharmacovigilance study on the risk of heart failure with incretin-based drugs for diabetes, published in the New England Journal of Medicine. The study evaluated data from 1.5 million patients in total and found no evidence of a link between incretin-based drugs and heart failure, even among individuals with a history of heart failure.
  - The Royal College of GPs and CPRD are collaborating on a joint project to use information within the data submitted to CPRD by GP practices to improve the quality of their patient care. The reports fed back to practices focus on prescribing at an individual patient level. This information allows practices to review patient treatment plans and benchmark themselves against others practices contributing to CPRD.
  - CPRD data was used to evaluate the benefit of a national vaccination programme for infant oral rotavirus, introduced in 2013. The research showed a 15% reduction in the rate of acute gastroenteritis in primary care and a 41% reduction during months of historically high rotavirus circulation following introduction of the vaccine. Across primary care, emergency department visits and hospitalisation, researchers estimate an annual NHS saving of £12.5 million since the introduction.

Spotlight on…..

The BBC produced a documentary, ‘The Drug Trial: Emergency At The Hospital’, which was screened in February 2017 on BBC 2.

Gerald Heddell, Adrian Bristow and David Webb took part in the documentary which included the role NIBSC played in investigating what went wrong during the TGN1412 clinical trial at Northwick Park Hospital ten years ago. MHRA’s side of the story was also featured.

The failure of the preclinical testing of TGN1412 highlighted a pressing need for better in vitro methods to predict the clinical safety of such potent biological medicines.
We have moved on a long way from the original investigation but the work it stimulated is still going on. To allow a better harmonisation of existing immunotoxicology assays in preclinical studies, NIBSC scientists have developed a panel of lyophilized recombinant antibodies to be used as controls in cytokine release assays including a TGN1412 analogue produced in-house. These reference reagents are currently evaluated in an international collaborative study and will be available to the wider scientific community by the end of 2017, allowing comparison of one cytokine release platform to another, and the comparison of cytokine release potential of new biotherapeutics with historical data.

Since it’s screening, the documentary has won an award for Feature of the Year [Broadcast] 2017.

http://www.bbc.co.uk/mediacentre/proginfo/2017/08/the-drug-trial

Secure global supply chains

Activities identified in the Business Plan under this theme included strengthening intelligence sharing and regulatory collaborations with our European and international partners, harmonising regulatory standards, whilst continuing to promote the safe purchasing of medicines and devices.

- This year we again participated in Operation Pangea IX, a month-long global crackdown on the illegal trade in medicines and medical devices from unregulated sources.The sale of unlicensed medicines and non-compliant medical devices from unregulated sources poses significant risks to patients who purchase such products. MHRA Enforcement officers with assistance from the UK Border Force and local police conducted a range of operational activities. As part of this Operation:

- MHRA joined forces with the British Dental Industry Association to warn of the risks of buying non-compliant and counterfeit dental devices and to promote awareness of the dangers that they present to patients and dentists. This has resulted in the seizure of more than 1,900 counterfeit and non-compliant dental devices.

- Criminal investigations have led to a number of successful prosecutions. An organised criminal group pleaded guilty at Leeds Crown Court and were sentenced for several offences including conspiracy to import medicinal products without a licence, handling stolen goods, money laundering and conspiracy to commit Trade Mark Act offences.

- Meetings have been held with the Home Office to promote exchange of information over authorisations relating to control drugs and correlation with information MHRA hold on new and existing wholesale dealers.

- We have worked on worldwide initiatives to help protect the supply chain:

  - NIBSC made considerable progress on highly significant standardization projects, notably Rituximab, which is completed, and Infliximab, which is well on the way. The rituximab study clearly demonstrated both the possibility and the added value of establishing bioassay standards for biosimilar monoclonal antibodies.
  - Launched the Agency's first sustained major public health campaign to discourage people from buying fake medical products. The initial target was slimming products, with a target audience of young women aged between 18 and 30. Then the focus moved to other products such as condoms, sexually transmitted infection self-test kits, erectile dysfunction medication, dental equipment and other medical products

prioritised based on their risk to public health and the likelihood that they would be fake. Partnerships for the campaign include Public Health England; Royal Pharmaceutical Society; Get Safe Online and Slimming World to name a few. This campaign is planned to run for the next three years.

- WHO meeting on Substandard, Spurious, Falsely labelled, Falsified and Counterfeit (SSFFC) Medical Products: the UK attend as Vice Chair of the Euro Region and lead one of the key priority activities in relation to global risk communication. To drive this activity forward a risk communication working group has been formed with representatives from across all WHO regions.

- Our Inspectorate continues to play an important role worldwide, working with other regulatory bodies and industry organisations. The provision of education and guidance to stakeholders on key inspection issues continues to form a significant part of the Inspectorate's role. This year we:

Conducted over 1850 inspections during the year with over 90 of these being performed at overseas companies

Maintained the Inspectorate blog at a high level. It has over 5000 subscribers, the most popular blogs having over 10,000 hits.

Organised major symposia on all aspects of inspections which were attended by around 2000 delegates

- Continued to develop Data Integrity Definitions and Guidance for Industry working alongside other global regulators. This topic formed a key part of a number of presentations delivered at various professional conferences.
- Contributed to several international training events for regulators organised by the European Medicines Agency, WHO and other international organisations.
- Hosted the 2016 Pharmaceutical Inspection Co-operation Scheme (PIC/S) annual seminar at the Museum of Science and Industry in Manchester, the European City of Science 2016. The seminar was attended by more than 180 participants from 53 countries.
- Continued to lead and participate in international groups responsible for the development and implementation of international standards, inspection strategies and harmonised working practices. This has included:
  Holding the PIC/S chairman role in 2016/17, chairing various PIC/S working groups and expert circles and co-chairing the newly formed Data Integrity working group.

Chairing the Organisation for Economic Co-operation and Development Good Laboratory Practice Working Group and actively participating in a number of European Medicines Agency and European Commission subgroups.

- Were elected to chair the International Coalition of Medicines Regulatory Authorities for the next two years. This demonstrates the trust and confidence that the global community has in MHRA, as well as a welcome sign that our fellow regulators are keen to see a continued active contribution from the UK to both European and international regulatory networks.

- 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.

- An issue was identified in May 2016 concerning the TPP SystmOne GP software, which approximately 40% of GPs in England use. This software incorporates an algorithm which calculates patients cardiovascular risk scores, which the GP can use to make treatment choices for the patient.
  Systems such as these are considered as Class 1 medical devices however this was not registered as such. Calculation errors were identified and a cross government incident team was established, led by the MHRA, to tackle the issue. A huge amount of work has gone into managing this incident from teams across the Agency. The algorithm has since been corrected and re-launched.

- New guidance from MHRA was published in August 2016 and revised in November 2016 to try and ensure that health apps which qualify as medical devices are being identified and comply with safety regulation.
  In the UK and throughout Europe, standalone software and apps that meet the definition of a medical device are required to be CE marked in line with the EU medical device directives in order to ensure they are regulated and acceptably safe to use and also perform in the way the manufacturer/developer intends them to.
  The guidance is presented as a step-by-step interactive PDF to help software and app developers identify if their product is a medical device. It also helps developers navigate the regulatory system so they are aware what procedures they need to have in place with regard to CE marking and post-market surveillance. We also included information on classification, suggestions on how to address the main aspects of the CE marking process and responsibilities for reporting and correcting when things go wrong.

- Our product testing capability has been called upon in several instances to deal with potential supply issues. We have also this year:

  - Established 7 new or replacement WHO International Standards and other important reference materials bringing our total number of catalogue items to 985. These include new International Standards for Ebola antigen, Batroxobin and detection of cancer mutation JAK2 V617F and replacement International Standards for Factor XI plasma, Ancrod, Prolactin (human) and Hepatitis B Virus DNA.
  - As part of the European Official Control Authority Batch Release scheme (OCABR) NIBSC has seen a 35% increase in OCABR testing of blood products in 2016 compared to 2015 – these figures indicate Brexit has had no effect on the volume of testing so far. Over 1600 certificates were issued for finished vaccine and blood products, and more than 2300 plasma pools.
  - Supported one of the German Official Medicines Control Laboratories by testing some samples taken from the German market for the presence of pyrrolizidine alkaloids (PAs) during 2016. Our data was provided to the sampling laboratory to

compare with their own in-house data to allow them to assess the levels of PAs present in products sold in Germany.

- Tested samples of commercially available cannabidiol oil (CBD) products on behalf of the MHRA Borderline Section. The work was designed to provide information on the composition of CBD products including the level of tetrahydrocannabinol in samples on the UK market. Work is ongoing, and so far over 40 samples of oils, balms, pastes and capsules have been sent for testing.

Spotlight on…..

In the build up to the 2016 Olympics, the Medicines Borderline Section carried out a review of the sale of unlicensed medicines marketed as sports supplements.

The Section reviewed 33 websites and found 16 companies selling 69 unlicensed medicines and took action to remove these products from the market. Although this figure is still a cause for concern, it compared favourably to the results of a similar review carried out prior to the 2012 London Olympics.

This and other work highlighted the continued availability of unlicensed medicinal products containing Dimethylamylamine. A 'Week of Action' was held in January 2017, working with stakeholders to highlight the safety concerns that are associated with the consumption of this substance.

Organisational excellence

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.

- We will be moving to the new government hub in Canary Wharf, probably in the first half of 2018. An Accommodation Needs and Vision Project group has produced a report setting out the agreed vision for our future accommodation and requirements for the move to Canary Wharf. As part of the project, the Corporate Executive Team agreed the vision for all the Agency's accommodation:

  - Our work environments will be inspiring and productive, supported by reliable and effective technology, enabling us to choose flexible work-styles.
  - This will enable us to deliver the Agency's mission, encourage a more inclusive, collaborative and professional culture, and provide the best service to our stakeholders and customers.

- This year we rolled out the first two phases of Oracle Fusion, our new Agency wide e-business solution, encompassing HR, Finance and Procurement. "Fusion" provides us with:

- We have made changes to the way we work in these areas to implement the modern, best practice processes enabled by the solution to unlock numerous benefits and efficiencies. The remaining phase will add completely new functionality in the areas of Learning, Talent Management, Performance Management, Succession Planning and Career Development.
  We also successfully completed a Digital Workplace pilot of new laptop computers and Office 365, and have commenced deployment across the Agency. This introduces cloud-based shared storage and modern collaborative tools for Smart Working, which will improve information security and access to data.

- 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 45 events and exhibitions.

- The Inspectorate's Divisional Business Unit provided critical support to other Divisional functions throughout the year:

  - Over 5400 export certificates (including 1500 urgent requests within 48 hours), and more than 1650 licences (a combination of Wholesale, Manufacturing and Active Pharmaceutical Ingredients) were issued.
  - A paperless system was introduced within the Defective Medicines Report Centre (DMRC) to improve efficiency.
  - The Unit co-ordinated and managed over 150 FOIs for the Division.

- Following competitive tendering a new contract was awarded to The Stationery Office for the publication of the British Pharmacopoeia. This includes significant commitments for improved service delivery and product innovation.

- Sales of British Pharmacopoeia Chemical Reference Standards have for this financial year exceeded all previous records, demonstrating the increasing global use and influence of the BP and associated reference standards throughout the world.

- The 9th Edition of the European Pharmacopoeia (EP) was successfully integrated into the British Pharmacopoeia 2017 ahead of schedule and the legal implementation date of 1 Jan 2017. The integration of EP content provides our users with a comprehensive collection of quality standards for medicines including both national and supranational European standards.

- The BP/NIBSC herbal team commissioned a new phytochemistry laboratory during 2016 which has enabled the team to perform both DNA and physico-chemical based identification techniques for herbal medicines. This will support further monographs for inclusion in subsequent editions of the BP.

- Projects have begun to scope and implement improvements via new IT investment to provide sustainable and more efficient data management systems for import notifications, DMRC and Borderline work.

- MHRA contributed to the Government's response to Professor David Walker's report on the Regulation of Herbal Medicines and Practitioners (March 2015) which was published on 28 February 2017 and will take forward work to respond to the Walker report's recommendations.

- The Patient Safety and vigilance Strategy is a joint Vigilance and Risk Management of Medicines and Devices-led high priority Agency project.

It was set up to pursue a common excellence model for patient safety and vigilance for both medicines and devices, with the ultimate goal of strengthening patient safety. A high-level strategy has been developed and we are now starting to implement the recommendations. There are three project teams looking at:

- Incident reporting and signal detection.
- Risk-benefit assessment.
- Improving delivery, targeting and audit of safety messages and risk communication.

The UK is leading a cross EU Task Force to develop a devices specific periodic safety update report.
A feasibility study on use of CPRD data for devices is near completion, and we are working to deliver a joint medicines and devices safety update bulletin.

- 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 results showed:
  - An increase in the response rate to 75%, this is 4 points up on the previous year.
  - 62% of staff were positive the Agency keeps them informed about matters that affect them.
  - 88% of staff have a clear understanding of how their role contributes to the Agency's objectives and this is further supported by a strong team mentality, with 81% giving positive feedback on this aspect of their work.
  - Staff think there is opportunity to develop their career at the Agency (an increase from 33% to 40% from 2014-16).
  - Learning and development activities help staff to develop their careers (an increase from 38% to 44% 2014-2016).
  - There is a continuing theme of dissatisfaction with pay and benefits (31%) and the impact of central constraints. There were also improved but disappointing scores for learning and development (51%) which confirm the need for its ongoing priority assisted by the training needs analysis undertaken in 2016 with plans for implementation.

- These improved results show the value of our employee engagement programme, which this year featured:

  - an increase in managers training opportunities including apprenticeship qualifications.
  - a calendar of health and wellbeing activities.
  - a refresh of HR Policies involving managers and staff representatives.
  - Two successful managers' conferences.
  - Two series of all-staff meetings.

- As part of the HR Annual Plan, we conducted a training needs analysis to assess Agency-wide needs:

  - Last year staff undertook more than 6100 days of training equivalent to 4.7 days per person, per year.
  - We run a three stage induction programme to ensure our staff settle in as effectively as possible as well as a managers induction – last year 250 staff attended.
  - We have a network of 7 training coordinators and 8 internal coaches to support our staff and learning in the Divisions and Centres.
  - We have agreed that all staff should have a career conversation in 2017 to help assess their aspirations against Agency needs. The majority of senior staff discussed their career aspirations using a structured tool to enable our internal

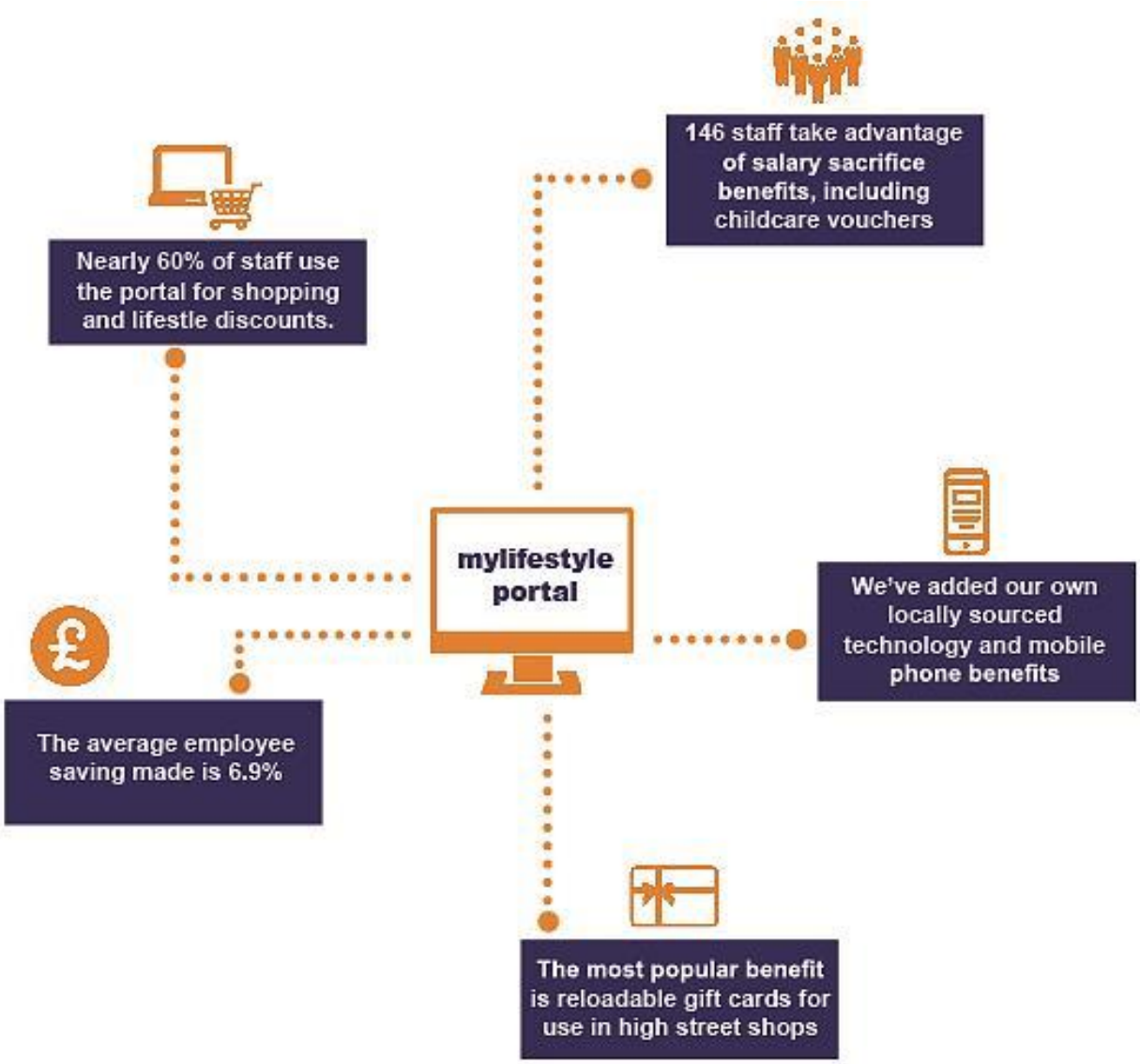
Talent Board to plan Agency-wide development initiatives and succession plans for the future.

- 100 staff recently took part in the launch of our career pathways framework. This is designed to help staff to understand the requirements of our jobs Agency-wide.

- The Agency has an ongoing commitment to promoting and achieving equality and diversity in the workplace. We aim to attract and retain people who are the best in their field, with the right skills and competencies and from a diverse range of backgrounds. We recognise that diversity adds value. We pledge our commitment to embracing equality and diversity and tackling discrimination in all aspects of our work. We have implemented Equality and Diversity objectives and identified areas in which these objectives are to be measured.

- The Health and Wellbeing policy and programme has the aim of improving the health and wellbeing of its employees and thereby increasing employee engagement and productivity. In addition, the aim was to reduce the average number of sickness absence days per employee and to increase overall staff engagement as measured in the annual employee survey. The programme was developed to address the top three reasons recorded for absence - musculoskeletal, stress and minor illnesses/infections - but also to promote general good health.
  An overall positive response to the programme has been reflected in the reduction in the average number of sickness absence days per employee. Looking ahead over the next 12 months the aim will be to embed and develop the programme further but with a greater emphasis on mental health wellness. The programme will include sessions on mindfulness and personal resilience. On-going monitoring of the effectiveness of the programme in addressing the key issue of staff engagement and sickness absence reduction will continue during 2017/18.

- We implemented a new employee benefits portal called ‘mylifestyle’ across the Agency offering discounts, salary sacrifice benefits and information on managing money smartly, designed to help staff find ways to save money and get the most out of working life.



Contributing to the Secretary of State's health inequalities agenda

During 2016/17, the Agency continued to support the Secretary of State in meeting his duty to reduce health inequalities across the health and care system.

Following clinical trials, the licensing for use of a medicine takes account of factors such as sex, age and race, particularly if any of these populations is a specific target for benefits or poses specific risks. Examples include the effects of a product on children, on the elderly, on those who are pregnant or on those from different ethnicities (such information will be included within the Summary of Product Characteristics). MHRA has continued to work with colleagues in the regulatory network to facilitate the development of medicines for the elderly through improved guidance on clinical and pharmaceutical development. We have continued our work on increasing the number of age appropriate formulations for children available on the UK market in the context of European Paediatric Regulation and have contributed to the planned 10-year review of the legislation to identify lessons learned and areas for improvement. A particular focus in 2016-17 has been strengthening guidance on paediatric pharmacovigilance.

We also contributed to regulatory discussions on dementia and antimicrobial resistance (AMR); and worked with international partners to increase the reach and public health impact of our efforts.

In addition, the Agency continued to work to ensure that the Yellow Card Scheme is accessible. It now includes reporting for medical device adverse incidents, suspected product quality issues, and suspected counterfeit products. It is open for anyone to report an adverse incident, and continues to have basic information about the scheme translated into 12 languages, which are available at the reporting website. We have also added a new entry point to our Yellow Card reporting portal to accept reports about safety and health effects of electronic cigarettes and refill containers. In all cases the intention is to maximise safety reporting from the different population groups.
MHRA has worked with Public Health England to establish a reporting system for harms with illicit drugs, particularly novel psychoactive substances. The RIDR (Reporting Illicit Drug Reactions) system went live in March 2017.
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 publishing 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 CPRD to support public health research internationally, broadening the range of deprivation and socioeconomic indicators linked to primary care data for research.

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
Relocation of BPR to Canary Wharf could result in: - loss of key staff if they perceive they are moving to a less accessible location with inadequate space and facilities which would cause disruption to the Agency's operations.	The Agency's Relocation Team will develop an internal communications programme to keep staff informed and will develop appropriate measures to mitigate the impact on staff.
Threat to the Agency stemming from Brexit. The impact on the ability of the Agency to undertake its Public Health protection role.	The cross-Agency task force has undertaken a range of analyses of different potential scenarios and implications for the Agency.
Failure to fulfil all statutory and other public health roles due to reduced funding.	The monthly Finance and Procurement report for the CET and Board has been redesigned to provide a regular update on the strategic forward financial look including the impact of operational transformation and the associated investments in IT, activity levels and the possibility of a reduction in activity because of Brexit.
Procurement risks relating to award of contracts and failure to comply with legislation.	The Agency's Finance Sub-Committee will monitor project and contract management, and share best practice across the Agency.
The referendum decision to leave the European Union will have an impact on the 5 year Portfolio plan that has been developed over the past 2 years and will create risk to delivery.	Criteria have been developed to assess the immediate impact of Brexit and analysis undertaken across the Portfolio.
The Agency is under increasing threat of data loss and or corruption from Cyber-attacks and new ways of working.	A programme has been established to respond to the issues, and a greater level of resource has been established within Information Management Division (IMD) with an insourcing of control into IMD.

1.2 Performance Analysis

Performance against targets 2016/17

No.	Area	Target description	2016/17 total	Rating (RAG)	Comments
PM1	**Medicines licensing – validation of applications**	a) For Type IB15 and Type II16 variations, 97% of scientific validation process completed within 14 days of case creation	99.5%	**Met**	Met - 99.5% validated within 14 days of case creation
		b) For new Marketing Authorisation applications, 97% of validation reports produced within 14 days of case creation.	100%	**Met**	Met - 100% 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.	99.8%	**Met**	Met - 99.8% 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	99.3%	**Met**	Met - 99.3% of applications 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	**95.8%**	**Nearly met**	Nearly met - assessed 95.8% of decentralised procedures for reference member states in 70 days
			99.8%	**Met**	Met - assessed 99.8% of decentralised procedures for concerned member states in 100 days
			98.0%	**Met**	Met - assessed 98% of mutual recognition procedures in 50 days
			94.1%	**Nearly met**	Nearly met - assessed 94.1% of centralised (co) rapporteurship applications in 80 days; only 1 out of the 17 applications received missed

					the target
		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.	97.2%	**Met**	Met - assessed 97.2% of Type II major variation applications in 90 days
			97.0%	**Met**	Met - assessed 97% of Type IB minor variations 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)	99.1%	**Met**	Met - assessed 99.1% of all authorisations within 30 days
			12.4	**Met**	Met - average application assessment time of 12.4 days for Phase 1 trials
		b) Timescales for clinical investigation notifications for medical devices: maximum of 60 days with an overall average of 54 days or less	100%	**Met**	Met - 100% handled within 60 days
			50	**Met**	Met - total of 50 average days
PM4	**Capturing and analysing adverse event reports – making reports available, issuing alerts and acting on signals**	a) Maximum timescales between receipt of reports and making them available for evaluation and analysis: For fatal and serious device adverse incidents: 95% within 2 working days and 100% (fatal and serious only) within 3 working days	99.4%	**Met**	Met - 99.4% made available within 2 working days
			100%	**Met**	Met - 100% available within 3 working days
		b) Medical Device Alerts will be issued: 95% within 10 days, 100% within 15 days	95.0%	**Met**	Met - 95% published within 10 days
			100%	**Met**	Met - 100% published within 15 days
		c) For fatal UK adverse drug reactions: 90% within 24 hours, 100% within 72 hours	100%	**Met**	Met - 100% within 24 hours
			100%	**Met**	Met - 100% within 72 hours
		d) For serious UK adverse drug reactions:	100%	**Met**	Met - 100% within 72 hours

		95% within 72 hours, 100% within 5 days	100%	**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	90.0%	**Met**	Met - 90% 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	99.3%	**Met**	Met - 99.3% PARs completed within 60 days
PM6	**Standards and control**	a) Biologics standards supply - 93% of all materials supplied within 6 working days	**91.0%**	**Nearly met**	Nearly met - 91% 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	100%	**Met**	Met - 100% completed within 10 days for Plasma Pools
			99.6%	**Met**	Met - 99.6% completed within 10 days for Parenterals
			99.7%	**Met**	Met - 99.7% completed within 15 days for Haemostasis
			100%	**Met**	Met - 100% completed within 60 days for vaccines
PM7	**CPRD activity**	a) Support 260 new observational research studies in 2016/17	272	**Met**	Met (exceeded) - 272 new observational research studies supported in 2016/17
		b) Drive the increase of CPRD GP coverage from 600 to 1000 GP practices	**790**	**Target not met**	Target not met - CPRD was unable to onboard The Phoenix Partnership (TPP) practices due to internal TPP issues.
PM8	**Answering Freedom of Information requests, letters and**	a) Respond to all requests under the Freedom of Information Act within 20 working days (or within permitted	99.0%	**Nearly met**	Nearly met - 99% of FOIA requests replied to within requisite timescales

	Parliamentary Questions	extension).			
		b) Return responses to Parliamentary Questions (PQs) to the Department of Health by noon on the date specified in at least 90% of cases with less than 5% returned to MHRA by the Department for rewriting.	98.6%	**Met**	Met - 98.6% of PQs answered on time
			1.4%	**Met**	Met - only 1.4% of PQs returned for rewriting
		c) Return Ministerial correspondence (POs) drafts to the Department of Health within 4 working days of receipt in at least 90% of cases with less than 5% returned to MHRA by the Department for rewriting.	96.5%	**Met**	Met - 96.5% of POs answered on time
			0.0%	**Met**	Met - 0% of POs returned 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	100%	**Met**	Met - 100% of opinions 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	100%	**Met**	Met - 100% of opinions 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.	100%	**Met**	Met - 100% of responses provided within the required timeframe to ensure timely response back to the Notified Body.

RAG status	**Met**	**Nearly met**	**Target not met**

Performance measures 2017/18

No.	Deliverables	2017-18 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 (MRP, DCP & CP) procedures: 97% assessed within the designated time 95% of CP assessed within the designated time
		c) The assessment of Type IB minor and Type II major variation applications in National and European (MRP, CP) 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 40 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 4 working days
		b) Medical Device Alerts will be issued: 95% within 10 days, 100% within 15 days
		c) For fatal UK adverse drug reactions: 90% within 24 hours, 100% within 72 hours
		d) For serious UK adverse drug reactions: 95% within 72 hours, 100% within 5 days
		e) Ensure all UK potential signals (relating to medicines) from whatever source are acted on promptly: 85% initially evaluated within 5 working days
PM5	**Publication of UK assessment reports for new Marketing Authorisations**	Publish 98% of UK assessment reports within 60 net calendar days of grant of new authorisations

[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.

PM6	**Standards and control**	a) Biologics standards supply – a maximum average response time of 6.0 working days for all standards despatches
		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 • 95% of all requested official control authority batch release (OCABR) and non-EU testing completed within agreed timelines: 60 days for vaccines
PM7	**CPRD activity**	a) 90% of research applications to receive initial feedback from ISAC review within 21 working days
		b) Expand coverage to 1200 contributing GP practices across the UK
		c) Increase the number of CPRD licence holders to 52
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) Aim to return all responses to Parliamentary Questions (PQs) to the DH by noon on the date specified[1] with less than 5% returned to the Agency by the Department for rewriting.
		c) Return Ministerial correspondence (POs) drafts to the DH within 4 working days of receipt in at least 90% of cases with less than 5% returned to the Agency 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.

[1] RAG status: <90% = red; 90-99% = amber; 100% = green

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 2016/17 was £128.7m.

The Agency is required by a HM Treasury Minute (reproduced in section 3 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.

Despite fee reductions on 1st April 2016, the Agency's trading income increased by £4.4m driven primarily by increased income from licensing activities (£3.2m) and from fees associated with notification activities following implementation of the EU Tobacco Products Directive (£0.9m). Staff costs increased by £4.7m (7%) due to the abolition of the National Insurance rebate (2%), pay award (1%) and increased headcount (4%). Operating costs increased by £10.9m (16%) mainly due to the Agency's Operational Transformation programme. As a result, the operating surplus before interest and dividends for 2016/17 was £13.8m, compared to £24.8m in 2015/16. After finance costs and dividends of £2.2m, a net surplus of £11.9m arose in 2016/17 and has been transferred to reserves.

2016/17 has seen cash inflows from operating activities for the Agency of £22.6m, compared to £30.5m in 2015/16. The cash inflow arose from trading activities and efficient working capital management.

Sustainability report

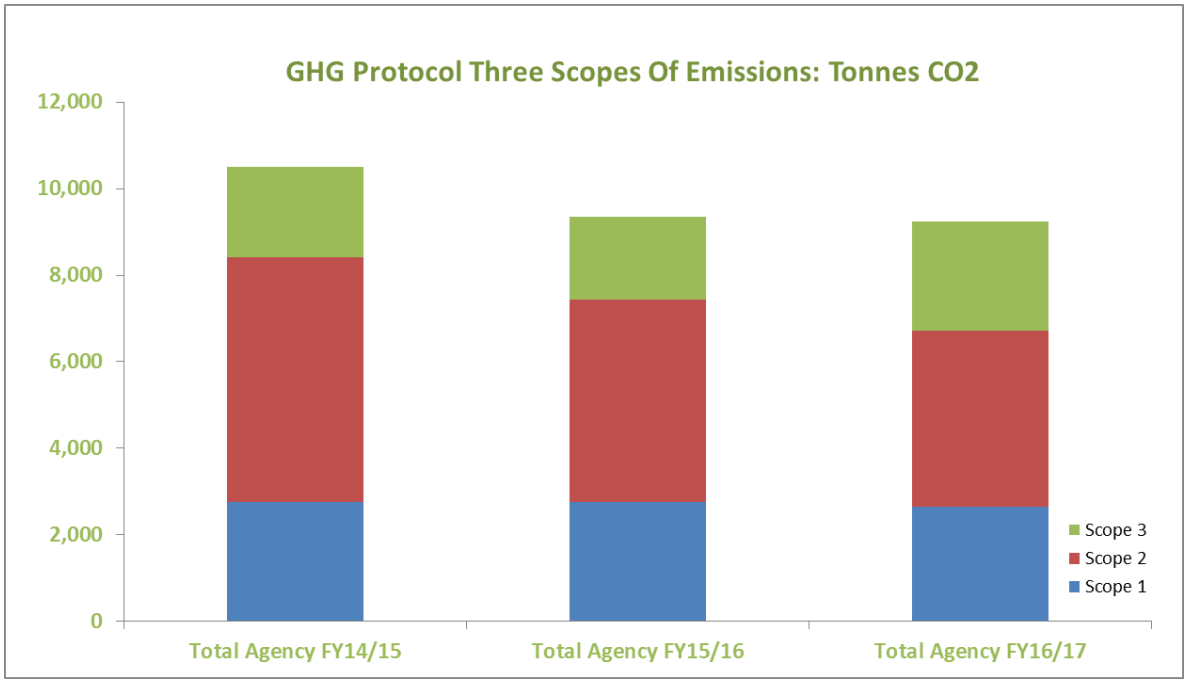
Greenhouse Gas (GHG) emissions performance

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 MHRA. Several factors have impacted on the emissions data over the year and 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	6,284	2,961	9,245
	Gross Gas Emissions	2,571	59	2,630
	Gross Electricity Emissions	3,421	651	4,072
	Gross Property Emissions	26	2	28
	Gross Transport Emissions	266	2,249	2,515
Energy Consumption ('000 kWh)	Gas Consumption	13,976	324	14,300
	Electricity Consumption	7,613	1,449	9,062
Financial Indicators (£k)	Expenditure on Energy	1,228	166	1,394
	Expenditure on Transport	411	1,614	2,025

Notes: 1. BPR expenditure includes electricity only; gas is consolidated in service charge.

2. Transport Emissions include air, rail, courier and air freight data.



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

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

The Carbon Footprint[1] for the South Mimms site has been produced since 2009/10. The figure has fallen from a baseline figure of 8,633 TCO_2 in the first year to 6,284 TCO_2 this year, representing a reduction of 27% over this period, a significant achievement.

Carbon emission data has been produce from 2013/14 for the BPR site; which has been used as the baseline year. The Carbon Footprint was 3,630 TCO_2 in the first year and 2,961 TCO_2 this year. The reduction seen in emissions is in direct relation to the floor consolidation project and we still continue to see the carbon benefit of this project.

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 utility consumption has been greatly reduced, and has also given a reduction 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 17% reduction in gas consumption has been achieved, and a reduction of 16% 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 Government's 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 CO_2 produced from energy sources. It is estimated that the payments for this financial year will be circa £105k.

However due to the significant savings made during the last six years on energy consumption, a considerable amount of the energy budget has been saved on utility bills for electricity and gas. This has been calculated as a total of £1.1 million, over this period, 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

[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 2016.*

Government organisations gained efficiencies from the collaboration. The new supplier is now in place and zero landfill has also been achieved following this change.

The resource re-use system, Warp-It, in place at South Mimms has brought substantial benefits and created behaviour change in the approach to waste. Warp-It allows staff to exchange work based items within the Institute. NIBSC has been used in case study examples by the organisation as well as the Environment and Energy Manager presenting and sharing experience with other Government bodies, such as the Whitehall Sustainability Practioners Forum. This initiative has produced significant savings as shown below and many other associated benefits.

Savings associated with resource re-use		
Re-use Savings		**Total**
Re-use of resources	Total Savings £	105,590
	Total savings $KgCO_2$ Emissions	31,308
	Total Savings Waste Reduction Kg	11,452

The Agency's Environment and Energy Manager has also joined forces with a Cabinet Office initiative to promote the re-use of Government assets. These additional efforts have also produced significant improvements 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 NIBSC and BPR sites, where furniture requirements have been identified and sourced as free issue from other Government organisations. This has saved the Agency an additional £78k to date as a result of not purchasing new furniture and is a great example of the commitment to reduce impacts on the environment.

Finite resource consumption

Water consumption financial and non-financial indicators		
Water		**Total**
Non-Financial Indicators (m^3)	Water Consumption (BPR)	5,129
	Water Consumption Estimated (South Mimms)	17,081
Financial Indicators (£k)	Water Supply Costs (BPR)	N/A
	Water Supply Costs (South Mimms)	18
Notes: 1. Water costs for BPR 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 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, which 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 and so initiatives have been underway to help reduce this - for instance, with the previously established car share scheme that has been in place at South Mimms for several years being 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 facilities being used by staff to make it easier 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.

Agency move into renewable technology

Following a site review by the Environment and Energy Manager a large scale energy saving project, namely Solar PV has been installed at the South Mimms site to further reduce energy consumption.

Following commissioning the Solar PV project was launched this financial year 2016/17. The project included installation of some 1,490 solar panels on seven south facing roofs.

The site will consume all of the electricity produced and this will equate to approximately 8% of overall consumption. Estimates over the lifecycle of the project predict it will bring savings of £2.5 million to the Agency. This includes 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.

NIBSC awards achievements

This year saw NIBSC enter national energy industry awards for the work undertaken at the site, and a very successful outcome was achieved. The coveted “Energy Institute’s Energy Manager of the Year Award” went to Jude Hughes, the Environment and Energy Manager. Praise was given by the judges for successfully engaging staff at all levels of her organisation and recognises outstanding individual performance in energy management. The Environment and Energy Awards in their 17th year means Jude joins with only 16 other energy professionals in the industry to be awarded this coveted title.

Following this, two further awards were received from the Energy Managers Association Public Sector Awards where Jude Hughes won the “Public Sector Energy Manager of the Year” as well as the “Public Sector Energy Champion in Government” award for the impressive Solar PV Project at the South Mimms site.

These prestigious awards are a great accolade and recognition for environmental work carried out at NIBSC. They have also brought the opportunity to showcase NIBSC’s experience and achievements in a follow up presentation at an annual energy conference and industry magazine interview.

The energy management and significant savings made in the consumption of energy, costs and carbon, as summarised above, demonstrate the Agency’s commitment to continually improving working practices to reducing its impact on the environment.

Health and Safety

The Agency is committed to promoting a positive health and safety culture across the organisation, with the aim of reducing risks associated with the Agency's activities. The Agency recognises that effective leadership is key to continual improvement in H&S performance.

Responsibility for health and safety lies with the Agency's Chief Executive Officer, cascading down through the Corporate Executive Team (CET) to Centre and Divisional management. The Health and Safety Strategy Group (HSSG) continues to develop and drive health and safety initiatives across the Agency, based on sector best practice. This is supported by monitoring and effective consultation with staff representatives via the Main Safety Committees and Sub-Committees.

Health and safety priorities are highlighted in the Agency's Health and Safety Action Plan which is developed by the Health and Safety Strategy Group on an annual basis. Key priorities for 2016-17 included:

1. Continued regulatory compliance
2. Maintaining OHSAS 18001 certification at the Buckingham Palace Road site
3. Accident / Incident reporting
4. Delivering the mandatory training programme
5. Reviewing overseas travel safety requirements
6. Continued staff engagement

This section gives a brief overview of the key activities and initiatives that have been carried out this financial year. Data is representative of the entire Agency, unless otherwise indicated.

Continued regulatory compliance

This section applies to the National Institute for Biological Standards and Control (NIBSC) centre of the Agency.

a. Health and Safety Executive (HSE) intervention plan

Due to the nature of activities undertaken at NIBSC, the HSE has assigned NIBSC the highest inherent hazard score. This prompts regular inspections as set out in an annual intervention plan.
There have been three planned intervention inspections which were scored as 'Broadly Compliant' to 'Fully Compliant' for different elements inspected; only minor issues were identified. Recommendations from inspections are incorporated into action plans and are promptly addressed.

b. Internal audits

Internal audits are carried out at least annually, in every Division at NIBSC by the Health and Safety Team. Results from audits are monitored by the Main Health and Safety Committee.

Maintaining OHSAS 18001 certification at the Buckingham Palace Road (BPR) site

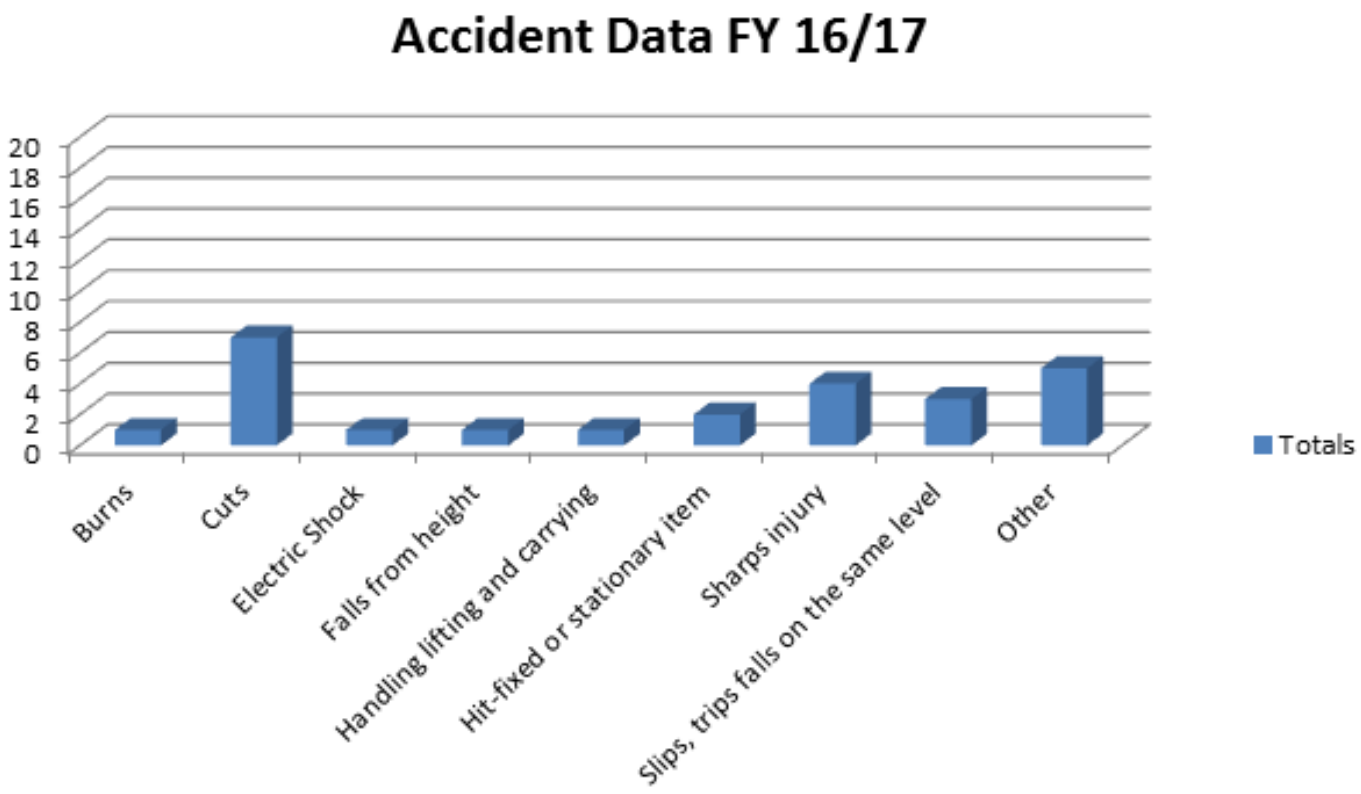
This section applies to the MHRA and CPRD centres of the Agency, based at BPR. BSI continuing assessment/surveillance inspections were completed in April and November 2016. Certification to OHSAS 18001 was maintained. Only minor non-conformities were raised and all have been resolved and accepted by BSI.

Accident / Incident reporting

a. Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR)

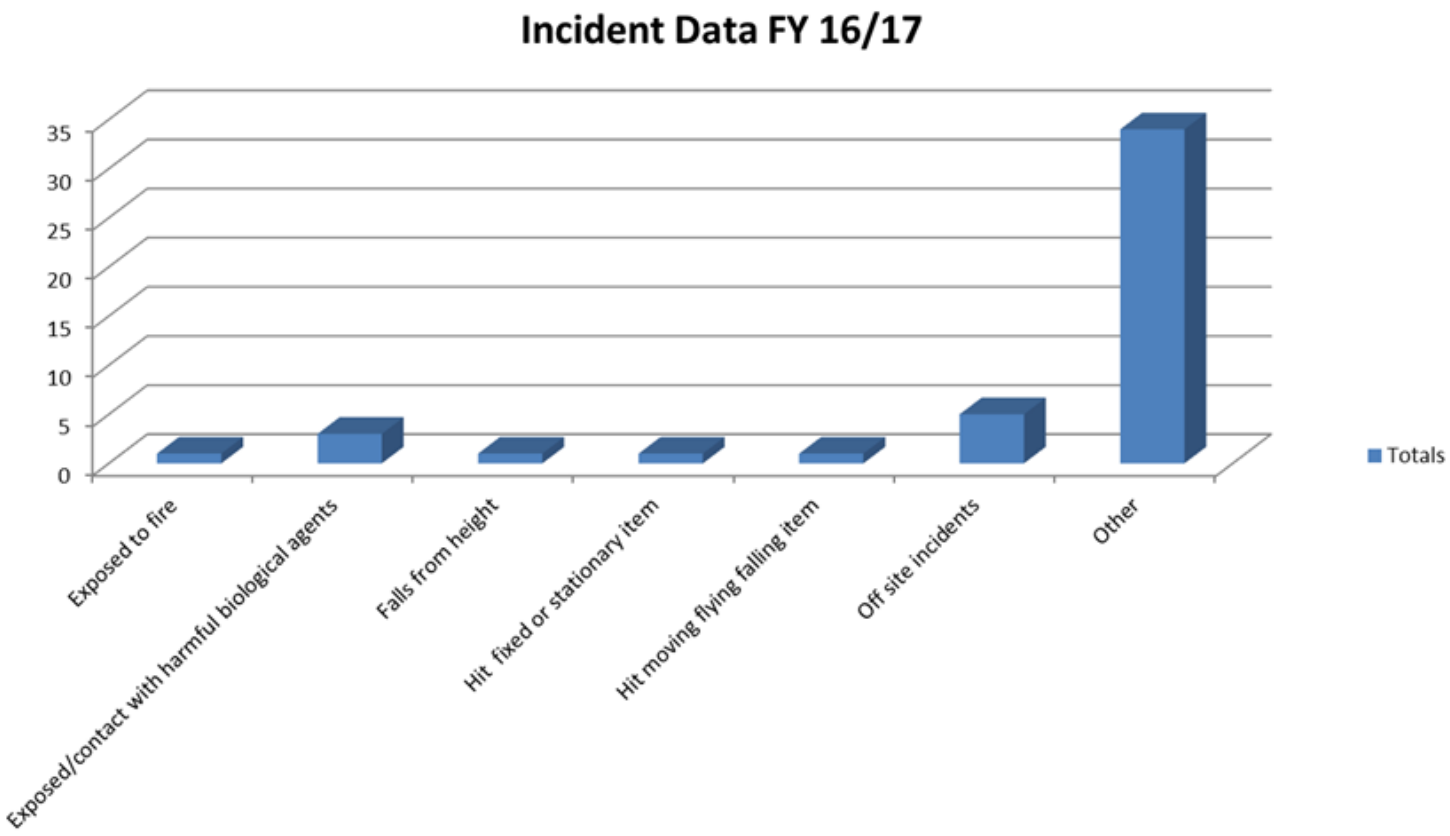
There have been two reportable incidents during 2016/17. Both incidents were reported as Biological specified near misses (occurred at NIBSC). Investigations have been completed and appropriate actions taken. The HSE investigated the second RIDDOR reportable incident and issued an enforcement letter.

b. Agency accident data



Accident reporting remains low, consistent with previous years. Where peaks have been identified, information with proposed actions has been cascaded through relevant committees to address trends identified.

c. Agency incident data



Near miss/Incident data is also consistent with previous years. Incident categories will be improved in the coming financial year to better define the incidents reported as 'other'.

Delivering the mandatory training programme

a. Laboratory workers at NIBSC

NIBSC specialist training has been provided for laboratory workers, laboratory managers, risk assessors and authorisers. The following number of employees have received training during the reporting period 2016-17:

Course	Total
Laboratory Managers H&S	26
Laboratory Workers H&S Module 1	77
Laboratory Workers H&S Module 2	75
Laboratory Workers H&S Module 3	68
Laboratory Workers H&S Module 4	84
Laboratory Workers H&S Module 5	93
Laboratory Workers H&S Module 6	79
Laboratory Workers H&S Module 7	96
Practical Manual Handling	44
Risk Assessor / Risk Authoriser	124
	766

b. Agency mandatory Civil Service Learning (CSL)

The following Civil Service Learning modules have been completed by employees:

Course	Total
Basic Fire Safety Awareness	402
Health & Safety Awareness for all Staff	177
Health & Safety Awareness for Managers	64
Manual Handling	164
	807

Training refresher periods range from annual to 3 yearly

c. Driving Monitor

All staff that drive on Agency business are required to complete an assessment on a system called Driving Monitor. Driver risk ratings are based on a risk assessment which combines driver history with an on-line assessment. Drivers deemed as medium and high risk receive appropriate additional training. The following data covers the whole Agency.

Centre	Risk Rating	Number of Drivers (%)
NIBSC	High	2
	Medium	11
MHRA / CPRD	High	1
	Medium	13

A total of 1407 staff have registered with Driving Monitor, with 1065 staff stating that they do not drive on Agency business.

d. Cardinus

Agency staff are required to complete Display Screen Equipment (DSE) training and assessments via the on-line Cardinus system. Staff with 'high risk' DSE assessments are assisted by the Health and Safety Team and DSE Co-ordinators to resolve their DSE Issues. Occupational Health referrals are available where required.

Reviewing overseas travel safety requirements

Overseas travel is a key risk area for the Agency. The Overseas Travel working group was established to review overseas travel safety requirements to ensure that appropriate systems were in place to mitigate the risks. The initial focus was on Inspectors travelling and working overseas, however a wider review is being carried out to ensure that an Agency wide approach is adopted in this area.

Continued staff engagement

The Agency carries out an annual Health and Safety survey to obtain staff feedback on Health and Safety priorities and performance. Staff feedback is acted upon and required actions are linked into the Agency's Health and Safety Action Plan.

Dr Ian Hudson
Chief Executive and Accounting Officer
Medicines and Healthcare products Regulatory Agency
4 July 2017

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.

The Chairman

Sir Michael Rawlins GBE

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 the Board

Martin Hindle

Martin serves as Deputy Chairman of the Board. He is currently Chairman of East Midlands Academic Health Science Network and a Non-Executive Director of Public Health England. He is a member of the council of Leicester University and the International Advisory Board of the University of Bradford Business School.

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

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

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

Dr Barbara Bannister

Dr Barbara Bannister is a specialist in acute medicine, infectious and tropical diseases, who has previously served on the Commission on Human Medicines (CHM) and as chair of a European Medicines Agency Scientific Advisory Committee.

Between 2005 and 2012, she worked with UK Department of Health colleagues on planning for infectious diseases emergencies, and also with European colleagues on several European Union public health and emergency medicine projects. 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 Dame Valerie Beral

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

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

Dame Valerie is Professor of Epidemiology at University of Oxford and the principal investigator for the Million Women Study. She leads international collaborations on breast, ovarian and endometrial cancer.

Professor Bruce Campbell

Bruce Campbell served on the Independent Review Group for the MHRA in 2013-14 and on the Topic Selection Panel for the MHRA's Technical Forums from 2008-13. He chaired the NICE Interventional Procedures Advisory Committee 2002-15 and the NICE Medical Technologies Advisory Committee 2009-15.

He has longstanding involvement with the IDEAL framework for research into new procedures and medical devices. Bruce Campbell is Honorary Vascular Consultant in Exeter and Honorary Professor at the University of Exeter Medical School.

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.

Professor Sir Alex Markham

A Fellow of the Academy of Medical Sciences, University of Leeds, Sir Alex has made contributions to medical science in various fields, is accredited in pathology and internal medicine and trained initially in medicinal chemistry. His commercial experience includes cancer drug development and the introduction of DNA fingerprinting for forensic and medico-legal applications, which was recognised by the Queen's Award for Technological Achievement in 1990.

A Fellow of the Academy of Medical Sciences, Professor Markham has previously served as Chairman of the National Cancer Research Institute (NCRI) in the UK and has been a member of the UK Clinical Research Collaboration Board and the National Institute of Health Research Advisory Board.

He was a member of the government's Cancer Reform Strategy Advisory Board, has chaired the National Institute for Medical Research (MRC) and Wellcome Trust committees and was a trustee of Arthritis Research UK. He chaired the Translational Medicine Board for MRC and NIHR under the auspices of the Occupational Safety & Health Consultants Register (OSCHR).

Professor Markham was Chief Executive of Cancer Research UK until 2007. He then returned to academic work at Leeds University. He received a knighthood in the 2008 New Year's Honours for services to medicine.

Deborah Oakley

Deborah works at Veritas Investment Management looking after private client portfolios, which she combines with her role as a non-executive director and chair of the audit committee of the Royal Free London NHS Foundation Trust and non-executive director of MHRA.

She is a former (until its abolition in 2013) board member of the Health Protection Agency and board member of NHS Camden from 2007 to 2011, where she chaired the audit committee.

Professor David Webb

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

A Fellow of the Academy of Medical Sciences, he holds the Christison Chair of Therapeutics and Clinical Pharmacology at the University of Edinburgh, and is a consultant physician and toxicologist at the Royal Infirmary of Edinburgh, running Edinburgh's Hypertension Excellence Centre.

He is President of the British Pharmacological Society (BPS), having been President-Elect until 2016, Honorary President of the European Association for Clinical Pharmacology and Therapeutics (EACPT), and Vice-President, Clinical Division of the International Union of Basic and Clinical Pharmacology (IUPHAR).

He is a Fellow of the Royal Society of Edinburgh and has held the Chair of the Scottish Medicines Consortium, Presidency of the Scottish Society of Physicians and Vice-Presidency of the Royal College of Physicians of Edinburgh.

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

Jon Fundrey

Jon joined the MHRA as Chief Operating Officer in 2016, prior to which he was Financial Controller at the Department for Work and Pensions. He has been in the civil service since he joined HMRC in 2007.

Prior to joining the civil service, Jon held a number of senior Finance, IT and global programme management roles at a FTSE50 company, The BOC Group Plc, during a seventeen-year career there.

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 2016/17.

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

Introduction

As Accounting Officer it is my responsibility to ensure there is a sound system of governance and internal control structures in place; and that the Medicines and Healthcare products Regulatory Agency (MHRA) business is conducted in accordance with Managing Public Money to ensure public money is safeguarded and properly accounted.

Governance framework

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

As the Agency's Chief Executive, I was appointed by the Department's Permanent Secretary through fair and open competition in line with the Civil Service Commission Recruitment Principles and I chair the Corporate Executive Team (CET). The CET devolves certain areas of its business to sub-committees, each chaired by a designated director.

The Permanent Secretary nominates a Senior Departmental Sponsor (SDS) who acts as the Agency's designated, consistent point of contact within the Department. The SDS acts as the link at executive level between the Agency and the senior officials of the Department, and also with Ministers. The SDS also supports the Permanent Secretary in holding the Agency to account and providing assurance on its performance.

A Departmental sponsor team supports the SDS by undertaking the principal day-to-day liaison between the Department and the Agency.

The Secretary of State has delegated some of his statutory responsibilities relating to medicines, medical devices and blood, amongst other things to the Agency. From 1 April 2013, the Agency has also performed the functions of the Secretary of State in relation to biological substances conferred under section 57 of the Health and Social Care Act 2012. These functions, which relate to ensuring the quality of biological medicines, were previously carried out by the Health Protection Agency through the non-statutory body, the National Institute of Biological Standards and Control (NIBSC).

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

The following structures and processes were in place to ensure accountability and give the Agency a framework for risk management:

- The Board made up of the Chairman, non-executive directors, the Chief Executive and Chief Operating Officer is primarily responsible for advising on the strategic development of the Agency and ensuring that targets set out in our Business Plan and endorsed by ministers are met.

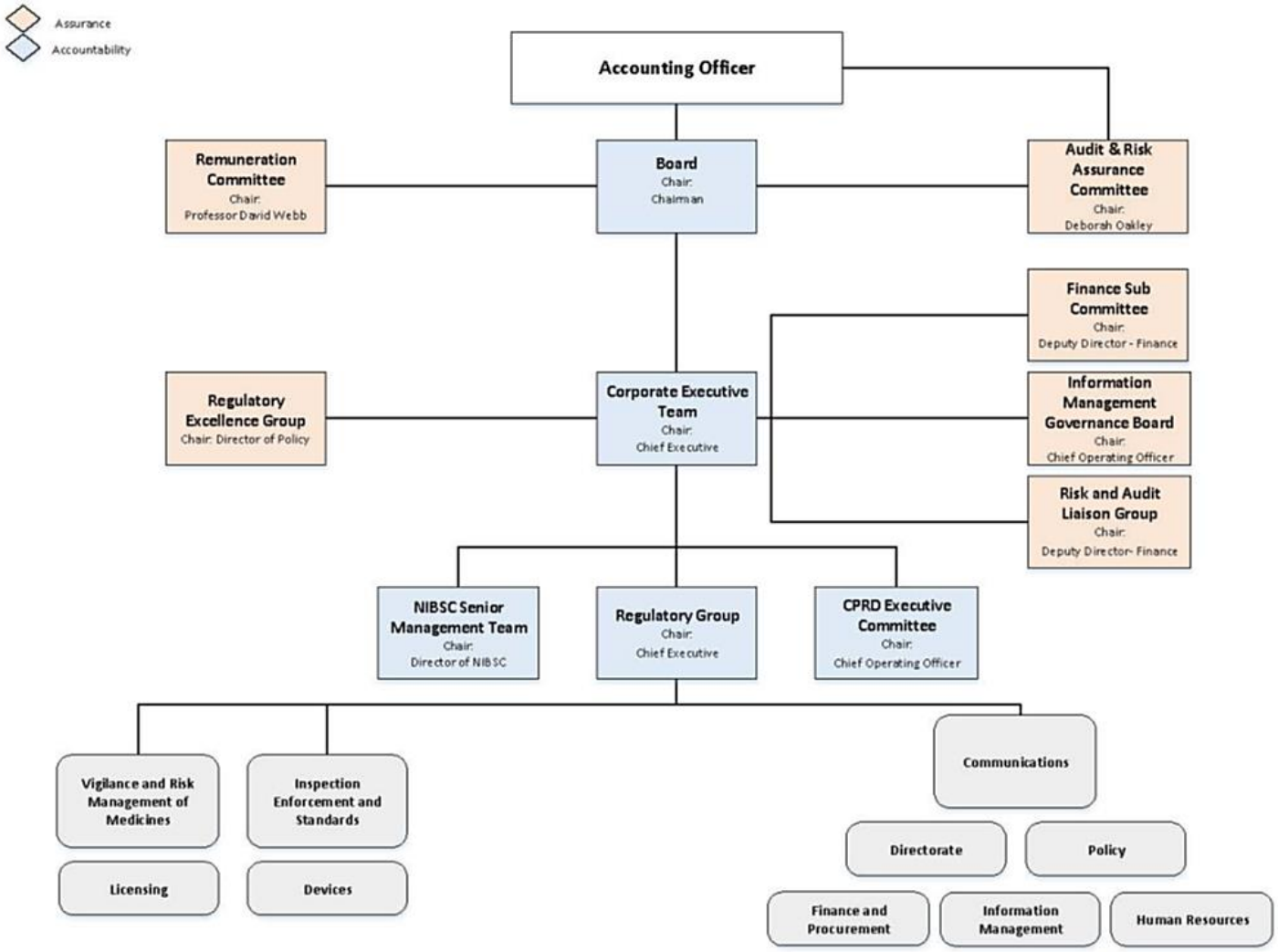
- The Corporate Executive Team (CET) consisting of the Agency's divisional directors takes overall responsibility for day-to-day management, strategic decision-making, line management, and all financial, policy, operational and resource management issues.

This statement also explains how the Agency has complied with the principles of good governance and reviews the effectiveness of these arrangements.

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



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. Additional high level priorities for 2016/17 were outlined in the Letter of priorities issued by the Department of Health to the Agency 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 listed on page 51.

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

Board Attendance

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

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

In addition, other executive directors attend the board as required during the year.

Role of the Chairman

The Chair is responsible to the Secretary of State, and will work closely with the Senior Departmental Sponsor to ensure that the Agency's affairs are conducted with probity and that the Agency's policies and actions support it in the discharge of its functions and duties efficiently and effectively and meet the Agency's objectives.

The Chair is responsible for:

- providing leadership to the Board and 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;
- annual evaluation and appraisal of the non-executive directors; and
- providing feedback on the CE's performance to the Permanent Secretary

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

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 was received in November 2016. An action plan has been agreed to implement all recommendations. The recommendations included inviting CET members to attend the Board to increase engagement, increasing the number of joint CET/Board away-days to two per year as well as ensuring feedback from the Board members on papers and information presented is acted upon to enable insight and scrutiny.

Audit and Risk Assurance Committee

The Agency Audit and Risk Assurance Committee (ARAC) has a formally agreed terms of reference which is reviewed on an annual basis. The Committee provides advice and support to the Chief Executive in delivering the Accounting Officer role for the Agency. The ARAC consists of four non-executive Directors. It is a sub-committee of the 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; the operation of the Conflict of Interests policy, assurance on Health & Safety and all types of Fraud, and Whistle-Blowing arrangements. The ARAC receives regular updates on any reported fraud or whistle-blowing cases. The ARAC also discussed and agreed the annual internal audit plan. In addition, ARAC asked for and received regular updates on Information and cyber security 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. ARAC members meet privately with the internal and external auditors on a regular basis.

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. 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. The ARAC considers and approves the Agency Governance Statement and the Annual Report and Accounts.

ARAC Attendance

Member	ARAC
Ms Deborah Oakley	4 (4)
Mr Martin Hindle	4 (4)
Mr Stephen Lightfoot	3 (4)
Professor Sir Alex Markham	4 (4)
Routine Attendees:	
Chief Executive	4 (4)
Chief Operating Officer	3 (4)
Deputy Director - Finance	4 (4)
Head of Internal Audit	3 (4)
Representative from the External Auditor	4 (4)
Representative from the Department of Health	0 (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.

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 together with the Director of Human Resources and me as Chief Executive; the Chair of the Board is not eligible for membership. 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	11 (12)
Mr Peter Commins	4 (6)
Mr Jon Fundrey	5 (5)
Mr Gerald Heddell	10 (12)
Dr Christian Schneider	11 (12)
Dr Siu Ping Lam	11 (12)
Mr Jonathan Mogford	10 (12)
Mr John Quinn	11 (12)
Dr June Raine, CBE	10 (12)
Dr Janet Valentine	11 (12)
Mr John Wilkinson, OBE	9 (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.

Operational Data

We launched an Information Governance Framework this year bringing together the various strands of information governance that support the operational management of information in the Agency encompassing:

- confidentiality and data protection, including data sharing arrangements;
- information security, including cyber security and information risk management;
- information lifecycle management, including records management;
- improvements to the quality of our legacy data;
- corporate governance, including transparency requirements under the Freedom of Information Act 2000 and Environmental Information Regulations 2004.

We have launched projects to deliver the underpinning Information Architecture, including Master Data Management and Global Data Integration, for programmes that will be replacing aging Devices Lotus Notes systems, Sentinel and CPRD systems with a new more flexible case management capability.

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. The corporate risks are also tracked on a Heat map, which the Agency uses to track the evaluations of the

probability of risk occurrence and the impact on the Agency in the event that a particular risk is experienced.

The Agency has a Risk Appetite Statement which sets out how it balances risk and opportunity in pursuit of achieving its objectives of promoting and protecting public health. The statement forms a key element of our governance and reporting framework. It is set by the Corporate Executive Team (CET) and approved by the Audit & Risk Assurance Committee (ARAC) on behalf of the Board, which also reviews the statement annually.

A corporate risk manager who oversees the risk management process and provides specialist advice is responsible for the continuous improvement in the Agency's risk management policies and procedures. The manager also provides support and advice on risk management issues where required.

The effectiveness of the Agency's risk management framework has been reviewed during the year. Our internal audit service has performed an independent and objective review on the existence and effectiveness of controls over the Agency's risk management framework. The review confirmed that a sound framework was in place but that the Agency could benefit from some further improvements to enhance the effectiveness of the framework of risk management.

Assessment of Risk

At 31 March 2017, the Agency's corporate risk register identified the following principal risks:

- Relocation of BPR to Canary Wharf could result in loss of key staff if they perceive they are moving to a less accessible location with inadequate space and facilities which would cause disruption to the Agency's operations;
- Threat to the Agency stemming from Brexit. The impact on the ability of the Agency to undertake its Public Health protection role;
- Failure to fulfil all statutory and other public health roles due to reduced funding;
- Procurement risks relating to award of contracts and failure to comply with legislation;
- Failure to fulfil all statutory and other public health roles due to reduced funding;
- The referendum decision to leave the European Union will have an impact on the 5 year Digital Transformation Portfolio plan that has been developed over the past 2 years. The plan identifies the projects, their timing and dependencies over a 5 year period. Requirements, priorities, strategic direction, the availability of funding and ongoing uncertainty on direction will lead to changes that could increase costs, slow pace, create complexity and divert capacity and capability. Re-planning and lack of direction creates a risk to delivery;
- The Agency is under increasing threat of data loss and or corruption from cyber- attacks and new ways of working. This risks loss of reputation, fines, legal action and the prevention of business through downtime and loss of data. During the recent cyber-attack, there were no infections at BPR. However, five PCs at NIBSC were infected. An immediate investigation into cyber security at NIBSC is planned and the outcome will inform any further actions to be taken in addition to current mitigation strategies.

Other risks include the failure to prevent falsified medical products reaching the public via the illegitimate supply chain and the risk of providing data to clients that may lead to reputational damage which compromises the effectiveness of Clinical Practise Research Datalink. The mitigations for these risks are discussed on page 35. 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 2017. 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 the 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

This year we delivered a new Information Security Management System (ISMS) aligned to the ISO 27001 Information Security Management standard that encompasses:

- hierarchical policies, procedures and guidelines, and the mechanisms to achieve compliance;
- culturally embedding Information Security into all of our activities as second nature through education and engagement;
- visible and recorded executive oversight, support and sponsorship.

We have undertaken internal reviews of our data security stance against both the CESG (Communications Electronics Security Group) 'Ten Steps to Cyber Security' and the National Data Guardian (NDG) for Health and Care's 'ten data security standards', and participated in the Health Group Internal Audit Service (HGIAS) Cross-Cutting Review of Cyber Security, from which we received a Moderate rating. The recommendations from that Cross-Cutting Review are being implemented by our Information Security Officer.

Effectiveness of whistleblowing arrangements

The Agency has an internal Whistleblowing Policy and Procedure, Guidance for Managers and Frequently Asked Questions documents based on a best practice policy created by Civil Service Employee Policy. The policy and accompanying documents have been publicised to managers and all staff in-year. 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. A Non-Executive Whistleblowing Champion provides oversight and assurance to the whistleblowing policy and procedure and challenges 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. ARAC has oversight of both whistleblowing and fraud cases and the action being taken as a result. It receives quarterly reports on these cases and an annual report. ARAC's role is to ensure it receives appropriate assurances from the Agency that action is being taken to prevent the issues occurring again.

During the year, there was one internal whistleblowing case raised by a member of staff. The concerns raised were investigated and a written report provided to the whistle blower and management is now taking forward actions and recommendations from the investigations in the areas of health and safety, procurement and overtime.

Internal Audit

The Agency's internal audit team transitioned from the Health Group Internal Audit Service (HGIAS) into the Government Internal Audit Agency (GIAA) as of 1 October 2016. This move increases the independence of the Internal Audit function and follows wider government priorities for Internal Audit Services within the Civil Service. Benefits include greater

consistency and joined up working for the provision of Internal Audit services across government.

GIAA carries out the internal audit reviews for the Agency. This team operates to prescribe Public Sector Internal Audit Standards and complies with procedures and standards set by the GIAA. The internal audit report provides me with an independent and objective opinion on the adequacy and effectiveness of the Agency's system of internal control, together with recommendations agreed to by management for improvement.

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 areas covered by these reviews were as follows:

- Key financial risks that relate to how Agency funds are utilised (the value for money question);
- Key risk areas that may impact efficiency of Agency operations, effectiveness of internal controls and efficacy of strategy (delivery of the Agency's strategic/corporate plan objectives);
- The key themes 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.

Eleven assurance based reviews have been performed during the year of which two were rated as substantial and six as moderate, one limited and two unsatisfactory.

Internal Audit reviews

- The review of the New Payroll Arrangements resulted in a Moderate assurance. This was an improvement on the same review carried out in the previous year which had been awarded a Limited assurance. The review highlighted a need for a senior member of HR division to review all documents shared with CGI at month end to ensure that all requests are genuine and authorised and can be agreed to the spreadsheet log of authorised amendments;
- The review of the Agency's Financial Forecasting which focused on financial forecasting and budgeting across all areas of business within MHRA, to ensure that this is a thorough, timely and accurate process was awarded a Moderate assurance. It recommended that management should consider creating a formal policy for budget revisions from the centre, which identifies the procedure for inputting and approving revisions on Oracle, along with the levels of delegated authorities for approving any revisions;
- The review of the Agency's Risk Management resulted in a Moderate assurance. The report highlighted a need for the Agency to ensure significant risks are identified and evaluated at corporate level considering the impact to the Agency as a whole and not just on Directorate by Directorate basis. It also recommended that horizon scanning

should be undertaken regularly in order to ensure low likelihood yet high impact risks are identified where possible prior to their crystallisation;

- Board Effectiveness review resulted in a Moderate assurance. At the time of the review the vote for Britain's exit from the European Union had been decided which presents some unique challenges and opportunities for the Agency going forward. The report advised that depending on the future strategy for the Agency, the existing governance arrangements should be reviewed to ensure that they are right for the organisation and that they support the achievement of its objectives;
- The review of MHRA - Corporate Plan and Strategy was awarded a Substantial assurance, the highest possible rating. The report noted that the Agency's corporate plan and strategy have been well designed and implemented effectively;
- The review of MHRA – Income & Accounts Receivable function was also awarded a Substantial assurance. On the whole the income and receivables function has well designed controls and they operate effectively;
- The review of Cyber Security was awarded a Moderate assurance with several positive findings reported. The review noted that the Agency has a well-established governance structure whereby cyber security is considered alongside other business risks;
- The review of Talent Management resulted in a Moderate Assurance;
- The review of e-cigarettes income recognition resulted in a limited assurance. This is a new area of work for the Agency and the policy in relation to income recognition is still in the process of being formalised;
- The review of Procurement & Contract management of NIBSC operations resulted in an Unsatisfactory rating. The review identified a number of significant control weaknesses, both with the design of controls and non-compliance with existing procedures. These included the need to put in place a framework agreement for preferred suppliers; a review of the exposure of the Agency to suppliers on an annual basis; clarification of roles and responsibilities of the procurement team in relation to tenders; establishing a supplier conflicts of interest register to promote an open and transparent procurement process; formal management training to be provided to all staff who manage contracts as well as ensuring appropriate authorisations are obtained from all budget holders and that overspends are highlighted and reviewed. A detailed plan of action to address all recommendations has been agreed with timelines for delivery.

  This was expanded to an Agency wide review which was undertaken after year end. The review reported similar issues across the Agency and resulted in an unsatisfactory rating. The report made several recommendations including ensuring contracts are approved in line with delegated authority; waivers are authorised in line with the waiver policy; the review of business case process and templates; provision of further guidance to staff; introducing a robust for capturing conflicts of interest and how these should be dealt with.

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

Areas of good practice

The reviews noted on good practice as follows:

- In the Accounts receivables team where appropriate segregation of duties were witnessed and standard procedures clearly identified for authorisation of credit notes and credit terms;
- The corporate plan review highlighted the Monitoring and Approval process for monitoring targets and activities set out in business plans, awareness of the 'Golden Thread' when creating Agency and Divisional Plans and communicating the Corporate Plan to employees;
- The process for monitoring and approval of budgets as well as the use of financial models in the Financial forecasting review as being positive steps;
- The quality checks carried out by the HR team over the processing of information for payroll to ensure it is processed accurately;
- The Cyber security review findings relating to the Information Asset Management framework, Access control and Information Governance where systems are in place to review business cases for new and existing systems;

Head of Internal Audit opinion

On the basis of the evidence obtained during 2016-17, the Head of Internal Audit was able to provide an overall Moderate level of assurance that the Agency has adequate and effective systems of control, governance and risk management in place. On the basis of reviews conducted during the year, the Risk Management and Governance areas were deemed as Moderate while the Control areas deemed as Limited mainly due to the Limited assurance on the e-cigarettes review and the Unsatisfactory assurance on the Procurement & Contract management of NIBSC operations.

Where enhancements were proposed, corrective action has been agreed and subsequent delivery of those actions is monitored closely with quarterly updates provided to CET and ARAC.

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 2017 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 2016/17.

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 2017 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

Civil Service appointments are made in accordance with the Civil Service Commissioners' Recruitment Code, which requires appointments to be based on fair and open competition but also includes the circumstances when appointments may otherwise be made. Unless otherwise stated below, the officials covered by this report hold appointments that are open-ended. Early termination, other than for misconduct, would result in the individual receiving compensation as set out in the Civil Service Compensation Scheme. The standard period of notice to be given by directors is 3 months. 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 David Webb (Chair), Dr Barbara Bannister, Professor Bruce Campbell and Mr. Matthew Campbell-Hill. Dr Ian Hudson and Professor Sir Michael Rawlins 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.

CET remuneration, bonus and benefits table (subject to audit)

2016/17	Salary £000	Performance pay and bonuses £000	Pension related benefits £000	Total £000
Dr Ian Hudson Chief Executive	150 - 155	10 - 15	35.0 - 37.5	195 - 200
Mr Jon Fundrey[1] Chief Operating Officer	55 - 60	Nil	20.0 - 22.5	75 - 80
Mr Peter Commins[2] Chief Operating Officer	75 - 80	Nil	10.0 - 12.5	90 - 95
Dr June Raine, CBE Director of Vigilance & Risk Management of Medicines	125 - 130	Nil	22.5 - 25.0	150 -155
Dr Christian Schneider Director of NIBSC	130 - 135	Nil	52.5 - 55.0	185 -190
Mr Gerald Heddell Director of Inspection. Enforcement and Standards	85 - 90	Nil	20.0 - 22.5	105 -110
Mr John Wilkinson, OBE Director of Devices	115 - 120	Nil	45.0 - 47.5	160 -165
Ms Rachel Bosworth Director of Communications	95 - 100	Nil	17.5 - 20.0	115 - 120
Mr Jonathan Mogford Director of Policy	95 - 100	10 - 15	17.5 - 20.0	130 - 135
Dr Siu Ping Lam Director of Licensing	115 - 120	10 - 15	20.0 - 22.5	150 - 155
Mr John Quinn Chief Information Officer	95 - 100	0 - 5	37.5 - 40.0	135 - 140
Ms Vanessa Birchall-Scott Director of Human Resources	90 - 95	10 - 15	35.0 - 37.5	140 - 145
Dr Janet Valentine Director of CPRD	90 - 95	Nil	60.0 - 62.5	155 - 160

Band of the highest paid directors total remuneration	160 - 165
Median total	39,304
Remuneration ratio	4.13
Range of staff remuneration	8 - 165

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

[1] Mr Jon Fundrey joined the Agency on 31st October 2016. The full year equivalent is £135k-140k.
[2] Mr Peter Commins retired from the Agency on 25th October 2016. The full year equivalent is £135k-140k.

2015/16	Salary £000	Performance pay and bonuses £000	Pension related benefits £000	Total £000
Dr Stephen Inglis[1] Director of NIBSC	170 - 175	Nil	N/A	170 - 175
Dr Ian Hudson Chief Executive	150 - 155	10 - 15	62.5 - 65.0	220 - 225
Mr Peter Commins[2] 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'.

[1] Mr Stephen Inglis retired from the Agency on 31st March 2016.
[2] Mr Peter Commins retired from the Agency on 25th October 2016.

Board remuneration, bonus and benefits table (subject to audit)

2016/17	Salary £000	Benefits in kind (taxable) to nearest £100*	Total £000
Professor Sir Michael Rawlins Chairman	60 - 65	100	60 - 65
Dr Barbara Bannister, MBE Non Executive Director	5 - 10	-	5 - 10
Professor Dame Valerie Beral Non Executive Director	5 - 10	-	5 - 10
Professor Bruce Campbell Non Executive Director	5 - 10	-	5 - 10
Mr Matthew Campbell-Hill Non Executive Director	5 - 10	9,900	15 - 20
Mr Martin Hindle Non Executive Director	5 - 10	700	5 - 10
Mr Stephen Lightfoot Non Executive Director	5 - 10	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	1,300	5 - 10

*Agency Board members received no performance pay, bonus or any pension related benefits. Benefits in kind relate to travel and other expenses.

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. Benefits in kind relate to travel and other expenses.

[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 20th July 2015.
[3] Mr John Williams appointment term ended on 31st August 2015.

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

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 2016/17 relate to performance in 2015/16 and the comparative awards reported in 2015/16 relate to performance in 2014/15.

Fair pay disclosure (subject to audit)

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 2016/17 was £160k-£165k (2015/16, £170k-175k). This was 4.1 times (2015/16, 4.4) the median remuneration of the workforce, which was £39,304 (2015/16, £38,973). No employee received remuneration in excess of the highest paid director in 2016/17 (2015/16, none).

The range of staff remuneration was £8k-165k (2015/16, £7k-175k).

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

Pension benefits table (subject to audit)

Neither the Chairman, nor Non Executive 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 2017 and related lump sum Bands of £5,000	Cash Equivalent Transfer Value at 1 April 2016 To nearest £1,000	Cash equivalent Transfer Value at 31 March 2017 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 Ian Hudson Chief Executive	0 - 2.5 plus Nil lump sum	55 -60 plus Nil lump sum	1,031	1,115	33	21
Mr Jon Fundrey Chief Operating Officer	0 - 2.5 plus Nil lump sum	30 -35 plus Nil lump sum	461	495	16	7
Dr Christian Schneider Director of NIBSC	2.5 - 5.0 plus Nil lump sum	0 - 5 plus Nil lump sum	7	38	21	18
Dr June Raine, CBE Director of Vigilance & Risk Management of Medicines	0 - 2.5 plus lump sum of 2.5 - 5.0	50 - 55 plus lump sum of 150 - 155	1,053	1,072	20	16
Mr Gerald Heddell Director of Inspection, Enforcement and Standards	0 - 2.5 plus Nil lump sum	25 -30 plus Nil lump sum	392	407	16	11
Mr John Wilkinson, OBE Director of Devices	2.5 - 5.0 plus Nil lump sum	10 -15 plus Nil lump sum	188	239	37	15
Ms Rachel Bosworth Director of Communications	0 - 2.5 plus lump sum of 2.5 - 5.0	25 - 30 plus lump sum of 75 - 80	467	508	16	12
Mr Jonathan Mogford Director of Policy	0 - 2.5 plus lump sum of 2.5 - 5.0	30 - 35 plus lump sum of 100 - 105	617	664	16	14
Dr Siu Ping Lam Director of Licensing	0 - 2.5 plus lump sum of 2.5 - 5.0	40 - 45 plus lump sum of 125 - 130	883	946	21	17
Mr John Quinn Chief Information Officier	0 - 2.5 plus Nil lump sum	25 - 30 plus lump sum of 75 - 80	437	475	15	13
Ms Vanessa Birchall-Scott Director of Human Resources	0.0 - 2.5 plus Nil lump sum	0 - 5 plus Nil lump sum	32	60	20	13
Dr Janet Valentine Director of CPRD	5.0 - 7.5 plus Nil lump sum	10 - 15 plus Nil lump sum	62	125	21	12

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 (subject to audit)

	Total	2016/17 Permanently Employed	Other	2015/16 Total
	£000	£000	£000	£000
Wages and salaries	**58,726**	**57,037**	**1,689**	55,898
Social security costs	**6,364**	**6,364**	**-**	4,952
Other pension contributions	**11,712**	**11,712**	**-**	11,168
Sub-total	**76,802**	**75,113**	**1,689**	72,018
Less recoveries in respect of outward secondment	**(159)**	**(159)**	**-**	(92)
Total staff costs	**76,643**	**74,954**	**1,689**	71,926

Staff resources (subject to audit)

During the year an average of 1,257 permanent full-time equivalent staff were employed.

	Total	2016/17 Permanently Employed	Other
Chairman	**1**	**1**	**-**
Chief Executive/Directors	**11**	**11**	**-**
Senior Civil Servants	**127**	**123**	**4**
Other Civil Service Staff	**1,118**	**914**	**204**
Total	**1,257**	**1,049**	**208**

	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

Staff composition – gender analysis

	Male	Female
Chairman/Chief Executive/Directors	9	4
Senior Civil Servants	68	59
Other Civil Service Staff	473	702
Total	550	765

Staff composition – ethnic breakdown

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

- White 63%
- BME 30%
- No data/prefer not to say 7%

Sickness absence

The average annual sickness rate for the calendar year 2016 was 5.7 working days per full time equivalent employee.

The annual turnover for the Agency was 12.9%.

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 & Diversity Group include recognised trade union representation included 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 and wellbeing.

Spend on consultancy and temporary staff

During 2016/17, expenditure on consultants was £15k (£28k in 2015/16).

The Agency continues to employ temporary staff where it is of operational necessity. The Agency temporary staff expenditure was £1,689k in 2016/17 (£1,944-k in 2015/16).

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

Exit packages (subject to audit)

2016/17	
Cost band	Total Number of exit packages by cost band
< £10,000	-
£ 10,000 - £ 25,000	1
£ 25,000 - £ 50,000	-
£ 50,000 - £100,000	1
£100,000 - £150,000	-
£150,000 - £200,000	-
Total number of exit packages	**2**
Total resource cost	**£111,530**

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 £112k (2015/16, £104k) 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 2017.

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.

	2016/17		
	Income	Expenditure	Surplus
Charging activity	**£000**	**£000**	**£000**
Licensing	**50,229**	**(40,654)**	**9,575**
Inspections	**9,153**	**(10,360)**	**(1,207)**
Vigilance, Risk Management and Enforcement	**29,604**	**(36,512)**	**(6,908)**
British Pharmacopoeia	**3,804**	**(3,280)**	**524**
Devices	**10,072**	**(12,238)**	**(2,166)**
Clinical Trials	**3,315**	**(3,291)**	**24**
Total Regulator	**106,177**	**(106,335)**	**(158)**
CPRD	**8,781**	**(8,687)**	**94**
Less: DH share of joint arrangement	**(4,391)**	**4,344**	**(47)**
	4,390	**(4,343)**	**47**
NIBSC	**42,400**	**(42,177)**	**223**
Total	**152,967**	**(152,855)**	**112**

Charging activity	Income £000	2015/16 Expenditure £000	Surplus £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

*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 (2015/16: 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.

During the year, the Agency undertook a further review of assets under construction and concluded that due to changing requirements during the year, it would be prudent to impair certain capital expenditure. Accordingly, £1.5m relating to the business Intelligence asset has been expensed in 2016/17.

There were no other material losses or special payments during the year (2015/16: £nil).

Dr Ian Hudson
Chief Executive and Accounting Officer
Medicines and Healthcare products Regulatory Agency
4 July 2017

2.7 The certificate and report of the Comptroller and Auditor General to the Houses of Parliament

I certify that I have audited the financial statements of the Medicines and Healthcare products Regulatory Agency for the year ended 31 March 2017 under the Government Trading Funds Act 1973. The financial statements comprise: the Statement of Comprehensive Income, Statement of Financial Position, Statement of Cash Flows, Statement of Changes in Taxpayers' Equity; and the related notes. These financial statements have been prepared under the accounting policies set out within them. I have also audited the information in the Remuneration and Staff Report and the Parliamentary Accountability and Audit Report, that is described in those reports 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 Accounting Officer is responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view. My responsibility is to audit, certify and report on the financial statements in accordance with the Government Trading Funds Act 1973. I conducted my audit in accordance with International Standards on Auditing (UK and Ireland). Those standards require me and my staff to comply with the Auditing Practices Board's Ethical Standards for Auditors.

Scope of the audit of the financial statements
An audit involves obtaining evidence about the amounts and disclosures in the financial statements sufficient to give reasonable assurance that the financial statements are free from material misstatement, whether caused by fraud or error. This includes an assessment of: whether the accounting policies are appropriate to the 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 2017 and of its surplus for the year then ended; and
- the financial statements have been properly prepared in accordance with the Government Trading Funds Act 1973 and HM Treasury directions issued thereunder.

Opinion on other matters
In my opinion:

- the parts of the Remuneration and Staff Report and the Parliamentary Accountability disclosures to be audited have been properly prepared in accordance with HM Treasury directions made under the Government Trading Funds Act 1973; and
- the information given in the Performance Report and Accountability Report for the financial year for which the financial statements are prepared is consistent with the financial statements.

Matters on which I report by exception
I have nothing to report in respect of the following matters which I report to you if, in my opinion:

- adequate accounting records have not been kept or returns adequate for my audit have not been received from branches not visited by my staff; or
- the financial statements and the parts of the Remuneration and Staff Report and the Parliamentary 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 **Date 12 July 2017**
Comptroller and Auditor General
National Audit Office
157-197 Buckingham Palace Road
Victoria
London SW1W 9SP

3 Financial Statements

STATEMENT OF COMPREHENSIVE INCOME
for the year ended 31 March 2017

	NOTE	2016/17		2015/16	
		£000	**£000**	£000	£000
Income					
Trading Income	3.1				
Income from trading activities		**128,689**		124,344	
Income from Department of Health*		**28,604**		28,619	
Total Trading Income			**157,293**		152,963
Other income	3.2		**10,416**		10,182
Total income			**167,709**		163,145
Expenditure					
Staff costs	6	**(76,643)**		(71,926)	
Operating costs	7	**(77,245)**		(66,373)	
Total Expenditure			**(153,888)**		(138,299)
Operating Surplus			**13,821**		24,846
Finance income	8		**289**		569
Finance costs	8		**(46)**		(47)
Surplus for the financial year			**14,064**		25,368
Other comprehensive income					
Realised gain on inventories			**(118)**		(104)
Net gain on revaluation of property, plant and equipment			**50**		16,322
Total comprehensive income for the year			**13,996**		41,586

*Includes £7.0m (2015/16 £7.0m) of capital funding recognised as income in line with FReM.

The notes on pages 92 to 113 form part of these accounts.

STATEMENT OF FINANCIAL POSITION as at 31 March 2017

	NOTE	2016/17		2015/16	
		£000	**£000**	£000	£000
Non-current assets					
Property, plant and equipment	9	**113,188**		113,998	
Intangible assets	10	**8,352**		11,799	
Total non-current assets			**121,540**		125,797
Current assets					
Inventories	12	**5,806**		6,289	
Trade and other receivables	13	**21,762**		23,852	
Cash and cash equivalents	14	**111,814**		211,428	
Total current assets			**139,382**		241,569
Total assets			**260,922**		367,366
Current liabilities					
Trade and other payables	15	**(41,763)**		(145,775)	
Other liabilities	16	**(29,385)**		(30,675)	
Provisions	17	**(119)**		(992)	
Total current liabilities			**(71,267)**		(177,442)
Total assets less current liabilities			**189,655**		189,924
Non-current liabilities					
Other liabilities	16	**(5,349)**		(7,360)	
Provisions	17	**(2,112)**		(2,120)	
Borrowings	18	**(1,328)**		(1,328)	
Total non-current liabilities			**(8,789)**		(10,808)
Assets less liabilities			**180,866**		179,116
Taxpayers equity					
Public dividend capital			**1,329**		1,329
Reserves					
Revaluation reserve			**78,025**		78,097
General reserve			**42,470**		42,470
Income and expenditure reserve			**954**		954
Retained earnings			**58,088**		56,266
Total equity			**180,866**		179,116

Dr Ian Hudson
Chief Executive and Accounting Officer
Medicines and Healthcare Products Regulatory Agency
4 July 2017

The notes on pages 92 to 113 form part of these accounts.

STATEMENT OF CASH FLOWS for the year ended 31 March 2017

	NOTE	2016/17		2015/16	
		£000	**£000**	£000	£000
Cash flows from Operating activities					
Operating surplus		**13,821**		24,846	
Depreciation and amortisation		**11,672**		11,396	
Disposal of assets		**143**		8	
Impairment and reversals		**1,553**		2,697	
Realised gain on inventories	12	**(118)**		104	
Decrease in inventories	12	**483**		538	
Decrease/(Increase) in trade and other receivables	13	**2,090**		(11,110)	
(Decrease)/Increase in trade and other payables	15	**(2,865)**		1,144	
(Decrease)/Increase in other liabilities	16	**(3,301)**		361	
(Decrease)/Increase in provisions	17	**(881)**		526	
Net cash inflow from operating activities			**22,597**		30,510
Cash flows from investing activities					
Purchase of property, plant & equipment	9	**(7,075)**		(4,749)	
Purchase of intangible assets	10	**(1,986)**		(2,838)	
Net cash (outflow) from investing activities			**(9,061)**		(7,587)
Cash flows from financing activities					
Interest received	8		**289**		569
Interest paid	8		**(46)**		(47)
Dividend paid			**(113,393)**		(4,551)
Net cash (outflow) from financing			**(113,150)**		(4,029)
Net (decrease)/increase in cash and cash equivalents in the financial year	14		**(99,614)**		18,894
Cash and cash equivalents at the beginning of the financial year	14		**211,428**		192,534
Cash and cash equivalents at the end of the financial year	14		**111,814**		211,428

The notes on pages 92 to 113 form part of these accounts.

STATEMENT OF CHANGES IN TAXPAYERS' EQUITY
for the year ended 31 March 2017

	PDC[1]	Retained earnings	Reval. reserve[2]	General reserve[3]	I & E reserve[4]	Total
	£000	£000	£000	£000	£000	£000
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**
Changes in taxpayers equity for 2016/17						
Surplus for the year	-	14,064	-	-	-	14,064
Other changes						
Net gain on revaluation of property, plant and equipment	-	-	50	-	-	50
Realised gain on inventories - biological standards	-	-	(118)	-	-	(118)
Transfers	-	4	(4)	-	-	-
Dividend payable	-	(12,246)	-	-	-	(12,246)
Sub total	-	(12,242)	(72)	-	-	(12,314)
Balance at 31 March 2017	**1,329**	**58,088**	**78,025**	**42,470**	**954**	**180,866**

The notes on pages 92 to 113 form part of these accounts

Key
1 Public Dividend Capital represents taxpayers' equity in the Agency.
2 Revaluation Reserve
3 General Reserve is the balance brought over on transfer of NIBSC to MHRA.
4 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 adapted and interpreted by the 2016/17 Government Financial Reporting Manual (FReM) issued by HM Treasury and under an accounts direction given by H M Treasury under Section 4(6)(a) of the Government Trading Funds Act 1973.. 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 2016/17. The application of the following Standards as revised would not have a material impact on the accounts for 2016/17, 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 date 1 January 2018. At this stage management are not able to determine whether the adoption of this standard would have a material impact.
- IFRS 16 Leases: was issued in January 2016. Subject to the FReM, MHRA will first be required to apply it in the 2019–20 financial statements, although earlier adoption may be permitted. IFRS 16 will require the recognition of all leases on balance sheet, including leases for rented office space. A lease liability and the related right of use asset will be recognised at the present value of the lease payments payable over the lease term. This will be a change of accounting treatment with a material impact on the MHRA's financial statements when it is adopted in due course.

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 costs 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.

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 full valuation took place at 31 March 2013. Valuation is on an open market (existing use) basis except for buildings of a specialised nature, where a market value is not readily obtainable, which are valued on a depreciated replacement cost basis. In line with FReM, an interim professional valuation was carried out at 31 March 2016. Where no revaluation is carried out, 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.

Other property, plant and equipment and furniture & fittings 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 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. All other assets held for operational use are carried at depreciated historic cost, as a proxy for fair value, as they have short lives, or low values (or both).

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 amortisation 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. Amortisation 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
CPRD architecture	8 years
Sentinel architecture	15 years
Risk Based Inspection	5 years
Pharmacovigilance	8 years

CPRD architecture is the application developed to manage the collection of patient's data including features required to support 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. This agreement was subsequently updated in April 2014 to reflect changes in the governance, funding and accounting. 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 (£25.2M): 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 schedules completed by customers listing fees payable for each product.
- 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. A number of processes have been assigned to determine the stage of work completed. This determines the income to recognise and to defer.
- British Pharmacopoeia income is recognised as and when earned. This is at the point where orders are fulfilled.
- E-cigarettes income which is based on the number of notified products. A number of processes have been assigned to determine the stage of work completed. This determines the income to recognise and to defer.
- Miscellaneous income: This is non-statutory income recognised as and when earned based on when the service is provided.
- 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. This is at the point where orders are fulfilled.
- 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 from Government Banking Service.

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. 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. 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 UK Government observational and interventional research service, jointly supported 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.

	2016/17			
	CPRD*	**NIBSC**	**Regulator**	**Total**
	£000	**£000**	**£000**	**£000**
Income from external customers	**4,390**	**22,896**	**101,403**	**128,689**
Income from DH	**-**	**19,504**	**9,100**	**28,604**
Total income**	**4,390**	**42,400**	**110,503**	**157,293**
Direct costs	**(3,381)**	**(36,699)**	**(51,008)**	**(91,088)**
Indirect costs	**(963)**	**(5,478)**	**(55,936)**	**(62,377)**
Total expenditure	**(4,344)**	**(42,177)**	**(106,944)**	**(153,465)**
Segment operating surplus	**46**	**223**	**3,559**	**3,828**

* represents MHRA's 50% share of joint arrangement

** Excludes Other income £10.1m (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.

	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

3 INCOME

3.1 Trading income

	2016/17 £000	2015/16 £000
Income from fee charging activities*	**152,967**	149,547
Miscellaneous income	**4,326**	3,416
Total Trading Income	**157,293**	152,963

*Includes £14.5M (2015/16, £10.4M) 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 VAT.

Analysis of trading income

	2016/17 £000	2015/16 £000
Licenses and inspections	**45,005**	45,432
Service fees	**29,604**	30,529
European Medicines Agency (EMA)	**14,377**	10,439
Devices	**10,072**	9,809
Clinical trials	**3,315**	3,757
British Pharmacopoeia	**3,804**	3,481
Other trading income	**4,326**	3,417
NIBSC	**42,400**	41,318
CPRD	**4,390**	4,781
Total	**157,293**	152,963

3.2 Other income

The Trading Fund received financial assistance in the form of additional funding of £10.1M (£10.2M in 2015/16) from the Department of Health to offset the additional costs of dividend £4.4M (£4.6M in 2015/16) and depreciation £5.7M (£5.6M in 2015/16), resulting from the transfer of the National Institute for Biological Standards and Control to the Agency on 1 April 2013.

In addition, the National Institute for Biological standards received grant in aid (£350k) from the Department of Health, Social Services and Public Safety (DHSSPS) of Northern Ireland in respect of a contribution to the statutory duties undertaken.

4 CLINICAL PRACTICE RESEARCH DATALINK

Joint arrangement memorandum account

The Clinical Practice Research Datalink (CPRD) is the UK Government observational and interventional research service, jointly supported 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

	2016/17	2015/16
	£000	£000
Revenue	**8,781**	9,562
Expenditure		
Operating expenditure	**(5,283)**	(6,550)
Staff costs	**(3,404)**	(2,658)
Operating surplus	**94**	354

Statement of financial position

	2016/17	2015/16
	£000	£000
Non-current assets		
Tangible assets	**26**	34
Intangible assets	**7,600**	7,336
Current assets		
Trade and other receivables	**3,487**	1,638
Cash and cash equivalents	**10,831**	12,567
Current liabilities		
Trade and other payables	**(696)**	(969)
Other liabilities	**(3,279)**	(2,731)
DH contribution to joint arrangement	**(16,127)**	(16,127)
Assets less liabilities	**1,842**	1,748
Equity		
Surplus b/f	**1,748**	1,394
Surplus for the year	**94**	354
Total Equity	**1,842**	1,748

Statement of cash flows

		2016/17 £000		2015/16 £000
Cash flow from operating activities				
Operating surplus	**94**		354	
Depreciation and amortisation	**1,212**		856	
Impairment and reversals	**-**		484	
(Decrease)/Increase in trade and other payables	**(273)**		678	
(Increase)/Decrease in trade and other receivables	**(1,849)**		276	
Increase in other liabilities	**548**		1,434	
Net cash (outflow)/inflow from operating activities		**(268)**		4,082
Cash flows from investing activities				
Interest received	-		-	
Purchase of intangible assets	**(1,468)**		(1,682)	
Net cash (outflow) from investing activities		**(1,468)**		(1,682)
Cash flows from financing activities		**-**		-
Net (decrease)/increase in cash and cash equivalents in the financial year		**(1,736)**		2,400
Cash and cash equivalents at the beginning of the financial year		**12,567**		10,167
Cash and cash equivalents at the end of the financial year		**10,831**		**12,567**

Non- current assets

	2016/17 £000	2015/16 £000
Cost		
At 1 April 2016	**8,642**	7,459
Additions	**1,468**	1,678
Impairment*	**-**	(495)
At 31 March 2017	**10,110**	8,642
Amortisation		
At 1 April 2016	**1,272**	427
Impairment	**-**	(11)
Charged during the year	**1,212**	856
At 31 March 2017	**2,484**	1,272
Net Book Value at 31 March 2017	**7,626**	7,370

*Dataline software consultancy fees previously capitalised.

5 FINANCIAL OBJECTIVE

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

The requirement is that the Agency should be managed so that its revenue:

a) consists primarily of receipts in respect of goods and services provided in the course of its funded operations;

b) is sufficient, taking one year with another, to meet outgoings that are properly chargeable to revenue account and to achieve a surplus on ordinary activities before interest and dividends equivalent to at least 3.5% return on average capital employed.

Net asset values are shown in the Statement of Financial Position. The Agency is required to pay dividends and interest to HM Treasury via the Department of Health each year equivalent to the 3.5% required rate of return. The dividend payable is £12.2M (2015/16 £13.4M plus a special dividend of £100.0M).

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

	2016/17 £000	2015/16 £000
Wages and salaries	**58,726**	55,898
Social security costs	**6,364**	4,952
Other pension contributions	**11,712**	11,168
Sub-total	**76,802**	72,018
Less recoveries in respect of outward secondment	**(159)**	(92)
Total operating costs	**76,643**	71,926

See staff report page 80

7 OPERATING COSTS

	2016/17 £000	2015/16 £000
Computing	**33,229**	22,699
Other operating costs	**13,265**	15,162
Depreciation and amortisation	**11,672**	11,396
Supplies and services	**5,455**	3,777
Medicines testing and laboratory expenses	**5,790**	4,637
Accommodation	**5,362**	6,409
Travel and subsistence	**2,472**	2,293
Total operating costs	**77,245**	66,373

Other operatings costs include:	2016/17 £000	2015/16 £000
Operating leases	3,649	2,920
Contracted out services	3,637	2,947
Audit fees	110	108

8 FINANCE INCOME AND COSTS

	2016/17 £000	2015/16 £000
Finance income		
Interest received from Government Banking Service	**254**	478
Interest received others	**2**	0
Discounting of provision	**33**	91
	289	**569**
Finance costs		
Interest paid to DH	**(46)**	(47)
Net cash inflow from returns on investments and servicing of Finance	**243**	**522**

9 PROPERTY, PLANT AND EQUIPMENT

2016/17	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 2016	1,101	99,124	6,357	23,000	9,356	138,938
Additions	4,188	-	2,521	366	-	7,075
Reclassification	345	-	-	-	-	345
Transfers	(3,204)	1,906	323	975	-	0
Revaluation	-	-	-	116	-	116
Disposals	-		(740)	(1,118)	(7)	(1,865)
At 31 March 2017	**2,430**	**101,030**	**8,461**	**23,339**	**9,349**	**144,609**
Depreciation						
At 1 April 2016	-	-	4,610	13,909	6,421	24,940
Charged during the year	-	3,725	1,179	1,589	1,662	8,155
Revaluation	-	-	-	66	-	66
Disposals	-	-	(681)	(1,055)	(4)	(1,740)
At 31 March 2017	**-**	**3,725**	**5,108**	**14,509**	**8,079**	**31,421**
Net book value at 31 March 2017	**2,430**	**97,305**	**3,353**	**8,830**	**1,270**	**113,188**
Net book value at 31 March 2016	1,101	99,124	1,747	9,091	2,935	113,998
Asset financing:						
Owned						
Net book value at 31 March 2017	**2,430**	**97,305**	**3,353**	**8,830**	**1,270**	**113,188**

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	-	-
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
Elimination of accumulated depreciation	-	(10,991)	-	-	-	(10,991)
Revaluation	-	-	-	78	24	102
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

*Reclassification of assets
During the year 2015/16, 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

2016/17	Computer systems £000	AUC £000	Software Licences £000	Total £000
Cost or valuation				
At 1 April 2016	25,026	2,808	5,172	33,006
Additions	394	1,592	-	1,986
Transfers	843	(1,069)	226	-
Reclassification	-	(345)	-	(345)
Reversals	-	(1,553)	-	(1,553)
Disposals	-	-	(156)	(156)
At 31 March 2017	**26,263**	**1,433**	**5,242**	**32,938**
Amortisation				
At 1 April 2016	17,340	-	3,867	21,207
Charged during the year	2,781	-	736	3,517
Disposals	-	-	(138)	(138)
Amortisation at 31 March 2017	**20,121**	**-**	**4,465**	**24,586**
Net book value at 31 March 2017	**6,142**	**1,433**	**777**	**8,352**
Net book value at 31 March 2016	7,686	2,808	1,305	11,799
Asset financing:				
Owned				
Net book value at 31 March 2017	**6,142**	**1,433**	**777**	**8,352**

2015/16	Computer systems £000	AUC £000	Software Licences £000	Total £000
Cost or valuation				
At 1 April 2015	24,019	8,541	4,816	37,376
Additions	113	2,520	-	2,633
Transfers	1,143	(1,560)	417	-
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 1 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

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 2016/17 £000**	**Land and buildings 2016/17 £000**	Others 2015/16 £000	Land and buildings 2015/16 £000
Minimum lease payments	**42**	**3,649**	-	2,920
Total	**42**	**3,649**	-	2,920

Total future minimum lease payments				
Payable:				
Within one year	**27**	**4,255**	-	2,800
Within two to five years	**11**	**1,064**	-	2,100
Over five years	**-**	**-**	-	-
Total	**38**	**5,319**	-	4,900

Finance Leases

The Agency had no finance leases in 2016/17 (2015/16 Nil).

12 INVENTORIES

	31 March 2017 £000	31 March 2016 £000
Biological standards	**5,656**	6,232
Laboratory consumables and other stores	**150**	57
	5,806	6,289

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 2016-17 was £118k (£104k in 2015/16). Inventories consumed during the year amounted to £753k (2015/16 £1,229K).

13 TRADE AND OTHER RECEIVABLES

	31 March 2017 £000	31 March 2016 £000
Amounts falling due within one year:		
Due from the Department of Health (see 13.1 below)	**10,242**	10,182
Trade receivables	**3,151**	5,695
Other receivables	**1,412**	1,256
Accrued income	**4,355**	3,966
Prepayments	**2,521**	2,423
	21,681	23,522
Amounts falling due after more than one year:		
Prepayments	**81**	330
Total	**21,762**	23,852

Trade receivables are shown net of a provision for bad debts of £1.0m (31 March 2016 £0.8m) and credit notes of £0.2m (31 March 2016 £0.2m). See Note 17.

13.1 Amount Due from the Department of Health consists of:

	31 March 2017 £000	31 March 2016 £000
Accrued income	**176**	-
DH Funding for NIBSC*	**10,066**	10,182
Total	**10,242**	10,182

* see Note 3.2

14 CASH AND CASH EQUIVALENTS

	31 March 2017 £000	31 March 2016 £000
Balance at 1 April	**211,428**	192,534
Net change in year	**(99,614)**	18,894
Balance at 31 March	**111,814**	211,428
Made up of:		
Government Banking Service	**111,814**	211,428
Cash and cash equivalents*	**111,814**	211,428

* includes £12.6m held on behalf of CPRD joint arrangement

15 TRADE AND OTHER PAYABLES

	31 March 2017 £000	31 March 2016 £000
Amounts falling due within one year:		
Due to the Department of Health (see 15.1 below)	**12,530**	113,693
Payments received on account	**12,825**	14,762
Taxation and social security costs	**3,184**	2,780
Other trade payables	**626**	3,064
Other payables	**32**	105
Accruals	**12,566**	11,371
Total	**41,763**	145,775
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 2017 £000	31 March 2016 £000
Accruals	**284**	301
Special dividend*	**-**	100,000
Dividend payable	**12,246**	13,392
Total	**12,530**	113,693

* see Note 5

16 OTHER LIABILITIES

	Current		Non-Current	
	31 March 2017	31 March 2016	**31 March 2017**	31 March 2016
	£000	£000	**£000**	£000
Deferred revenue:				
Licence fees - applications and variations	**11,797**	14,237	**4,818**	4,496
Other fees	**3,241**	2,254	**531**	2,864
Others:				
DH Contribution to CPRD joint arrangement*	**14,347**	14,184	**-**	-
Total	**29,385**	30,675	**5,349**	7,360

*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, identified in Note 13, is reviewed each year and reflects the level of trade receivables 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 2.70% (short term).

	Current		Non-current	
	31 March 2017	31 March 2016	**31 March 2017**	31 March 2016
	£000	£000	**£000**	£000
EC grant refund	**119**	-	**-**	-
Dilapidations	**-**	992	**2,112**	2,120
Total	**119**	992	**2,112**	2,120

Movement in provisions

	Total
	£000
At 1 April 2016	**3,112**
Arising during the year	**-**
Used during the year	**(71)**
Provision not required written back	**(802)**
Unwinding of provision	**(8)**
At 31 March 2017	**2,231**
Expected timing of cash flows:	
Between 1 April 2016 and 31 March 2017	**119**
Between 1 April 2017 and 31 March 2020	**2,112**
Beyond 2020	**-**
Total	**2,231**

18 BORROWINGS

	Non-current	
	31 March 2017	31 March 2016
	£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 2016/17	**Less than one year**	**Between one and five years**	**More than five years**	**Total 2015/16**
	£000	**£000**	**£000**	**£000**	**£000**
Fixed interest rate					
3.50%	**1,328**	**-**	**-**	**1,328**	1,328
At 31 March 2017	**1,328**	**-**	**-**	**1,328**	1,328
At 31 March 2016				1,328	1,328

19 CAPITAL COMMITMENTS

Contracts entered into not provided for in the accounts

	Intangible 31 March 2017	**Tangible 31 March 2017**	Intangible 31 March 2016	Tangible 31 March 2016
	£000	**£000**	£000	£000
Contracted	**707**	**3,063**	5,143	3,398
Total	**707**	**3,063**	5,143	3,398

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.

In addition, the Agency has had various material transactions with other government departments and other central government bodies. Most of these transactions have been with Her Majesty's Revenue and Customs, Department for Work and Pensions and the Department for Business, Energy & Industrial Strategy.

During 2016/17, 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 and staff 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.

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.

	2016/17	2015/16
	£000	£000
Government Banking Service*	**111,814**	211,428
Total	**111,814**	211,428

* Includes £52k Proceeds of Crime Act funds which are the Agency's share of confiscated monies resulting from successful prosecutions and £132k Enforcement cash which is confiscated monies held pending a court decision.

Interest rate risk

The Agency's exposure to interest rate risk is negligible. The average total of loans, which are at a fixed rate of interest of 3.5%, held throughout the year was £1.328M (2015/16: £1.328M). This resulted in interest payable of £0.046M (2015/16: £0.047M) out of total expenditure of £153.9M (2015/16: £138.3M).

Currency risk

The level of currency risk is determined by the level of income generated by activity undertaken on behalf of the EMA. For 2016/17 this was £14.463M (Euro 16.779M) (2015/16: £10.347M; Euro 13.167M). This represents 8.6% (2015/16: 6.4%) of the total gross income for the year. The risk is mitigated by ensuring EMA euro receipts are paid into the sterling account and exposure is minimised.

Sensitivity analysis

Changes to the £ / Euro exchange rates will have an impact on EMA income. Fluctuations in the exchange rate will have the following impact on EMA income as at 31 March 2017:

	2016/17		2015/16	
	Increase	**Decrease**	Increase	Decrease
	£000	£000	£000	£000
Movement 1%	**(144)**	**146**	(102)	105
Movement 3%	**(421)**	**447**	(302)	320

Credit risk

Credit risk arises from accounts receivable. The Agency's exposure to credit risk arising from its operations is low as a large proportion of fees are paid up front and the level of aged debts is minimal (debts over twelve months amounted to £183k at year end).

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. Fees and charges are reviewed on an annual basis before being confirmed in the Fees Regulations.

22 EVENTS AFTER THE REPORTING PERIOD

The Agency's Trading Fund accounts are laid before the Houses of Parliament by the Department of Health. IAS10 requires the Agency to disclose the date on which the accounts are authorised for issue. This is interpreted as the date of the Certificate and Report of the Comptroller and Auditor General.

The Accounting Officer authorised these financial statements for issue on 12 July 2017.

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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