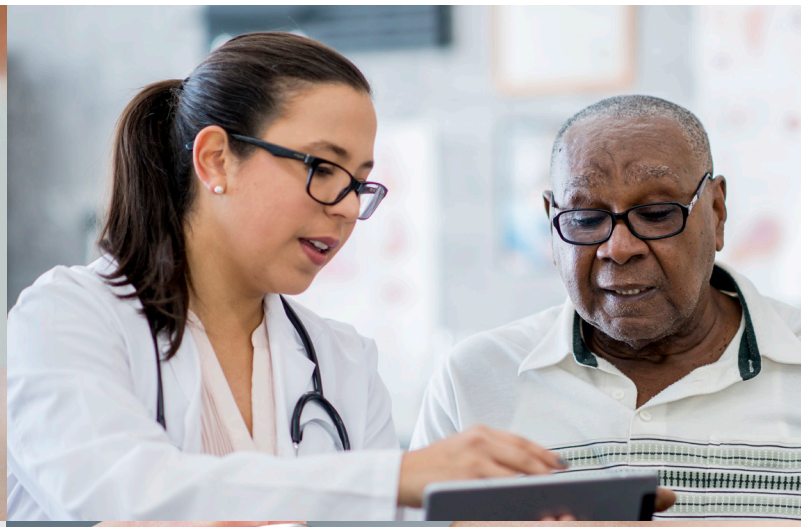
Medicines & Healthcare products Regulatory Agency

Annual Report and Accounts 2018/19

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Medicines and Healthcare products Regulatory Agency Annual Report and Accounts 2018/19

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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, the MHRA regulator, and the National Institute for Biological Standards and Control) make it unique. The Agency is a truly world-class regulator and centre for scientific research and innovation. That is a view I have heard so often across the UK and internationally.

As Dr Ian Hudson, Chief Executive, has mentioned in his foreword, when and on what basis the UK will leave the EU will have significant implications for the future direction of the Agency and its funding model. Accordingly, I am very grateful to the Agency's staff, legal advisers and those who support us who have worked so hard to prepare the Agency for all possible outcomes. I and my fellow Board members take a deep interest in the work to develop the Agency's strategic response to EU Exit, to ensure we get the best outcome for the protection of UK public health, as well as making a leading contribution to wider global public health.

As I write this foreword, arrangements to find a successor to Dr Hudson, who will retire in September 2019, are under way. I, along with the Board, are immensely grateful to Dr Hudson for all he has done to safeguard public health since he joined the Agency's predecessor, the Medicines Control Agency, as Director of Licensing in 2001. Under Dr Hudson's leadership, the Agency has continued to play a pivotal role in European and global medicines and medical devices regulation; and its contribution to the safeguarding of health in the UK and internationally has been significant.

Throughout the year, I, along with Dr Hudson, have continued to meet with a wide range of stakeholders. These include our Ministers and senior officials from across Government, where we have fed into discussions on a range of issues, for example, the vitally important Life Sciences Strategy. Additionally, we have met with industry trade associations, the Presidents of the Royal Medical Colleges, the Chief Medical Officers, Chief Pharmaceutical Officers and other officials in the Devolved Administrations. This is something I will continue to do with Dr Hudson and his successor in 2019/20.

In August 2018, I was sorry to lose three members of the Board whose terms of appointment came to an end on 31 August: Matthew Campbell-Hill, Martin Hindle and Deborah Oakley. Thankfully their departure was made good by the appointment of their successors in September and December: Amanda Calvert, Anne-Toni Rodgers and Michael Whitehouse, whose skills and experience are greatly welcomed.

Looking ahead, I and the members of the Board, are conscious that the Agency faces a range of challenges in 2019/20. Helping the Agency adjust to whatever Brexit outcome is settled on; the continued roll-out of the Operational Transformation programme; and, all on top of the "routine" work of the Agency regulating medicines and devices as well as developing our other services including the Clinical Practice Research Datalink and new biological standards. Moreover, I and the Board look forward to working with the Agency's new Chief Executive.

In conclusion, the Agency continues to perform very well in addressing the public health challenges it faces as well as meeting a range of unexpected events, including international public health emergencies. But we must

continue to be alert and agile to anticipate and meet the demands of an ever-changing world. We are, however, very fortunate and privileged in having an Agency staffed by highly motivated and talented individuals committed to protecting the public health – which gives me great confidence that we can navigate through EU Exit and make the most of opportunities that arise.

Sir Michael Rawlins GBE Kt

Chairman

Chief Executive's perspective on performance of the organisation

This is the sixth foreword to the Annual Report I have written since I was appointed as Chief Executive in September 2013, and sadly it will be my last as I stand down in September 2019. Over the past six years, 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 the safeguarding of public health across the UK and beyond.

While 2018/19 has been another very busy year, there has been one subject that has been ever present in the minds of staff and the wide spectrum of our stakeholders: leaving the EU. Throughout, the Agency has prepared for two models for the post-Brexit regulation of medicines and medical devices - one in which we continue to operate in partnership of some form with the European regulatory network; another in which we would be a standalone regulatory Agency outside European procedures, with the opportunity to develop new partnerships with other countries. Part of this work has also entailed financial modelling for either outcome, and the implications that will have for the Agency and its ambitious Operational Transformation programme.

I would like to pay tribute to staff across the Agency and our legal advisers for the tremendous effort that went into preparing for a 'No Deal' scenario including our No Deal Legislation, our technical guidance and our IT systems as well as ensuring operationally we were ready in the event of a 'No Deal'. As I write this foreword, the Agency continues to be ready for whatever outcome takes place before or by 31 October 2019, when the flexible extension of Article 50 will come to an end. We will also continue our work to prepare for whatever outcome transpires beyond that, working closely with our partners across Government, the devolved administrations, and our stakeholders.

At the same time, the Agency's day-to-day work, which is so vital to the safeguarding of public health in the UK and beyond, continues.

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 the work of the EMA and Heads of Medicines Agencies.

During 2018/19, the National Institute for Biological Standards and Control (NIBSC) developed a large number of new and replacement biological standards; and standards sales have continued to be strong across many areas.

The Clinical Practice Research Datalink (CPRD) has made excellent progress this year with one in every seven GP practice across the UK now committed to sharing de-identified patient data with CPRD, leading to a doubling in population coverage and significant expansion in the volume of linked electronic health data available for vital public health and drug safety studies.

As a public body, the Agency is keen to meet public and patient expectations of engagement and transparency. We have committed to deliver a step-change in the way we conduct our patient and public engagement, building on the good progress we have made in recent years. We want to ensure that the views and interests of patients and the public are at the heart of our decision-making and culture. This will include how the Agency adopts a more systematic approach to listening to and involving patients ensuring the patient voice is heard when safety issues are identified.

During the year the Agency has provided oral and written evidence to the Government's Independent Medicines and Medical Devices Safety Review (IMMDS), which was established in February 2018 under the Chairpersonship of Baroness Cumberlege. The work of the IMMDS Review continues and we look forward to the publication of its report and findings later this year.

Internationally, the Agency continues to be very active. The Agency continues to chair the International Coalition of Medicines Regulatory Authorities (ICMRA) which addresses current and emerging human medicine regulatory and safety challenges globally and strategically. At the same time, the Agency is developing its portfolio of formal ties with other regulators and is developing close ties with organisations, such as the Bill and Melinda Gates Foundation. The latter has provided funding for us to help build pharmacovigilance capacity in low and middle-income countries as part of the Smart Safety Surveillance project.

We have also made a significant contribution to the fight against fake medicines and medical devices. In October, over £2 million of counterfeit and unlicensed medicines and medical devices were seized as part of the annual Operation Pangea. More recently, as part of our award-winning #FakeMeds campaign, coverage secured in major media sources including The Sun, Men's Health Magazine, BBC Online, and the television series Casualty featured our key messages highlighting the dangers of purchasing counterfeit or unlicensed medical products over the internet.

There have been a range of high-profile medicine and device issues that have been handled highly professionally, as well as progress in taking forward various aspects of regulation.

During a very busy year the Agency relocated from its offices in Victoria to a new Government hub complex in Canary Wharf. The move, which involved over 900 members of staff, and which took place over three weeks in June and early July, went very smoothly without any interruption to operational delivery.

In November, the Department of Health and Social Care's Investment Committee approved the business case for 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.

In April 2018, the Agency published its next five-year Corporate Plan for 2018-2023. which by necessity was prepared around all the uncertainties associated with EU Exit. The process and the feedback that was received, both internally and from our Board and external stakeholders, was reassuring and very helpful.

The Agency's achievements over the past year would not have been possible without the expertise and dedication of all of our staff. That high level of commitment has been a constant theme of the Agency since it was established in 2003.

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

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: Anne-Toni Rodgers, Professor Sir Alex Markham Kt, Dr Ian Hudson, Jon Fundrey, Stephen Lightfoot, Professor Bruce Campbell, Michael Whitehouse OBE

Seated: Amanda Calvert, Dr Barbara Bannister MBE, Sir Michael Rawlins GBE Kt, Professor David Webb, Professor Dame Valerie Beral AC DBE

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

Our mission is to enhance 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

Our Corporate Plan 2018-23 sets the direction for what the Agency will do over the next five years, which will continue to be organised around five strategic aims:

1. **Public health and partnerships** – to protect public health and promote patient safety by ensuring the safety, efficacy and quality of medicines and healthcare products through enhanced partnerships in the UK and internationally.
2. **Enhancing innovation** – to support and enhance innovation and accelerate routes to market to benefit public health and be a magnet for life sciences.
3. **Proactive, robust surveillance** – to deliver robust proactive surveillance for medicines and medical devices to achieve measurable public health benefit.
4. **Secure global supply chains** – to ensure the safe production and supply of medicines and medical devices.
5. **Organisational excellence/efficiency** – to be an exemplar of organisational excellence and efficiency.

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 **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.

» The **National Institute for Biological Standards and Control** (NIBSC), a global leader in the standardisation and control of biological medicines.

» The **Clinical Practice Research Datalink** (CPRD) is a research data service that supplies anonymised NHS clinical data for public health research.

Agency operational funding is structured as follows:

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

» **Devices regulation** is primarily funded through a service level agreement with the DHSC with approximately 10% of its revenue from fees charged for services.

» **NIBSC** derives approximately half of its revenue from fees charged for services, including the sale of biological standards, and from research funding. DHSC provides the remaining funding to finance its important public health functions.

» **CPRD** is jointly funded by MHRA and DHSC's National Institute for Health Research but managed and operated by MHRA with DHSC having oversight through membership of the CPRD Executive Committee.

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.

Our centres

The Agency has a globally unique concentration of expertise in data, standards and regulation in a single organisation. We offer our customers a full range of services and products which is not replicated anywhere else in the world.

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

» Operating the UK's Official Medicines Control Laboratory (OMCL) for chemical medicines, testing medicines to identify and address quality

defects, and providing analytical support to the Agency's regulatory activities as required

» 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 clinical investigations of medical devices

» Promoting good practice in the safe use of medicines and medical devices and providing information to help inform treatment choices.

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. NIBSC is the UK's Official Medicines Control Laboratory (OMCL) for biological medicines, carrying out Official Control Authority Batch Release (OCABR) testing for biological medicines within the framework of the EU, and biological medicines evaluation for international stakeholders such as the World Health Organisation. Alongside this NIBSC carries out world class research and is the home of the UK Stem Cell Bank.

Clinical Practice Research Datalink (CPRD) is a real-world research service supporting retrospective and prospective public health and clinical studies.

CPRD collects de-identified patient data from a network of GP practices across the UK. Primary care data are linked to a range of other health related data to provide a longitudinal, representative UK population health dataset. The data encompass over 35 million patient lives, including 11 million currently registered patients.

Our centres work together to benefit patients and enable us to protect public health and improve lives.

Brief overview of how we regulate

The Agency authorises clinical trials for medicines and grants marketing authorisations, through various routes to make medicines available to patients. 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.

We work collaboratively with other regulatory bodies and agencies across the UK and worldwide to meet our regulatory aims, the review of the year in this report gives some examples of this in practice.

Review of the year 2018/19

The Agency business plan for 2018/19 set out the key actions to support the delivery of the five strategic objectives in our Corporate Plan 2018-23. In reviewing the year, we focus on our key activities and achievements, mapping these to our strategic objectives.

Theme: Public health and partnerships

Aim: We will protect public health and promote patient safety by ensuring the safety, efficacy and quality of medicines and healthcare products through enhanced partnerships in the UK and internationally.

Preparations for EU Exit

The Agency fed into cross Government preparations for the future relationship with the EU, securing specific references in the white paper on the desired future relationship and continued participation within the European Medicines Agency, accepting the rules of the agency and contributing to its costs.

We have also worked on re-designing the legislative frameworks for medicines, medical devices and clinical trials, to ensure the regulatory regimes are operational in the event of a no deal exit. We have taken steps to ensure the operational readiness of the Agency this year which has included:

» Close working with stakeholders throughout, including the publication of initial Technical Notices last August, running a four week public consultation in October and publishing final policy proposals in January.

» We prepared and laid the replacement Statutory Instruments in Parliament in January, alongside an Impact Assessment.

» Worked closely with the Department for International Trade to ensure continuity in the recognition of testing (Good Manufacturing Practice and Good Laboratory Practice).

» Published underlying technical guidance for medical devices, converting Centrally Authorised Products (into UK national licences) and parts of inspection/assurance work.

» We have worked closely with The National Institute for Health and Care Excellence (NICE) to ensure we have alignment with their 90-day assessment target.

» Work related to the IT platforms that the Agency uses under the current regulatory and operational arrangements. There are 40 EU systems that we interact with and use, 11 of which we need to manage in a no deal scenario. To replace the functionality these offer we have built three core systems: an e-submission portal, a case management system and a publishing system. In developing these we have:

  - Sought to make the replacement systems as similar to the European systems as possible, so that any additional requirements for stakeholders are kept to a minimum.
  - Engaged the Government Digital Service (GDS) at key points.
  - Used webinars to communicate with our stakeholders (published on gov.uk) – these have been very well received.

- On the reverse side we have worked with Member States that use an existing system which we developed to inform them of our decommission plans.

Throughout the year we have continued to hold regular quarterly cross UK meetings with the Devolved Administrations, updating on preparations for our exit from the EU, as well as regular communication and engagement on medicines and devices safety issues.

Our Regulatory centre has continued its work to introduce the Falsified Medicines Directive (FMD). The Directive introduced new harmonised measures to ensure that medicines are safe and that trade in medicines is properly controlled. The final part was introduced in February and involves a unique identifier which can be scanned at points during the supply chain and tamper evident features.

Our Inspectorate, part of our Regulatory centre, continues to play an important role worldwide. We welcome and actively seek opportunities to partner and collaborate with other regulatory bodies and industry organisations in the important assurance work that the Inspectorate is responsible for. This has included representation on the Executive Bureau of the Pharmaceutical Inspection Cooperation Scheme (PIC/S) and taking a leading role in various PIC/S working groups, Expert Circles and Joint Visit Programmes. This year the Inspectorate has:

» Participated in PIC/S joint visits for pharmacovigilance, a scheme whereby individual inspectors from global health authorities are grouped with two other inspectors from different health authorities to observe inspections, share best practice and increase collaboration. The team hosted two visits involving representatives from the US FDA, Health Canada, Croatia and Spain.

» Collaborated with WHO to host a pharmacovigilance inspection workshop in China. The workshop provided practical inspection training and was attended by 35 delegates from the China Food and Drug Administration (CFDA) and China Provincial Adverse Drug Reaction Monitoring Centres.

» Agreed a 6-monthly exchange of information with Therapeutic Goods Administration (TGA) pharmacovigilance colleagues.

» Chaired the Drug Information Association (DIA) Pharmacovigilance Conference.

» Played a major role in the Indian Pharmaceutical Alliance Advanced Good Manufacturing Practice (GMP) workshops in conjunction with the Indian Pharmaceutical Alliance, FDA, Central Drugs Control Organisation (CDSCO) and WHO. The workshop was delivered in three major Indian cities to over 320 attendees from 31 companies and 60 members of the Indian Regulatory Authority.

» Supported the US FDA China Office to deliver a two-day GMP workshop across two venues in China providing training to regulators and industry.

» Led an international group working to redraft the EU GMP Annex covering sterile medicinal products.

» Chaired meetings of the Compliance Group which manages the Joint Audit Programme (JAP) of EEA GMP inspectorates. The observation of JAP audits provided a key means for US FDA to assess EU inspectorates for the EU-US Mutual Recognition Agreement.

- Co-hosted a two day 'Data Integrity in Global Clinical Trials' event with the US FDA, attended by 150 delegates and live-streamed to 3500 registered participants from 68 countries around the world. The overarching objective of the conference was to promote the importance of data integrity in clinical trials, including bioequivalence.
- Provided training for GCP Inspectors and Advisors from Health Canada on data management, computer system validation, and the inspection of bioanalytical techniques and the resulting data from bioequivalence studies.
- Fostered international collaboration by hosting inspectors from the Russian Federal Service for Accreditation (RusAccreditation) as part of a technical co-operation project between the Organisation for Economic Co-operation and Development (OECD) and the Russian Federation.
- Led the OECD group which is developing international Good Laboratory Practice guidance on data integrity.
- Raised awareness of Good Distribution Practice (GDP) and supply chain integrity by supporting training for regulators from Chile, Malaysia, Mexico, Indonesia, Korea, Papua New Guinea, Peru, The Philippines, Singapore, Thailand and Vietnam.
- Shared knowledge and expertise through the PIC/S Expert Circle on Good Distribution Practices (GDP) hosted by our Spanish counterparts in Madrid. The focus of the meeting was to provide advanced training to GDP inspectors in difficult and challenging topics relating to the global supply chain.

The Devices team within our Regulatory centre has worked closely with the Scan4safety programme to develop mechanisms to use information from scanned GS1 barcodes to populate the national joint registry. This programme will allow the tracking of people and products in the healthcare supply chain and across hospital sites, meaning clinicians will be better able to ensure the safety and security of the product they are administering.

Work has also progressed to develop new Medical Device Alert annexe templates designed to support the rapid location of medical devices where specific actions to improve safety are required.

The team have led the introduction of a new form for manufacturer incident reports, which we expect to lead to further templates for the European vigilance system. The new template includes unique device identifiers, international coding for incident classification along with sales and other incident volumes to assess the extent of the issue. Our work has supported developing a periodic summary report and the EU's first Periodic Safety Update Report for medical devices.

This year we granted a UK marketing authorisation for a high dose trivalent influenza vaccine (TIV), which is indicated for active immunisation of people 65 years of age and older against influenza disease. This decision means the UK is the only European country where TIV High Dose is approved, supporting UK patient access to this medicine

The UK approval of TIV High Dose followed a national procedure which allowed for an accelerated assessment of the dossier. The initial assessment report was issued within 71 days, which was expedited from the 100 days allowed by the timetable. Overall, the vaccine was licensed in 165 days in total (compared to the full timetable for an un-expedited assessment of 240 days)

as we completed the assessment in two thirds the usual time.

Our NIBSC centre, which is a WHO Essential Research Laboratory for Influenza, plays a critical role in the global vaccine response against both seasonal and pandemic influenza through preparation of candidate vaccine strains and vaccine potency measurement standards. Alongside this important work, the centre has, this year:

» Provided input to a WHO collaborating centres meeting for the standardisation of Blood Products and in-vitro diagnostics (IVDs). The focus was to ensure the timely progression of physical standards in the area of emerging pathogens, the prioritisation of the development of standards across the field of infectious diseases and technical discussions on data derived from international collaborative studies to develop a range of materials for blood products and IVD's.

» Supported the Coalition for Epidemic Preparedness Innovations (CEPI) programme to develop vaccines for emerging pathogens in preparedness for potential outbreaks. A programme of work commenced this year to produce International Standards for the evaluation of vaccines against Lassa fever virus, to speed up vaccine development for this high priority pathogen. Both antibody and antigen materials will be produced which will take in the region of 2-3 years to generate. Working materials will be produced initially to meet the immediate demands from developers of Lassa fever vaccines.

» Signed a cooperation agreement with the University of Texas Medical Branch (UTMB). The agreement includes an exchange programme for PhD students.

» In conjunction with the International Vaccine Institute (IVI) organised a two-day conference, funded by the Bill and Melinda Gates Foundation, on International Standards for Oral Whole Cell Killed Cholera Vaccines.

» Signed a Memorandum of Understanding (MoU) in July 2018 with the Caribbean Public Health Agency to enable exchange of materials focussed on pathogens endemic to the Caribbean and to use these materials to develop reference materials.

» Continued our collaboration with our Chinese counterpart, National Institute for Food and Drug Control (NIFDC) China. Highlights this year included a visit to the National Institute of Diagnostics and Vaccine Development in infectious diseases (NIDVD), to build the relationship for further collaboration. We presented at the Protein and Peptide Therapeutic and Diagnostics Conference (PPTD-2018) in October and our scientists attended the International Symposium of Progress on Development and Quality Control of Vaccines hosted by NIFDC.

» Continued our collaboration with the Korean National Institute of Food and Drug Safety Evaluation (NIFDS) with reciprocal exchange visits and collaborations across the areas of virology and biotherapeutics. Planning is taking place to host a member of NIFDS to work on the influenza ELISA potency assay.

» Continued work to support global polio eradication. New oral polio vaccines developed by NIBSC scientists are now being tested in clinical trials through programmes of research funded by the Bill and Melinda Gates Foundation.

» Held the 2018 International Standardisation of Genome Amplification

Techniques (SoGAT) workshop, with a focus on the detection and harmonisation of infectious disease diagnostics for improved patient care.

» Successfully delivered our first joint webinar with the Institute of Biomedical Science (IBMS) on the subject of quality control materials. Feedback from delegates was very positive and planning is underway for a wider webinar series.

» Secured a second, £5m, five-year fund from DHSC to support work across six areas including the threat of global infectious disease and the use of biologics to overcome anti-microbial resistance.

In January 2018 NIBSC and the Agency signed the Concordat on Openness with Understanding Animal Research (UAR). This year we have continued working towards the commitments laid down by the Concordat: to be more open about our use of animals, enhancing our communications with the media and the public about when, how and why we use them. We have provided new information via the NIBSC website highlighting the work we do, the numbers and types of animals used and our commitment to animal welfare and animal regulation.

We continue our work in ensuring we follow the principles of the 3Rs (**R**eplacement, **R**eduction and **R**efinement) that focus on how to:

» Replace the use of animals, or avoid the use of animals altogether by using alternative models and tools, such as cells or computer models

» Reduce the number of animals by using methods that minimise the number of animals used for an experiment

» Refine aspects of animal use, from housing and care to procedures, to minimise suffering and improve animal welfare

Our CPRD centre has continued to grow its data and services to support vital public health and clinical research. The major expansion in patient numbers and population coverage comes as a result of increasing the network of GP practices contributing data to CPRD.

Over 35 million

patient lives for public health research.

More than 9 million

patient lives for public health research.

11 million

currently registered patients to recruit into clinical studies.

The number of currently registered patients in the database has doubled this year, to cover 17% of the UK population.

14 datasets

routinely linked to primary care data.

Addition of three new datasets and an increase in the coverage periods for linked data. New linked datasets include the National Radiotherapy Dataset and small area data linked to the practice postcode.

1400 GP practices

signed-up to sharing de-identified patient data with CPRD.

CPRD's GP practice network has grown, with more than 300 practices signing up this year. One in 7 GP practices across the UK now contribute de-identified patient data to CPRD.

336 new

observational research studies using CPRD data approved during 2018/19.

The number of studies using CPRD data continues to increase, up from 294 approved applications last year.

Over 2,200

publications from research using CPRD data.

More than 220 peer-reviewed publications published this year, helping to inform advances in patient safety and delivery of care.

1173 quality

improvement drug safety reports sent to contributing GP practices to help improve prescribing and patient care.

Increasing the number of prescribing indicators from four to six in these GP practice-level reports, produced in partnership with the Royal College of GPs. An additional 600 GP practices received reports over the past year.

Theme: Enhancing innovation

Aim: We will support and enhance innovation and accelerate routes to market to benefit public health and be a magnet for life sciences

We are committed to making our regulation more supportive of safe innovation and there have been a number of activities this year which support this aim.

Our Regulatory centre successfully bid, in conjunction with NHS Digital to the Regulators Pioneer Fund. The Fund supports projects linked to opportunities in the government's modern industrial strategy. Our successful bid is for a project aimed at producing synthetic datasets which will help innovators validate software and apps to be able to bring them to market at the earliest, safest opportunity, maximising the public health benefits from these innovative new products

Patient safety is paramount to the work of our regulatory centre and new technology presents opportunities for development in this area. We will look at the feasibility of using artificial intelligence (AI) to identify safety signals in large datasets of health records, enabling real-time identification of issues arising with medicines. In addition to clear patient benefit, industry will better understand how their products work in a real clinical setting.

Alongside this we are exploring whether a Yellow Card Biobank can be developed to capture genetic information from patients experiencing adverse drug reactions (ADRs). This would create a resource to help us identify where genetics influence who is most at risk from ADRs so that these ADRs can be reduced, this would represent a clear benefit to patients and the wider health system.

Our Innovation Office celebrated its sixth year in March, handling a further 192 enquiries this year, giving a total of 719 since inception. The Office is in place to support organisations of all backgrounds to develop innovative medicines, medical devices or novel manufacturing processes. We offer advice throughout the product lifecycle, whilst encouraging early engagement at the research/pre-clinical stage. Recent efforts have been focussed on promoting the service to small and medium enterprises (SMEs) and academic institutions, which has been successful as reflected in an increase in enquiries from these sources.

Our 'One Stop Shop' for advice on regenerative medicine, a collaboration with other UK regulators, continues to grow and remains an important service to provide support for innovators in the field of advanced therapies. A further 26 enquires were handled in 2018, giving a total of 81 since inception. In addition, the agency held 274 national scientific and regulatory advice meetings to assist companies to address specific scientific/technical queries with respect to the development of their products or regulatory uncertainties.

We have continued to pioneer fast-tracked and safe patient access to ground-breaking treatments, benefiting both patients (through early access to medicines) and the sector (they are able to better gather evidence for the medicines licensing process). We are building on the success of the Early Access to Medicines Scheme (EAMS) which helps innovative medicines reach patients quickly and safely, ahead of licensing, with over 1,500 patients benefiting so far. The Scheme continues to be a success with 18 Promising Innovative Medicine (PIM) designations awarded (which indicate a product may be eligible for EAMS based on early clinical data). Three scientific opinions were awarded this year (this describes the risks and benefits

and supports the prescriber and patient in making a decision on using the medicine).

Next year and beyond we will work with industry and other partners to define a supportive framework for the collection of real-world data. This will support the evidence gathering required for licensing applications, in addition to early engagement with MHRA, NICE and the health system. Patients will continue to benefit from earlier access to medicines, often for conditions with unmet clinical need.

We have acted as rapporteur or co-rapporteur this year in the authorisation of a number of new medicines across Europe, demonstrating the important role we play in bringing innovative new medicines to patients. We have included a number of these below to show the breadth of our assessment work:

» Buvidal (buprenorphine): for the treatment of dependence on opioid (narcotic) drugs such as heroin or morphine.

» Luxturna (voretigene neparvovec): used to treat children and adults who suffer from a loss of vision due to inherited retinal dystrophy, which is a rare genetic disorder of the retina.

» Symkevi (tezacaftor and ivacaftor): for the treatment of cystic fibrosis.

» Udenyca (pegfilgrastim): used in cancer patients to reduce the duration of neutropenia and to prevent febrile neutropenia. Neutropenia can leave patients vulnerable to infections and is a common side effect of cancer treatment.

» Vyxeos (daunorubicin / cytarabine): used to treat adults with newly diagnosed acute myeloid leukaemia.

This year our NIBSC centre:

» Has progressed work to develop novel techniques, based on Next Generation Sequencing (NGS), that can assure the quality and safety of new cellular therapies entering the market. With funding from Innovate UK's medicine and manufacturing challenge fund, this work will support the regulation and use of next generation advanced therapies that offer new hope for many incurable diseases.

» We also received an Innovate UK Grant to develop further microbiome standards in 2019-2020. Alongside a grant to develop serological vaccine standards for the Emerging Diseases identified by the UK's Vaccine Network. This award followed on from the success of a pilot project studying Ebola, Zika and Middle East respiratory syndrome-related coronavirus (MersCoV) reference materials and a large amount of work continued this year on these topics.

» Prepared reference materials to support the standardisation of lung microbiome techniques, analysing how the lung microbiome may influence treatment of Chronic Obstructive Pulmonary Disease (COPD).

» Through the UK Stem Cell Bank, received a £2.1 million grant to continue to support the development of the European Union Tissue and Cells Directives (EUTCD)-grade cell line programme, which aims to distribute 'regulator-ready' stem cell lines for research and clinical applications. This includes testing stem cell lines to detect abnormal prion proteins responsible for causing Variant Creutzfeldt-Jakob disease (vCJD).

Theme: Proactive, robust surveillance

Aim: We will deliver robust, proactive surveillance for medicines and medical devices including through:

- improved use of real world data
- enhanced information sharing

This year our Regulatory centre has focused on a number of safety issues including:

» Safer medicines in pregnancy and breast feeding: we have worked to implement the recommendations of the report of the Review of Hormone Pregnancy Tests (HPTs) undertaken by an Expert Working Group (EWG) of the Commission on Human Medicines (CHM). A cross-sector group comprising clinical experts, professional organisations and public health bodies, was established to oversee implementation of the recommendations. In response to one of the recommendations we held a focussed workshop on better use of non-clinical pregnancy data. The workshop, which was well attended by researchers, industry representatives and EU regulators, discussed the current non-clinical testing paradigm for medicines and the opportunities to move forward with new approaches using in silico methods and computer technology.

» Sodium valproate: we have continued to work with a range of stakeholders to implement a Pregnancy Prevention Programme for the antiepileptic medicine valproate (Epilim) following the completion of an EU wide review which found that measures which had been implemented in 2015 had not been effective in preventing exposed pregnancies. We have used several data sources to monitor the response of the health system to the strengthened regulations and have responded to evidence of gaps and inconsistencies in implementation. We will continue to monitor progress in risk minimisation and will take further action as necessary to prevent the serious harms caused by exposure to valproate in pregnancy. (We talk later in this report about our work with patients and patient groups in relation to valproate).

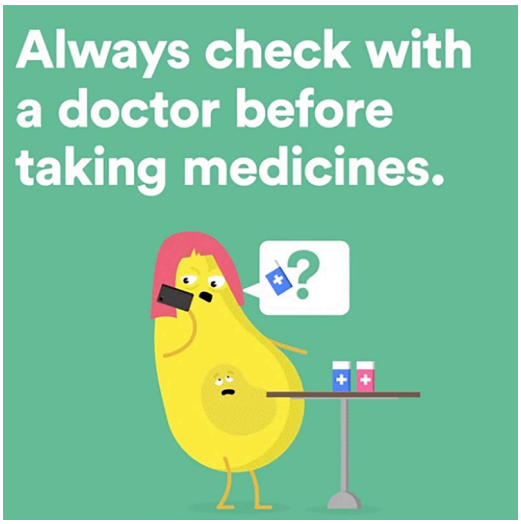
» The release of an updated version of the Yellow Card App to support the monitoring of the safety of medicines used during pregnancy. This included a pilot of additional ‘smart’ questions focused on drug exposure during pregnancy (covering areas such as trimester in which drug exposure occurred, scans, previous pregnancies, use of supplements and whether any suspected adverse effect occurred in either mother or child). Feedback from the public will be considered in order to further improve the questions to reporters, before being added to the Yellow Card website reporting form.

» Emollients: we have kept under review the risk of severe and fatal burns when dressings, clothing or bedding, which have been in contact with paraffin-containing skin products, are accidentally ignited. Recent evidence has suggested that products containing less than 50% paraffin carry this risk. An EWG of the CHM met twice to consider the available evidence and concluded that the product information and labelling for all products for emollient use should carry a warning about the risk and advice not to smoke, and that the outer packaging and container should carry a pictogram. We will be working with stakeholders to develop information, education and training to inform healthcare professionals patients and the public of this risk.

» Opiods: following national and international concern about dependence and addiction with opioid analgesics, an EWG of the CHM has been convened to advise on the extent of the problem in the UK and on measures to minimise the risk, with the opening meeting of the group held in February. We are working with other bodies in the healthcare system which are undertaking work in this area to ensure action is aligned and communications co-ordinated.

» Fluoroquinolone antibiotics: we have engaged with patients and a support group to help inform national communications following an EU safety referral (resulting in strengthened warnings and restricted indications) which evaluated the risk of disabling and persistent adverse reactions to fluoroquinolone antibiotics, mainly musculo-skeletal. Alongside an article in our Drug Safety Update bulletin and a letter to healthcare professionals, the national communications will include a patient-focused information sheet to support discussions with patients and minimise the risks of fluoroquinolone antibiotics. (We talk later in this report about our work with patients and patient groups in relation to fluoroquinolones).

We have continued to investigate how social media can support and promote the reporting of adverse incidents. In November we worked in partnership with the Uppsala Monitoring Centre (a collaborating centre of the World Health Organisation) to lead the third social media ADR awareness week campaign to promote use of the Yellow Card Scheme by patients and the public. This year the focus was on the reporting of ADRs that occur in babies, children and pregnant women and breastfeeding mothers. The campaign was supported by various materials some stills from which are shown below. The



key campaign message was that reporting suspected side effects helps the safer use of medicines and protects public health. The use of #medsafetyweek saw 3,791 tweets reaching 8 million people, with 20 million impressions across the globe. In the UK, our campaign reached 587,566 people in total with 161,713 views of the animation and 5,515 engagements (e.g. likes, clicks, retweets and shares) on social media alone. The campaign week of the 16-25 November 2018 saw an overall increase of 24% in Yellow Card reports, with an 11% increase in reports from patients, parents and carers compared to the ADR campaign week in November 2017. This was followed by a 7% (139) increase in direct ADR reporting in December 2018 compared to December 2017.

This year we worked with NHS Improvement to develop the National Patient Safety Alert Committee (NaPSAC); the Committee fulfils a key

recommendation of the 'Future Safety Messaging' Conference held in January 2018. In addition, we have worked alongside them to support the development of the new Patient Safety Incident Management System (PSIMS).

We have looked at where digital tools and data can support our vigilance activities. Reports from healthcare professionals and patients/public are very important to our vigilance activities and we have undertaken research with these groups to understand their experience when reporting to us. We have engaged directly with NHS Trusts to explore how we can encourage reporting through Yellow Card and data capture direct from hospital sites.

The Vigilance and Risk Management of Medicines (VRMM) Division within the Regulatory centre continues to use CPRD data to support pharmacovigilance and conduct pharmacoepidemiological studies. CPRD is routinely used to monitor the impact of, and adherence to, changes in regulatory recommendations including the Pregnancy Prevention Programme for sodium valproate. Recently, VRMM has conducted a feasibility study to explore the value of the CPRD data to support Devices Division and their vigilance processes.

Theme: Secure global supply chains

Aim: We will ensure safe production and supply of medicines and medical devices through:

- enhanced systems
- strong international partnerships
- educating consumers

The medicines enforcement activity undertaken by our Regulatory centre forms an important part of our work to protect public health. This year has seen:

» A continuation of our investigations into the diversion of medicines from the supply chain. 5.6 million packs of medicines (with a value of £115 - £200 million) were diverted between 2013 and 2016. To date 13 wholesale dealers have had their licences discontinued/terminated, 8 pharmacists have been suspended by the General Pharmaceutical Council and 14 prosecution cases are in preparation.

» The hosting of our first ever Medical Devices Anti-Counterfeiting Forum. Over 50 national and international stakeholders comprised of industry, Notified Bodies, law enforcement agencies and regulatory bodies attended.

» Support of Interpol's Operation Pangea XI week of action. Our contribution included the seizure of 1,037,860 doses of unlicensed medicines and medical devices; over 10% of the global total.

» We have had eight successful prosecutions this year, with 17 defendants convicted and sentenced, often to terms of imprisonment. We have also obtained confiscation orders worth over £450,000.

This year we have:

Conducted over 1200 inspections during the year with over 183 being performed at overseas companies.

Issued over 5,550 export certificates (including 1,615 requests within 48 hours).

Issued over 2,075 licences (a combination of Wholesale, Manufacturing and Active Pharmaceutical Ingredients), supporting those conducting processing activities.

Continued to develop the Inspectorate blog: we now have 10,471 subscribers and our most popular posts have received over 43,000 hits.

Organised major symposia on all aspects of inspections which were attended by around 3,000 delegates.

We spoke at over 30 conference events.

Our British Pharmacopoeia (BP) team have this year established an innovation board to drive improvements in products and services, ensuring new reference standards are available earlier than ever before while improving the availability of our reference standards portfolio. We have continued working towards a strategy for pharmacopoeial public quality standards for biological medicines, with a working party established to explore performance-based and class-based standards, furthermore, informal workshops with

stakeholders to consider the role of standards in supporting the field of advanced therapies were held. The BP supports secure supply chains by providing public quality standard that set the benchmark for medicines and these may be used by anyone to confirm that a medicine in the supply chain is of the requisite quality.

Our NIBSC centre, a WHO collaborating centre for biological standardisation, plays a key role in developing, holding and distributing international standards and reference materials for quality control and assurance of clinically relevant biological materials. This year WHO approved 12 standards projects for developing international standards and reference materials, six of which were for first WHO International Standards or WHO Reference Reagents.

Our work to establish international standards for biosimilar medicines has continued this year with projects now underway to establish WHO International Standards for Darbepoietin, Trastuzumab, Cetuximab and Adalimumab. The introduction of biosimilars can result in increased price competition, lower healthcare costs and consequential increases in patient access to these medicines, but it brings risks in the form of variability and lack of consistency in the quality of these new versions of the product, making comparability studies against the original product essential to ensure therapeutic benefit for patients.

Our NIBSC centre is the UK's Official Medicines Control Laboratory (OMCL) for biological medicines, carrying out Official Control Authority Batch Release (OCABR) testing for biological medicines within the framework of the EU. This year 1179 certificates were issued for finished vaccine and blood products, and more than 3287 plasma pools.

#FakeMeds campaign

Our #fakemeds campaign which launched in August 2016 has continued to deliver excellent results, positively impacting public health. Fake medicines and medical devices bought online can lead to serious negative health consequences, while websites selling such products also increase the risk of a purchaser being subjected to card fraud or identify theft. This campaign helps the public protect their health and money by providing quick and easy tools to help them avoid fake medical products when shopping online.

This year we have delivered a new phase, seeking to reduce consumer buying of fake sexually transmitted infections (STI) self-test kits online. All our objectives to date have been achieved and content has engaged more than 2.1million 18-30 year olds against expenditure of <£5,000.

The success of the campaign has been recognised - winning the best healthcare campaign in the Chartered Institute of Public Relations (CIPR) annual awards, receiving a 'Mark of Excellence' in the public sector campaign category. Comments from the judges included:

"It was an imaginative campaign which turned a potentially dry topic into something engaging and impactful. The judges were impressed by the reach, engagement and clear shift in behaviour the campaign achieved."

"This is a great example of best-practice which incorporated great stakeholder relations and clearly demonstrates what can be achieved in a short period of time, on a small budget and with a very small team".

Some stills from animations developed for the campaign can be found below.

Theme: Organisational excellence/efficiency

Aim: We will be an exemplar of organisational excellence and efficiency through our:

- Operational Transformation programme
- resourcing strategy; and
- communications

Operational Transformation programme

The Operational Transformation programme has now commenced following the approval of the programme business case by the Agency Board and DHSC in November 2018. The programme will deliver substantial benefits for the Agency and improve services to stakeholders and outcomes for patients underpinned by new ways of working, processes and technology.

The programme comprises seven workstreams aligned to the services the Agency provides, with each workstream having a Corporate Executive Team (CET) sponsor responsible for the activities and outcomes of that stream. Sponsors are supported by cross-Agency staff leading the individual change initiatives through early governance, design and execution. These are further supported by a newly formed Transformation Division providing engagement, design and delivery services to deliver lasting change and outcomes.

Good progress has been made during the year with 35 change initiatives launched and benefits starting to be realised. Change management training has been successfully delivered to all senior leaders across the Agency with toolkits and communication plans in place to prepare the way for the larger scale transformation planned for financial year 2019/20. The programme continues to be subject to significant risk in establishing new ways of working and delivering benefits and outcomes; especially with the delays in resolving the outcome of Brexit and the focus of existing Agency capacity on preparation for a no deal scenario which has diverted effort away from transformation.

The programme continues to move forward during 2019/20 with areas less dependent on the Brexit outcome as part of its mitigation approach. External factors, including the outcomes of the Cumberlege Review may play a further part in increasing pressure on the cashable efficiencies of the programme as additional requirements start to be known. Risks to delivery scope, timescales, costs and benefits are continuously monitored against the programme business case and milestones are adjusted accordingly to ensure forward progress despite the high levels of uncertainty in some areas.

Clinical trials combined ways of working pilot

The Clinical Trials Unit within our Regulatory centre are leading a combined ways of working pilot:

» We are working with our partners in the Health Research Authority (HRA) and research ethics services across the UK to assess clinical trial applications collaboratively and maintain the UKs reputation as a great place to do research.

» As of 28 February 2019, 40 initial applications, 25 amendments and 4 end-of-trial notifications have been received through the pilot. These include phase I to phase IV studies for commercial and non-commercial sponsors

and includes first-time-in-UK and first-time-in-human investigational medicinal products.

» Of the 40 initial applications, 27 have been completed (approved), 12 are still under assessment and 1 was withdrawn. Feedback from participants has been positive.

» We are continuing our regular meetings with the Health Research Authority (HRA) and Devolved Administrations to further develop the process and IT system requirements for the pilot as well as increasing external communications to encourage further uptake.

This year has seen our NIBSC centre introduce a new sales system, compliant with the NHS e-Procurement strategy, allowing us to start accepting orders via the PEPPOL European-wide procurement network and introduce GS1-compliant bar codes to the products we sell.

Engaging with patients and patient groups

Patients and patient groups have increased expectations of the level of interaction and influence they have with government and other public bodies, including regulators. As a public body, we are keen to meet those expectations of engagement and transparency.

We have made good progress over the last three years in actively seeking to involve patients in our work. Examples of our patient and public engagement this year include:

» **Raxone**: we involved patient and carer representatives in a patient-focused ad hoc expert meeting to consider the continued Early Access to Medicines Scheme (EAMS) licence for Raxone in the light of a recent negative European Medicines Agency scientific opinion. We worked with Action Duchenne, DMD Pathfinders, Duchenne UK and Muscular Dystrophy UK to recruit patient and carer representatives and to make the necessary practical arrangements to facilitate their participation on the day of the meeting; including briefing and background documentation. The meeting was attended by three patients and their carers plus four mothers who have children living with Duchenne Muscular Dystrophy. Their combined input provided the expert group with insight to the likely impact on patients should Raxone no longer be available through EAMS. Taking this into account, the Commission on Human Medicines decided to continue with a positive scientific opinion for Raxone.

» **Fluoroquinolones**: we supported Quinolone Toxicity Support UK (QTSUK) with submitting its evidence to the European Medicines Agency (EMA) review of Fluoroquinolones and its appearance at the public hearing. Following the subsequent announcement of the EMA Pharmacovigilance Risk Assessment Committee recommendations for restricted use, we sought QTSUK's views to inform the drafting of our communications to UK healthcare professionals. Once the EMA Committee for Medicinal Products for Human Use had issued its opinion to confirm restricted use, we sought comments and suggestions from QTSUK on a draft patient sheet for circulation to UK healthcare professionals via the Agency's Drug Safety Update bulletin. The final version of the patient sheet incorporated many of the changes suggested by QTSUK including their advice, from the patient's perspective, that the sheet should emphasise the importance of always reading the Patient Information Leaflet. In addition, QTSUK representatives commented on draft instructional videos aimed at explaining to the public how to complete an adverse drug reaction or adverse medical device event using the Agency's online Yellow Card

reporting form. The QTSUK feedback, together with comments received from other patient representatives, has informed further development of these videos.

» Valproate: we established the Valproate Stakeholder Network (VSN) in 2016, which comprises representatives from over 50 different organisations including healthcare professional bodies, health system delivery agencies and regulators, patient groups/research charities (for the indications of bipolar, epilepsy and migraine) plus campaign groups and individuals representing the families affected. The VSN's purpose is to provide stakeholders with opportunities to input to the development of the materials to support implementation of the regulatory measures and to assist with the dissemination of the information, to healthcare professionals and patients, through their own networks and communication channels. The input of the campaign and family representatives helped in particular with the development of the content for patient-facing communication materials and subsequent monitoring of the impact of the latest regulatory measures introduced in 2018. Feedback from the campaign and family representatives, based on their experience with primary care services, indicated a continued lack of healthcare professional compliance with the new measures. This has informed consideration of further regulatory action to improve compliance, including the incorporation of valproate as an indicator of good practice within inspections conducted by the Care Quality Commission and the General Pharmaceutical Council.

» Looking ahead: over the next year we are taking forward actions to ensure that the views and interests of patients and the public are at the heart of our decision-making and culture. We aim to become more systematic in listening to and involving patients, ensuring the patient voice is heard when safety issues are identified, as well as in the licensing of new medicines and medical devices. We are also planning to do more to communicate more widely our role in supporting public health and to raise awareness of our decisions and their impact for the public.

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.

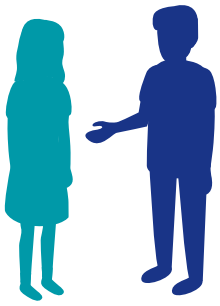
Published a gender pay gap report and action plan.

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

Staff support and benefits

Our Agency staff EU support network has met throughout the year, sharing information on the implications of the UK's exit from the EU. The network is directly linked to the wider Cross-Government EU Nationals network.

Our learning and development strategy continues to promote the development of all staff. A blend of online and face-to-



face training as well as coaching is available, as part of a commitment to 5 development days per year per staff member. Over the past year, there has been a particular focus on development activities aligned to Operational Transformation, to support our staff in navigating change.

There has also been particular investment in identifying and developing our most high potential and high performing future leaders, in line with the Agency's Talent Management strategy. All staff record their individual development needs in annual Personal Development Plans, which they review with their line manager to focus their development activity for the year ahead.

We took the opportunity this year to enhance our range of employee benefits, helping us to attract and retain high calibre people in our organisation.

Contributing to the Secretary of State's health inequalities agenda

During 2018/19, 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).

We have continued to work 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 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.

The UK has been leading the European Network of Paediatric Research at the European Medicines Agency (Enpr-EMA) cross-stakeholders' work on paediatric clinical trial preparedness with the aim to streamline the conduct and timely completion of paediatric clinical trials which would facilitate the prompt availability of new and better paediatric medicines. We have been working on developing strategic guidance to facilitate paediatric study development and implementation along with members of paediatric research networks, patients and parents' representatives and Industry.

We 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.

We have continued to work to ensure that patients and healthcare professionals report to the Yellow Card Scheme 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. In November 2018, to support the monitoring of the safety of medicines used during pregnancy, the Yellow Card App began a pilot of additional 'smart' questions focused on drug exposure during pregnancy. Feedback from the public will be considered to improve the questions further, before being added to the Yellow Card website reporting form.

We have 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 to maximise safety reporting from the different population groups.

NIBSC works closely in line with the Coalition for Epidemic Preparedness Innovations (CEPI) and the WHO R&D Blueprint for Action against Epidemics, receiving funding 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 and evaluating novel attenuated and non-replicating vaccines through programmes of research funded by the WHO and Bill and Melinda Gates Foundation (BMGF). Further efforts are underway to better understand circulating non-polio enteroviruses.

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.

CPRD data have been used to study the distribution of and contributors to health inequalities. Recent studies in this area using CPRD data include investigations into clinical factors underlying ethnic inequalities in Type 2 diabetes, social determinants of uptake of maternal vaccinations, and the impact of not speaking English as a first language on diabetes control and outcomes in primary care. 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 continues to be expanded to enable further study of inequalities.

Key issues and risks facing the Agency in delivering its objectives

Risks	Mitigating factors and actions
The Agency recognises the risk of threat stemming from the exit from the European Union including loss of business both from the Regulator and NIBSC. Allied to this risk also is the fact that the Agency currently has access to functionality and data to some European systems. A No Deal Brexit might prevent continued access which might affect some of the Agency's operations.	We have a cross-Agency Task-force team which co-ordinates preparations for our exit from the EU and provides regular updates to CET and the Board. The Agency fed into cross Government preparations for the future relationship with the EU, securing specific references on the desired future relationship and continued participation within the European Medicines Agency, accepting the rules of the agency and contributing to its costs. We have also worked on re-designing the legislative frameworks for medicines, medical devices and clinical trials, to ensure the regulatory regimes are operational in the event of a no deal exit. We have taken steps to ensure the operational readiness of the Agency. We have been working on the development and testing of a European systems contingency (ESC) platform that must be present for Day 1 of no-deal Brexit. The ESC programme will ensure we have a system available for use should there be a no deal Brexit.
There is a continued threat of the diversion of medicines from the regulated supply chain as well as prevention of falsified medical products reaching the public via illegitimate supply chain.	There is continued inspection by our Inspectorate, Enforcement & Standards division of wholesale dealers. Analytical data shows that we have reduced diversion, in some cases by up to 73% year on year. There is a dedicated Enforcement Group (EG) with specialist staff to undertake all intelligence and investigation work, including a dedicated resource for identifying issues on the Internet. An "Approach to Enforcement" strategy is in place and a Strategic Threat Assessment relating to threats to public health from criminality undertaken and documented. The Agency plays a vital role in all relevant international initiatives undertaken by worldwide counterparts and relevant stakeholders. There are successful prosecutions and convictions for issues relating to falsified medicines, fraud, and money laundering. The Agency holds regular meetings with the Crown Prosecution Service (CPS) to ensure standards of evidence are obtained.
The Agency, like every other organisation, is at risk from cyberattacks and the threat of system disruption and/or data loss.	The Agency has a suite of security tools in place. In particular improving our control of applications across the network through a whitelisting approach; improve our cyber security threat detection and prevention capability by engaging intrusion detection and data loss prevention capabilities available from current suppliers; raising the profile of security performance with senior leaders by designing and publishing periodic security metrics including incidents closed, phishing emails blocked etc; running a cyber incident response scenario training exercises; and strengthening the MHRA domain management to eliminate copying/spoofing.

The Agency's ability to fulfil its statutory and other public health roles and to operate as a trading fund may be impacted by: - changes to the revenue-generating and funding model post-EU exit; - the requirement to invest in Operational Transformation (OT) - funding required to address new/ emerging areas of public health such as the exponential growth in devices regulation, innovation in life sciences, the increased patient and public expectations post the Cumberlege review	The Agency and its executives engage on a regular basis with the Board, with DHSC and HMT, and with Ministers regarding the future shape and funding of the Regulator. CET and Board receive regular updates on: i. Funding and revenue expectations, annual and 5-year financial forecasts. ii. The key assumptions that underpin the current estimates for the Agency's finances and OT including a sensitivity analysis of key variables iii. Estimates of the efficiencies that the Agency is expecting to deliver during the next 5 years, especially as these apply to the costs of regulation; A cross-Agency financial model with a range of potential Brexit outcomes is used to communicate with relevant stakeholders and to generate scenarios and options in support of investment and spend decisions as well as long-term strategic direction.
The Agency's capacity and capability for change will be challenged by the scale, complexity, and ambition of the Operational Transformation (OT) programme. OT is the Agency's proactive response to the need for investment in changes that enable improvements to operational efficiency and productivity. Its scope also addresses our customers' changing needs and the replacement of ageing IT systems. External factors, including EU Exit and outcomes of the Cumberlege Review, may increase pressure on the benefits case of the OT programme as additional risks are identified and elaborated.	Delivery of the OT continues to move forward during 2019/20. Workstreams that are less dependent on EU Exit outcomes are prioritised as part of the programme's risk mitigation strategy. These priorities include a focus on Customers, Corporate Services, and Safety & Surveillance. Risks to programme timescales, scope, costs, and benefits are monitored closely against the programme business case. Planning assumptions and milestone performance remain under review to ensure forward progress despite high levels of uncertainty in some areas.

1.2 Performance Analysis

Performance against targets

No.	Area	Target description	Target	2018/19 total	Rating (RAG)	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	**97%**	**100%**	Met	
		b) For new Marketing Authorisation applications, 97% of validation reports produced within 14 days of case creation.	**97%**	**100%**	Met	
		c) 97% of Change of Ownership applications validated or Request For Information (RFI) issued within 42 days of receipt.	**97%**	**83%**	Target not met	Unusually high volumes in Q2 led to KPI not being met in that quarter with successful return to fully on target again in Q4
PM2	Medicines licensing – assessment of applications	a) The assessment of applications for new Marketing Authorisations for UK only: 97% assessed in 150 days	**97%**	**99%**	Met	
		b) The assessment of applications for new Marketing Authorisations in European (MRP, DCP & CP) procedures: 97% assessed within the designated time* 95% of CP assessed within the designated time*	**97%**	**98%** (% DCP RMS in 70 days)	Met	
			97%	**100%** (% DCP CMS in 100 days)	Met	
			97%	**100%** (% MR in 30 days)	Met	
			95%	**100%** (% Centralised rapporteur / co-rapporteur in 80 days)	Met	
		c) The assessment of Type IB minor and Type II major variation applications in National and European (MRP, CP) procedures: 97% assessed within the designated time.	**97%**	**95%** (% Type II in 90 days)	Nearly met	Met - assessed 98% of Type II within 90 days
			97%	**97%** (% Type IB in 30 days)	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)	**98%**	**100%**	Met	Met - assessed 100% of all authorisations within 30 days
			14 day average	**12.37**	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	**within 60 days**	**100%**	Met	Met - 100% handled within 60 days
						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	**95%**	**97%**	Met	
			100%	**100%**	Met	
		b) Medical Device Alerts will be issued: 95% within 10 days, 100% within 15 days	**95%**	**91%**	Nearly met	4 MDAs (out of 45 published) delayed by 1 day due to various issues related to agreement of content/ manufacturers' comments.
			100%	**100%**	Met	
		c) For fatal UK adverse drug reactions: 90% within 24 hours, 100% within 72 hours	**90%**	**100%**	Met	
			100%	**100%**	Met	
		d) For serious UK adverse drug reactions: 95% within 72 hours, 100% within 5 days	**95%**	**99%**	Met	
			100%	**100%**	Met	
		e) Ensure all UK potential signals (relating to medicines) from whatever source are acted on promptly: 85% initially evaluated within 5 working days	**85%**	**94%**	Met	
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	**98%**	**100%**	Met	

PM6	Standards and control	a) Batch release activity – 99% of all requested official control authority batch release (OCABR) and non-EU testing completed within agreed timelines: • 10 days for Plasma Pools • 10 days for Molecular Immunology • 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	**99%**	**100%**	Met	
			99%	**100%**	Met	
			99%	**100%**	Met	
			95%	**100%**	Met	
PM7	CPRD activity	a) 90% of research applications to receive initial feedback from ISAC review within 30 working days	**90%**	**91%**	Met	
		b) Expand coverage to 1500 contributing GP practices across the UK	**1500**	**1391**	Target not met	Target was ambitious, however CPRD have recruited 33% (net) new GP practices since the close of 2017/18 (346 new practices)
		c) 3 new routine linkages available for observational research studies	**3**	**4**	Met	
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).	**100%**	**99.2%**	Met	5 FOIs out of 634 missed the target. As total compliance is over 99% we have hit the performance target once it is rounded up in line with Departmental practice.
		b) Aim to return all responses to Parliamentary Questions (PQs) to the DHSC by noon on the date specified	**100%**	**100%**	Met	88 PQs were answered during the year, all were answered on time.
		c) Return Ministerial correspondence (POs) drafts to the DHSC within 4 working days of receipt in at least 90% of cases	**90%**	**100%**	Met	83 POs were answered during the year, all were answered on time.

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%**	**100%**	Met	
		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%**	**100%**	Met	
		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%**	**100%**	Met	
PM10	IT Operations	a) 10% reduction in major incidents (Category - Priority 1 and 2)	**10%**	**36%**	Met	
		b) Fewer than 5 major incidents (Categories: Priority 1 and 2 caused by change)	**less than 5**	**0**	Met	
		c) No major problem tickets open for more than 6 weeks	**0**	**0**	Met	
PM11	Information Management	a) Cybersecurity: Information Security Incidents resolved within 15 days of being reported	**95%**	**95%**	Met	
		b) Data: Subject Access Requests provided with a response within one month of receipt	**95%**	**97%**	Met	The Agency received 32 valid SARs this year of which 31 were due for response in this financial year. One response breached the target deadline this year.

Financial Review

The Agency has continued to produce a sustainable financial performance, despite the uncertainty caused by UK's decision to exit the European Union and the resulting reduction in revenue from pan-EU authorisations through the European Medicines Agency (EMA).

The Agency is required by a HM Treasury Minute (reproduced in section 3 of this document) to achieve a return averaged over the five-year period from 1 April 2018 to 31 March 2023, of at least 3.5% in the form of an operating surplus on ordinary activities before interest and dividends expressed as a percentage of average capital employed. Capital employed consists of the Agency's capital and reserves.

As a government trading fund, the Agency is funded mostly by income from fee-charging activities. Income from fee-generating activities in 2018/19 was £124.0m and income from the sponsoring DHSC was £34.6m. The Agency's income from trading activities was £4.7m lower than 2017/18 primarily as a result of the UK preparations to exit the EU, which has led to a reduction in revenue from centralised (EMA-managed) as well as decentralised (EU-member states led) licence applications. The above reduction was more than offset by £6m of EU Exit support payments from DHSC. Consequently the 2018/19 overall trading income of £158.6m was £1.1m higher than that in 2017/18.

Staff costs increased by £2.4m (3%) reflecting a Civil Service staff pay award (1.5%) and an increase in the overall number of employees, mostly contingent labour contracted to address an internal digital transformation skills gap. Operating costs reduced by £24.6m. This was due to (i) a £15.7m reduction in computing costs, and (ii) lower Other operating costs, which reflect the release of provisions no longer required (£2.1m) along with an adjustment (£2.2m reduction) in project-related costs as digital development expenditure was reclassified from cost to intangible assets. As a result, the 2018/19 operating surplus before interest and dividends was £25.8m compared to £1.7m in 2017/18. After interest and dividends of £14m, a net surplus of £11.8m was transferred to reserves.

2018/19 has seen a net cash inflow from operating activities of £15m compared to a net cash outflow of £23.7m in 2017/18. The current year operating cash inflow was driven by the operating surplus of £25.8m adjusted for non-cash items (movement in provisions [-£2.1m], depreciation [+£10.7m] and DHSC non-cash funding [-£12.2m]) less a £7.2m increase in working capital. The latter reflects a reduction in the backlog of authorisation applications, mostly EMA-related and an increase in trade receivables.

Offsetting the cash inflow from operating activities was £15.1m cash outflow from investing activities for purchases of tangible and intangible assets and a net cash outflow of £1.4m from financing activities, mainly the payment of a cash dividend to DHSC. As a result, cash and cash equivalents at the end of 2018/19 financial year were £1.5m lower than at the end of 2017/18.

Sustainability report

Greenhouse Gas (GHG) emissions performance

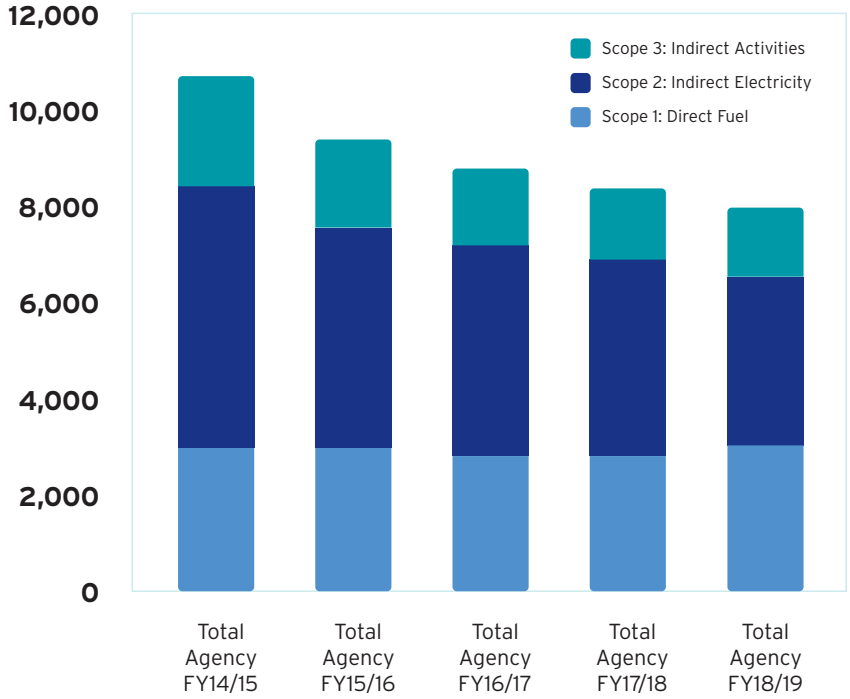
The Carbon Footprint for the sites at South Mimms and 10 South Colonnade (10SC) have been produced individually and then combined to give an overall Carbon Footprint for the Agency.

A significant change during this reporting period has been the move in May 2018 of the London Office from Buckingham Palace Road (BPR) to 10SC, and as such a new Carbon Footprint has been established and will form the baseline for this portion of the Agency.

Greenhouse gas emissions financial and non-financial indicators				
Greenhouse gas emissions		South Mimms	10SC	Total
GHG Emissions (TCO_2)	Total Gross Emissions	5,522	2,199	7,721
	Gross Gas Emissions	2,873	59	2,932
	Gross Electricity Emissions	2,351	496	2,847
	Gross Property Emissions	48	2	50
	Gross Transport Emissions	250	1,642	1,892
Energy Consumption ('000 kWh)	Gas Consumption	13,711	284	13,995
	Electricity Consumption	7,652	1,615	9,267
Financial Indicators (£k)	Expenditure on Energy	1,371	0	1,371
	Expenditure on Transport	438	1,230	1,668

Notes: 1. 10SC utility expenditure is consolidated into the service charge
2. Transport Emissions & Expenditure include courier and air freight data
3. Please note that estimates have been used in the above data.

GHG Protocol Three Scopes Of Emissions: Tonnes CO2



The GHG Protocol provides an international accounting framework for GHG emissions and divides these into three 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 - controlled resources i.e. gas, fuel oil and fugitive emissions
- Scope 2 Indirect Emissions - electricity purchases
- Scope 3 Indirect Emissions - all others e.g. water, waste, travel and movement of goods (This is considered an optional category but has been reported for the Agency.)

The Carbon Footprint[1] for the South Mimms site has been produced since 2009/10. The figure has fallen from a baseline figure of 8,633 TCO2 in the first year to 5,522 TCO2 this year, representing a reduction of 36% 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 previously been used as the baseline year. However due to the move of offices a new baseline and Carbon Footprint have been compiled of 2,199 TCO2 this year. The 10SC site has had a rolling programme of new tenants arriving and as such it is anticipated that the following year may show changes due to building occupancy.

The two sites have different impacts where 10SC 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 26% which is a considerable reduction to achieve.

1 *Carbon Footprint calculations have followed the methodology set by Defra in the report: Environmental Reporting Guidelines: Including mandatory greenhouse gas emissions reporting guidance, June 2013, and UK Government conversion factors for Company Reporting 2018.*

Gas and electricity consumption

Gas and electricity consumption have been collated for the new 10SC building however, there are several factors that may alter consumption going forward. The Landlord's Facility Company are still reviewing final billing data with the utility companies, full building occupancy was only established from May 2018 and there are improvements planned once occupancy and usage have settled.

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 18% in gas consumption and a reduction of 15% in electricity consumption have been realised. Numerous factors have contributed to these savings such as the replacement of old equipment with more energy efficient versions and maintenance improvements.

The site has successfully implemented 'switch off' initiatives, including 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, while maintenance staff adjust plant and equipment usage to further impact energy reduction. Over Christmas 2018 such an initiative saved £3.4k on utility bills equating to 13% of site energy consumption and demonstrates the results that can be achieved.

There is a mandatory requirement for the South Mimms site to participate in Phase II of the Government's Carbon Reduction Commitment (CRC) 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, with estimated payments for the financial year of circa £110k. Changes to this legislation are anticipated in 2019.

Due to the significant savings made during the last eight 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 £1.5 million, over this period, on electric and gas expenditure, as well as a corresponding reduction in CRC payments.

Display Energy Certificates (DEC) are a requirement for the 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 had a direct impact on the sites DEC performance. The initial baseline assessment rating was 544 in 2008, when the scheme commenced, compared to this year's rating of 241. This is a significant reduction and further demonstrates the results produced from targeting energy consumption onsite.

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 has resulted in efficiencies. The current LUPC Tender is due to be concluded in March 2019. Work continues to make improvements to waste management practices to reduce the impact on the environment as well as reducing the waste management budget, which over the last eight years has saved over £200k on waste costs. For example, sourcing free issue replacement internal bins, no longer required by another Government organisation, has saved over £8k.

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. Success in this area has been recognised with the award of a "Certificate of Excellence" by Warp-It for being one of the organisations to achieve over £100k in cost savings.

Savings associated with resource re-use		
Re-use savings		Total
Re-use of resources	Total Savings £	177
	Total Savings Carbon Emissions (TCO2)	65
	Total Savings Waste (Tonnes)	16

Re-use work also took place in the build up to the move from the BPR site to 10S, including a campaign to encourage staff to de-clutter and recycle unwanted items, ultimately reducing the number of items that need to be moved.

As part of the move we focused on the re-use of surplus furniture, including identifying furniture that could be re-used at South Mimms or re-used by the new tenant. This brought significant savings both in terms of not purchasing new furniture, which saved over £83k and reduced both waste disposal costs and the total value of waste from this project.

The catering company at 10SC rolled out a "Keep Cup" initiative to reduce waste from this source, by introducing a new coffee cup scheme. The scheme means that eco-reusable cups will be used as an alternative to disposable coffee cups, where staff and visitors are able to either buy or rent a cup instead. The scheme has proved very successful and has helped to reduce waste for this site, as well as changing staff behaviour, and the use of single-use products.

Finite resource consumption

Water consumption has been collated for the new 10SC building however, there are several factors that may alter consumption in the following years, impacted as it is by the review of final billing data as described for electricity and gas consumption.

Due to the nature of the work carried out, the South Mimms site has a higher water consumption; however ongoing site improvements, for example, replacement of older plant and equipment help to reduce this impact.

Water consumption financial and non-financial indicators		
Water		Total
Non-Financial Indicators ('000 M3)	Water Consumption (10SC)	3
	Water Consumption (South Mimms)	29
Financial Indicators (£k)	Water Supply Costs (10SC)	0
	Water Supply Costs (South Mimms)	43
Notes: 1. Water costs for 10SC are consolidated into the service charge 2. 10SC is mainly office consumption and NIBSC is mainly laboratory consumption 3. Please note that estimates have been used in the above data		

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 7% of the main site electricity requirements.

This has made a positive impact on reducing the mains grid electricity consumption and has made savings of over £125k on this utility so far. Additional benefits to the site include reducing carbon emissions and improving security of electricity supply as a portion is now generated onsite. Following completion of this large-scale project we have been awarded

accreditation for the Government Feed In Tariff (FIT) Scheme which will bring over £700k payments for electricity produced over the lifetime of the project; which is a considerable income benefit.

Future sustainable plans

In the next financial 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 continued use of recycled 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.

Responsibility for H&S 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 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 2018/19 included:

» Achieving excellence in leadership and culture

» Continued regulatory compliance

» Maintaining OHSAS 18001 certification at the 10SC site and planned migration to ISO45001

» Accident/Incident reporting and investigation

» Delivering the mandatory training programme

» Reviewing overseas travel safety requirements

» Continued staff engagement, with a focus on staff health and wellbeing

» Ensuring H&S requirements related to the move from BPR to 10SC were identified and managed

This section gives a brief overview of the key activities and initiatives carried out this 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 that H&S issues were suitably prioritised; and a review of existing H&S Committee structures to streamline reporting and clarify roles and responsibilities. This included a responsibility of Divisional Directors to actively monitor H&S arrangements.

This year has seen 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 fire safety management and completion of mandatory H&S training being addressed by CET. The CET H&S Champion continued to support H&S initiatives and provide a strong link between Centre H&S committees, the HSSG and CET.

A draft 5-year H&S strategy was developed and consulted on at HSSG. This document is due to be finalised shortly by CET. The H&S strategy sets out the Agency's vision for H&S and Wellbeing, focussing on a number of key objectives for example staff health and wellbeing, enhanced collaboration across similar organisations and internal Divisions to enhance lessons learnt and achieve best practice.

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, prompting regular inspections as set out in an annual intervention plan.

There have been three planned intervention inspections (including the annual review of work at the highest level of containment - Specified Animal Pathogens Order – SAPO 4). NIBSC was deemed broadly compliant across all areas inspected, though some improvements in documented management arrangements were identified.

b. Internal audits

There is an audit schedule in place which covers all Divisions across the Agency. Internal audits are carried out by the H&S team at least once a year, with results monitored by the H&S committees.

Maintaining OHSAS 18001 certification at the 10SC site

This section applies to the Regulatory and CPRD centres of the Agency, based at 10SC.

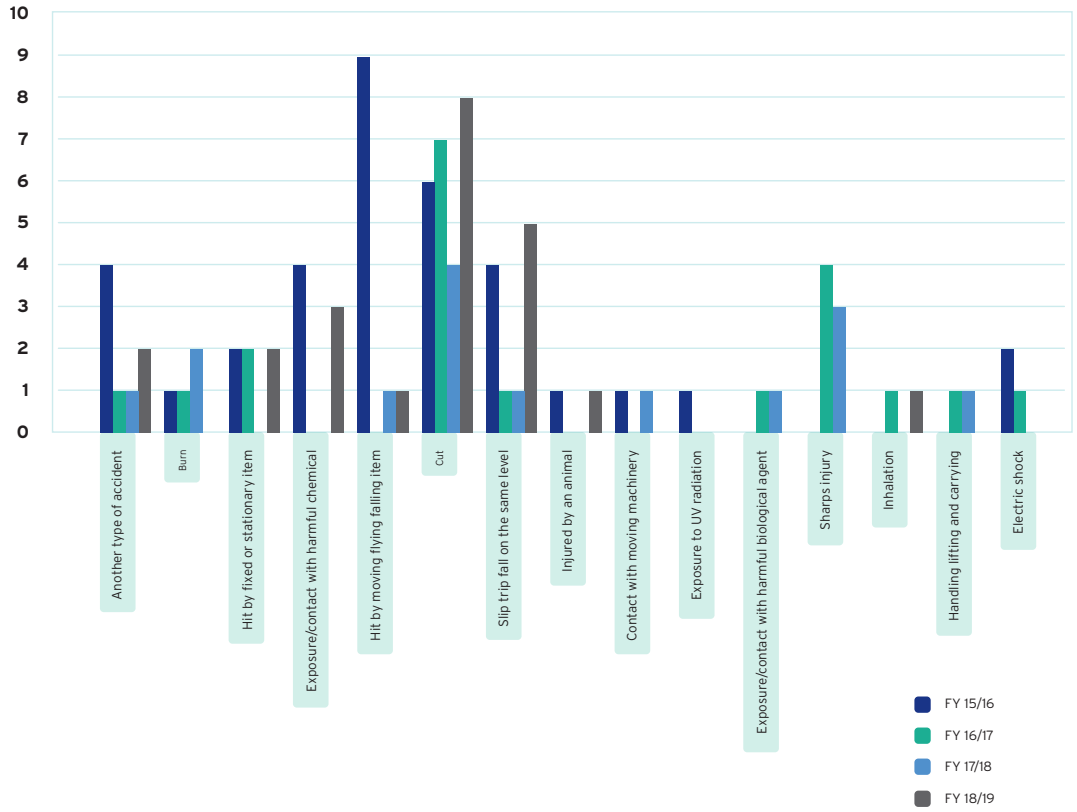
British Standards Institution continuing assessment/surveillance inspections were completed in July (surveillance audit), December 2018 and January 2019 (surveillance audit shadowing practical activities). Certification to OHSAS 18001 was maintained following the re-certification audit with one minor non-conformity raised and one opportunity for improvement. Progress against these actions will be reviewed during the next audit on 2 May 2019.

Accident / Incident reporting

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

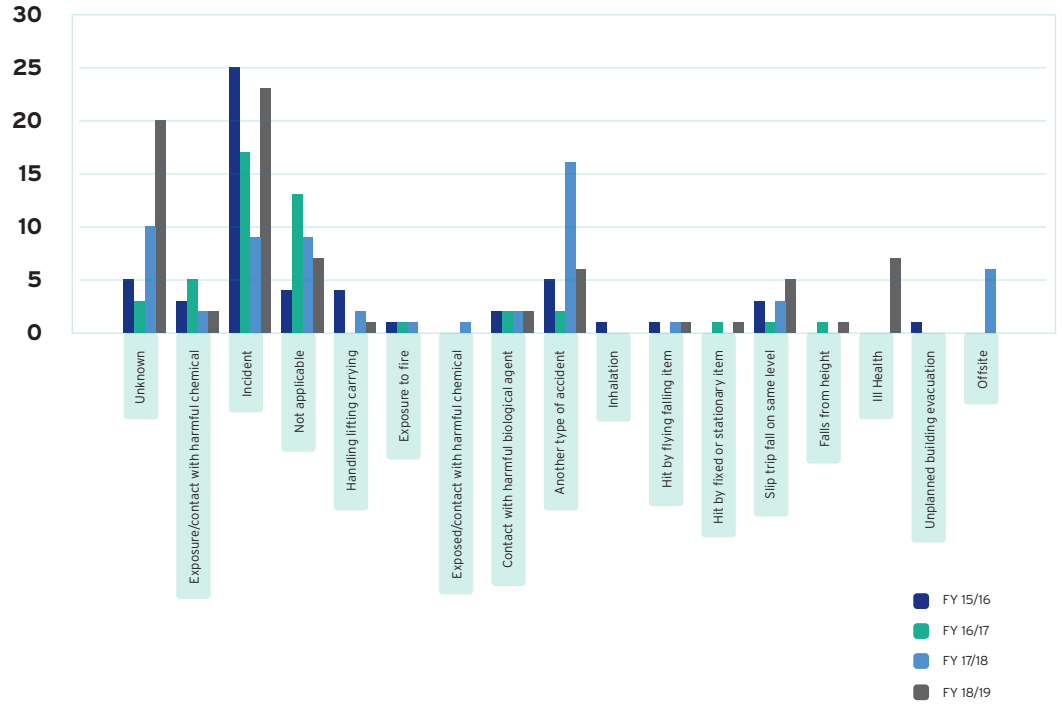
There has been one RIDDOR reportable event during 2018/19, where the Agency reported a case of Hand Arm Vibration Syndrome. The local investigation has been completed and appropriate actions taken to prevent reoccurrence. The Agency received an Improvement Notice from the HSE to improve risk assessment processes relating to vibration assessment and control.

b. Agency Accident Statistics (4 financial year period)



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 have been improved this financial year with the addition of categories for offsite incidents and ill-health incidents (work related, and non-work related).

Delivering the mandatory training programme

a. Laboratory workers at NIBSC

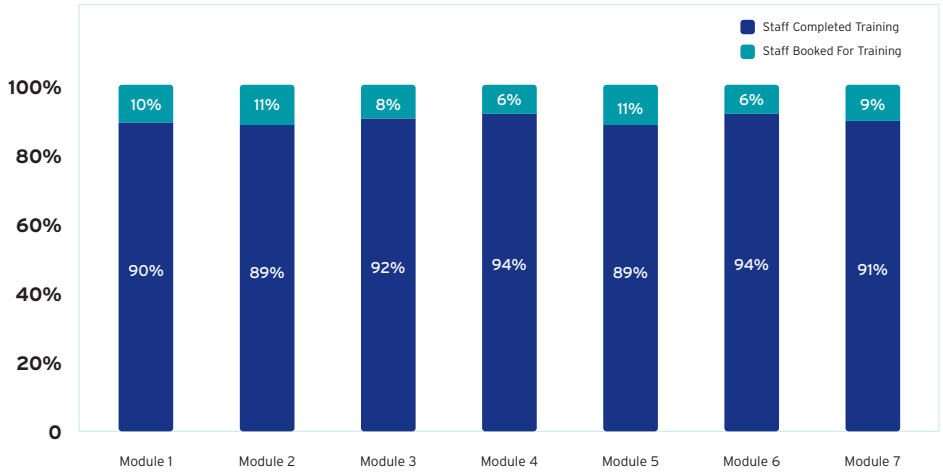
At NIBSC, specialist training has been provided for laboratory workers, laboratory managers, risk assessors and authorisers. The courses have been delivered this year:

Course	Total courses delivered in 2018/19
Laboratory Managers health and safety	3
Practical Manual Handling	3
Risk Assessors	3
Risk Authorisers	3
Lab Module 1 – Legal Matters	3
Lab Module 2 – Facilities	3
Lab Module 3 – PPE & Signage	3
Lab Module 4 – Biological Safety	3
Lab Module 5 – Waste	3
Lab Module 6 – Hazard and Risk	3
Lab Module 7 – Behavioural Safety	3

A second Containment Level 3 (CL3) training course consisting of 13 modules was delivered to CL3 users and support staff, primarily engineering staff, in February 2019. 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 was completed prior to delivery, taking on board attendee feedback. Additional practical elements were included in the updated version of the course which were well received.

The graph below shows the percentage of laboratory workers who have completed training:

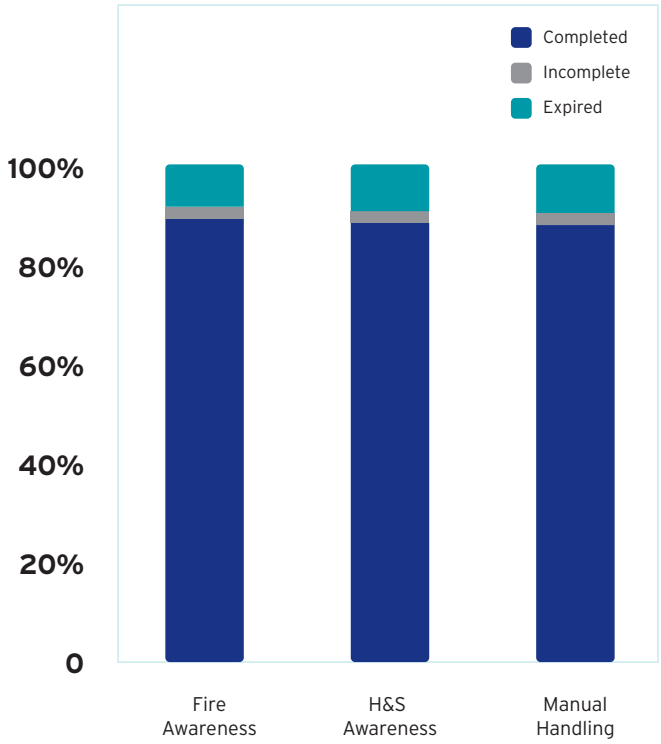
Lab Worker Module Completion Stats April 2019



b. Agency mandatory Civil Service Learning (CSL)

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

Mandatory CSL Training Completion



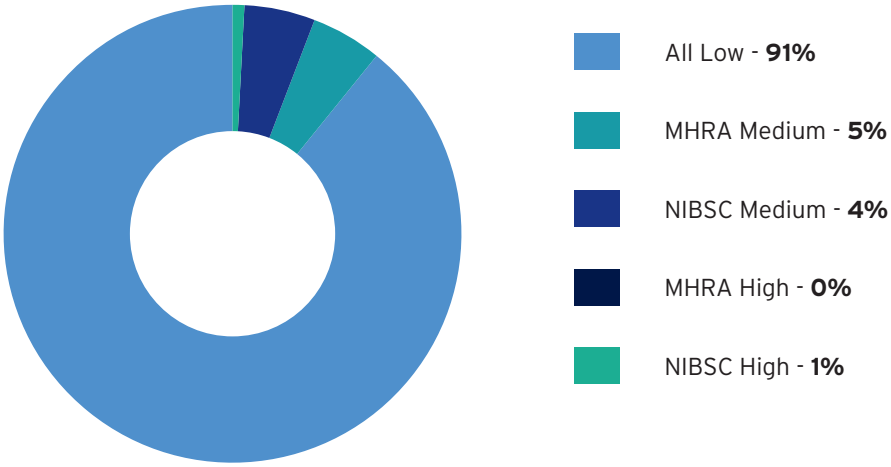
Training refresher periods range from annual to 3 yearly. Completion of mandatory training remains a priority for the Agency.

c. Driving Monitor

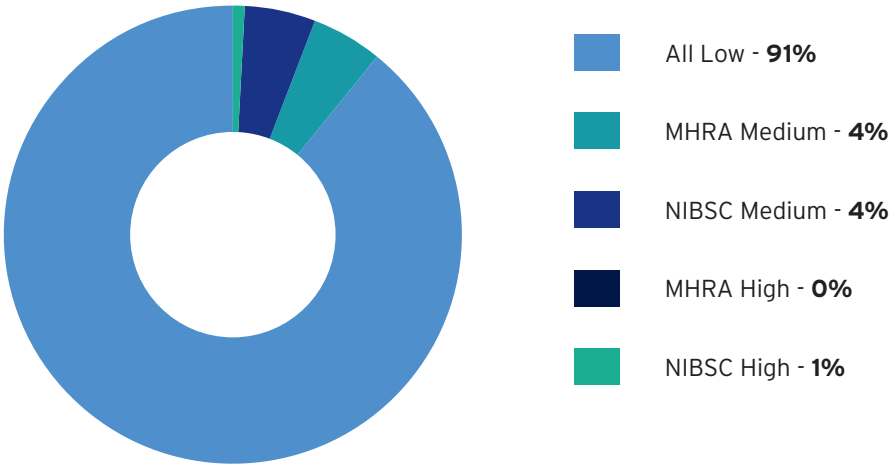
All staff that drive on Agency business are required to complete an assessment on a system called Driving Monitor. Driver risk ratings are based on a risk assessment which combines driver history with an on-line assessment. Drivers deemed as medium and high risk receive appropriate additional training.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

Agency Driver Risk Ratings

March 2018 Driving Monitor Stats:



March 2019 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 H&S team and DSE Co-ordinators to resolve their DSE Issues. Occupational Health referrals are available where required. Improved online assessment and training completion rates were seen across 2017/18, with an overall compliance at 91%. This year the Agency migrated to an updated version of the software and staff are currently updating their records on the new system.

Reviewing overseas working safety requirements

Overseas working safety remains a key area of focus for the Agency. The UK and Overseas Working Group (UOWG) has developed a robust management system for overseas working to ensure staff safety whilst working overseas on Agency business, with the overseas working policy and procedure finalised this year. The new system included the introduction of Hostile Environment Awareness Training for staff travelling to medium and high-risk destinations, the production of country information packs and a simplified travel application and risk assessment process which has helped staff understand 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. Newly appointed Safety Advocates have been supporting their Divisions during Divisional audits, incident reporting and supporting initiatives such as the new overseas working arrangements. Safety Advocates act as a local point of contact on safety matters for both staff and the H&S Team.

The Agency has recently signed the Time to Change Action Plan to demonstrate commitment to creating a workplace free from stigma and discrimination. Using the existing support mechanisms in place – HR Policies, Occupational Health, Employee Assistance Programme, Mindfulness, Massage Therapy, and the Staff Support Network, the Agency can create a working environment that is caring and supportive. The Mental Health Champions play an important role in bringing this to life by supporting staff in speaking up without the fear of negative consequences. Their role is to offer support to colleagues who have an issue with themselves, with a colleague, or with a manager. They are there to listen, in a supportive and non-judgmental way to

support staff to take the next step in resolving the issue, which may include referral to one of the HR Advisers for more structured support.

Occupational Health

January 2019 saw the introduction of Sugarman Occupational Health Services as the Agency's new OH provider. They will continue to work with both manager and employee to provide bespoke and generalist support to help staff stay safe and well, and able to perform to their full potential. The contract is for an initial 3-year period, with a 6-month contract review timetabled for July 2019 to ensure the contract, and OH provision, are achieving against expectations. Sugarman will provide monthly oversight reports to HR. The Diversity and Wellbeing Lead will provide a summary of these reports to the HSSG meetings.

The move to 10SC

The Agency's move to Canary Wharf was completed successfully in July 2018. The H&S Team contributed to relevant groups and committees including those reviewing IT equipment needs for homeworkers to ensure that H&S issues were identified and managed appropriately. H&S inductions specific to the new building were delivered prior to the move.

Dr Ian Hudson
Chief Executive and Accounting Officer
Medicines and Healthcare products Regulatory Agency
01 July 2019

2 Accountability Report

2.1 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 Kt

Sir Michael Rawlins is a clinical pharmacologist and specialist in internal medicine. He was Ruth and Lionel Jacobsen Professor of Clinical Pharmacology, University of Newcastle upon Tyne (1973-2006), and Consultant physician and clinical pharmacologist, Newcastle upon Tyne NHS Hospitals' Trust (1973-2006).

Sir Michael was chairman of the Committee on Safety of Medicines (1993-1998), chairman of the Advisory Council on the Misuse of Drugs (1998-2008) and founding chairman of 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.

Deputy Chair

Professor David Webb, Deputy Chair

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.

Non-Executive Directors

Dr Barbara Bannister MBE

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 DHSC 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 AC DBE

Professor 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.

Amanda Calvert

Amanda Calvert spent 28 years in the Life Sciences sector working for ICI, Zeneca and AstraZeneca where she held senior operational roles across a wide range of business functions. She led major change programmes including; setting up a global IT function and investment programme to support pharmaceutical operations and manufacturing; pioneering new ways of working to deliver greater value from the global product supply-chain; working with teams to bring new thinking and ways of working to IT compliance and security to create a culture of collaboration and accountability supported by modern technology.

Professor Bruce Campbell

Professor 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.

Bruce 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 is Honorary Vascular Consultant in Exeter and Honorary Professor at the University of Exeter Medical School.

Stephen Lightfoot

Stephen Lightfoot, currently Deputy Chair of Sussex Community NHS Foundation Trust, Director of Gainsborough Property Development UK Limited and Non-Executive Director of Elite Hotels (Rotherwick) 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 business, Managing Director of Daiichi Sankyo's UK pharmaceutical business and Commercial Director of Schering Healthcare's UK pharmaceutical business.

Professor Sir Alex Markham Kt

Professor Sir Alex Markham 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.

Sir Alex 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.

Anne-Toni Rodgers

Anne-Toni Rodgers is recently retired and runs her own management consultancy. A pharmacologist by training she has over 35 years healthcare experience in both the public and private sector. She was a founding Director of the National Institute for Clinical Excellence and has senior experience in both the pharmaceutical and device industries.

Michael Whitehouse OBE

Michael Whitehouse is a qualified accountant and auditor with over 30 years' experience as an external auditor of central government on behalf of Parliament. For 15 years he was an Executive Board Member of the National Audit Office and he spent eight years as Chief Operating and Board Member responsible for finance until his retirement in 2017. He now holds a range of non-executive portfolio appointments.

Chief Executive

Dr Ian Hudson

Dr Ian 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 in 2013, Ian 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 Fundrey joined the Agency 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. Jon is a qualified chartered accountant and chartered IT professional.

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.

Members who left the Board during the year

Mr Martin Hindle, Ms Deborah Oakley and Mr Matthew Campbell-Hill left the Agency Board on 31st August 2018.

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 declare their interest in any items being discussed at Board meetings and will declare any new conflict of interest openly at the next Board meeting they attend.

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.

Executive directors and senior managers submit annual conflict of interest declarations to confirm the absence of or to disclose any significant interests which may conflict with their responsibilities. The annual declarations must be submitted by a certain date and are kept on record.

Declaration of Interests

The Register of Interests for each member of the Board can be found by clicking onto their profile on the Agency website at the following location:

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

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 2018/19.

2.2 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.

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 Agency's auditors are unaware, and I have taken all steps to make myself aware of any relevant audit information and to establish that the Agency'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 judgements 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.

2.3 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 Corporate

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

The Permanent Secretary nominates a Senior Departmental Sponsor (SDS) who acts as the Agency's designated, consistent point of contact within the Department. The SDS acts as the link at executive level between the Agency and the senior officials of the Department and 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 Biological Standards and Controls (NIBSC).

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.

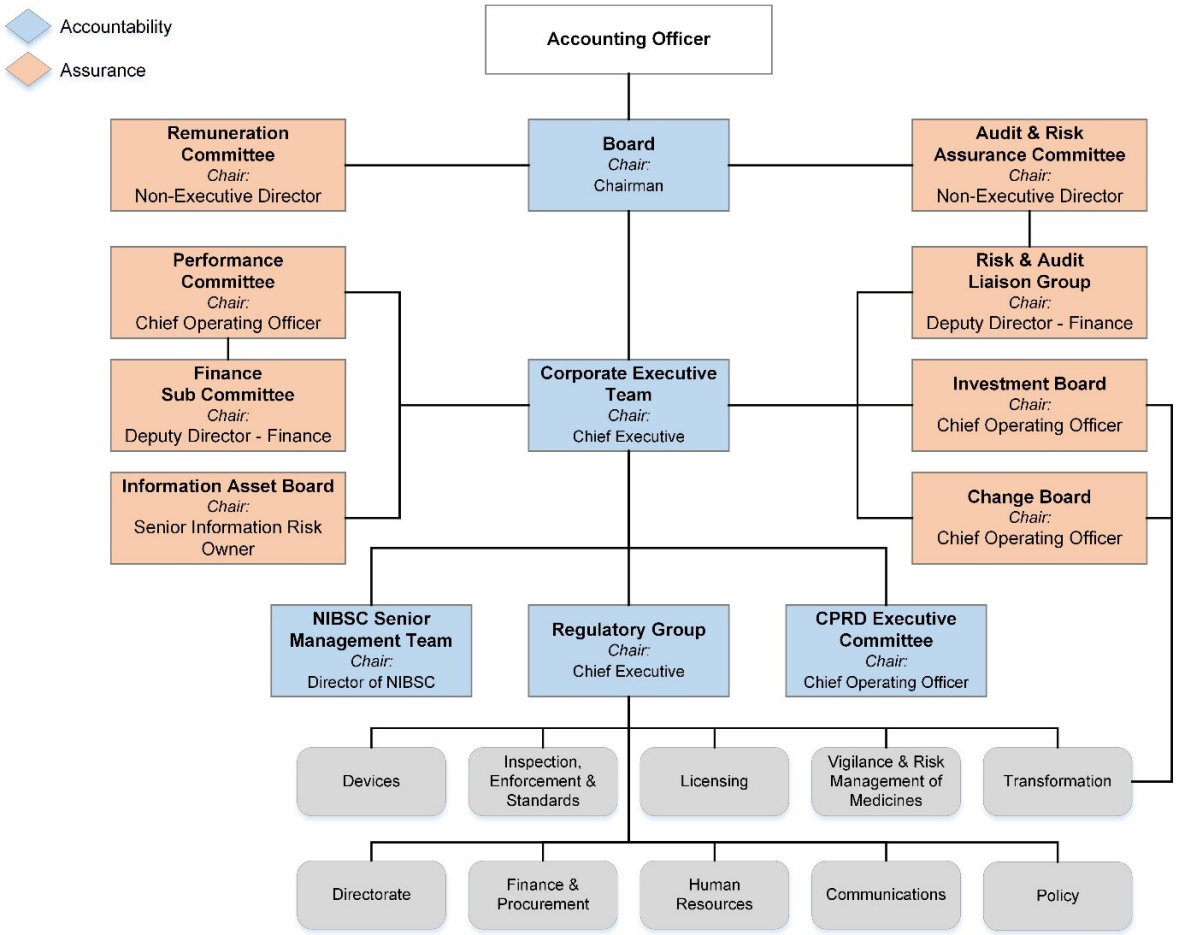
As the Agency's Chief Executive, I am responsible for service delivery and resources.

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.

The Governance Structure



At the beginning of the year, following the retirement of the Director of Inspection, Enforcement & Standards and the appointment to that post of the Director of Operational Transformation (OT), the Information Management Division and OT Division were merged into the Transformation Division, under the leadership of a new Director of Transformation.

Effectiveness of the Corporate Governance Framework

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

The Secretary of State for Health & Social Care 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 54.

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	7(9)	1(2)
Professor Dame Valerie Beral	6(9)	2(2)
Ms Amanda Calvert[1]	5(5)	2(2)
Professor Bruce Campbell	7(9)	2(2)
Mr Stephen Lightfoot	9(9)	2(2)
Professor Sir Alex Markham	6(9)	2(2)
Ms Anne-Toni Rodgers[1]	4(5)	2(2)
Professor David Webb	6(9)	2(2)
Mr Michael Whitehouse[2]	4(4)	1(1)
Mr Martin Hindle[3]	4(4)	N/A
Ms Deborah Oakley[3]	4(4)	N/A
Mr Matthew Campbell-Hill[3]	4(4)	N/A
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.

1 Ms Amanda Calvert, Ms Anne-Toni Rodgers were appointed Non-Executive Director with effect from 1st September 2018.
2 Mr Michael Whitehouse, OBE, was appointed Non-Executive Director with effect from 1st December 2018.
3 Mr Martin Hindle, Ms Deborah Oakley, Mr Matthew Campbell-Hill left the Agency Board on 31st August 2018.

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 a joint Board and Corporate Executive Team awayday in January 2018. The discussion was informed by a report that had been prepared by Woodnewton Associates, an external consultancy. The outcome of the awayday discussion was a range of actions to be taken forward during 2018.

Among these were:

- To prepare a draft Board Operating Framework (BOF). A draft BOF was prepared and endorsed by the Board at its meeting in May 2018. It was subsequently published on the Agency's page on GOV.UK.
- A VIP guest speaker from the public health field to attend a future Board dinner. The Chief Medical Officer (England) was invited to attend a Board dinner in October 2018, but because of an official meeting commitment overseas, was unable to attend. For reasons of economy, the Board subsequently decided not to hold a Board dinner.
- The Board's work plan/forward programme of business to come to the Board on a regular basis. This has been a standing item at every Board meeting since February 2018.
- New formats for finance and business plan reporting to come to the Board. A new and shorter version of the Finance and Procurement Report was prepared for the Board during the summer of 2018, which was furthered revised following discussion at the Board in October and November 2018.
- The Board to 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. During the 2018 Board recruitment campaign, of the three new Non-Executive Directors who were appointed to the Board, two were female.

Audit and Risk Assurance Committee (ARAC)

During the year two members left having completed their term and were subsequently replaced by two new members. During this period, Mr Stephen Lightfoot served as interim chair.

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 non-executive Directors. It is a sub-committee of the Board and reports independently to the Accounting Officer and the Board on: the adequacy of the Agency's governance arrangements, assurance and the risk management framework and the associated control environment; the Agency's financial and non-financial performance to the extent that it affects the Agency's exposure to risk and weakens the control environment; oversight of the financial reporting process; the operation of the Conflict of Interests policy, assurance on Health & Safety and all types of fraud, and Whistle-Blowing arrangements. The ARAC also discussed and agreed the annual internal audit plan. In addition, ARAC asked for and received regular updates on, procurement waivers, 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.

Conflict of Interest Declaration

The process for recording declarations of conflicts of interests in ARAC mirrors the processes used at Board level. Each member of the Committee took personal responsibility to declare pro-actively any potential conflict of interest arising out of business undertaken by the Agency, arising on the Committee's agenda or from changes in the member's personal circumstance.

International Standards on Auditing (UK) require the C&AG and his staff to comply with the Financial Reporting Council's Revised Ethical Standard ('the ethical standard'). Michael Whitehouse, the Audit and Risk Committee (ARAC) chair, was employed as the Chief Operating Officer of the NAO until his retirement on 18 April 2017. The ARAC Chair has notified the Agency and the Audit Committee that, given his level of seniority at the NAO, he is considered the equivalent of a 'partner in the firm' and falls within the definition of a 'covered person' with respect to the NAO for the purposes of the ethical standard until 18 April 2019.

The NAO has introduced safeguards to ensure that there are no actual or perceived threats to their independence and discussed these with management and all members of the audit committee. MHRA and the ARAC have considered the safeguards put in place and are satisfied that any actual or perceived threats to the NAO's independence arising from the appointment of the ARAC chair have been identified and mitigated.

Review of ARAC Effectiveness

The committee's 2018/19 annual effectiveness survey showed that 88% of answers in the returned questionnaires were in the 'above average'/'fully satisfactory' categories. This was same as observed for the previous year's results.

ARAC Attendance

Members	ARAC
Ms Deborah Oakley (Chair)*	1(1)
Mr Martin Hindle*	1(1)
Mr Michael Whitehouse (New Chair)	4(4)
Mr Stephen Lightfoot	4(5)
Professor Sir Alex Markham	3(5)
Ms Mandy Calvert	4(4)

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

*Mr Martin Hindle and Ms Deborah Oakley, left the Agency Board on 31st August 2018..

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 Chief Financial Accountant
- The Head of Internal Audit
- Representatives from the External Auditor
- Representatives from the DHSC.

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 responsibilities and composition of the Agency's Remuneration Committee are set out in the Remuneration Report on page 79.

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 (page 79 of this report) gives details of the remuneration paid to the members of the Board and CET.

CET Members Attendance

	CET
Dr Ian Hudson (Chief Executive Officer)	11(12)
Mr Jon Fundrey	11(12)
Ms Vanessa Birchall-Scott	12(12)
Ms Rachel Bosworth	9(12)
Dr Christian Schneider	12(12)
Dr Siu Ping Lam	9(12)
Mr Jonathan Mogford	10(12)
Mr John Quinn	11(12)
Dr June Raine, CBE	10(12)
Dr Janet Valentine	11(12)
Mr John Wilkinson, OBE	11(12)
Dr Samantha Atkinson	12(12)

Data Quality to Support the Needs of the Board

Financial Data

The CET and Board receive reports at their meetings to support their 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, monthly management information is discussed at the Finance Sub Committee and Performance Committee prior to submission to the CET and Board and any resource or financial implications are highlighted.

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 2019. 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 2019, the Agency's corporate risk register had identified the following principal risks:

- The Agency recognises the risk of threat stemming from Exiting the European Union including loss of business both from the Regulator and NIBSC. Allied to this risk also is the fact that the Agency currently has access to functionality and data to some European systems. A No Brexit Deal may prevent continued access which might affect some of the Agency's operations.
- There is a continued threat of the diversion of medicines from the regulated supply chain as well as prevention of falsified medical products reaching the public via illegitimate supply chain.
- The Agency, like every other organisation, is at risk from cyberattacks and the threat of system disruption and/or data loss.
- The Agency has financial risk arising from shortfall in funding available to address new/emerging areas of public health e.g. devices regulation, life sciences etc.
- Potential risk of CPRD inability to generate proposed Interventional Research (IR) income.

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 34.

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.
- Introducing data governance and master data management concepts into our Information Governance arrangements.
- Corporate governance, including transparency requirements under the Freedom of Information Act 2000 and Environmental Information Regulations 2004.
- The Information Asset Board has continued to meet quarterly to give feedback on information governance issues and to ensure that Information Asset Owners are up-to-date on the work being carried out to strengthen the information governance framework in the Agency.

Data Protection

We have worked to further improve compliance around General Data Protection Regulation (GDPR) requirements and improve awareness. We have published briefings onto the Agency's intranet site to raise awareness of key areas of GDPR such as Subject Access Requests and to improve engagement by making the legislation understandable and clear. 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. The action plan is based on the Information Commissioner's Twelve Steps to prepare for the General Data Protection Regulation.

We have introduced privacy by design principles – including Privacy Impact Assessments for new systems or processing activities that utilize personal data. This will help the Agency to identify risks to personal data up front and propose mitigation solutions. This helps to reduce the risk of personal data being compromised, thereby reducing the risk of a significant breach. These also enable the Agency to ensure that oversight of suppliers is included in the risk assessment, giving the Agency more assurance that personal data is being handled appropriately.

We have completed our register of personal data processing as required under Article 30 of the GDPR. This allows for the Agency to see what personal data is being processed and to ensure that there is an appropriate legal basis as required under the legislation.

Information Risk

The Agency continues to prioritise information risk and have taken positive steps to improve data security and its resilience to the growing and evolving cyber security threat.

- We have embedded information security risk management in our project and change lifecycle. Information risk is therefore a key consideration in the design process and features in key governance groups such as Information Asset Board, Solutions Design Board and Technology Steering Group.
- We have assessed our security tooling such as software to detect and neutralise malware that may enter our network through email, internet or other digital links. Although we remain in a strong position we need to improve and are in the process of improving our data loss prevention and intrusion detection and prevention capability.
- We have carried out further IT health Checks and are making steady progress to closing the high-risk vulnerabilities that were identified. Some longer-term vulnerabilities still exist in relation to our legacy systems, but it is expected that work to upgrade the Agency IT infrastructure soon will remove these vulnerabilities.
- In September we awarded a contract to deliver security testing and an emergency cyber-attack response service. These services give assurance that our new products and services will be secure and have improved our ability to detect and respond to a major cyber incident.
- We performed well against the National Data Guardian (NDG) data security standards and recently have registered to complete the Data Security Protection toolkit, which is anticipated to be very positive.
- We have improved our security incident reporting process. A simple tool on the Agency intranet site has led to greater numbers of incidents being reported and passed through to the Data and Information team for investigation.

Information Skills

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

We have worked hard to improve the security education, awareness and culture of staff. Agency staff still complete Responsible for Information General user as

its mandatory security learning product although it is now expected to complete this every two years, rather than annually. The Data and Information team have also delivered Data Security, risk and GDPR training to over 300 staff with further sessions planned for 2019.

To further improve staff awareness of security threats we have carried out two simulated phishing campaigns. The second campaign saw a reduction in 'click through' rate from 9 to 2%. Although this is very positive, there is evidence that there is a small group of staff who continue to be unaware of the threat posed by phishing and for which we are planning a targeted awareness campaign. All staff have access to the online Knowledge Hub, providing links to dozens of tip sheets and online tutorials for handling information.

Digital Workplace

The Digital Workplace Programme was completed in July and this means that team sites are in use across the Agency, enabling cross-site and cross-team collaboration. This means that information can be shared more effectively and provides an evergreen repository for storing records.

Our records management tool has been upgraded and will enable retention periods to be applied to records within SharePoint more effectively. This will reduce the risk of over-retaining records and improve compliance against GDPR and the Public Records Act.

Information Asset Board (IAB)

We have identified that improvements need to be made to the structure of the IAB and the mode of operation in order to ensure the Board is as effective as it can be and operates on a proactive rather than a reactive basis. A new Information Governance Framework was introduced at the end of March 2019, and IAB activities will be reported against this framework going forwards.

Effectiveness of whistleblowing arrangements

The Agency has an internal Whistleblowing Policy and Procedure, Guidance for Managers and Frequently Asked Questions documents based on a best practice policy created by Civil Service Employee Policy. The 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 a report at each meeting 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.

There were no whistleblowing cases this year. Various methods were used this year to raise staff awareness of how to raise concerns including placing posters at printing points and on TV screens and an article on the intranet.

Effectiveness of Anti-Fraud and Bribery Policy

The Agency has an internal Anti-Fraud and Bribery Policy and Procedure which sets out the Agency's stance on non-regulatory fraud, bribery and corruption 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. The Agency has a comprehensive awareness programme including the annual mandatory CSL online training for all staff, and bespoke workshops for staff in key roles. We undertake an annual risk assessment programme with all divisions. ARAC has oversight of all cases and receives a report at each meeting. One new case was opened for investigation in 2018/19.

Procurement

During 2017/18 procurement activity within the Agency was subject to several internal audits. Of the forty-three recommendations identified, all the recommendations (30) that relate to operational processes have been addressed by the Head of Procurement with strengthened processes and enhancements to eSourcing and P2P systems.

Following the earlier audits, many of the required manual procurement controls have been enhanced. 'Sourcing Strategy', 'Specification Sign-off' and 'Tender Evaluation Sign-off' documents have been introduced and have become standard practice in all tender processes commenced in 2019. These documents flag key milestones and checkpoints during pre-sourcing, prior to contract award and following completion of the tender process. The 13 remaining recommendations relate to the ongoing strategic wider Agency-wide procurement and contract management review being carried out by the Deputy Commercial Director.

A report on the possible options for the "Strategic Review" of procurement and contract management review was delivered in December 2018. This was further enhanced by a detailed analysis of the Agency's external expenditure undertaken as part of our Operational Transformation programme. This has confirmed that a move to a more formal category management approach would help deliver further savings across the Agency. A new Deputy Director, Commercial joined the Agency from the Government Commercial Organisation (GCO) in June 2019 to take this forward.

Operational Transformation

The Transformation Division retains responsibility for delivering the Agency's corporate digital services and now also has responsibility for managing the Agency's Portfolio of change. To do this, the resources of the former Operational Transformation (OT) Division have been incorporated as the Business Design Group alongside the Enterprise Portfolio Management Office (EPMO).

The Operational Transformation Programme is ongoing and achieved a major milestone in November 2018. The DHSC Investment Committee approved the Operational Transformation Programme Business Case (PBC). The decision approved the overall investment needed as well as the funding to deliver the first tranche of change.

Portfolio governance remains unchanged. The Change Board oversees delivery of the required in-flight strategic change activities in line with the direction set by the approved programme/project plan and aligned to the Corporate Plan and Strategic Imperatives. The Investment Board manages and monitors 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 provides 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 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 provides 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 2018/19 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.

9 assurance-based reviews have been performed during the year of which 2 were rated as 'Substantial', 7 as 'Moderate' assurances and none were rated as 'Limited' or 'Unsatisfactory' assurance. 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 CPRD Quality Assurance, which considered the quality assurance processes applied to the CPRD GOLD database following receipt of the data from the 'In Practice Systems' was awarded a Substantial assurance; the highest possible rating awarded to this arm of the Agency for the third consecutive period.

- The review of the Human Resources Records and Payments which considered the controls over people related records and payments, particularly in light of the changes resulting from the 2017/18 introduction of the Oracle Fusion business system, was awarded a Moderate' assurance. The audit covered processes for updating staff records, with a particular focus on the approval and payment of overtime and other non-salary allowances and the sufficiency of management information reporting across the organisation.

- The review of the Agency's Financial Forecasting and Planning covered the Agency's financial planning and forecasting arrangements and alignment of financial planning to the Agency's strategy and priorities, including the budget setting process and ongoing consideration of European Union Exit; it was awarded a Moderate assurance. The complexity of the Agency's business and the financially challenging context in which it operates makes it imperative to ensure there is assurance that forecasts/predictions are based on sound inputs, calculations and outputs and that management make effective use of this information in making decisions to deliver business objectives.

- The review of the Agency's IT Security/Cyber Security assessed the extent to which current cyber security controls and processes are sufficient to mitigate the risk of a data breach and support the maintenance of the confidentiality, integrity and availability of data was awarded a Moderate assurance. The audit reviewed the controls in operation covering Information Security, notably the control environment in relation to potential cyber threats, such as External Breaches, Insider Threats, External Breach via Third-party or Physical Breaches.

- The review of the Agency's Procurement followed on from a 2017 NIBSC Procurement and Contract Management review which made a number of recommendations to resolve inadequate financial and procurement controls and issues relating to contract management, procurement policy and process design and operating effectiveness. That review was supplemented with an Agency-wide procurement and contract management review, which identified findings relating to key themes such as a lack of spend analysis, operating model design to deliver category management, managing conflicts of interest, processing of waivers and business cases. Both of these reviews received Unsatisfactory Assurance Opinions. The review this year was awarded a Moderate assurance.

The Agency's ability to mitigate the risk of failure to comply with legislation or Government procurement policy has been strengthened in recent years, with the implementation of Oracle Fusion and enhancements to the configuration of the Bravo e-procurement solution

- The review of the Agency's Operational Transformation Programme: Programme Assurance - covered the key risk that 'project activities and dependencies are not effectively managed or controlled, preventing delivery in accordance with time, cost and quality criteria'. The audit reviewed a series of business process areas, all of which underpin programme governance and management. These processes included overarching programme governance structures, planning and control arrangements, financial and workforce management, benefits management and programme assurance arrangements.

It was awarded a Moderate assurance.

- The review of the Agency's Aged Debt Controls assessed the operation and adequacy of controls over the prevention, identification, recovery and reporting of aged debt, whilst also analysing performance in identifying, pursuing, tracking, providing for monitoring and recovering aged debt. It was awarded a Moderate assurance.
- The review of GDPR was to provide independent and objective assurance that there are robust and effective governance and risk management arrangements in place to comply with the Data Protection Act 2018/GDPR. GDPR applies to the collection, storage, processing, transfer and destruction of personal data. GDPR reforms existing data protection rules and introduces several new concepts and restrictions on data processing. The new rules significantly increase sanctions for data breaches, expand the audit and investigatory power of the Information Commissioner's Office (ICO) and the rights of data subjects. It also forces data controllers and data processors to be much more transparent and accountable for their data processing operations. The review awarded a Moderate assurance.
- The review of the Agency's Variations and Notices which assessed how MHRA responded to and recorded adverse medicinal reports via the Yellow Card scheme and how variations or notices, when required, were communicated to users was awarded a Substantial assurance.

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

The reviews noted on good practice as follows:

- The review of CPRD Quality Assurance highlighted the (i) Processing of the Data Collections is highly automated (ii) Effective Methods of Communication and (iii) Technical ability of staff as particular areas of good practice.
- The review of the Human Resources Records and Payments acknowledged the substantial details of assurances for the controls in place for managing the potential risk of overtime and other non-salary payments to staff not being in accordance with their contracted terms and conditions of employment.
- The review of the Agency's Financial Forecasting and Planning identified a number of areas of good practice, including the role of Corporate Executive Team challenge sessions in the divisional budgeting process.
- The review of the Agency's IT Cyber Security identified good practice in areas such as clear cyber governance structure, the Agency's completion of IT Health Checks in line with Public Services Network Code of Connection, our understanding of the value of data assets and more than 95% of staff had received Information Governance and Information Security training in 2017/18 which was the year the GDPR came into force.
- The review of Procurement noted the Agency's ability to mitigate the risk of failure to comply with legislation or Government procurement policy has been strengthened in recent years, with the implementation of Oracle Fusion This investment has provided the Agency with the capability to strengthen controls around the Procure-to-Pay (P2P) process and enhancements to the configuration of the Bravo e-procurement solution. Progress has also been made in implementing the management actions arising from previous Internal Audit reviews.
- The review of the Agency's Operational Transformation Programme: Programme Assurance - indicated that the Programme has a clear vision which

is presented in the Programme Business Case. The Programme's governance structure facilitates senior oversight at CET, with a Programme Steering Committee enabling more detailed senior discussion and decision-making. Comprehensive terms of reference have been produced for PSC and the various other meetings and forums that have been established to govern the Programme – these terms of reference are comprehensive and responsibilities are clearly documented.

- The review of Aged Debt Control identified appropriate and regular Control Account Reconciliation.
- The review of the Agency's GDPR noted good practices in many areas audited. Notably, the Agency has completed a register of processing activities, which is a requirement under Article 30 of GDPR, implemented a number of key policies, including a Data Protection Impact Assessment (DPIA) Policy, a Subject Access Request (SAR) Policy, Security Marking Procedure, Information Management Policy, Information Security Policy and a Retention and Disposal Policy, assigned accountability for information governance through an Information Governance Framework Document and made it a requirement to perform DPIAs for all new projects. The Agency has introduced 'RecordPoint' which is a tool that automatically reviews share point folders and triggers a review and disposal process once the retention period is reached and introduced processes for logging and tracking all GDPR incidents and SARs.
- The review of the Agency's Variations and Notices highlighted (i) Effective Communication, (ii) Efficient Processing of Signals and (iii) Adequate follow-up on signal cases as particular areas of good practice.

Head of Internal Audit opinion

In accordance with the requirements of the UK Public Sector Internal Audit Standards, I am required to provide the Accounting Officer with my annual opinion of the overall adequacy and effectiveness of the organisation's risk management, control and governance processes.

His opinion is 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 both risk management and governance, a moderate opinion is appropriate. Based on the 2018/2019 audit fieldwork, there have been appropriate and proportionate systems in place. There are also suitable and effective governance routes which facilitate the effective management and monitoring of performance and controls.
- In the case of control, that a moderate opinion is appropriate. Nine assurance-based reviews have been conducted. The majority of the reviews were rated as 'moderate', with two rated as 'substantial'. None of the audits were rated as 'limited' or 'unsatisfactory'. The Agency has continued to make steady progress, accompanied by ongoing senior ownership and scrutiny, in driving improvements in Procurement.

In summary, the HIA's overall opinion was that of moderate assurance to the Accounting Officer that the MHRA has had adequate and effective systems of

control, governance and risk management in place for the reporting year 2018/19.

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 2019 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 2018/19.

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 2019 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 2017 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 their controls could be improved, and 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 these 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.

2.4 Remuneration and staff 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 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 Ms Anne-Toni Rodgers (with effect from 19 November 2018). Dr Ian Hudson and Professor Sir Michael Rawlins 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 80.

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

2018/19	Salary	Performance pay and bonuses	Pension related benefits	Total
	£000	£000	£000	£000
Dr Ian Hudson Chief Executive	150 - 155	Nil	47	195 - 200
Mr Jon Fundrey Chief Operating Officer	135 - 140	10 - 15	54	200 - 205
Dr June Raine, CBE Director of Vigilance & Risk Management of Medicines	125 - 130	10 - 15	8	145 - 150
Dr Christian Schneider Director of NIBSC	135 - 140	10 - 15	53	200 - 205
Mr John Wilkinson, OBE Director of Devices	120 -125	Nil	46	160 - 165
Ms Rachel Bosworth Director of Communications	95 - 100	0 - 5	13	115 - 120
Mr Jonathan Mogford Director of Policy	100 - 105	Nil	28	125 - 130
Dr Siu Ping Lam Director of Licensing	115 - 120	0 - 5	10	130 - 135
Mr John Quinn[1] Chief Information Officer and Director of Transformation	110 - 115	Nil	112	220 - 225
Ms Vanessa Birchall-Scott Director of Human Resources	95 - 100	Nil	38	130 - 135
Dr Janet Valentine Director of CPRD	110 - 115	Nil	66	175 - 180
Dr Samantha Atkinson[2] Director of Inspection. Enforcement and Standards	110 - 115	Nil	110	220 - 225

Band of the highest paid director's total remuneration	150-155
Median total	40,867
Remuneration ratio	3.7
Range of staff remuneration	8-155

* CET members receive no 'benefits in kind'.

1 Mr John Quinn took on responsibility as Director of Transformation on 1st April 2018.
2 Dr Samantha Atkinson was appointed Director of I E&S on 1st April 2018.

2017/18	Salary £000	Performance pay and bonuses £000	Pension related benefits £000	Total £000
Dr Ian Hudson Chief Executive	150 - 155	Nil	13	160 - 165
Mr Jon Fundrey Chief Operating Officer	135 - 140	Nil	53	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	53	185 - 190
Mr Gerald Heddell Director of Inspection. Enforcement and Standards	85 - 90	Nil	17	105 - 110
Mr John Wilkinson, OBE Director of Devices	115 - 120	Nil	46	165 - 170
Ms Rachel Bosworth Director of Communications	95 - 100	0 - 5	8	105 - 110
Mr Jonathan Mogford Director of Policy	100 - 105	10 - 15	4	115 - 120
Dr Siu Ping Lam Director of Licensing	115 - 120	Nil	3	120 - 125
Mr John Quinn Chief Information Officer	95 - 100	10 - 15	25	130 - 135
Ms Vanessa Birchall-Scott Director of Human Resources	95 - 100	Nil	37	130 - 135
Dr Janet Valentine Director of CPRD	95 - 100	Nil	60	155 - 160
Dr Samantha Atkinson[1] Director of Operational Transformation	85 - 90	Nil	25	110 - 115

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

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.

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

2018/19	Salary £000	Benefits in kind (taxable) to nearest £100*	Total £000
Professor Sir Michael Rawlins Chair	60 - 65	Nil	60 - 65
Dr Barbara Bannister, MBE Non Executive Director	5 - 10	Nil	5 - 10
Professor Dame Valerie Beral Non Executive Director	5 - 10	Nil	5 - 10
Professor Bruce Campbell Non Executive Director	5 - 10	Nil	5 - 10
Professor Sir Alex Markham Non Executive Director	5 - 10	Nil	5 - 10
Professor David Webb Non Executive Director	5 - 10	800	5 - 10
Mr Stephen Lightfoot Non Executive Director	5 - 10	100	5 - 10
Amanda Calvert[1] Non Executive Director	0 - 5	Nil	0 - 5
Anne – Toni Rodgers[1] Non Executive Director	0 - 5	1,800	5 - 10
Mr Michael Whitehouse, OBE[2] Non Executive Director	0 - 5	Nil	0 - 5
Mr Martin Hindle[3] Deputy Chair	0 - 5	Nil	0 - 5
Ms Deborah Oakley[3] Non Executive Director	5 - 10	Nil	0 - 5
Mr Matthew Campbell-Hill[3] Non Executive Director	0 - 5	4,800	5 - 10

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

1 Amanda Calvert, Anne-Toni Rodgers were appointed Non-Executive Director with effect from 1st September 2018.
2 Mr Michael Whitehouse, OBE, was appointed Non-Executive Director with effect from 1st December 2018.
3 Mr Martin Hindle, Ms Deborah Oakley, Mr Matthew Campbell-Hill left the Agency Board on 31st August 2018.

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.

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 2018/19 relate to performance in 2017/18 and the comparative awards reported in 2017/18 relate to performance in 2016/17.

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 2018/19 was £150k-£155k (2017/18, £150k-£155k). This was 3.7 times (2017/18, 3.8) the median remuneration of the workforce, which was £40,867 (2017/18, £39,897) 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 2018/19 (2017/18, none).

The range of staff remuneration was £8k-£155k (2017/18, £8k-£155k).

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:

2018/19	Real increase in pension and related lump sum at 60 Bands of £2,500	Total accrued pension at age 60 at 31 March 2019 and related lump sum Bands of £5,000	Cash Equivalent Transfer Value at 1 April 2018. To nearest £1,000	Cash equivalent Transfer Value at 31 March 2019. 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	2.5 - 5.0 plus Nil lump sum	65 - 70 plus Nil lump sum	1,206	1,347	49	37
Mr Jon Fundrey Chief Operating Officer	2.5 - 5.0 plus Nil lump sum	40 - 45 plus Nil lump sum	563	667	41	34
Dr Christian Schneider Director of NIBSC	2.5 - 5.0 plus Nil lump sum	10 - 15 plus Nil lump sum	71	118	26	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 160 - 165	1,089	1,128	6	32
Mr John Wilkinson, OBE Director of Devices	2.5 - 5.0 plus Nil lump sum	20 - 25 plus Nil lump sum	297	373	42	29
Ms Rachel Bosworth Director of Communications	0 - 2.5 plus lump sum of 2.5 - 5.0	25 - 30 plus lump sum of 80 - 85	552	627	12	24
Mr Jonathan Mogford Director of Policy	0 - 2.5 plus Nil lump sum	35 - 40 plus lump sum of 105 - 110	713	804	13	25
Dr Siu Ping Lam Director of Licensing	0 - 2.5 plus lump sum of 0 - 2.5	40 - 45 plus lump sum of 135 - 140	1,013	1,090	10	29
Mr John Qiunn Chief Information Officer	5 - 7.5 plus lump sum of 7.5 - 10.0	35 - 40 plus lump sum of 85 - 90	515	669	79	27
Ms Vanessa Birchall-Scott Director of Human Resources	0 - 2.5 plus Nil lump sum	5 - 10 plus Nil lump sum	91	131	23	24
Dr Janet Valentine Director of CPRD	5 - 7.5 plus Nil lump sum	20 -25 plus Nil lump sum	199	291	28	27
Dr Samantha Atkinson Director of Inspection, Enforcement and Standards	5.0 – 7.5 plus Nil lump sum	25 - 30 plus Nil lump sum	230	341	66	27

2017/18	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 85 and 86.

Staff report

Staff costs (subject to audit)

	2018/19			2017/18
	Total £000	Permanently Employed £000	Other £000	Total £000
Wages and salaries	63,344	59,723	3,621	61,515
Social security costs	6,996	6,996	-	6,822
Other pension contributions	12,442	12,442	-	12,081
Sub-total	82,782	79,161	3,621	80,418
Less recoveries in respect of outward secondment	-	-	-	(65)
Total staff costs	**82,782**	**79,161**	**3,621**	**80,353**

Staff resources (subject to audit)

During the year an average of 1,324 permanent full-time equivalent staff were employed.

	2018/19		
	Total	Permanently Employed	Other
Chair	1	1	-
Chief Executive/Directors	12	12	-
Senior Civil Servants	125	124	1
Other Civil Service Staff	1,186	1,056	130
Total	**1,324**	**1,193**	**131**

	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**

Senior Civil Servants by grade band (£000)	2018/19	2017/18
SCS1	127	133
SCS2	9	8
SCS3	2	2
Total	**138**	**143**

Staff composition - gender analysis

	Male	Female
Chairman/Chief Executive/ Directors	8	5
Senior Civil Servants	63	62
Other Civil Service Staff	475	663
Total	**546**	**730**

*Based on submitted returns

Staff composition – ethnic breakdown

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

- White 62%
- BME 29%
- No data/prefer not to say 9%

Sickness absence

The sickness absence calculation now includes all days lost to this absence, including those staff who left during the reporting year. The average annual sickness rate for the year was 8.2 working days per full time equivalent employee (2018, 5.9 days).

The annual turnover for the Agency was 13% (2017/18, 13.4%).

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 10SC) 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.

We are committed to operating a guaranteed interview scheme for any applicant who discloses a disability and meets the minimum essential requirements of the job. We operate an open and fair recruitment process.

We are committed to supporting disabled staff through occupational health provision and health and safety support and guidance, and in addition utilise our Workplace Adjustments Policy to enable staff who become disabled to remain in work, through reasonable adjustments.

We deliver learning and development in a variety of formats to ensure it is accessible to all staff, including online (with accessible versions) and face to face and actively promote a goal of 5 days training per year. We publicise a career pathway tool for all staff to ensure clear communication about career development opportunities across the Agency.

Spend on consultancy and temporary staff

During 2018/19, expenditure on consultants was £217k (2017/18, £87k).

The Agency continues to employ temporary staff where it is of operational necessity. The Agency temporary staff expenditure was £3,621k in 2018/19 (2017/18, £2,754k).

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

Exit packages (subject to audit)

	Total number of exit packages by cost band	
	2018/19	2017/18
<£10,000	4	-
£10,000 - £25,000	2	1
£25,000 - £50,000	3	-
£50,000 - £100,000	-	-
£100,000 - £150,000	-	-
£150,000 - £200,000	-	-
Total number of exit packages	**9**	1
Total resource cost	**£169,753**	£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 £170k (2017/18, £13k) 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 2019 (31 March 2018, 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 2018/19, 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
£0 to £21,636	4.60%	4.60%
£21,637 to £51,515	5.45%	5.45%
£51,516 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:

	2017/18 Annual pensionable pay banding	2017/18 Employee Contribution
Tier 1	Up to £15,431.99	5.0%
Tier 2	£15,432.00 to £21,477.99	5.6%
Tier 3	£21,478.00 to £26,823.99	7.1%
Tier 4	£26,824.00 to £47,845.99	9.3%
Tier 5	£49,846.00 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 2018/19 (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 2018/19, employers' contributions for the agency employees of £12,442,297, were payable to the PCSPS and NHSPS (2017/18, £11,941,354 and a further £8,842 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 (2017/18, 16.7 per cent to 24.3 per cent) for PCSPS and 14 per cent (2017/18, 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 £110,931 (2017/18, £136,177) 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 (2017/18, 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 £2,894 (2017/18, £6,153), 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 £Nil. No contributions were prepaid at that date.

There were no cases of retirement on ill-health grounds during 2018/19 (2017/18, Nil). No additional pension liabilities were accrued.

2.5 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 DHSC 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 DHSC 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. DHSC 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.

2018/19

Charging activity	£000 Income	£000 Expenditure	£000 Surplus
Licensing	40,971	(34,193)	6,778
Inspections	8,959	(8,108)	851
Vigilance, Risk Management and Enforcement	31,633	(32,394)	(761)
British Pharmacopoeia	4,500	(2,989)	1,511
Devices	10,107	(10,645)	(538)
Clinical Trials	3,467	(3,616)	(149)
Regulator total	99,637	(91,945)	7,692
CPRD*	10,360	(12,230)	(1,870)
DHSC share of joint venture	(5,180)	6,115	935
	5,180	(6,115)	(935)
NIBSC	42,072	(44,201)	(2,129)
Total	**146,889**	**(142,261)**	**4,628**

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)**

* 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 (2017/18: Nil).

During the annual asset verification exercise, the agency undertakes a review of assets and checks if any impairment is necessary. The CPRD asset custodians concluded that due to significant design faults with the EpViz which could not be rectified at economic cost, it would be prudent to impair the asset as it longer has any value to the Agency. The asset was capitalised in April 2018 (cost £543k). The Net Book Value at the time of the review was £497k.

EpViz was a prototype piece of software designed on behalf of CPRD. The purpose of this software was to allow epidemiologists to perform cohort definition and data set extraction in a faster way than was possible using CPRD's current online data portal – Citrix. After a period of prototype development and testing, it was determined that the application was not fit for CPRD's needs and the decision made to stop any further investment and impair what been paid.

There were no other material losses or special payments during the year (2017/18: Nil).

Dr Ian Hudson
Chief Executive and Accounting Officer
Medicines and Healthcare products Regulatory Agency
01 July 2019

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 2019 under the Government Trading Funds Act 1973. The financial statements comprise: the Statement of Comprehensive Income, Statement of Financial Position, Statement of Cash Flows, Statement of Changes in Taxpayers' Equity; and the related notes, 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 2019 and of its surplus for the year then ended; and
- the financial statements have been properly prepared in accordance with the Government Trading Funds Act 1973 and HM Treasury directions issued thereunder.

Opinion on 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. In applying the Ethical Standard, I have considered the potential implications for my audit arising from the relationship between a former employee of the National Audit Office and the Medicines and Healthcare products Regulatory Agency, further details of which are disclosed on page 65 of the Annual Report and Accounts. I am satisfied that appropriate safeguards have been implemented to protect my and the NAO team's independence and objectivity throughout the audit. 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.

Conclusions relating to going concern

I am required to 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 for a period of at least twelve months from the date of approval of the financial statements. 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. I have nothing to report in these respects.

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.
- 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 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.

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 or the 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.

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.

Gareth Davies **Date** 03 July 2019

Comptroller and Auditor General

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

3 Financial Statements

Statement of comprehensive income for the year ended 31 March 2019

	NOTE	2018/19		2017/18	
		£000	£000	£000	£000
Income					
Total Income	3.1				
Income from marketing authorisations[1]		**29,499**		-	
Income from clinical trials		**3,467**		-	
Income from research activities[2]		**2,753**		-	
Income from other trading activities		**88,291**		128,744	
Income from Department of Health and Social Care		**34,559**		28,800	
Total Trading Income			**158,569**		157,544
Other income	3.2		**12,192**		11,244
Total income			**170,761**		168,788
Expenditure					
Staff costs	6	**(82,782)**		(80,353)	
Operating costs	7	**(62,204)**		(86,753)	
Total Expenditure			**(144,986)**		(167,106)
Operating Surplus			**25,775**		1,682
Finance income	8		**421**		225
Finance costs	8		**(52)**		(46)
Surplus for the financial year			**26,144**		1,861
Other comprehensive income					
Realised gain on inventories*			**(78)**		(106)
Net gain on revaluation of property, plant and equipment*			**79**		30,058
Total comprehensive income for the year			**26,145**		31,813

* All gains and losses arise from continuing operations.

The notes on pages 104 to 127 form part of these accounts.

1 Regulator income in Note 2
2 NIBSC income in Note 2

Statement of financial position as at 31 March 2019

	NOTE	31 March 2019		31 March 2018	
		£000	£000	£000	£000
Non-current assets					
Property, plant and equipment	9	**136,884**		139,404	
Intangible assets	10	**11,597**		5,004	
Trade and other receivables	14	**8,483**		6,630	
Total non-current assets			**156,964**		151,038
Current assets					
Inventories	12	**5,667**		5,868	
Contract assets	13	**6,592**		-	
Trade and other receivables	14	**27,784**		30,479	
Cash and cash equivalents	15	**79,938**		81,408	
Total current assets			**119,981**		117,755
Total assets			**276,945**		268,793
Current liabilities					
Contract liabilities	13	**(11,694)**		-	
Trade and other payables	16	**(32,958)**		(31,277)	
Other liabilities	17	**(15,329)**		(28,895)	
Provisions	18	**(321)**		(2,468)	
Total current liabilities			**(60,302)**		(62,640)
Total assets less current liabilities			**216,643**		206,153
Non-current liabilities					
Contract liabilities	13	**(3,533)**		-	
Other liabilities	17	**(21)**		(4,822)	
Borrowings	19	**(1,328)**		(1,328)	
Total non-current liabilities			**(4,882)**		(6,150)
Assets less liabilities			**211,761**		200,003

Taxpayers equity		
Public dividend capital	**1,329**	1,329
Reserves		
Revaluation reserve	**107,978**	107,977
Income and expenditure reserve	**954**	954
General fund	**101,500**	89,743
Total equity	**211,761**	200,003

Dr Ian Hudson
Chief Executive and Accounting Officer
Medicines and Healthcare Products Regulatory Agency
01 July 2019

The notes on pages 104 to 127 form part of these accounts.

Statement of cash flows for the year ended 31 March 2019

	NOTE	2018/19		2017/18	
		£000	£000	£000	£000
Cash flows from Operating activities					
Operating surplus		**25,775**		1,682	
Depreciation and amortisation		**10,695**		11,283	
Disposal of assets		**307**		423	
Impairment and reversals		**61**		140	
Realised gain on inventories		**(78)**		(106)	
Decrease/(Increase) in inventories	12	**201**		(62)	
Contract assets	13	**(6,592)**		-	
Contract liabilities	13	**15,227**		-	
Decrease/(Increase) in trade and other receivables	14	**842**		(15,347)	
(Decrease) in trade and other payables	16	**(10,925)**		(20,981)	
(Decrease) in other liabilities	17	**(18,367)**		(1,017)	
(Decrease)/Increase in provisions	18	**(2,147)**		237	
Net cash inflow/(outflow) from operating activities			**14,999**		(23,748)
Cash flows from investing activities					
Purchase of property, plant & equipment	9	**(5,622)**		(4,656)	
Purchase of intangible assets	10	**(9,435)**		-	
Net cash (outflow) from investing activities			**(15,057)**		(4,656)
Cash flows from financing activities					
Interest received	8		**421**		225
Interest paid	8		**(52)**		(46)
Dividend paid			**(1,781)**		(2,181)
Net cash (outflow) from financing			**(1,412)**		(2,002)
Net (decrease) in cash and cash equivalents in the financial year	15		**(1,470)**		(30,406)
Cash and cash equivalents at the beginning of the financial year	15		**81,408**		111,814
Cash and cash equivalents at the end of the financial year	15		**79,938**		81,408

The notes on pages 104 to 127 form part of these accounts.

Statement of changes in taxpayer's equity for the year ended 31 March 2019

	PDC	General Fund	Reval reserve	I & E reserve	Total
	£000	£000	£000	£000	£000
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**
Changes in taxpayer's equity for 2018/19					
Surplus for the year	-	26,145	-	-	26,145
Other changes					
Net gain on revaluation of property, plant and equipment	-	-	79	-	79
Realised gain on inventories - biological standards	-	-	(78)	-	(78)
Dividend payable	-	(14,388)	-	-	(14,388)
Sub total	-	(14,388)	1	-	(14,387)
Balance at 31 March 2019	**1,329**	**101,500**	**107,978**	**954**	**211,761**

The notes on pages 104 to 127 form part of these accounts.

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 2018/19 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 2018/19. The application of the following Standards as revised would not have a material impact on the accounts for 2018/19, were they applied in that year:

- 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. However this is expected to have a material impact.
- IFRS 17 Insurance Contracts: Effective 1 January 2021 but not yet adopted by FReM. Not expected to have any effect.

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 preparation of the financial statements 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 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.

- Valuation of Property, Plant and Equipment

We have applied judgement in the classification of costs into assets under construction.

There are no other judgements or estimates made by management that have a significant impact on the financial statements.

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. 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 UK Government observational data and interventional research service, jointly supported by the National Institute for Health Research and the agency, 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 (licensing events) have been assigned to determine the stage of work completed. Revenue in respect of services provided is recognised when (or as) performance obligations are satisfied. This determines the income to recognise and to defer in line with IFRS 15.
- 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 licenses held on 31 December the previous year. This is the performance obligation and is the trigger point for income recognition.
- 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. These stages are recognised as performance obligations and determine the fees. 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. These are agreed performance obligations for recognition of income in line with IFRS 15.
- Applications for clinical trials authorisations and variations. A number of processes have been assigned to determine the stage of work completed. Revenue in respect of services provided is recognised when (or as) performance obligations are satisfied. This determines the income to recognise and to defer in line with IFRS 15.
- British Pharmacopoeia income is recognised as and when earned. This is at the point where orders are fulfilled and is deemed to be the performance obligation.
- 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. Publication on the website is the performance obligation to recognised income.
- Miscellaneous income: This is non-statutory income recognised as and when earned based on when the service is provided. The provision of service is considered to be the performance obligation and the trigger point for recognition of income.

- Revenue grants from the Department of Health and Social care for the provision of services are treated as income. Grant funding for ongoing work recognised in line with IAS20.
- 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 as outlined in agreements and in line with IFRS 15. These stages are recognised as performance obligations.
- Capital grants receivable from governmental and non-government bodies for the purchase of specific capital assets are recognised as income in line with IAS 20 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 and disclosed as contract liabilities in line with IFRS 15.

The first-time application of IFRS 9 and IFRS 15 mandated by HM Treasury does not permit restatement of comparatives. The transition to IFRS9 and IFRS 15 is not material

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 Leases

Operating lease rental payments are recognised as an expense on a straight-line basis over the lease term. A prepayment for fit out costs for the Agency's office accommodation is shown as a prepayment in the statement of financial position. The prepayment is released annually to operating costs over the life of the lease on a straight line basis.

The Agency has no finance leases.

1.10 Income and Expenditure Reserve

Income and Expenditure Reserve is a one off capital grant from the DHSC and represents taxpayer's equity in the agency.

1.11 Public Dividend Capital (PDC)

Public dividend capital represents taxpayers' equity in the agency. PDC is recorded at the value received. As PDC is issued under legislation rather than under contract, it is not treated as an equity financial instrument.

1.12 Provisions

A provision is recognised when the agency has a legal or constructive obligation as a result of a past event, it is probable that an outflow of

economic benefits will be required to settle the obligation and a reliable estimate can be made of the amount of the obligation. If the effect is material, expected future cash flows are discounted using the real rate set by HM Treasury.

The dilapidation for the headquarters building has been agreed at £156k and the balance has been released. As payment is due to be made imminently, this has not been discounted.

The provision for bad debts and credit notes, identified in Note 14, 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.

1.13 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. 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

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

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

We consider our chief operating decision maker to be our Corporate Executive Team (CET). The segmental information below is based on information presented to the CET. The CET reviews financial information based on three reportable segments. 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 Agency's activities are inter-related and contiguous, the objective is to protect, promote and improve public health. Corporate costs are reported separately for transparency and are subsequently recharged to the three centres.

2018/19

	CPRD* £000	NIBSC £000	Regulator £000	Total £000
Income from external customers	5,180	22,613	96,217	124,010
Income from DHSC	-	19,459	15,100	34,559
Total income**	5,180	42,072	111,317	158,569
Direct costs	(4,874)	(37,938)	(51,703)	(94,515)
Indirect costs	(1,241)	(6,263)	(42,967)	(50,471)
Total expenditure	(6,115)	(44,201)	(94,670)	(144,986)
Segment operating (deficit)/ surplus	(935)	(2,129)	16,647	13,583

* represents MHRA's 50% share of joint arrangement

** Excludes Other income £12.2m (see note 3.2)

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

2017/18

	CPRD* £000	NIBSC £000	Regulator £000	Total £000
Income from external customers	4,615	22,232	101,897	128,744
Income from DH	-	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)

3. Income

3.1 Trading income

	2018/19	2017/18
	£000	£000
Income from fee charging activities*	**146,889**	151,665
Miscellaneous income	**11,680**	5,879
Total Trading Income	**158,569**	157,544

* Includes £10.1M (2017/18, £13.7M) 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

	2018/19	2017/18
	£000	£000
Licenses and inspections	**39,772**	41,551
Service fees	**31,633**	31,549
European Medicines Agency (EMA)	**10,158**	13,748
Devices	**10,107**	10,193
Clinical trials	**3,467**	3,397
British Pharmacopoeia	**4,500**	4,680
Other trading income	**11,680**	5,879
NIBSC	**42,072**	41,932
CPRD	**5,180**	4,615
Total	**158,569**	157,544

As part of its preparation for EU exit, the Agency received additional funding of £6m from DHSC to cover the cost of its preparatory work in advance of the exit.

3.2 Other income

The Trading Fund received financial assistance in the form of additional funding of £12.2M (2017/18, £10.9M) from the DHSC to offset the additional costs of dividend £5.3M (2017/18, £5.1M) and depreciation £6.9M (2017/18, £5.8M), resulting from the transfer of the National Institute for Biological Standards and Control to the agency on 1 April 2013.

4. Clinical practice research datalink

Joint arrangement memorandum account

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

	2018/19	2017/18
	£000	£000
Revenue	**10,360**	9,230
Expenditure		
Operating expenditure	**(8,007)**	(7,525)
Staff costs	**(4,223)**	(3,906)
Operating (deficit)	**(1,870)**	(2,201)

Statement of financial position

	2018/19	2017/18
	£000	£000
Non-current assets		
Tangible assets	**228**	19
Intangible assets	**3,654**	5,446

Current assets		
Trade and other receivables	**3,040**	2,048
Cash and cash equivalents	**8,391**	9,991

Current liabilities		
Trade and other payables	**(565)**	(188)
Other liabilities	**(850)**	(1,548)
DHSC contribution to joint arrangement	**(16,127)**	(16,127)
Assets less liabilities	**(2,229)**	(359)

Equity		
Surplus b/f	**(359)**	1,842
(Deficit)/Surplus for the year	**(1,870)**	(2,201)
Total Equity	**(2,229)**	(359)

Statement of cash flows

	2018/19	2017/18
	£000	£000
Cash flows from operating activities		
Operating (deficit)	**(1,870)**	(2,201)
Depreciation and amortisation	**1,692**	2,161
Disposals of assets	**491**	-
Increase/(Decrease) in trade and other payables	**377**	(508)
(Increase)/Decrease in trade and other receivables	**(992)**	1,439
(Decrease) in other liabilities	**(698)**	(1,731)
Net cash (outflow) from operating activities	**(1,000)**	(840)
Cash flows from investing activities		
Purchase of intangible assets	**(600)**	-
Net cash (outflow) from investing activities	**(600)**	-
Cash flows from financing activities	**-**	-
Net decrease in cash and cash equivalents	**(1,600)**	(840)
Cash and cash equivalents at the beginning of the financial year	**9,991**	(840)
Cash and cash equivalents at the end of the financial year	**8,391**	9,991

Non-current assets

	2018/19	2017/18
	£000	£000
Fixed Asset		
Cost		
At 1 April	**10,110**	10,110
Additions	**600**	-
Disposals	**(1,117)**	-
At 31 March	**9,593**	10,110
Amortisation		
At 1 April	**4,645**	2,484
Charge for the year	**1,692**	2,161
Disposals	**(626)**	-
At 31 March	**5,711**	4.645
Net Book Value at 31 March	**3,882**	5,465

5. Financial objective

The agency's financial objective is set out in full in a HM Treasury minute dated 5 June 2019, 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.

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 DHSC each year equivalent to the 3.5% required rate of return. The dividend payable is £14.4m (2017/18 £12.7M).

The agency planned its fee strategy so as to achieve a return averaged over the period 1 April 2018 to 31 March 2023 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

	2018/19	2017/18
	£000	£000
Wages and salaries	**63,344**	61,515
Social security costs	**6,996**	6,822
Other pension contributions	**12,442**	12,081
Sub total	**82,782**	80,418
Less recoveries in respect of outwards secondment	**-**	(65)
Total	**82,782**	80,353

See staff report page 88.

7. Operating costs

	2018/19	2017/18
	£000	£000
Computing	**24,746**	40,399
Depreciation and amortisation	**10,695**	11,283
Medicines testing and Laboratory expenses	**9,355**	9,896
Accommodation	**7,812**	7,903
Other operating costs	**7,576**	14,884
Travel and subsistence	**2,020**	2,388
Total	**62,204**	86,753

Other operating costs include:	£000	£000
Contracted out services	**5,993**	4,956
Operating leases	**2,561**	4,255
Statutory audit fees	**110**	110

8. Finance income and costs

	2018/19	2017/18
	£000	£000
Finance income		
Interest received from Government Banking Service	**420**	105
Interest received others	**1**	62
Discounting of provision	**-**	58
	421	225

Finance costs		
Interest on DHSC loan	**(46)**	(46)
Others	**(6)**	-
	(52)	(46)
Total	**369**	179

9. Property, plant and equipment

2018/19	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 2018	3,374	123,974	8,694	24,546	9,355	169,943
Additions	5,613	-	9	-	-	5,622
Transfers	(4,649)	2,051	1,450	1,148	-	-
Reclassification	132	-	-	130	-	262
Reversal	(6)	-	-	-	-	(6)
Indexation	-	-	-	180	-	180
Disposals	-	-	(2,103)	(585)	*(9,247)	(11,935)
At 31 March 2019	**4,464**	**126,025**	**8,050**	**25,419**	**108**	**164,066**
Depreciation						
At 1 April 2018	-	-	6,354	14,861	9,324	30,539
Reclassification	-	-	-	130	-	130
Charge for the year	-	4,795	1,587	1,890	10	8,282
Indexation	-	-	-	101	-	101
Disposals	-	-	(2,091)	(532)	*(9,247)	(11,870)
At 31 March 2019	**-**	**4,795**	**5,850**	**16,450**	**87**	**27,182**
Net book value						
At 31 March 2019	**4,464**	**121,230**	**2,200**	**8,969**	**21**	**136,884**
Net book value at 31 March 2018	3,374	123,974	2,340	9,685	31	139,404
Owned						
Net book value at 31 March 2019	**4,464**	**121,230**	**2,200**	**8,969**	**21**	**136,884**

* These represent fully depreciated fixtures and fittings disposed when the Agency relocated its main office.

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 2017	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 £29.974m. 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.

10. Intangible assets

2018/19	Computer systems	AUC	Software licences	Total
	£000	£000	£000	£000
Cost or valuation				
At 1 April 2018	**25,134**	**602**	**3,772**	**29,508**
Additions	233	9,202	-	9,435
Transfers	4,216	(4,216)	-	-
Reversals	-	(55)	-	(55)
Reclassification	50	(132)	(50)	(132)
Disposals	(5,548)	-	(106)	(5,654)
At 31 March 2019	**24,085**	**5,401**	**3,616**	**33,102**
Amortisation				
At 1 April 2018	**20,940**	**-**	**3,564**	**24,504**
Reclassification	42	-	(42)	-
Charge for the year	2,231	-	182	2,413
Disposal	(5,306)	-	(106)	(5,412)
Amortisation at 31 March 2019	**17,907**	**-**	**3,598**	**21,505**
Net book value at 31 March 2019	**6,178**	**5,401**	**18**	**11,597**
Net book value at 31 March 2018	4,194	602	208	5,004
Asset financing				
Owned				
Net book value at 31 March 2019	**6,178**	**5,401**	**18**	**11,597**

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

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	2018/19	2018/19	2017/18	2017/18
	£000	**£000**	£000	£000
Minimum lease payments	**49**	**2,561**	11	4,255
Total	**49**	**2,561**	11	4,255

Total future minimum lease payments	2018/19	2018/19	2017/18	2017/18
	£000	**£000**	£000	£000
Payable:				
Within one year	**-**	**1,997**	11	1,064
Between two to five years	**-**	**7,987**	-	-
Over five years	**-**	**18,430**	-	-
Total	**-**	**28,414**	11	1,064

Finance Leases

The agency had no finance leases in 2018/19 (2017/18 Nil).

12. Inventories

	31 March 2019	31 March 2018
	£000	£000
Amounts falling due within one year		
Biological Standards	**5,608**	5,765
Laboratory consumables and other stores	**59**	103
Total	**5,667**	5,868
Inventory consumed	677	808

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 2018/19 was £78k (2017/18, £106k).

13. Contract assets and contract liabilities

	Current		Non current	
	31 March 2019 £000	31 March 2018 £000	31 March 2019 £000	31 March 2018 £000
Contract assets (unbilled receivables)	**6,592**	-	**-**	-
Contract liabilities (customer advances)	**11,694**	-	**3,533**	-

We receive payments from customers based on a billing schedule, as established in our contract (Fees Regs) and in line with our inputs to the satisfaction of the performance obligations. The Fees Regs also specify levels of credits to be issued where applications are withdrawn at different stages. Contract asset relates to our conditional right to consideration for our completed performance under the contract. Accounts receivables are recognised when the right to consideration becomes unconditional. Contract liability relates to payments received in advance of performance under the contract. Contract liabilities are recognised as revenue as (or when) we perform under the contract.

14. Trade and other receivables

	31 March 2019 £000	31 March 2018 £000
Amounts falling due within one year		
Due from the DHSC (see 14.1 below)	**12,192**	10,894
Trade receivables*	**9,729**	8,760
Other receivables	**1,604**	1,145
Accrued income	**1,954**	7,190
Prepayments**	**2,305**	2,490
Total	**27,784**	30,479
Amounts falling due after more than one year:		
Prepayments**	**8,483**	6,630
Total	**36,267**	37,109

*Trade receivables are shown net of a provision for bad debts of £79k (31 March 2018 £1.1m) calculated using the simplified approach in line with IFRS 9 and credit notes for all unpaid periodic fees at year end of £0.6m (31 March 2018 £0.1m).

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

14.1 Amount Due from the DHSC consists of:

	31 March 2019 £000	31 March 2018 £000
DHSC funding for NIBSC costs*	**12,192**	10,894
Total	**12,192**	10,894

* see Note 3.2

15. Cash and cash equivalents

	31 March 2019 £000	31 March 2018 £000
Balance at 1 April	**81,408**	111,814
Net change in year	**(1,470)**	(30,406)
Balance at 31 March	**79,938**	81,408

Made up of		
Government Banking Service	**79,938**	81,408
Cash and cash equivalents	**79,938**	81,408

* includes £8.4m held on behalf of CPRD joint arrangement

16. Trade and other payables

	31 March 2019 £000	31 March 2018 £000
Amounts falling due within on		
Due to DHSC (see 16.1 below)	**14,465**	12,824
Payments received on account	**2,584**	5,622
Taxation and social security	**3,093**	3,151
Other trade payables	**1,721**	2,039
Accruals	**11,095**	7,641
Total	**32,958**	31,277

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

16.1 Amount Due to the Department of Health and Social Care consists of:

	31 March 2019 £000	31 March 2018 £000
Accruals	**50**	148
Other payables	**27**	-
Dividend payable	**14,388**	12,676
Total	**14,465**	12,824

17. Other liabilities

	Current		Non-current	
	31 March 2019 £000	31 March 2018 £000	31 March 2019 £000	31 March 2018 £000
Deferred revenue:				
Licence fees (applications and variations)	**-***	10,846	**-***	4,218
Other fees	**2,115**	3,879	**21**	604
Others:				
DHSC Contribution to CPRD joint arrangement**	**13,214**	14,170	**-**	-
Total	**15,329**	28,895	**21**	4,822

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

18. Provisions

	Current		Non-current	
	31 March 2019 £000	31 March 2018 £000	31 March 2019 £000	31 March 2018 £000
EC grant refund	**165**	343	**-**	-
Dilapidations	**156**	2,125	**-**	-
Total	**321**	2,468	**-**	-

Movement in provisions

	Total £000
At 1 April 2018	2,468
Arising during the year	-
Unwinding of discount	-
Change in discount rate	-
Provision not required written back	(2,147)
At 31 March 2019	**321**

Expected timing of cash flows:

Within one year	**321**
Between two to five years	**-**
Over five years	**-**
Total	**321**

19. Borrowings

	Non-current	
	31 March 2019 £000	31 March 2018 £000
Loan from Department of Health and Social Care	**1,328**	1,328
Total	**1,328**	1,328

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

	Total 2018/19	Less than one year	Between one and five years	More than five years	Total 2017/18
	£000	£000	£000	£000	£000
Fixed interest rate 3.50%	**1,328**	**-**	**-**	**1,328**	1,328
At 31 March 2019	**1,328**	**-**	**-**	**1,328**	1,328
At 31 March 2018	1,328	-	-	1,328	1,328

20. Capital and other financial commitments

Contracts entered into not provided for in the accounts

	Intangible	Tangible	Intangible	Tangible
	31 March 2019	31 March 2019	31 March 2018	31 March 2018
	£000	£000	£000	£000
Contracted	**571**	**1,340**	-	4,979
Total	**571**	**1,340**	-	4,979

21. Related party transactions

The agency is a Government Trading Fund and an Executive Agency of the DHSC. DHSC 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 2018/19, 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 except those disclosed in the table below. Details of compensation for key management staff are disclosed in the remuneration and staff report.

22. 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. 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.

	2018/19 £000	2017/18 £000
Government Banking Service*	**79,938**	81,408
Total	**79,938**	81,408

* Includes £1k Proceeds of Crime Act funds which are the Agency's share of confiscated monies resulting from successful prosecutions and £72k 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 (2017/18: £1.328M). This resulted in interest payable of £0.046M (2017/18: £0.046M) out of total expenditure of £145.0M (2017/18: £167.1M).

Currency risk

The level of currency risk is determined by the level of income generated by activity undertaken on behalf of the EMA. For 2018/19 this was £10.158M (Euro11.859M) (2017/18: £13.748M; Euro 15.710M). This represents 5.9% (2017/18: 8.2%) 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 2019:

	2018/19		2017/18	
	Increase	Decrease	Increase	Decrease
	£000	£000	£000	£000
Movement 1 %	**97**	**(99)**	(138)	141
Movement 3 %	**286**	**(303)**	(406)	431

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 £1.4M (2017/18 £110k).

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.

23. Events after the reporting period

The agency's Trading Fund accounts are laid before the Houses of Parliament by the DHSC. 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 5 June 2019

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 2018 to 31 March 2023 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 24 February 2014.

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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