Medicines & Healthcare products Regulatory Agency

Annual Report and Accounts 2017/18




CPRD NIBSC MHRA

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Medicines and Healthcare products Regulatory Agency Annual Report and Accounts 2017/18

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Chairman's Foreword

As I write this foreword, 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. It 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 Agency's plans to prepare for the UK's exit from the EU continues to feature in the thinking of our staff and stakeholders. Throughout the year, the Agency has worked with our partners across Government as well as with our stakeholders to prepare for a managed transition after the UK's exit from the EU, where the Agency will have a different role in both global and European regional regulatory networks for medicines and medical devices.

Closely related to this is the Agency's five-year Corporate Plan (2018-2023), which was published at the beginning of the new financial year. The Corporate Plan sets the direction on what the Agency will do over the next five years to address proactively the uncertainties posed by the UK's exit from the EU. I would like to pay tribute to the Agency's staff who led on developing the Corporate Plan during a period of uncertainty. 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 the UK's exit from the EU to ensure we get the best outcome for the protection of public health for the UK.

Throughout the year I, along with Dr Hudson, 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 important Life Sciences Strategy. Additionally, we have met with industry trade associations, the Presidents of the Royal Medical Colleges, and a range of visitors from overseas. Officials from the Devolved Administrations continue to attend our Board meetings as observers, and during the coming summer, Dr Hudson and I will again visit the Devolved Administrations for a series of bilateral meetings with the Chief Medical Officers and Chief Pharmaceutical Officers of Northern Ireland, Scotland and Wales. This is something to which I attach high importance.

There are significant changes ahead, not least the UK's exit from the EU, but I am confident the Agency, with its globally unique concentration of expertise in data, standards, and regulation will continue to offer our customers a full range of services and products which is not replicated anywhere else in the world. In addition, by 30 June, the Agency will have moved to its new offices in Canary Wharf, which is something a great deal of work and planning has gone into over the past two years; and throughout the coming year the Agency will continue the roll-out of its Operational Transformation programme.

There will also be the "routine" work of the Agency of regulating medicines and devices as well as developing our other services, including 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 we face 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 fifth 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 2017/18 has been a very busy and, at times, difficult year, there has been one subject that has been ever present in the minds of staff and the wide spectrum of our stakeholders: the UK's exit from the EU. The Agency's Brexit task force (involving colleagues from across all parts of the Agency) continues to lead work on examining options and opportunities, working with stakeholders that feeds into broader Government discussions as the UK prepares to leave the EU. The exact nature of the Agency's relationship with EU regulators after the exiting the EU will be determined through the negotiations, but it is the Government's intention to retain a close working partnership with both the EU and other global regulators in the interest of ensuring patients continue to have time access to safe medicines, medical devices and medical innovations. This is something the Agency will work closely with our partners across Government to achieve.

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. 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). In November, the Government's response to the recommendations that came out of the independent Accelerated Access Review was published. The Agency contributed significantly to the Review, which aimed to speed up access to innovative healthcare and technologies and to improve efficiency and outcomes for NHS patients. We are now taking forward work on the Review's recommendation.

The Agency continues to be very busy internationally with a wide range of work, which includes the quarterly cycle of the Heads of (European) Medicines Agencies meetings. We continue to work 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. One of those events was the 40th meeting of the Competent Authorities on Medical Devices (CAMD), was held at London's County Hall which the Agency was heavily involved. The year was also marked by the annual Global Regulators Summit in Japan, and meetings of the International Coalition of Medicines Regulatory Authorities (ICMRA), which the Agency chairs. These are networks through which we lead on a range of initiatives. The CAMD meeting coincided with the Medical Devices Regulations and In Vitro Diagnostic Regulations coming into force on 25 May 2017.

In January 2018, I joined a UK trade delegation to China that was led by our Prime Minister. During the visit I signed a new Memorandum of Understanding with China's State Food and Drug Administration; the signing ceremony took place in the presence of the UK's and China's prime ministers in the Great Hall of the People in Beijing. In November, the Agency received a grant from the Bill and Melinda Gates Foundation towards the cost of capacity building in pharmacovigilance in low and middle-income countries. This we are doing in

collaboration with the World Health Organisation.

The past year has seen the Agency make a significant contribution to the fight against fake medicines and medical devices. During Operation Pangea X from 12-19 September 2017, which Interpol coordinated, and in which the Agency played a key role, a record number of 25 million illicit and counterfeit medicines were seized worldwide. Medical devices were also seized, including dental devices, surgical equipment and condoms.

During 2017/18, NIBSC developed many new and replacement biological standards, and standards sales have continued to be strong across many areas. Control testing also continues to increase. The Clinical Practice Research Datalink (CPRD) has continued to make excellent progress, working with GP software providers to increase coverage of the population enabling more linkages of data, and developing the clinical trial offering. In March 2018, the CPRD marked a significant milestone: one thousand GP practices had signed up to currently contributing near real-time data to CPRD, ie 1 in 10 GP practices across the UK.

In February 2018, the Government asked Baroness Julia Cumberlege CBE to lead a review into how the NHS responds to safety concerns raised by patients about medicines or medical devices. Looking ahead, the Agency will of course respond to any requests for input for the Review. Also, during the year, the Agency took forward work on implementing three key EU regulations: the revised Clinical Trials Regulations, the Falsified Medicines Directive, and the Medical Devices and in-vitro diagnostics (IVD) Regulations. This is important work that will continue into 2019.

During the year, work on the Agency's Patient Safety and Vigilance Strategy has progressed well. This is a project that is led by jointly by Devices Division, and Vigilance and Risk Management of Medicines Division. A Health Summit, involving stakeholders, including key healthcare partners, took place in January, which was rated a major success.

We have also made good progress with 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.

The 2017 MHRA Annual Lecture ('Disease knows no borders: why global health must survive political upheaval'), which was delivered by Dr Jeremy Farrar of the Wellcome Trust, proved to be a great success. The lecture had to be postponed from 8 June (the General Election day) to October.

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. I was very pleased to see that the Agency's high response and engagement rates to the annual Civil Service People Survey have been maintained during a period of considerable change and uncertainty. This is something the Corporate Executive Team and I are very keen to build on, recognising that there is still much to do to address the feedback we received from staff. 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 several staff and members

of the Agency's expert advisory committees, as well as welcomed new colleagues. At the turn of the year, Dr Peter Nightingale stepped down as the founding Chair of the Devices Expert Advisory Committee (DEAC), whose leadership, clinical expertise and chairing skills the Agency will greatly miss. Thanks to Dr Nightingale, DEAC has made a significant contribution to the safety of medical devices in the UK and beyond. Dr Nightingale's successor will be in post by the summer. In March 2018, Gerald Heddell, Director of Inspection, Enforcement and Standards Division, retired after fourteen years of distinguished service to the Agency, to be succeeded on 1 April by Dr Samantha Atkinson, formerly Director of Business Transformation.

Finally, in June 2017, I was delighted to learn that our Chairman, Sir Michael Rawlins, was appointed Knight Grand Cross of the Most Excellent Order of the British Empire (GBE) in the Queen's Birthday Honours for services to the safety of medicines, health and innovation. The following month, Sir Michael was reappointed as the Chairman for a second three-year term from 1 December 2017.

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 Bruce Campbell, Stephen Lightfoot, Deborah Oakley, Dr Ian Hudson, Professor David Webb, Professor Sir Alex Markham

Seated: Dame Valerie Beral, Martin Hindle, Professor Sir Michael Rawlins GBE, Dr Barbara Bannister, 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 and Social Care (DHSC) and operates as a government trading fund. The Secretary of State for Health and Social Care 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:

- The Clinical Practice Research Datalink (CPRD) is a research data service that supplies anonymised NHS clinical data for public health research.
- The National Institute for Biological Standards and Control (NIBSC), a global leader in the standardisation and control of biological medicines.
- The Medicines and Healthcare products Regulatory Agency (MHRA), the UK's regulator of medicines, medical devices and and blood components for transfusion, responsible for ensuring their safety, quality and effectiveness.

Agency operational funding is structured as follows:

- CPRD provides services for observational and interventional research, with a 50:50 investment contribution by the National Institute for Health Research and the Agency.
- NIBSC derives approximately 60% of its non-capital revenue from fees charged for services, including the sale of biological standards, and from research funding. DHSC provides the remaining 40% to finance its important public health functions.
- 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 DHSC.
- 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

CPRD is the UK's pre-eminent 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), carrying out Official Control Authority Batch Release (OCABR) testing for biological medicines within the framework of the EU. NIBSC also carries out world class research and is the home of the UK Stem Cell Bank.

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.

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, for public health research to ensure the safety and effectiveness of medicines and to provide evidence to inform clinical guidance and care delivery.

Review of the year 2017/18

The Agency has a five-year Corporate Plan cycle, and the start of this reporting year coincided with the final year of our 2013-2018 plan. Each year a Business Plan is developed to identify the objectives and activities for the year ahead which will contribute to meeting the overarching Corporate Plan objectives. The information in this section reflects the five Corporate Plan (and thus Business Plan 2017/18) themes, we have set out below the key activities and achievements in each of the five areas over the year.

We recently published our new Corporate Plan 2018-23 which sets out to Government, strategic partners and customers our ambitions on the added value which the Agency will bring to improving public health over the next five years. It sets out the key actions and activities which will be tracked through our annual business plans. It seeks to build on our unique capabilities and drives a competitive global edge that works for industry and the Agency, so we can flourish as an influential and respected regulator within the UK and internationally.

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. We have sought to establish strong, effective and purposeful partnerships.

- The Agency has worked closely with the Department of Health & Social Care, across Government as well as with industry, research and patient representative groups to develop models for the future regulation of medicines and medical devices for all conceivable scenarios resulting from the UK's exit from the EU. We remain firmly focused on protecting public health, facilitating innovation, and minimising burden on industry to maintain the UK's position as an attractive global regulator.

International work

- We strengthened our focus on growing the UK's role in international fora and further developing bilateral relationships. This involved:
    - » Signing a new Memorandum of Understanding (MoU) with the China Food and Drug Administration (CFDA) in China, signed in front of the Prime Minister and Premier Li.
    - » A delegation from National Institute for Food and Drug Control (NIFDC) China visited NIBSC to deepen the cooperating relationship. Further collaboration opportunities. were identified in areas such as monoclonal antibodies, in-vitro diagnostic (IVD) products, and pseudotype viruses.
    - » Following the MoU signed with the Korean National Institute of Food and Drug Safety Evaluation (NIFDS) NIBSC hosted representatives from the Korean Ministry of Food and Drug Safety (MFDS) and SK Chemicals, which focused on Cell Culture derived Influenza vaccines and emerging infections. NIBSC also had representation at a WHO Implementation Workshop on the Quality, Safety and Efficacy of Typhoid Conjugate Vaccines in South Korea, in November.
    - » Serving as Chair of the International Coalition of Medicines Regulatory Authorities (ICMRA), including a successful Kyoto meeting

in conjunction with Japan's Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA), with greater co-ordination of work, internally and externally.

  - » Creating a new International Office to co-ordinate our expanding focus in this area.

National Strategy

- This year we enhanced our national strategy for collaboration and engagement with key partners and stakeholders to facilitate better regulation, innovation, and delivery of our strategic priorities. This includes new partnership agreements/MoUs signed with:
  - » Care Quality Commission (CQC).
  - » Food Standards Agency (FSA).
  - » Health Improvement Scotland (HIS).
  - » Health Inspectorate Wales (HIW).
- We also held constructive quarterly meetings with the Devolved Administrations, NICE (National Institute for Health and Care Excellence) and our cross-industry Medicines Industry Liaison Group (MLG).

Collaborative partnerships

We work in collaboration with others in our sector including academia, health and social network partners and other regulators both in the UK and worldwide to help us broaden our influence and deliver positive outcomes.

- British Pharmacopoeia (BP) is very active internationally and we continue to support the global pharmaceutical industry through numerous presentations at events in Brazil, China, Europe and the US, helping ensure that the BP is the international partner of choice.
  - » We have continued to build our relationships with international peers to collectively consider the role of pharmacopoeias and public standards in supporting complex and innovative biological medicines and advanced therapies.
  - » We have collaborated with the Therapeutic Goods Administration (TGA) in Australia as part of our study into the application of Quality by Design (QbD) to analytical procedures.
- Our Enforcement Group has representation at the World Health Organisation (WHO) (Member State Mechanism on Substandard and Falsified Medicines, Council of Europe (Expert Committee on Falsified and Counterfeit Medical products) and the Heads of Medicines Agencies Working Group of Enforcement Officers.
- Our scientific expertise in the licensing of medicines continues to be held in high regard. This is reflected in the work we have led this year, as illustrated in the following graphic.
- Through our NIBSC centre we have continued to strengthen relationships with key academic and public health organisations through their involvement in working groups and research projects.
- We are supporting the Coalition for Epidemic Preparedness Innovations (CEPI) programme to develop vaccines for emerging pathogens in

preparedness for potential outbreaks, with representatives on the Joint Coordination Group and Standards and Assays Working Group and the production of reference materials for Middle East Respiratory Syndrome Corona Virus (MERS-CoV), Nipah Virus (NiV) and Lassa fever.

- We are collaborating with several institutes to establish a UK Centre of Excellence for Engineering Biology, Metrology and Standards. The initiative aims to support the fast-growing UK synthetic biology industry with a 'toolbox' of metrology and technical standards.
- We are one of 26 organisations promoting innovative vaccine research and development through the new European Commission (EC)-funded initiative TRANSVAC2.
- We are a partner on the European Bank for induced Stem Cells (EBiSC) project that aims to provide high quality induced pluripotent stem cell (iPSC) lines with a range of diseases, to researchers.
- In January 2018 NIBSC and the Agency signed the Concordat on Openness with Understanding Animal Research (UAR), agreeing to become more open about our use of animals to support the Agency's vital role in protecting and improving public health and the work of NIBSC towards the principles of '3Rs' (Replacement, Reduction, and Refinement).

Grant funding and research projects

- NIBSC will work with University of Oxford and University College London to develop a strategy for efficient delivery of lentiviral vectors to primary T-cells in-vivo for human immunodeficiency virus (HIV) therapy as part of a one-year grant from the American Foundation for AIDS Research (amfAR).
- We made a successful application to the European Cooperation in Science and Technology (COST) Action Proposal to ENOVA "European Network of Vaccine Adjuvants". The goal of the network is to establish a platform to share available knowledge on adjuvants and vaccine formulations and to coordinate the translation into successful, safe and innovative vaccines.
- NIBSC has continued its work on polio vaccines this year. This has included:
    - » A grant from Bill and Melinda Gates Foundation to develop protocols and optimise methods for direct detection of poliovirus from environmental samples. This project aims to improve understanding of poliovirus transmission in humans and refine the detection and identification of poliovirus strains in the environment and clinics.
    - » A research publication, in collaboration with Public Health England, about monitoring poliovirus vaccine strains found in sewage samples, which supports the development of a sensitive surveillance system to detect circulating wild and vaccine-derived poliovirus strains in the environment.
    - » Progressing other candidate polio vaccines and the publication of new research to develop safer polio vaccines using virus-like particles.

- Through NIBSC we coordinated the four-year EC FP7 infrastructures project European Research Infrastructures for Poverty Related Diseases (EURIPRED). The project, which concluded in October, aimed to collect clinically relevant materials at biobank sites around the world and create a suite of reagents that could be made available to researchers to support research into the Poverty Related Diseases such as Tuberculosis, Hepatitis B/C, Malaria and HIV.
- Our NIBSC centre received funding from Innovate UK to establish model systems for evaluating the protective efficacy of serological responses generated by experimental Chikungunya Virus vaccines. We also participate as part of a hub to advance the manufacture and deployment of cost-effective vaccines such as rabies and chikungunya.
- This year NIBSC published a total of 72 papers in scientific journals, demonstrating the importance of the research we undertake and facilitate.
- Work took place this year to establish and evaluate novel approaches for evaluating or predicting immunogenicity and immune-toxicity of Biological therapeutics in human; using a study of immune responses in the humanised mouse immune system model involving primary human hematopoietic cells for investigation of a range of biologics including:
    - » Stem cells.
    - » Immune-check-point tumour therapeutics.
    - » Novel targeted adjuvants.
    - » Vaccines against human pathogens such as malaria and Tuberculosis (TB).
- Progress has been made in reconstituting human immune cells in mice and work is under way to look at responses to therapeutic antibody and lentiviruses.
- NIBSC contributed to the establishment of bioassay standards for biosimilar monoclonal antibodies, establishing two International standards for Rituximab and Infliximab.
- In 2017 NIBSC was involved in work to develop a forum of public sector stakeholders to drive forward the defence of the role of public standards in the Biosimilars environment.

Paediatric Regulation

- In 2017 the European Commission published its report on the impact of the EU Paediatric Regulation, ten years after its implementation. Prior to 2007 the development and testing of paediatric medicines was unsatisfactory and needed to be incentivised as paediatricians often turned to off-label prescribing of adult medicines without evidence-based dosage or age-appropriate formulations, risking inefficacy or serious side effects. The report has found that:
    - » Overall the regulation has been successful at greatly increasing the development and licensing of paediatric medicines in the EU, including the UK, with paediatric medicine development now an integral part of overall medicine development.

  - » Our MHRA centre has made a strong contribution to decisions on the development of paediatric medicines at European level through the provision of delegates and UK experts to the Paediatric Committee (PDCO), its working-groups and ad hoc groups.
  - » The Regulation has led to an increase in prescribing of approved paediatric medicines with more than half of the respondents to a survey on prescribing habits indicating that medicines now prescribed are those licensed for children.
  - » The report acknowledges that further focus is needed on paediatric-only medicines development. The proportion of clinical trials that include children has significantly increased and we play a leading role through the NIHR Clinical Research Network (CRN).
  - » The EU Regulation has fostered pan-European expert discussion about the optimal design of paediatric trials, and we have led work on trial preparedness. The report concludes that the Regulation was both needed, and effective at boosting development of paediatric medicines.

- We conducted a Post-implementation review (PIR) of the Human Medicines Regulations 2012, which included a public consultation exercise and industry engagement. The Regulatory Policy Committee endorsed the review's finding that the 2012 Regulations remain fit for purpose, awarding it a 'green' rating.
- This year we have continued to chair the Competent Authorities for Medical Devices (CAMD) Executive Group, which has overseen working groups that have been inputting into the implementation of the new EU regulations for medical devices and in vitro diagnostic devices. Through CAMD we have led a European Joint Action targeted at improving market surveillance processes and practice across the system and played a leading role in the creation of a European Implementation Roadmap. The engagement with European stakeholders in creating the roadmap ensures it is a tool which all parts of the system can sign up to, supporting the best utilisation of resource and expertise and creating a consistent approach to implementation across Member States. We are also a member of the Transition Subgroup, which has been tasked with interpreting the transition-related provisions. This includes identifying areas with the potential for inconsistent application, providing recommendations on interpretation, and, where appropriate, seeking legal input to underpin proposals.

Enabling innovation

Within this theme the 2017/18 Business Plan identified our desire to support innovation and growth in Life Sciences, to support innovative regulatory and legislative measures, to continue our focus on real world evidence and data and to look to new areas of scientific development, research and horizon scanning.

Government's Life Sciences Strategy

- Building on our track record in innovation and early access to medicines, we played a key role supporting the Government's Life Sciences Industrial Strategy (August 2017), particularly with respect to clinical trials and accelerated product licensing, and its new Accelerated Access Collaborative.

Implementation of the new EU Regulations for Medical Devices and In Vitro Diagnostic device legislation

- We have continued the implementation of the new Medical Device and In Vitro Diagnostic device (IVD) legislation. This included:
    - » Publishing an interactive Introductory Guide to the regulations in August 2017, aiming to help new manufacturers who may be looking at the regulations for the first time, and also experienced manufacturers to navigate the changes in the new regulations.
    - » Continuing to collaborate with other member states to deliver on implementation priorities at a European level, as well as becoming more involved in international programmes of work, through the International Medical Device Regulators Forum (IMDRF) and the Medical Device Single Audit Programme (MDSAP).
    - » We are leading the EU task force that is working towards a consensus on implementation of the new regulations (which introduce a new definition and conformity assessment procedure) for companion diagnostic IVDs and we have submitted an explanatory article commissioned for The Organisation for Professionals in Regulatory Affairs (TOPRA) Regulatory Rapporteur journal.
    - » The launch of a consultation on our guidance for health institutions wishing to apply the exemption set out in the new regulations.
    - » We are leading the EU task force which is developing guidance on the clinical evidence needs for IVDs in the new regulations, including the clinical evidence needs for genomics, bioinformatic software and companion diagnostics.
    - » Ongoing work with the UK bioinformatics community to develop tactics for appropriate application of the IVD regulations, recognising that the appropriate regulation of bioinformatics software is critical to the success of a UK genomics strategy.
- Our Early Access to Medicines Scheme (EAMS) continues to supports access to innovative medicines for patients with life threatening or seriously debilitating conditions when there is a clear unmet medical need; and EAMS continues to be a success.

Promising Innovative Medicine (PIM) designation which indicates a product may be eligible for EAMS based on early clinical data.

EAMS scientific opinion, which describes risks and benefits and supports the prescriber and patient in making a decision on using the medicine.

This year we reach a significant milestone of PIM designations, since the scheme's launch in 2014.

- We have acted as rapporteur or co-rapporteur this year in the authorisation of a number of new medicines across Europe. Including:
  - » Alofisel (darvadstrocel) was granted as an advanced therapy for the treatment of complex perianal fistulas in patients with Crohn's disease.
  - » Jorveza (budesonide) was granted under the accelerated assessment process to treat eosinophilic esophagitis, a rare inflammatory condition of the oesophagus
  - » Verkazia (ciclsoporin) was granted under the accelerated assessment process to treat severe vernal keratoconjunctivitis in children and adolescents
  - » Maviret (glecaprevir / pibrentasvir) and Vosevi (sofosbuvir / velpatasvir / voxilaprevir) was granted under the accelerated assessment process for the treatment of chronic hepatitis C virus (HCV) infection

  - » Spherox (spheroids of human autologous matrix-associated chondrocytes) was granted as an advanced therapy to treat adult patients who have symptomatic articular cartilage defects in the knee where the size of the affected area is no larger than 10 cm✣
  - » Spinraza (nusinersen) was granted under the accelerated assessment process to treat patients with spinal muscular atrophy (SMA)
  - » Brineura (cerliponase alfa) was granted under the accelerated assessment process to treat neuronal ceroid lipofuscinosis type 2 (CLN2) disease.
- Our Innovation Office celebrated its five-year anniversary in March, handling a further 148 enquiries this year, giving a total of 572 since inception. It continues to diversify the support offered to innovators. It now includes a Regulatory Advice Service for Regenerative Medicine, a collaboration with other UK regulators in the field of advanced therapies. Through the Innovation Office we are currently undertaking a series of meetings with a government-funded academic-industry partnership to discuss:
  - » Automated clinical pharmacy (a process by which labelled investigational medicinal products are made to order within a short timeframe).
  - » The creation of a manufacturing facility dedicated to innovation.
  - » Potential uses for patient apps.

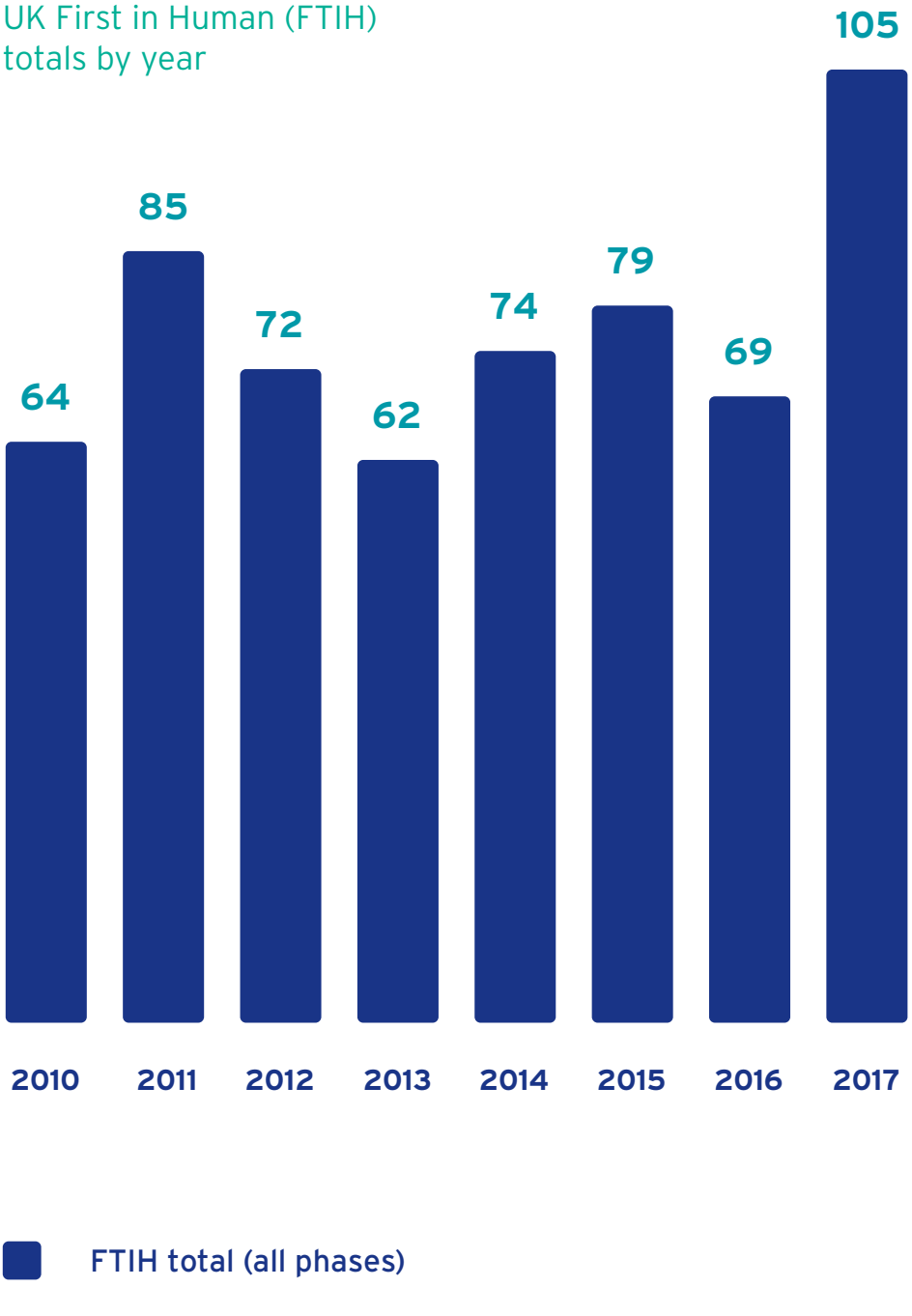
Clinical trials

- Our Clinical Trials unit (CTU) has remained at the forefront of trial innovations. Examples of the range of applications for innovative studies it assessed include:
  - » Its first Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) genome editing technology trial.
  - » Two faecal microbiota transplant trials.
  - » A gene therapy trial for Retinitis Pigmentosa that delivers a photoactivatable protein needs a device with a certain light intensity to work.
- The unit has made a significant contribution to the harmonisation of multi-national clinical trial assessment. In 2017, we participated in 116 voluntary harmonisation procedures (VHP) of multi-EU Member State clinical trials and acted as Reference National Competent Authority (Ref-NCA) for 34 procedures (~29 % of the VHPs MHRA were involved in. MHRA were included in more VHPs than any other NCA).
- The number of trials of investigational medicinal products has grown with encouraging increases in the innovative areas of phase 1 and particularly first-in-human trials:
  - » Increase in total trial numbers from 978 in 2016 to 1,000 in 2017
  - » Increase in phase 1 studies from 143 in 2016 to 167 in 2017
  - » Increase in the number of first-in-human studies from 69 in 2016 to 105 in 2017

- CTU assessors 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 considers the lessons learnt from a first-in-human clinical trial in France where a volunteer died. The revised guidance was presented to the European Commission in May 2017 prior to adoption in June 2017. There was a concern that the updated guidance would lead to increased regulatory burden for sponsors of first-in-human or early stage trials which might lead to a decrease in numbers. However, since the guidance largely represents current UK practice, feedback from our stakeholders has been largely positive and indeed we have seen a large increase in the numbers of first-in-human studies this year.

  » In 2017, CTU assessed almost 50% more first in human trials than the previous year.

UK First in Human (FTIH) totals by year



- In 2014 the Innovative Medicines Initiative (IMI) WEB-RADR project was established with an international consortium led by MHRA to evaluate the opportunities of mobile technologies and social media for pharmacovigilance. This year the project:
  - » Re-platformed the mobile reporting apps to reduce maintenance cost and effort and facilitate adoption of the technology by new partners.
  - » Had numerous policies around use of both social media and mobile apps ratified by the project leadership. These are planned for consideration for inclusion in updated EU Good Vigilance Practice guidance modules later in 2018.
  - » Has successfully bid for additional 'exploitation' funding from IMI, which will see the WEB-RADR2 project enhance the mobile app platform to enable components to be integrated into other health apps and websites and facilitate exchange of information between the regulatory system and electronic healthcare record systems through delivery of mapping between core medical and regulatory terminologies.
- NIBSC hosted the Standardisation of Genomic Amplification Techniques and Serology/ Standardisation of Infection Diagnostics (SoGATS/SID) meeting in June that addressed topics such Next Generation Sequencing (NGS) in the clinical setting, bacterial molecular diagnostics, and addressing serological issues.
- Following recommendations to invest in research into the role of the gut microbiome in human disease, NIBSC have:
  - » Developed a new ribosomal ribonucleic acid (rRNA) assay and a metagenomics sequencing assay for analysis of the gut microbiome.
  - » Produced a 10 strain lung microbiome DNA reference material in collaboration with PHE Colindale and University of East Anglia.
  - » Started a large microbiome study of inflammatory bowel diseases (IBD) with Warwick Medical School,
  - » Initiated a Microbiome Vaccine Research Program to investigate the use of commensal gut microbiome strains as vaccine delivery systems.
- NIBSC have developed several physicochemical assays to assess Group B Streptococcus (GBS) conjugated polysaccharides. To facilitate measurement of antibody response to GBS vaccines and standardisation using an ELISA/Multiplex luminex assay, NIBSC have prepared and characterised 5 different serotypes of GBS biotin-polysaccharide conjugates and sent them for evaluation in the ELISA assay.

Reclassification

- In 2014 a UK stakeholder Platform on Reclassification of prescription medicines was set up to consider how to maximise the input from stakeholders to the process of reclassifying medicines, analysing all aspects of the reclassification process. Key outputs include a re-design of the public consultation process and the introduction into the assessment process of ad hoc Stakeholder Groups for innovative reclassification applications. During 2017 three innovative reclassification applications were approved:

- Maloff Protect Tablets containing atovaquone 250mg/proguanil 100mg for the prevention of malaria in adults;
- Dovonex Psoriasis cream and ointment containing 50 micrograms/g calcipitriol for the treatment in adults of mild to moderate plaque psoriasis which has been previously diagnosed by a doctor in adults;
- Viagra Connect tablets containing sildenafil 50mg for the treatment of erectile dysfunction in adult men.

The Clinical Practice Research Datalink

4 million

more patients have been added to the CPRD database bringing the total number of patient lives on the database to 26 million.

42%

increase in the number of GP practices signed up to CPRD.

294

new observational research studies using CPRD data approved during 2017/18.

6 million

recruitment pool of registered patients.

Over 200

peer-reviewed publications from research using CPRD data. Bringing the total since CPRD was established to more than 2,000 publications.

7.8%

growth in CPRD's customer base with more than 83 unique clients based in the UK and internationally.

- Over the course of this year, CPRD has continued to grow its data and services to support public health research by:
  - » Signing-up more than 300 practices to its GP network, bringing the total to over 1,000 GP practices (representing 1 in 10 practices in the UK) to contribute anonymised patient data to CPRD.
  - » Launching a new primary care database for public health research (CPRD Aurum) offering customers access to data from GP practices using EMIS GP software for the first time. Developed in partnership with EMIS, the GP practice software provider, the database allows CPRD to link patients to other health-related datasets and enables GP practices to participate in CPRD-supported real world clinical studies.
  - » Increasing the number of data sets routinely linked to primary care data to 11, including cancer chemotherapy and mental health data. These enable CPRD to provide a fuller picture of the patient care record to support vital public health research, informing advances in patient safety and delivery of care.
  - » Providing, in partnership with the Royal College of GPs, confidential bespoke practice and patient-level drug prescribing reports to contributing GP practices to facilitate improvements in patient care.

Horizon scanning

- There has been a big move forward this year in the horizon scanning work across the Agency, with a new Agency Horizon Scanning Strategic Lead in post and based at NIBSC. Horizon scanning is important in future-proofing the Agency and ensuring that we stay up-to-date with emerging trends in products and technologies that are likely to have a major impact on the development of medicines and diagnostics.

Vigilance

- The Business Plan identified our overall goal within this theme which was to continue to play a leadership role in the development of EU and global networked vigilance for medicines and devices to enhance public safety. Delivery of the Patient Safety and Vigilance Strategy would form a key part of this.

Patient Safety and Vigilance Strategy

- The Patient Safety and Vigilance Strategy, set up to pursue a common excellence model for patient safety and vigilance for both medicines and devices, continues to be a high priority for the Agency with the ultimate goal of strengthening patient safety systems. There are three project teams looking at i) incident reporting and signal detection; ii) risk benefit assessment and iii) improving delivery, targeting and audit of safety messages and risk communication.
    - » Work has been progressing to develop signal detection methodologies for medical devices, and the recommendations of an independent technical report are being taken forward.
    - » Working with 13 key healthcare partners, we organised a Health Summit in January 2018, where health organisations discussed how to improve the impact of safety messaging in the healthcare sector and shared ideas for a strategy to deliver streamlined and risk-prioritised safety messages on medicines and medical devices.
- We are undertaking further work with the Bill and Melinda Gates Foundation, having been awarded a grant to strengthen capacity in pharmacovigilance in low and middle- income countries (LMIC). The Agency will be working alongside WHO and other partners in areas such as:
    - » Adverse drug reactions (ADR) reporting
    - » Signal assessment and risk communication with a focus on local legal and regulatory frameworks
- There will be three product and vaccine-specific pilot programmes running in a number of countries in Africa, Asia, Europe and South America.
- Through our NIBSC centre we have continued to support the global vaccine response against both seasonal and pandemic influenza in our role as a WHO Essential Regulatory laboratory (ERL), organising two meetings for WHO ERLs, collaborating centres and vaccine manufacturers and producing candidate vaccine virus strains in response to the Southern Hemisphere strain selection, and for a highly pathogenic influenza strain.
- In November 2016 we developed and led a European-wide social media campaign to improve the reporting of adverse drug reactions (ADRs). During the campaign period we saw increased reporting: 11% in Europe and 17% in the UK.
    - » The success of that work has been recognised this year, with the campaign winning the 2017 Public Relations and Communications Association (PRCA) best health and well-being campaign and was a Bronze winner at the Government Communications Service awards.
    - » We ran the campaign again in November (2017), which we led and co-ordinated alongside the WHO's Uppsala Monitoring Centre, it involved

27 medicines regulators across the globe - reaching 2.3 million people.

» In the UK, it helped to increase reporting by 16% compared to the previous year.

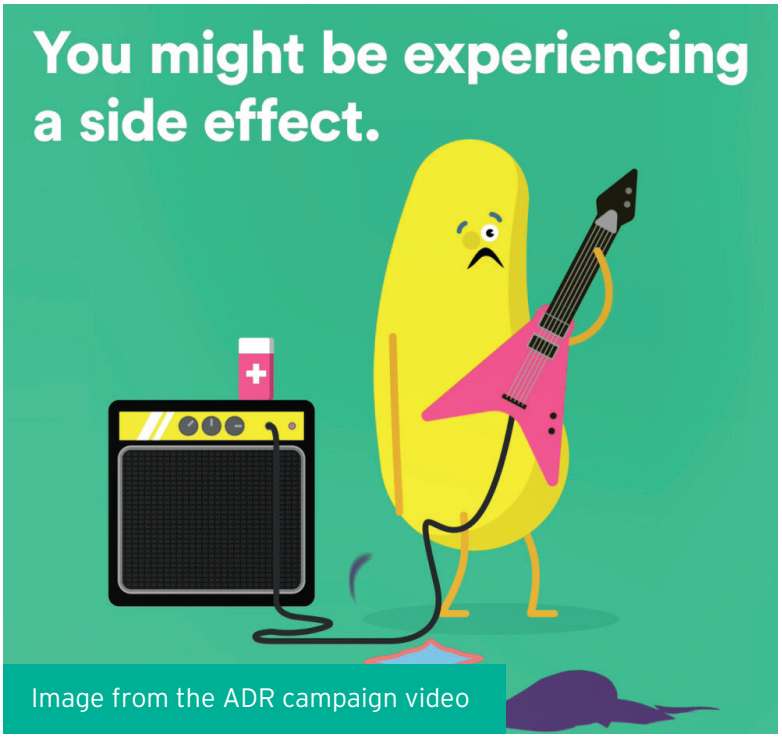


Image from the ADR campaign video

- Suspected ADR reporting figures are at the highest since the Yellow Card Scheme was established over fifty years ago. The MHRA and its five regional Yellow Card Centres have been working hard to improve the quality and increase the number of suspected ADR reports.
- We have completed the implementation of the Tobacco Products Directive, fulfilling our responsibility as the Competent Authority to establish a notification scheme for electronic cigarettes and refill containers. We continue to process and publish notifications for electronic cigarette products to be supplied to the UK market. We monitor the safety in use of these products via our Yellow Card reporting portal which accepts reports about suspected adverse events from healthcare professionals, consumers and Trading Standards officers. We have also worked with Trading Standards to support business compliance and enforcement action in the retail sector.
- In 2014 the SCOPE Joint Action was set up under MHRA leadership to help European medicines regulators strengthen national pharmacovigilance systems and build capacity for pharmacovigilance. The SCOPE initiative completed on time in 2017, delivering a variety of tools such as guidance documents and pharmacovigilance training materials (eg e-learning modules), available on the SCOPE website. Work has continued to communicate the availability of these materials and to embed their use via the EU Network Training Centre hosted by the European Medicines Agency and via incorporation into a pharmacovigilance curriculum under development for National Competent Authorities.

- As part of the SCOPE project, a 45-minute e-learning package about ADR reporting was developed for healthcare professionals which achieved the highest order of accreditation from the European Accreditation Council for Continuing Medical Education (EACCME®). Doctors across the EU are awarded an EACCME credit for Continuing Medical Education or Continuing Professional Development purposes which is recognised by National Accreditation Authorities upon completion of the ADR module. Since launch, two other medicines regulators are developing local versions of the e-learning module for their national use. A publication summarising the SCOPE Joint Action has been prepared for publication in the journal Drug Safety, and a final report is in preparation for submission to the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA), including a financial report.

- 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 cited in 70 different papers and posters by researchers from eight different countries across the UK, Europe and North America at the annual International Conference on Pharmacoepidemiology 2017.

  - CPRD data confirmed that patients with a raised platelet count presenting to their GP are at an increased risk of cancer and warrant referral for further tests. This article was one of the British Journal of General Practice's 'top read' publications in 2017.

  - A study conducted by Leite et al showed that CPRD data is a potential data source for conducting near real-time vaccine safety surveillance. Researchers implemented a safety detection system for the incidence of Guillain-Barré Syndrome following influenza vaccine. The study found that CPRD data could be used to detect a positive safety signal, which has important implications for safety monitoring of new and established vaccines.

  - CPRD interventional services supported and contributed to the publication of a novel research study that supplemented electronic health record data with patient diaries, to investigate adrenal function in patients with rheumatoid arthritis. The study was important to show how supplementing data can help to address missing information within the electronic health record.

  - Overall, research using CPRD data has resulted in over 2,000 peer-reviewed publications.

- The UK Stem Cell Bank (UKSCB) at NIBSC released its first EU Tissue and Cells Directive (EUTCD) (Clinical) grade embryonic stem cell lines suitable for development into novel cell-based medicines. The UKSCB received approval this year for a further three years of funding from the Medical Research Council.

- Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) is a rare form of lymphoma that was recognised as a provisional entity by the WHO in 2016. Worldwide research into BI-ALCL is yet to provide a definitive answer as to the aetiology although there are several competing theories including the impact of the surface texture of the implant. In response to the emerging information about ALCL and the need for it to be considered as a potential diagnosis in breast conditions we:

  - » Published two Medical Device Alerts, one in 2011 (MDA2011/017) and the second in 2014 (MDA2014/027).
  - » Published this year a webpage on GOV.uk about BIA-ALCL to provide clear, timely and authoritative information to patients and clinicians which is updated regularly.
- The first UK case was reported in 2012, with a total of 41 reports received to date via the yellow card system, 33 of which meet the WHO diagnostic criteria. Three deaths have been reported to us, however only one of these meets the diagnostic criteria for BIA-ALCL. BIA–ALCL usually appears more than five years after the implant was put in and most commonly presents with rapid, painless swelling of one breast. If diagnosed early, BIA-ALCL can be successfully treated, usually with surgery alone.
- We formed an independent expert advisory group in early 2017 the Plastic, Reconstructive and Aesthetic Surgery Expert Advisory Group (PRASEAG), who have been tasked to consider BIA-ALCL. This sits alongside our collaboration with European Union and international regulatory counterparts. We continue to collect and analyse information from UK healthcare professionals and other sources about this issue in order to build a fuller picture of the occurrence of this rare disease in the UK and worldwide.

Secure global supply chains

Under this theme the Business Plan stated a top priority was to secure global supply chains for medicines and medical devices through global strategic alliances, including harmonisation of standards, information sharing, inspection and enforcement, underpinned by programmes to educate the public on the dangers of falsified medicines and fake medical devices.

Our enforcement activity

- Our Enforcement Group has continued to investigate the diversion of medicines from the legal supply chain. This year:
    - » One operation resulted in the seizure of over two million doses of medicines, our largest ever recovery of medicines – the majority of these were diverted from the legitimate supply chain and destined for the criminal market.
    - » Comparative analysis of data indicates that the trade in some diverted medicines has reduced by up to 64% since 2016. Our News Centre has been working closely with media outlets to promote the Enforcement Group's work on diversion. Releases have been covered in the BBC, Daily Mail, Independent, Daily Record, Chemist+Druggist, Pharmaceutical Journal, and European Pharmaceutical Manufacturer Magazine. We have also created striking graphics for social media which were shared by stakeholders such as the General Pharmaceutical Council.
    - » Over 40 arrests have been made.
- Since January 2017, our Enforcement and Devices teams have worked together to remove over 500 unsafe devices from online market places such as eBay and Amazon. Devices included non-compliant STI and HIV self-test kits and counterfeit dental equipment. Proactive work continues with Border Force and Trading Standards focussing on the importation of non-compliant and counterfeit medical devices.
- In January 2018, we were alerted to a consignment of syringes (1,600kgs) from China destined for a UK distributor for onward supply to the NHS. Concerns were raised as the distributor was subject to a NHS suspension as a result of the supply of non-compliant syringes. On inspection, the syringes were confirmed to be unsafe and subsequently seized.
- We hosted stakeholder meetings relating to Falsified Medicines and Counterfeit Devices to help support our work in this area, we held two courses in 2017. We frequently liaise with industry through the Pharmaceutical Security Institute and patient forums.
- In 2017, Operation Arca took place at Felixstowe Container Port alongside Border Force and the National Crime Agency. At one location, 266 barrels of white powders were identified, with falsified manufacturing and retest dates. These barrels were due to be supplied to a pharmaceutical manufacturer based in Mumbai, India, and used in the manufacture of antibiotics, posing a danger to health. Liaison took place with Authorities in India and the consignment was successfully detained by Indian Custom officials who instigated an investigation.

- We have had nine successful prosecutions at Crown Court resulting in the sentencing of 10 defendants. We have also secured confiscation orders amounting to over two million pounds under the Proceeds of Crimes Act 2002.
- During the tenth Operation Pangea, a global operation relating to medical product crime being facilitated by the internet:

1.3 million
doses of falsified and unlicensed medicines seized in the UK.

£4.1 million
estimated value of seized medicines.

3,500
websites were closed or suspended.

Our News Centre worked with media outlets to promote these, including taking BBC and Vice Media on a raid in Essex.

FakeMeds campaign

- In 2017/18, the MHRA seized over 9.5 million falsified medical products with side effects including heart attacks, strokes and death.
    - » Our #FakeMeds campaign protects public health and the money of the nation by providing accessible and trusted information, alongside simple online tools to help people avoid fake medicines and medical devices when shopping online.
    - » Buying from illegitimate websites and unscrupulous retailers also increases the risk of falling victim to credit card fraud, identity theft and IT attacks. Research shows that whilst shoppers believe themselves to be "internet-savvy", 79% of the public were unaware of the risks posed by fake medical products. (MHRA research 2016).
    - » In the last year our #FakeMeds campaign has focused on preventing the purchase of so-called 'dodgy' diet pills. Our research highlights that interrupting a customers purchasing journey could reduce the likelihood of a person buying fake medical products online. We used integrated communications to encourage checking the EU register of authorised online sellers of medicine before purchasing.

- Our campaign strategy focused on our target audience (18-30 years – bias towards women, UK-wide). We used Instagram as a new social media channel, to deliver our serious health risk message using humorous animations (example sequence below) and worked with corporate partners Slimming World to innovatively deliver our message.
- We reached over 55% of our target audience (over 5.6 million 18-30-year-olds), exceeding objectives by an additional 30% (3.1 million). The searches of the EU register of legitimate online sellers increased by 33,706 (16% increase) a month, exceeding objectives by 1% or 1,262 searches per month.
- The societal cost of care for a stroke, one of the side effects of the campaign's targeted slimming pills, is £45,409 in the first 12 months plus £24,778 in subsequent years. (Stroke UK "Current, future and avoidable costs of stroke in the UK") When considering the £6,850 campaign costs we would need to prevent 1 person from buying the falsified diet pills and having a stroke, the campaign has created the following return on investment to the nation's finances (through NHS treatment savings): £38,559 in the first year and £24,778 in subsequent years.

Our FakeMeds campaign video:

WHO programme to combat Substandard and Falsified Medical Products

- The UK attend as Vice Chair of the Euro Region and as part of our leadership of the global communications programme, during the year we undertook a number of knowledge gathering initiatives with a variety of stakeholders. The most valuable of these was a global survey with country representatives responsible for communications to better understand the guidance and support required by member states to develop their own risk communications campaigns. The outputs and insight generated by this work were then used to inform the development of a prototype communications model to be subsequently tested, reviewed and refined in workshop environments.

Medicines Inspectorate

- Our Inspectorate continues to play an important role worldwide, working and collaborating 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 as does leading 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 Pharmaceutical Inspection Cooperation Scheme (PIC/S) chairman role in 2016/17, holding representation on the Executive Bureau and chairing various PIC/S working groups and expert circles.
- Our strive to proactively driving high levels of regulatory compliance was aided through presentations at high profile meetings such as: Drug Information Association (DIA) Annual Meeting, DIA Qualified Person for Pharmacovigilance (QPPV) Forum, DIA Pharmacovigilance Conference Workshop, Medicines for Europe Regulatory and Scientific Affairs Conference, World Drug Safety Congress and the British Herbal Manufacturers Association Conference.

Conducted over 1,700 inspections during the year with over 130 of these being performed at overseas companies.

Maintained the inspectorate blog at a high level. It has over 7,000 subscribers, the most popular blogs having over 20,000 hits.

Organised major symposia on all aspects of inspections which were attended by around 2,500 delegates.

- On 1 November 2017, the first phase of the EU-US Food and Drug Administration (FDA) mutual recognition agreement (MRA) of good manufacturing practice (GMP) inspections of human manufacturers came into force.
    - » This phase started with recognition of the FDA and the first eight EU member states: Austria, Croatia, France, Italy, Malta, Spain, Sweden and UK's MHRA. A further four, Czech Republic, Greece, Hungary and Romania were recognised by the FDA on 1 March 2018, a key milestone in the journey that started in 1998.
    - » In 2015 MHRA agreed to lead the EU audit team which assessed the FDA, this audit built on previous work such as the audit by Pharmaceutical Inspection Co-operation Scheme (PIC/S) for FDA's accession and also the EU assessment for listing to import Active Pharmaceutical Ingredients.
    - » The FDA's assessment of EU member state authorities is primarily based on observing the audits conducted by EU GMP authorities on the other authorities – known as the Joint Audit Programme (JAP). JAP belongs to the Heads of Medicines Agencies and is run on their behalf by the Compliance Group. The group is part of the Good Manufacturing Practice and Good Distribution Practice (GMDP) Inspectors Working Group of the EMA where secretarial support is by EMA staff, and MHRA involvement continues with the chair of the group since 2012.
    - » The group has managed a challenging audit programme in order to meet the reporting deadlines set out in the MRA, so that FDA can assess all EU authorities in time for each milestone, starting with 1 November 2017 through to the 15 July 2019 completion date. MHRA also provided significant resource to the audit programme - seven lead auditors and four in an audit team.
    - » The MRA initially covers medicinal products for human use with veterinary products not later than July 2019. Vaccines and plasma derived medicinal products will be covered not later than July 2022.
- We led the International Coalition of Medicines Regulatory Authorities (ICMRA) GMP inspection project on the better global use of inspection resource and reliance on other inspectorate's outcomes. This was progressed and passed onto PIC/S for making operational.
- Our Good Clinical Practice (GCP) inspectorate has continued to collaborate with the US FDA. This year:
    - » Has developed and refined, working under the terms of the current confidentiality agreement, programmes for the exchange of information on inspections outcomes for clinical trials.
    - » Has worked to develop training programmes which focus on the technical skills required to inspect IT service providers who offer digital solutions to the clinical trials community. This collaboration has resulted in meetings and the participation in MHRA/FDA seminars and workshops.
- Our Good Laboratory Practice (GLP) and laboratories group are playing a leading role in developing strategies for the identification of data integrity issues associated with bioequivalence studies. Currently the UK are leading a cross Agency group which includes EMA, FDA, HC and WHO,

designed to identify signals which may be an indicator of data integrity issues.

- Our Pharmacovigilance inspectorate plays a leading role in influencing the standards of pharmacovigilance inspection programmes across Europe and many other countries around the world. This has included the training of European inspectors through the EU Inspectors Working Group training, participation in the EMA/DIA Signal Detection Information day, providing training for inspectors from National Pharmaceutical Regulatory Agency (NPRA) (Malaysia), Polish Inspectorate and TGA (Australia).
- This year we:
  - » Investigated 1,550 defective medicines reports, issued 15 drug alerts and supported five company led drug alerts.
  - » Issued over 5,900 export certificates (including 1,607 requests within 48 hours), supporting exporters in supplying and registering their medicinal products in overseas markets.
  - » Issued over 1,900 licences (a combination of Wholesale, Manufacturing and Active Pharmaceutical Ingredients), supporting those conducting processing activities.
  - » Issued 491 registrations for distance selling logos, authorising the sale of medicines via the Internet.
- NIBSC successfully renewed its designation as a WHO collaborating centre, with its key role in developing, holding and distributing international standards and reference materials for quality control and assurance of clinically relevant biological materials, including products for the prevention, treatment and diagnosis of disease. This year:
  - » WHO approved 23 new standards projects for developing international standards and reference materials.
  - » 17 of these were for new (i.e. first) WHO International Standards or WHO Reference Reagents.
  - » Work has been undertaken on a collaborative study towards the first Zika antibody standard.
- Our NIBSC centre is the UK's Official Medicines Control Laboratory (OMCL), carrying out Official Control Authority Batch Release (OCABR) testing for biological medicines within the framework of the EU. This year:
  - » NIBSC has seen an 18% decrease in OCABR testing of vaccines and blood products in 2017 compared to 2016.
  - » Over 1,700 certificates were issued for finished vaccine and blood products, and more than 2,100 plasma pools.

British Pharmacopoeia

- This year the British Pharmacopoeia (BP):
  - » Saw sales of chemical reference standards exceed all previous records (by total number of vials sold). This year we sold 30,636 vials, (up from 27,315 in 2016/17 and 23,705 in 2015/16) demonstrating the increasing global use and influence of the BP.
  - » Integrated supplements 9.1 and 9.2 from the European Pharmacopoeia into the BP, providing users with a comprehensive

set of quality standards for medicines, including national and supranational European standards.

» Published a finalised strategy on the production of pharmacopoeial standards for biological medicines. These standards are part of an overall framework that assure the quality of medicines, with the development of the strategy recognising the increasing importance of biological medicines to global healthcare strategies. This strategy includes objectives to support innovation in this area.

» Published the 2018 edition of the BP in August 2017, one month earlier than previous editions. The earlier publication provides users with additional time with which to ensure their compliance and shows the commitment to continuously improve products and services to better support users.

» The 2018 edition included 35 new monographs and 185 revised monographs.

Organisational excellence

Organisational excellence is key to innovating internally, delivering an excellent service in a competitive environment, and fostering innovation in the UK life sciences sector. Our objectives under this theme in the 2017/18 Business plan covered five areas: our people strategy, operational transformation, finance and commercial strategy, regulatory excellence and communications and reputation strategy.

Our people

- Each year we produce an Agency-wide action plan to build on any areas for development which our staff have told us about in the annual Civil Service People Survey. This year results showed:
    - » Our response rate was 75%, the same as last year, and 8% higher than the overall response rate for the Civil Service as a whole (67%).
    - » 84% of our staff can see how their work aligns to the Agency's organisational objectives and purpose, and there is a strong alignment to team working (85% whole of Civil Service).
    - » 92% of our staff feel they have the skills to do their jobs effectively, with 80% gaining a sense of personal accomplishment through the work that they do.
    - » 67% feel they are able to access the right learning and development opportunities at the Agency (3% higher than the Civil Service overall).
    - » There remains a dissatisfaction with pay and benefits (30%), with leadership and managing change (50%), and resources and workload (73%). These three themes form the basis of the Agency-wide People Survey Action Plan for this year.

Our results show the need to continually engage with our staff through regular all staff meetings, health and wellbeing initiatives, and managers' conferences.

- We enhanced our employee benefits offer. Staff can now buy an additional five days holiday a year and managers can recognise excellent performance with a reward voucher. The 'mylifestyle' benefits portal where staff can save money, continues to be popular:

69% of staff use the benefits platform, an increase of 9% compared to last year.

The average saving staff made was 6.5%.

The most popular benefit is reloadable gift cards for use in high street shops.

- We provide a healthy and safe environment for all staff, including mental wellbeing. If early symptoms of mental health issues are identified, we can signpost staff to support services, which ensure better outcomes for the individual and the Agency, as good mental health is important in the workplace. Our approach to health and wellbeing is based on tackling the top three reasons for sickness absence: musculoskeletal (back pain), respiratory (coughs/colds/flu) and mental health/stress. We want to reduce the number of sick days per an employee and improve our wellbeing index which is part of the annual People Survey. Our wellbeing index has shown a modest increase over the past year and is now at 64% positive. Over the past two years we have developed a wellbeing calendar of events and activities, such as:
    - Alexander technique sessions and desk back/neck massage – to address musculoskeletal problems.
    - Free annual flu jabs to tackle respiratory related absences.
    - 'Being a Mindful Manager' and 'Keeping well at Work' training sessions for managers and employees, and we have signed up to the Mindful Employer charter.
    - We offer an Employee assistance programme, a free confidential telephone counselling advice/support service.
- Our training across the Agency is aligned with our strategic, as well as our technical requirements, and it supports our divisions and centres with their training plans. Over the past year:
    - We have continued to roll out the Career Pathways framework which will enable staff to broaden their career options, the tool sets out the experience, skills and qualifications required for the many grades/ roles we have at the Agency.
    - We have promoted heavily the requirement for all Agency staff to complete their mandatory e-learning. Completions across the Agency have more than doubled between April 2017 and February 2018.
    - We have trained up a further seven coaches across the Agency, providing career and pastoral support across the divisions and centres, and we have established a supervision network for all Agency coaches.
    - We have introduced the use of Learning Management System Taleo Learn, to bring rigour and uniformity to the advertisement, administration and recording of training across the Agency.
- Diversity and Inclusion
    - We have a strong commitment to promoting and achieving equality, diversity and inclusion 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 an Equality and Diversity pledge and measurable objectives.

» Focus areas for this year have been the establishment of an EU Staff Network related to the UK's exit from the EU, analysis of staff profile data intended to highlight areas for priority action and the Gender Pay Gap report required by new UK Regulations.

The agency has an Equality Working group which is made up of each centre and division of the Agency.

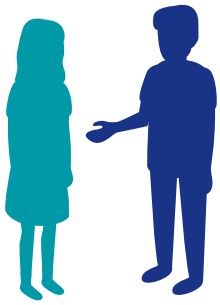
The Equality Working group has ensured Equality Impact Assessments are used in each division.

We now have in place informal contacts for those who perceive to have experienced bullying or discrimination.

We have developed face to face learning and this is now part of our ongoing training plan.

Published a gender pay gap report and action plan.

A general Diversity Network and a Parents Network have been launched in line with staff feedback.



Communications

- Our My Story Campaign was an ambitious, low-cost, internal campaign to engage staff and managers, using the power of storytelling, to explain how everyone contributed to improving public health in the UK.
  - » We collected over 200 potential stories to help bring our strategic narrative to life, we used a selection of these stories for the campaign by sharing a different story every week over the course of more than a year.
  - » The stories were presented in a variety of channels and formats, including videoing staff telling their individual stories of how they or their teams made a difference to protecting public health.
  - » We carried out an internal survey using Survey Monkey six months after the campaign was launched. It was completed by nearly a quarter of our staff and showed 88% were aware of the campaign and 60% said it had helped them better understand how the different parts of the Agency contribute to better public health outcomes.
  - » The My Story Campaign won the 'Best Storytelling' category at the Institute of Internal Communications' 2017 Awards Ceremony, and 'Best Internal Communications Campaign of the Year' at the Public Relations and Communications Association's Dare Awards, 2017.

Our working environment

- We will be moving to a new government hub in Canary Wharf, in late June. A cross-Agency group of staff representatives have been actively involved in project managing and helping colleagues, and the Agency prepare for the move. As part of the project, the Corporate Executive Team (CET) 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.

Our external engagement and activities

- We continue to use a range of activities to engage with and support our stakeholders, and our events programme helps us to do this. This year we organised and delivered 30 events and exhibitions. Income generated from events in 2017/18 is forecast to be c£1.35m, this represents an additional £150k income compared to 2016/17. This has been achieved with only c.£40k additional expenditure. We have increased access to some of our most popular income generating events including the various Good Practice Inspections (GxP) series by IE&S, and the Variations/ Abridged Applications series by Licensing.
    - We delivered several successful stakeholder engagement events in 2017/18. The CAMD 40 Meeting brought together 80 Member State representatives from across the EU. The Annual Lecture which brought together 250 senior figures in the life sciences and health sector to hear from Dr Jeremy Farrar, Director of the Wellcome Trust. The Annual Lecture generated significant media coverage including an interview with Dr Farrar the day after the event.
    - We delivered several GxP events across 2017/18 which generated significant income for the Agency and allowed us to share important GxP developments with stakeholders. For example, the GMDP events in London and Glasgow generated over £700,000 in income and attracted 1,300+ delegates.
    - In 2017/18 we began offering webinars, with the Vigilance and Risk Management of Medicines division delivering two Hot Topics in Advertising webinars. These webinars attracted a total of 220 delegates, with 84.5% of delegates rated them as being excellent or good.
- Licensing organised some 'MHRA Variations Masterclass and Workshop' events, which covered a range of regulatory subjects. These events were quick to sell out and received positive feedback.
- In November, licensing held an external two-day event 'Applying for a Marketing Authorisation Application (MAA) in the UK?', aimed at 'Minimising deficiencies in new MAA's' and 'getting it right first time'. The event was a success with 90 plus delegates attending.

Improving how we do things

- The Agency is making significant improvements to information management through successful delivery of its Digital Workplace Programme.
- All staff now have a new laptop and Office365 account, and we are moving all information from unstructured network drives into SharePoint in Office365 online. We now have a complete audit trail for every article of information. A new records management tool manages the retention and disposal of documents in SharePoint in accordance with the Agency Retention Schedule.
- The Information Processing Unit (IPU) Reform Programme has focused on the submission validation activities of the unit with a view to ensuring our

processes are as efficient as they can be. The programme has:

- » Delivered more efficient approaches to validation
- » Delivered new services to the industry
- » Harnessed new technology to improve our service to internal and external stakeholders.

- We have introduced robotic process automation to automate many of the data entry tasks in this area, enabling processing outside of normal working hours and providing a quicker validation decision.

- The **Operational Transformation (OT) programme** sets the Agency on the path to significant change. The case for change is based on:

  - » Meeting the changing requirements of users of our products and services;
  - » The need for significant updates to the aging technology currently supporting our existing work; and
  - » The need for resilience in the context of leaving the EU and the office move.

  To address these requirements, we made the decision to begin work on the OT programme with the aim of revolutionising the way we work by:

  - » Redesigning;
  - » Realigning; and
  - » Improving our functions and operations

  To:

  - » Maximise public health impact; and
  - » Optimise our role in the health system.

  The objectives of OT are to:

  - » Deliver superior products and services across every journey our customers experience;
  - » Improve the experience of our customers;
  - » Provide flexibility to meet changing customer requirements; and
  - » Ensure services are delivered giving best value for money.

  An external challenge was commissioned and delivered to the Agency's Corporate Executive Team in April 2017. The report highlighted a number of points, including:

  - » Recognition that there was benefit in improving and enhancing co-operation – amongst divisions, partners and stakeholders to identify collective business benefits;
  - » There would be benefit in aligning the digital (IT) strategy with the operational direction the Agency needs to take to continue to position itself successfully for the future; and
  - » As with any transformation, we must ensure value for money.

The initial phase of the transformation included gathering a significant amount of external and internal research to evidence and shape the desired future state. In summer 2017 the programme engaged with over 140 customer contacts (across industry, academia, patient groups, government and healthcare delivery) from over 80 organisations and drew on over 770 online survey responses. Internally, the programme has undertaken detailed internal analysis, involving over 55 Agency experts.

The following strengths were identified, as highlighted by the customer insight work, as elements to nurture:

» **People**: highly knowledgeable, competent, technically expert and committed staff;

» **Pragmatism**: including supporting innovation via schemes such as the Early Access to Medicines Scheme (EAMS) and the Innovation Office;

» **Quality**: working within statutory timelines, quality is a differentiator;

» **Global credibility**: with regulatory influence beyond that expected for the UK market;

» **Partnerships**: working closely with the World Health Organisation (WHO) and other national regulators;

» **Research expertise**: across standards, biologicals and real-world evidence; and

» **Emergency response**: as showcased in the Agency response to Ebola.

To retain influence and remain globally recognised, the research highlighted that the transformation should address the following customer and market trends:

» Regulation continues to change, and the Agency must respond, for example, to the new Clinical Trials Regulation and the new Medical Devices and In Vitro Diagnostics Regulation;

» Government strategy continues to change, and the Agency must respond, such as the Accelerated Access Review and the Life Sciences Industrial Strategy;

» Products are rapidly changing, and the Agency must continue to be able to regulate. Medicines and medical devices are no longer the distinct entities referred to in the regulation and new product types continue to emerge, for example, the rapid rise of digital health, Advanced Therapy Medicinal Products and personalised medicines. Innovations to cut research and development (R&D) costs are also driving new approaches;

» Patient needs are changing; notably an ageing population with increasing comorbidities adds to the challenge for authorising and monitoring safe treatments. Patient's attitudes are changing too, demanding more personalised care and easy to use digital innovations, providing new goals for industry to pursue and the Agency to regulate;

» Customers expect digital journeys that offer transparency, automation and engagement that the Agency simply doesn't offer today, with the website cited repeatedly as a specific pain point; and

» A customer-oriented cultural shift is required to move away from managing multiple disjointed customer journeys.

Work is ongoing to define the future state of the Agency and develop the high-level IT requirements needed to support this. A Programme Business Case is being developed, which will outline the preferred future state together with the indicative costs and benefits, and transformation portfolio roadmap.

Contributing to the Secretary of State's health inequalities agenda

During 2017/18, 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).

Through our MHRA centre we have 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 medicines licensed for children as well as age appropriate formulations for paediatric patients of all age groups available on the UK market in the context of European Paediatric Regulation (PR). We have contributed to the planned 10-year review of the implementation of the PR to identify lessons learned and areas for improvement and have committed to undertaking a review of the impact in the UK.

Our MHRA centre has also been influencing use and leading in the provision of information in product information on excipients for both children and older populations (e.g. effects on activity and attention in children and lactose intolerance and gastrointestinal symptoms which can occurs with aging).

We've developed guidance to industry on the administering of medicines via feeding tubes, which is particularly relevant to provision of care for premature babies and some older patients with swallowing difficulties caused by conditions such as stroke or Parkinson's disease.

We've supported initiatives, such as the European Paediatric Formulation Initiative (EuPFI), by providing speakers for their conferences and highlighting issues such as "the use of colours in medicines" (2017) and "oral syringes for children" (2018). 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, we have continued to work to ensure that patients and healthcare professionals report to the Yellow Card Scheme and that the system is accessible. The scheme allows for the reporting of suspected adverse drug reactions, medical device adverse incidents, suspected product quality issues, and suspected counterfeit products. It is open for anyone to report adverse incidents and continues to provide information about the scheme translated into 12 languages, which are available at the reporting website. Users can also access interactive profiles of all adverse drug reaction reports for all drugs. 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.

We have 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.

Our NIBSC centre 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.

Work is being undertaken at NIBSC in line with initiatives from the Coalition for Epidemic Preparedness Innovations (CEPI) and the WHO R&D Blueprint for Action against Epidemics, to produce assay reference materials to support vaccine development and diagnosis of infectious disease outbreaks that are identified to cause a public health emergency of international concern.

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 (BMGF).

Diarrhoea and dysentery disproportionately afflict children from low income backgrounds. With funding from PATH and BMGF, NIBSC continues to contribute, through its standardisation work, to the development of novel paediatric vaccines.

NIBSC evaluates biological medicines under the WHO pre-qualification scheme, which facilitates the access of essential medicines by the United Nations for use in Low and Middle Income Countries (LMIC).

CPRD has been used to study health inequalities between different groups. Recent examples include the identification of social determinants of zoster disease, the prediction of groups most vulnerable to cold weather, and socioeconomic variations in Attention deficit hyperactivity disorder (ADHD) incidence rates. The Agency aims to increase the use of CPRD to support public health internationally and the range of deprivation and socioeconomic indicators linked to primary care data has recently been broadened.

Key issues and risks facing the Agency in delivering its objectives

Risks	Mitigating factors and actions
The Agency has a risk of losing some income depending upon the agreement that is reached during the exit-from-the-european-union negotiations.	Staff engagement: this has included divisional and all staff meetings and engagement in wider DHSC network for EU staff. Ongoing work by task force and cross-government liaison, with strong links into DExEU and DHSC - specifically on what the Implementation Period agreement will mean for ability of UK to attend meetings and act as a leading authority.
The Agency is investing in a major Operational Transformation programme and there is a risk that not all of the benefits will be achieved.	There is a team working on simplifying complexities with the aim to reduce overall cost. The Agency's Finance team works to refine funding position, determine routes to get additional funding and potential any external envelope available. The programme team works on quantifying the tangible benefits where cost savings can be achieved.
The Agency currently has access to European systems and data which could be disrupted if an agreement for continued access is not reached during the exit-from-the-european-union negotiations.	The Agency initiated a European Systems Analysis (ESA) Project that produced a Strategic Outline Case considering this risk, and made recommendations for contingency arrangements, which was approved. Three European Systems contingency business cases (submission Capability, Case Management Capability, and Publishing Capability) have been approved by DHSC for delivery.
The Agency, like every other organisation, is at risk from cyber-attacks and the threat of system disruption and/or data loss.	The Agency has completed a Configuration Management Database (CMDB) documenting our infrastructure. A Head of IT solutions has been appointed, an Information Asset Owner (IAO) network has been established and a first complete Information Asset Register (IAR) is now in place.
The Agency has some financial control risk associated with non-compliant procurement that could lead to poor value for money.	A number of policies have been introduced and revised. A RACI (Responsible, Accountable, Consulted and Informed) matrix is in the process of being prepared to assist in defining roles and responsibilities. The Oracle Fusion system introduced in April 2017 has greater controls in place to prevent non-compliant spend.

1.2 Performance Analysis

Performance against targets 2017/18

No.	Area	Target description	2017/18 total	Rating	Comments
PM1	**Medicines licensing – validation of applications**	a) For Type IB and Type II variations, 97% of scientific validation process completed within 14 days of case creation	**100%**	**Met**	Met - 100% validated within 14 days of case creation
		b) For new Marketing Authorisation applications, 97% of validation reports produced within 14 days of case creation.	**100%**	**Met**	Met - 100% validations reports produced within 14 days
		c) 97% of Change of Ownership applications validated or Request For Information (RFI) issued within 42 days of receipt.	**100%**	**Met**	Met - 100% granted within 42 days of receipt
PM2	**Medicines licensing – assessment of applications**	a) The assessment of applications for new Marketing Authorisations for UK only: 97% assessed in 150 days	**100%**	**Met**	Met - 100% of applications assessed in 150 days
		b) The assessment of applications for new Marketing Authorisations in European (MRP, DCP & CP) procedures:	**99%**	**Met**	Met - assessed 99% of decentralised procedures for reference member states in 70 days
		97% assessed within the designated time	**100%**	**Met**	Met - assessed 100% of decentralised procedures for concerned member states in 100 days
		95% of CP assessed within the designated time	**97%**	**Met**	Met - assessed 97% of mutual recognition procedures in 50 days
			100%	**Met**	Met - assessed 100% of centralised (co) rapporteurship applications within 80 days
		c) The assessment of Type IB minor and Type II major variation applications in National and European (MRP, CP) procedures:	**98%**	**Met**	Met - assessed 98% of Type II within 90 days
		97% assessed within the designated time.	**97%**	**Met**	Met - assessed 97% of Type IB within 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)	100%	Met	Met - assessed 100% of all authorisations within 30 days
			12.3	Met	Met - average applications assessment time of 12.3 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
			53	Met	Met - total of 53 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	98%	Met	Met - assessed 97% of mutual recognition procedures in 50 days
			99.5%	Met*	Met - on the basis of rounding up 99.5% available within 3 working days (in line with agreed convention)
		b) Medical Device Alerts will be issued: 95% within 10 days, 100% within 15 days	97%	Met	Met - 97% 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: 95% within 72 hours, 100% within 5 days	100%	Met	Met - 100% within 72 hours
			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%	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%	Met	Met - 99% PARs completed within 60 days

PM6	**Standards and control**	a) Biologics standards supply – a maximum average response time of 6.0 working days for all standards despatches	**c6.10**	**Met***	Met - on the basis of rounding down 6.10 average working days for all standards dispatches (in line with agreed convention)
		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	**100%**	**Met**	Met - 100% completed within 10 days for Plasma Pools
		• 10 days for Parenterals	**100%**	**Met**	Met - 100% completed within 10 days for Parentals
		• 15 days for Haemostasis	**100%**	**Met**	Met - 100% completed within 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	**100%**	**Met**	Met - 100% completed within 60 days of vaccines
PM7	**CPRD activity**	a) 90% of research applications to receive initial feedback from ISAC review within 21 working days	**62%**	**Target not met**	Target not met - CPRD timeframes dependent on external Committee members
		b) Expand coverage to 1200 contributing GP practices across the UK	**1045**	**Target not met**	Target not met - CPRD unable to meet target due to resourcing issues
		c) Increase the number of CPRD licence holders to 52	**53**	**Met**	Met (exceeded) - number of CPRD licence holders increased to 53

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).	**99.7%**	**Met***	Met - on the basis of rounding up 99.7% of FOIA requests replied to within requisite timescales (in line with agreed convention)
		b) Aim to return all responses to Parliamentary Questions (PQs) to the DH by noon on the date specified with less than 5% returned to the Agency by the Department for rewriting.	**98.7%**	**Nearly met**	Nearly met - 98.7% of PQs answered on time
			9.3%	**Target not met**	Target not met - 9.3% PQs returned for rewriting, in part, due to greater scrutiny
		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.	**100%**	**Met**	Met - 100% of POs answered on time
			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 the 4 weeks from 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 the 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

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 2017/18 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 all the Agency's capital and reserves.

The Agency's income from trading activities at £128.7m remained at the same level as last year. Staff costs increased by £3.7m (5%) due to a pay award (1%) and increased headcount (4%) mainly in CPRD in line with planned expansion plus temporary resource brought in to clear backlog following implementation of Oracle Fusion and permanent resource brought in to handle NIBSC transactions previously outsourced. Operating costs increased by £9.5m (12%) mainly due to the Agency's Operational Transformation programme (£7.2m) and a full year increase of £2.4m in rental and other payments for the Agency's accommodation at BPR. As a result, the operating surplus before interest and dividends for 2017/18 was £1.7m, compared to £13.8m in 2016/17. After interest and dividends of £1.7m, a net surplus of £0.1m arose in 2017/18 and has been transferred to reserves.

2017/18 has seen cash outflows from operating activities for the Agency of £23.7m compared to inflows of £22.6m in 2016/17. A reduction in payments on account (£7.2m) following the move to pay on invoice at the start of the year together with a payment to Government Property Agency for the Agency's contribution to fit out costs for its new office accommodation (£6.9m) being the main drivers.

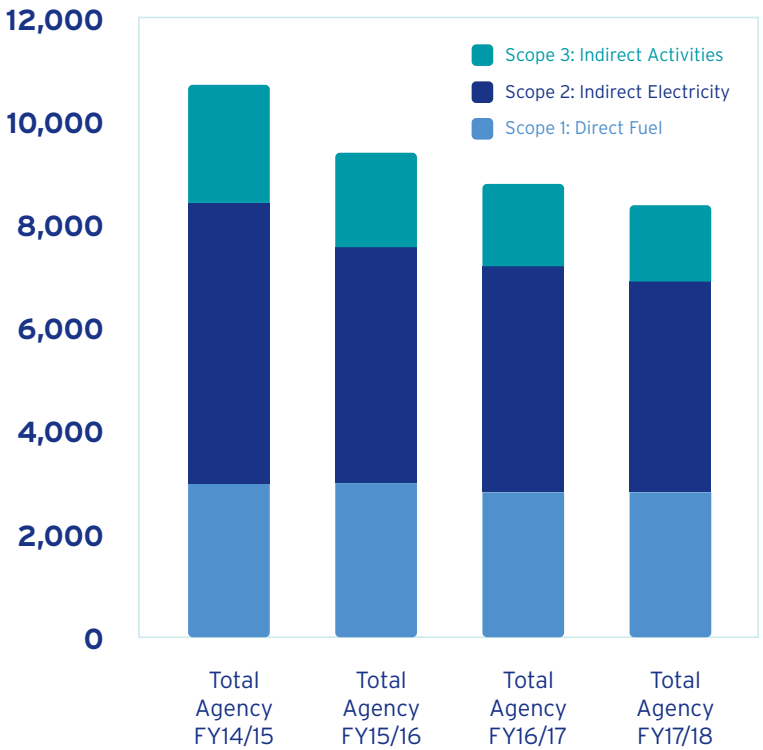
Sustainability report

Greenhouse Gas (GHG) emissions performance

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

Greenhouse gas emissions financial and non-financial indicators				
Greenhouse gas emissions		South Mimms	BPR	Total
GHG Emissions (tCO2)	Total Gross Emissions	5,855	2,250	8,105
	Gross Gas Emissions	2,585	63	2,648
	Gross Electricity Emissions	2,928	563	3,491
	Gross Property Emissions	98	2	100
	Gross Transport Emissions	242	1,621	1,863
Energy Consumption ('000 kWh)	Gas Consumption	14,045	346	14,391
	Electricity Consumption	7,618	1,465	9,083
Financial Indicators (£k)	Expenditure on Energy	1,242	167	1,409
	Expenditure on Transport	404	1,301	1,705
Notes: 1. BPR expenditure includes electricity only; gas is consolidated in service charge. 2. Transport emissions include air, rail, courier, and air freight data.				

GHG Protocol Three Scopes Of Emissions: Tonnes CO2



The Greenhouse Gas (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 and a comparison over each financial year. The scope types are as follows:

- Scope 1 direct emissions cover controlled resources and include gas consumption, fuel oil usage and fugitive emissions.
- Scope 2 indirect emissions cover electricity purchases.
- Scope 3 indirect emissions cover all others 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 Footprint1 for the South Mimms site has been produced since 2009/10. The figure has fallen from a baseline figure of 8,633 TCO2 in the first year to 5,855 TCO2 this year, representing a reduction of 32% over this period, a significant achievement largely due to initiatives that have reduced energy consumption.

Carbon emission data has been produced from 2013/14 for the BPR site; which has been used as the baseline year. The Carbon Footprint was 3,630 TCO2 in the first year and 2,250 TCO2 this year. The reduction seen in emissions is in direct relation to the floor consolidation project which continues to show the carbon benefits of this project.

The two sites have different impacts; BPR has a significant impact from business travel and South Mimms has a significant impact from energy consumption, which is due to the differing nature of the work and activities carried out at each site. Overall the Agency's Carbon Footprint has reduced by 22% which is a considerable reduction achieved from the sites.

Gas and electricity consumption

Gas and electricity consumption have been collated for the BPR site from 2013/14. The floor consolidation project greatly reduced utility consumption, giving a reduction in corresponding electricity costs.

Both gas and electricity consumption at the South Mimms site have been collated since 2009/10 and both have shown significant reductions. An overall reduction of 17% in gas consumption has been achieved, and a reduction of 16% in electricity consumption has been realized. Numerous factors have contributed to these savings such as the replacement of old equipment with energy efficient versions and maintenance improvements.

The site has successfully implemented 'switch off' initiatives at key periods across the year, which has resulted in an official site shutdown, over the Christmas period, aimed specifically at reducing energy consumption. Staff are encouraged to take responsibility for the equipment they use, including maintenance staff adjusting plant and equipment usage to further impact energy reduction.

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 CO2 produced from energy sources, payments this year are estimated to be £110k. Changes to this legislation are anticipated in 2019 and details are awaited.

Due to the significant savings made during the last seven years on energy consumption, a considerable amount of the energy budget has been saved on utility bills for electricity and gas. This has been estimated as a total of £1.3 million, over this period, on electric and gas expenditure as well as a corresponding reduction in carbon tax payments.

Display Energy Certificates (DECs) are a requirement on the owned site at South Mimms and are reviewed annually by an external assessor. This assessment is based purely on facts such as energy consumption and the use of the buildings onsite. The above achievements in energy reduction

have also had a direct impact on the DEC performance at the site. The initial baseline assessment rating was 544 in 2008, when the scheme commenced, compared to this year's rating of 237. This is a significant reduction and further demonstrates the results produced from the site targeting energy consumption.

Waste management performance

At South Mimms waste management has been tendered in conjunction with LUPC (London Universities Purchasing Consortium); this joint approach with other Government organisations gained efficiencies from the collaboration. The new supplier is now in place and zero landfill has also been achieved following this change. Work continues to make improvements to waste management practices to reduce the impact on the environment as well as reducing the waste management budget.

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 received high praise from Warp-It on the achievements made at the site. The site recently carried out a declutter campaign over the Christmas period to further encourage staff to share resources and raise awareness for re-use as a first stage for unwanted items.

The initiative produced a good response from staff and this in combination with savings made over the rest of the year achieved total savings of £60k; as well as many other benefits such as waste reduction and a reduction in associated carbon emissions.

Savings associated with resource re-use		
Re-use savings		Total
Re-use of resources	Total Savings £	164,564
	Total savings KgCO2 Emissions	57,721
	Total Savings Waste Reduction Kg	15,808

Work has started recently at BPR to declutter and recycle unwanted items, driven by the relocation to Canary Wharf. The aim is to encourage staff to reduce items that will need to be moved and has been supported by the introduction of a clear desk policy for the new office.

The Facilities Manager and Environment and Energy Manager are collaborating, as part of this planned move, to re-use surplus furniture from the existing site. Including identifying furniture that can be re-used at South Mimms or re-used by the new tenant, helping reduce the volume of waste from this project.

Finite resource 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 and the benefits of this can still be seen.

Due to the nature of the work carried out, the South Mimms site has been a relatively high water consumer; work is ongoing to reduce this impact and good progress has been made.

Water consumption financial and non-financial indicators		
Water		Total
Water consumption financial and non-financial indicators	Water Consumption (BPR)	5
	Water Consumption (South Mimms)	31
Financial Indicators (£k)	Water Supply Costs (BPR)	N/A
	Water Supply Costs (South Mimms)	28
Notes: 1. Water costs for BPR are built into the service charge. 2. BPR is mainly office consumption and NIBSC is mainly laboratory consumption.		

Renewable energy production

The South Mimms site made its first move into renewable technology by implementing a large scale solar PV scheme. This involved installation of 1,490 solar PV panels on seven of the south facing roofs. Because of the nature of the work at the site all electricity generated will be consumed by the site and this currently equates to approximately 6% of the main site electricity requirements.

This has made a good impact on reducing the mains grid electricity consumption and has made savings of £68k on this utility so far but has also brought additional benefits to the site. Including reducing the environmental impact and carbon emissions; as well as adding to the security of electricity supply as a portion is now generated onsite.

External achievements

Environmental achievements have also been acknowledged externally following on from the three awards achieved at South Mimms in the previous year (Energy Institute's Energy Manager of the Year, Public Sector Energy Manager of the Year, as well as the Public Sector Energy Champion in Government).

The awards recognised environmental and energy management work carried out at the site and have given NIBSC the opportunity to showcase the achievements made and share knowledge gained. This has included for example Jude Hughes, the Environment and Energy Manager for the Agency presenting at an annual energy conference on environmental initiatives and the results achieved. Also, knowledge sharing with other organisations for instance focusing on behaviour change initiatives which have also impacted on carbon reduction.

Follow up media interviews have also been undertaken including, for instance, a 'talking heads' style interview in an energy industry publication; discussing achievements and savings made, as well as case studies for other stakeholders involved in the site.

Future sustainable plans

Next year there are plans to make improvements to waste management facilities, further explore the benefits of renewable technology for the site at South Mimms. As well as reviewing the Agency's continued use of recycled furniture to reduce its impact on the environment and save costs on new furniture.

The Agency's energy and environmental management activities, discussed above, show significant achievements in savings relating to energy costs, consumption, and carbon. And further demonstrate the Agency's commitment to continually improving working practices to reduce its impact on the environment and carbon emissions.

Health and Safety

The Agency is committed to promoting a positive health and safety (H&S) 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.

H&S Responsibility 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 best practice across the sector. This is supported by monitoring activities and effective consultation with staff representatives via the main safety committees and sub-committees.

H&S priorities are highlighted in the Agency's Health and Safety Action Plan which is developed by the HSSG on an annual basis. Key priorities for 2017/18 included:

- Achieving excellence in leadership and culture
- Continued regulatory compliance
- Maintaining OHSAS 18001 certification at the Buckingham Palace Road (BPR) site
- Accident / Incident reporting
- Delivering the mandatory training programme
- Reviewing overseas travel safety requirements
- Continued staff engagement, with a focus on staff health and wellbeing and the introduction of Safety Advocates at BPR
- Ensuring H&S requirements related to the office move were identified and managed

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.

Achieving excellence in leadership and culture

Objectives in this area focused on visible H&S Leadership from CET level through to the Divisions, ensuring H&S issues were suitably prioritised. Divisional Directors were required to actively monitor H&S arrangements within their areas of responsibility and it was also planned to develop a 5-year strategy for H&S across the Agency.

In 2017/18 there has been continued evidence of H&S being given priority at a senior level, with proposals such as overseas travel safety arrangements being considered and endorsed and issues such as completion of mandatory training being addressed by CET. The CET H&S Champion continues to support H&S initiatives and provide a strong link between central H&S committees, the HSSG and CET.

A draft 5-year H&S strategy has been developed with support from Dr Mayatt OBE, Mayatt Risk Consulting. The strategy will be finalised in 2018/19.

Continued regulatory compliance

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 and a relicensing visit for work with animal pathogens. NIBSC was deemed compliant across all areas inspected and the licence for work with animal pathogens renewed (Specified Animal Pathogens Order – SAPO).

b. Internal audits

There is an audit schedule in place which covers all Divisions across the Agency. Internal audits are carried out at least annually, by the Health and Safety Team. Results from audits are monitored by the main health and safety committees.

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.

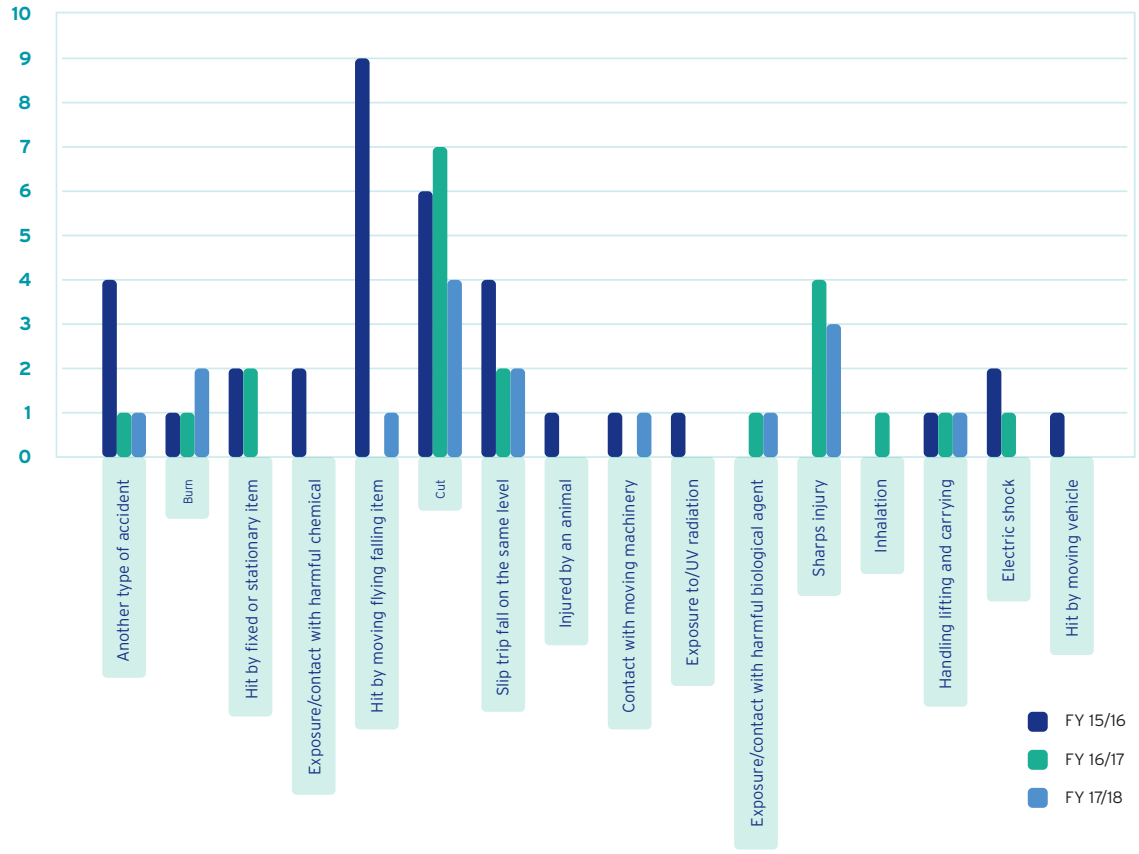
British Standards Institution (BSI) continuing assessment/surveillance inspections were completed in May and November 2017. Certification to OHSAS 18001 was maintained. Only two minor non-conformities were raised and all have been resolved and accepted by BSI.

Accident / Incident reporting

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

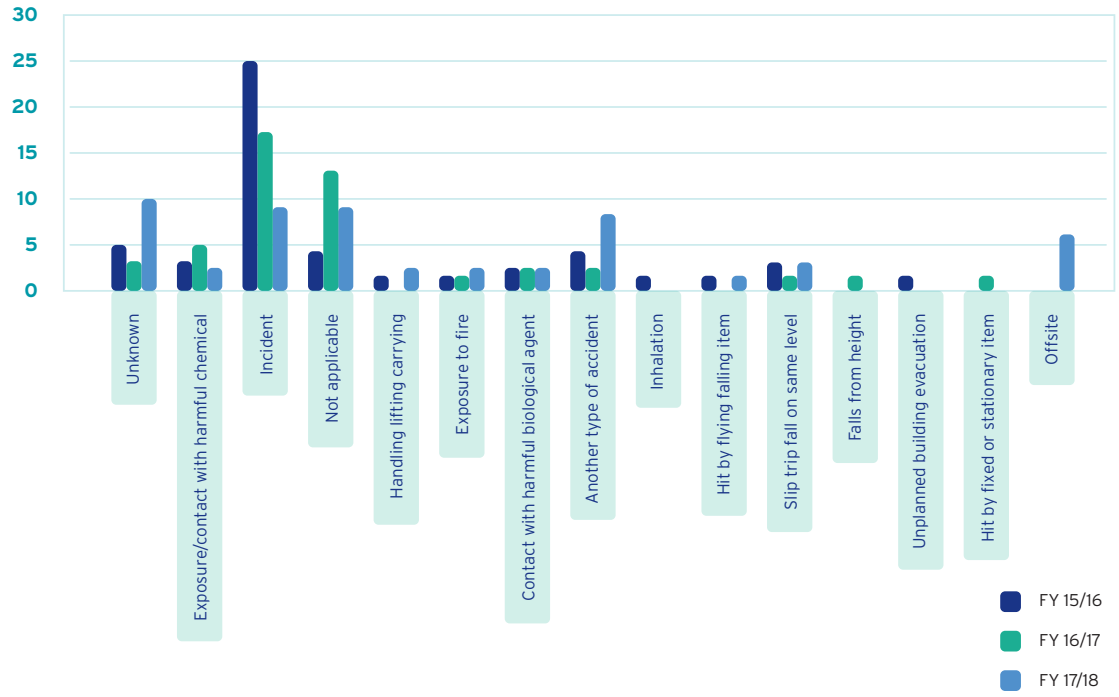
There has been one RIDDOR reportable incident during 2017/18. The incident was reported as a Biological specified near miss and occurred at NIBSC. The investigation has been completed and appropriate actions taken.

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'. There has been an increase in reporting of 'offsite incidents' due to the improved awareness of overseas working risks.

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 courses have been delivered during the reporting period 2017/18:

Course	Total courses delivered in 2017/18
Laboratory Managers health and safety	3
Practical Manual Handling	4
Risk Assessors	8
Risk Authorisers	4
Lab Module 1 – Legal Matters	8
Lab Module 2 – Facilities	7
Lab Module 3 – PPE & Signage	8
Lab Module 4 – Biological Safety	8
Lab Module 5 – Waste	7
Lab Module 6 – Hazard and Risk	9
Lab Module 7 – Behavioural Safety	8

Work has taken place to assess the cohorts of staff applicable for each category of training so that there can be effective monitoring of completion and improved targeting of training courses to maintain this. In addition work is continuing to develop appropriate refresher training at the required frequency.

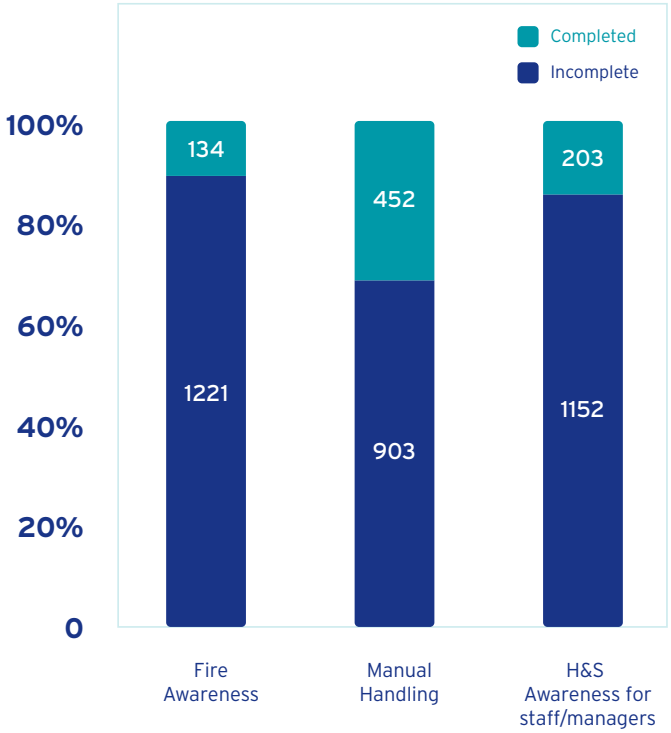
It was planned to develop tailored training sessions for managers on H&S leadership and management as well as H&S training for scientific managers at NIBSC. Dr Vanessa Mayatt, OBE, delivered a training course for Heads of Division at NIBSC which was well received. The training course planned for other managers across the Agency was put on hold pending

further consideration regarding how this training can be incorporated into existing Civil Service Learning training for managers.

A Containment Level 3 (CL3) training course consisting of 13 modules was delivered to CL3 users and support staff, primarily engineering staff, in October 2017. This course was developed following consultation with Public Health England (PHE) and material from the Health and Safety Laboratory (HSL). A review of the course content and style of delivery is currently underway to ensure that the next round of training is streamlined with less duplication of information.

b. Agency mandatory Civil Service Learning (CSL)

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



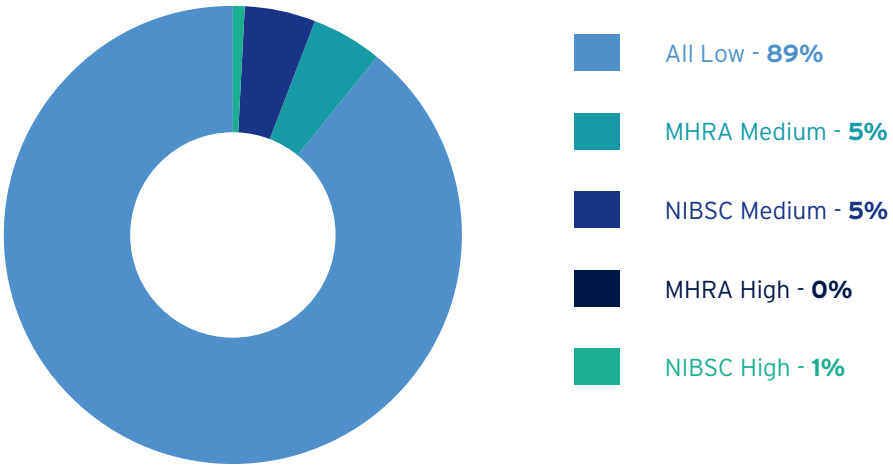
Training refresher periods range from annual to 3 yearly. Completion of mandatory training remains a priority for the Agency and a target of 90% completion rate has been set for the forthcoming year for all training.

c. Driving Monitor

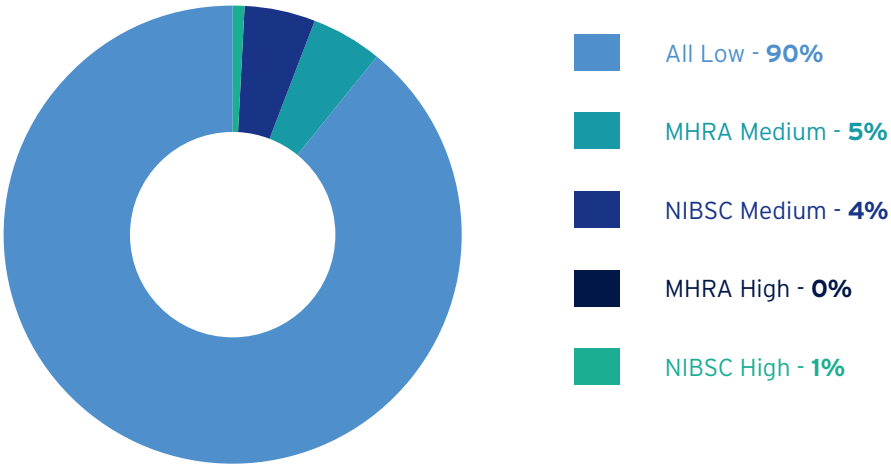
All staff that drive on Agency business are required to complete an assessment on a system called Driving Monitor. Driver risk ratings are based on a risk assessment which combines driver history with an on-line assessment. Drivers deemed as medium and high risk receive appropriate additional training.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

Agency Driver Risk Ratings

February 2017 Driving Monitor Stats:



March 2018 Driving Monitor Stats:



A total of 1487 staff have registered with Driving Monitor, with 1126 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 online 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. Improved online assessment and training completion rates have been seen across 2017-18.

February 2017

WSP active users

1193 of 1536 78%

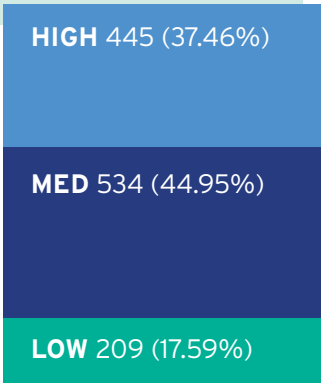
Users with completed training records

WSP active users

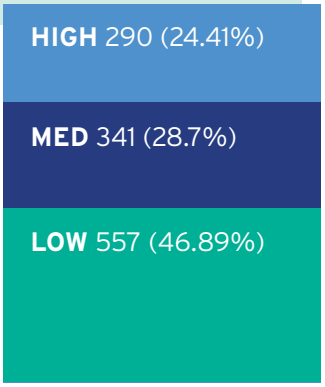
1187 of 1536 77%

Users with risk assessments

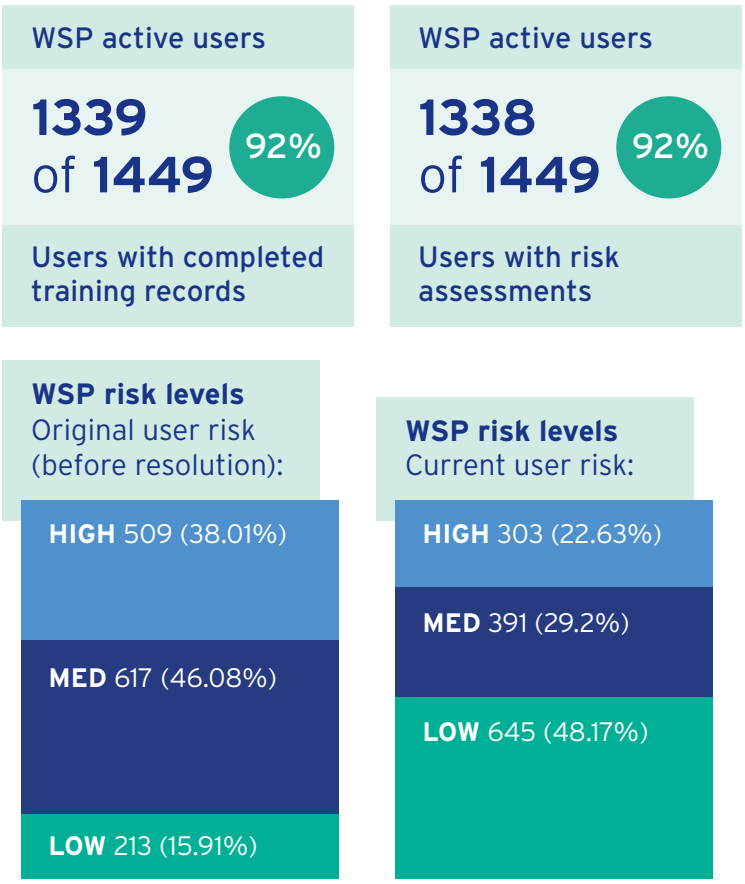
WSP risk levels
Original user risk (before resolution):



WSP risk levels
Current user risk:



March 2018



Reviewing overseas working safety requirements

Overseas working is a key risk area for the Agency. The UK and Overseas Working Group was established to review overseas working 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. This review has resulted in, for example, the introduction of Hostile Environment Awareness Training for staff travelling to high risk destinations, the production of country information packs, a simplified travel application and risk assessment process and raised awareness of the risks associated with overseas working. Further work is planned to review off site working arrangements in the UK.

Continued staff engagement

The beneficial role of Safety Advocates (in place at NIBSC) was recognised as best practice and was endorsed by CET, to roll out across other centres of the Agency. Safety Advocates were identified for each Division (with some smaller Divisions sharing the resource) and suitable training was delivered to the newly appointed advocates.

A plan was also developed to roll out the Safety Organiser system across MHRA and CPRD. This was successfully completed through the new BPR Safety Advocates.

The move to Canary Wharf

The Health and Safety Team has contributed to relevant groups and committees including those reviewing IT equipment needs for homeworkers. H&S issues were identified and are being discussed and action taken through

the Agency Move Group. H&S inductions specific to the new building at Canary Wharf were delivered (during Divisional meetings and dedicated sessions) prior to the move.

Dr Ian Hudson
Chief Executive and Accounting Officer
Medicines and Healthcare products Regulatory Agency
16 July 2018

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 Chair

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 Chair of the Board. He is currently Chairman of East Midlands Academic Health Science Network, the Chair of Porton Biopharma Limited and a Non-Executive Director of Public Health England. He is also a member of the council of Leicester University.

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 published extensively on aspects of health technology assessment and 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

Sir Alex has made contributions to medical science in various fields. He trained initially in medicinal chemistry (PhD), then molecular biology, and subsequently qualified in medicine, becoming a Fellow of both the Royal Colleges of Pathologists and Physicians. He was appointed Professor of Medicine by Leeds University and Leeds Teaching Hospitals NHS Trust, in 1992. At ICI Pharmaceuticals in the 1970s and 80s, he was involved in developing several effective cancer drugs, in molecular diagnostics and in the worldwide introduction of DNA Fingerprinting for forensic medicine (Queen's Award for Technological Achievement, 1990).

A Fellow of the Academy of Medical Sciences, he has chaired many Medical Research Council, Wellcome Trust, Arthritis Research UK, Cancer Research UK and National Institute for Health Research funding committees. He also chaired the National Cancer Research Institute, the National Cancer Intelligence Network and HM Treasury Office for the Strategic Coordination of Health Research (OSCHR) Translational Medicine and Health Informatics Boards. He served on the UK Clinical Research Collaboration and NIHR Boards, and now sits on the National Genomics Board. In addition, Sir Alex is a non-executive Board Director of UK Biobank, Health Data Research UK and the

Innovate UK Medicines Discovery Catapult.

Professor Markham was the first substantive Chief Executive of Cancer Research UK (2003-2008). He is currently Director of an MRC Medical Bioinformatics Centre in Leeds, with research interests in molecular genetics and precision medicine. Sir Alex advises the German and Singapore Governments on medical research strategy and has represented the UK on many international bodies. He is chair of the Lister Institute of Preventive Medicine and received a Knighthood for Services to Medicine in the 2008 New Year's Honours.

Deborah Oakley

Deborah has worked for over 30 years in financial services. She is a member of the Chartered Institute of Financial Analysts. She has been in her current employment at Veritas Investment Management since 2010. She heads the pooled funds team and is a fund manager looking after private client, trust and charity portfolios.

Deborah has been a non-executive in the public sector since 2007. She concluded her role as a non-executive director and chair of the audit committee at the Royal Free London NHS Foundation Trust in May 2017. She was audit chair at NHS Camden and was also a board member of the Health Protection Agency.

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 kidney disease.

A Fellow of the Academy of Medical Sciences and of the Royal Society of Edinburgh, David 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 European Society of Hypertension-accredited Hypertension Excellence Centre and Lead for the Hypertension and Renal Theme of Edinburgh University's Centre for Cardiovascular Science.

David has been Chair of the Scottish Medicines Consortium, President of the Scottish Society of Physicians and Vice-President of the Royal College of Physicians of Edinburgh. He is currently President of the British Pharmacological Society (BPS), Honorary President of the European Association for Clinical Pharmacology and Therapeutics (EACPT), and Chair of the Clinical Division of the International Union of Basic and Clinical Pharmacology (IUPHAR), for whom he will be President for the World Congress of Basic and Clinical Pharmacology in 2022.

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 2017/18.

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 (MHRA) to prepare for each financial year a statement of accounts in the form and on the basis set out in the Accounts Direction. The accounts are prepared on an accruals basis and must give a true and fair view of the state of affairs of the Agency and of its income and expenditure, recognised gains and losses, changes in taxpayers' equity and cash flows for the financial year.

The accounts shall be prepared so as:

a. to give a true and fair view of the state of affairs as at 31 March 2018 and of the income and expenditure, changes in taxpayers' equity, and cash flows of the trading fund for the year then ended; and

b. to provide disclosure of any material income or expenditure that has not been applied to the purposes intended by Parliament, or material transactions that have not conformed to the authorities which govern them.

In preparing the accounts, as Accounting Officer I am 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 I am aware, there is no relevant audit information of which the MHRA's auditors are unaware, and I have taken all steps to make myself aware of any relevant audit information and to establish that the MHRA's auditors are aware of that information
- confirm that the annual report and accounts as a whole is fair, balanced and understandable and that I take 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 me as the Chief Executive of the Medicines and Healthcare products Regulatory Agency and 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 MHRA business is conducted in accordance with Managing Public Money to ensure public money is safeguarded and properly accounted.

Agency's Statutory Duties

In line with recommendations in the Harris Review, where relevant and appropriate, the Agency has carried out its functions in line with the statutory duties placed on the Secretary of State by the Health and Social Care Act 2012, and this includes the health inequalities duty. The Agency's statutory duties include:

- operating a system of licensing, classification, monitoring and enforcement to ensure that medicines for human use, sold or supplied in the UK, are of an acceptable standard;
- ensuring compliance with statutory obligations relating to the investigation of medicines in clinical trials and assessing notifications or proposals for clinical trials from manufacturers of medical devices;
- discharging statutory obligations, including those of the UK's EU competent authority, for medical devices and contributing to developing the safety and performance standards that support this work;
- operating and contributing to systems at both UK and EU level of post-marketing surveillance for medicines and medical devices, taking action to safeguard public health;
- ensuring compliance, in the UK, with statutory obligations relating to the manufacture, distribution, sale, labelling, advertising and promotion of medicines;
- devising and drawing up standards for the purity and potency of biological substances and designing appropriate test procedures;
- preparing, approving, holding and distributing standard preparations of biological substances;
- providing, or arranging for, the provision of laboratory testing facilities for the testing of biological substances, carrying out such tests, examining records of manufacture and quality control and reporting on the results;
- carrying out, or arranging for the carrying out, of research in connection with biological standards and control function.

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

Governance framework

The Agency is an executive Agency of the DHSC 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 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 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 for 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:

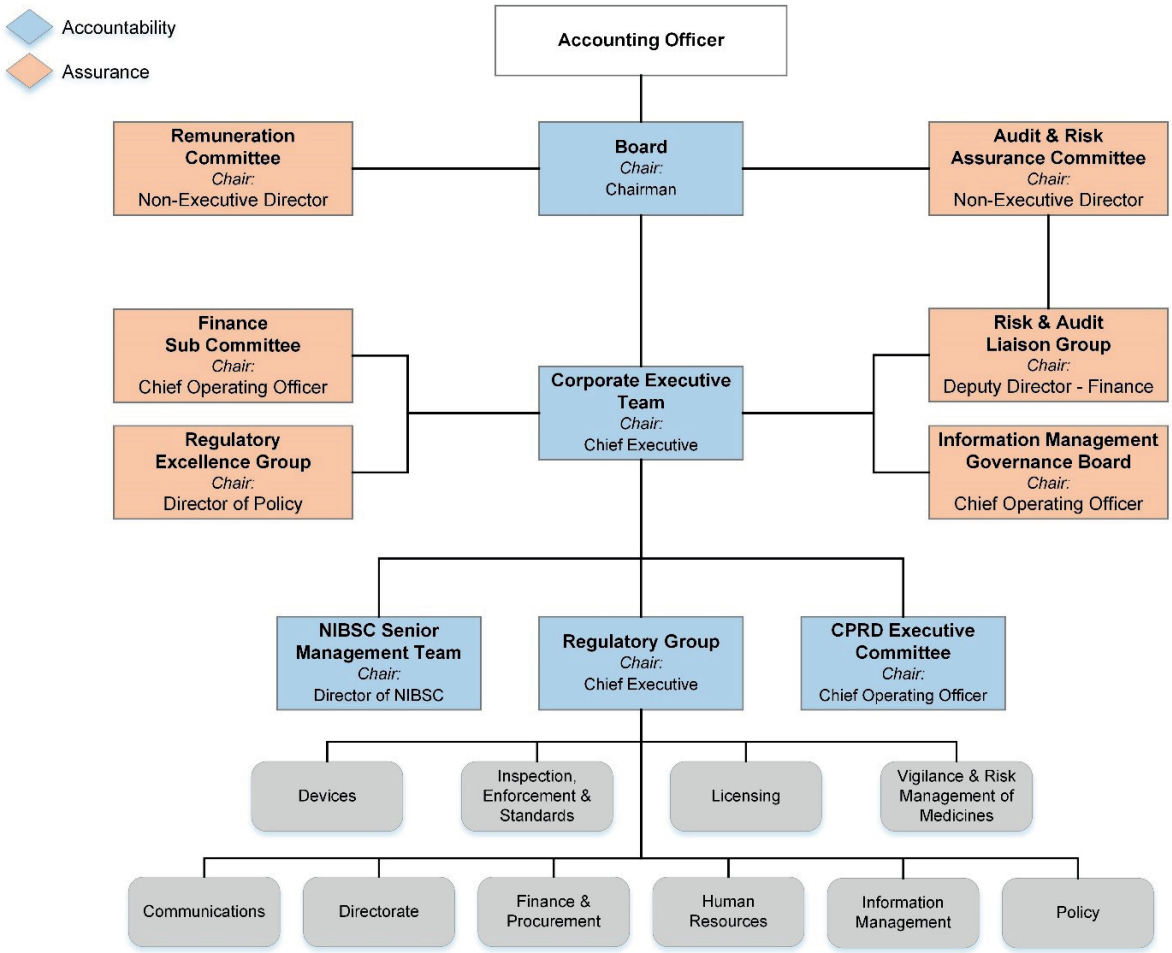
- The Board comprising the Chair, non-executive directors, Chief Executive and Chief Operating Officer is primarily responsible for advising on the strategic development of the Agency and ensuring that targets set out in our Business Plan and endorsed by ministers are met.
- The CET consisting of the 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 explains how the Agency has complied with the principles of good governance and reviews the effectiveness of these arrangements.

As Accounting Officer, I am 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, I am 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.

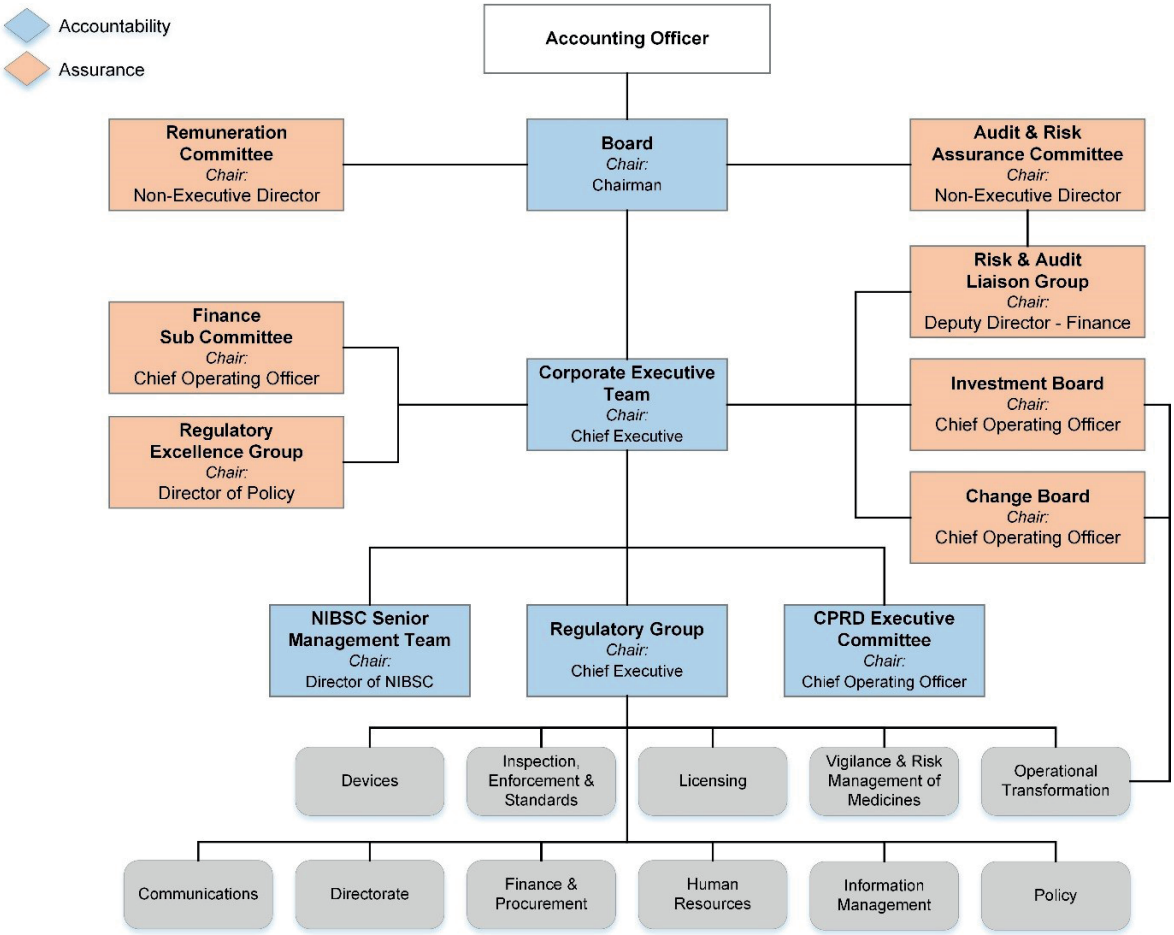
The Governance Structure up to 31st January 2018



The diagram above shows the Agency's governance structure up until 31 January 2018. With the development of the Operational Transformation (OT) programme, the Agency needed more robust governance for its investment activities. The Agency's investment activities used to be approved by the Information Management Governance Board (IMGB) whose focus was limited to IT spend, while investments decisions at NIBSC were made locally apart from IT. The structure was suitable for the level of investment activity until the OT programme was developed. It was recognised that this structure would not be sufficient for the level of investment required by the OT across the Agency. There was a need to widen governance at strategic levels beyond just digital change programmes and projects. Prior to the establishment of the Change Board, the Operational Transformation Programme Board (OTPB) governed the development of the OT programme business case.

From 1 February 2018 the revised governance structure was implemented as shown below.

The Governance Structure from 1st February 2018



The new structure replaces the IMGB with the two Boards, a Change Board and an Investment Board, that review and approve all change activities and programme investments covering all digital and non-digital projects. Additionally, the OT Director has joined the Agency's Corporate Executive Team. The new structure builds resilience to ensure the Agency's statutory obligations are met in any exit-from-the-european-union scenario. It commits the Agency to transform in a customer centric way, embracing best practice systems and processes and enhancing collaboration across the UK health systems to maximise health benefits.

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 H & S C determines the policy and financial framework, within which the Agency operates, agrees high level performance targets and approves its corporate and business plans, but is not involved in the day-to-day management of the Agency. The terms under which the Agency operates are set out in its Framework Document which was updated in March 2016.

The Board

The responsibilities of the Agency's board, known as the Board, are set out in the Agency's framework document and are listed on page 66.

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 Members Attendance

Non Executive Directors	Board	Board Away Day
Professor Sir Michael Rawlins (Chair)	9 (9)	2 (2)
Dr Barbara Bannister, MBE	9 (9)	2 (2)
Professor Dame Valerie Beral	6 (9)	2 (2)
Professor Bruce Campbell	9 (9)	2 (2)
Mr Matthew Campbell-Hill	8 (9)	2 (2)
Mr Martin Hindle	9 (9)	2 (2)
Mr Stephen Lightfoot	9 (9)	1 (2)
Professor Sir Alex Markham	7 (9)	2 (2)
Ms Deborah Oakley	9 (9)	2 (2)
Professor David Webb	8 (9)	1 (2)
Executive Directors		
Dr Ian Hudson (CEO)	9 (9)	2 (2)
Mr Jon Fundrey (COO)	9 (9)	2 (2)

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 Chair

The Chair is responsible to the Secretary of State and works 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 Chief Executive's performance to the Permanent Secretary
- The role of the Chair, 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

Board and Executive interaction was discussed at joint Board and Corporate Executive Team awayday on 29 January 2018. The discussion was informed by a report that had been prepared by Woodnewton Associates, an external consultancy, which in turn was informed by a series of interviews with every member of the Agency's Board and members of the Corporate Executive Team, including its Chair and Chief Executive. Woodnewton's report considered two specific areas: (i) Interaction between the Board and the Executive – and where there is room for improvement; and (ii) the mix of skills among the Board's Non-Executive Directors (NEDs) needed for the future. The outcome of the awayday discussion was a range of actions to be taken forward during 2018.

Among these were: (i) to prepare a draft Board Operating Framework, which was sent to the Board for comment in April 2018 and was discussed by the Board in May 2018; (ii) a VIP guest speaker from the public health field to attend a future Board dinner; (iii) the Board's work plan / forward programme of business to come to the Board on a regular basis (this will now be a standing item of business at every board meeting); (iv) new formats for finance and business plan reporting to come to the Board (new style reporting will now be a feature of board business); and (v) a number of representatives of patients and public forums to attend a future Board meeting, as distinct from the periodic Board meetings in public session (this is being arranged for the autumn of 2018). The Board will also consider the diversity of the Board, which the sponsor department (DHSC), along with Agency officials, will aim to address during future recruitment campaigns for Board members.

Audit and Risk Assurance Committee (ARAC)

The ARAC has 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 NEDs. 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 Cyber and Information security, procurement waivers, actions to enhance H & S for staff and the general control environment within the Agency.

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 in advance of every meeting.

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 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 & Accounts.

Review of ARAC Effectiveness

The committee's 2017/18 annual effectiveness survey showed that 88% of answers in the returned questionnaires were in the 'above average' / 'fully satisfactory' categories. This showed an increase of 5% when compared to the previous year's results.

ARAC Attendance

Members	ARAC
Ms Deborah Oakley (Chair)	5 (5)
Mr Martin Hindle	5 (5)
Mr Stephen Lightfoot	4 (5)
Professor Sir Alex Markham	3 (5)

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

The following persons routinely attended all Committee meetings:

- The Accounting Officer
- The Chief Operating Officer
- The Director of NIBSC or a deputy
- The Chief Information Officer

- The Deputy Director of Finance
- The Commercial Deputy Director, Finance & Procurement
- The Head of Internal Audit
- Representatives from the External Auditor
- Representatives from the Department of Health and Social Care.

The secretariat was provided by the Accounting Officer's staff.

The Committee also required other officials of the organisation to attend Committee meetings or to provide written reports to assist the Committee with its discussions on any particular matter.

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. Details of its membership is listed in the Remuneration report section of the Agency's Annual Report and Accounts. 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 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 regular 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 Members Attendance

	CET
Dr Ian Hudson (CEO)	12 (12)
Ms Vanessa Birchall-Scott	12 (12)
Ms Rachel Bosworth	8 (12)
Mr Jon Fundrey	12 (12)
Mr Gerald Heddell	11 (12)
Dr Christian Schneider	10 (12)
Dr Siu Ping Lam	11 (12)
Mr Jonathan Mogford	12 (12)
Mr John Qiunn	11 (12)
Dr June Raine, CBE	10 (12)
Dr Janet Valentine	12 (12)
Mr John Wilkinson, OBE	8 (12)
Dr Samantha Atkinson (from July 2017)	8 (9)

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.

Oracle Fusion

The Oracle Fusion E-Business Programme to replace the Agency's HR, Finance and Procurement systems and to move off the shared service provided by Public Health England (PHE) into NIBSC was implemented in this reporting year. The programme sought to unify the Agency onto one set of processes, to bring about greater data security and governance, reduce costs and, via the introduction of new features, improve capability.

The implementation of the new software was split into two phases, with Phase 1 going live in April 2017. Phase 1 transitioned the majority of activities, with only Income and Receivables elements for MHRA and CPRD remaining on the previous Oracle system.

Phase 1 encountered a number of issues connected with data migration, temporary loss of functionality and the data backlog handed over from PHE. This led to an interruption in the production of Finance monthly information. Each issue was addressed by a dedicated cross-Agency team and resolved.

Phase 2 was implemented in November 2017, with little disruption meaning that the whole of the organisation is now using the same operating software. An internal audit review of Phase 2 gave assurance that issues encountered in Phase 1 had been resolved.

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 CET and approved by the 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 corporate risk register is reviewed quarterly by the CET and updated as appropriate. Each corporate risk is vested in specific CET members, who own and monitor 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 2018. 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.

Assessment of Risk

As at 31 March 2018, the Agency's corporate risk register had identified the following principal risks:

- The Agency has a risk of losing some income depending upon the agreement that is reached during the exit-from-the-european-union negotiations.
- The Agency currently has access to European systems and data which could be disrupted if an agreement for continued access is not reached during the exit-from-the-european-union negotiations.
- The Agency is investing in a major Operational Transformation programme and there is a risk that not all of the benefits will be achieved.
- The Agency, like every other organisation, is at risk from cyber-attacks and the threat of system disruption and/or data loss.
- The Agency has some financial control risk associated with non-compliant procurement that could lead to poor value for money.

Detailed action plans and mitigations have been put in place to minimise and manage all of these risks. The mitigations for these risks are discussed on page 48.

Other potential risks include the failure to prevent falsified medical products reaching the public via the illegitimate supply chain, the risk of providing data to clients that may lead to reputational damage which compromises the effectiveness of Clinical Practise Research Datalink. The Agency, like other organisations has a risk of loss of key staff and/or difficulty in recruiting to key roles as a result of market forces.

Information Governance

We continue to strengthen and improve our Information Governance Framework which brings 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 and preparation for implementation of General Data Protection Regulation on 25 May 2018.
- Information security, including cyber-security and information risk management
- Information lifecycle management – reviewing our retention schedule and employing technologies to automate retention.
- Reviewing and reducing our legacy data where possible, keeping only data that is required.
- Corporate governance, including transparency requirements under the Freedom of Information Act 2000 and Environmental Information Regulations 2004.

We have transferred responsibility for Data Protection and Records Management from Policy Division to Information Management Division. We have recruited a Data Protection Officer and have brought our knowledge, information and data specialists together into a new function to strengthen corporate advice on data and information assurance to better support the Agency in implementation of the Information Governance Framework.

The Agency has been working on an action plan for compliance with the new GDPR rules since September 2017, as part of a wider piece of work to establish an Information Management governance framework in MHRA. The action plan is based on the Information Commissioner's Twelve Steps to prepare for the General Data Protection Regulation (GDPR).

Good progress has been made, and the Agency had all the key requirements in place by 25 May 2018. These being: documenting our records of personal data processing; reviewing privacy notices and how we bring them to individuals' attention; refreshing consent where necessary; approving procedures relevant to data subjects rights and conducting data protection impact assessments; and raising staff awareness of key changes such as breach reporting, through training and topic-based, bite-sized articles.

An internal audit on Information Governance and Data Retention recognised the good progress and assessed the Agency as having a Moderate assurance rating.

Information Risk

The Agency takes information risk very seriously and we are actively working to reduce our exposure.

We have sought assurance that our security tooling investments are effective. 1The Agency has been placed in the top 9% of organisations when measured against email security controls.

We are making steady progress to closing some high-risk vulnerabilities that have been identified in our IT security health-check.

We are performing well against the National Data Guardian (NDG) for Health and Care's 'ten data security standards', but more needs to be done to move away from redundant or out of service software and hardware, and to improve our security incident management.

We are about to increase our security threat detection capability using new tooling which identifies potential security threats and allows them to be isolated and removed.

All staff are required to complete mandatory online training in their responsibilities for information. The numbers that completed the training were 1,321, approximately 98% of staff in post.2

Information Skills

Raising skill across the Agency's 1,350 staff is the best way to protect our information and exploit it. The Digital Workplace Programme has delivered the following.

- 1,000 people have attended at least three face-to-face presentations on managing information on the new desktop
- More than 1,000 people, have considered the information they previously kept on their personal drives and moved what should be available to others to a shared area or Team Site, deleted what they no longer

need and moved what is left onto their OneDrive – they have done this themselves

- All staff at NIBSC have consolidated the information they previously held in various scattered personal email archives and moved it to a new online archive – again they have largely done this themselves following instructions provided by the programme, with assistance when needed
- 601 people from the seven divisions now using SharePoint team sites have attended an additional 2.5 hours training on Team Sites and information management
- 102 extra Bits and Bytes sessions have been offered, covering subjects such as managing information using Team Site and Delve searching, OneNote and co-authoring – 40 per cent of all places have been taken;
- over 80 people have attended voluntary sessions on Information Security, Risk and Data Protection
- staff across the seven divisions that now have Team Sites have considered the validity of Agency information they previously kept on network drives and deleted 40-50 per cent in total
- everyone has access to the online Knowledge Hub, providing links to dozens of tip sheets and online tutorials for handling information.

Improving operational information

The Agency is making significant improvements to information management through successful delivery of its Digital Workplace Programme.

All staff now have a new laptop and Office365 account, and we are moving all information from unstructured network drives into SharePoint in Office365 online. This gives us, for every article of information, a complete audit trail showing who has contributed to it, how and when. A new records management tool manages the retention and disposal of documents in SharePoint in accordance with the Agency Retention Schedule.

The management of this change has included educating all staff about their responsibilities for thinking about the information they create – what kind of information it is, who needs to see it and how long it should be kept for. Moving our information online is not only more secure but is also consistent with our intention to move our technology into the Cloud where possible.

Information Processing Unit Reform

The Information Processing Unit (IPU) Reform Programme has focused on the submission validation activities of the unit with a view to ensuring our processes are as efficient as they can be.

The programme has:

- delivered more efficient approaches to validation
- delivered new services to the industry
- harnessed new technology to improve our service to internal and external stakeholders.

We have introduced robotic process automation to automate many of the data entry tasks in this area, enabling processing outside of normal working hours and providing a quicker validation decision. We have also introduced a validation correction function which allows us to work with applicants to

correct validation issues during processing.

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. These documents were reviewed based on learning from whistleblowing cases and republished this year, with accompanying awareness raising methods including an article on the Whistleblowing Champion. 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. The 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 assessing the timeliness of whistleblowing investigations, setting out lessons being learned, and action taken, highlighting any themes and including relevant data and plans to raise awareness further. ARAC's role is to ensure it receives appropriate assurances from the Agency that action is being taken to prevent the issues occurring again. Recommendations from an internal audit review of fraud and whistleblowing which took place during the year have been considered and implemented.

During the year, there was one internal whistleblowing case raised by a member of staff. The concerns raised were investigated, confirmation was provided to the whistle-blower that the investigation was completed, and management took appropriate action as a result.

Effectiveness of Anti-Fraud and Bribery Policy

The Agency has an internal Anti-Fraud and Bribery Policy and Procedure which was updated in October 2017. This sets out the Agency's stance on non-regulatory fraud and bribery, defines both terms and reminds staff of the standards of behaviour expected of them under the Civil Service Code. The Agency has two Fraud Officers who manage any non-regulatory fraud cases, ensuring they are investigated appropriately, and lead on increasing awareness of fraud generally. A number of changes were made to the Anti-Fraud and Bribery Policy and Procedure in response to the 2017/18 internal audit to provide better linkages with the Whistleblowing Policy and Procedure. In addition, the Agency's intranet pages on Fraud and Whistleblowing were brought together onto one page headed "Raising a Concern" to provide a one-stop-shop for staff. The Agency has a comprehensive awareness programme including the annual mandatory CSL online training for all staff, intranet articles and targeted workshops for staff in key roles. We undertake an annual risk assessment programme with all divisions. ARAC has oversight of all cases and receives quarterly reports. 4 new cases were opened in for investigation in 2017/18.

Procurement

During 2017/18, an initial Audit was undertaken on Procurement and Contract Management at NIBSC which resulted in an "unsatisfactory" outcome. Subsequently, a further audit was conducted on "MHRA Agency Wide" resulting in another unsatisfactory outcome. Agency Management accepted the findings and agreed an action plan with many elements around process

and compliance already successfully implemented. Within the Agency Wide report, one of the recommendations was as follows:

"The agency should consider its appetite for risk regarding disaggregated and non-compliant expenditure and whether to invest in additional resources to support category management".

As such, it was agreed to undertake a full "Strategic Review" of procurement and contract management, both of which are currently very varied in terms of approaches adopted across the Agency, exacerbated by "ownership" being fragmented. Whilst general awareness is perceived as being low, it is starting to gain traction and there is an apparent appetite to improve the commercial value offering which can be delivered through effective Strategic Sourcing. The output from this review will be incorporated into the wider OT programme with the revised, optimum Operating Model being implemented by end of 2018 calendar year.

Operational Transformation

The OT Programme, at the direction of the CET, has delivered the new Agency governance structure together with an Enterprise Portfolio Management Office (EPMO), where all the change activity across the Agency is now consolidated into a single portfolio that is governed by a single governance structure.

The Change Board will oversee delivery of the required in-flight strategic change activities in line with the direction set by the approved project/ programme plan and aligned to the Corporate Plan and Strategic Imperatives. The Investment Board will manage and monitor the approval of all requests for spend and specifically supports the delivery of the required investment and benefits management in line with the vision / strategic direction set by the CET. A Business Case Challenge Group will provide a first level of challenge and rigour before business cases are submitted to the Investment Board for approval.

The members of the Change and Investment Boards are Executive Directors from across the Agency with representation from the sponsor and investment teams at Department of Health and Social Care (DHSC). The Business Case Challenge Group is formed of Deputy Directors and Senior Civil Servants, many of whom will be Senior Responsible Owners (SROs) for the different programmes and projects that comprise the OT Programme and the broader change portfolio. It will provide an environment for these SROs to work together to ensure that the proposals for how to deliver change are as effective, efficient and coordinated as possible. The EPMO is the Secretariat for the governance boards and holds their full Terms of Reference.

Internal Audit

During the 2017/18 financial year, the internal audit services was provided by the Government Internal Audit Agency (GIAA). This team operates to prescribed 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 GIAA 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.

11 assurance-based reviews have been performed during the year of which 2 were rated as 'Substantial', 8 as 'Moderate and 1 as 'Limited' assurances. The table provided by the GIAA describes the assurance ratings.

Substantial	In Internal Audit's opinion, the framework of governance, risk management and control are adequate and effective.
Moderate	In Internal Audit's opinion, some improvements are required to enhance the adequacy and effectiveness of the framework of governance, risk management and control.
Limited	In Internal Audit's opinion, there are significant weaknesses in the framework of governance, risk management and control such that it could be or could become inadequate and ineffective.
Unsatisfactory	In Internal Audit's opinion, there are fundamental weaknesses in the framework of governance, risk management and control such that it is inadequate and ineffective or is likely to fail.

Internal Audit reviews

- The review of Devices Handling of Incidents, which analysed the process for recording, responding to and reporting device incidents, was awarded a **Substantial assurance**; the highest possible rating awarded to this arm of the Agency for second consecutive period.
- The review of MHRA Managing and Countering Non-Regulatory Fraud resulted in **Moderate assurance**. The review highlighted a need for better linkages between the Agency's Whistleblowing policy and the Anti-Fraud and Bribery Policy. This has now been fully implemented.
- The review of MHRA-NISBC Batch Release Testing which was to evaluate whether appropriate governance and assurance arrangements were in place and assess the mechanisms in place to manage stakeholder relationships and finances was awarded a **Moderate assurance**. Work is ongoing and on target for full implementation of recommended improvements that would further enhance the adequacy and effectiveness of the framework of governance, risk management and control.
- The review of the Agency's Business Continuity (BC) plan resulted in a **Moderate assurance**. The review recognised the documented plans that

have been put in place to promote a resilient IT environment and BC structure and that a number of the findings highlighted in the review were already recognised by the Agency prior to the audit, with action plans evidenced.

- The review of the Agency's E-Business Programme – Phase 1 focused on the implementation and amendment of financial controls across the organisation, aligned to and resulting from the introduction of the new system; it was awarded a **Moderate assurance**. One of the areas noted in the review was Agency's new supplier details verification process. The Agency has strengthened its controls and verification processes.

- The review of the Agency's E-Business Programme – Phase 2 focused on the second phase of implementation of the Programme and was awarded a **Moderate assurance**. This review considered any outstanding issues from Phase 1 implementation that were continuing to hamper performance and could potentially impact the ease with which the Agency could produce its year end accounts, potentially impacting on the National Audit Office (NAO) audit of the Agency. The review did not identify any areas of control design deficiencies from the auditors' walkthroughs of accounts receivable, journals and fixed assets. Other issues such as Accounts Payable, Cash Management and General Ledger/Reporting identified in the Phase 1 review were found to have all been addressed.

- The review of Information Governance and Data Retention, which was awarded a **Moderate assurance**, assessed if current information governance and data retention practices are sufficient to manage the Agency's information and data risks. The one recommendation on retention and data storage is on track for full implementation.

- The review on the Licensing and Use of Data was awarded a '**Moderate**' assurance. The Licensing Division has a diverse range of responsibilities, including the assessment and approval of marketing authorisations for new medicinal products, new routes of administration or new formulations for existing drugs. In addition, the Division has responsibility for assessing and granting clinical trial authorisations. Activities span national and European licensing, making a significant contribution to the activities of the European Medicines Agency (EMEA).

- The review of Agency-wide Procurement was awarded a '**Limited**' assurance. This was a slight improvement on the previous audit where it had been awarded an 'Unsatisfactory' assurance. The review provided assurance that the issues relating to Procurement, identified in the previous reviews, were being addressed as part of the agreed management action plans.

- The review of Management of H & S, which was awarded a '**Moderate**' assurance considered plans and processes, including the adequacy of effectiveness of training provision and reporting. The Health and Safety Team are aware also aware of the areas considered in the report for further and are considering future actions to address them.

- The review of CPRD: External Access to Data which reviewed the adequacy of controls over external security access to CPRD GOLD database was awarded a '**Substantial**' assurance, the highest possible rating awarded. The report has found overall that external access is well regulated.

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

reports. There was 1 High risk recommendation which is on track to be fully implemented by agreed target date, 16 Medium risks of which 7 have been fully implemented and 23 Low risk recommendations of which 13 have been fully implemented. All other outstanding items are on track to be fully implemented by agreed target dates.

Areas of good practice

The reviews noted on good practice as follows:

- The Devices Handling review acknowledged timely recording. It was noted that this risk is being managed appropriately. There is a KPI in place that all incidents must be recorded within 3 working days and all of audited sample of 25 incidents met this requirement.
- The Managing and Countering Fraud review highlighted that Agency has developed a comprehensive fraud awareness training and activities schedule, detailing what activities have been delivered to whom and when. Activities included targeted fraud awareness training sessions, published articles, posters and presentations at Divisional Managers Meetings. Comprehensive risk registers have been developed using the Agency's Risk Management Framework. The areas which feature most heavily on these registers are used to target future fraud awareness training sessions.
- The NIBSC-Batch Release Testing noted that the Agency regularly reviews data on the size and share of the control testing market. Internal data is plotted against data obtained on other comparable Official Medicines Control Laboratories (OMCLs) and this is used to develop trend analysis and support pricing strategies. This information is also being analysed to understand any potential downward trends in activity which may arise as a result of exit-from-the-european-union.
- The BC review highlighted that a robust BC policy and management system has been established and documented through the use of an overarching BC policy and management system framework. A resilience plan has been created as a framework for dealing with agency-level emergencies or crises.
- The implementation of the E-Business Programme resulted in a lessons learned exercise which captured 46 potential issues or learning opportunities. These issues were analysed by the internal auditors who were satisfied that the Agency has appropriately considered learning opportunities and what could be done differently if a similar future situation arose. The Agency has shared these with other Arm's Length Bodies (ALBs) going through a similar implementation programme.
- The H&S audit review highlighted that appropriate H&S risk assessments are undertaken with risks being identified, assessed and managed to acceptable levels. The Safety Organiser system is used to effectively record all accidents and near misses.
- The CPRD review of External Access to Data highlighted that CPRD staff are fully trained on using the GOLD system and training is provided to all new licence users outside the organisation to ensure that users are able to navigate and use the database. The training materials and guides are current and well detailed.

Head of Internal Audit opinion

In accordance with the requirements of the UK Public Sector Internal Audit Standards, the Head of Internal Audit (HIA) was able to provide an annual opinion of the overall adequacy and effectiveness of the organisation's risk management, control and governance processes.

The HIA's opinion was based on the outcomes of the work that Internal Audit has conducted throughout the course of the reporting year and on the follow up action from Internal Audits conducted in the previous reporting year. There have been no undue limitations on the scope

of audit work and the appropriate level of resource has been in place to enable the function to satisfactorily complete the work planned.

For the areas of risk management, governance and control on which the HIA must report, the following were concluded:

- In the case of risk management and governance - satisfactory. Based on the 2017/18 audit fieldwork, there have been appropriate and proportionate systems in place, including, where necessary, the introduction of appropriate tactical arrangements implemented during, and following, the introduction of the MHRA's new E-Business system.
- In the case of control – satisfactory. Eleven assurance-based reviews, including two reviews of the E-Business Programme introduction, have been conducted. The majority of the reviews were rated as 'moderate', with two rated as 'substantial'. None of the audits were rated as 'unsatisfactory' although one audit (Agency-wide Procurement) was rated as 'limited'. This latter review had been preceded by two 'unsatisfactory' reviews of this area during 2016/17. The Agency has made steady progress, accompanied by ongoing senior ownership and scrutiny, in driving improvements in Procurement. Further progress is required, although the HIA remain satisfied that MHRA management has instigated appropriate action or developed adequate plans to remediate the issues that have been identified.

In summary, the HIA's overall opinion was that of moderate assurance that the MHRA has had adequate and effective systems of control, governance and risk management in place for the reporting year 2017/18.

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 2018 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 his 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 2017/18.

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 2018 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 DHSC 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 Chair and non-executive directors are appointed by the Secretary of State for Health and Social Care 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 Rawlin's GBE, salary and bonus awards are set by a DHSC Pay Committee in accordance with the Department's senior salaries review processes. Remuneration for non-executive directors is determined by DHSC 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. This is reported on page 97.

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

2017/18	Salary £000	Performance pay and bonuses £000	Pension related benefits £000	Total £000
Dr Ian Hudson Chief Executive	150-155	Nil	12.5-15.0	160-165
Mr Jon Fundrey Chief Operating Officer	135-140	Nil	52.5-55.0	185-190
Dr June Raine, CBE Director of Vigilance & Risk Management of Medicines	125-130	10-15	Nil	140-145
Dr Christian Schneider Director of NIBSC	135-140	Nil	52.5-55.0	185-190
Mr Gerald Heddell Director of Inspection. Enforcement and Standards	85-90	Nil	15.0-17.5	105-110
Mr John Wilkinson, OBE Director of Devices	115-120	Nil	45.0-47.5	165-170
Ms Rachel Bosworth Director of Communications	95-100	0-5	7.5-10.0	105-110
Mr Jonathan Mogford Director of Policy	100-105	10-15	2.5-5.0	115-120
Dr Siu Ping Lam Director of Licensing	115-120	Nil	2.5-5.0	120-125
Mr John Qiunn Chief Information Officer	95-100	10-15	25.0-27.5	130-135
Ms Vanessa Birchall-Scott Director of Human Resources	95-100	Nil	35.0-37.5	130-135
Dr Janet Valentine Director of CPRD	95-100	Nil	60.0-62.5	155-160
Dr Samantha Atkinson[1] Director of Operational Transformation	75-80	Nil	25.0-27.5	100-105

Band of the highest paid director's total remuneration	150-155
Median total	39,897
Remuneration ratio	3.8
Range of staff remuneration	8-155

* CET members receive no 'benefits in kind'.

1 Dr Samantha Atkinson became a member of CET on 17 May 2017. The full year equivalent is £85-90k. Excludes performance pay in her previous role.

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 Qiunn 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 director's 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 31 October 2016. The full year equivalent is £135k-£140k.
2 Mr Peter Commins retired from the Agency on 25 October 2016. The full year equivalent is £135k-£140k.

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

2017/18	Salary £000	Benefits in kind (taxable) to nearest £100*	Total £000
Professor Sir Michael Rawlins Chair	60-65	-	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	5,600	10-15
Mr Martin Hindle Deputy Chair	5-10	300	5-10
Mr Stephen Lightfoot Non Executive Director	5-10	100	5-10
Professor Sir Alex Markham Non Executive Director	5-10	300	5-10
Ms Deborah Oakley Non Executive Director	10-15	-	10-15
Professor David Webb Non Executive Director	5-10	1,400	5-10

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

2016/17	Salary £000	Benefits in kind (taxable) to nearest £100*	Total £000
Professor Sir Michael Rawlins Chair	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 Deputy Chair	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.

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 2017/18 relate to performance in 2016/17 and the comparative awards reported in 2016/17 relate to performance in 2015/16.

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

The banded remuneration of the highest paid director in the Agency in the financial year 2017/18 was £150k-£155k (2016/17, £160k-165k). This was 3.8 times (2016/17, 4.1) the median remuneration of the workforce, which was £39,897 (2016/17, £39,304) and was due to a decrease in banding for the highest paid director. No employee received remuneration in excess of the highest paid director in 2017/18 (2016/17, none).

The range of staff remuneration was £8k-155k (2016/17, £8k-165k).

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 Chair, 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 2018 and related lump sum Bands of £5,000	Cash Equivalent Transfer Value at 1 April 2017. To nearest £1,000	Cash equivalent Transfer Value at 31 March 2018. 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	60-65 plus Nil lump sum	1,115	1,206	13	37
Mr Jon Fundrey Chief Operating Officer	2.5-5 plus Nil lump sum	35-40 plus Nil lump sum	495	563	39	33
Dr Christian Schneider Director of NIBSC	2.5-5 plus Nil lump sum	5-10 plus Nil lump sum	38	71	22	33
Dr June Raine, CBE Director of Vigilance & Risk Management of Medicines	0-2.5 plus lump sum of 0-2.5	50-55 plus lump sum of 155-160	1,072	1,089	Nil	32
Mr Gerald Heddell Director of Inspection. Enforcement and Standards	0-2.5 plus Nil lump sum	25-30 plus Nil lump sum	407	425	11	22
Mr John Wilkinson, OBE Director of Devices	2.5-5 plus Nil lump sum	15-20 plus Nil lump sum	239	297	39	29
Ms Rachel Bosworth Director of Communications	0-2.5 plus lump sum of 0-2.5	25-30 plus lump sum of 75-80	508	552	7	24
Mr Jonathan Mogford Director of Policy	0-2.5 plus lump sum of 0-2.5	35-40 plus lump sum of 105-110	664	713	3	25
Dr Siu Ping Lam Director of Licensing	0-2.5 plus lump sum of 0-2.5	40-45 plus lump sum of 130-135	946	1,013	3	29
Mr John Qiunn Chief Information Officer	0-2.5 plus Nil lump sum	30-35 plus lump sum of 75-80	475	515	7	24
Ms Vanessa Birchall-Scott Director of Human Resources	0-2.5 plus Nil lump sum	5-10 plus Nil lump sum	60	91	21	23
Dr Janet Valentine Director of CPRD	5-7.5 plus Nil lump sum	15-20 plus Nil lump sum	125	191	22	23
Dr Samantha Atkinson Director of Operational Transformation	0-2.5 plus Nil lump sum	15-20 plus Nil lump sum	206	230	7	21

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.

Full pension scheme disclosures are shown on pages 102 to 105.

Staff report

Staff costs (subject to audit)

	2017/18			2016/17
	Total £000	Permanently Employed £000	Other £000	Total £000
Wages and salaries	61,515	58,766	2,749	58,726
Social security costs	6,822	6,822	-	6,364
Other pension contributions	12,081	12,081	-	11,712
Sub-total	80,418	77,669	2,749	76,802
Less recoveries in respect of outward secondment	(65)	(65)	-	(159)
Total staff costs	**80,353**	**77,604**	**2,749**	**76,643**

Staff resources (subject to audit)

During the year an average of 1,306 permanent full-time equivalent staff were employed.

	2017/18		
	Total	Permanently Employed	Other
Chair	1	1	-
Chief Executive/Directors	11	11	-
Senior Civil Servants	131	126	5
Other Civil Service Staff	1,163	950	213
Total	**1,306**	**1,088**	**218**

	2016/17		
	Total	Permanently Employed	Other
Chair	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**

Staff omposition - 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 29%
- No data/prefer not to say 8%

Sickness absence

The average annual sickness rate for the calendar year 2017 was 5.9 working days per full time equivalent employee (2016/17, 5.7 days).

The annual turnover for the Agency was 13.4% (2016/17, 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 2017/18, expenditure on consultants was £87k (2016/17, £15k).

The Agency continues to employ temporary staff where it is of operational necessity. The Agency temporary staff expenditure was £2,754k in 2017/18 (2016/17, £1,689k).

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

Exit packages (subject to audit)

Cost band	Total number of exit packages by cost band
< £10,000	-
£10,000-£25,000	1
£25,000-£50,000	-
£50,000-£100,000	-
£100,000-£150,000	-
£150,000-£200,000	-
Total number of exit packages	**1**
Total resource cost	**£13,000**

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 £13k (2016/17, £112k) 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 2018 (31 March 2017, None).

Pensions

Pension scheme participation

Employees who joined on or after 1 April 2015 are members of the Civil Service Pensions (CSP) alpha scheme. Current employees with over 13 and a half years to retirement as at 1 April 2012 joined alpha and those with less than ten years remained in their current scheme. Those within ten to thirteen and a half years to normal pension age on 1 April 2012, were given the option to join alpha or remain in their existing scheme. The service to date of employees in their old scheme whom transferred to alpha was frozen, therefore past and present employees of the agency are covered by the provisions of the Principal Civil Service Pension Schemes (PCSPS). Employees in the NIBSC Centre who transferred from the Health Protection Agency (HPA) have retained their membership of the NHS Pension Scheme.

Civil Service Pensions

The PCSPS is an unfunded multi-employer defined benefit scheme and Alpha is a defined benefit scheme worked out on a career average basis. The agency is unable to identify its share of the underlying assets and liabilities. A full actuarial valuation was carried out at 31 March 2012. Details can be found in the resource accounts of the Cabinet Office: Civil Superannuation (www.civilservice-pensions.gov.uk).

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

For 2017/18, employees contributions were payable at one of five rates in the range 4.60% to 8.05% of pensionable pay, based on salary bands. The scheme's actuary reviews employer contributions every four years following a full scheme valuation. The contribution rates reflect benefits as they are accrued, not when the costs are actually incurred, and reflect past experience of the scheme.

The employee contribution rates are as follows:

Full time pay range	Classic and Alpha scheme	Classic plus, Premium and Nuvos schemes
Up to £15,000	4.60%	4.60%
£15,001 to £21,422	4.60%	4.60%
£21,423 to £51,005	5.45%	5.45%
£51,006 to £150,000	7.35%	7.35%
£150,001 and above	8.05%	8.05%

Benefits in classic accrue at the rate of 1/80th of final pensionable earnings for each year of service. In addition, a lump sum equivalent to three years initial pension is payable on retirement. For premium, benefits accrue at the rate of 1/60th of final pensionable earnings for each year of service. Unlike classic, there is no automatic lump sum. Classic plus is essentially a hybrid with benefits for service before 1 October 2002 calculated broadly as per classic and benefits for service from October 2002 worked out as in premium. In nuvos a member builds up a pension based on their pensionable earnings during their period of scheme membership. At the end of the scheme year (31 March) the member's earned pension account is credited with 2.3% of their pensionable earnings in that scheme year and the accrued pension is uprated in line with Pensions Increase legislation. In alpha a member builds up a pension based on their pensionable earnings during their period of scheme membership. The scheme year runs 01 April to 31 March and alpha pension is built up by adding 2.32% of pensionable earnings in the scheme year. In all cases members may opt to give up (commute) pension for a lump sum up to the limits set by the Finance Act 2004.

The partnership pension account is a stakeholder pension arrangement. The employer makes a basic contribution of between 8% and 14.75% (depending on the age of the member) into a stakeholder pension product chosen by the employee from a panel of three providers, one of which is now closed to new members. The employee does not have to contribute, but where they do make contributions, the employer will match these up to a limit of 3% of pensionable salary (in addition to the employer's basic contribution). Employers also contribute a further 0.8% of pensionable salary to cover the

cost of centrally-provided risk benefit cover (death in service and ill health retirement).

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

Further details about the Civil Service pension arrangements can be found at: http://www.civilservicepensionscheme.org.uk/

The NHS Pension Scheme (NHSPS)

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

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

For early retirements other than those due to ill health the additional pension liabilities are not funded by the scheme. The full amount of the liability for the additional costs is charged to the employer.

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

The employee contribution rates for NHS pensions are as follows:

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

The Government Financial Reporting Manual 2017/18 (FReM) requires the scheme to be accounted for as defined contribution in nature.

Employer contributions

The Agency has accounted for its employer contributions to these schemes as if there were defined contribution schemes. The Agency's contributions were as follows:

For 2017/18, employers' contributions for the agency employees of £11,941,354 with a further £8,842 respect of staff on secondment were payable to the PCSPS and NHSPS (2016/17, £11,924,518 and a further £26,077 in respect of staff on secondment) at one of four rates in the range 16.7 per cent to 24.3 per cent of pensionable pay (2016/17, 16.7 per cent to 24.3 per cent) for PCSPS and 14 per cent (2016/17, 14 per cent) for NHSPC, based on salary bands. The scheme's actuary reviews employer contributions every four years, following a full scheme valuation. The contribution rates reflect benefits as they are accrued, not when costs are actually incurred, and reflect past experience of the scheme.

Employees can opt to open a partnership pension account, a stakeholder pension with an employer contribution. Employers' contributions of £136,177 (2016/17, £152,013) were paid to one or more of a panel of three appointed stakeholder pension providers. Employer contributions are age related and range from 3 per cent to 12.5 per cent of pensionable pay (2016/17, 3 per cent to 12.5 per cent). Employers can also match employee contributions up to a limit of 3 per cent of pensionable pay. In addition, employer contributions of £6,153 (2016/17, £5,645), 0.8 per cent of pensionable pay, were payable to the PCSPS to cover the cost of the future provision of lump sum benefits on death in service and ill-health retirement of these employees.

Contributions due to the partnership pension providers at the reporting period date were £3,469. No contributions were prepaid at that date.

There were no cases of retirement on ill-health grounds during 2017/18 (2016/17, Nil). No additional pension liabilities were accrued.

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 and Social Care 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 Social care 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 and Social Care 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.

2017/18			
Charging activity	£000 Income	£000 Expenditure	£000 Surplus
Licensing	46,289	(44,102)	2,187
Inspections	9,010	(10,979)	(1,969)
Vigilance, Risk Management and Enforcement	31,549	(36,966)	(5,417)
British Pharmacopoeia	4,680	(3,212)	1,468
Devices	10,193	(15,855)	(5,662)
Clinical Trials	3,397	(3,393)	4
Regulator total	105,118	(114,507)	9,389
CPRD*	9,230	(11,432)	(2,202)
DHSC share of joint venture	(4,615)	5,716	1,101
	4,615	(5,716)	(1,101)
NIBSC	41,932	(46,278)	(4,346)
Total	**151,665**	**(165,501)**	**(14,836)**

2016/17			
Charging activity	£000 Income	£000 Expenditure	£000 Surplus
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
Regulator total	106,177	(106,335)	(158)
CPRD*	8,781	(8,687)	94
DHSC share of joint venture	(4,391)	4,344	(47)
	4,390	(4,343)	47
NIBSC	42,400	(42,177)	223
Total	**152,967**	**(152,855)**	**112**

* 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 (2016/17: 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.

Our review of assets under construction at 31 March 2018 identified no impairment (2016/17: £1.5m).

There were no other material losses or special payments during the year (2016/17: Nil).

Dr Ian Hudson
Chief Executive and Accounting Officer
Medicines and Healthcare products Regulatory Agency
16 July 2018

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

Opinion on financial statements

I certify that I have audited the financial statements of the Medicines and Healthcare products Regulatory Agency for the year ended 31 March 2018 under the Government Trading Funds Act 1973. The financial statements comprise: the Statements of Comprehensive Income, Financial Position, Cash Flows, Changes in Taxpayers' Equity; and the related notes, including the significant accounting policies. These financial statements have been prepared under the accounting policies set out within them. I have also audited the information in the Accountability Report that is described in that report as having been audited.

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 2018 and of the 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 regularity

In my opinion, in all material respects the income and expenditure 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.

Basis of opinions

I conducted my audit in accordance with International Standards on Auditing (ISAs) (UK) and Practice Note 10 'Audit of Financial Statements of Public Sector Entities in the United Kingdom'. My responsibilities under those standards are further described in the Auditor's responsibilities for the audit of the financial statements section of my certificate. Those standards require me and my staff to comply with the Financial Reporting Council's Revised Ethical Standard 2016. I am independent of the Medicines and Healthcare products Regulatory Agency in accordance with the ethical requirements that are relevant to my audit and the financial statements in the UK. My staff and I have fulfilled our other ethical responsibilities in accordance with these requirements. I believe that the audit evidence I have obtained is sufficient and appropriate to provide a basis for my opinion.

Responsibilities of the Accounting Officer for the financial statements

As explained more fully in the Statement of Accounting Officer's Responsibilities, the Chief Executive as Accounting Officer is responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view.

Auditor's responsibilities for the audit of the financial statements

My responsibility is to audit, certify and report on the financial statements in accordance with the Government Trading Funds Act 1973.

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. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs (UK) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As part of an audit in accordance with ISAs (UK), I exercise professional judgment and maintain professional scepticism throughout the audit. I also:

- identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for my opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.

- obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Medicines and Healthcare products Regulatory Agency's internal control.

- evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management.

- conclude on the appropriateness of management's use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Medicines and Healthcare products Regulatory Agency's ability to continue as a going concern. If I conclude that a material uncertainty exists, I am required to draw attention in my auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify my opinion. My conclusions are based on the audit evidence obtained up to the date of my auditor's report. However, future events or conditions may cause the entity to cease to continue as a going concern.

- evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and whether the consolidated financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

I communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that I identify during my audit.

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.

Other Information

The Chief Executive as Accounting Officer is responsible for the other information. The other information comprises information included in the annual report, other than the parts of the Accountability Report described in that report as having been audited, the financial statements and my auditor's report thereon. My opinion on the financial statements does not cover the other information and I do not express any form of assurance conclusion thereon. In connection with my audit of the financial statements, my responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or my knowledge obtained in the audit or otherwise appears to be materially misstated. If, based on the work I have performed, I conclude that there is a material misstatement of this other information, I am required to report that fact. I have nothing to report in this regard.

Opinion on other matters

In my opinion:

- the parts of the Accountability Report to be audited have been properly prepared in accordance with HM Treasury directions made under the Government Trading Funds Act 1973;
- in the light of the knowledge and understanding of the entity and its environment obtained in the course of the audit, I have not identified any material misstatements in the Performance Report and Accountability Report 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 and have been prepared in accordance with the applicable legal requirements.

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 Accountability Report to be audited are not in agreement with the accounting records and returns; or
- I have not received all of the information and explanations I require for my audit; or
- the Governance Statement does not reflect compliance with HM Treasury's guidance.

Report

I have no observations to make on these financial statements.

Sir Amyas C E Morse
Comptroller and Auditor General
National Audit Office
157-197 Buckingham Palace Road
Victoria
London SW1W 9SP

Date 18 July 2018

3 Financial Statements

Statement of comprehensive income for the year ended 31 March 2018

	NOTE	2017/18		2016/17	
		£000	£000	£000	£000
Income					
Trading Income	3.1				
Income from trading activities		**128,744**		128,689	
Income from Department of Health*		**28,800**		28,604	
Total Trading Income			**157,544**		157,293
Other income	3.2		**11,244**		10,416
Total income			**168,788**		167,709
Expenditure					
Staff costs	6	**(80,353)**		(76,643)	
Operating costs	7	**(86,753)**		(77,245)	
Total Expenditure			**(167,106)**		(153,888)
Operating Surplus			**1,682**		13,821
Finance income	8		**225**		289
Finance costs	8		**(46)**		(46)
Surplus for the financial year			**1,861**		14,064
Other comprehensive income					
Realised gain on inventories			**(106)**		(118)
Net gain on revaluation of property, plant and equipment			**30,058**		50
Total comprehensive income for the year			**31,813**		13,996

* Includes £7.0m (2016/17 £7.0m) of capital funding recognised as income in line with FReM.

The notes on pages 115 to 137 form part of these accounts.

Statement of financial position as at 31 March 2018

	NOTE	2017/18		2016/17	
		£000	£000	£000	£000
Non-current assets					
Property, plant and equipment	9	**139,404**		113,118	
Intangible assets	10	**5,004**		8,352	
Total non-current assets			**144,408**		121,540
Current assets					
Inventories	12	**5,868**		5,806	
Trade and other receivables	13	**37,109**		21,762	
Cash and cash equivalents	14	**81,408**		111,814	
Total current assets			**124,385**		139,382
Total assets			**268,793**		260,922
Current liabilities					
Trade and other payables	15	**(31,277)**		(41,763)	
Other liabilities	16	**(28,895)**		(29,385)	
Provisions	17	**(2,468)**		(119)	
Total current liabilities			**(62,640)**		(71,267)
Total assets less current liabilities			**206,153**		189,655
Non-current liabilities					
Other liabilities	16	**(4,822)**		(5,349)	
Provisions	17	**-**		(2,112)	
Borrowings	18	**(1,328)**		(1,328)	
Total non-current liabilities			**(6,150)**		(8,789)
Assets less liabilities			**200,003**		180,866

Taxpayers equity				
Public dividend capital			**1,329**	1,329
Reserves				
Revaluation reserve			**107,977**	78,025
Income and expenditure reserve			**954**	954
General fund			**89,743**	100,558
Total equity			**200,003**	180,866

Dr Ian Hudson
Chief Executive and Accounting Officer
Medicines and Healthcare Products Regulatory Agency
16 July 2018

The notes on pages 115 to 137 form part of these accounts.

Statement of cash flows for the year ended 31 March 2018

	NOTE	2017/18		2016/17	
		£000	£000	£000	£000
Cash flows from Operating activities					
Operating surplus		**1,682**		13,821	
Depreciation and amortisation		**11,283**		11,672	
Disposal of assets		**423**		143	
Impairment and reversals		**140**		1,553	
Realised gain on inventories		**(106)**		(118)	
(Increase)/Decrease in inventories	12	**(62)**		483	
(Increase)/Decrease in trade and other receivables	13	**(15,347)**		2,090	
(Decrease) in trade and other payables	15	**(20,981)**		(2,865)	
(Decrease) in other liabilities	16	**(1,017)**		(3,301)	
Increase/(Decrease) in provisions	17	**237**		(881)	
Net cash (outflow)/inflow from operating activities			**(23,748)**		22,597
Cash flows from investing activities					
Purchase of property, plant & equipment	9	**(4,656)**		(7,075)	
Purchase of intangible assets	10	**-**		(1,986)	
Net cash (outflow) from investing activities			**(4,656)**		(9,061)
Cash flows from financing activities					
Interest received	8		**225**		289
Interest paid	8		**(46)**		(46)
Dividend paid			**(2,181)**		(113,393)
Net cash (outflow) from financing			**(2,002)**		(113,150)
Net (decrease) in cash and cash equivalents in the financial year	14		**(30,406)**		(99,614)
Cash and cash equivalents at the beginning of the financial year	14		**111,814**		211,428
Cash and cash equivalents at the end of the financial year	14		**81,408**		111,814

The notes on pages 115 to 137 form part of these accounts.

Statement of changes in taxpayer's equity for the year ended 31 March 2018

	PDC1	General Fund	Reval reserve[2]	I & E reserve[3]	Total
	£000	£000	£000	£000	£000
Balance at 31 March 2016	1,329	98,736	78,097	954	179,116
Changes in taxpayer's equity for 2016/17					
Surplus for the year	-	14,064	-	-	14,064
Other changes					
Net gain on revaluation of non-current assets	-	-	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**	**100,558**	**78,025**	**954**	**180,866**
Changes in taxpayer's equity for 2017/18					
Surplus for the year	-	1,861	-	-	1,861
Other changes					
Net gain on revaluation of property, plant and equipment	-	-	30,058	-	30,058
Realised gain on inventories - biological standards	-	-	(106)	-	(106)
Dividend payable	-	(12,676)	-	-	(12,676)
Sub total	-	(12,676)	29,952	-	17,276
Balance at 31 March 2018	**1,329**	**89,743**	**107,977**	**954**	**200,003**

The notes on pages 115 to 137 form part of these accounts

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

NOTES TO THE ACCOUNTS

1 ACCOUNTING POLICIES

1.1. General

1.1.1 Compliance with government accounting requirements

The financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) as adapted and interpreted by the 2017/18 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 2017/18. The application of the following Standards as revised would not have a material impact on the accounts for 2017/18, were they applied in that year:

- IFRS 9 Financial Instruments: Effective date 1 April 2018. This will impact trade receivables as the Agency has no other financial assets. HMT has mandated the use of the simplified approach. This requires recognition of a loss at an amount equal to lifetime expected credit losses. A review of trade receivables has indicated there will be credit losses of £111k under IFRS 9. The current bad debt provision is £1.1m.
- IFRS 15 Revenue from Contracts with Customers: Effective date 1 April 2018. A full review of all income streams has been undertaken and management have determined that several streams are subject to IFRS 15. However current processes to recognise income from these streams over time are already compliant with IFRS 15 and it is not expected to have any impact.
- IFRS 16 Leases: Effective date 1 April 2019. IFRS 16 will require the recognition of all leases on the balance sheet, including leases for rented office space. Application guidance is awaited from HM treasury before a full impact assessment can be made.

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 2018. This was based on updated GIAs which now include all areas (previous valuations were based on used space only). 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. Where no revaluation is carried out, land and buildings are reviewed to ensure that carrying amounts are not materially different from those that would be determined at the end of the reporting period.

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 basis 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 DHSC

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: 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. Income is recognised when the application has been validated and published on the website.
- 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 and Social care 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. As discussed in the "Chief Executive's perspective on performance of the organisation" at the front of this document, as the UK prepares to leave the EU the exact nature of the Agency's future relationship with EU regulators after exiting the EU will be determined through the negotiations. The Agency continues to work on examining options and opportunities, working with stakeholders that feeds into broader Government discussions, to ensure that it remains able to continue to operate.

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 Agency 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.

2017/18				
	CPRD*	NIBSC	Regulator	Total
	£000	£000	£000	£000
Income from external customers	4,615	22,232	101,897	128,744
Income from DHSC	-	19,700	9,100	28,800
Total income**	4,615	41,932	110,997	157,544
Direct costs	(3,668)	(37,356)	(54,139)	(95,163)
Indirect costs	(2,049)	(8,922)	(60,972)	(71,943)
Total expenditure	(5,717)	(46,278)	(115,111)	(167,106)
Segment operating deficit	(1,102)	(4,346)	(4,114)	(9,562)

* represents MHRA's 50% share of joint arrangement

** Excludes Other income £10.9m (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.

2016/17				
	CPRD* £000	NIBSC £000	Regulator £000	Total £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

3 INCOME

3.1 Trading income

	2017/18	2016/17
	£000	£000
Income from fee charging activities*	**151,665**	152,967
Miscellaneous income	**5,879**	4,326
Total Trading Income	**157,544**	157,293

*Includes £13.7M (2016/17, £14.4M) 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

	2017/18	2016/17
	£000	£000
Licenses and inspections	**41,551**	45,005
Service fees	**31,549**	29,604
European Medicines Agency (EMA)	**13,748**	14,377
Devices	**10,193**	10,072
Clinical trials	**3,397**	3,315
British Pharmacopoeia	**4,680**	3,804
Other trading income	**5,879**	4,326
NIBSC	**41,932**	42,400
CPRD	**4,615**	4,390
Total	**157,544**	157,293

3.2 Other income

The Trading Fund received financial assistance in the form of additional funding of £10.9M (2016/17, £10.1M) from the Department of Health and Social Care to offset the additional costs of dividend £5.1M (2016/17, £4.4M) and depreciation £5.8M (2016/17, £5.7M), 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, (2016/17 £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 Social Care 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

	2017/18	2016/17
	£000	£000
Revenue	**9,230**	8,781
Expenditure		
Operating expenditure	**(7,526)**	(5,283)
Staff costs	**(3,906)**	(3,404)
Operating surplus	**(2,201)**	94

Statement of financial position

	2017/18	2016/17
	£000	£000
Non-current assets		
Tangible assets	**19**	26
Intangible assets	**5,446**	7,600
Current assets		
Trade and other receivables	**2,048**	3,487
Cash and cash equivalents	**9,991**	10,831
Current liabilities		
Trade and other payables	**(188)**	(696)
Other liabilities	**(1,548)**	(3,279)
DHSC contribution to joint arrangement	**(16,127)**	(16,127)
Assets less liabilities	**(359)**	1,842
Equity		
Surplus b/f	**1,842**	1,748
(Deficit)/Surplus for the year	**(2,201)**	94
Total Equity	**(359)**	1,842

Statement of cash flows

	2017/18	2016/17
	£000	£000
Cash flows from operating activities		
Operating surplus	**(2,201)**	94
Depreciation and amortisation	**2,161**	1,212
Disposals of assets	**-**	-
Impairments and reversals	**-**	-
(Decrease) in trade and other payables	**(508)**	(273)
Decrease/(Increase) in trade and other receivables	**1,439**	(1,849)
(Decrease)/Increase in other liabilities	**(1,731)**	548
Net cash inflow from operating activities	**(840)**	(268)
Cash flows from investing activities		
Purchase of intangible assets	**-**	(1,468)
Net cash (outflow) from investing activities	**-**	(1,468)
Cash flows from financing activities	**-**	-
Net decrease in cash and cash equivalents	**(840)**	(1,736)
Cash and cash equivalents at the beginning of the financial year	**10,831**	12,567
Cash and cash equivalents at the end of the financial year	**9,991**	10,831

Non-current assets

	2017/18	2016/17
	£000	£000
Fixed Asset		
Cost		
At 1 April	**10,110**	8,642
Additions	**-**	1,468
At 31 March	**10,110**	10,110
Amortisation		
At 1 April	**2,484**	1,272
Charge for the year	**2,161**	1,212
At 31 March	**4,645**	2,484
Net Book Value at 31 March	**5,465**	7,626

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 & Social Care each year equivalent to the 3.5% required rate of return. The dividend payable is £12.7M (2016/17 £12.2M).

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

	2017/18	2016/17
	£000	£000
Wages and salaries	**61,515**	58,726
Social security costs	**6,822**	6,364
Other pension contributions	**12,081**	11,712
Sub total	**80,418**	76,802
Less recoveries in respect of outwards secondment	**(65)**	(159)
Total	**80,353**	76,643

See staff report page 100.

7 OPERATING COSTS

	2017/18	2016/17
	£000	£000
Computing	**40,399**	33,229
Other operating costs	**14,884**	18,720
Depreciation and amortisation	**11,283**	11,672
Medicines testing and Laboratory expenses	**9,896**	11,245
Accommodation	**7,903**	5,362
Travel and subsistence	**2,388**	2,472
Total	**86,753**	77,245

Other operating costs include:		
Contracted out services	4,956	3,637
Operating leases	4,255	3,649
Audit fees	**110**	110

8 FINANCE INCOME AND COSTS

	2017/18	2016/17
	£000	£000
Finance income		
Interest received from Government Banking Service	**105**	254
Interest received others	**62**	2
Discounting of provision	**58**	33
	225	289
Finance costs		
Interest on DHSC loan	**(46)**	(46)
Total	**179**	243

9 PROPERTY, PLANT AND EQUIPMENT

2017/18	AUC	Land and Buildings	Computer and telecom equipment	Plant and equipment	Fittings, furniture and office equipment	Total
	£000	£000	£000	£000	£000	£000
Cost or valuation						
At 1 April 2017	2,430	101,030	8,461	23,339	9,349	144,609
Additions	4,656	-	-	-	-	4,656
Transfers	(3,572)	484	420	2,668	-	-
Reversal	(140)	-	-	-	-	(140)
Revaluation	-	29,974*	-	201	6	30,181
Elimination of accumulated depreciation	-	(7,514)	-	-	-	(7,514)
Disposals	-	-	(187)	(1,662)	-	(1,849)
At 31 March 2018	**3,374**	**123,974**	**8,694**	**24,546**	**9,355**	**169,943**
Depreciation						
At 1 April 2017	-	3,725	5,108	14,509	8,079	31,421
Charge for the year	-	3,789	1,423	1,779	1,239	8,230
Revaluation	-	-	-	117	6	123
Elimination of accumulated depreciation	-	(7,514)	-	-	-	(7,514)
Disposals	-	-	(177)	(1,544)	-	(1,721)
At 31 March 2018	**-**	**-**	**6,354**	**14,861**	**9,324**	**30,539**
Net book value						
At 31 March 2018	**3,374**	**123,974**	**2,340**	**9,685**	**31**	**139,404**
Net book value at 31 March 2017	2,430	97,305	3,353	8,830	1,270	113,188
Owned						
Net book value at 31 March 2018	**3,374**	**123,974**	**2,340**	**9,685**	**31**	**139,404**

Land and buildings

A professional valuation of land and buildings was carried out on 31 March 2018 which resulted in a net revaluation of £29.974k. In line with International Accounting Standard 16, accumulated depreciation has been eliminated against the carrying amount of the asset with the net amount restated to equal the revalued amount.

* This is due to three factors:

1. An increase of 13% in the general index applicable to the Depreciated Replacement Cost valuation of specialised assets.
2. A change in estimation technique to now include all areas (including plant rooms and other unused space) resulting in an increase of 42% in the Gross Internal Area (GIA).
3. A downward adjustment which is primarily for aspects of physical and functional obsolescence.

2016/17	AUC	Land and Buildings	Computer and telecom equipment	Plant and equipment	Fittings, furniture and office equipment	Total
	£000	£000	£000	£000	£000	£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	-	-
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
Charge for 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
Owned						
Net book value at 31 March 2017	2,430	97,305	3,353	8,830	1,270	113,188

10 INTANGIBLE ASSETS

2017/18	Computer systems	AUC	Software licences	Total
	£000	£000	£000	£000
Cost or valuation				
At 1 April 2017	26,263	1,433	5,242	32,938
Transfers	831	(831)	-	-
Disposals	(1,960)	-	(1,470)	(3,430)
At 31 March 2018	**25,134**	**602**	**3,772**	**29,508**
Amortisation				
At 1 April 2017	**20,121**	**-**	**4,465**	**24,586**
Charge for the year	2,546	-	507	3,053
Disposal	(1,727)	-	(1,408)	(3,135)
Amortisation at 31 March 2018	**20,940**	**-**	**3,564**	**24,504**
Net book value at 31 March 2018	**4,194**	**602**	**208**	**5,004**
Net book value at 31 March 2017	6,142	1,433	777	8,352
Asset financing				
Owned				
Net book value at 31 March 2018	**4,194**	**602**	**208**	**5,004**

2016/17	Computer systems	AUC	Software licences	Total
	£000	£000	£000	£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
Charge for 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

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.

	Others	Land and buildings	Others	Land and buildings
Payments recognised as an expense	2017/18	2017/18	2016/17	2016/17
	£000	**£000**	£000	£000
Minimum lease payments	**11**	**4,255**	42	3,649
Total	**11**	**4,255**	42	3,649

Total future minimum lease payments	**2017/18**	**2017/18**	2016/17	2016/17
	£000	**£000**	£000	£000
Payable:				
Within one year	**11**	**1,064**	27	4,255
Between two to five years	**-**	**-**	11	1,064
Over five years	**-**	**-**	-	-
Total	**11**	**1,064**	38	5,319

Finance Leases

The agency had no finance leases in 2017/18 (2016/17 Nil).

12 INVENTORIES

	31 March 2018	31 March 2017
	£000	£000
Amounts falling due within one year		
Biological Standards	**5,765**	5,656
Laboratory consumables and other stores	**103**	150
Total	**5,868**	5,806
Inventory consumed	808	753

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 2017/18 was £106k (2016/17, £118k). Inventories consumed during the year amounted to £808k (2016/17, £753K).

13 TRADE AND OTHER RECEIVABLES

	31 March 2018 £000	31 March 2017 £000
Amounts falling due within one year		
Due from the Department of Health and Social Care (see 13.1 below)	**10,894**	10,242
Trade receivables*	**8,760**	3,151
Other receivables	**1,145**	1,412
Accrued income	**7,190**	4,355
Prepayments**	**2,490**	2,521
Total	**30,479**	21,681
Amounts falling due after more than one year:		
Prepayments**	**6,630**	81
Total	**37,109**	21,762

*Trade receivables are shown net of a provision for bad debts of £1.1m (31 March 2017 £1.0m) and credit notes of £0.1m (31 March 2017 £0.2m).

** This is the Agency's contribution to fit out costs for its new office accommodation.

13.1 Amount Due from the Department of Health consists of:

	31 March 2018 £000	31 March 2017 £000
Accrued income	**-**	176
DHSC funding for NIBSC costs*	**10,894**	10,066
Total	**10,894**	10,242

* see Note 3.2

14 CASH AND CASH EQUIVALENTS

	31 March 2018 £000	31 March 2017 £000
Balance at 1 April	**111,814**	211,428
Net change in year	**(30,406)**	(99,614)
Balance at 31 March	**81,408**	111,814

Made up of		
Government Banking Service	**81,408**	111,814
Cash and cash equivalents	**81,408**	111,814

* includes £10m held on behalf of CPRD joint arrangement

15 TRADE AND OTHER PAYABLES

	31 March 2018 £000	31 March 2017 £000
Amounts falling due within on		
Due to Department of Health and Social Care (see 15.1 below)	**12,824**	12,530
Payments received on account	**5,622**	12,825
Taxation and social security	**3,151**	3,184
Other trade payables	**2,039**	626
Other payables	**-**	32
Accruals	**7,641**	12,566
Total	**31,277**	41,763
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 and Social Care consists of:

	31 March 2018 £000	31 March 2017 £000
Accruals	**148**	284
Dividend payable	**12,676**	12,246
Total	**12,824**	12,530

16 OTHER LIABILITIES

	Current		Non-current	
	31 March 2018 £000	31 March 2017 £000	31 March 2018 £000	31 March 2017 £000
Deferred revenue:				
Licence fees (applications and variations)	**10,846**	11,797	**4,218**	4,818
Other fees	**3,879**	3,241	**604**	531
Others:				
DHSC Contribution to CPRD joint arrangement*	**14,170**	14,347	**-**	-
Total	**28,895**	29,385	**4,822**	5,349

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

17 PROVISIONS

	Current		Non-current	
	31 March 2018 £000	31 March 2017 £000	31 March 2018 £000	31 March 2017 £000
EC grant refund	**343**	119	**-**	-
Dilapidations	**2,125**	-	**-**	2,112
Total	**2,468**	119	**-**	2,112

Movement in provisions

	Total £000
At 1 April 2017	2,231
Arising during the year	243
Unwinding of discount	(57)
Change in discount rate	51
At 31 March 2018	**2,468**

Expected timing of cash flows:

Within one year	**2,468**
Between two to five years	**-**
Over five years	**-**
Total	**2,468**

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.

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).

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.

18 BORROWINGS

	Non-current	
	31 March 2018 £000	31 March 2017 £000
Loan from Department of Health and Social Care	**1,328**	1,328
Total	**1,328**	1,328

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

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

	Total 2017/18	Less than one year	Between one and five years	More than five years	Total 2016/17
	£000	£000	£000	£000	£000
Fixed interest rate 3.50%	**1,328**	**-**	**-**	**1,328**	1,328
At 31 March 2018	**1,328**	**-**	**-**	**1,328**	1,328
At 31 March 2017				1,328	1,328

19 CAPITAL AND OTHER FINANCIAL COMMITMENTS

Contracts entered into not provided for in the accounts

	Intangible	Tangible	Intangible	Tangible
	31 March 2018	31 March 2018	31 March 2017	31 March 2017
	£000	£000	£000	£000
Contracted	**-**	**4,979**	707	3,063
Total	**-**	**4,979**	707	3,063

Commitments outstanding at 31 March 2018 for the Agency's new office accommodation was £2.9m, the remaining relate to non-current assets.

20 RELATED PARTY TRANSACTIONS

The agency is a Government Trading Fund and an Executive Agency of the Department of Health and Social Care. The Department of Health and Social Care is regarded as a related party. During the year, the agency has had a significant number of material transactions with the Department and with other entities for which the Department is regarded as the parent Department, notably various NHS Trusts.

In addition, the agency has had various material transactions with other government departments and other central government bodies. Most of these transactions have been with the Department for Business, Energy & Industrial Strategy.

During 2017/18, 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.

	2017/18 £000	2016/17 £000
Government Banking Service*	**81,408**	111,814
Total	**81,408**	111,814

* Includes £75k Proceeds of Crime Act funds which are the Agency's share of confiscated monies resulting from successful prosecutions and £110k 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 (2016/17: £1.328M). This resulted in interest payable of £0.046M (2016/17: £0.046M) out of total expenditure of £167.1M (2016/17: £153.9M).

Currency risk

The level of currency risk is determined by the level of income generated by activity undertaken on behalf of the EMA. For 2017/18 this was £13.748M (Euro15.710M) (2016/17: £14.377M; Euro 16.429M). This represents 8.2% (2016/17: 8.5%) 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. Possible fluctuations in the exchange rate will have the following impact on EMA income as at 31 March 2018:

	2017/18		2016/17	
	Increase	Decrease	Increase	Decrease
	£000	£000	£000	£000
Movement 1 %	**(138)**	**141**	(144)	146
Movement 3%	**(406)**	**431**	(421)	447

Credit risk

Credit risk arises from accounts receivable. The agency's exposure to credit risk arising from its operations is minimal. At year end, the level of aged debts over twelve months was £110k (2016/17 £183k).

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 office relocation to 10 South Colonade, Canary Wharf was completed in June 2018.

The agency's Trading Fund accounts are laid before the Houses of Parliament by the Department of Health and Social Care. 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.

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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