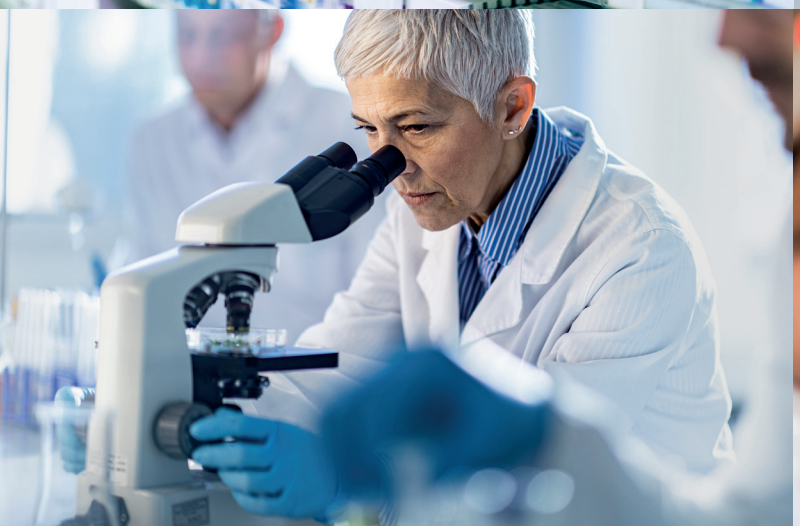
Medicines & Healthcare products Regulatory Agency

Annual Report and Accounts 2019/20



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Medicines and Healthcare products Regulatory Agency Annual Report and Accounts 2019/20

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1 Performance Report

Chairman's Foreword

This is my sixth foreword to the Annual Report since I was appointed in 2014 and sadly also my last as I will stand down in November. It has been my privilege to Chair an Agency whose work touches the lives of everyone in the UK and which makes a major contribution to safeguarding public health across the UK and beyond. Never has this been so clearly demonstrated than in recent months with our staff, including over one hundred laboratory and support staff at the National Institute for Biological Standards and Control (NIBSC), using their wealth of talent and commitment to deal with the COVID-19 pandemic.

The UK's departure from the EU has significant implications for the future direction of the Agency and its funding model. I am very grateful to the Agency's staff, IT specialists and legal advisers who have worked so hard to prepare the organisation for all possible outcomes at the end of the Transition Period.

In September 2019 we bade farewell to Dr Ian Hudson OBE who retired after having served as Chief Executive for six years. I, along with the Board, are grateful to Dr Hudson for his past service. I was indeed very fortunate that Dr June Raine CBE, the then Director of Vigilance and Risk Management of Medicines Division, agreed to lead the MHRA on an interim basis as the DHSC recruit a permanent successor who is expected to take up her / his post in 2021. Since September 2019, Dr Raine has led the Agency in an exemplary manner while overseeing the development of the Agency's transformative Change Strategy.

In August 2019, I was sorry to say goodbye to two distinguished non-executive members of the Board (Professors Dame Valerie Beral and Sir Alex Markham) who stepped down after having served six years. Their successors, Mercy Jeyasingham MBE and Professor Liam Smeeth, were appointed in the spring of 2020. In May 2019, I was delighted to welcome two lay observers, Susan Bradford and Sara Payne, to the Board's meetings. I also continue to be impressed by the added value of the Board's meetings in public which have increased from four to six times a year.

Looking ahead, the Agency faces a range of challenges and opportunities in 2020/21. Among these are the legacy of the COVID-19 pandemic; the UK's relationships with Europe and the rest of the world following our departure from the EU; the completion of the Agency's transformative Change Strategy; and the Agency's response to the Independent Review of Medicines and Medical Devices Safety Review. This will be in addition to the "routine" work of the Agency regulating medicines and devices as well as developing our other services including the Clinical Practice Research Datalink (CPRD).

In conclusion, we must be alert and agile to anticipate and meet the demands of an ever-changing world so that we can continue to protect public health.

Sir Michael Rawlins GBE Kt

Chairman

Chief Executive's perspective on performance of the organisation

When I was appointed as interim Chief Executive in September 2019, I never expected that when I came to write this foreword, I would be leading the Agency during the most challenging public health emergency of modern times. Our response to the coronavirus pandemic has been outstanding, with staff across the Agency, including at NIBSC's laboratories, plus many independent experts, supporting the national effort. This is proof of our strength-in-depth: a science-led international regulator that is agile, patient-focused and whose staff are exceptionally dedicated and talented.

I would like to thank Dr Ian Hudson OBE for all he did in the safeguarding of public health. On succeeding Ian, my initial focus was to ensure that the Agency was ready for the UK's exit from the EU, which came on 31 January 2020. These preparations were achieved thanks to the tremendous effort of staff who worked on different possible outcomes and work is now focused on supporting the negotiations during the transition period.

At the same time, I set in motion work to map out a new strategic model for the future, and that work continues. My vision is one that supports, enables and delivers innovation, making the UK one of the best places in the world to develop innovative technologies and conduct clinical research, ensuring patients get timely and safe access to the most advanced healthcare products. This approach chimes with the theme of the Agency's 2019 Annual Lecture by Sir John Bell "The future of life sciences: keeping the UK at the forefront of medical and scientific excellence".

Over the past year, the National Institute for Biological Standards and Control (NIBSC) and the Clinical Practice Research Datalink (CPRD) have made tremendous strides in their specialist fields. NIBSC has developed new biological standards and is delivering ground-breaking science, for example, in the global push to eradicate polio, and in developing the world's pre-eminent stem-cell bank. One in five GP practices in the UK now contribute data to CPRD which means that CPRD now has an incredible 20% coverage of the UK's population. The Innovation Office is working with other healthcare bodies in order to deliver transformative medicines to patients and is evolving further in the context of the government's Accelerated Access Collaborative.

In addition to these, we have handled a busy mix of high-profile medicines and medical device safety issues, our inspectorate and enforcement teams continue to keep the supply chain safe, and in a significant step forward, we have undertaken a major consultation to inform our new Patient and Public Engagement Strategy. Vital work has also taken place in relation to the Medical Devices Regulations and the Medicines and Medical Devices Bill.

We have also had the opportunity to contribute to the work of the Government's Independent Medicines and Medical Devices Safety (IMMDS) Review. The Review was published on 8 July 2020 and is of profound importance to the Agency, since the safety of the public is our first priority. We take this report and its findings extremely seriously. Throughout the Review's work we have collaborated fully by providing information and evidence. We will now carefully study its findings and recommendations, which address the areas of the healthcare and regulatory systems, which have failed patients and which need to improve. In particular, we will put patients and the public at the heart of everything we do.

Looking ahead, I am certain that by building on our unique assets of cutting-edge science, innovation in regulation and real-world evidence, we will create the world-leading Agency for the coming decade that we aspire to be.

In doing so, we continue to optimize and improve our service to patients and the public.

Dr June Raine CBE
Interim Chief Executive

1.1 Overview

Purpose and activities

Who we are

The Medicines and Healthcare products Regulatory Agency is an Executive Agency of the Department of Health and Social Care (DHSC). 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 protect and improve public health by enabling the earliest access and high-quality supply of safe, effective, and innovative products through proportionate, data-driven decisions on risk and benefits.

Aims

Our Agency Business Plan 2020-21 sets the direction for what the Agency will achieve over the next financial year. It is organised around five strategic goals:

1. **Patients, Public and Health Service** – to ensure information and advice is available to enable well-informed decisions by patients and healthcare professionals, by engaging proactively with the public, patients, health services, and health care professionals.
2. **Innovation and Regulatory Science** – to support the development of better, safer healthcare products for patients, underpinned by innovation, scientific evidence, and technology.
3. **Lifecycle and Safety Management** – to improve proportionate decision-making in the interests of patients
4. **Data and Analytics** – to enhance access to data, data services, and evidence-based data analysis to underpin our regulatory and science processes.
5. **Governance and Partnerships** – to develop reinforced governance, delivery capacity and external partnership working.

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 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.

The MHRA 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 by DHSC with approximately 10% of its revenue generated 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 public health functions.

» **CPRD** is jointly funded by MHRA and DHSC's National Institute for Health Research. It is 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. Biological medicines include vaccines, antibodies, cells and hormones, which influence the systems of the body to improve resistance to and defence against diseases. Some such medicines can be purpose-designed to suit individual need, for instance for treating cancer or leukaemia, and are in the category of 'personalised 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.

CPRD is a real-world research service supporting retrospective and prospective public health and clinical studies. Retrospective studies compare health events in different patient groups using already recorded real world data; and in prospective, pre-planned trials, specifically selected patients given different health care are compared in terms of health outcomes. In both cases, specialist statistical methods are used to analyse results.

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 database encompasses more than 47 million patients, including 13.5 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 currently 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 in 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 their product 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.

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.

Our highlights at a glance

Tackling coronavirus

We played a key role in tackling coronavirus, working with others across the health system and with industry to support the UK's response, demonstrating our agility by quickly re-prioritising our work to meet the unprecedented demand. This has included supporting the development of treatments and vaccines, developing and publishing specifications for new ventilators and diagnostics, working with the NHS to secure the supply of medicines and other healthcare products to the UK, as well as supporting manufacturers in a challenging environment.

Supporting research

We have expanded our CPRD services supporting public health and clinical research, with over one in every five GP practices across the UK choosing to contribute patient data.

Helping eradicate polio

We have supported the polio eradication programme by ensuring ability to prepare and distribute suitable reference materials post eradication, provide vaccine control/vaccine development and environmental surveillance to support our WHO Collaborating Centre function and prepare for being a Poliovirus Essential Facility, essential to support future activities.

Driving innovation

Our Innovation Office campaign promoted the expert regulatory guidance we provide to support organisations to develop innovative medicines, medical devices or novel manufacturing processes.

Driving early access to medicines

Our Promising Innovative Medicine (PIM) scheme has supported a diverse range of treatments including; five positive scientific opinions have been issued for amyloid cardiomyopathy, lung cancer, B-cell lymphoma, renal cancer and multiple myeloma treatments.

Improving patient and public engagement

We conducted an extensive 12-week public consultation on how we can best engage and involve patients, and the feedback has been used to inform our long-term strategy on how we engage patients and the public in our work.

Opioid addiction warning

Our review and advice led to the Government announcing that all opioid medications will carry prominent addiction warnings ensuring that patients are aware of the potential risks.

Highlighting risk

Our work on emollient skin creams has highlighted the potential risks to the public, and in future all emollient creams will include a prominent fire hazard warning.

Improving reporting

We have enhanced the capability of our Yellow Card reporting app, enabling

other organizations to integrate it into their own platforms.

Monitoring, improving and regulating medical devices

We have focused engagement with patients and healthcare professionals on major issues such as breast implants and the use of mesh for the treatment of pelvic organ prolapse and stress urinary incontinence.

Tackling crime and fake medicines

We used new powers to remove the criminal proceeds of pharmaceutical-based crime leading to the seizure of nearly £1 million of criminal finance and continue to take enforcement action against the selling of counterfeit medical products and manufacturers, highlighting the risks to the public through our #FakeMeds campaign.

Delivering our aims

Tackling coronavirus

In the latter part of the year we joined the global response to tackle COVID-19, collaborating across government departments to mobilise immediate support for the development of new therapeutics and vaccines to directly target the virus as well as securing the UKs supply of critical medicines and devices. Our task force addressed the following specific areas through dedicated workstreams: UK devices supply; UK medicines supply; development of therapeutics; support for pre-clinical vaccine development; accelerated vaccine development; expedited clinical trial approvals; tailored vigilance; and regulatory easements.

Initially priorities focussed on identifying and supporting promising antivirals, establishing expedited processes to bring unlicensed imports safely to the UK, as well as developing an understanding of supply concerns for medicines and devices (including Personal Protective Equipment - PPE) produced in at risk countries. We collaborated with the WHO to build our understanding of the disease model and a global roadmap for therapeutics and vaccine development. Using our experience with the 2014 Ebola outbreak, we implemented expedited processes, mobilising rapid support for clinical trial applications as well as working to increase testing capacity.

We expanded our activities as the COVID-19 outbreak progressed, working innovatively with manufacturers to provide UK patients access to the most promising therapeutics, defining specifications for urgently needed in vitro diagnostics tests and for ventilators through the Ventilator Challenge. Our efforts have also included working with the NHS to ensure the supply of critical medicines and medical gas for the Nightingale hospitals and Intensive Treatment Units (ITUs), helping Public Health England (PHE) to expand their testing capacity and granted derogations allowing the use of non-CE marked medical devices in the treatment of patients. Finally, we have supported research organisations to develop promising vaccines, and published expert advice on potential medicine safety concerns.

At an early stage we recognised the need to support manufacturers to operate in a rapidly changing environment and worked with trade associations to introduce temporary regulatory flexibilities. These were designed as an urgent response to COVID-critical issues, reducing the burden of compliance on industry and healthcare professionals and supporting Agency business continuity by reducing operational burden of regulatory administration.

We are monitoring the benefits of these flexibilities and continue to engage internationally, across government, the health system and with industry to ensure our response meets global needs to tackle COVID-19.

Enabling innovation

We recognise the importance of standards that can support and enable innovation in new areas of medicine. A key focus area of the MHRA has been on Advanced Therapy Medicinal products (ATMPs) working with industry partners to determine the role of standards in the development of these medicines. We have engaged and developed networks with stakeholders, recognising the system wide approach, both national and international that is required for these medicines.

Launched in 2013, our Innovation Office is now an established source of expert regulatory guidance that supports organisations of all backgrounds and sizes

to develop innovative medicines, medical devices or novel manufacturing processes. This demonstrates a commitment to make the UK one of the best places in the world to develop life sciences projects, protecting health and improving lives, here and around the globe.

The Innovation Office has handled almost 1000 enquiries since launch and has supported academia, industry and SMEs in innovative activities such as developing a novel gene therapy to tackle a life-threatening orphan disease affecting young people. The number of enquiries submitted monthly continues to increase steadily and this year we received 246 new enquiries and held over 60 meetings.

Our Early Access to Medicines Scheme (EAMS) provides early access of medicines to patients where these medicines have a major advantage over existing therapies in the UK and address an unmet need. It enables patients with life-threatening and seriously debilitating disease to have fast-tracked access to safe, ground-breaking treatments prior to approval of the licence. The Promising Innovative Medicine (PIM) designation is the first necessary step in EAMS and, this year, ten designations have been issued for a diverse range of treatments.

Realising the power of data

Our CPRD centre provides anonymised data, supporting clinical and public health research and in 2019/20, we increased our network of GP practices choosing to share data with us by 33%. As a result, CPRD data coverage now represents over 20% of the UK population.

Our database holds the anonymised health records of 47 million patients, 13.5 million of whom are registered with currently contributing GP practices. The primary care data we hold is now routinely linked to 17 secondary health related datasets, adding three new datasets this year.

In the last year, over 270 new observational research studies using our data were approved. Research using our data informs drug safety guidance and clinical practice with more than 260 publications this year alone bringing the total to 2400 peer reviewed publications.

Working with the Royal College of General Practitioners (RCGP), we have continued to produce patient safety and prescribing reports for GP practices that contribute to the CPRD, leading to direct improvements in patient care. So far, 1540 GP practices have received these reports, highlighting more than 85,000 patients across seven different conditions, whose care may benefit from review.

We also recruited 25% of the target patient number into a pioneering type 2 diabetes real world clinical effectiveness trial (DECIDE). A third of patients have now completed this real-world clinical trial.

Taking action

Our collaborative approach to enforcement has continued through a range of activities which has included involvement in coordinated international action with Interpol's Operation Pangea and Europol's Operation Mismed.

The introduction of the new Proceeds of Crime Act (POCA) powers enabled Accredited Financial Investigators to freeze bank accounts believed to be used to facilitate crime. In the last year these powers have been highly successful in disrupting criminality, seizing close to £1 million of criminal finance.

Across the year, we have continued to increase our understanding of

criminality within the regulated supply chain. This has been underpinned by ambitious intelligence analysis to understand the demands and throughput within legitimate business. Our enforcement activity during the last year has resulted in the conviction of offenders with significant terms of imprisonment.

We embarked on a review of opioid medicines to address increasing concern in the UK and internationally about their overuse and misuse which has led to a growing problem of dependence and addiction. An expert working group was established, supported by a network of stakeholder organisations. Following their advice, the Government announced that all opioid medications will now carry prominent addiction warnings on their labels.

We helped highlight to the healthcare professionals and the public the associated risks with the use of emollient skin creams, which help manage different chronic skin conditions, but become flammable when they dry into clothing.

We established an expert working group to conduct a review of paraffin-based skin emollients, identifying the benefits and risks in response to the fire risk associated with use of these products. Following their advice, we announced that all emollients (both paraffin and paraffin free) and non-emollient skin creams should include a prominent fire hazard warning to avoid naked flames. These warnings are being added to product packaging.

A toolkit of resources highlighting the risks has now been developed for patients, carers, healthcare professionals (HCPs), health organisations and healthcare professional educators, which will be launched in 2020.

Driving improvement

We have continued to see an increase in medical device adverse incident reports from manufacturers or their representatives, healthcare professionals and directly from members of the public, as a result of our efforts to raise the visibility of the Yellow Card reporting scheme. We use these reports to identify emerging issues and take appropriate action.

We recently launched a pilot scheme designed to provide the public with greater transparency and information on medical device adverse events, without compromising commercial interests and patient confidentiality.

Our Devices Expert Advisory Committee (DEAC) advises us on major issues involving medical devices, such as the causes of infections from blood heater/cooler systems used during cardiac surgery.

We have taken part in a major research programme for the past eighteen months to prove the concept of synthetic datasets to validate machine learning, or Artificial Intelligence, algorithms. This project was funded through an award from the Regulators' Pioneer Fund.

Through our work with other government agencies we continue to develop guidance for the safe implementation of AI technologies into healthcare.

Engaging public and patients

The Agency intends to adopt a more systematic approach to listening to and involving patients. We wish to make sure that we hear and listen to the concerns and views of patients when safety issues, regarding medicines or medical devices, are identified and in the licensing of new medicines. We want to deliver a step-change in how the agency communicates with, engages and involves patients and the public in its work. To inform this future engagement with patients and the public we ran a 12-week public consultation, from 15 July

to 7 October 2019, on how to best engage and involve patients in our work. The broad areas covered included public awareness and understanding of our work, involving patients and the public in our work, and finally how patients and the public raise concerns with us.

We received a total of 808 responses to the consultation and run five engagement events held in all four nations. We will publish our response to the consultation on GOV.UK in the 2020-21 financial year and the findings will inform our longer-term patient and public engagement/involvement strategy, on which we will also seek the views of patients and the public in 2020.

#FakeMeds is our award-winning public campaign and we ran a second wave of activity focused on raising awareness with younger female and male adults of the dangers of buying fake STI self-testing kits online. The digital campaign was supported by stakeholder engagement to increase and target those particularly at risk.

Cumberlege Review

The Independent Medicines and Medical Devices Safety Review led by Baroness Cumberlege, had been due to publish its report on 24 March, however it was postponed due to COVID-19 and was published on 8 July. We take this report and its findings extremely seriously. Throughout the Review's work MHRA engaged and gave full support to the Review Team, providing information as required. The Agency has been working with DHSC and other partners to implement actions in response to the emerging issues from the review, to improve safety and better support patients. We will now carefully study the findings and recommendations of the Report. We are determined to put patients and the public at the heart of everything we do.

Delivering globally

We support the polio eradication programme by ensuring ability to prepare and distribute suitable reference materials post eradication, provide vaccine control/vaccine development and environmental surveillance. In the last year, we presented submissions to the World Health Organisation (WHO) for future polio International Standards (IS). We play an important role in vaccine control, vaccine development and training activities.

Environmental surveillance is an essential aspect of global eradication. NIBSC has been redesignated as a WHO Collaborating Centre for Reference & Research on Poliomyelitis, renewed until 2025. WHO International Standards have been produced to support the ongoing global eradication programme. As a WHO Collaborating Centre, we provide this for poliovirus to confirm its presence or absence in clinical samples and characterise poliovirus isolates from surveillance activities. Finally, we have applied to be a Poliovirus Essential Facility (PEF) which is essential to support future activity as all facilities that handle and store poliovirus type 2 will require this certification to maintain their ability to work with and store infectious and potentially infectious materials.

We are at the forefront of tackling emerging and re-emerging infections, working with other leading global organisations including the WHO, the Coalition for Epidemic Preparedness Innovations (CEPI) and the UK's Vaccine Network. A key focus of our work has been on the development of new standards to address the global spread of re/emerging pathogens, enabling rapid, accurate diagnosis coupled with pre-clinical and para-clinical research to develop vaccines.

The standardisation programme supports the development and evaluation of

appropriate reference materials. This has included work on the Lassa virus which causes viral haemorrhagic fever, as well as the development of an international standard for antibodies and nucleic acid amplification technique assays for Rift Valley Fever Virus.

On regulation, we have continued to build close links with key international regulators to ensure that they maintain a leading role in the development and interpretation of guidance and share intelligence which impacts on our risk-based inspection strategy. This work has ensured that we are at the forefront of the global regulatory decision-making process, enabling innovators to bring their products to market quickly whilst ensuring patient safety.

Our first UK joint symposium with the US FDA was attended by over 450 people, with hundreds from over 20 countries live streaming the event.

Our WEB-RADR project was designed to evaluate the value of mobile apps, and social media data for pharmacovigilance, and has significantly enhanced the capability of our Yellow Card reporting app. The collaboration with the WHO enhanced the global information on the side effects of medicines, and the platform has now been adopted by a further eight new countries.

In addition, we have worked closely with the Bill and Melinda Gates Foundation, WHO and national regulators to help support the launch of novel treatments and the development of pharmacovigilance systems.

Regulating and setting standards

Although Advanced Therapy Medicinal Products (ATMPs) such as Strimvelis represent a range of different products, they share challenges in an area with few regulatory standards and are often unregulated and unlicensed. We are at the forefront of ATMP developments, also being home to the UK Stem Cell Bank, a primary source of clinical-grade stem cells for regenerative medicine applications.

The Clinical Trials Unit within our Regulatory centre has continued to lead a Combined Ways of Working (CWOW) pilot scheme, working with our partners in the Health Research Authority (HRA) and Research Ethics Services (RES) across the UK to assess clinical trial applications collaboratively and maintain the UK's reputation as a great place to do research.

This year we have focused our device regulation engagement on major issues such as breast implants and the use of mesh for the treatment of pelvic organ prolapse and stress urinary incontinence. We have helped prepare for the introduction of the new Medical Device Regulations (MDR), originally scheduled for May 2020, advising manufacturers and providing written guidance during the transition phase.

The lack of microbiome standards has presented a challenge for the translation of research into innovative therapeutics and is an area where we have made important progress. A microbiome is the normal range of microbes (usually friendly), which inhabits some parts of the body such as the bowel, the nose, mouth and throat, the skin and the reproductive tracts. Particularly in the bowel, disruption of the normal microbiome is becoming recognised as playing a part in many health problems both locally, and in the body as a whole. Research seeks to determine what the normal microbiome should be like, and what kind of abnormalities can be identified as affecting health and disease.

Technological advances have facilitated detailed studies of the microbiota that colonise humans, so much so that many health problems are now attributed

to an imbalance in a person's natural microflora, and microbiome therapies are now the subject of numerous clinical studies. This year we submitted proposals to the WHO to create six new International Reference Reagents for Next Generation Sequence (NGS) analysis of the microbiome, covering gut, lung, skin, oral, nasopharynx and vaginal microbiomes.

Ensuring stability following departure from the EU

Finally, the impact of Brexit on our role within the EU required and continues to require a great deal of preparatory work in anticipation of operating a stand-alone regulatory system for medicines and medical devices in the UK at the end of the transition period.

1.2 Performance Analysis

Sustainability report

The Agency is committed to embedding sustainability and reducing its carbon emissions, to help the environment and people to lead healthier lives in the future.

Energy management performance

It is mandatory for the Agency to participate in the Government's Carbon Reduction Commitment Scheme. This obligation requires payment on energy usage, previously £101k per annum. This year's Carbon Tax was £90k due to energy reductions, saving £11k (legislative changes are anticipated in 2020).

Jude Hughes, the Environment and Energy Manager, was asked to write an article on "NIBSC and Energy Management", for the Energy Managers Association Magazine. This was a great opportunity to showcase the achievements over the past 10 years and enhance the Agency's already green reputation.

Carbon emission performance

Carbon footprint at the South Mimms laboratory complex has fallen from a 2009/10 baseline of 8,633 TCO2 to 5,524 TCO2 this year, giving a 36% reduction.

Following the move of the MHRA Headquarters to modern offices at 10 South Colonnade in Canary Wharf, a new data set was produced with 2019/20 being 2,038 TCO2, compared to 2,296 TCO2 for the previous premises in Victoria, showing a reduction following the move.

For 10 South Colonnade the reduction is from business travel and for the South Mimms site it is from energy consumption, due to the nature of the work at each site, with both contributing to an overall 31% reduction in the Agency's carbon footprint.

The UK Government recognised the benefits of a greener estate by setting out high level targets, namely Greening Government Commitments. Although the MHRA is exempt from directly reporting, as advised by the DHSC, it has still met these targets (changes are anticipated in 2020).

South Mimms, which has the 2009/10 baseline to compare to 2019/20, results are below:

- cut greenhouse gas emissions by 32%, South Mimms by 36%
- reduce domestic flight carbon emissions by 30%, South Mimms by 58%
- reduce waste to landfill to less than 10%, South Mimms to 0%
- continue to reduce water consumption (no target given), South Mimms by 33%

Renewable technology performance

The Agency made its first step into renewable technology with a large-scale Solar Project and after being awarded accreditation for the Ofgem "Feed in Tariff" (FIT) Scheme, this year we have received the first income of £100k. The FIT Scheme accreditation means we will receive an attractive income throughout the 20-year lifetime totalling £700k, close to the original project cost of £795k. Further benefits also include saving £2.1m on electricity costs and 8,350 MWh generation.

Following this success, and a review, a new innovative Renewable Technology

Installation Project is being developed. It will utilise "dead space" above parking bays with a frame and solar panel design. When presented to SMT it received both endorsement and capital budget. Benefits include £2.5m lifetime savings on electricity costs and 10,962 MWh onsite generation. It will include electric vehicle charging, which will be promoted to staff.

This project will give another step down in energy consumption, demonstrating the Agency's commitment to continually reducing its impact on the environment.

Health and safety report

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. 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, along with sharing of incidents and lessons learnt with external partners.

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 2019/20 included: achieving excellence in leadership and culture, continued regulatory compliance, maintaining OHSAS 18001 certification at the 10SC site and continued migration to ISO45001, delivering overseas travel safety requirements, fire safety management and continued staff engagement with a focus on staff health and wellbeing. High standards of Health and Safety are essential to preventing disruption to the role of the Agency in protecting and improving public health.

Following a review of Agency overseas travel safety requirements, a robust overseas working policy and procedure has been implemented to support staff, who must travel abroad, as part of their role e.g. attendance at international scientific meetings and inspection of manufacturers, importers, wholesale dealers and hospital sites. This has been well-received and ensures all trips are adequately risk assessed and individuals are provided with appropriate training (Hostile Environment Awareness Training), country information packs, equipment and travel assistance. Work is now underway to determine safety requirements for staff working off site in the UK and will include ensuring best practice for lone workers.

Ensuring regulatory compliance and working proactively with the Health and Safety Executive (HSE) supports the safe working of scientists at NIBSC, on existing new or emerging pathogens, at appropriate biological containment levels and in adjusting to legislative changes. Building on expertise gained through work on previous virus outbreaks, NIBSC is now tasked with supporting the public health response to coronavirus (COVID-19) by developing biological reference materials which are needed to support a quick and reliable diagnosis of infection, evaluate vaccines and the effectiveness of treatments. Clearance to commence in vitro work has been granted by the HSE, following submission of detailed H&S documentation developed by the Biological Safety Officer with support from the Biological Safety Sub Committee.

Performance against targets

No.	Area	Target description	Target	2019/20 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%**	**100%**	Met	
PM2	Medicines licensing – assessment of applications	A) The assessment of applications for new Marketing Authorisations for UK only: 97% assessed in 150 days	**97%**	**100%**	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%**	**100%**	Met	
			97%	**100%**	Met	
			97%	**99%**	Met	
			95%	**93%**	Nearly Met	37 out of 40 applications were assessed within target but the small volume means that three misses put the target out of reach
		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%**	**99%**	Met	
			97%	**98%**	Met	

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	
			14-day average	**12.29**	Met	
		b) Timescales for clinical investigation notifications for medical devices: maximum of 60 days	**Within 60 days**	**100%**	Met	
PM4	Capturing and analysing adverse event reports – making reports available, issuing alerts and acting on signals	b) Medical Device Alerts will be issued: 95% within 10 days, 100% within 15 days	**95%**	**100%**	Met	
			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%**	**100%**	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%**	**95%**	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: • 8 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%**	**97%**	Met	
		b) Expand CPRD database coverage to 20% of the total UK population	**20%**	**21.5%**	Met	
		c) 3 new routine linkages available for observational research studies	**3**	**3**	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%**	Nearly Met	We received 604 FOI requests in total. We answered 590 within the 20-day deadline and a further 9 were not due at time of completion of the tracker but they are on track. Five requests were not answered on time for various reasons for example, awaiting agreement from a third party to release information.
		b) Aim to return all responses to Parliamentary Questions (PQs) to the DHSC by noon on the date specified	**100%**	**99%**	Nearly Met	14 PQs were answered in Q4 - all were answered and returned on time. Over the course of the year, 1 PQ out of 78 was returned to DHSC late just after the noon deadline.
		c) Return Ministerial correspondence (POs) drafts to the DHSC within 4 working days of receipt in at least 90% of cases	**90%**	**100%**	Met	

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%**	**26%**	Met	
		b) Fewer than 5 major incidents (Categories: Priority 1 and 2 caused by change)	**less than 5**	**3**	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%**	**84%**	Not Met	The Information Security Team has dealt with an increased number of incidents that have required investigation and responses from users. This has meant that some of the larger investigations have exceed 15 days.
		b) Data: Subject Access Requests provided with a response within one month of receipt	**95%**	**100%**	Met	

Financial review

The Agency's financial performance in 2019/20 reflects the change in the revenue streams after the UK's exit from the European Union. The reduction in revenue from pan-EU authorisations and inspections through the European Medicines Agency (EMA) has been mitigated by EU Exit funding from DHSC.

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 2019/20 was £104.6m, which was £13.2m lower than in 2018/19 primarily as a result of a reduction in revenue from centralised (EMA-managed) as well as decentralised (EU-member states led) marketing authorisations. The above reduction was partly offset by an increased EU Exit transition funding from DHSC, which amounted to £12.6m in 2019/20 compared to £6m in 2018/19. Income from research activities in 2019/20 also increased from last year. Consequently the 2019/20 total trading income of £154.7m was £3.8m lower than that in 2018/19.

Staff costs increased by £3.4m (4.1%) reflecting a Civil Service staff pay award (2%) and an increase in employer pension contributions. Offsetting these was an overall reduction in the average number of employees, mostly in the core regulatory functions of the MHRA. Operating costs increased by £1.4m from last year. However, a £5m reduction in computing costs in 2019/20 has been negated by an apparent increase in other operating costs compared to 2018/19, when costs benefited from some £4.3m of provision releases and prior year adjustments. The resulting 2019/20 operating surplus before interest and dividends was £16.9m compared to £25.8m in 2018/19.

Total comprehensive income for the year was £24.6m after net interest income of £0.5m and a £7.3m revaluation gain on land and buildings at the South Mimms site. After dividends payable of £14.6m a net surplus of £10m was transferred to reserves.

2019/20 has seen a net cash inflow from operating activities of £16.3m compared to £15m in 2018/19. The current year operating cash inflow was driven by the operating surplus of £16.9m adjusted for non-cash items (add back depreciation of £8.8m; less DHSC non-cash funding of £12m) along with a £2.6m cash inflow from a reduction in working capital.

Offsetting the cash inflow from operating activities was £5.3m cash outflow from investing activities for purchases of tangible and intangible assets and a net cash outflow of £1.7m from financing activities, mainly the payment of a cash dividend to DHSC. As a result, cash and cash equivalents at the end of 2019/20 financial year were £9.3m higher than at the end of 2018/19.

Dr June Raine CBE
Chief Executive and Accounting Officer
Medicines and Healthcare products Regulatory Agency
14 July 2020

2 Accountability Report

2.1 Corporate Governance 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 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 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

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 and Director of Gainsborough Property Development UK Limited, also has wide-ranging experience of the medicines and medical devices industries.

Previous positions include serving as General Manager of GE

Healthcare's global medical diagnostics 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 a pharmacologist by training with 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 Officer and Board Member responsible for finance until his retirement in 2017. He now holds a range of non-executive portfolio appointments.

Executive Directors

Chief Executive

Dr Ian Hudson OBE (until 20 September 2019), Chief Executive

Dr Ian Hudson became chief executive of the Medicines and Healthcare products Regulatory Agency in September 2013.

He is a physician who practiced as a paediatrician for several years, before working in the pharmaceutical industry in clinical research and development between 1989 and 2001, when he joined the former Medicines Control Agency as director of its licensing division.

Before being appointed as chief executive, Ian was the Agency's licensing director, responsible for the majority of its medicines licensing activities. He was also the UK delegate to the Committee for Human Medicinal Products and was its vice chairman from October 2012 to September 2013.

Interim Chief Executive

Dr June Raine CBE (from 21 September 2019)

Dr June Raine was appointed interim Chief Executive with effect from on 21 September 2019 following Dr Hudson's retirement on 20 September 2019.June qualified in medicine at Oxford University, and undertook postgraduate research leading to an MSc in pharmacology. After general medical posts and Membership of the Royal Colleges of Physicians (MRCP), she joined the then Medicines Division in 1985, and has worked in several licensing areas including the Review of Medicines, new drugs and abridged.

June has worked on a wide range of topics from paracetamol toxicity to paediatric medicines, patient information to proactive pharmacovigilance. She now chairs the European Pharmacovigilance Working Party, and in the last five years has been closely involved in developing the European Risk Management strategy with other agencies.

Chief Operating Officer

Jon Fundrey

Jon Fundrey joined the Agency as Chief Operating Officer and Director of Finance 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

Professor Dame Valerie Beral left the Board on 31 August 2019 having served two three-year terms.

Professor Sir Alex Markham left the Board on 31 August 2019 having served two three-year terms.

Directors' 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.

The Register of Interests for each member of the Board can be found on the Agency website at the following location: https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/about/our-governance.

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 Interim Accounting Officer of the MHRA. 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

Scope of responsibility

Dr Ian Hudson retired as Chief Executive of MHRA on 20 September 2019. In the weeks leading up to his departure, Dr Ian Hudson had handover meetings with me, who succeeded him as interim Chief Executive on 20 September 2019. Moreover, in the weeks after taking up post, I received briefings from relevant staff on the Agency's work; among these were updates on EU Exit, the Agency's International Strategy, and Business Continuity and counter-fraud work. I also attended formal training courses, e.g. Regulatory Investigatory Powers Act, and Accounting Officer, so that I could carry out my role as interim Chief Executive.

As Accounting Officer, it is my responsibility to ensure there is a sound system of governance and internal controls in place; and that the Agency business is conducted in accordance with Managing Public Money to ensure public money is safeguarded and properly accounted. Following from the retirement of my predecessor Dr Ian Hudson on 20 September 2019, I was appointed as interim Accounting Officer from the same date.

The purpose of this Governance Statement is to give an explanation of the Agency's governance framework, including how it has supported the discharge of these duties in the financial year 2019/20, and how it enables the Agency to comply with cross-government frameworks, such as the Corporate Governance Code for Central Government Departments.

Agency's Statutory Duties

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 competent authority, for medical devices and contributing to developing the safety and performance standards that support this work;
- currently 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.

MHRA 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.

Following the retirement of Dr Ian Hudson, Chief Executive, on 20 September 2019, the Board Chair invited me to lead the organisation on an interim basis, until a permanent successor to Dr Hudson has taken up post. My appointment as interim Chief Executive was agreed with DHSC.

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 the MHRA 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 responsible for advising on the strategic development of the Agency and ensuring that targets set out in our Business Plan and endorsed by ministers are met.

- The Corporate Executive Team (CET) consisting of the Agency's divisional directors takes overall responsibility for day-to-day management, strategic

decision-making, line management, and all financial, policy, operational and resource management issues.

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

Notification of classification of the MHRA

The Office for National Statistics (ONS) has undertaken a classification assessment of the Medicines and Healthcare products Regulatory Agency (MHRA).

The MHRA is the body that acts on behalf of the Secretary of State for Health and Social Care in making decisions on the approval of marketing authorisations for medicines and medical devices. ONS has assessed the classification status of MHRA and has concluded that it is subject to public sector control for reasons including that all board members are appointed by the Secretary of State for Health and Social Care.

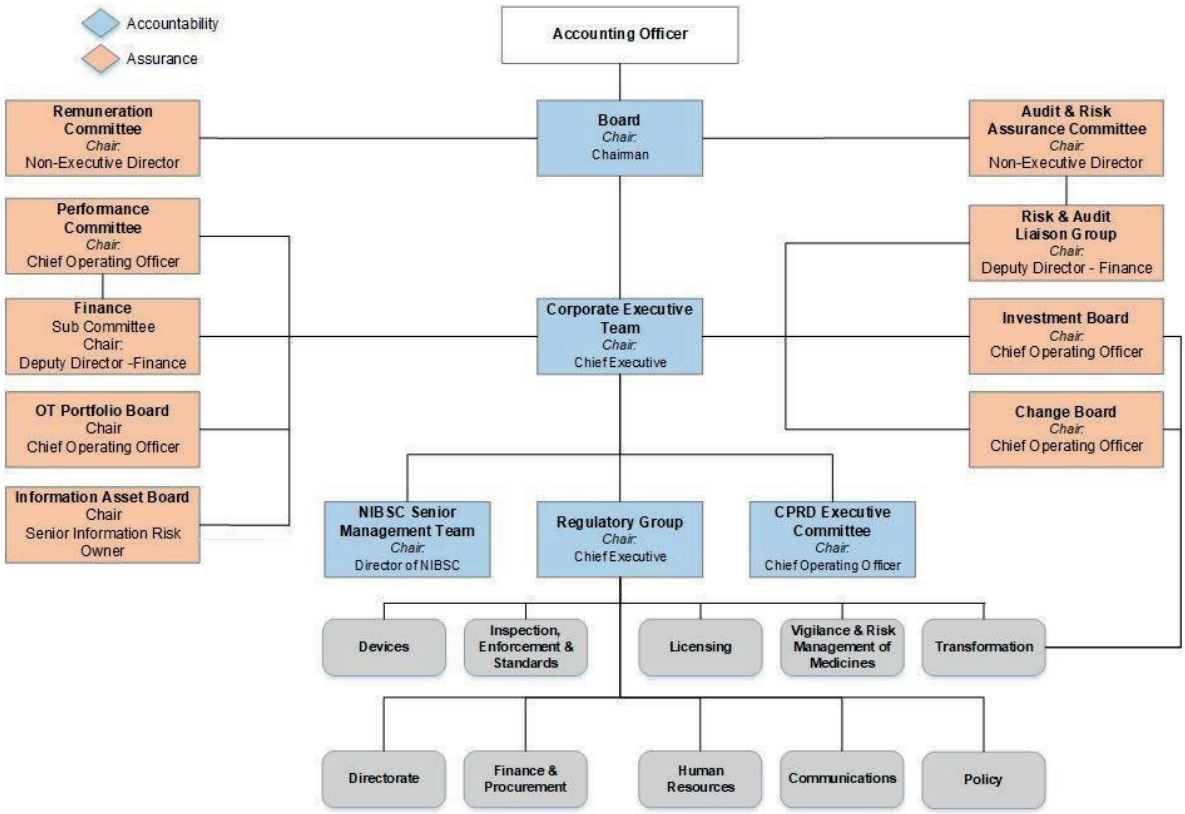
Economic Statistics Classification Committee (ESCC) further concluded that MHRA's inspection, licensing, devices, and periodic fees revenue were compulsory, as if a corporation wishes to sell medicine or medicinal products, it must receive a licence from MHRA.

The assessment also concluded that MHRA is a non-market producer as the revenue it receives from inspections, licensing, medical device assessments, and periodic fees are non-market fees (P.131). As such, MHRA has been classified to the central government subsector (S.1311) with effect from 1 April 2003, the date it came into existence.

ESCC also considered the NIBSC revenue and concluded that although this does not impact the sector classification of MHRA, if the funding arrangements changed, then ESCC members may need to review the impact of such changes on the classification decision.

The Agency is in discussions with DHSC and HMT in relation to the consequences of the ONS classification decision and its implementation. There are no changes to the Agency's Trading fund status for the financial year ending 31 March 2020.

The Governance Structure



Effectiveness of the Corporate Governance Framework

Corporate Governance is the way in which organisations are directed and controlled. 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 last updated in March 2016.

The Agency Board

The Agency Board is the principal governance body within the Agency, and its remit is to support the Secretary of State in the strategic and operational leadership of the Agency. Non-executive members are appointed by the Secretary of State following open competition and do not represent any specific customer, sectoral or stakeholder interests.

It sets the Agency's strategy, oversees the required resource and capability to deliver the strategy, and leads on scrutinising performance and risk. The Agency Board is supported in its work by an Audit and Risk Assurance

Committee (ARAC) and a Remuneration Committee.

The Board met eleven times during 2019/20, which included two joint Board / Corporate Executive Team (CET) strategic awaydays. The Board is chaired by Professor Sir Michael Rawlins.

In April 2019, the Board agreed to invite two lay members: Susan Bradford of the Commission on Human Medicines (CHM) and Sara Payne of the Devices Expert Advisory Committee (DEAC) to attend the Board from May 2019. The Board agreed that Ms Bradford and Ms Payne should attend Board meetings until a Patient Representative was appointed to the Board. In May 2020, Mercy Jeyasingham was appointed as the Patient Representative.

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)	2(2)
Professor Dame Valerie Beral[1]	3(4)	N/A
Ms Amanda Calvert	9(9)	2(2)
Professor Bruce Campbell	8(9)	2(2)
Mr Stephen Lightfoot	8(9)	2(2)
Professor Sir Alex Markham[2]	3(4)	N/A
Ms Anne-Toni Rodgers	7(9)	2(2)
Professor David Webb (Deputy Chair)	6(9)	1(2)
Mr Michael Whitehouse	4(4)	2(2)
Executive Directors		
Dr Ian Hudson OBE, Chief Executive (retired)	5(5)	N/A
Dr June Raine CBE, Interim Chief Executive	4(4)	2(2)
Mr Jon Fundrey, Chief Operating Officer	8(9)	2(2)
Lay members		
Ms Susan Bradford[3]	8(8)	2(2)
Ms Sara Payne[4]	7(9)	2(2)

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

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 objective.

The Chair is responsible for:

- providing leadership to the Board and the Agency, enabling all Board members to make a full contribution to the Board's affairs and 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

1 Left the Board on 31 August 2019.
2 Left the Board on 31 August 2019.
3 Started attending Board meetings as a lay observer with effect from 20 May 2019.
4 Started attending Board meetings as a lay observer with effect from 20 May 2019.

- 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.

The Board Members support and challenge the executive management of the Agency and provide independent and impartial perspectives. As experts from outside government, these Non-Executives Directors bring a wealth of experience and insight to advise on performance, operational issues, and on the effective management of the Agency.

The Board has considered items from across the breadth of the Agency's remit, to ensure that all activities contributed towards the Agency's goals. The Board has scrutinised the Agency's capability to deliver on short-term and long-term priorities, advising on areas for capability-building to ensure high standards of future delivery. Alongside the regular discussions on the Agency's EU Exit preparations, other important agenda items over the financial year 2019/20 included the discussions on the Agency's investment priorities, most of which were informed by the Operational Transformation programme and the Agency's Change strategy.

Board operation is set out in a Terms of Reference and in a Board Operating Framework. All Board Members are required to declare any personal or business interest which may be reasonably perceived to influence their judgement in performing their functions and obligations. These are recorded in a published register of interests. Where a Board Member declares a potential conflict at meetings, it is recorded in the minutes and the Board Member takes no part in the meeting for the duration of that item of discussion.

During the year, two Board members completed their term and left the Agency; their successors were appointed in May 2020.

Board performance and effectiveness

James Humphreys of Woodnewton Associates Consultancy submitted a report on Board/Executive interaction, which was considered at a joint Board/CET strategic awayday on 29 January 2018. The report, which the Board endorsed, made a series of recommendations including how to help improve collaborative working between the Board and the Executive. Among the recommendations was one that the Agency should follow the example of many other publication bodies and have a Board Operating Framework (BOF). The Agency duly produced a BOF, which was published on GOV.UK in July 2018. The Woodnewton report also recommended making better use of Board strategic awaydays, e.g. by inviting guest speakers. The report went on to recommend other opportunities for Board / Executive interaction, e.g. through sponsor roles, and that Board members should attend divisional and cross-agency group meetings and staff events. Woodnewton also recommended that opportunities for staff mentoring by Board members be

explored. Together, these initiatives would also raise the profile of the Board across the organisation. All the recommendations were acted out.

During 2019/20, the following developments were introduced by the Board. These follow on from the Woodnewton report's recommendations.

- During the 2019/20, there were two joint Board/CET strategy and planning days in November 2019 and February 2020. The focus of each day was on the evolving Change Strategy for the Agency.
- At the end of each strategy and planning day, a distinguished guest speaker from the public health field was invited to join the Board and CET. In November 2019, Sir Mark Walport, Chief Executive of UK Research and Innovation, was the guest speaker, while in February 2020, Sir Patrick Vallance, the Government's Chief Scientific Advisor, was the guest of honour.
- Since May 2019 two lay observers (one each from the Devices Expert Advisory Committee and the Commission on Human Medicine) have attended Board meetings and events. The Board thought it important to have a lay person's input into Board discussions while the Agency awaited the appointment of a patient representative to the Board by DHSC, who was subsequently appointed to the Board in May 2020
- From 1 January 2020, the number of public sessions of Board meetings was increased from four to six per year.
- For those members of the public who attend public sessions of the Board and who would prefer not to ask a question in person at the public session, the Board introduced a procedure whereby questions could be submitted in advance and answered by the Board and relevant officials at the meeting. The new procedure was introduced as a standing item on the agenda of every public session of the Board from September 2019.

Engagement and transparency

Directorate (Office of the Chairman and Chief Executive) provides the Secretariat to the Board. The Minutes of Board meetings are published on GOV.UK and actions are followed up under matters arising where the Board's Actions list is reviewed. To promote further transparency, the Board has open sessions which staff and members of the public may attend as observers. The number of public sessions of the Board increased from four to six with effect from 1 January 2020. Feedback has shown that public and staff observers find the public sessions to be informative and helpful.

Subcommittees of the Agency Board

The Agency Board has two subcommittees chaired by Non-Executive Board Members, who report to the Board. These are the Audit & Risk Assurance Committee (ARAC) and the Remuneration Committee.

Audit and Risk Assurance Committee (ARAC)

The Audit and Risk Assurance Committee (ARAC) provides independent advice to support the Board and Accounting Officer in their responsibilities for issues of risk, control and governance. It meets a minimum of four times a year, and it presented its Annual Report to the Agency Board on 22 June 2020. The Committee carries out its role in line with HM Treasury's ARAC Handbook covering the Committee's usual activities, including reviewing MHRA's Annual Report and Accounts, internal and external audit activities, and the development of the risk management framework.

Conflict of Interest Declaration

The process for recording declarations of conflicts of interests in ARAC mirrors the processes used at Board. 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 circumstances.

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.

ARAC Attendance

Members	ARAC
Mr Michael Whitehouse (Chair)	4(4)
Mr Stephen Lightfoot	4(4)
Professor Sir Alex Markham*	1(1)
Ms Amanda Calvert	4(4)
Ms Anne-Toni Rodgers**	2(3)

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

* Prof. Sir Alex Markham stepped down in August 2019.
** Anne-Toni Rodgers joined ARAC in October 2019.

The following The following persons routinely attended all Committee meetings:

- The Accounting Officer
- The Chief Operating 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. The Remuneration Committee will make recommendations about the total individual remuneration package for each member of the CET, including bonus payments where applicable. The review of any proposed severance arrangements for CET members would also fall within their remit.

The membership of the Remuneration Committee consists of four non-executive members of the Board together with the Director of Human Resources and me as Chief Executive; the Chair of the Board is not eligible for membership. The Remuneration Committee meets in person or by tele-conference on an annual basis. The Chair of the Committee provides a confidential oral report of the meeting to the Board.

The Corporate Executive Team and its subcommittees

The CET comprises me as Chief Executive, the Chief Operating Officer and the other Divisional Directors. The Corporate Executive Team (CET) Committee drives the Agency's overall performance and delivery against the Agency's mission, vision and objectives. CET ensures the effective management of the Agency through scrutiny of performance, finance and risk, and strategic leadership on fiscal events and the people agenda.

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 Remuneration Report (section 2.4) gives details of the remuneration paid to the members of the Board and CET.

The CET also makes decisions on issues escalated from its subcommittees. There are eight subcommittees of the CET that meet regularly over the year. The Performance Committee, Finance Sub-Committee, Investment Board and Risk & Audit Liaison Group ensure that the Agency has robust planning, performance, investment, finance, and risk frameworks by monitoring and challenging the Agency's performance, financial control and risk management. The Change Board's role is to oversee and manage delivery of the required strategic change in line with the vision and strategic direction set by the CET and assure that requests for project expenditure deliver the identified benefits. The Information Asset Board provides governance over Agency Information Assets. The OT Portfolio Board drives progress, prioritises resources and sets the strategic direction that supports the Operational Transformation Programme in its overall task of defining, developing and delivering the Agency's transformational operating model. The Individual Pay Case Committee fulfils responsibilities relating to the governance of a range of operational, pay/compensation related issues.

All sub-committees are chaired either by CET members or senior members of staff. This maintains a strong link between the CET and its subcommittees and further strengthens the subcommittees' line of sight across the Agency.

All CET Members are required to declare any personal or business interest which may be reasonably perceived to influence their judgement in performing their functions and obligations. These are recorded in a published register of interests.

CET Members Attendance

Members	CET Meeting	Joint AB/CET
Dr Ian Hudson, OBE (CEO)[1]	6(6)	N/A
Dr June Raine, CBE (Interim CEO)[2]	9(10)	2(2)
Mr Jon Fundrey	9(10)	2(2)
Ms Vanessa Birchall-Scott	8(10)	2(2)
Ms Rachel Bosworth	9(10)	2(2)
Dr Christian Schneider	9(10)	1(2)
Dr Siu Ping Lam	7(10)	2(2)
Mr Jonathan Mogford	8(10)	1(2)
Mr John Quinn	9(10)	1(2)
Dr Janet Valentine	8(10)	2(2)
Mr John Wilkinson, OBE[3]	5(7)	N/A
Dr Samantha Atkinson	8(10)	1(2)
Mr Graeme Tunbridge[4]	3(3)	2(2)
Dr Sarah Branch[5]	4(4)	2(2)

Data Quality to Support the Needs of the Board

The Chief Operating Officer is the senior executive with responsibility over Finance. The CET and Board receive financial reports at their meetings to support its discussions. All reports comply with a prescribed layout to ensure that the CET and Board are able to focus on the key issues and the decisions that are required.

Finance reports containing clear consistent and comparable performance information are discussed at the regular monthly meetings of the Performance Committee prior to submission to the CET and Board and any resource or financial implications are highlighted.

Governance Review

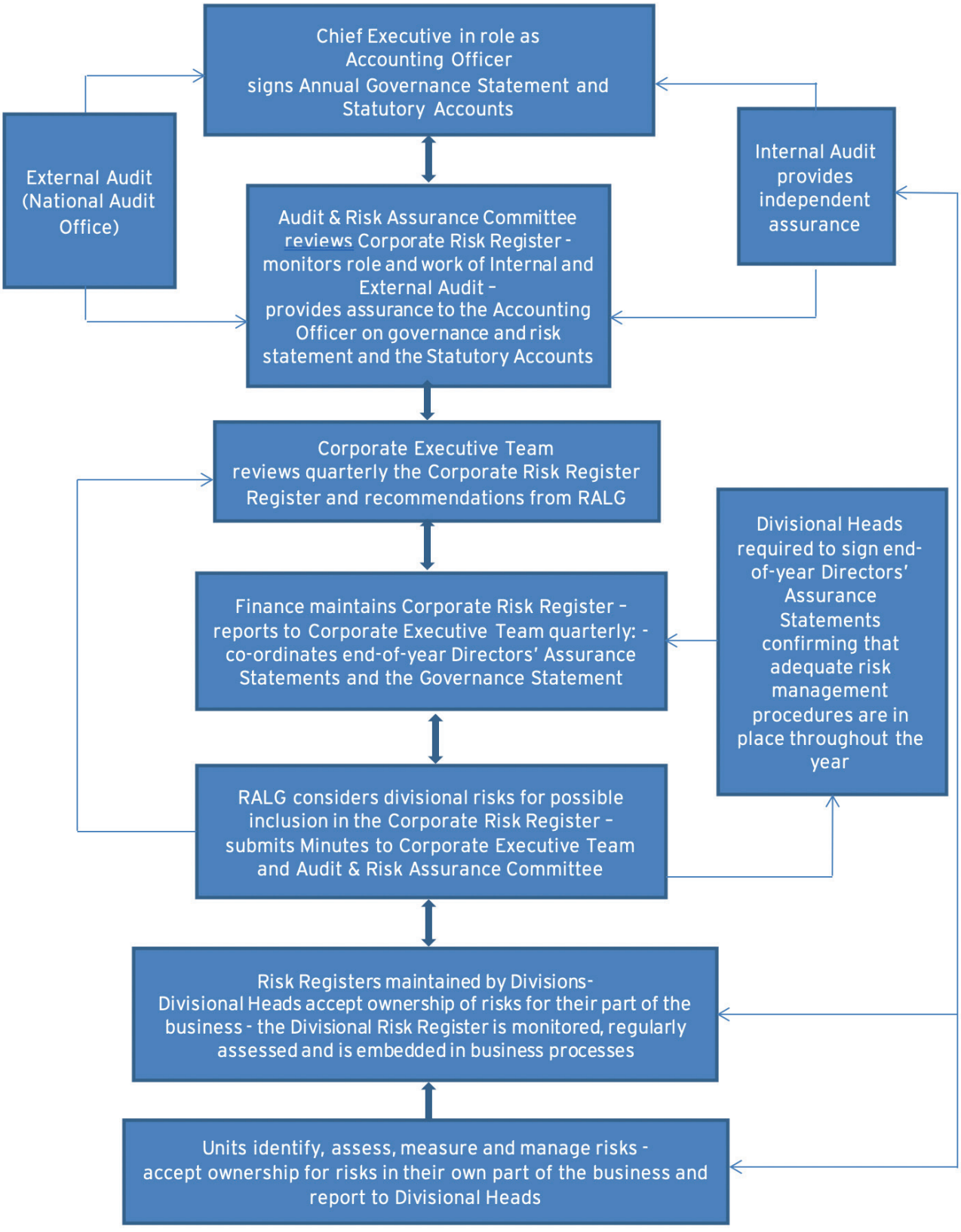
The Agency's governance structure has grown over the years and needs to be rationalised. We have engaged Ernst & Young to undertake an independent review of our governance and to provide recommendations that would help us to drive strategic change, bringing together resources, workforce and strategic outcomes.

Our goal with the governance review is to achieve greater agility of decision-making, as the agency enters a period of change, where there are exciting opportunities to build a new future and strengthen our ability to protect public health. This will align governance with the Agency's future strategy and ensure ownership and visibility of the changes required, thereby strengthening strategic alignment between the Executive, Board and DHSC.

1 Dr Ian Hudson retired as CEO on 20th September 2019.
2 Dr June Raine attended as Director of VRMM to 20th September and as Interim CEO after that.
3 Mr John Wilkinson retired on 18th October 2019.
4 Graeme Tunbridge became interim director of Devices on 21st October 2019.
5 Sarah Branch became interim director of VRMM on 23rd September 2019.

Risk Management

The Agency's risk management structure:



Capacity to handle risk and change

As Accounting Officer, I have overall responsibility for the Agency's Risk Framework, with CET owners assigned for the Agency's most significant risks to delivery of its objectives. 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.

The diagram above sets out the Agency's risk management structure. The objective is to identify and evaluate risks, 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 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 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 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. In addition, any risks that are considered by divisional management to be of a cross-Agency 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 Risk Register and the process which supports its development have been scrutinised and challenged by the ARAC and reviewed by the Agency Board on a regular basis. The ARAC reviews the Risk Register and conducts deep-dive reviews of strategic risks. It provides independent challenge to Agency's management in order to assure me, as Accounting Officer, and the Board that risks are being appropriately identified and mitigated. The Chair of ARAC provides regular readouts of the Committee meetings to the Agency Board, including raising specific risks and the supporting mitigation plans.

The RALG is a forum where divisional risks and audit issues are discussed and monitored by senior representatives from all divisions of the Agency. It held four meetings in the year to 31 March 2020. 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.

Agency's significant risks and key mitigating factors

During 2019/20 the principal risks to the Agency were as follows:

The UK's departure from the EU

In keeping with the Government's commitment to maintain the UK as a global hub for life sciences, leaving the EU provides opportunities and challenges in the development of a sovereign UK system which maintains and enhances public health protection. The Agency is actively managing the transition to a stand-alone Regulator post 1 Jan 2021. We are at an advanced stage of our work to enable new, expedited licensing pathways for medicines to help attract innovative medicines to the UK.

A cross-Agency Task-force team co-ordinates preparations for our departure 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 with the EU.

We have also re-designed the legislative frameworks for medicines, medical devices and clinical trials, to ensure the regulatory regimes are operational at the end of the transition period. This included the development of a European Systems Contingency (ESC) platform, that will be deployed if there is no Trade agreement before 1 January 2021, to ensure we have a system available for use at the end of the transition period.

People resources and capability

Failure to forecast and plan for the future staffing, skills and capabilities required in order to perform future Agency functions and priorities could impact the Agency's delivery of its statutory functions. As mitigation there is an ongoing identification of skills needed to retain and related reassurances including regular updates on developing plans and opportunities; Division/ Centre and pan-Agency workforce plans with sufficient detail and flexibility to respond to environmental changes (internal and external); clear Division/ Centre and pan-Agency action plans and ownership and assurance re progress towards continually evolving workforce plans and identification of priority skills gaps and related action plans/ownership to address key risks.

Financial and Delivery Alignment

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) and strategic change;
- 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 following the publication of the recommendations of the Independent Medicines and Medical Devices Safety (IMMDS) Review.

The Agency engages on a regular basis with the Board, DHSC and HMT, and with Ministers regarding the future shape and funding of the Regulator. In parallel the MHRA is looking at funding availability to finance the new

regulatory offerings through the existing or amended fees to industry and/or through funding from other sources.

It is important that the Agency integrates its financial, workforce and delivery planning to ensure it can use its resources effectively to deliver its objectives. Work in this area during 2019/20 has included:

- Introducing new financial monitoring reports;
- Introducing new performance metrics and internal reporting mechanisms; and
- Developing a new workforce planning tool.

Priorities for improvement in 2019/20 have included strengthening our finance staff capacity and capability; improving the quality and consistency of financial information and advice provided to budget holders; and Investing in finance systems and processes to increase the timeliness of availability of our financial data to support decision-making. A transparent cost allocation method has been developed that forms the basis of an updated fees and charges model and provides transparency to the financial outcomes for each funding centre.

Illegal Supply/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. There is continued inspection by our Inspectorate, Enforcement & Standards division of wholesale dealers.

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.

Regulatory fraud

There is a continued risk of falsified data/information presented on a licensing application.

Evidence requirements, validation checks including bonafide checks via Enforcement of Responsible Persons for wholesale distribution and Qualified Persons for manufacturing and others. There has been an exercise to verify contact details and responsible person details for all existing wholesale dealer licence holders. Records are updated following responses received. The exercise to validate existing Home Office licences is nearing completion, a report will be issued on completion. Business processes are in place to ensure that applicants are appropriately licensed (new applications and variations) and the Process Licensing (PcL) Portal has been updated to ensure the required supporting documentation is provided and there would be refusal/ rejection of applications where supporting evidence is not satisfactory.

In addition, an enhancement request is with the software vendor to update the application process to include information/updates requested by the

Common Logo E-Referral (CLERG) committee. The CLERG Committee have met on several occasions and letters of intention to suspend have been served to a number of companies.

Cyber security

In common with the rest of government, the Agency's ongoing Digital Transformation brings with it risks to the confidentiality, integrity and availability of our digital products, IT systems & data. Cyber risks are driven by multiple factors including the possibility of malicious cyber-attack from outside the Agency, inadequate or immature cyber security controls in and around products and systems, and the developmental state of the security culture within the Agency and its partners.

The Agency has made important progress in securing its digital products, systems and information, with the GIAA reporting an overall 'moderate' audit opinion last year: 2018/19.

Factors which heighten possible cyber threats to the Agency include: our international role and increasing profile, businesses and agencies; contractors and staff; an increasing level of transparency requiring a higher level of digital maturity and awareness; and the development of our commercial activities.

The programme of mitigation activity has included technical and process steps, developing awareness of cyber risks and helping our staff work securely through the tool tools we deploy to them. Some of these are improving control of applications through a whitelisting approach; improving cyber security threat detection and prevention capability by engaging intrusion detection/ data loss prevention capabilities; raising the profile of security performance with senior leaders; running a cyber incident response scenario training exercises; and strengthening domain management to eliminate copying/ spoofing.

Raising a Concern

The Agency has an internal Raising a Concern Policy and Procedure, Guidance for Managers and Guidance for Investigators documents based on a best practice Civil Service Employee Policy documents. 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.

All concerns that have been raised formally were investigated according to the policy and procedure and were reported to ARAC. Various methods were used this year to raise staff awareness of how to raise concerns including placing posters at print points and on TV screens and an article on the intranet for 'Speak Up' week.

Effectiveness of Anti-Fraud and Bribery Policy

The Agency has worked to comply with the Government's Counter Fraud Functional Standards, the common fundamentals that organisations should have in place to effectively deal with fraud. In the assessment for 2019/20, the Agency expects to meet the standard.

The Agency's internal Anti-Fraud and Bribery Policy and Procedure sets out the Agency's stance on non-regulatory fraud and bribery, defines both terms and reminds staff of the standards of behaviour expected of them under the Civil Service Code. The two Fraud Officers 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 mandatory CSL online Responsible for Information training for all staff, which includes a fraud module, 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.

Operational Transformation

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

The Operational Transformation Programme Business Case (PBC) received approval from the Department of Health and Social Care (DHSC) Investment Committee in November 2018. The decision approved the overall level of investment needed as well as the funding to deliver the first tranche of change projects. An update to the OT business case is expected early in the next financial year.

Overall portfolio governance remains unchanged from 2018/19. The Agency's Change Board oversees delivery of the required in-flight strategic change projects in line with the direction set by the approved programme/project plan and aligned to the Corporate Plan and Strategic Imperatives. The Agency's Investment Board approves all requests for project expenditure and specifically monitors the delivery of change benefits in line with the strategic vision and direction set by the CET. A Business Challenge Group (BCG) 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. Representatives of the DHSC Sponsor and Investment teams have standing invitations to attend those boards. The BCG membership comprises 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 portfolio, and also for the wider regulatory compliance and operational maintenance portfolios. The EPMO provides the secretariat for the Investment and Change Boards and holds their full terms of reference.

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 measures have continued to be improved, to ensure compliance with the Data Protection Act 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 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.
- The National Archives conducted an Information Management Assessment to benchmark the Agency's information management practice and found that in most areas the Agency had made significant improvements and was performing well, with some recommendations to take forward with regard to the reviewing and transfer of records to National Archives in compliance with the Public Records Act.
- An annual statement of information assurance was developed and delivered to the Audit and Risk Committee, and quarterly updates to this statement are now discussed at Information Asset Board.

Data Protection

We have worked to improve compliance and raise awareness of our obligations under the General Data Protection Act and Law Enforcement Directive, to embed data protection by design and default principles throughout the Agency and to monitor compliance. We have published insights on the intranet to raise awareness of key areas of GDPR such as Subject Access Requests and to improve engagement by making the legislation understandable and clear.

Last year we introduced privacy by design principles – including Privacy Impact Assessments for new systems or processing activities that utilise personal data, and this year that process has bedded in and has helped 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.

We have completed and updated 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.
- One cyber security incident has been dealt with effectively this year, and the team continue to strengthen our response to new and emerging information risks. The incident was reported to the ICO, which advised no further action to be taken. As a prosecution is underway the Agency would be able to publish the number but not details of the incident.
- We have carried out further IT health checks and are making steady progress to closing the high-risk vulnerabilities that were identified.
- Last year we successfully implemented the Data Security Protection toolkit for the first time and continue to perform well against the National Data Guardian (NDG) data security standards.
- The team has continued to develop cyber security capability and capacity, taking on a third cyber security apprentice, under a cross government scheme led by Cabinet Office. Our two existing cyber security apprentices are completing their apprenticeships and are already enabling the Agency to be more proactive in responding to cyber security incidents.

Information Skills

Raising skill across the Agency's staff continues to be the best way to protect our information and exploit it. All agency staff complete Responsible for Information General user training as the mandatory security learning product every two years. To reinforce the messages here, and to deliver role specific training the Data and Information team have also developed and delivered a range of face to face training which now includes mandatory information governance training for new starters, as well as high level data protection training and role based sessions on conducting data protection impact assessments. To widen the uptake the sessions now range from 15-minute overviews at team meetings to targeted hour long sessions

This year, we have seen an improvement in responses to phishing emails which demonstrates the effectiveness of the two simulated phishing campaigns which we ran last year. 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 we are planning for a further phishing campaign in the next financial year.

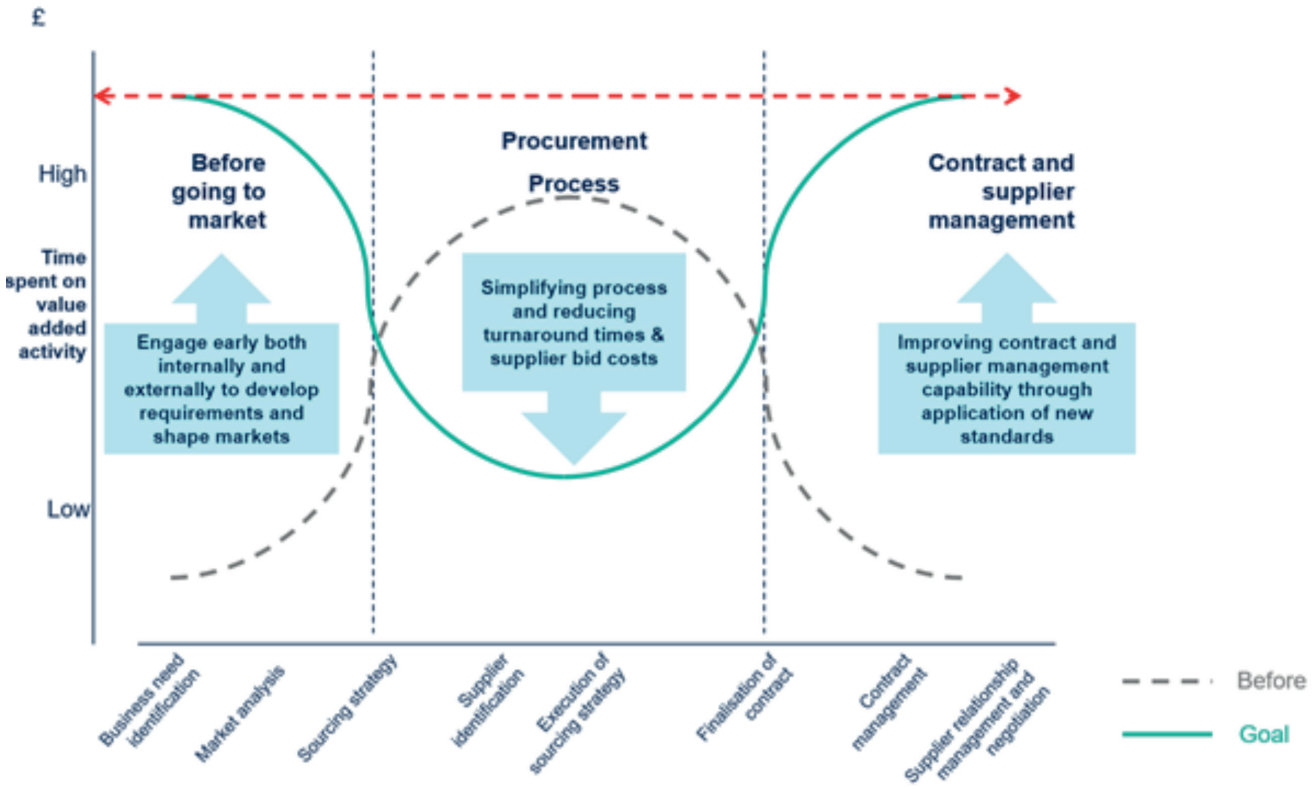
All staff have access to the online Knowledge Hub, providing links to dozens of tip sheets and online tutorials for handling information, This year, the Knowledge Hub has been refreshed to update our training, and Digital Workplace refresher training is being rolled out across the Agency to ensure that skills stay updated.

Digital Workplace

The Digital Workplace has delivered several continuous improvements this year, to continue to improve enabling cross-site and cross-team collaboration. Improvements delivered this year have included the ability to edit and collaborate on documents more effectively, including from mobile devices. This means that information can be shared more effectively.

Commercial and Procurement

In 19/20 the Commercial function executed a substantial transformation in strategy, structure and scope from its Procurement team foundation. A new Commercial Strategy was developed with the goal of driving improvements in the planning, management and execution of commercial activities, ensuring contracts and relationships with suppliers realise value for money to support the Agency's mission to protect and improve the nation's health.



The new strategy ensures alignment with the Government Commercial Operating Standards and transition of the team's remit from procurement to commercial in support of the Agency for all of its 3rd party expenditure; covering of the full contract lifecycle: market engagement, business case development, procurement, contract management and exit.

Other areas

During 2019/20 the MHRA identified control deficiencies in how it pays non-executive directors which has resulted in under- and overpayments to several non-executive directors for a number of years. The MHRA has begun to recover the overpayments and has corrected the underpayments.

To address the identified deficiencies the MHRA commissioned an external review of its onboarding and offboarding practices for non-executives. The review has come up with recommendations and suggestions for improvement. The MHRA has started work to implement the recommendations and to realign its internal processes with best practices in public sector organisations.

Audit

Management 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 2020 with Divisional Directors confirming compliance with all Agency SOPs and policies.

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

Internal Audit

Internal Audit services were provided in 2019-20 by the Government Internal Audit Agency (GIAA), which operates to prescribed Public Sector Internal Audit Standards. Through its annual programme of work, Internal Audit provides the Accounting Officer with an independent and objective opinion on the effectiveness of the Agency's system of internal control, together with recommendations to help secure continuous improvement or to remedy any shortcomings.

ARAC received and considered 10 reports from Internal Audit:

Areas reviewed	Assurance Rating
1. Cash Planning and Funding	Moderate
2. Payroll and Core Processes	Moderate
3. Clinical Investigations and Trials	Moderate
4. Devices - Handling of Incidents	Substantial*
5. Contract Management and Procurement	Moderate
6. Operational Transformation Governance	Moderate
7. Workforce Planning	Limited**
8. NIBSC Business Planning	Moderate
9. CPRD Research Income	Moderate
10.GPRD Compliance	Moderate

* ARAC considered it premature to accept the substantial assurance until after the publication of the Independent Medicines and Medical Devices Safety Review later this year.

** ARAC received assurance that action was in progress to put in place a robust workforce plan to address the limited assurance. The Committee will monitor implementation.

Areas of focus for the Audit and Risk Assurance Committee

The areas of focus in 2019-20 were "deep dive" risk reviews enabling the Committee to scrutinise risk management arrangements, challenge actions where appropriate and offer advice to support continuous improvement. The following topics were covered:

- Procurement and commercial management
- Operational Transformation
- Digital strategy and replacement of legacy systems
- Risk management to support a more strategic and integrated approach
- Transformation of the finance function to embed a more strategic approach to financial management
- In -depth quarterly reviews of financial performance
- Actions to prevent and detect regularity and non-regularity fraud.

The Committee reviewed the outcome from external and internal audit reports and received regular reports on the implementation of audit recommendations. In addition, the Committee reviewed annual assurance reports from management on information governance, information security, resilience and whistleblowing arrangements.

The Chair of the Audit Committee, supporting the Agency's Accounting Officer and Chief Operating Officer, met with the Chair of the Department of Health and Social Care Audit Committee to discuss the Agency's approach to risk management .This was part of the Department's Audit Committee's programme of taking assurance for risk management across the whole group of agencies supporting the Department.

Review of ARAC Effectiveness

ARAC carried out its annual review of effectiveness in April 2020, which showed that 86% of the responses in the returned questionnaires were in the 'above average'/'fully satisfactory' categories. This was 2 % lower than recorded for last year. Members considered the Committee's performance over the previous financial year, reviewed and updated its terms of reference and identified actions to continue to build on its effectiveness over the coming year.

Health and safety

My senior management team and I are committed to providing a safe and healthy working environment for Agency staff, visitors and contractors wherever they are based, and that commitment is clearly set out in the Agency's Health and Safety Policy. A member of the Executive Committee is appointed as the Health and Safety Champion and chairs the Health and Safety Strategy Group and H&S committee meetings at each site, through which we engage and consult to identify new legal and Agency requirements, discuss recent accidents, incidents and emerging risks and review the effectiveness of the health and safety management system. The new overseas travel process is now working well, and Hostile Environment Awareness training has been provided to regular Agency travellers. There have been no RIDDOR (Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013) accidents during this time period.

Head of Internal Audit (HIA) opinion

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

The HIA's view is that a 'Moderate' overall assurance rating is appropriate for 2019-20. This is consistent with last year's opinion.

Overall, the HIA judged that appropriate measures have been put in place during the year to maintain effective arrangements in risk management, governance and internal control. She has used these three headings to structure the narrative in this part of the report. She has also provided views on the areas where audit work suggests further improvements could be made.

Risk Management

The auditors' work during the year together with observations at Audit & Risk Assurance Committee has concluded that effective arrangements are in place to identify and manage risk. At the strategic level, work took place during the year involving the Corporate Executive Team, to review the corporate risk register (CRR). At an operational level, the auditors confirmed, that risks are being identified, assessed and managed through directorate level risk registers.

Audit reviews of NIBSC Business Planning and Workforce Planning identified that there is further opportunity to strengthen the arrangements in place, by creating more overt linkages between risks and organisational objectives by recording actions to mitigate risks in business and workforce plans where appropriate.

Governance

The auditor's work has confirmed that there are effective governance arrangements in place. There has been a Board in place throughout the period, which is responsible for advising on the strategic development of the Agency and for ensuring the targets set out in the Agency's business plan are met. The Board is advised by the Corporate Executive Team comprising senior management from across the Agency. We note that there is work underway to review the Agency's governance arrangements to allow for clearer strategic direction, performance oversight and effective delegation to deliver the Agency's new vision.

The Board, at its meeting on 23 March 2020 has endorsed a new Business Plan, which ensures that the Agency will grip key work in 2020/21 to make sure that the Agency is robustly contributing to cross-sector action to combat COVID-19; the Agency is delivering agreed strategic change and will be ready to operate as a fully Third Country to the EU from 1 January 2021.

Internal Controls

Audits completed in 2019/20 have confirmed that there is an effective control framework in place with controls generally found to be operating in practice. Core financial controls were found to be operating effectively in our audits of Payroll and Cash Planning and Funding.

The auditors confirmed that there were appropriate arrangements for staff to declare conflicts of interest in the Clinical Investigations and Trials audit and we confirmed that the outstanding action relating to conflicts of interest in the Contract Management and Procurement audit had been completed.

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 2019/20.

Accounting Officer's review of effectiveness of Internal Control Framework

As Accounting Officer, I am required to conduct an annual review of the effectiveness of the Agency's governance structures, risk management and internal control 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 inform the Head of Internal Audit's opinion on the overall adequacy of the Agency's internal control framework, which is reported in her annual report;

I have considered the evidence provided with regards to the production of the Governance Statement. The conclusion of the review is that the Agency's overall governance and internal control structures have been appropriate for the Agency's business and working satisfactorily throughout 2019/20.

Compliance with the Corporate Governance Code

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 2020 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 colleagues 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 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; 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 64.

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

2019/20	Salary	Performance pay and bonuses	Pension related benefits	Total
	£000	£000	£000	£000
Dr Ian Hudson, OBE[1] Chief Executive	70 - 75	Nil	41	110 - 115
Mr Jon Fundrey Chief Operating Officer	135 - 140	Nil	54	190 - 195
Dr June Raine, CBE[2] Interim Chief Executive	75 - 80	Nil	88	160 - 165
Dr June Raine, CBE[33] Director of VRMM	60 - 65	10 - 15	Nil	75 - 80
Dr Christian Schneider Director of NIBSC	135 - 140	Nil	54	190 - 195
Mr John Wilkinson, OBE[4] Director of Devices	65 - 70	Nil	8	70 - 75
Ms Rachel Bosworth Director of Communications	100 - 105	Nil	17	115 - 120
Mr Jonathan Mogford Director of Policy	100 - 105	Nil	34	135 - 140
Dr Siu Ping Lam Director of Licensing	120 - 125	Nil	19	140 - 145
Mr John Quinn Chief Information Officer and Director of Transformation	115 - 120	10 - 15	39	160 - 165
Ms Vanessa Birchall-Scott Director of Human Resources	95 - 100	Nil	38	135 - 140
Dr Janet Valentine Director of CPRD	105 - 110	10 - 15	61	180 - 185
Dr Samantha Atkinson Director of Inspection. Enforcement and Standards	105 - 110	Nil	41	150 - 155
Dr Sarah Branch[5] Director of Vigilance & Risk Management of Medicines	100 - 105	10 - 15	53	165 - 170
Mr Graeme Tunbridge[6] Director of Devices	85 - 90	10 - 15	28	125 - 130

Band of the highest paid director's total remuneration	150 - 155
Median total	41,536
Remuneration ratio	3.7
Range of staff remuneration	8 - 150

* CET members receive no 'benefits in kind'.

1 Dr Ian Hudson retired on 20th September 2019.(Full time equivalent £150-£155k).
2 Dr June Raine, CBE was appointed as interim Chief Executive on 20th September 2019 (Full time equivalent £140-£145k. The pension related benefits are for both roles).
3 Dr June Raine was Director of VRMM until 20th September 2019 (Full time equivalent £125-£130k and her bonus relates to this role).
4 Mr John Wilkinson, OBE, retired on 19th September 2019. (Full time equivalent £120-£125k).
5 Dr Sarah Branch was appointed as Director of VRMM on 21st October 2019. Full time equivalent £105-£110k).
6 Mr Graeme Tunbridge was appointed Director of Devices on 21st October 2019. (Full time equivalent £90-95k).

2018/19	Salary £000	Performance pay and bonuses £000	Pension related benefits £000	Total £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	40,890
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 IE&S on 1st April 2018.

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

2019/20	Salary £000	Benefits in kind (taxable) to nearest £100*	Total £000
Professor Sir Michael Rawlins, GBE Kt Chair	60 - 65	Nil	60 - 65
Dr Barbara Bannister, MBE Non Executive Director	5 - 10	Nil	5 - 10
Professor Dame Valerie Beral[1] Non Executive Director	0 - 5	200	0 - 5
Professor Bruce Campbell Non Executive Director	5 - 10	700	5 - 10
Professor Sir Alex Markham[1] Non Executive Director	0 - 5	800	0 - 5
Professor David Webb Deputy Chair Non Executive Director	5 - 10	6,500	10 - 15
Mr Stephen Lightfoot Non Executive Director	5 - 10	400	5 - 10
Amanda Calvert Non Executive Director	5 - 10	2,100	5 - 10
Anne – Toni Rodgers Non Executive Director	5 - 10	2,000	10 - 15
Mr Michael Whitehouse, OBE Non Executive Director	10 - 15	Nil	10 - 15

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

1 Professor Dame Valerie Beral and Professor Sir Alex Markham left the Board on 31st August 2019.

2018/19	Salary £000	Benefits in kind (taxable) to nearest £100*	Total £000
Professor Sir Michael Rawlins, GBE Kt 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 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.

Disclosure of remuneration, bonus and benefits in kind 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 2019/20 relate to performance in 2018/19 and the comparative awards reported in 2018/19 relate to performance in 2017/18.

Fair pay disclosure

Reporting bodies are required to disclose the relationship between the remuneration of the highest-paid director in their organisation and the median remuneration of the organisation's workforce. 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 2019/20 was £150k-£155k (2018/19, £150k-£155k). This was 3.7 times (2018/19, 3.7) the median remuneration of the workforce, which was £41,536 (2018/19, £40,890) 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 2019/20 (2018/19, none).

The range of staff remuneration was £8k-£140k (2018/19, £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:

2019/20	Real increase in pension and related lump sum at 60 Bands of £2,500	Total accrued pension at age 60 at 31 March 2020 and related lump sum Bands of £5,000	Cash Equivalent Transfer Value at 1 April 2019. To nearest £1,000	Cash equivalent Transfer Value at 31 March 2020. 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, OBE Chief Executive	0 - 2.5 plus Nil lump sum	65 - 70 plus Nil lump sum	1,347	1,371	41	22
Mr Jon Fundrey Chief Operating Officer	2.5 - 5.0 plus Nil lump sum	40 - 45 plus Nil lump sum	667	752	42	42
Dr Christian Schneider Director of NIBSC	2.5 - 5.0 plus Nil lump sum	10 - 15 plus Nil lump sum	118	161	27	42
Dr June Raine, CBE Director of Vigilance & Risk Management of Medicines	2.5 – 5.0 plus lump sum of 12.5 – 15.0	55 – 60 plus lump sum of 175 - 180	1,128	1,202	76	34
Mr John Wilkinson, OBE Director of Devices	0 - 2.5 plus Nil lump sum	20 - 25 plus Nil lump sum	373	390	7	6
Ms Rachel Bosworth Director of Communications	0 - 2.5 plus lump sum of 2.5 - 5.0	25 - 30 plus lump sum of 85 - 90	627	677	17	31
Mr Jonathan Mogford Director of Policy	0 - 2.5 plus Nil lump sum	35 - 40 plus lump sum of 105 - 110	713	804	13	31
Dr Siu Ping Lam Director of Licensing	0 - 2.5 plus lump sum of 2.5 - 5.0	45 - 50 plus lump sum of 140 - 145	1,090	1,113	19	37
Mr John Qiunn Chief Information Officer	0.0 - 2.5 plus Nil lump sum	40 - 45 plus lump sum of 85 - 90	669	724	19	34
Ms Vanessa Birchall-Scott Director of Human Resources	0 - 2.5 plus Nil lump sum	10 - 15 plus Nil lump sum	131	169	24	30
Dr Janet Valentine Director of CPRD	5 - 7.5 plus Nil lump sum	20 - 25 plus Nil lump sum	221	298	26	32
Dr Samantha Atkinson Director of Inspection, Enforcement and Standards	0.0 - 2.5 plus Nil lump sum	25 - 30 plus Nil lump sum	341	380	17	34
Dr Sarah Branch[1] Director of Vigilance & Risk Management of Medicines	0.0 - 2.5 plus lump sum of 5.0 - 7.5	40 - 45 plus lump sum of 140 - 145	1,014	1,051	50	31
Mr Graeme Tunbridge[2] Director of Devices	0 - 2.5 plus Nil lump sum	20 - 25 plus Nil lump sum	259	276	13	26

1 Dr Sarah Branch was appointed Director of Vigilance & Risk Management of Medicines 21st October 2019.
2 Mr Graeme Tunbridge was appointed Director of Devices on 21st October 2019.

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

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. CETVs are calculated in accordance with SI 2008 No.1050 Occupational Pension Schemes (Transfer Values) Regulations 2008.

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 or 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 69 and 70.

Staff costs (subject to audit)

	2019/20			2018/19
	Total £000	Permanently Employed	Other £000	Total £000
Wages and salaries	64,302	58,476	5,826	63,344
Social security costs	6,768	6,768	-	6,996
Other pension contributions	15,343	15,343	-	12,442
Sub-total	86,413	80,587	5,826	82,782
Less recoveries in respect of outward secondment	(189)	(189)	-	-
Total staff costs	**86,224**	**80,398**	**5,826**	**82,782**

Staff resources (subject to audit)

During the year an average of 1,291 full-time equivalent staff were employed.

	2019/20		
	Total	Permanently Employed	Other*
Chair	1	1	-
Chief Executive/Directors	12	12	-
Senior Civil Servants	123	121	2
Other Civil Service Staff	1,155	991	164
Total	**1,291**	**1,125**	**166**

* includes contingent workers

	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**

SCS by grade

Senior Civil Servants by salary band (£000)	2019/20	2018/19
65 - 70	2	7
70 - 75	28	22
75 - 80	20	22
80 - 85	32	35
85 - 90	25	23
90 - 95	12	12
95 - 100	7	3
100 -105	6	7
105 - 110	3	-
110 - 115	2	-
115 - 120	1	1
120 - 125	1	-
125 - 130	-	-
130 - 135	-	-
135 - 140	2	1
Total	**141**	**132**

Staff composition - gender analysis

	Male	Female
Chairman/Chief Executive/ Directors	7	6
Senior Civil Servants	56	67
Other Civil Service Staff	479	668
Total	**542**	**741**

*Based on submitted returns

Staff composition – ethnic breakdown

- White 59%
- BME 32%
- No data/prefer not to say 9%

Sickness absence

The sickness absence calculation now includes all days lost to sickness absence, including those staff who left during the reporting year. The average annual sickness rate for the year was 5.4 working days per full time equivalent employee (2019, 8.2 days).

The annual turnover for the Agency was 12% (2018/19 was 13%).

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. 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. We undertake 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 workplace adjustment policy. We have focussed on mental wellbeing and supporting staff's resilience during periods of change through learning and development and through our promotion of mental health champions.

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 run a monthly Diversity & Inclusion 'surgery' for confidential signposting and support on all diversity issues.

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 and run career pathway drop in sessions at both 10SC and NIBSC.

We have good employee relations with our recognised trade unions and hold informal and formal partnership meetings with them, valuing their input and expertise in all people related policies and activity.

Other employee matters

55 members of the Agency Senior Leadership Group participated in training during 2019 focused on working more collaboratively as leaders, to improve the Agency's delivery for patients and customers. 95% of participants rated the training as excellent or very good and said that they were taking away practical insights for leading differently and in partnership with colleagues.

A larger number of the manager population has now undertaken Managing Reactions to Change training – over 200 managers to date– with further cohorts of this training running in March 2020. This training focuses on how to build your own and your team's resilience and how to help your team prepare for and embrace change to strengthen our organisational performance as we transform. Over 90% of participants who have now completed the training rated the training as excellent or very good. In a further survey six months after the training, 96% of those managers reported they felt fairly confident

or very confident about managing their own and team members' reactions to change.

As part of the operational transformation programme, we have looked to better understand our workplace culture in the face of our future challenges. We know that organisational values and behaviours are critical for our future success, so we have reviewed these through a wide-ranging staff engagement exercise, where we talked to over 800 staff. This has led us to change our values and develop a set of supporting behaviours that we will start to promote and integrate into our performance and reward and recognition initiatives from April 2020.

Spend on Consultancy and Temporary Staff

During 2019/20, expenditure on consultants was £312k (2018/19, £217k).

The Agency continues to employ temporary staff where it is of operational necessity. The Agency temporary staff expenditure was £5,833k in 2019/20 (2018/19, £3,621k).

The Government Apprentice scheme

The MHRA pays 0.5% of its annual pay bill (excluding on costs) – a total of approximately £250, 000 per annum depending on headcount. This money is payable irrespective of number of apprentices and is not recouped by the MHRA. The cost of each apprentice is salary cost plus on cost. For staff who undertake an apprenticeship who were already employed this results in no extra cost. There are 18 positions occupied which were recruited directly as apprenticeships, the salary costs in total for these current roles would be approximately £540,000 per annum assuming an average grade of EO.

Training undertaken by each apprentice is paid through the apprenticeship levy. This training is formal and leads to accreditation and qualification. This training would be very expensive for the individual or the MHRA should we decide not to go through the apprenticeship route. An example of this is the TOPRA Regulatory Affairs L7 qualification, masters equivalent, which would cost up to £27,000 per learner if not funded by the Levy. We will shortly have 8 current employees becoming qualified through this apprenticeship standard.

Apprenticeships give the organisation the opportunity to grow our own skills which are difficult to recruit to in the job market, saving money in the long term on specialist recruitment, consultants and external providers. There are currently 10 apprentices on Digital L4 apprenticeships, covering areas such as Digital Innovation, Data Analysis and Cyber Security. Ultimately these apprentices would be in a position to provide the organisation with alternatives to expensive external consultants.

In addition, there is a corporate social responsibility element to our use of the apprenticeship scheme. The scheme aids social inclusion, certainly at the MHRA where there is a tendency to recruit a high percentage of candidates who are university graduates. Our roles which have been recruited as new apprenticeships in areas such as HR, Communications, Finance and ICT have allowed us to recruit applicants who have not studied at university and given them the opportunity to both gain valuable work experience while learning skills and behaviours, which will help them become established in their career of choice.

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

Exit packages (subject to audit)

Cost band	Total number of exit packages by cost band	
	2019/20	2018/19
<£10,000	3	4
£10,000 - £25,000	3	2
£25,000 - £50,000	-	3
£50,000 - £100,000	-	-
£100,000 - £150,000	1	-
£150,000 - £200,000	-	-
Total number of exit packages	**7**	9
Total resource cost	**£209,786**	£169,753

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 £209k (2018/19, £170k) 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 2020.

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 ½ 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 2019/20, 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, Classic plus, Alpha, Premium and Nuvos schemes
£0 to £21,636	4.60%
£21,637 to £51,515	5.45%
£51,516 to £150,000	7.35%
£150,001 and above	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 1 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 https://www.nhsbsa.nhs.uk/nhs-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:

	2019/20 Annual pensionable pay banding	2019/20 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 2019/20 (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 2019/20, employers' contributions for the agency employees of £15,342,469 were payable to the PCSPS and NHSPS (2018/19, £12,442,354) at one of four rates in the range 26.6 per cent to 30.3 per cent of pensionable pay (2018/19, 16.7 per cent to 24.3 per cent) for PCSPS and 20.6 per cent (2018/19, 14.6 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 £127,602 (2018/19, £110,931) 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 (2018/19, 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 £4,260 (2018/19, £2,894), 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 2019/20 (2018/19, Nil). No additional pension liabilities were accrued.

Trade Union

Trade Union Facility Time

Under the Trade Union (Facility Time Publication Requirements) Regulations 2017[1], the Executive Agency has a statutory requirement to disclose information as prescribed by Schedule 2 of the above Regulations. The format of these tables in is as prescribed by the Regulations.

Trade Union Facility Time Disclosure

The disclosure has been compiled in line with the Regulations[2]. It is for this reason that the information discloses the trade union facility time utilised by Medicines and Healthcare products Regulatory Agency staff only. The statutory reporting requirement is met through the entity's underlying Annual Report and Accounts, where an entity is in scope of this requirement.

Relevant Union Officials

Number of employees who were relevant union officials during the relevant period	Full-time equivalent employee number
19	19

Percentage of time spent on facility time

Percentage of time	Number of employees
0%	0
1-50%	19
51-99%	0
100%	0

Percentage of pay bill spent on facility time

Description	Figures
Total cost of facility time	£30,405
Total pay bill	£86,224K
Percentage of the total pay bill spent on facility time*	0.037%

* calculated as: (total cost of facility time ÷ total pay bill)

Paid Trade Union Activities

Description	Figures
Time spent on paid trade union activities as a percentage of total paid facility time hours*	0%

* total hours spent on paid trade union activities by relevant union officials during the relevant period ÷ total paid facility time hours

1 http://www.legislation.gov.uk/uksi/2017/328/made
2 http://www.legislation.gov.uk/uksi/2017/328/made

2.5 Parliamentary Accountability and Audit Report

This section is subject to audit

Contingent liabilities

A contingent liability is a possible obligation that arises from past events and whose existence will be confirmed only by the occurrence or non-occurrence of one or more uncertain future events not wholly within the control of the agency, or a present obligation that is not recognised because it is not probable that a payment will be required to settle the obligation or the amount of the obligation cannot be measured sufficiently reliably. A contingent liability is disclosed unless the possibility of a payment is remote.

The Department of Health and Social Care has agreed that it will meet the costs of any liabilities arising from legal claims in respect of regulatory functions performed by the agency and that such costs should not be met from the agency's Trading Fund. Consequently, the agency does not have any contingent liability in this regard.

Fees and charges

Treasury guidance on fees and charges is applied when setting fee levels for the agency. Fees are set following consultation with Industry, the Department of Health and Social Care and HM Treasury and are intended, taking one year with another, to cover the costs of the agency. Fees are set to recover the full cost incurred by the agency. The agency has complied with the cost allocation and charging requirements as set out in HM Treasury's guidance. Department of Health and Social Care funding in relation to devices activities is intended to cover the costs of providing this specific service.

The agency's income is derived from its regulatory function in achieving its objectives of protecting, promoting and improving public health.

2019/20

	£000 Income	£000 Expenditure	£000 Surplus
Licensing	28,855	(34,837)	(5,982)
Inspections	6,485	(10,214)	(3,729)
Vigilance, Risk Management and Enforcement	33,051	(30,316)	2,735
British Pharmacopoeia	4,742	(1,566)	3,176
Devices	11,986	(12,057)	(71)
Clinical Trials	3,322	(4,168)	(846)
Regulator total	88,441	(93,158)	(4,717)
CPRD	10,070	(11,514)	(1,444)
DHSC share of joint venture	(5,035)	5,757	722
	5,035	(5,757)	(722)
NIBSC	43,028	(47,152)	(4,124)
Total	**136,504**	**(149,067)**	**(9,563)**

2018/19	£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**

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 financial year.

There were no other material losses or special payments during the financial year.

Dr June Raine CBE
Chief Executive and Accounting Officer
Medicines and Healthcare products Regulatory Agency
14 July 2020

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 2020 under the Government Trading Funds Act 1973. The financial statements comprise: the Statements of Comprehensive Income, Financial Position, Cash Flows, Changes in Taxpayers' Equity; and the related notes, including the significant accounting policies. These financial statements have been prepared under the accounting policies set out within them. I have also audited the information in the Accountability Report that is described in that report as having been audited.

In my opinion:

- the financial statements give a true and fair view of the state of the Medicines and Healthcare products Regulatory Agency's affairs as at 31 March 2020 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.

Emphasis of matter – material uncertainty regarding property valuation

I draw attention to the disclosures made in notes 1.3 and 1.4.1 to the financial statements which state that the valuation of the Medicines and Healthcare products Regulatory Agency's property, plant and equipment is subject to material uncertainty with respect to the estimated cost of replacing the service potential of these assets, arising from the impacts of COVID-19 on land markets and building costs. My opinion is not modified in respect of this matter.

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 Standards, 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 42 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 have nothing to report in respect of the following matters in relation to which the ISAs (UK) require me to report to you where:

- the Medicines and Healthcare products Regulatory Agency's use of the going concern basis of accounting in the preparation of the financial statements is not appropriate; or
- the Medicines and Healthcare products Regulatory Agency have not disclosed in the financial

statements any identified material uncertainties that may cast significant doubt about the Medicines and Healthcare products Regulatory Agency's ability to continue to adopt the going concern basis of accounting for a period of at least twelve months from the date when the financial statements are authorised for issue.

Responsibilities of the Accounting Officer for the financial statements

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

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 financial statements represent the underlying transactions and events in a manner that achieves fair presentation.
- conclude on the appropriateness of the Medicines and Healthcare products Regulatory Agency's use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Medicines and Healthcare products Regulatory Agency's ability to continue as a going concern. If I conclude that a material uncertainty exists, I am required to draw attention in my 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 report. However, future events or conditions may cause the Medicines and Healthcare products Regulatory Agency to cease to continue as a going concern.

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 Accounting Officer is responsible for the other information. The other information comprises information included in the Annual Report and Accounts, but does not include 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** 14 July 2020

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 2020

	NOTE	2019/20		2018/19	
		£000	£000	£000	£000
Income					
Trading Income	3.1				
Income from marketing authorisations[1]		**24,710**		29,499	
Income from clinical trials		**3,323**		3,467	
Income from research activities[2]		**3,362**		2,753	
Income from other trading activities		**79,899**		88,291	
Income from Department of Health and Social Care		**43,450**		34,559	
Total Trading Income			**154,744**		158,569
Other income	3.2		**11,953**		12,192
Total income			**166,697**		170,761
Expenditure					
Staff costs	5	**(86,224)**		(82,782)	
Operating costs	6	**(63,569)**		(62,204)	
Total Expenditure			**(149,793)**		(144,986)
Operating Surplus			**16,904**		25,775
Finance income			**584**		421
Finance costs			**(47)**		(52)
Surplus for the financial year			**17,441**		26,144
Other comprehensive income					
Realised gain on inventories*			**(89)**		(78)
Net gain on revaluation of property, plant and equipment*	7		**7,266**		79
Total comprehensive income for the year			**24,618**		26,145

* All gains and losses arise from continuing operations.

The notes on pages 89 to 110 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 2020

	NOTE	31 March 2020		31 March 2019	
		£000	£000	£000	£000
Non-current assets					
Property, plant and equipment	7	**137,789**		136,884	
Intangible assets	8	**14,235**		11,597	
Trade and other receivables	12	**7,753**		8,483	
Total non-current assets			**159,777**		156,964
Current assets					
Inventories	10	**5,838**		5,667	
Contract assets	11	**6,611**		6,592	
Trade and other receivables	12	**27,475**		27,784	
Cash and cash equivalents	13	**89,285**		79,938	
Total current assets			**129,209**		119,981
Total assets			**288,986**		276,945
Current liabilities					
Contract liabilities	11	**(11,124)**		(11,694)	
Trade and other payables	14	**(34,458)**		(32,959)	
Other liabilities	15	**(15,044)**		(15,329)	
Provisions	16	**-**		(321)	
Total current liabilities			**(60,626)**		(60,303)
Total assets less current liabilities			**228,360**		216,642
Non-current liabilities					
Contract liabilities	11	**(3,555)**		(3,533)	
Other liabilities	15	**(25)**		(21)	
Provisions	16	**(1,711)**		-	
Borrowings		**(1,328)**		(1,328)	
Total non-current liabilities			**(6,619)**		(4,882)
Assets less liabilities			**221,741**		211,761

Taxpayers equity					
Public dividend capital			**1,329**		1,329
Reserves					
Revaluation reserve			**115,155**		107,978
Income and expenditure reserve			**954**		954
General fund			**104,303**		101,500
Total equity			**221,741**		211,761

Dr June Raine CBE
Chief Executive and Accounting Officer
Medicines and Healthcare products Regulatory Agency
14 July 2020

The notes on pages 89 to 110 form part of these accounts.

Statement of cash flows for the year ended 31 March 2020

	NOTE	2019/20		2018/19	
		£000	£000	£000	£000
Cash flows from Operating activities					
Operating surplus		**16,904**		25,775	
Depreciation and amortisation	7/8	**8,754**		10,695	
Disposal of assets	7	**5**		307	
Impairment of property, plant and equipment, and intangible assets	7/8	**261**		61	
Realised gain on inventories		**(89)**		(78)	
(Increase)/Decrease in inventories	10	**(171)**		201	
(Increase) in contract assets	11	**(19)**		(6,592)	
(Decrease)/Increase in contract liabilities	11	**(548)**		15,227	
Decrease in trade and other receivables	12	**1,039**		842	
(Decrease) in trade and other payables	14	**(10,942)**		(10,925)	
Increase/(Decrease) in other liabilities	15	**(281)**		(18,367)	
Increase/(Decrease) in provisions	16	**1,390**		(2,147)	
Net cash inflow from operating activities			**16,303**		14,999
Cash flows from investing activities					
Purchase of property, plant & equipment	7	**(1,529)**		(5,622)	
Purchase of intangible assets	8	**(3,768)**		(9,435)	
Net cash (outflow) from investing activities			**(5,297)**		(15,057)
Cash flows from financing activities					
Interest received			**584**		421
Interest paid			**(47)**		(52)
Dividend paid			**(2,196)**		(1,781)
Net cash (outflow) from financing			**(1,659)**		(1,412)
Net increase/(decrease) in cash and cash equivalents in the financial year	13		**9,347**		(1,470)
Cash and cash equivalents at the beginning of the financial year	13		**79,938**		81,408
Cash and cash equivalents at the end of the financial year	13		**89,285**		79,938

The notes on pages 89 to 110 form part of these accounts.

Statement of changes in taxpayer's equity for the year ended 31 March 2020

	PDC	General Fund	Reval reserve	I & E reserve	Total
	£000	£000	£000	£000	£000
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**
Changes in taxpayer's equity for 2019/20					
Surplus for the year	-	17,441	-	-	17,441
Other changes					
Net gain on revaluation of property, plant and equipment	-	-	7,266*	-	7,266
Realised gain on inventories - biological standards	-	-	(89)	-	(89)
Dividend payable	-	(14,638)	-	-	(14,638)
Sub total	-	(14,638)	7,177	-	(7,461)
Balance at 31 March 2020	**1,329**	**104,303**	**115,155**	**954**	**221,741**

* See Note 7

The notes on pages 89 to 110 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 2019/20 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 2019/20.

- IFRS 16 Leases: Effective date 1 April 2021. IFRS 16 will require the recognition of all leases on the Statement of Financial Position, including leases for rented office space. This is expected to have a material impact (Note 11).
- 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.

- Valuation of Property, Plant and Equipment

Plant and Equipment have been revalued in line with Office of National Statistics indices.

A desktop valuation of the NIBSC estate at 31 March was carried out by the Valuation Office Agency. An initial valuation exercise was carried out in February 2020, which was subsequently updated in June 2020 to incorporate the latest indices available for March 2020. In applying the Royal Institute of Chartered Surveyors (RICS) Valuation Global Standards 2020 ('Red Book') the valuer has declared a 'material valuation uncertainty' in the valuation report. This is on the basis of uncertainties caused by COVID-19. The values in the report have been used to inform the measurement of property assets at valuation in these financial statements. With the valuer having declared this material valuation uncertainty, the valuer has continued to exercise professional judgment in providing the valuation and this remains the best information available to the Agency.

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. 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. A desktop valuation of the NIBSC estate at 31 March 2020 was carried out by the Valuation Office Agency. Of the £126.2m net book value of land and buildings subject to valuation, £120.6m relates to specialised assets valued on a depreciated replacement cost basis. Here the valuer based their assessment on the cost to the MHRA of replacing the service potential of the assets. The uncertainty explained in the preceding note 1.3 relates to the estimated cost of replacing the service potential, rather than the extent of the service potential to be replaced.

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 have been assigned to determine the stage of work completed. 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 schedules completed by customers listing fees payable for each product.
- Inspections: Fees are for pre-inspection preparation, travelling time, reporting of inspections and resolving issues. It also incorporates activities such as evaluation of compliance assessment report and other support functions and directly related overheads. Income is recognised on completion of all the inspection processes.
- EMA (European Medicines Agency): Income from EMA work is recognised on completion of predetermined stages, where there is a contract in place or payment is received.
- Applications for clinical trials authorisations and variations: Income is recognised as and when earned. A number of processes have been assigned to determine the stage of work completed. This determines the income to recognise and to defer.
- British Pharmacopoeia income is recognised as and when earned. This is at the point where orders are fulfilled.
- E cigarettes income which is based on the number of notified products. Income is recognised when the application has been validated and published on the website.
- Miscellaneous income: This is non-statutory income recognised as and when earned based on when the service is provided.
- Revenue grants from the Department of Health and Social care for the provision of services are treated as income.
- NIBSC standards income is recognised as and when earned. This is at the point where orders are fulfilled.
- NIBSC research grants, income is recognised in line with expenditure incurred at pre-determined stages as outlined in agreements and in line with IFRS 15.

- Capital grants receivable from governmental and non-government bodies for the purchase of specific capital assets are recognised as income as they are received provided no conditions are attached. Where there are conditions attached to the grant, the income is transferred to deferred income until those conditions are met.

The proportion of the fees receivable for marketing authorisation applications, and variations representing the work estimated to be outstanding to complete the processing of such applications is deferred to future periods and disclosed as contract liabilities in line with IFRS 15.

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. Provisions

A provision is recognised when the agency has a legal or constructive obligation as a result of a past event, it is probable that an outflow of economic benefits will be required to settle the obligation and a reliable estimate can be made of the amount of the obligation. If the effect is material, expected future cash flows are discounted using the real rate set by HM Treasury.

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

1.11. Going concern basis

Based on normal business planning and control procedures, the Agency Board has reasonable expectation that the Agency has adequate resources to continue in operational existence for the foreseeable future. For this reason, the Board continues to adopt the going concern basis for preparing the financial statements.

2. Operating segments

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

The Clinical Practice Research Datalink (CPRD) is the UK Government observational and interventional research service, jointly supported by the National Institute for Health Research and the Medicines and Healthcare products Regulatory Agency.

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

part of the agency it is a world leader in supporting science and research and the regulation of medicines and medical devices, strengthening the support provided to the UK medicine's industry.

MHRA regulatory centre: The regulator is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe.

The 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.

2019/20

	CPRD* £000	NIBSC £000	Regulator £000	Total £000
Income from external customers	5,035	23,468	82,791	111,294
Income from DHSC	-	19,560	23,890	43,450
Total income**	5,035	43,028	106,681	154,744
Direct costs	(4,290)	(39,662)	(54,053)	(98,005)
Indirect costs	(1,467)	(7,490)	(42,831)	(51,789)
Total expenditure	(5,757)	(47,152)	(96,884)	(149,793)
Segment operating (Deficit)/ Surplus	(722)	(4,124)	9,797	4,951

* represents MHRA's 50% share of joint arrangement

** Excludes Other income £12m (see note 3.2)

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

2018/19

	CPRD* £000	NIBSC £000	Regulator £000	Total £000
Income from external customers	5,180	22,613	96,217	124,010
Income from DH	-	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)	(935)	(2,129)	16,647	13,583

3. Income

3.1. Trading income

	2019/20	2018/19
	£000	£000
Income from fee charging activities*	**104,482**	115,577
Income from research activities	**3,362**	2,753
Income from Department of Health and Social Care	**28,660**	28,559
	136,504	146,889
Department of Health and Social Care Miscellaneous**	**14,760**	6,000
Other miscellaneous	**3,450**	5,680
Total Trading Income	**154,744**	158,569

*Includes £3.0M (2018/19, £10.1M) 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.

** Funding from DHSC of £14.8m for EU Exit preparation (£12.6m) and employers pensions contribution (£2.2m).

Income is stated net of VAT.

Analysis of trading income

	2019/20	2018/19
	£000	£000
Licenses and inspections	**32,363**	39,772
Service fees	**33,051**	31,633
European Medicines Agency (EMA)	**2,977**	10,158
Devices	**11,986**	10,107
Clinical trials	**3,322**	3,467
British Pharmacopoeia	**4,742**	4,500
Other trading income	**18,240**	11,680
NIBSC	**43,028**	42,072
CPRD	**5,035**	5,180
Total	**154,744**	158,569

As part of its preparation for EU exit, the Agency received additional funding of £12.6m 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 £12.0M (2018/19, £12.2M) from the Department of Health and Social Care to offset the additional costs of dividend £5.4M (2018/19, £5.3M) and depreciation £6.6M (2018/19, £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 Department of Health and Social Care and the Medicines and Healthcare products Regulatory Agency.

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

Income and expenditure

	2019/20	2018/19
	£000	£000
Income	**10,070**	10,360
Expenditure		
Operating costs	**(7,251)**	(8,007)
Staff costs	**(4,263)**	(4,223)
Operating (deficit)	**(1,444)**	(1,870)

Statement of financial position

	2019/20	2018/19
	£000	£000
Non-current assets		
Tangible assets	**194**	228
Intangible assets	**4,419**	3,654

Current assets		
Trade and other receivables	**3,191**	3,040
Cash and cash equivalents	**8,727**	8,391

Current liabilities		
Trade and other payables	**(937)**	(565)
Other liabilities	**(3,140)**	(850)
DHSC contribution to joint arrangement	**(16,127)**	(16,127)
Assets less liabilities	**(3,673)**	(2,229)

Equity		
(Deficit) b/f	**(2,229)**	(359)
(Deficit)	**(1,444)**	(1,870)
Total Equity	**(3,673)**	(2,229)

Statement of cash flows

	2019/20		2018/19	
Cash flows from operating activities				
Operating (deficit)	**(1,444)**		(1,870)	
Depreciation and amortisation	**1,232**		1,692	
Disposals of assets	**-**		491	
Increase in trade and other payables	**372**		377	
(Increase) in trade and other receivables	**(151)**		(992)	
Increase/(decrease) in other liabilities	**2,290**		(698)	
Net cash inflow/(outflow) from operating activities		**2,299**		(1,000)
Cash flows from investing activities				
Purchase of intangible assets	**(1,963)**		(600)	
Net cash (outflow) from investing activities		**(1,963)**		(600)
Cash flows from financing activities		**-**		-
Net increase/(decrease) in cash and cash equivalents		**336**		(1,600)
Cash and cash equivalents at the beginning of the financial year		**8,391**		9,991
Cash and cash equivalents at the end of the financial year		**8,727**		8,391

Non-current assets

	2019/20	2018/19
	£000	£000
Fixed Asset		
Cost		
At 1 April	**9,593**	10,110
Additions	**1,963**	600
Disposals	**(1,914)**	(1,117)
At 31 March	**9,642**	9,593
Amortisation		
At 1 April	**5,711**	4,645
Charge for the year	**1,232**	1,692
Disposals	**(1,914)**	(626)
At 31 March	**5,029**	5,711
Net Book Value at 31 March	**4,613**	3,882

5. Staff costs

	2019/20	2018/19
	£000	£000
Wages and salaries	**64,302**	63,344
Social security costs	**6,768**	6,996
Other pension contributions	**15,343**	12,442
Sub total	**86,413**	82,782
Less recoveries in respect of outwards secondment	**(189)**	-
Total	**86,224**	82,782

See staff report page 71.

6. Operating costs

	2019/20	2018/19
	£000	£000
Computing	**19,756**	24,746
Accommodation	**10,416**	7,812
Medicines testing and Laboratory expenses	**9,850**	9,355
Depreciation and amortisation	**8,754**	10,695
Travel and subsistence	**2,022**	2,020
Other operating costs	**12,771**	7,576
Total	**63,569**	62,204

Other operating costs include:	£000	£000
Contracted out services	**6,369**	5,993
Operating leases (land and buildings)	**2,439**	2,561
Statutory audit fees	**105**	110

7. Property, plant and equipment

2019/20	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 2019	**4,464**	**126,025**	**8,050**	**25,419**	**108**	**164,066**
Additions	1,529	-	-	-	-	1,529
Transfers	(3,970)	2,610	673	687	-	-
Reclassification	-	-	23	77	-	100
Impairment	(261)	-	-	-	-	(261)
Revaluation	-	7,231	-	84	(1)	7,314
Elimination of accumulated depreciation	-	(9,710)	-	-	-	(9,710)
Disposals	-	-	(640)	(361)	(1)	(1,002)
At 31 March 2020	**1,762**	**126,156**	**8,106**	**25,906**	**106**	**162,036**
Accumulated depreciation						
At 1 April 2019	**-**	**4,795**	**5,850**	**16,450**	**87**	**27,182**
Reclassification	-	-	13	77	-	90
Charge for the year	-	4,915	1,028	1,681	10	7,634
Revaluation	-	-	-	49	(1)	48
Elimination of accumulated depreciation	-	(9,710)	-	-	-	(9,710)
Disposals	-	-	(637)	(359)	(1)	(997)
At 31 March 2020	**-**	**-**	**6,254**	**17,898**	**95**	**24,247**
Net book value						
At 31 March 2020	**1,762**	**126,156**	**1,852**	**8,008**	**11**	**137,789**
Net book value at 31 March 2019	4,464	121,230	2,200	8,969	21	136,884
Owned						
Net book value at 31 March 2020	**1,762**	**126,156**	**1,852**	**8,008**	**11**	**137,789**

Land and buildings

A professional desktop valuation of land and buildings was carried out on 31 March 2020 which resulted in a net revaluation of £7,266k. 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.

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
Accumulated 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.

8. Intangible assets

2019/20	Computer systems	AUC	Software licences	Total
	£000	£000	£000	£000
Cost or valuation				
At 1 April 2019	**24,085**	**5,401**	**3,616**	**33,102**
Additions	-	3,768	-	3,768
Transfers	871	(881)	10	-
Reclassification	(23)	-	(77)	(100)
Disposals	(949)	-	(121)	(1,070)
At 31 March 2020	**23,984**	**8,288**	**3,428**	**35,700**
Accumulated amortisation				
At 1 April 2019	**17,907**	**-**	**3,598**	**21,505**
Reclassification	**(13)**	**-**	**(77)**	**(90)**
Charge for the year	1,108	-	12	1,120
Disposal	(949)	-	(121)	(1,070)
Amortisation at 31 March 2020	**18,053**	**-**	**3,412**	**21,465**
Net book value at 31 March 2020	**5,931**	**8,288**	**16**	**14,235**
Net book value at 31 March 2019	6,178	5,401	18	11,597
Asset financing				
Owned				
Net book value at 31 March 2020	**5,931**	**8,288**	**16**	**14,235**

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
Accumulated 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

9. 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	2019/20	2019/20	2018/19	2018/19
	£000	**£000**	£000	£000
Minimum lease payments	**43**	**2,439**	49	2,561
Total	**43**	**2,439**	49	2,561

Total future minimum lease payments	2019/20	2019/20	2018/19	2018/19
	£000	**£000**	£000	£000
Payable:				
Within one year	**-**	**2,439**	-	1,997
Between two to five years	**-**	**9,757**	-	7,987
Over five years	**-**	**20,076**	-	18,430
Total	**-**	**32,272**	-	28,414

10. Inventories

	31 March 2020 £000	31 March 2019 £000
Biological Standards	**5,719**	5,608
Laboratory consumables and other stores	**119**	59
Total	**5,838**	5,667
Inventory consumed	1,423	677

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 2019/20 was £89k (2018/19, £78k).

11. Contract assets and contract liabilities

	Current		Non current	
	31 March 2020 £000	31 March 2019 £000	31 March 2020 £000	31 March 2019 £000
Contract assets (unbilled receivables)	**6,611**	6,592	**-**	-
Contract liabilities (customer advances)	**11,124**	11,694	**3,555**	-

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.

12. Trade and other receivables

	31 March 2020 £000	31 March 2019 £000
Amounts falling due within one year		
Due from the DHSC (see 14.1 below)	**11,953**	12,192
Trade receivables*	**8,710**	9,729
Other receivables	**998**	1,604
Accrued income	**3,183**	1,954
Prepayments	**2,631**	2,305
Total	**27,475**	27,784
Amounts falling due after more than one year:		
Prepayments	**7,753**	8,483
Total	**35,228**	36,267

*Trade receivables are shown net of a provision for bad debts of £113k (31 March 2019 £79k) calculated using the simplified approach in line with IFRS 9 and credit notes for all unpaid periodic fees at year end of £417k (31 March 2019 £601k).

13. Cash and cash equivalents

	31 March 2020 £000	31 March 2019 £000
Balance at 1 April	**79,938**	81,408
Net change in year	**9,347**	(1,470)
Balance at 31 March	**89,285**	79,938

Made up of		
Government Banking Service	**89,285**	79,938
Cash and cash equivalents	**89,285**	79,938

* includes £4.4m held on behalf of CPRD joint arrangement

14. Trade and other payables

	31 March 2020 £000	31 March 2019 £000
Amounts falling due within on		
Due to Department of Health and Social Care (see 14.1 below)	**14,684**	14,465
Payments received on account	**4,648**	2,584
Taxation and social security	**3,329**	3,093
Other trade payables	**1,739**	1,721
Accruals	**10,058**	11,095
Total	**34,458**	32,958

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

	31 March 2020 £000	31 March 2019 £000
Accruals	**46**	50
Other payables	**-**	27
Dividend payable	**14,638**	14,388
Total	**14,684**	14,465

15. Other liabilities

	Current		Non-current	
	31 March 2020 £000	31 March 2019 £000	31 March 2020 £000	31 March 2019 £000
Deferred revenue:				
Other fees	**2,474**	2,115	**25**	21
Others:				
DHSC Contribution to CPRD joint arrangement*	**12,570**	13,214	**-**	-
Total	**15,044**	15,329	**25**	21

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

16. Provisions

	Current		Non-current	
	31 March 2020 £000	31 March 2019 £000	31 March 2020 £000	31 March 2019 £000
EC grant refund	**-**	165	**-**	-
Dilapidations	**-**	156	**1,711**	-
Total	**-**	321	**1,711**	-

Movement in provisions

	Total £000
At 1 April 2019	**321**
Arising during the year	**1,711**
Used during the year	**(321)**
At 31 March 2020	**1,711**

Expected timing of cash flows:

Within one year	**-**
Between two to five years	**-**
Over five years	**1,711**
Total	**1,711**

17. Capital and other financial commitments

Contracts entered into, not provided for in the accounts

	Intangible	Tangible	Intangible	Tangible
	31 March 2020	31 March 2020	31 March 2019	31 March 2019
	£000	£000	£000	£000
Contracted	**1**	**1,377**	571	1,340
Total	**1**	**1,377**	571	1,340

18. Related party transactions

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

In addition, the agency has had various material transactions with other government departments and other central government bodies. Most of these transactions have been with the Government Property Agency.

During 2019/20, 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 and members of the key management staff may hold. Details of compensation for key management staff are disclosed in the remuneration and staff report.

19. Financial instruments

All financial assets and financial liabilities held by MHRA are measured at amortised cost.

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.

	2019/20 £000	2018/19 £000
Government Banking Service*	**89,285**	79,938
Total	**89,285**	79,938

* Includes £54k Proceeds of Crime Act funds which are the Agency's share of confiscated monies resulting from successful prosecutions and £239k 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 (2018/19: £1.328M). This resulted in interest payable of £0.046M (2018/19: £0.046M) out of total expenditure of £149.8M (2018/19: £144.9M).

Currency risk

The level of currency risk is determined by the level of income generated by activity undertaken on behalf of the EMA. For 2019/20 this was £2.977M (Euro 3.336M) (2018/19: £10.158M; Euro 11.859M). This represents 1.9% (2018/19: 5.9%) 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 2020:

	2019/20		2018/19	
	Increase £000	Decrease £000	Increase £000	Decrease £000
Movement 1 %	**22**	**(23)**	97	(99)
Movement 3 %	**66**	**(70)**	286	(303)

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 £2.8M (2018/19 £1.4m).

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.

20. Events after the reporting period

The outbreak of the novel coronavirus (COVID-19), declared by WHO as a "Global Pandemic" on 11 March 2020, has impacted activity and valuations in the real estate market. In recognition of the scale of the impact we have reassessed the valuation of the Specialised Assets Value at the NIBSC estate adopting the retrospectively revised Building Cost Information Service (BCIS) Index, as published by BCIS in June 2020, in respect of the valuation date of 31 March 2020.

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

HM Treasury minute dated 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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