Medicines & Healthcare products Regulatory Agency

Annual Report and Accounts 2020/21




CPRD NIBSC MHRA

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Medicines and Healthcare products Regulatory Agency Annual Report and Accounts 2020/21

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Chairman's Foreword

I feel very privileged to have been appointed as the fourth Chair of the MHRA Board and I would like to start by thanking my predecessor Professor Sir Michael Rawlins GBE Kt, who was the Chair of the Board from 2014 to 2020, for his significant contribution both to the Agency and to UK public health. It is an honour to follow in his illustrious footsteps.

2020 has been a year like no other and the unique breadth of the agency's scientific expertise has been in the public spotlight more than at any other time in its history as the MHRA has supported the UK response to the COVID-19 pandemic. This has involved pro-active advice, team work as "one agency", streamlined processes and robust, evidence-based decisions from our highly talented staff as we have approved clinical trials, diagnostic tests, ventilators, therapeutics and vaccines, before monitoring safety signals, working with partners and updating our guidance quickly as new information became available.

The pandemic would have been more than enough to test any organisation's capabilities, but the MHRA has also been supporting the Government and the life sciences industry through the UK exit from the European Union. This required new legislation, new regulatory processes, extended regulatory transition arrangements and pragmatic guidance. In addition, the Agency has continued to respond to the findings of the Independent Medicines and Medical Devices Safety Review with a genuine commitment to improve our safety monitoring, patient communication and integrated working in the health system.

The combination of COVID-19, EU exit and the Independent Medicines and Medical Devices Safety Review (IMMDSR) has given us a once-in-a generation opportunity to redefine the regulation of medicines, medical devices, diagnostics and digital health technologies in this country, so that the MHRA can be become a global exemplar of progressive, pragmatic and risk-proportionate regulation based on scientific evidence and partnership working that puts patients at the centre of everything we do.

Our ambition is for the MHRA to enable the research, development, manufacturing and regulatory approval of innovative medical technologies and medicines in the UK so that patients can gain earlier and safer access to new medical products than ever before.

To realise these opportunities, the MHRA must build on its strengths, develop its people, invest in its own technology infrastructure and prioritise its activities so that our organisation can become leaner, more focused and more responsive to the needs of patients, healthcare professionals, researchers, developers, manufacturers and the general public.

This starts with the strategic leadership and strong governance provided by our new unitary Board of Directors, which is comprised of seven Executive Directors (including five new Chief Officer roles) and seven independent Non-Executive Directors, plus myself as the Non-Executive Chair. All of our Board Meetings are now held in public and video recordings are published on our websites so that members of the public and our staff can see how we make decisions and drive the organisation forward.

None of this would have been possible without the incredible dedication and expertise of everyone working at the MHRA and I'd like to express my grateful thanks to everyone involved in the last year as we look forward to the future with confidence and optimism.

Stephen Lightfoot
Chair

Chief Executive's perspective on performance of the organisation

After this truly exceptional year, I would like to start by wholeheartedly commending all the Agency's staff for their dedicated work during the most challenging period to date for our organisation. Not only has the Agency made a major contribution to the nation's fight against COVID-19 and successfully managed the transition from EU Exit, but we have made substantial progress in delivering an exciting new future operating model which places patients at the heart of all our activities.

This is my second foreword, first as interim Chief Executive from September 2019 and now, I am pleased to say, in the substantive role as from February 2021. In August 2020 Professor Sir Michael Rawlins GBE Kt stepped down after six years of distinguished service as Chairman of the Agency Board, and I would like to record the Agency's utmost gratitude for his contribution to safeguarding public health through effective regulation. I was delighted to welcome our new Chairman, Stephen Lightfoot, as his successor to guide the Agency in this time of change and opportunity.

The COVID-19 pandemic fully demonstrated the vital part a progressive, flexible regulator can play in supporting speedy initiation of clinical trials and prompt access to vital healthcare products and diagnostic tests. We approved the first COVID-19 vaccines, leading the way to the end of the pandemic. The Clinical Practice Research Datalink (CPRD) enabled data flows for vaccine surveillance, and the Coalition for Epidemic Preparedness Innovations (CEPI) selected the National Institute for Biological Standards and Control (NIBSC) to form part of a centralised laboratory to standardise the measurement of immune responses generated by multiple COVID-19 vaccines. This was an outstanding 'One Agency' response.

I was particularly proud that staff across the Agency stepped up to support the response to the pandemic in difficult circumstances, under a national lockdown which saw most members of staff working from home while others, in particular those at NIBSC, were on site to keep the essential laboratory work of the Agency such as medicines batch control testing going, including for COVID-19 vaccines. As I write this, the roadmap out of lockdown is entering its final phase, and the new collaborative ways of working established in our response to the pandemic have been distilled to ensure that the Agency is well positioned to build back better.

New opportunities in how we regulate medicines and medical devices are opening up with the end of the year-long transition period after leaving the EU. Our initial approach to preparing for our new role as a sovereign regulator has been pragmatic, including introduction of reliance on EU decisions and the implementation of grace periods for medical device requirements. We continue to work with the EU as the responsible regulatory authority for Northern Ireland and we have supported industry in relation to the provisions of the Northern Ireland Protocol. The supply of medicines, medical devices and blood products to UK patients has continued and the impressive scale of staff achievements to ensure this happened cannot be overestimated.

The publication on 8 July 2020 of the Report of the Independent Medicines and Medical Devices Safety Review, chaired by Baroness Julia Cumberlege, was a landmark of profound importance for the Agency, since the safety of the public is and always has been our first priority. A broad programme of work to address the recommendations of the Review has been established, encompassing developing our patient and public engagement and involvement, developing a more responsive safety and reporting system, and improving evidence for patient safety decisions.

The driver for change of the IMMDSR, the opportunities of EU Exit, the emergence of the Agency as a progressive regulator during the pandemic, together with the demonstrable excellence of the UK Life Sciences industry, have all shaped the case for transformational change. We have created a future operating model based on the principle of 'One Agency - delivering for patients', with a clear focus on innovation and integration around the product lifecycle. In parallel, we launched the Innovative Access Licensing Pathway (ILAP) to reduce the time to market for innovative medicines, readying the MHRA for a new era in medicines approvals in the UK. This transformation must be delivered if we are to achieve our mission and have a viable organisation for the future.

Over the last year the Agency has also focused on building our international role. A particularly important step forward was joining the ACCESS Consortium with regulators from Australia,

Canada, Singapore and Switzerland, aligned by common values of high standards of scientific rigour and integrity, together with the aim of reduced regulatory duplication to bring more timely access to medicines to an even larger population. We joined the United States Food and Drug Administration's (FDA) Project Orbis to review and approve promising cancer treatments. International collaborations such as ACCESS and Orbis will enable cutting-edge treatments to be safely fast-tracked to patients.

None of these achievements, and none of these plans to grasp these once-in-a-generation opportunities, would be possible without our talented and expert staff. Staff retention, talent development and wellbeing are key priorities. As well as the launch of our mental health and wellbeing campaign, work is under way to develop an Equality Framework to consider how we can support all colleagues to reach their full potential and a new BAME staff network was established in June 2020. Together these initiatives will help us to consider the best ways to progress a culture of inclusion and achievement for everyone.

In conclusion, after a year of outstanding achievement and regulatory agility, I am committed to delivering our One Agency vision, to optimize and improve our service to patients and the public as a patient-focused world-leading regulator, establishing innovative pathways across the product lifecycle for medicines and devices supported by robust and responsive vigilance systems.

Dr June Raine CBE
Chief Executive

1.1 Overview

Purpose and activities

Who we are

The Medicines & Healthcare products Regulatory Agency (MHRA) safeguards public health in the UK through the licensing & enforcement of medicinal products for human use, and enforcement of the laws relating to medical devices. The MHRA also regulates clinical trials of medicines & medical devices.

Mission

Our mission is to protect and improve patient health by enabling the earliest access to and high-quality supply of safe, effective and innovative medical products through proportionate, data-driven assessment of risks and benefits.

Aims

Our work in 2020-21 was focused on the five key objectives as set out in our Business Plan for the year:

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 healthcare 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 risk-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 work with external partners.

Composition

The Agency has a globally unique concentration of expertise in data, standards and regulation in a single organisation. Our three complementary centres work together to enable us to protect patients and public health and improve lives.

The Medicines and Healthcare products Regulatory centre is the UK regulator of medicines, medical devices and blood components for transfusion, responsible for ensuring their safety, quality and effectiveness. 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.

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

NIBSC:

- Is responsible for developing and producing over 90% of the standards in use around the world to assure the quality of biological medicines and diagnostics
- Is a World Health Organization (WHO) Collaborating Centre for Biological Standardization
- Is the UK's Official Medicines Control Laboratory (OMCL) for biological medicines, carrying out independent medicines control testing and biological medicines evaluation for the UK and international stakeholders such as the WHO; and investigating potentially defective biological medicines from the UK and globally

- Is a stand-alone National Control Laboratory since 1 January 2021; Official Control Authority Batch Release (OCABR) testing for biological medicines was previously undertaken within the framework of the EU until the end of the Transition Period
- Performs world class research with expertise in regulatory science
- Is the home of the UK Stem Cell Bank, the Influenza Resource Centre (encompassing a WHO Essential Regulatory Laboratory), and a WHO Collaborating Centre on poliovirus research and surveillance

The **Clinical Practice Research Datalink** (CPRD) is a real-world research service supporting retrospective and prospective public health and clinical studies. CPRD collects de-identified patient data from a network of GP practices across the UK. Primary care data are linked to a range of other health related data to provide a longitudinal, representative UK population health dataset. The data encompass over 60 million patient records, including 16 million currently registered patients.

The Agency's activities are funded as set out below:

- **Medicines regulation** is funded from fees charged to the regulated industry. 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 from fees charged for services
- **NIBSC** derives approximately half of its revenue from fees charged for services, including the sale of biological standards, and from research funding. DHSC provides the remaining funding to finance its important public health functions
- **CPRD** is jointly funded by MHRA and DHSC's National Institute for Health Research but managed and operated by MHRA with DHSC having equal voting rights in direction setting and decision making

Each of the Agency's centres – the Regulator, NIBSC and CPRD - operates with segmented accounts which highlight their respective financial positions, bearing their appropriate share of corporate services costs. The key principle is that the three centres do not cross-subsidise each other. Following the Governance Review and the work undertaken on the transformation strategy to define a Future Operating Model for the Agency, the centre-based structure of the Agency is expected to change; however, this report is representative of the Agency's structure in the 2020-21 financial year.

MHRA at a glance – our highlights

Responding to the coronavirus pandemic

The Agency has played a key role in the UK's response to the COVID-19 pandemic, from changes in regulatory requirements for medical devices to flexibility around protocols for clinical trials and rapid provision of standards for assay calibration, we have continued to work to ensure the safety, efficacy, quality of medicines and healthcare products across the health system to protect public health and promote patient safety throughout the pandemic.

The intense focus on research and development of candidate vaccines to protect against the COVID-19 virus required prioritised regulatory oversight of clinical trials at a global level. This allowed clinical trials for COVID-19 vaccines to proceed at pace, without compromising any of the usual, high standards of scientific rigour. The MHRA became the first regulator in the Western world to approve a COVID-19 vaccine for use. Preparation at the NIBSC for COVID-19 vaccine control testing has provided the essential pre-market quality assessment for added assurance in the products and enabled the first batch of vaccines to be available on the day the vaccine was approved by the MHRA.

EU Exit

We have worked closely with central government to ensure an effective progression into a post-transition regulatory system and supported DHSC's work to secure supply of medicines for UK patients. We also worked with industry in preparation for the end of the transition period by publishing extensive detailed guidance documents to support the implementation of the legislation.

Supporting clinical research

We have significantly expanded our CPRD population coverage, with one in every five GP practices across the UK now contributing anonymised patient data to CPRD. Working with Brunel University, CPRD researchers have developed a novel method to generate high-fidelity synthetic data, which replicates the complex clinical relationships within the original patient data but is completely artificial. In July 2020 we released a synthetic dataset which focuses on cardiovascular disease risk factors and a COVID-19 synthetic dataset.

Driving innovation

We have launched our Innovative Licensing and Access Pathway (ILAP) which aims to reduce the time to market and patient access for innovative medicines.

The British Pharmacopoeia (BP) has worked to develop standards that will enhance innovation; we have worked collaboratively with the NHS, academia and industry to develop guidance and standards that support the assurance of quality across the product lifecycle.

The NIBSC developed a portfolio of coronavirus-related biological reagents to support diagnostics, vaccine development and research on COVID-19 and SARS-CoV-2, including the first WHO International Standards for SARS-CoV-2 RNA and anti-SARS-CoV-2 immunoglobulin. SARS-CoV-2 variants of concern (VOC) are being made available with support from CEPI and in collaboration with Public Health England (PHE).

Advancing early access to medicines

We have accelerated Early Access to Medicines Scheme (EAMS) reviews and sought expert advice on COVID-19 specific treatments to ensure medicines are made available to patients to cover an unmet clinical need. During 2020/21 we continued to make new medicines available to patients prior to their regulatory approval. We awarded 17 Promising Innovative Medicine (PIM) designations and approved 11 EAMS scientific opinions.

Improving patient and public engagement

Building on our public consultation in 2019, we have developed an ambitious patient and public involvement strategy which will put patients at the centre of our work. Our patient involvement strategy was informed through public consultation, and the resulting draft strategy was one of the first to navigate our new assurance processes, receiving approval from the Patient Safety & Engagement Committee and MHRA Board. Patients and the public will have a final opportunity to input their views through a public consultation prior to approval and publication in 2021/22.

We have engaged with patients and healthcare professionals to help improve the Agency's ability to proactively monitor and act on patient safety insights across the lifecycle of a medicine or healthcare product via our SafetyConnect programme.

In parallel, we have been making great strides to engage and involve patients more in our work, highlighted by the significant increase in the number of workshops and consultations that we have run across the year. We have also participated in events during the year to reach groups and communities, answering questions on COVID-19 vaccines.

We worked closely with stakeholders and pharmaceutical industry Trade Associations to develop an additional safety information leaflet for all opioid medications, which includes prominent addiction warnings ensuring that patients are aware of the potential risk.

We launched our emollients campaign and worked with stakeholders to develop information, education and training to inform healthcare professionals patients and the public of this risk of severe and fatal burns when dressings, clothing or bedding have been in contact with emollient skin products.

The culture change required to deliver our patient-first ambition for the organisation is also making good progress with the successful rollout of a new patient-focused value, aligned personal objectives, and the launch of patient engagement training, with much more planned in the year ahead.

Monitoring, improving, and regulating medical devices

We have reviewed technical evidence for medical devices to reduce counterfeits entering the supply chain and to provide assurance that devices were compliant with relevant standards and were fit for use in COVID-19 health care settings.

We have been working on improving the impact of our safety messaging. To achieve this we have instigated a new governance committee called the Signals Risk and Messaging Committee (SRM), developed new tools for issuing safety messages called Devices Safety Information and issued the first MHRA National Patient Safety Alert (NatPSA).

We have also developed a new safety messaging tool called 'Devices Safety Information' which is used for safety messages that do not meet the specific National Patient Safety Committee criteria but are still important for healthcare professionals to be aware of.

In early 2020 we undertook an extensive credentialling process and were successfully accredited to issue National Patient Safety Alerts by the NaPSAC in March 2020. NatPSAs are aimed at senior people in the NHS who are able to affect change and are only issued for the most serious and important issues that will have a widespread impact on the healthcare system.

Supporting the health system

We worked closely with DHSC, Public Health England (PHE) and the National Health Service (NHS) to maintain supply of medicines to treat COVID-19 patients.

The NIBSC responded to requests from the NHS to produce control reagents to support the molecular detection of COVID-19 and other common winter respiratory viruses such as influenza. These reagents helped the differentiation between viruses and aided the prevention of hospital-acquired infections by ensuring that patients received the most appropriate treatment.

Tackling crime and fake medicines

We lead on the protection of the medicines supply chain from serious threats posed by the supply of falsified medicines. We worked with enforcement partners that stretched across Europe and as far afield as Singapore and Australia to dismantle an international crime network involved in the illegal sale of medicines online. MHRA investigators seized over half a million doses of unlicensed medicines and class C controlled drugs from residential and commercial premises in the UK.

We continue to work with domestic and international enforcement teams to secure positive outcomes from our enforcement work and the risk to the public was either removed entirely or reduced rapidly to acceptable levels.

Our values and culture

We are committed to improving patient health by enabling early access and high-quality supply of safe, effective and innovative medical products. To do this we consider and make evidence-based decisions on risks and benefits. We focused our attention throughout 2020-21 on supporting the priority objective of delivering a clear embedded focus on patients and the public across our workforce.

Programmes of work such as the Values & Behaviours roll out remained a priority, contributing to the plan to increasingly focus on priorities such as engagement of patients and the public, working together pan-agency with mutual respect and taking responsibility and ultimately accountability for outcomes. We also reformulated and refreshed our Transformation Programme to build our new capability, to deliver for patients and public health by putting the patient at the heart of how we operate, in our operating model, in our structure and in our ways of working.

Delivering our aims

COVID-19

We continue to play a key role in tackling the coronavirus pandemic. The Agency has been at the forefront of the UK's response, demonstrating our dedication to safeguarding public health in the UK. The MHRA became the first regulator in the Western world to approve a COVID-19 vaccine for use. We have worked on redesigning the legislative frameworks for medicines, medical devices and clinical trials to meet the unprecedented demand.

» We accelerated COVID-19 specific applications for medicinal products to be used as first line treatment or supportive treatment for patients affected by COVID-19.

» We have modified the clinical trial authorisation processes to ensure that COVID-19-related trial activity was supported at pace. We were able to approve COVID-19 initial applications in days rather than weeks or months as we have procedures for rapid scientific advice, reviews and approvals. For example, we approved the Oxford University/ AstraZeneca COVID-19 vaccine trial in just seven working days – without compromising any of the robust requirements.

» We worked to support the continued supply of medicines for UK patients by leading and contributing to the MHRA COVID-19 Task Force for medicines supply, working flexibly and responsively across the system with DHSC, NHSE and PHE.

» The inspectorate swiftly adapted its inspection model to deliver over 700 remote inspections to ensure regulatory oversight of the quality and safety of medicines during the COVID-19 pandemic. Targeted physical inspections of clinical trials and manufacturing sites played a critical role in the rapid delivery of the first COVID-19 vaccines.

» Our medical devices division has developed Target Product Profiles (TPPs) to assist manufacturers in designing and delivering new COVID-19 tests, processed many applications for exceptional use authorisation for COVID-19 tests in support of the National Testing Strategy, and worked with DHSC/NHS Test and Trace to bring lateral flow tests for COVID-19 into widespread use.

» At the start of the pandemic we played a key role in the Government's ventilator challenge to provide an estimated 30,000 ventilators to treat COVID-19 patients. We worked with stakeholders, including external consultant agencies, independent testing labs, and manufacturers who were inexperienced in medical device production.

» Throughout the pandemic we have supported the Government's strategy to stabilise and build resilience in the supply and distribution of Personal Protective Equipment (PPE). We played a key role supporting 'UK-Make': providing authoritative regulatory and technical advice to DHSC and industry. Example products include transparent face masks to aid communication with patients and reusable medical gowns.

» We participated in the WHO's "Global Research and Innovation Forum: Towards a Roadmap for the 2019 Novel Coronavirus" meeting in February 2020 in Geneva. Staff continue to contribute to scientific workstreams, and participation has led to involvement in WHO-led serology initiatives.

» The NIBSC rapidly prioritised the development of reference materials and

research reagents for the global scientific community. These were made available early to support diagnostics and vaccine research. International Standards for SARS-CoV-2 antibodies and SARS-CoV-2 RNA developed by the NIBSC were formally established by the WHO in December 2020.

» The NIBSC applied its expertise in poliovirus surveillance to the analysis of SARS-CoV-2 RNA in wastewater with earliest detection in samples from early 2020 and has published scientific papers in this area. This unbiased surveillance approach allows for early identification of virus variants circulating in a population such as those first detected in the UK (Alpha), paving the way for detection of other variants e.g. Delta. The team collaborates with academia and is associated with the Defra Group and the Joint Biosecurity Centre (JBC).

» As the UK's Official Medicines Control Laboratory, the NIBSC is responsible for the independent control testing of each batch of COVID-19 vaccines, as supported by the Commission on Human Medicines (CHM). This critical quality verification step takes place prior to vaccine deployment. The NIBSC engaged with multiple vaccine manufacturers from July 2020 to ensure specialised laboratory testing was established in preparation for the UK vaccination programme.

» Financial support to the NIBSC is enabling specialised testing of vaccine clinical trial materials (with CEPI's centralised laboratory), and evaluation of model systems to study pathology and immune responses to the virus (with Innovate UK and UK Research Institute's Medical Research Council (UKRI-MRC)).

» Early in the pandemic we developed a proactive vigilance strategy to monitor the post-marketing safety of any approved COVID-19 vaccines given to the UK public.

» CPRD has fast-tracked review of prioritised COVID-19 research protocols using CPRD data. Research topics include investigating risk factors for COVID-19 infection due to underlying health conditions or pharmacological risk factors, studying outcomes following COVID-19 infection and understanding use of the health service as a result of the pandemic.

» We continually used our various communication channels to regularly update patients and health care professionals. Our social media channels and GOV.UK engagement rates have increased significantly; notably, in March 2021 alone our GOV.UK content generated over 2.3 million unique page views.

» We run the Central Alerting System, which is used to send safety alerts and other safety messaging direct to healthcare providers. Throughout the pandemic we have used this channel to communicate our own alerts and those from the Chief Medical Officer, the Department of Health and Social Care, NHS England & NHS Improvement and Public Health England, helping providers to receive quickly and act upon safety critical actions, including out of hours.

EU Exit

The Agency has supported cross-Government preparations for the future relationship with the EU. This major area of work required the development of new systems and we published detailed guidance on how medicines and medical devices will be regulated after the end of the Transition Period. We will continue to cooperate bilaterally and multilaterally with global regulators,

working together to address current and emerging global regulatory challenges that will benefit patients.

» In preparation for the UK's departure from the EU, our medical devices division published detailed guidance documents to support industry with the implementation of the legislation.

» We contributed to the successful passage through Parliament of medicines and medical device legislation for operating outside the transition period and we continue to work with industry to ensure that they understand the licencing pathways for medicines and that all devices on the UK market are registered with the MHRA.

» The NIBSC provides ongoing support for manufacturers on medicines control requirements to ensure continued market availability.

» We launched the Innovative Licensing and Access Pathway (ILAP) on 1 January 2021 with the ambition to reduce the time to market and patient access for innovative medicines. The ILAP combines the MHRA's globally recognised strengths of independence and high standards of quality, safety, and efficacy, with improved efficiency and flexibility, readying the MHRA for a new era in medicines approvals in the UK.

» We ran an Agency wide "End of Transition Period Task Force". This provided updates on transition, allowed for discussion of regulatory issues and allowed senior oversight of the transition programme to make sure it stayed on track and that we continued to secure supply of medicines and medical devices for UK patients.

» We delivered new IT systems and publishing services to manage regulatory data and safety reports as a standalone regulator. This meant that after 1 January 2021 the Agency was able to continue licensing of medicines, such as COVID-19 vaccines, and registration of medical devices, as well as patient safety monitoring through systems that receive Yellow Card reports.

» We also delivered external webinars ahead of 1 January 2021 to walk industry through the required changes to systems and processes. These webinars were attended by over 13,000 stakeholders.

IMMDS Review

The Independent Medicines and Medical Devices Safety Review (IMMDS Review) was published in July 2020. We have taken this report and its findings extremely seriously and have been responding to the recommendations, working with DHSC and other partners to implement actions in response the review. We are working to improve safety and support patients better. We are determined to put patients and the public at the heart of everything we do as patient safety is the MHRA's top priority.

» We continue to support work for safer medicines in pregnancy and breast feeding as part of the Safer Medicines in Pregnancy and Breastfeeding Consortium, a partnership of 16 leading organisations. The aim of the Consortium is to work together to improve the health information available to women thinking about becoming pregnant and those who are pregnant or are breastfeeding.

» We have continued to work with a range of stakeholders to implement a Pregnancy Prevention Programme for the antiepileptic medicine valproate. The Commission on Human Medicines (CHM) considered an MHRA assessment of the available safety data on the use of epilepsy

medicines during pregnancy. The review findings were communicated publicly in January 2021 to support decisions around the best treatment options for girls and women.

» The Patient Safety and Engagement Committee (PSEC) was established in February 2021 to provide independent consideration of patient safety and patient engagement, such that these are paramount in regulatory decision-making.

» The ILAP combines leading expertise from the UK health system and provides a single integrated platform for sustained collaborative work. Medicines developed through the ILAP will have a stronger focus on patient engagement, including patients being involved in the types of evidence required for regulatory decision making.

Protecting public health

Although the COVID-19 pandemic has made progressing criminal investigations and prosecutions especially challenging this year, the Agency has secured positive outcomes from our enforcement work. Noteworthy results in court this year include sentences of fourteen months imprisonment suspended for two years, with 100 hours of unpaid work, handed down to two defendants for controlled drugs and offences involving the illegal supply of prescription-only medicines. Separately, two registered pharmacists pleaded guilty to supplying millions of doses of controlled drugs and await sentencing following the trial of a third defendant.

The cases highlighted above reflect the ongoing threat from corrupt professionals within the legal medicines supply chain. The MHRA's investigations have protected the public by removing a huge source of supply of addictive tranquiliser medication.

An Adrenaline Auto-injector Expert Working Group (EWG) of CHM was formed in March 2020 to examine ways to ensure the effective and safe use of adrenaline auto-injectors (AAIs) for the emergency treatment of anaphylaxis. The CHM endorsed recommendations from the group which encompassed the prescribing and use of AAIs, improvements in adverse event and defect reporting. They also endorsed the collection of more robust data on device usage and that in principle AAIs should be made available in public locations for use in exceptional circumstances. A key recommendation was that an effective communications strategy would be needed to underpin the delivery, and understanding, of key messages to patients, carers and healthcare professionals as well as to the wider public. The release of the AAI EWG public report will support the implementation of the recommendations.

As part of our proactive vigilance strategy to monitor the post-marketing safety of the approved COVID-19 vaccines, we have gathered data that will be used alongside that generated from academia and other international experts to identify any new risks that may emerge as the vaccines are used. Any identified risks will be fed into a continuous evaluation by the MHRA of the balance of benefits of a vaccine versus risks. The MHRA will consult the CHM and its Expert Groups and, if deemed necessary, regulatory action would be taken to minimise risk and support safe use of a given vaccine.

Regulating and setting standards

The British Pharmacopoeia (BP) has worked to develop standards that will enhance innovation. As part of the BP's strategy for Advanced Therapy Medicinal Products, we have worked collaboratively with the NHS, academia and industry to develop guidance and standards that support the assurance

of quality across the product lifecycle. This has been supported by the development of strategic collaborative partnerships, for example the development of an innovative staff exchange programme with the UK's Cell and Gene Therapy Catapult. This has built capability across both organisations and enabled enhanced stakeholder engagement with the cell and gene therapy community.

The successful publication of the strategy for the application of Analytical Quality by Design principles to pharmacopeial standards is a pivotal outcome of the BP's recent work to collaborate with industry stakeholders. It has laid the foundation for the transformation of BP's standards, ensuring they enhance innovation by enabling the adoption of innovative analytical technologies.

This year we have published consultation draft guidance on Randomised Controlled Trials Generating Real-World Evidence (RWE) to Support Regulatory Decisions. Real-world data is routinely collected while patients go about their regular lives, as opposed to being specifically collected in a clinical trial. RWE has the potential to increase the speed and reduce the cost of development programmes, which would see effective medications being approved more quickly, or even programmes which were previously thought to be unfeasible becoming feasible, with the consequent benefit to public health.

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 seen many medical device innovations ranging from in vitro diagnostics to novel mask designs and ventilators. In relation to medicinal products, the Innovation Office has been particularly busy in providing early-stage advice on novel clinical trial designs including the use of RWE in a number of therapeutic areas that has required a close collaboration to provide joint advice with the Health Research Authority.

The NIBSC plays an essential role in safeguarding public health because the effective use of vaccines, biotherapeutic products and diagnostics depends on the availability of the biological standards supplied by the NIBSC. The institute remained operational during the series of national lockdowns by implementing its business continuity plan and ensuring COVID-secure measures on the site. To support laboratory diagnosis of COVID-19, the NIBSC developed CE-marked external run controls that monitor the day-to-day performance of molecular and serological tests.

1.2 Performance Analysis

Sustainability report

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

Energy management performance

Electricity and gas consumption at the NIBSC site at South Mimms, Hertfordshire (laboratory site) have been collated since 2009/10 and at the MHRA London offices at 10 South Colonnade (10SC), Canary Wharf, since 2018/19. The electricity and gas consumption reduction for South Mimms is 15% and 12% and for 10SC is 8% and 13% respectively. Overall, there was a slight reduction this year as activity continued on the South Mimms site throughout the lockdowns. There are some contributing factors which are detailed below.

Carbon emission performance

South Mimms' and 10SC's carbon footprints continue to fall year on year. South Mimms' has fallen from a 2009/10 baseline of 8,633 TCO2 to 5,419 TCO2 this year, giving an overall 37% reduction. 10SC's has fallen from 2019/20 baseline of 2,038 TCO2 to 387 TCO2 this year, giving an 81% reduction. The impacts are different for the two sites, with 10SC's change being from business travel and South Mimms' from energy consumption, due to the nature of the work at each site. This has resulted in an overall 46% reduction in the Agency's carbon footprint.

The significant reduction in the carbon footprint for the 10SC site is mainly due to the travel restrictions in place with the pandemic. This has had a big impact on the Agency's work activities. The reduction for the South Mimms site is much lower because the NIBSC remained operational during the series of lockdowns throughout the year in order to continue its role in safeguarding public health.

The UK Government recognised the benefits of a greener estate by setting out high level targets, namely Greening Government Commitments. Although the Agency is exempt from direct reporting, as advised by the DHSC, it has still met these targets.

The 2020/21 results are shown below, with South Mimms' results compared to a 2009/10 baseline, and 10SC's results compared to a 2019/20 baseline:

- cut greenhouse gas emissions by 32%: South Mimms by 39% and 10SC by 12%;
- reduce domestic flight carbon emissions by 30%: South Mimms by 99% and 10SC by 100% – both due to the travel restrictions due to the pandemic
- reduce waste to landfill to less than 10%: both sites have 0% waste to landfill
- continue to reduce water consumption (no target given): South Mimms & 10SC by 33%

Renewable technology performance

The Agency continues to benefit from its first step into renewable technology with a large-scale solar project put in place after being awarded accreditation for the Ofgem "Feed in Tariff" (FIT) Scheme, with income to date from this scheme of £124k. The FIT Scheme accreditation means that throughout the

20-year lifetime of the asset we expect to receive an estimated income of £700k in addition to saving an estimated £2.1m on electricity costs and 8,350 MWh generation. This project has reduced our energy consumption and carbon footprint, demonstrating the Agency's Green commitment to keep 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, with Agency leadership assigned to the Chief Scientific Officer, and cascading down through the Executive Committee (ExCo) to Centre and Divisional management. The Unitary Board supports the Chief Executive in maintaining high standards of corporate governance and health and safety risk 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 subcommittees, 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 2020/21 included: achieving excellence in leadership and culture, continued regulatory compliance, successful migration to ISO 45001 certification at the London site, 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. The Agency staff responded rapidly to health and safety measures implemented during the COVID-19 pandemic which enabled critical work of the Agency to continue, both on site and from home, whilst ensuring the safety of all staff and others involved in supporting the work of the Agency. Health and safety training courses and procedures for auditing were adapted to enable remote delivery due to increased homeworking and social distancing requirements.

The management system for overseas travel within the Agency is continuing to work well and further work was completed to include the risks presented by the COVID-19 pandemic. Individual COVID-19 risk assessments were implemented for essential travel. A Travel Safety Application has been introduced across the Agency to ensure the safety of staff when working offsite in the UK and overseas.

Ensuring regulatory compliance and working proactively with the Health and Safety Executive (HSE) supports the safe working of scientists at the NIBSC, on existing new or emerging pathogens, at appropriate biological containment levels and in adjusting to legislative changes. This year it included approval from HSE for work on SARS-CoV-2 virus.

Performance against targets in 2020/21

No.	Area	Target description	Target	2020/21 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%**	**91%**	Not met	New MA area was significantly impacted by operational pressures in the Centrally Au-thorised Products (CAP) Grandfather-ing area during Q4. Various technical issues surrounding the CAP Grandfathering processing necessitated the short-term rede-ployment of experi-enced staff from the business as usual (BAU) new MA area into sup-porting CAP Grand-fathering. This re-sulted in some limited slippage in per-formance against the PM1 target. This area is now beginning to return to normal in-target performance but a residual impact will be seen in Q1 2021-22
		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) procedures: 97% assessed within the designated time*	**97%**	**98%**	Met	
			97%	**96%**	Nearly met	
		c) The assessment of Type IB minor and Type II major variation applications in National and European (MRP) procedures: 97% assessed within the designated time.	**97%**	**98%**	Met	
			97%	**98%**	Met	
PM3	Assessment of clinical trials and investigations	a) The initial 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	**12.2**	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%**	**99%**	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 25% of the total UK population	**20%**	**21.5%**	Met	
		c) 1 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	The deadline for response was not met in a small minority of cases for reasons including resourcing issues and increased workload due to COVID-19.
		b) Aim to return all responses to Parliamentary Questions (PQs) to the DHSC by noon on the date specified	**100%**	**97%**	Nearly Met	The deadline for response was not met in a small minority of cases for reasons including resourcing issues and increased workload due to COVID-19.
		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 12 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%**	**43%**	Met	
		b) Fewer than 5 major incidents (Categories: Priority 1 and 2 caused by change)	**less than 5**	**0**	Met	
		c) No major problem tickets open for more than 6 weeks	**0**	**0**	Met	
PM11	Information Management	a) Cybersecurity: Information Security Incidents resolved within 15 days of being reported	**95%**	**81%**	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 Protection: Individual Rights Requests (IRR) provided with a response within GDPR timescales.	**95%**	**100%**	Met	

Financial review

The Agency's financial performance in 2020/21 reflects the continued change in the Agency's sources of funding and revenue after the UK's exit from the European Union. This financial year the agency's performance has also been impacted by the pandemic.

As a Trading fund 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.

The Agency is funded mostly by income from fees for both statutory and non-statutory sales of products and services. Income from external customers arising from fee-charging statutory activities as well as other commercial activities in 2020/21 was £103.2m which was £8.1m lower than in 2019/20. The decline in revenues reflected primarily a reduction in the level of annual service fee, and lower non-statutory sales at NIBSC as focus and capacity during the year was diverted onto the COVID-19 effort, leading to deferral of work in other areas. Income from research activities in 2020/21 also decreased from last year. As in the preceding financial year, the Agency received EU Exit transition funding from DHSC, which amounted to £12.8m in 2020/21 - broadly comparable to that received in 2019/20 of £12.6m. Consequently the 2020/21 total trading income of £146.5m was £8.2m lower than that in 2019/20.

Staff costs increased by £6.2m (7.2%) reflecting mainly a 7.5% increase in the average number of employees, both permanently and temporarily employed, the latter primarily to increase capacity for peak workload during EU Exit transition and for the COVID-19 effort. Also contributing to the cost increase was a Civil Service pay settlement of 2.5%. Operating costs increased by £2.9m from last year. A £3.4m increase in computing costs in 2020/21 and a further £1.6m increase in depreciation and amortisation have been partially offset by lower accommodation and travel and subsistence costs, the latter substantially reduced due to the national lockdowns and travel restrictions, which prevailed through most of the year.

The resulting 2020/21 operating surplus before interest and dividends was £0.03m compared to £16.9m in 2019/20. The reduction in operating surplus in 2020/21 was due to a combination of lower revenue (£7.7m) and an increase in costs (£9.2m). Total comprehensive loss for the year was £3.5m after net financing costs of £0.015m and a £3.34m revaluation loss on property, plant and equipment, largely the land and buildings at the South Mimms site, which reversed some of the revaluation gain recorded in 2019/20.

After dividends payable of £15.3m a net deficit of £15.3m was transferred to general reserves.

2020/21 has seen a net cash outflow from operating activities of £3.0m compared to £16.3m inflow in 2019/20. The current year operating cash outflow was driven by the small operating surplus of £0.03m adjusted for non-cash items (add back depreciation of £10.3m and provisions of £2.1m; less DHSC non-cash funding of £12.4m) along with a £3.3m cash outflow from an increase in working capital.

Cash for purchases of tangible and intangible assets was a further outflow of £4m and there was a net cash outflow of £2.7m from financing activities, mainly the payment of a cash dividend to DHSC. As a result, cash and cash equivalents at 31 March 2021 were £9.7m lower than those at 31 March 2020.

Dr June Raine CBE
Chief Executive and Accounting Officer

Medicines and Healthcare products Regulatory Agency
14 July 2021

2 Accountability Report

2.1 Corporate Governance

Agency Board

The Agency Board, which comprises Executive and Non-Executive Directors, is the principal governance body within the Agency. Its remit is to support the Secretary of State in the strategic leadership of the Agency. Non-executive members are appointed by the Secretary of State following open competition and do not usually represent any specific customer, sectoral or stakeholder interests, although Mercy Jeyasingham was appointed as a Patient Representative Non-Executive Director in May 2020.

In September 2020 the Board moved to a full unitary model, with an equal number of Executive and Non-Executive Directors, plus a Non-Executive Chair, supported by three Board Assurance Committees. The Audit and Risk Assurance Committee continues to support the Board on risk and audit matters; the Remuneration Committee was replaced by the Organisational Development and Remuneration Committee (ODRC); and the Patient Safety and Engagement Committee (PSEC) was established, both following the governance changes introduced in September 2020. These governance changes are described fully on page 36.

The Chair

Stephen Lightfoot

Stephen Lightfoot became the Agency's Chair on 1 September 2020, having been a Non-Executive Director of the Agency since September 2015. He is also Deputy Chair of Sussex Community NHS Foundation Trust and Non-Executive Chair of Sussex Primary Care Limited.

Before joining the Agency Board, Stephen had a 30-year career in the life sciences industry working on the development and commercialisation of a wide range of medicines and medical devices in UK and global healthcare companies. His most recent executive roles were General Manager of the global pharmaceutical diagnostics business of GE Healthcare, Managing Director of the UK pharmaceutical business of Daiichi Sankyo and Commercial Director of the UK pharmaceutical and medical device business of Schering Healthcare.

Deputy Chair

Professor David Webb CBE

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 at the Royal Infirmary of Edinburgh, running Edinburgh's European Society of Hypertension-accredited Hypertension Excellence Centre and 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, Vice-President of the Royal College of Physicians of Edinburgh, 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 at the World Congress of Basic and Clinical Pharmacology in 2023.

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 (EMA) Scientific Advisory Committee.

Between 2005 and 2012, she worked with UK DHSC colleagues on planning for infectious diseases emergencies and 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.

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.

Amanda is currently a Non-Executive Director of The Guinness Partnership Limited, a provider of social housing and care services, and a member of the Advisory Board of the Cambridge Judge Business School.

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.

Mercy Jeyasingham MBE

Mercy Jeyasingham has been working in the voluntary health and social care sector for over 30 years, most recently as the CEO of the umbrella organisation for the eye health and sight loss sector. She has been a charity trustee for local, regional and national charities and has held a number of government appointments. She was Vice Chair of the Afiya Trust, a national organisation campaigning to reduce inequalities in health and social care provision for racialised groups. She was a non-executive director of NICE for 12 years, and Chair of their HR committee for 8 years, as well as a member of the NICE Appeal panel for technology appraisals for 14 years both as a patient advocate and then as a member of the board. She Chaired Fitness to Practice committees for the General Optical Council for 10 years. Mercy was a member of the Ministerial Advisory Board of the Medicines Control Agency just before the MHRA was established.

Anne-Toni Rodgers

Anne-Toni Rodgers is a pharmacologist by training with over 35 years of healthcare experience in both the public and private sector; with a career encompassing pure research, regulatory affairs, sales & marketing, market access, strategy, communications, advocacy and Government & corporate affairs.

A leader and innovator in the development of market access and real-world evidence, she was a founding Director of the National Institute for Clinical Excellence and has established new business and functions for a number of global pharmaceutical and device companies.

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 Committee

The Executive Committee (ExCo) comprises 7 Executive Directors. It is chaired by the Chief Executive and its members are the Chief Officers. ExCo has overall responsibility for developing strategic options for the Board's consideration; leading and managing the delivery of the approved Business Plan; day-to-day management of the organisation including all financial, policy, operational and resource management issues.

Before the implementation of the new governance structure, the Corporate Executive Team (CET), the precursor to the Executive Committee, was made up of the Chief Executive Officer, Chief Operating Officer, and the Directors of each of the following Divisions:

» Licensing

» Vigilance and Risk Management of Medicines

» Inspection, Enforcement & Standards

- Devices
- National Institute of Biological Standards and Control
- Clinical Practice Research Datalink
- Communications
- Human Resources
- Policy

Prior to October 2020, the Executive Directors on the Board were the Chief Executive Officer and the Chief Operating Officer. After the establishment of the Unitary Board, all Executive Committee members joined the Board to form the Unitary Board. At present only 5 Executive Directors are in post, of which 3 are interim appointments.

Chief Executive

Dr June Raine CBE

Dr June Raine trained in general medicine and pharmacology and her interest in drug safety led to a career in public health which has spanned a number of roles in management and strategic development within medicines and medical devices regulation. In 2012, after leading the development of the European Risk Management Strategy, June was elected as the first chair of the European Pharmacovigilance Risk Assessment Committee, and she also co-chaired the WHO's Advisory Committee on Safety of Medicinal Products. June has published on risk management and communication and also on medicines for women's health.

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.

Interim Chief Science Officer

Dr Christian Schneider

Dr Christian Schneider joined the National Institute for Biological Standards and Control (NIBSC) in January 2016, taking over as Director in April 2016.

Christian is qualified in medicine and previously worked as Medical Head of Division Medicines Licensing and Availability at the Danish Medicines Agency, Head of Division EU Cooperation/Microbiology at the Paul-Ehrlich Institute in Germany, and was a postdoctoral researcher at the Max-Planck-Institute for Neurobiology (Germany). He has a strong

scientific background with an extensive publication record and a wealth of experience with a broad range of biological medicinal products. Christian acts as Head of Profession for scientists and engineers at MHRA.

Christian is a former Chair of the Committee for Advanced Therapies at the European Medicines Agency (EMA), and former Chair of EMA's Biosimilar Working Party, as well as a former co-opted member of EMA's Committee for Medicinal Products for Human Use (CHMP).

Interim Chief Quality and Access Officer

Dr Sam Atkinson

Sam was appointed to Interim Chief Quality & Access Officer in September 2020. Prior to this Sam held several roles at the MHRA including Director of Inspection, Enforcement & Standards (IE&S), Director of Business Transformation, Deputy Director for IE&S, and Scientific Director for the British Pharmacopoeia (BP) and Laboratory Services. Sam also worked in the Inspectorate for several years, performing inspections, nationally and overseas. Prior to joining the MHRA, Sam worked in industry for a number of years.

Sam studied chemistry at Reading University, completed an MBA at Warwick University and has also completed the Civil Service Major Project Leadership Academy. Sam is a member of the Royal Society of Chemistry and a Visiting Research Fellow at Reading University, playing an active role promoting public sector opportunities to science graduates.

Interim Chief Technology Officer

John Quinn

John Quinn joined the MHRA in February 2014 as Chief Information Officer (CIO) and Senior Information Risk Officer (SIRO), becoming Director of Transformation and Chief Digital and Information Officer in April 2018.

Prior to joining the Agency, John was Head of Business Solutions at the Department for Education (DfE) until January 2014, where he was responsible for delivering the IT strategy, and was the department's Chief Knowledge Officer (CKO).

Members who left the Board during the year

Professor Sir Michael Rawlins GBE Kt

Professor Sir Michael Rawlins GBE Kt was MHRA Chair from December 2014 until August 2020. Sir Michael 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). Sir Michael is honorary professor at the London School of Hygiene and Tropical Medicine, and emeritus professor at the University of Newcastle upon Tyne.

Professor Liam Smeeth

Professor Liam Smeeth joined the Board as a Non-Executive Director on 1 July 2020. Professor Smeeth trained in medicine and continues to do clinical work as a general practitioner in north London. He joined the London School of Hygiene and Tropical Medicine (LSHTM) in 1999 and has held fellowships from NIHR, MRC and Wellcome. As well as academic and clinical work he is involved in a range of activities for the National Institute of Health and Care Excellence (NICE), the Medicines and Healthcare products Regulatory Agency (MHRA) and the UK National Health Service more widely. He was previously a Trustee of the British Heart Foundation, is a member of the steering group for UK Biobank, and an elected Fellow of the Academy of Medical Sciences. Following his appointment as Director of the London School of Hygiene and Tropical Medicine, Professor Smeeth left the MHRA Board on 28 February 2021 having served eight months.

Conflicts of interest

All Board members are required to declare any personal or business interest, or any significant interests held by close family or friends, which may be reasonably perceived to influence their judgement in performing their functions and obligations. These are recorded in a published register of interests. Furthermore, all Board 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. 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.

Executive directors along with senior managers also 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.

Personal data related incidents

One personal data related incident was reported to the Information Commissioner's Office (ICO). This involved an internal email sent to a group of staff which included confidential information about the staff within the group. The ICO advised that no further action was necessary.

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, 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 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 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.

As the Accounting Officer, I have taken all steps that I ought to have taken to make myself aware of any relevant audit information and to establish that the Agency's auditors are aware of that information. So far as I am aware, there is no relevant audit information of which the Agency's auditors are unaware.

2.3 Governance Statement

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.

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 also responsible for service delivery.

The purpose of this statement is to explain the Agency's governance framework, including how it has supported the discharge of these duties in the financial year 2020/21, and how the Agency has complied with the principles of good governance and relevant cross-government frameworks.

The MHRA's statutory duties

The Secretary of State has delegated some of his statutory responsibilities relating to medicines, medical devices and blood, amongst other things to the Agency.

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, including 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 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.

MHRA Governance Framework

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 Agreement 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 and 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.

MHRA trading fund status

The MHRA is an executive Agency of the DHSC. It was established on 1 April 2003 and has been operating as a government trading fund.

In 2019 the Office for National Statistics (ONS) reviewed the sector classification of the MHRA as part of a wider exercise involving similarly classified public sector entities and determined that the MHRA should be re-classified as a central government entity for the purposes of National Accounts, rather than remain a trading fund. The MHRA reclassification to the Central government sub-sector will have no effect on the MHRA's service delivery. However, our change of status will affect some features of our governance, in particular the way our funding is secured and managed. These changes and the revocation of the MHRA's trading fund status are currently being discussed with DHSC and HM Treasury.

Governance review

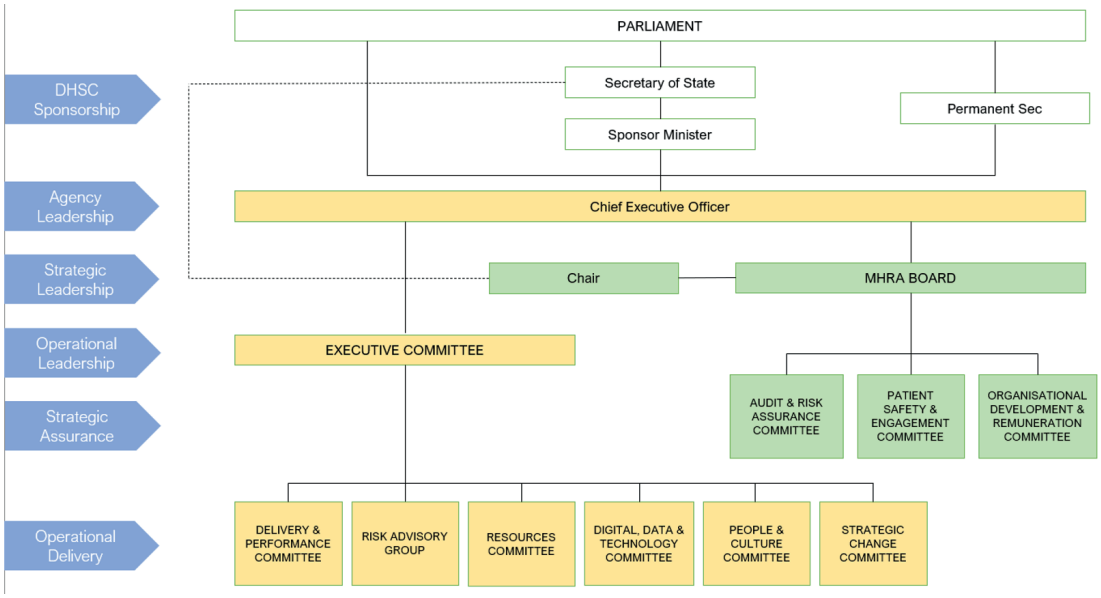
In May 2020 MHRA commissioned Ernst & Young LLP to undertake a review and make recommendations for changes to the existing governance structures within the Agency to improve decision-making, organisational management, control and accountability across the organisation. This was the first phase of the substantial work to revitalise our Transformation Programme and lay the foundations for a new operating model for the Agency.

Following the completion of the first phase of the work, which was focused on our governance structures, we have made a number of changes to improve our Board, Executive and operational level governance and tighten operational control. These changes have included, amongst others, improving the balance of executive and non-executive Board members to better enable operation as a true unitary Board; creation of a new Executive leadership team to provide leadership to the organisation and take and execute key strategic decisions required to lead the organisation successfully; a refreshed set of management committees to support the Executive, taking enabling decisions to secure operational delivery or provide assurance to the Executive and ultimately the Board.

Since September 2020, we have used the following structures to our ensure accountability and give the Agency a framework for risk management:

» The Unitary Board comprising the Chair, Non-Executive Directors, Chief Executive and Chief Officers is responsible for advising on the strategic development of the Agency; providing assurance on the Agency performance in the delivery of its statutory duties and relevant corporate and business plans agreed with ministers; and agree the Agency's risk appetite and ensure effective controls are in place to manage risks.

» The Executive Committee (ExCo) comprising the Chief Executive and Chief Officers takes overall responsibility for the delivery of the objectives in the approved Business Plan along with the day-to-day management of the organisation including all financial, policy, operational and resource management issues.



Role of the Board and the Chair

The Board supports the Chief Executive in the effective delivery of services and overall performance of the organisation by providing leadership, developing strategy, advising on the delivery of policies, maintaining high standards of corporate governance, scrutinising performance and ensuring that controls are in place to manage risk.

The Board does not have involvement in any regulatory decisions affecting medicines or medical devices. These are the responsibility of the Chief Executive and Executive Committee.

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.

The Board considered a wide range of topics throughout the 2020/21 financial year. Alongside regular vital discussions on the Agency's response to the COVID-19 pandemic, other important agenda items over the financial year included (but were not limited to) the Change Strategy and the revised 2-year delivery plan, the Agency's response to the IMMDS Review, the Patient and Public Involvement Strategy, the implications of EU Exit, new devices legislation, and a number of strategic items the Agency is taking forward to deliver public health impact.

Board Members' Attendance

Prior to the change to the Unitary Board, the Board met five times between April 2020 and August 2020, and was chaired by Professor Sir Michael Rawlins GBE Kt. From September 2020 until the end of the 2020-21 financial year, the Board met seven times and was chaired by Stephen Lightfoot. There were no strategic Board away days in 2020-21 due to the COVID-19 pandemic.

Board meetings from April 2020 to August 2020:

Member	Board meetings
Professor Sir Michael Rawlins GBE Kt	5 (5)*
Barbara Bannister	5 (5)
Amanda Calvert	5 (5)
Bruce Campbell	5 (5)
Jon Fundrey	4 (5)
Mercy Jeyasingham	4 (4)**
Stephen Lightfoot	5 (5)
June Raine CBE	5 (5)
Anne-Toni Rodgers	4 (5)
Liam Smeeth	2 (2)***
David Webb	5 (5)
Michael Whitehouse	5 (5)

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

* Prof. Sir Michael Rawlins GBE Kt stepped down from the Board in August 2020
** Mercy Jeyasingham joined the Board in May 2020
*** Professor Liam Smeeth joined the Board in July 2020

Unitary Board meetings from September 2020 to March 2021:

Member	Unitary Board meetings
Stephen Lightfoot (Chair)	7 (7)
June Raine CBE	7 (7)
Sam Atkinson	6 (7)
Barbara Bannister	7 (7)
Amanda Calvert	7 (7)
Bruce Campbell	7 (7)
Jon Fundrey	7 (7)
Mercy Jeyasingham	7 (7)
John Quinn	7 (7)
Anne-Toni Rodgers	7 (7)
Christian Schneider	7 (7)
Liam Smeeth	5 (6)*
David Webb	7 (7)
Michael Whitehouse	7 (7)

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

* Professor Liam Smeeth stepped down from the Unitary Board in February 2021 due to his appointment as Director of London School of Hygiene and Tropical Medicine.

Board performance and effectiveness

The operation of the Board had to adapt to the COVID-19 pandemic as all staff and Directors had to work from home during the year, so all Board Meetings and its Committees had to be conducted by video conference rather than face-to-face throughout the year.

The Board continued to implement and embed the recommendations from the 2018 Woodnewton report on the Board's effectiveness in the first quarter of the year and this included the:

» Appointment of Mercy Jeyasingham as a Non-Executive Director and Patient Representative on the Board in May 2020

In parallel, the Board commissioned a Governance Review in May 2020 with the independent support of Ernst & Young LLP to review and transform the Agency's governance and leadership structures to enable agile and effective decision-making throughout the organisation. The focus of this work was the top three levels of the Agency, including the relationship with and operation of the Board. This review resulted in the Board's decisions to:

» Move to a Unitary Board structure with an equal number of Executive and Non-Executive Directors, plus a Non-Executive Chair

» Establish a new Regulation and Patient Safety Committee

» Establish a new Executive Committee and supporting management committees

These recommendations were implemented with the appointment of a new Non-Executive Chair on 1 September 2020. Other notable improvements were also made to the operation and effectiveness of the new Unitary Board from October 2020 and included:

» Extending the remit of the new Regulation and Patient Safety Committee to become the Patient Safety and Engagement Committee

- Extending the remit of the Remuneration Committee to become the Organisational Development and Remuneration Committee
- All Board Meetings from October 2020 to March 2021 were conducted in public and advertised on the MHRA website, with around 40 - 50 members of the public and members of staff observing each meeting
- An opportunity was provided at every Board Meeting for members of the public to submit questions on any relevant topic in advance or ask questions on the day through the video technology for the Board to answer in a dedicated public question & answer session
- Recordings of every Board Meeting were published on the MHRA website and each one has had around 300 viewings
- Regular attendance and involvement of the Devolved Administrations and DHSC Sponsor Team in Board Meetings
- Board agendas have been structured around the strategic priorities of the Agency and agenda topics have been based around a specific strategic question
- The quality of Board papers has been improved and are now circulated 5 days before the Board Meeting in a single PDF Board Pack
- Key board papers have also been co-developed and co-presented by an Executive Director in partnership with a Non-Executive Director
- Board Seminars have also been held almost every month for the Board to discuss draft proposals and issues at an early stage of development

In March 2021 the Chair asked the Senior Independent Director, Michael Whitehouse, to conduct an informal review with all the Executive and Non-Executive Directors (excluding the Chair) to self-assess the effectiveness of the Board in providing strategic leadership to the MHRA and the effectiveness of the Chair in chairing the Board. The feedback from the Board was overwhelmingly positive and included comments that:

- All colleagues acknowledged and welcomed the significant changes that have happened to the Board during the year
- The new Board committees are contributing to a stronger assurance framework and culture
- Board papers are much shorter and more focused which encourages strategic discussion
- There is widespread support for the Chair's inclusive approach
- There is a need for ongoing development of the Board with good induction for new members
- There is a need to improve the Board's visibility of performance and culture within the organisation

Data quality to support the needs of the Board

ExCo and the Board receive reports at their meetings to support their discussions. All reports comply with a prescribed layout to ensure that the ExCo and the Board are able to focus on the key issues and the decisions that are required. Papers to the Board are first reviewed at ExCo or a relevant subcommittee. Financial performance is monitored and reported using monthly reports. There is a procedure for setting annual budgets and

reviewing financial performance and full-year forecasts. Finance reports containing clear consistent and comparable performance information are discussed at the regular monthly meetings of the Resources Committee prior to submission to the ExCo and Board and any resource or financial implications are highlighted..

Engagement and transparency

Directorate (the 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 holds every session in public; staff and members of the public may attend these sessions as observers and can ask questions to the Board. Recordings of the Board meetings are published on GOV.UK. 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 three subcommittees chaired by Non-Executive Board Members, who report to the Board. These are the Audit & Risk Assurance Committee (ARAC), the Organisational Development and Remuneration Committee (ODRC), and the Patient Safety and Engagement Committee (PSEC).

Audit and Risk Assurance Committee (ARAC)

The Audit and Risk Assurance Committee (ARAC) provides independent advice and assurance to support the Board and Accounting Officer in their responsibilities on issues of risk, control and governance. It meets a minimum of four times a year and presents its Annual Report to the Agency Board. 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. 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.

ARAC Attendance

ARAC meetings from April 2020 to March 2021:

Members	ARAC meetings
Michael Whitehouse	5 (5)
Stephen Lightfoot	2 (2)
Amanda Calvert	5 (5)
Anne-Toni Rodgers	3 (3)
Barbara Bannister	2 (2)
June Raine CBE	5 (5)
Jon Fundrey	5 (5)

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

The following persons routinely attended all Committee meetings:

- The Accounting Officer
- The Chief Operating Officer
- The Deputy Director of Finance
- The Chief Financial Accountant
- The Head of Internal Audit
- Representatives from the External Auditor
- Representatives from the DHSC
- Risk, Assurance & Governance Manager

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.

Organisational Development and Remuneration Committee (ODRC)

The ODRC was established in February 2021 to replace the Remuneration Committee.

The Remuneration Committee met once a year, meeting in June 2020 prior to the establishment of the ODRC.

Remuneration Committee meetings from April 2020 to January 2021:

Members	Remuneration Committee
David Webb	1 (1)
Bruce Campbell	1 (1)
Anne-Toni Rodgers	1 (1)
Barbara Bannister	1 (1)
June Raine CBE	1 (1)

The Director of Human Resources also routinely attended all Remuneration Committee meetings.

ODRC meetings from February 2021 to March 2021:

Members	ODRC
Anne-Toni Rodgers	1 (1)
June Raine CBE	1 (1)
Jon Fundrey	1 (1)
Amanda Calvert	1 (1)
Liam Smeeth	1 (1)

The following persons routinely attend all ODRC Committee meetings:

- The Director of Human Resources
- The Director of Transformation
- The Transformation Strategy Lead

Patient Safety and Engagement Committee (PSEC)

The PSEC was established in February 2021 and met once during the 2020/21 financial year. The PSEC succeeded the Regulation and Patient Safety Committee which was established in July 2020 but did not meet until the after it had become the Patient Safety and Engagement Committee.

Members	CET Meeting
Mercy Jeyasingham	1 (1)
Sam Atkinson	1 (1)
June Raine CBE	1 (1)
Christian Schneider	1 (1)
Bruce Campbell	1 (1)
David Webb	1 (1)

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

The following persons routinely attend all PSEC Committee meetings:

- The Director of Communications
- Two Lay Representatives
- The Head of Patient, Public and Stakeholder Engagement
- The Engagement Manager

The Executive Committee and its subcommittees

The Executive Committee (ExCo) drives the Agency's overall performance and delivery against the Agency's mission, vision and objectives. The ExCo 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 ExCo also makes decisions on issues escalated from its subcommittees. There are six subcommittees of the ExCo that meet regularly over the year. The Performance & Delivery Committee, Risk Advisory Group, Resources Committee, Digital, Data & Technology Committee, People & Culture Committee, and Strategic Change Committee.

All ExCo 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.

ExCo Members' attendance

CET meetings – April–September 2020:

CET member	CET meetings in 2020/21
June Raine CBE	6 (6)
Jon Fundrey	2* (6)
Christian Schneider	5 (6)
Sam Atkinson	5 (6)
John Quinn	6 (6)
Sarah Branch	6 (6)
Graeme Tunbridge	6 (6)
Siu Ping Lam	6 (6)
Janet Valentine	6 (6)
Vanessa Birchall-Scott	6 (6)
Rachel Bosworth	6 (6)
Jonathan Mogford	6 (6)

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

* Jon Fundrey was seconded to DHSC as part of the COVID-19 response from March-August 2020. During the period of Jon Fundrey's secondment his responsibilities as CFO were covered by the Deputy Director of Finance who also attended CET meetings as his delegate.

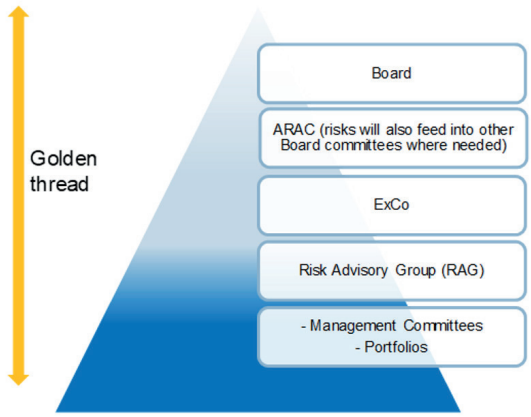
ExCo meetings – September 2020-March 2021:

ExCo member	ExCo meetings in 2020/21
June Raine CBE	11 (11)
Jon Fundrey	10 (11)
Christian Schneider	10 (11)
Sam Atkinson	11 (11)
John Quinn	10 (11)

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

Risk Management

As Accounting Officer, I have overall responsibility for the Agency's Risk Framework, with ExCo owners assigned for the Agency's most significant risks to the delivery of its objectives. The Agency follows the principles and good practice outlined in the HMG Orange Book which can be accessed here https://www.gov.uk/government/publications/orange-book.



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. There is a close relationship between corporate risks and the Agency delivery/business plan.

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 maturity. The corporate risk register is reviewed quarterly by the ExCo and individual risks have been assigned to specific Management/Board Committees for day-to-day oversight.

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.

Agency's risk landscape

The corporate risk register has a number of strategic risks, all of which are linked to the themes of the Agency's delivery plan. The risks are proportionate given the degree of change which the Agency is undergoing and external factors such as COVID-19 and EU exit. The agency manages risks in line with our risk appetite statement. Our approach is based on judgement and circumstances of each potential intervention and an assessment of its impact. Risks are managed through the risk management governance framework outlined above. The key risks to the agency relate to the following areas, a more detailed breakdown is available via the corporate risk register:

» Standalone regulator – ensuring that we successfully reposition the Agency as a standalone, world class regulator that is able to attract the best talent. To this end, we are working to maximise the opportunities to support the UK Life Sciences sector and capitalising on the creation of new international regulatory relationships. The passing of the Medicines and Medical Devices Act (2021) brings with it the opportunity to evolve the UK's regulatory regime. We will develop our strategy for the products we regulate and ensure we encourage and enable developers to bring products to the UK market.

» Independent Medicines and Medical Devices Safety (IMMDS) Review – ensuring that the culture within the Agency allows us to listen to and respond to the voice of patients more effectively. It also means working better across systems and being agile enough to adapt quickly. The Agency is implementing all of the recommendations from the IMMDS Review that fall within its remit and they are being given priority. Overall governance is being strengthened by the recent appointment of a new Chief Safety Officer.

» Legacy systems - The Agency is dependent on technology to deliver efficient and cost-effective services. Some of these technologies are out of date and at risk of failure, which represents a significant risk to our operations. We are finalising plans to overhaul the costly legacy systems and start to deliver improved service to the Agency as well as cost savings.

» Financial sustainability – ensuring that we remain financially sustainable and have an agile operating model which enables us to operate efficiently as a regulator and meet statutory duties. A clear strategy has been developed which outlines what is needed to deliver a financially sustainable agency. This includes specific objectives which have been embedded into a delivery plan with clear timelines for delivery. We also undertook an analysis of our current fees and the associated costs of doing the work and have formed a Fees Strategy Group to determine our future fee structure.

Management assurance

ExCo members complete annual management assurance statements to assess the effectiveness of internal controls within their directorates. These statements are a key part of the system of internal controls. All such accountability statements have been received for the year to 31 March 2021 with ExCo members confirming compliance with all Agency standard operating procedures (SOPs) and policies and their delegated responsibilities. The Agency has not delegated any of its statutory functions to other organisations.

Internal Audit

Internal Audit services were provided in 2020-21 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 systems of governance, risk management and internal control, together with recommendations to help secure continuous improvement or to remedy any shortcomings.

ARAC received and considered the following reports from Internal Audit:

Audit	Assurance opinion
IR35 Compliance	Limited assurance
Financial Control Framework	Moderate assurance
CPRD Disposal of Data	Moderate assurance
Patient Engagement	Moderate assurance
Medical Devices	Limited assurance
Health & Safety of Enforcement team	Moderate assurance
Assurance over the Governance Review	Moderate assurance
Business Planning	Moderate assurance
Customer Service Centre	Substantial assurance and Limited assurance*
Cyber Security	Moderate assurance
Legacy Systems	Moderate assurance

* Customer Services Centre resulted in two separate opinions to cover different stages of the project.

ARAC reviewed the outcome from the internal audit reports, as well as separate external reports, and received regular reports on the implementation of audit recommendations. In particular, ARAC reviewed the action plans to implement audit recommendations from the limited assurance audits and were satisfied that sufficient progress had been made in addressing the identified control weaknesses. In addition, the Committee reviewed annual assurance reports in relation to a number of policy areas.

Head of Internal Audit (HIA) opinion

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

The overall opinion is that internal auditors gave Moderate assurance that the Medicines and Healthcare products Regulatory Agency (MHRA) has had adequate and effective systems of control, governance and risk management in place for the reporting year 2020-21.

The agency has experienced an unprecedented year, having had a significant role in the UK's response to the COVID-19 pandemic including providing proactive advice, approval of clinical trials, diagnostic tests, ventilators, therapeutics and vaccines and monitoring safety signals.

Alongside this, the agency has also been supporting the Government and the life sciences industry on the UK exit from the European Union with new legislation, extended regulatory transition arrangements, pragmatic guidance and new regulatory processes.

This opinion is derived from the internal audit work delivered over the year, together with observations from attending Audit & Risk Assurance Committee (ARAC), management's responses to internal audit reports and recommendations and review of the minutes from the newly created ExCo and supporting committees.

Internal auditors have completed all planned audit work from the 2020/21 internal audit plan which has provided sufficient coverage for the annual opinion. The risk-based audit plan was prepared to cover identified risks faced by the agency, together with business as usual audits to ensure sufficient coverage of governance, risk management and internal control. The outcomes of completed audits support an overall opinion of Moderate assurance with 1 Substantial, 8 Moderate and 3 Limited opinions issued, no audits resulted in an opinion of Unsatisfactory.

Risk management

Whilst internal audit did not undertake a dedicated audit of risk management, it was covered within individual audits. Internal audit observed the significant progress made on the corporate risk register over the year, particularly following the recent appointment of the Risk Assurance Lead.

Where audits have covered risk management, arrangements have generally been found to be appropriate.

The Cyber Security audit confirmed that an Executive Committee chaired by the Chief Executive has been established looking at strategical and operational priorities. Our review of the meeting minutes from 21 December 2020 confirmed that both internal and external risks had been considered and reported.

The Individual Health & Safety (Enforcement Officers) audit confirmed that there is a guidance document covering risk in relation to their work; the Intelligence Development Unit's ''Guide to the Application and Management of Risk in Covert Operations'. It was identified that risk assessments are a key aspect of preparing for an operation, although the audit did identify that these should be completed more consistently across operations.

The audit of Patient Safety identified that the MHRA is currently tracking the implementation of the Patient Engagement Strategy using a milestone-tracking spreadsheet; this is also used to document risk management processes that have been undertaken. The strategy risk management tracking includes a description of identified risks, a risk owner, a risk rating, a mitigating action for each risk, an owner for the mitigating action, the date at which the risk was last reviewed and a current status indicator in the form of a Red/Amber/Green rating.

The audit of Legacy Systems Replacement identified that there were effective arrangements for managing risk at this stage in the programme. The Programme Business Case included the programme risks and there is a risk and issues log for the programme which is regularly updated. The risks and issues log was compiled in accordance with the MHRA framework for risk and issue management within Agency projects and programmes.

It was identified that risk management within the Customer Services Centre project could have been strengthened, as mitigating actions did not always fully address the risk. This recommendation will be taken forward for future projects and programmes.

Governance

Internal audit assurance over the Governance Review audit provided Moderate assurance over the arrangements to implement the actions identified through the Governance Review undertaken in 2020. The review found that most of the actions had been implemented and there was a plan to complete the remaining actions. At the time of the audit, it was too early to give assurance over the effectiveness of the actions; we intend to cover this in our planned Corporate Governance audit in 2021/22.

The audit did conclude that the Unitary Board, ExCo and their supporting committees had been set up and were operational at the time of the audit. Standardised Terms of Reference had been introduced ensuring there was clarity over their roles and responsibilities and delegated authority of these.

An audit of Business Planning confirmed that there is a new approach to business planning which is less siloed than in previous years, addressing the theme from last year's annual audit report around the need for greater cross agency working. The agency has agreed on a single set of business objectives and there is a process of peer challenge to prioritise actions. There is also effective oversight of business plan objectives through quarterly monitoring reports to the Delivery and Performance Committee (DPC), ExCo, the Agency Board, and the DHSC Sponsors.

The audit of Cyber Security confirmed there were effective governance arrangements in place with the Governance roles for information management recorded in an Information Governance Management Framework. A Corporate Executive Committee provides operational and strategic leadership and oversight of priorities, resource allocation, and risk and performance management.

The audit of Legacy Systems confirmed that there are effective governance arrangements in place for this stage of the programme. At the time of our audit the governance arrangements for this programme consisted of:

» Investment Board

» Programme Board

» Change Board

» Performance Committee

Internal audit confirmed that there were terms of reference in place for all, detailing their roles, responsibilities and decision-making authority. The governance arrangements have since been reviewed and, as a result, the Change Board and Investment Board were replaced with the Strategic Change Committee (SCC) and Executive Committee (ExCo).

From review of the minutes from ExCo and its supporting committees, it was confirmed that the groups all have terms of reference (ToR) setting out their roles, responsibilities and delegated authority. Meetings are generally well attended and meeting roughly at the frequency stated in their ToRs.

Some committees had set out a forward plan of papers due at future meetings whilst others had not. In addition, the Patient Safety Committee had agreed to develop a programme of work aligned with the committee's responsibilities.

It was not confirmed that ExCo has a forward workplan or schedule of papers due to come to future meetings. In addition, whilst ExCo's terms of reference set out its responsibilities in relation to corporate functions including risk management, health & safety, conflicts of interest, information governance, without a forward work plan it is unclear how these responsibilities will be fulfilled and in particular how ExCo will be assured that the agency is following appropriate policies and procedures in these areas.

It is recommended that when the committees are due to review their terms of reference and their own effectiveness, consideration is given to introducing forward workplans so that the committees are clear about how their work delivers against their stated responsibilities.

Internal control

Internal controls were generally found to be adequate and effective.

The Customer Service Centre audit identified that effective controls were in place to onboard new services into the centre, including creating 'as-is' and 'to-be' process maps using specialist expertise to do this. Training and guidance notes were provided for staff new to the centre and regular meetings are in place with the services to resolve any issues as they arise.

The Cyber Security audit identified that there were good examples of controls being risk assessed, although the review identified that controls were not always being documented as evidence they had been performed.

The Individual Health & Safety (Enforcement Team) audit concluded that there was an effective framework of internal controls to support the health & safety of staff, with recommendations made to further strengthen the application of the controls.

The Patient Engagement audit identified that patient safety is now included in the induction training for all new staff and training is being developed for existing staff.

The Financial Controls Framework audit confirmed that there is an adequate and effective control framework in place with controls built into the Oracle Fusion system.

The Business Planning audit confirmed that guidance was issued for the preparation of divisional business plans and a template was required to be used to ensure consistency across the agency and to ensure all key information was included.

VAT Special Payment

In 2020 a query relating to non-statutory services provided by CPRD to academic institutions with charitable status led to an internal review of certain VAT-exempt sales of research data. The Agency sought and received technical tax advice from HMRC which determined that all sales of research data are subject to VAT. This ruling is retrospective and applies to all sales of research data to academic institutions, which had been invoiced as VAT-exempt sales at the time. The VAT liability to HMRC extends to the last four years including the current financial year. A full provision for VAT and interest payable to HMRC in the amount of £1.8 million has been made in the 2020/21 annual accounts. Appropriate action has been taken to avoid a recurrence: the Agency's VAT guidance has been updated and includes specific reference to sales of research data and VAT for charitable institutions; a newly-appointed Tax & Compliance officer provides support and advice on all tax related matters.

Review of ARAC effectiveness

ARAC reviewed a number of areas including: financial performance, internal and external audit reports, risk management, governance arrangements, conflict of interests, counter fraud, and whistleblowing arrangements.

An ARAC effectiveness survey was sent to all full ARAC members (excluding the Chair). The questionnaire had two sections: the first on behaviours and the second on processes. Responses were graded on a scale of 1 to 5 (with 5 being the best grading). Overall, 96% of all responses were given a grading of 4 or a 5.

Raising a concern

The Agency has an internal Raising a Concern Policy and Procedure, Guidance for Managers and Guidance for Investigators documents based on best practice Civil Service Employee Policy documents. ARAC has oversight of both raising concerns (also referred to as '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 investigations, setting out lessons being learned, and action taken, highlighting any themes and including relevant data and plans to raise awareness further. All concerns that have been raised formally were investigated according to the policy and procedure and were reported to ARAC.

The effectiveness of the Agency's control framework was assessed as part of a DHSC internal audit to ensure that whistleblowing policies, procedures, guidance and governance were up to date, reviewed regularly and support a culture where staff have the awareness and confidence to speak out, and this received moderate assurance in March 2021.

Effectiveness of Anti-Fraud and Bribery Policy

The Agency's Anti-Fraud and Bribery Policy is aligned with the Government's Counter Fraud Functional Standard. We undertake an annual risk assessment of non-regulatory fraud and identify actions to reduce fraud risk further. ARAC has oversight of all cases and receives a report at each meeting and an annual report setting out counter fraud activities, a summary of cases and future plans. The Agency submits a quarterly data return on fraud and error to the Cabinet Office via DHSC.

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 lifecycle management: the retention schedule has been reviewed, and we have employed technologies to automate retention where possible.

» The agency has developed an action plan in response to the Information Management Assessment carried out by National Archives in 2019 and has made good progress in implementing this. The recommendation to take forward the transfer of records to the National Archives in compliance with Public Records Act has been paused as the National Archives are not accepting physical records transfers due to COVID-19 restrictions.

Cyber security

The Agency continues to prioritise cyber risk and has taken positive steps to improve data security and its resilience to an increasingly high level of security threat. The security threat profile for the agency has increased since March 2020 and continues to increase as the MHRA's global profile rises considering the important work being undertaken.

The UK's National Cyber Security Centre (NCSC), the US's Cybersecurity and Infrastructure Security Agency (CISA), and other government agencies responsible for cyber security have issued warnings that there is clear evidence that state-backed cyber groups are targeting organisations involved in coronavirus research and clinical trials data. We have regular meetings with NCSC and they have warned us that we are one of the top four organisations in the UK that they are monitoring against threats. The nature of these cyber-attacks will continue to increase in intensity and sophistication than seen previously.

» We have embedded information security risk management in our project and change lifecycle. Information risk is therefore a key consideration in the design process and features in key governance groups such as Information Asset Board, Solutions Design Board and Technology Steering Group.

» We have been working closely with National Cyber Security Centre to respond to new security threats.

» We have dealt with a number of cyber-attacks this year, the most significant of which involved an attack on a public facing website. This year, 37 security breaches have been reported and investigated, and 32,505 phishing emails captured.

» We have carried out further IT health checks throughout the year and are making steady progress to closing the high-risk vulnerabilities that were identified.

» We have again successfully implemented the Data Security Protection Toolkit 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. Our first two cyber apprentices completed their training, and one apprentice has now secured a permanent role in the agency as a Cyber Security Manager. Our other two cyber apprentices continue to perform well.

Data protection

We have worked to improve compliance and raise awareness of our obligations under the General Data Protection Act (GDPR) and Law Enforcement Directive, to embed data protection by design and default principles throughout the Agency and to monitor compliance. We have done this by publishing 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. This year we have introduced virtual induction sessions for all new starters to set out their data protection responsibilities.

We have completed and updated our register of personal data processing as required under Article 30 of the GDPR. This allows 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.

We have continued to handle all subject access requests and data breaches in a timely fashion. One data breach was reported to the Information Commissioner this year, consistent with reporting levels in previous years since introduction of the GDPR. We have introduced some technical measures to prevent accidental email breaches and are working towards implementation of further data loss prevention technology this year.

Commercial and procurement

In 2020-21 we continued to deliver our commercial strategy, with a focus on the entire commercial lifecycle. We have driven 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.

This has been achieved by:

» Addressing all Internal Audit recommendations from procurement audits

» Conducting a self-assessment against Government Commercial Operating Standards and implementing a plan to improve our score

» Streamlining our procedures to meet the needs of MHRA commercial objectives whilst ensuring Cabinet Office regulations and policies are adhered to

» Building commercial prowess internally through improved stakeholder engagement and implementation of a formal contract management training platform, provided by the Government Commercial Office.

The commercial team has been the catalyst for improving strategic sourcing thinking internally; stressing the importance of supplier and contract management; and holding suppliers to account.

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.

Health and Safety Strategy Group and H&S committee meetings continue to take place. These meetings allow us to 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.

Accounting Officer's review of the effectiveness of the 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, the assurance provided by ExCo members 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 ExCo. A plan of action to address control weaknesses and ensure continuous improvement of the control framework 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 ExCo members;

» 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;

» Following a review of our governance structures, during the year we made a number of changes to improve our Board, Executive and operational level governance and tighten operational control. These changes have included, amongst others, improving the balance of executive and non-executive Board members to enable better decision-making; creation of a new Executive leadership team to provide leadership to the organisation and execute key strategic decisions required to successfully lead the organisation; a refreshed set of management committees to support the Executive, taking enabling decisions to secure operational delivery and provide assurance to the Executive and ultimately the Board.

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 2020/21.

Compliance with the Corporate Governance Code

The systems for corporate governance, risk management, internal control and assurance are monitored by the Board, ARAC and ExCo, and have been in existence throughout the year to 31 March 2021 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.

Account 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 ExCo, 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 MHRA 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 three 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 here.

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. Executive and Board members) of the Agency. Executive Team members' salary and bonus awards were decided by the Organisational Development and 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. The information in this report covers both CET members and ExCo members, as the change in executive leadership took place halfway through the financial year.

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 60.

Organisational Development and Remuneration Committee

The purpose of the Organisational Development and Remuneration Committee is to provide independent and objective advice to the Agency Board and the Chief Executive on their responsibilities relating to workforce planning, development and rewards at the Medicines and Healthcare products Regulatory Agency (MHRA). The Remuneration Committee continued until November 2020 when the Organisational Development & Remuneration Committee was established. The Remuneration Committee met once during the year, as has normally been the case, to consider CET ratings and related bonus allocation. The ODRC met once and considered diversity and inclusion, culture and the draft people strategy.

The Committee is comprised of the following:

- Anne-Toni Rodgers (Chair, NED Member)
- Liam Smeeth (NED Member) (left on 28 February 2021)

- Amanda Calvert (NED Member)
- June Raine CBE (Chief Executive Officer)
- Jon Fundrey (Chief Operating Officer)
- Vanessa Birchall-Scott (Director of Human Resources)

Executive Team members salaries, bonus and benefits table – (subject to audit)

2020/21	Salary	Performance pay and bonuses	Pension related benefits	Total
	£000	£000	£000	£000
Mr Jon Fundrey Chief Operating Officer	140 - 145	5 - 10	55	200 - 205
Dr June Raine, CBE Chief Executive	140 - 145	Nil	100	240 - 245
Dr Christian Schneider[1] Interim Chief Scientific Officer	135 - 140	5 - 10	65	210 - 215
Ms Rachel Bosworth Director of Communications	100 - 105	5 - 10	25	135 - 140
Mr Jonathan Mogford Director of Policy	100 - 105	10 - 15	45	160 - 165
Dr Siu Ping Lam Director of Licensing	120 - 125	Nil	32	150 - 155
Mr John Quinn[2] Interim Chief Technology Officer	110 - 115	Nil	48	160 - 165
Ms Vanessa Birchall-Scott Director of Human Resources	95 - 100	5 - 10	38	140 - 145
Dr Janet Valentine Director of CPRD	105 - 110	Nil	42	150 - 155
Dr Samantha Atkinson[3] Interim Chief Quality and Access Officer	110 - 115	10 - 15	46	170 - 175
Dr Sarah Branch Director of Vigilance & Risk Management of Medicines	105 - 110	Nil	79	185 - 190
Mr Graeme Tunbridge Director of Devices	90 - 95	5 - 10	55	150 - 155
Ms Boryana Stambolova[4] Interim Chief Operating Officer	40 - 45	Nil	16	55 - 60

1 Dr Christian Schneider took on this role on 5th November 2020. Prior to that he was Director of NIBSC.
2 Mr John Quinn took on this role on 5th November 2020. Prior to that he was Chief Information Officer and Director of Transformation.
3 Dr Samantha Atkinson took on this role on 5th November 2020. Prior to that she was Director of Inspection, Enforcement and Standards.
4 Ms Boryana Stambolova deputised as Chief Operating Officer from 1 April to 31 August 2020. Full year equivalent is £105k-£110k.

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[3] Director of Vigilance & Risk Management of Medicines	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

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

Non-Executive Directors' salaries, bonus and benefits table (subject to audit)

2020/21	Salary	Benefits in kind (taxable) to nearest	Total
	£000	£100*	£000
Professor Sir Michael Rawlins, GBE Kt[1] Chair (until 31 August 2020)	25-30	Nil	25 - 30
Mr Stephen Lightfoot[2] Non Executive Director, Chair (from 1 September 2020)	40 - 45	Nil	40 - 45
Dr Barbara Bannister, MBE Non Executive Director	5 - 10	Nil	5 - 10
Professor Bruce Campbell Non Executive Director	5 - 10	Nil	5 - 10
Professor David Webb Deputy Chair Non Executive Director	5 - 10	Nil	5 - 10
Mr Michael Whitehouse, OBE Non Executive Director	10 - 15	Nil	10 - 15
Amanda Calvert Non Executive Director	5 - 10	Nil	5 - 10
Anne – Toni Rodgers Non Executive Director	5 - 10	Nil	5 - 10
Mercy Jeyasingham[3] MBE Non Executive Director	5 - 10	Nil	5 - 10
Professor Liam Smeeth[4] Non Executive Director	5 - 10	Nil	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 Professor Sir Michael Rawlins GBE Kt left the Board on 31st August 2020. Full year equivalent £60k-£65k.
2 Mr Stephen Lightfoot was appointed Chairman on 1st September 2020.Full year equivalent £60k-£65k.
3 Mercy Jeyasingham joined the Board on 1st May 2020. Full year equivalent £5k-£10k.
4 Professor Liam Smeeth joined the Board on 1st July 2020 and left on 28th February 2021. Full year equivalent £5k-£10k.

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.

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 2020/21 relate to performance in 2019/20 and the comparative awards reported in 2019/20 relate to performance in 2018/19.

Fair pay disclosure (subject to audit)

Reporting bodies are required to disclose the relationship between the remuneration of the highest-paid director in their organisation and the median remuneration of the organisation's workforce. Total remuneration includes salary, non-consolidated performance-related pay and benefits-in-kind. It does not include severance payments, employer pension contributions and the cash equivalent transfer value of pensions.

The banded remuneration of the highest paid director in the Agency in the financial year 2020/21 was £145k-£150k (2019/20, £135k-£140k). This was 3.5 times (2019/20, 3.8) the median remuneration of the workforce, which was £42,224 (2019/20, £41,536) 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 2020/21 (2019/20, none).

The range of staff remuneration was £8k-£150k (2019/20, £8k-£140k).

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 Executive Team members:

2020/21	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 June Raine, CBE Chief Executive	2.5 - 5.0 plus lump sum of 12.5 - 15.0	60 - 65 plus lump sum of 190 - 195	1,202	1,269	84	36
Mr Jon Fundrey Chief Operating Officer	2.5 - 5.0 plus Nil lump sum	45 - 50 plus Nil lump sum	752	837	43	42
Dr Christian Schneider Interim Chief Scientific Officer	0 - 2.5 plus Nil lump sum	15 - 20 plus Nil lump sum	161	205	38	42
Ms Rachel Bosworth Director of Communications	0 - 2.5 plus lump sum of 2.5 - 5.0	30 - 35 plus lump sum of 90 - 95	677	730	26	31
Mr Jonathan Mogford Director of Policy	2.5 - 5.0 plus lump sum of 0 - 2.5	40 - 45 plus lump sum of 105 - 110	864	927	30	31
Dr Siu Ping Lam Director of Licensing	0 - 2.5 plus lump sum of 5.0 - 7.5	40 - 45 plus lump sum of 145 - 150	1,113	1,134	31	37
Mr John Qiunn Interim Chief Technology Officer	2.5 - 5.0 plus lump sum of 0 - 2.5	40 - 45 plus lump sum of 85 - 90	724	780	27	34
Ms Vanessa Birchall-Scott Director of Human Resources	0 - 2.5 plus Nil lump sum	10 - 15 plus Nil lump sum	169	209	26	29
Dr Janet Valentine Director of CPRD	2.5 - 5.0 plus Nil lump sum	20 - 25 plus Nil lump sum	270	316	27	33
Dr Samantha Atkinson Interim Chief Quality and Access Officer	2.5 - 5.0 plus Nil lump sum	30 - 35 plus Nil lump sum	380	422	21	34
Dr Sarah Branch Director of Vigilance & Risk Management of Medicines	2.5 - 5.0 plus lump sum of 10 - 12.5	50 - 55 plus lump sum of 155 - 160	1,051	1,111	73	33
Ms Boryana Stambolova[1] Interim Chief Operating Officer	0 - 2.5 plus Nil lump sum	0 - 5 plus Nil lump sum	60	77	12	29
Mr Graeme Tunbridge Director of Devices	2.5 - 5.0 plus Nil lump sum	25 - 30 plus Nil lump sum	276	317	25	28

1 Ms Boryana Stambolova deputised as Chief Operating Officer from 1 April to 31 August 2020. The pension information relates to this period only.

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

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.

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.

Staff costs (subject to audit)

	2020/21			2019/20
	Total £000	Permanently Employed	Other £000	Total £000
Wages and salaries	69,745	64,002	5,743	64,302
Social security costs	7,067	7,067	-	6,768
Other pension contributions	15,873	15,873	-	15,343
Sub-total	92,685	86,942	5,743	86,413
Less recoveries in respect of outward secondment	(246)	(246)	-	(189)
Total staff costs	**92,439**	**86,696**	**5,743**	**86,224**

Staff resources (subject to audit)

During the year an average of 1,388 full-time equivalent staff were employed.

	2020/21		
	Total	Permanently Employed	Other*
Chair	1	1	-
Chief Executive/Directors	14	14	-
Senior Civil Servants	121	118	3
Other Civil Service Staff	1,252	1,049	203
Total	**1,388**	**1,182**	**206**

* includes contingent workers

	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**

SCS by grade

Senior Civil Servants by salary band (£000)	2020/21	2019/20
65 - 70	-	2
70 - 75	27	28
75 - 80	16	20
80 - 85	32	32
85 - 90	26	25
90 - 95	13	12
95 - 100	12	7
100 -105	5	6
105 - 110	4	3
110 - 115	3	2
115 - 120	1	1
120 - 125	1	1
125 - 130	-	-
130 - 135	-	-
135 - 140	1	1
140 - 145	3	-
Total	**144**	**140**

Staff composition - gender analysis*

	Male	Female
Chairman/Chief Executive/ Directors	9	6
Senior Civil Servants	56	65
Other Civil Service Staff	483	703
Total	**548**	**774**

* Of those who declared

Staff composition – ethnic breakdown

- White 794
- BME 456
- No data/prefer not to say 127

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 3.7 working days per full time equivalent employee (2019/20, 5.4 days).

The annual turnover for the Agency was 8.5% (2019/20, 12%).

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, whether this be in respect of location or facilities. During 2020-21, all interviews have taken place via video link which has proven to be successful in increasing accessibility for all candidates.

Our learning and development strategy actively promotes the development of all staff, including the offer of both formal training courses as well as informal learning 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 or virtually, as we have done during 2020-21.

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, organisational change 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 focused on mental wellbeing and supporting staff's resilience during periods of change through learning and development and through our promotion of mental health champions and information and signposting for sources of support. We appointed a Mental Health Champion at Board level in 2020.

We operate a guaranteed interview scheme for any candidate who discloses a disability during the application process and who meets the minimum essential requirements of the job. We operate an open and fair recruitment process, fully compliant with the Civil Service Commission Recruitment Principles. We are committed to supporting disabled staff through occupational health support, 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, whether this be through the provision of equipment or changes to ways of working. We run a series of articles for signposting and support on all diversity issues on our intranet as part of a planned programme to increase awareness of diversity and inclusion across the workforce. We deliver learning and development in a variety of formats to ensure it is accessible to all staff and during 2020 all pan-Agency learning was moved to virtual delivery. To support career development, we publicise a career pathway tool for all staff to ensure clear communication about development opportunities across the Agency and support this with specific virtual coaching sessions that staff can easily access. More general coaching opportunities for staff are also offered via our network of qualified Agency coaches.

We actively promote good employment practice and adherence to employment law through provision of a comprehensive suite of HR policies and procedures, which are all consulted upon with our trade unions and Senior Management Teams prior to authorisation and publication. 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. Our newly formed People & Culture Committee includes membership of our Trade Union Side Chair.

Other employee matters

Since March 2020, responding to the pandemic situation, all pan-Agency learning and development opportunities have been delivered remotely and in-house learning has been quickly adapted to suit an online delivery format. Additionally, to support many individuals adapting to the move to remote working, HR have delivered interactive sessions on the challenges of remote working to over 200 staff. As the pandemic has continued, recognising the potential impact of the ongoing situation on individuals and teams at work, the Agency has subsequently designed and currently delivered a Wellbeing session to over 200 staff members with additional sessions planned to cover a further 200.

To support managers in selecting the best fit candidates for advertised roles, the Agency has delivered regular training programmes for managers on recruitment and selection techniques incorporating the use of Success Profiles. This training has been well received: on evaluation, 100% of respondents confirmed they had increased their knowledge, skills and understanding of the subject.

A set of Agency values and supporting behaviours, developed during 2019 following extensive consultation with staff, were introduced across the Agency in 2020 and in a recent follow-up survey, the majority of respondents agreed these were the right values and behaviours to shape the required culture for the future Agency. To assist in the adoption of the values, the Agency invested in a comprehensive learning programme to support managers understanding how these values influence our organisational culture and the importance of the individual impact of managers in embedding the values and behaviours within their teams. To date, over 200 attendees have participated in sessions in the programme. The values and behaviours will also be integral to the Agency's proposed revised performance management scheme for delegated grades from 2021.

Throughout the year, a pilot reverse mentoring scheme has been taking place involving 18 mentees at ExCo or Director level who have been matched with volunteer mentors of different grades from across the Agency. The scheme is designed to build an open and transparent culture across the Agency, encouraging effective communication and upholding our values. Feedback at the mid-scheme point has been very positive, with early benefits identified as: senior leaders gaining a broader perspective of how changes land across different parts of the Agency; getting honest feedback and building constructive partnerships. A more detailed evaluation will be conducted at the end of the programme to inform any plans for extending the scheme further.

During this year the Agency completed a development programme for senior managers as well as launching a programme aimed at middle managers. We remain committed to support the career development of all staff and intend to introduce a subsequent offer for staff at more junior grades on completion of this current programme.

Spend on consultancy and temporary staff

During 2020/21, expenditure on consultants was £761k (2019/20, £312k).

The Agency continues to employ temporary staff where it is of operational necessity. The Agency temporary staff expenditure was £5,753k in 2020/21 (2019/20, £5,833k).

The Government Apprentice scheme

The agency currently pays approximately £302,000 per annum as an Apprenticeship Levy and recognises that this money is lost to the organisation unless used to pay for apprenticeship learning provision. There remains a commitment to this scheme, but also a recognition that apprenticeships need to be appropriate in terms of current and future roles and in this respect the agency currently falls short of full utilisation, but continues to factor into workforce plans.

There are 22 directly recruited apprentices in the agency. 12 apprenticeships were started in the Agency in 2020/21 compared to 14 in the previous year.

It is recognised that entry level apprenticeships are especially important in aiding social inclusion. Apprenticeships at entry level this year have been undertaken in our Human Resources, Communications and Transformation (TD) divisions. There are also 5 apprenticeships ongoing at the NIBSC, supporting the development of in-house skills which are difficult to source in the local area. Similarly, the range of digital apprenticeships in Transformation Division (TD) are providing the organisation with the opportunity to develop capability, skills and knowledge identified as being required in the longer term and therefore ultimately contributing to effective workforce sourcing and planning.

For the future, the Agency has identified an organisational need to develop Project Management (PM) skills. Apprenticeships may offer the opportunity to build that capability both through recruitment of new staff, or by current staff undertaking the Level 4 PM apprenticeship and we will continue to explore options, along with developing other suitable apprenticeship opportunities.

Reporting of civil service and other compensation schemes

Exit packages (subject to audit)

Cost band	Total number of exit packages by cost band	
	2020/21	2019/20
<£10,000	1	3
£10,000 - £25,000	-	3
£25,000 - £50,000	-	-
£50,000 - £100,000	9	-
£100,000 - £150,000	-	1
£150,000 - £200,000	-	-
Total number of exit packages	**10**	7
Total resource cost	**£556,619**	£209,786

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 £556,619 (2019/20, £209k) 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 2021.

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 13¾ years to retirement 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 who 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 on 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 2020/21, 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 £22,600	4.60%
£22,601 to £54,900	5.45%
£54,901 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 the NIBSC are covered by the provisions of the NHS Pensions Scheme. Details of the benefits payable under these provisions can be found on the NHS Pensions website at www.nhsbsa.nhs.uk/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:

	2020/21 Annual pensionable pay banding	2020/21 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 2020/21 (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 2020/21, employers' contributions for the agency employees of £15,873,194 were payable to the PCSPS and NHSPS (2019/20, £15,342,469) at one of four rates in the range 26.6 per cent to 30.3 per cent of pensionable pay (2019/20, 26.6 per cent to 30.3 per cent) for PCSPS and 20.6 per cent (2019/20, 20.6 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 £133,731 (2019/20, £127,602) 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 (2019/20, 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 £4,788 (2019/20, £4,260), 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 2020/21 (2019/20, 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 employ-ee number
20	19.4

Trade Union Percentage of time spent on facility time

Percentage of time	Number of employees
0%	0
1-50%	20
51-99%	0
100%	0

Percentage of pay bill spent on facility time

Description	Figures
Total cost of facility time	£30,862
Total pay bill	£92,439k
Percentage of the total pay bill spent on facility time*	0.03%

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

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.

2020/21

	£000 Income	£000 Expenditure	£000 Surplus /(Deficit)
Licensing	28,188	(30,991)	(2,803)
Inspections	4,202	(9,756)	(5,554)
Vigilance, Risk Management and Enforcement	30,952	(32,575)	(1,623)
British Pharmacopoeia	5,388	(1,885)	3,503
Devices	9,856	(14,181)	(4,325)
Clinical Trials	3,574	(3,315)	259
Regulator total	82,160	(92,703)	(10,543)
CPRD*	11,440	(16,150)	(4,710)
DHSC share of joint venture	(5,720)	8,075	2,355
	5,720	(8,075)	(2,355)
NIBSC	39,463	(48,695)	(9,232)
Total charging activities	**127,343**	**(149,473)**	**(22,130)**
DHSC Funding	27,365	-	27,365
Other non-attributable	4,263	(9,472)	(5,209)
Total revenue	**158,971**	**(158,945)**	**26**

As part of its preparation for EU exit, the Agency received additional funding of £12.8m from DHSC to cover the cost of its preparatory work in advance of the exit; funding of £2.1m to cover the employer's pensions increase and £12.4m in non-cash funding to cover the additional expenditure resulting from the transfer of the National Institute for Biological Standards and Control to the Agency were also received.

2019/20	£000 Income	£000 Expenditure	£000 Surplus /(Deficit)
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)**
DHSC Funding	26,743	-	26,743
Other non-attributable	3,450	(3,726)	(276)
Total revenue	**166,697**	**(149,793)**	**16,904**

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.

Pending settlement with HMRC, a £1.8m provision was set up for VAT and estimated interest due to HMRC in relation to certain MHRA sales of non-regulatory services to academic institutions with charitable status, where VAT had not been charged at the time of the sale.

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 2021

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 2021 under the Government Trading Funds Act 1973. The financial statements comprise: the Statement of Comprehensive Income, Statement of Financial Position, Statement of Cash Flows, Statement of Changes in Taxpayers' Equity; and the related notes, including the significant accounting policies. These financial statements have been prepared under the accounting policies set out within them. The financial reporting framework that has been applied in their preparation is applicable law and International Accounting Standards as interpreted by HM Treasury's Government Financial Reporting Manual.

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 Medicines and Healthcare Products Regulatory Agency's affairs as at 31 March 2021 and of its surplus for the year then ended; and
- the financial statements have been properly prepared in accordance with the Government Trading Funds Act 1973 and HM Treasury directions issued thereunder.

Opinion on regularity

In my opinion, in all material respects the income and expenditure recorded in the financial statements have been applied to the purposes intended by Parliament and the financial transactions recorded in the financial statements conform to the authorities which govern them.

Basis of opinions

I conducted my audit in accordance with International Standards on Auditing (ISAs) (UK), applicable law 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 2019. I have also elected to apply the ethical standards relevant to listed entities. I am independent of the Medicines and Healthcare Products Regulatory Agency in accordance with the ethical requirements that are relevant to my audit of the financial statements in the UK. My staff and I have fulfilled our other ethical responsibilities in accordance with these requirements.

I believe that the audit evidence I have obtained is sufficient and appropriate to provide a basis for my opinion.

Conclusions relating to going concern

In auditing the financial statements, I have concluded that the Medicines and Healthcare Products Regulatory Agency's use of the going concern basis of accounting in the preparation of the financial statements is appropriate.

Based on the work I have performed, I have not identified any material uncertainties relating to events or conditions that, individually or collectively, may cast significant doubt on the Medicines and Healthcare Products Regulatory Agency's ability to continue as a going concern for a period of at least twelve months from when the financial statements are authorised for issue.

My responsibilities and the responsibilities of the Accounting Officer with respect to going

concern are described in the relevant sections of this certificate.

The going concern basis of accounting for the Medicines and Healthcare Products Regulatory Agency is adopted in consideration of the requirements set out in HM Treasury's Government Reporting Manual, which require entities to adopt the going concern basis of accounting in the preparation of the financial statements where it is anticipated that the services which they provide will continue into the future.

Other information

The other information comprises information included in the Annual Report, 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 certificate thereon. The Chief Executive as Accounting Officer is responsible for the other information. My opinion on the financial statements does not cover the other information and except to the extent otherwise explicitly stated in my certificate, 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 I identify such material inconsistencies or apparent material misstatements, I am required to determine whether this gives rise to a material misstatement in the financial statements themselves. 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;
- the information given in 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

In the light of the knowledge and understanding of the Medicines and Healthcare Products Regulatory Agency and its environment obtained in the course of the audit, I have not identified material misstatements in the Performance and Accountability Report. 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
- certain disclosures of remuneration specified by HM Treasury's Government Financial Reporting Manual are not made; 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.

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 in accordance with the applicable financial

reporting framework and for being satisfied that they give a true and fair view;

- internal controls as the Accounting Officer determine is necessary to enable the preparation of financial statement to be free from material misstatement, whether due to fraud or error.

- assessing the Medicines and Healthcare Products Regulatory Agency's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the Accounting Officer anticipates that the services provided by the Medicines and Healthcare Products Regulatory Agency will not continue to be provided in the future.

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.

My objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue a certificate that includes my opinion. 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.

I design procedures in line with my responsibilities, outlined above, to detect material misstatements in respect of non-compliance with laws and regulation, including fraud.

My procedures included the following:

- Inquiring of management, the Medicines and Healthcare Products Regulatory Agency's head of internal audit, and those charged with governance, including obtaining and reviewing supporting documentation relating to the Medicines and Healthcare Products Regulatory Agency's policies and procedures relating to:

    - identifying, evaluating and complying with laws and regulations and whether they were aware of any instances of non-compliance;

    - detecting and responding to the risks of fraud and whether they have knowledge of any actual, suspected or alleged fraud; and

    - the internal controls established to mitigate risks related to fraud or non-compliance with laws and regulations including the audited entity's controls relating to Managing Public Money, Medical Devices Regulations 2002, General Product Safety Regulations 2005, Human Medicines Regulations 2012 and the Medicines Act 1968.

- discussing among the engagement team, regarding how and where fraud might occur in the financial statements and any potential indicators of fraud. As part of this discussion, I identified potential for fraud in the following areas: revenue recognition and posting of unusual journals;

- obtaining an understanding of Medicines and Healthcare Products Regulatory Agency's framework of authority as well as other legal and regulatory frameworks that the Medicines and Healthcare Products Regulatory Agency operates in, focusing on those laws and regulations that had a direct effect on the financial statements or that had a fundamental effect on the operations of the Medicines and Healthcare Products Regulatory Agency. The key laws and regulations I considered in this context included the Government Trading Funds Act 1973, Managing Public Money, Employment Law and tax Legislation.

In addition to the above, my procedures to respond to identified risks included the following:

- reviewing the financial statement disclosures and testing to supporting documentation to assess compliance with relevant laws and regulations discussed above;
- enquiring of management, the Audit Committee and in-house legal counsel concerning actual and potential litigation and claims;
- reading minutes of meetings of those charged with governance and the Board;
- in addressing the risk of fraud through management override of controls, testing the appropriateness of journal entries and other adjustments; assessing whether the judgements made in making accounting estimates are indicative of a potential bias; and evaluating the business rationale of any significant transactions that are unusual or outside the normal course of business; and
- in addressing the risk that the financial statements may be materially misstated through fraudulent revenue recognition, testing the appropriateness of income recognition policies and controls, assessing whether income has been appropriately calculated based on work recorded as performed at year end.

I also communicated relevant identified laws and regulations and potential fraud risks to all engagement team members and remained alert to any indications of fraud or non-compliance with laws and regulations throughout the audit.

A further description of my responsibilities for the audit of the financial statements is located on the Financial Reporting Council's website at: www.frc.org.uk/auditorsresponsibilities. This description forms part of my certificate.

In addition, I am required to obtain evidence sufficient to give reasonable assurance that the income and expenditure reported in the financial statements have been applied to the purposes intended by Parliament and the financial transactions conform to the authorities which govern them.

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.

Report

I have no observations to make on these financial statements.

Gareth Davies

Comptroller and Auditor General

National Audit Office
157-197 Buckingham Palace Road
Victoria, LondonSW1W 9SP

Date 16 July 2021

3 Financial Statements

Statement of comprehensive income for the year ended 31 March 2021

	NOTE	2020/21		2019/20	
		£000	£000	£000	£000
Income					
Trading Income	3.1		**146,546**		154,744
Other income	3.2		**12,425**		11,953
Total income			**158,971**		166,697
Expenditure					
Staff costs	5	**(92,439)**		(86,224)	
Operating costs	6	**(66,506)**		(63,569)	
Total Expenditure			**(158,945)**		(149,793)
Operating Surplus			**26**		16,904
Finance income			**6**		584
Finance costs			**(47)**		(47)
(Deficit)/Surplus for the financial year			**(15)**		17,441
Other comprehensive income					
Realised loss on inventories			**(188)**		(89)
Net loss on revaluation of property, plant and equipment*	7		**(3,334)**		7,266
Total comprehensive (loss)/ income for the year			**(3,537)**		24,618

* All gains and losses arise from continuing operations.

The notes on pages 82 to 101 form part of these accounts.

Statement of financial position as at 31 March 2021

	NOTE	31 March 2021		31 March 2020	
		£000	£000	£000	£000
Non-current assets					
Property, plant and equipment	7	**128,464**		137,789	
Intangible assets	8	**13,389**		14,235	
Trade and other receivables	12	**7,291**		7,753	
Total non-current assets			**149,144**		159,777
Current assets					
Inventories	10	**9,563**		5,838	
Contract assets	11	**6,948**		6,611	
Trade and other receivables	12	**36,994**		27,475	
Cash and cash equivalents	13	**79,601**		89,285	
Total current assets			**133,106**		129,209
Total assets			**282,250**		288,986
Current liabilities					
Contract liabilities	11	**(12,761)**		(11,124)	
Trade and other payables	14	**(42,693)**		(34,458)	
Other liabilities	15	**(14,135)**		(15,044)	
Provisions	16	**(1,781)**		-	
Total current liabilities			**(71,370)**		(60,626)
Total assets less current liabilities			**210,880**		228,360
Non-current liabilities					
Contract liabilities	11	**(4,574)**		(3,555)	
Other liabilities	15	**(28)**		(25)	
Provisions	16	**(1,998)**		(1,711)	
Borrowings		**(1,328)**		(1,328)	
Total non-current liabilities			**(7,928)**		(6,619)
Assets less liabilities			**202,952**		221,741

Taxpayers equity					
Public dividend capital			**1,329**		1,329
Reserves					
Revaluation reserve			**111,633**		115,155
Income and expenditure reserve			**954**		954
General fund			**89,036**		104,303
Total equity			**202,952**		221,741

Dr June Raine CBE
Chief Executive and Accounting Officer
Medicines and Healthcare products Regulatory Agency
14 July 2021

The notes on pages 82 to 101 form part of these accounts.

Statement of cash flows for the year ended 31 March 2021

	NOTE	2020/21		2019/20	
		£000	£000	£000	£000
Cash flows from Operating activities					
Operating surplus		**26**		16,904	
Depreciation and amortisation	7/8	**10,338**		8,754	
Loss on disposal of assets	7/8	**40**		5	
Impairment of property, plant and intangible assets	7/8	**462**		261	
Realised loss on inventories	10	**(188)**		(89)	
(Increase) in inventories	10	**(3,725)**		(171)	
(Increase) in contract assets	11	**(337)**		(19)	
Increase/(Decrease) in contract liabilities	11	**2,656**		(548)	
(Increase)/Decrease in trade and other receivables	12	**(9,057)**		1,039	
(Decrease) in trade and other payables	14	**(4,330)**		(10,942)	
(Decrease) in other liabilities	15	**(906)**		(281)	
Increase in provisions	16	**2,068**		1,390	
Net cash (outflow)/ inflow from operat-ing activities			**(2,953)**		16,303
Cash flows from investing activities					
Purchase of property, plant & equipment	7	**(2,214)**		(1,529)	
Purchase of intangible assets	8	**(1,789)**		(3,768)	
Net cash (outflow) from investing ac-tivities			**(4,003)**		(5,297)
Cash flows from financing activities					
Interest received			**6**		584
Interest paid			**(47)**		(47)
Dividend paid			**(2,687)**		(2,196)
Net cash (outflow) from financing			**(2,728)**		(1,659)
Net (decrease)/increase in cash and cash equivalents in the financial year	13		**(9,684)**		9,347
Cash and cash equivalents at the beginning of the financial year	13		**89,285**		79,938
Cash and cash equivalents at the end of the financial year	13		**79,601**		89,285

The notes on pages 82 to 101 form part of these accounts.

Statement of changes in taxpayer's equity for the year ended 31 March 2021

	PDC	General Fund	Reval. reserve	I & E reserve	Total
	£000	£000	£000	£000	£000
Balance at 31 March 2019	1,329	101,500	107,978	954	211,761
Changes in taxpayer's equi-ty for 2019/20				`	
Surplus for the year	-	17,441	-	-	17,441
Other changes					
Net loss on revaluation of property, plant and equipment	-	-	7,266	-	7,266
Realised loss 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**
Changes in taxpayer's equity for 2020/21				`	
(Deficit) for the year	-	(15)	-	-	(15)
Other changes					
Net loss on revaluation of property, plant and equipment	-	-	(3,334)	-	(3,334)
Realised loss on inventories - biological standards	-	-	(188)	-	(188)
Dividend payable	-	(15,252)	-	-	(15,252)
Sub total	-	(15,252)	(3,522)	-	(18,774)
Balance at 31 March 2021	**1,329**	**89,036**	**111,633**	**954**	**202,952**

The notes on pages 82 to 101 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 2020/21 Government Financial Reporting Manual (FReM) issued by HM Treasury and under an accounts direction given by HM 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 2020/21.

- 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 9).
- 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 in 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. The valuation of properties is prepared based on building cost indices in order to reflect the cost of building a replacement asset in the same location. The indices utilised in preparing the valuation are subject to retrospective update and therefore may change. While the valuation provides an estimate of the cost of rebuilding the current estate if a new property were to be built then changes may be adopted in how space was provided that could lead to changes in the final value. The pandemic and the measures taken to tackle COVID-19 continue to affect economies and real estate markets globally. Nevertheless, as at the valuation date some property markets have started to function again, with transaction volumes and other relevant evidence returning to levels where an adequate quantum of market evidence exists upon which to base opinions of value. Accordingly, and for the avoidance of doubt, the valuation is not reported as being subject to 'material valuation uncertainty' as defined by VPS 3 and VPGA 10 of the RICS Valuation – Global Standards. The values in the report have been used to inform the measurement of property assets at valuation in these financial statements.

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 if:

- they are held for use in delivering services or for administrative purposes;
- it is probable that future economic benefits will flow, or service potential will be supplied;
- they are expected to be used for more than one financial year;
- 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 (RICS). A desktop valuation took place at 31 March 2021. 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.

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. Reductions in value are only taken to the revaluation reserve to the extent that they reverse a previous upward valuation of the same asset, any other downward valuations would be charged to the Statement of Comprehensive Income. 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 an asset meets the impairments criteria the value is restated to the underlying recoverable amount.

Impairment losses that arise from a clear consumption of economic benefit are taken to expenditure. 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 expenditure.

1.4.3 Intangible assets

Intangible assets are capitalised if:

- They are held for use in delivering services or for administrative purposes;
- it is probable that future economic benefits will flow to, or service potential will be supplied;
- they are expected to be used for more than one financial year;
    - 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 in 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 data including features required to support clinical trials.

Sentinel architecture is the suite of Sentinel applications used by the MHRA Regulatory centre e.g. Product Licensing Case Folder.

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.

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.

1.5 Value Added Tax

All statutory 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. Non statutory sales of products and services are generally subject to standard rate VAT. Non-recoverable 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)

This project is accounted for as a joint arrangement and complies with IFRS11. Any surplus or deficit generated are to be shared equally. To supplement the original business case, a Memorandum of Understanding was agreed between the Agency and DHSC stating that as of 1 April 2013 all income / expenditure and assets / liabilities are to be split equally between parties to the joint arrangement. This agreement was subsequently updated in April 2014 to reflect changes in the governance, funding and accounting for the joint arrangement. This is a joint operation where the MHRA acts as a host for the operation and that an initial contribution was made by DHSC to fund their share of the cost of CPRD, the remaining balance of which is held as a liability on the MHRA balance sheet. Details of the joint arrangement are in note 4 CPRD joint arrangement memorandum account.

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 and stages completed. The agency has the following income streams:

- Applications for marketing authorisations and subsequent variations: A number of licensing milestones accepted as part of the application process have been identified and have been allocated a percentage to reflect the completed performance obligation. 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 inspections as well as for pre-inspection preparation, travel 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.
- 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 to reflect the performance obligations. 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 is based on the number of notified products. Income is recognised when the performance obligation is complete; this is when the application has been validated and published on the Agency's 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, as research projects progress, deferred income is recognised in line with expenditure incurred. Income is recognised at pre-determined stages as outlined in agreements and in line with IFRS 15. Any remaining deferred income at the reporting date is reported as a contract liability.
- Capital grants receivable from governmental and non-government bodies for the purchase of specific capital assets are recognised as income when 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.

Payment for marketing authorisations, variations, clinical trials and e-cigarettes notifications is due on invoicing. 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 along with any payments received for these services not

yet delivered, is deferred to future periods and disclosed as contract liabilities in line with IFRS 15.

As contracts for marketing authorisations, variations, clinical trials and e-cigarettes notifications are expected to have a duration of less than one year the practical expedient has been applied in line with IFRS 15.

1.8 Inventories

Inventories are valued at the lower of cost or net realisable value. 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 (flu standards over two years old), slow-moving (sales of less than 24 items in the year) and defective inventories in accordance with IAS 2. The historic cost of inventory is estimated by calculating the average sales over the last four years and projecting this to a maximum of fifteen years and applying the unit cost for year of production.

1.9 Leases

Leases are classified as finance leases when substantially all the risks and rewards of ownership are transferred to the lessee. All other leases are classified as operating 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 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.

1.11 Going concern basis

Non-trading entities in the public sector are assumed to be going concerns where the continued provision of a service in the future is anticipated, as evidenced by inclusion of financial provision for that service in published documents. The regulatory services provided by the Agency are enshrined in current legislation and will continue to be funded as they are an essential part of HMG's public services. 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

MHRA income and expenditure are analysed and reported in line with management information as used to report to ExCo and Board. The Agency reports against three operating segments as defined within the scope of IFRS 8 (Segmental Reporting) under paragraph 12 (aggregation criteria). These are:

The Clinical Practice Research Datalink (CPRD) is an observational and interventional data research service, jointly supported by the National Institute for Health Research and the MHRA.

The National Institute for Biological Standards and Control (NIBSC) is the UK's Official Medicines Control Laboratory (OMCL) for biological medicines, carrying out independent medicines control testing and biological medicines. It performs world class research with expertise in regulatory science.

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

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.

2020/21

	CPRD* £000	NIBSC £000	Regulator £000	Total £000
Income from external customers	5,720	20,167	77,323	103,210
Income from DHSC	-	19,296	24,040	43,336
Sub total	5,720	39,463	101,363	146,546
Other income not attributable to segments	-	-	-	12,425
Total income	5,720	39,463	101,363	158,971
Direct costs	(5,666)	(36,780)	(53,454)	(95,900)
Indirect costs	(2,409)	(11,915)	(48,721)	(63,045)
Total expenditure	(8,075)	(48,695)	(102,175)	(158,945)
Segment operating (Defi-cit)/ Surplus	(2,355)	(9,232)	(812)	26

* represents MHRA's 50% share of joint arrangement

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
Sub total	5,035	43,028	106,681	154,744
Other income not attributable to seg-ments	-	-	-	11,953
Total income	5,035	43,028	106,681	166,697
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	16,904

3. Income

3.1. Trading income

	2020/21 £000	2019/20 £000
Licenses and inspections	**32,268**	32,363
Service fees	**30,952**	33,051
European Medicines Agency (EMA)	**122**	2,977
Devices	**9,856**	11,986
Clinical trials	**3,574**	3,322
British Pharmacopoeia	**5,388**	4,742
Other trading income	**19,203**	18,240
NIBSC	**39,463**	43,028
CPRD	**5,720**	5,035
Total	**146,546**	154,744

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 £12.4M (2019/20, £12.0M) from the Department of Health and Social Care to offset the additional costs of dividend £5.5M (2019/20, £5.4M) and depreciation £6.9M (2019/20, £6.6M), resulting from the transfer of the NIBSC to the agency on 1 April 2013.

4. Clinical Practice Research Datalink

Joint arrangement memorandum account

The Clinical Practice Research Datalink (CPRD) is an observational and interventional research service, jointly supported by the Department of Health and Social Care and the Medicines and Healthcare products Regulatory Agency.

Following a review of the accounting presentation, the DHSC original contribution which was originally shown as CPRD cash with a corresponding liability, has been removed from the memorandum as it is cash paid to MHRA and correctly recorded as a liability of the MHRA and as reflected in note 15. The Agency's share of 50% of the CPRD income and expenditure and non-current assets, currents assets and current liabilities are reflected in the Agency accounts.

Income and expenditure

	2020/21	2019/20
	£000	£000
Income	**11,440**	10,070
Expenditure		
Operating costs	**(11,080)**	(7,251)
Staff costs	**(5,070)**	(4,263)
Operating (deficit)	**(4,710)**	(1,444)

Statement of financial position

	31 March 2021	31 March 2020
	£000	£000
Non-current assets		
Tangible assets	**140**	194
Intangible assets	**3,319**	4,419
Current assets		
Trade and other receivables	**3,679**	3,191
Current liabilities		
Trade and other payables	**(990)**	(937)
Other liabilities	**(3,802)**	(3,140)
Assets less liabilities	**(8,383)**	(3,673)
Reserves		
Reserves	**(3,673)**	(2,229)
Total Reserves	**(8,383)**	(3,673)

Non-current assets

	2020/21	2019/20
	£000	£000
Fixed Asset		
Cost		
At 1 April	**9,642**	9,593
Additions	**420**	1,963
Disposals	**-**	(1,914)
At 31 March	**10,062**	9,642
Amortisation		
At 1 April	**5,029**	5,711
Charge for the year	**1,574**	1,232
Disposals	**-**	(1,914)
At 31 March	**6,603**	5,029
Net Book Value at 31 March	**3,459**	4,613

5. Staff costs

	2020/21	2019/20
	£000	£000
Wages and salaries	**69,745**	64,302
Social security costs	**7,067**	6,768
Other pension contributions	**15,873**	15,343
Sub total	**92,685**	86,413
Less recoveries in respect of outwards secondment	**(246)**	(189)
Total	**92,439**	86,224

See staff report page 63.

6. Operating costs

	2020/21	2019/20
	£000	£000
Computing	**23,228**	19,756
Accommodation	**8,951**	10,416
Medicines testing and Laboratory expenses	**9,487**	9,850
Depreciation and amortisation	**10,338**	8,754
Travel and subsistence	**72**	2,022
Other operating costs	**14,430**	12,771
Total	**66,506**	63,569

Other operating costs include:	£000	£000
Contracted out services	**12,767**	6,369
Operating leases	**2,463**	2,439
Movement in inventory	**(3,894)**	(110)
VAT partial exemption refund	**(1,013)**	(895)
Statutory audit fees	**105**	105

7. Property, plant and equipment

2020/21	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 2020	**1,762**	**126,156**	**8,106**	**25,906**	**106**	**162,036**
Additions	2,214	-	-	-	-	2,214
Transfers	(3,217)	42	456	2,719	-	-
Revaluation	-	(8,503)	-	(1,405)	-	(9,908)
Disposals	(4)	-	-	(194)	-	(198)
At 31 March 2021	755	117,695	8,562	27,026	106	154,144
Accumulated depreciation						
At 1 April 2020	**-**	**-**	**6,254**	**17,898**	**95**	**24,247**
Charge for the year	-	5,365	689	1,657	8	7,719
Revaluation	-	-	-	(747)	-	(747)
Elimination of accumulat-ed depreciation	-	(5,365)	-	-	-	(5,365)
Disposals	-	-	-	(174)	-	(174)
At 31 March 2021	**-**	**-**	**6,943**	**18,634**	**103**	**25,680**
Net book value						
At 31 March 2021	**755**	**117,695**	**1,619**	**8,392**	**3**	**128,464**
Net book value at 31 March 2020	1,762	126,156	1,852	8,008	11	137,789
Owned	**755**	**117,695**	**1,619**	**8,392**	**3**	**128,464**
Net book value at 31 March 2021	**755**	**117,695**	**1,619**	**8,392**	**3**	**128,464**

Land and buildings

A professional desktop valuation of land and buildings was carried out on 31 March 2021 which resulted in a net decrease of £3,138k. 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.

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	1,762	126,156	1,852	8,008	11	137,789
Net book value at 31 March 2020	1,762	126,156	1,852	8,008	11	137,789

8. Intangible assets

2020/21	Computer systems	AUC	Software licences	Total
	£000	£000	£000	£000
Cost or valuation				
At 1 April 2020	**23,984**	**8,288**	**3,428**	**35,700**
Additions	-	1,789	-	1,789
Transfers	9,607	(9,607)	-	-
Disposals	-	(14)	(105)	(119)
At 31 March 2021	**33,591**	**456**	**3,323**	**37,370**
Amortisation				
At 1 April 2020	**18,053**	**-**	**3,412**	**21,465**
Charge for the year	2,614	-	5	2,619
Disposal	-	-	(103)	(103)
Amortisation at 31 March 2021	**20,667**	**-**	**3,314**	**23,981**
Net book value at 31 March 2021	**12,924**	**456**	**9**	**13,389**
Net book value at 31 March 2020	5,931	8,288	16	14,235
Owned	12,924	456	9	13,389
Net book value at 31 March 2021	**12,924**	**456**	**9**	**13,389**

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

Owned	5,931	8,288	16	14,235
Net book value at 31 March 2020	5,931	8,288	16	14,235

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	2020/21	2020/21	2019/20	2019/20
	£000	**£000**	£000	£000
Minimum lease payments	**24**	**2,439**	43	2,439
Total	**24**	**2,439**	43	2,439

Total future minimum lease payments	2020/21	2020/21	2019/20	2019/20
	£000	**£000**	£000	£000
Payable:				
Within one year	**24**	**2,439**	-	2,439
Between two to five years	**13**	**9,757**	-	9,757
Over five years	**-**	**22,516**	-	20,076
Total	**37**	**34,712**	-	32,272

10. Inventories

	31 March 2021	31 March 2020
	£000	£000
Biological Standards	**9,424**	5,719
Laboratory consumables and other stores	**139**	119
Total	**9,563**	5,838

Inventory consumed	5,298	1,423
Obsolete inventories	1,277	1,431
Provision for slow moving items	1,335	1,447

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 2020/21 was £188k (2019/20, £89k).

11. Contract assets and contract liabilities

	Current		Non current	
	31 March 2021	31 March 2020	31 March 2021	31 March 2020
	£000	£000	£000	£000
Contract assets (unbilled receivables)	**6,948**	6,611	**-**	-
Contract liabilities (customer advances)	**12,761**	11,124	**4,574**	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.

	31 March 2021	31 March 2020
Revenue recognised in the period from	£000	£000
Amounts included in the contract liability at the beginning of the period	**9,531**	10,839

12. Trade and other receivables

	31 March 2021	31 March 2020
	£000	£000
Amounts falling due within one year		
Due from the Department of Health and Social Care	**20,854**	11,953
Trade receivables*	**9,091**	8,710
Other receivables	**601**	998
Accrued income	**3,683**	3,183
Prepayments	**2,765**	2,631
Total	**36,994**	27,475
Amounts falling due after more than one year:		
Prepayments	**7,291**	7,753
Total	**44,285**	35,228

*Trade receivables are shown net of a provision for bad debts of £33k (31 March 2020 £113k) calculated using the simplified approach in line with IFRS 9 and credit notes for all unpaid periodic fees at year end of £447k (31 March 2020 £417k).

13. Cash and cash equivalents

	31 March 2021 £000	31 March 2020 £000
Balance at 1 April	**89,285**	79,938
Net change in year	**(9,684)**	9,347
Balance at 31 March	**79,601**	89,285

Made up of		
Government Banking Service	**79,601**	89,285
Cash and cash equivalents	**79,601**	89,285

14. Trade and other payables

	31 March 2021 £000	31 March 2020 £000
Amounts falling due within on		
Due to Department of Health and Social Care	**15,300**	14,684
Payments received on account	**6,081**	4,648
Taxation and social security	**3,568**	3,329
Other trade payables	**2,680**	1,739
Other payables	**379**	-
Accruals	**14,685**	10,058
Total	**42,693**	34,458

15. Other liabilities

	Current		Non-current	
	31 March 2021 £000	31 March 2020 £000	31 March 2021 £000	31 March 2020 £000
Deferred revenue:				
Other fees	**2,787**	2,474	**28**	25
Others:				
DHSC Contribution to CPRD joint arrangement	**11,348**	12,570	**-**	-
Total	**14,135**	15,044	**28**	25

16. Provisions

	Current		Non-current	
	31 March 2021 £000	31 March 2020 £000	31 March 2021 £000	31 March 2020 £000
Other provisions	**1,781**	-	**-**	-
Dilapidations	**-**	-	**1,998**	1,711
Total	**1,781**	-	**1,998**	1,711

Movement in provisions

	Total £000
At 1 April 2020	**1,711**
Arising during the year	**2,068**
Used during the year	**-**
At 31 March 2021	**3,779**

Expected timing of cash flows:

Within one year	**1,781**
Between two to five years	**-**
Over five years	**1,998**
Total	**3,779**

Other provisions established during the year are in respect of:

- A provision in lieu of unpaid VAT and estimated interest on certain sales of research and data services to academic institutions with charitable status where VAT had not been charged, has been created pending settlement with HMRC; The provision has not been discounted as payment is expected to be made with the next twelve months. In line with the requirements of managing public money this has been disclosed as a loss in the Accountability Report.

17. Capital and other financial commitments

Contracts entered into, not provided for in the accounts

	Intangible	Tangible	Intangible	Tangible
	31 March 2021	31 March 2021	31 March 2020	31 March 2020
	£000	£000	£000	£000
Contracted	**56**	**567**	1	1,377
Total	**56**	**567**	1	1,377

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 2020/21, 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. EVENTS AFTER THE REPORTING PERIOD

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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