Medicines & Healthcare products Regulatory Agency

Annual Report and Accounts 2021/22

HC 475

Medicines and Healthcare products Regulatory Agency

Annual Report and Accounts 2021 / 2022

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1 Performance report

1.1 Performance Overview

This section describes the role of the Medicines and Healthcare products Regulatory Agency ('the Agency'), explains our purpose, strategic objectives and goals and provides a summary of our performance in 2021/22.

Chair's foreword

As I approach the end of my second year as Chair of the MHRA Agency Board, I feel immensely proud of how the Agency has responded to both the latest phase of the pandemic and its wider transformation into a sovereign regulator that is trusted, pro-active and proportionate.

The Agency has supported the UK wide COVID-19 vaccination programme through the approval and batch release of new COVID-19 vaccines for the UK market. This year has also seen the introduction of the first oral antiviral agents through the rolling review programme, expedited approval of clinical trials, diagnostic tests, ventilators, and therapeutics. These achievements herald the beginning of a new and more efficient response to living with COVID, which would not have been possible without the expertise and tenacity of everyone working at the Agency.

The MHRA has remained at the forefront of improved public health outcomes through a range of pioneering projects such as the Innovative Licensing and Access Pathway (ILAP) in conjunction with the National Institute for Health and Care Excellence (NICE), the Scottish Medicines Consortium (SMC) and the All Wales Therapeutics and Toxicology Centre (AWTTC). New medicines continue to be made available to patients via the Early Access to Medicines Scheme (EAMS) and the Agency is working to improve our approach to clinical trials approval in partnership with the Health Research Authority (HRA). This has included the launch of a public consultation on new proposals for the future of clinical trials legislation in the UK with an ambition of putting patient participation at the heart of every trial that is conducted. Building regulation around patient need and safety was also at the core of the consultation on the new regulatory framework for medical devices.

To deliver the Agency's vision of being a world class sovereign regulator, with the patient at its core, the Agency has implemented a new organisational structure based on the medical product lifecycle. The new dynamic organisation has a clear focus on enabling scientific innovation, accelerating patient access to new medical products and strengthening the safety and surveillance monitoring of products being used in patients, which is underpinned with collaborative partnerships and a financially sustainable business model.

There will be further opportunities and challenges ahead for the Agency and I am confident that we will be able to address these by utilising the wealth of skill and expertise of our staff throughout the Agency. Developing our leadership and people, improving our technology infrastructure and completing the transformation programme will enable us to deliver an even more responsive and efficient regulatory service to meet the needs of patients, health professionals, researchers, developers, manufacturers and the general public.

Stephen Lightfoot

Chair

Chief Executive's perspective on 2021-22 performance

After a landmark year, I would like to begin by commending all the Agency's staff for their commitment and dedication during the most challenging period to date for our organisation. Not only has the Agency continued to deliver in a time of change and challenge, maintaining our contribution to the nation's response to the pandemic, but we have implemented an exciting new organisational structure which places patients at the heart of all our activities and forms a strong foundation for our supporting role in the government's Life Sciences Vision.

"We have fully recognised the importance of collaboration with partners in healthcare in all our work"

Our response to the evolving challenges of the COVID-19 pandemic has demonstrated how a progressive, agile regulator can support speedy initiation of clinical trials and prompt access to vital healthcare products while maintaining the highest independent scientific standards. We have approved new COVID-19 vaccines in a range of formats, played a central role in access to diagnostic tests, and authorised the first oral antiviral for COVID-19 coupled with a pioneering approach to its evaluation in community use. Our vaccine safety surveillance has used new tools and methodologies, including artificial intelligence and data from the Clinical Practice Research Datalink. Our scientific research program has developed the first International Standard for COVID-19, endorsed by the World Health Organisation, and via our work on new variants we have enabled greater understanding of the pandemic's evolution.

Inspired by our 'One Agency' response to the pandemic, this year we have put in place a new, integrated organisational structure with a clear mission for end-to-end oversight of healthcare products from first discovery and development through to deployment. Implemented at the beginning of 2022, our redesigned Agency is geared to delivering on our commitment to patients for robust, timely decisions on safety and access to healthcare products. I am immensely proud of the way in which our new leadership team and all our staff have engaged throughout the process of transformation to ensure the very best outcome for all our stakeholders, and for the huge effort to build our new groups which has been supported by our Communications, Human Resources and Finance teams.

During this year we have fully embraced the opportunities of EU exit as a standalone regulator, commencing a programme of legislative reform for which the Medicines and Medical Devices Act 2021 provides a base. New legislative provisions on point of care manufacture and on early access to

medicines fully demonstrate our commitment to meeting patient needs and to supporting innovation. Working closely with government we have ensured the supply of medicines into the UK and continued supply of medicines into Northern Ireland through the Northern Ireland MHRA Authorised Route. We have consulted on innovative proposals to reframe our clinical trials legislation, particularly to make trial participation accessible to all, and on a comprehensive new regulatory regime for medical devices, including the most innovative technologies, which prioritises patient safety.

We have fully recognised the importance of collaboration with partners in healthcare in all our work. Our Innovative Licensing and Access pathway (ILAP), launched as the UK left EU, is founded on joint working with the National Institute for Health and Care Excellence, the All Wales Therapeutics and Toxicology Centre and the Scottish Medicines Consortium. Designed to reduce time to patient access for potentially transformative products, ILAP has gained considerable interest and support over the last year. We are now ready to consolidate this valuable experience and further enhance the pathway including similar provisions for medical devices. Collaborative working has also flourished via international partnerships, notably the ACCESS consortium with Australia, Canada, Singapore and Switzerland, and the FDA's Project Orbis for cancer medicines, both of which enable cutting-edge treatments to safely reach patients.

Two years on from the Report of the Independent Medicines and Medical Devices Safety Review (IMMDSR), chaired by Baroness Julia Cumberlege, we have made considerable progress towards ensuring that patients are listened to, and their views acted on, in every aspect of our work. This year saw publication of our first Patient and Public Involvement strategy, a multifaceted approach to delivering change. So far, we have developed a more responsive safety reporting system, SafetyConnect, which has been informed by patients' views and will reach full deployment in the coming year. Patients' views and input have been sought on major safety reviews, strengthening the evidence for regulatory decisions, and patients contribute routinely to our Innovative Licensing and Access Pathway.

After a year of change and challenge one conclusion is clear – that it is only through the skills, expertise and dedication of our staff that delivery of high standards of public health protection has been possible. At the completion of a demanding year, I wish to sincerely thank all members of staff for their remarkable commitment to continuing to deliver and to excel. A key priority for the coming year will be supporting all colleagues to reach their full potential in a culture of inclusion and achievement for everyone. With our unique assets as an integrated Agency – world-leading basic science, innovative approaches to regulation, and state-of-the art real-world data - I am confident that we now have the foundation to embed new ways of working and fully realise the opportunities to optimise and improve our service to all our stakeholders, and most of all patients and the public.

June M Raine

June M Raine

Who we are and what we do

The Medicines and Healthcare products Regulatory Agency ('the agency') plays a leading role in protecting and improving public health through rigorous evidence-led decision making underpinned by excellent science.

We do this by:

- **Regulation of medicines, medical devices, and blood components for transfusion in the UK** to ensure that these meet applicable standards of safety, quality and efficacy and that the supply chain is safe and secure
- **Standardisation and control of biological medicines,** promoting international standardisation and harmonisation to assure the effectiveness and safety of biological medicines
- **Supporting healthcare innovation** through scientific, regulatory focused research and development, underpinning the development of new standards and reference materials
- **Provision of data research services** through the Clinical Practice Research Datalink (CPRD), which aims to improve public health using anonymised NHS clinical data
- **Education of the public and healthcare professionals** about the risks and benefits of medicines, medical devices and blood components, leading to safer and more effective use
- **Influencing UK and international regulatory frameworks** to ensure they are risk-proportionate and effective at protecting public health

We are an Executive Agency of the Department of Health and Social Care (DHSC). The DHSC holds us to account for our performance, and we work in partnership to serve ministers and Parliament and to serve patients and the public. Details on our relationship with DHSC can be found in our Framework Agreement which can be found on www.gov.uk.[1]

Last year, our workforce included more than 1,380 staff working across facilities in London, York and South Mimms, Hertfordshire.

Our mission

Our mission is to **enhance and safeguard the health of the public** by ensuring that medicines and medical devices work effectively and are acceptably safe.

Our composition

The Agency has historically operated as three complementary centres, working together to protect patients and public health through a combined portfolio of expertise in regulation, data and standards. For much of the year the three centres have operated with defined and separate activities, with each centre responsible for its own outcomes under a single Agency leadership.

Bringing together of these specialisms make us unique as a regulator in having an innovative regulator, a world-leading WHO research and standards capability as well as a clinical data service all under one roof. We are a science driven organisation that uses our expertise in scientific research, standards, data and risk-based regulation to ensure that medicines and devices deliver better outcomes for patients and public health. We have therefore addressed the integration of our functions through an ambitious transformation programme, bringing our specialisms together to create new benefits from operating as one Agency while still preserving the expertise we have developed over previous years.

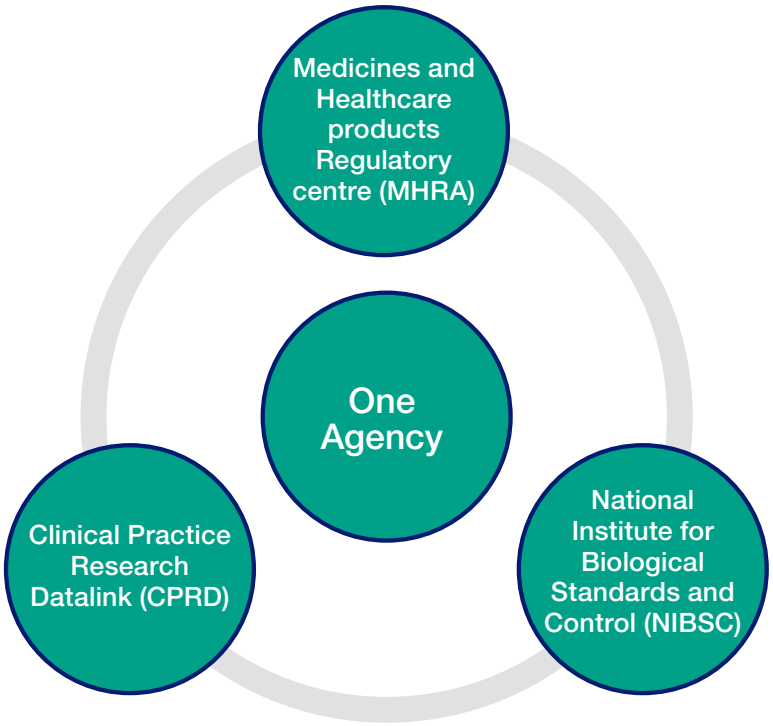
This report is based on the Agency's structure in the 2021/22 financial year. Initial transition away from our three-centre structure began in January 2022 and will complete over the course of 2022.

Further details of our new organisational structure can be found in the "Our Future" section on page 19.

1. GOV.UK. Welcome to GOV.UK. 2022. Available at: https://www.gov.uk/. Accessed July 2022.

One Agency

This year we have embarked on an ambitious transformation programme to create our new One Agency structure, drawing together our expertise and experience from our three centres to create a proactive and agile regulator.



The new One Agency structure brings together expertise from across our three centres:

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

The MHRA 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) is a global leader in the standardisation and control of biological medicines.

NIBSC is responsible for:

- Assuring the quality of biological medicines and diagnostics by developing and producing over 90% of the standards in use around the world as the WHO Collaborating Centre for Biological Standardisation
- 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 as the UK's OMCL for biological medicines
- Performing world class research with expertise in regulatory science

NIBSC is a stand-alone National Control Laboratory from 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. NIBSC also houses the UK Stem Cell Bank, the Influenza Resource Centre (encompassing the WHO Essential Regulatory Laboratory), and the WHO Collaborating Centre on polio virus research and surveillance.

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

CPRD is responsible for collecting and making available 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 63 million patient records, including 16.4 million currently registered patients.

How are we funded?

Last year our activities were funded as follows:

- Medicines regulation was funded from fees charged to the regulated industry according to the full cost recovery rules set out in Her Majesty's Treasury's Managing Public Money
- Devices regulation was primarily funded by DHSC with approximately 10% of its revenue from fees charged for services
- NIBSC derived almost half its revenue from fees charged for services, including the sale of biological standards; NIBSC also received research funding, including DHSC research funding through the Regulatory Science Research Unit (RSRU); and DHSC provided the remaining funding to finance its important public health functions
- CPRD is jointly funded by the Agency and DHSC's National Institute for Health Research (NIHR) and managed and operated by the Agency with DHSC having equal voting rights in direction setting and decision making

From 1 April 2022, the Agency ceased to be a Government Trading Fund, and our finances are now consolidated within the DHSC accounting boundary. Additional details about our funding can be found in the "Financial review" section on page 48.

Our goals and deliverables

We are halfway through our ambitious two year, transformative Delivery Plan *Delivery Plan 2021-2023: A new Era – delivering for patients*.[1] This plan is the roadmap to our future. It represents the beginning of a new era in the protection of patients, their closer involvement in how we operate and the improvement of public health through innovative regulation based on excellence in science.

Through our Delivery Plan, we are building a new organisation that is fit for the future and underpinned by a robust long-term business model. Our ambition is to become a world-leading, enabling regulator which protects public health through excellence in regulation and science, whilst holding the patient at the heart of everything we do.

Our work in 2021/22 was guided by the six strategic areas of focus set out in our Delivery Plan: **scientific innovation, healthcare access** and **patient safety** underpinned by the creation of a **dynamic organisation**, leveraging **international partnerships** and ensuring **financial sustainability:**

1. GOV.UK. The Medicines and Healthcare products Regulatory Agency Delivery Plan 2021-2023. July 2021. Available at: https://www.gov.uk/government/publications/the-medicines-and-healthcare-products-regulatory-agency-delivery-plan-2021-2023. Accessed July 2022.

Our goals

Priority for all staff

1. Deliver better patient and public involvement to ensure we put patients first

Scientific innovation

2. Deliver public health impact, world-leading research innovation and a unique proposition
3. Overhaul the clinical trials system to support innovation and reduce time to approval

Healthcare access

4. Develop and deliver our future strategy and approach for access to medicines and devices
5. Establish a new medical devices legislative framework to support safe innovation and ongoing access to products

Patient safety

6. Deliver a more responsive safety surveillance and risk management system, for all medical products, to keep patients safe
7. Deliver innovative interventions to ensure the UK has a secure supply chain providing high quality products

Dynamic organisation

8. Deliver our Transformation Programme to make us a truly world-leading, innovative regulator
9. Deliver a programme to enhance our leadership capability and to attract, retain and develop talent so that we can fuel innovation and drive change

Collaborative partnerships

10. Leverage international partnerships to drive better outcomes
11. Leverage UK healthcare system partnerships to integrate processes and drive better outcomes
12. Build public and stakeholder trust in our organisation through a programme of proactive and innovative communications

Financial sustainability

13. Establish a new business model for the future that increases income, reduces costs, and improves productivity
14. Deliver an optimised IT infrastructure to improve our service and reduce our costs with fewer digital technologies

Performance summary at a glance

During 2021/22, we made good progress in challenging circumstances due to continued pressures of the COVID-19 pandemic, EU Exit and a programme of regulatory revision via the Medicines and Medical Devices Act 2021, ensuring continued supply of medicines into Northern Ireland, and implementation of our ambitious transformation programme for the Agency.

Highlights include:

- Playing a central role in the UK's efforts to combat the COVID-19 pandemic through regulatory approval of new vaccines and treatments, batch release safety testing of vaccine batches and publication of adverse events
- Following the UK's exit from the EU, launching a major programme of legislative change to ensure that as a sovereign regulator we continue to provide safe access to new products, to improve safety for patients and to align with the best international healthcare standards; this includes holding public consultation Point of Care manufacture, the Early Access to Medicines Scheme, clinical trials and the future medical device regime including software as a medical device
- In January 2022, launching the Innovative Licensing and Access Pathway which supports innovation and facilitates rapid access to new medicines via collaboration with the National Institute for Health and Care Excellence, the Scottish Medicines Consortium and the All Wales Therapeutics and Toxicology Centre; the pathway is increasing the efficiency with which new medicines come to market through cross disciplinary working, bringing together expertise from the wider healthcare system, and through the creation of national authorisation procedures for medicines
- Publishing our *MHRA Patient Involvement Strategy 2021-2025*[1] setting out our commitment to engaging and involving the public and patients at every step of the regulatory journey
- Forming new partnerships in the UK healthcare system and internationally to develop our role as a UK and international regulator and to enable patients to benefit from timely access to high quality, safe and effective medicines
- Continuing to work closely with central government to develop our system of regulation following EU Exit, on negotiations with the European Union, and to secure the supply of medicines for UK patients, including to Northern Ireland through a new regulatory route, the Northern Ireland MHRA Authorised Route (NIMAR)
- Commencing the design and implementation of our transformation programme to our new operating model, which is based around the product lifecycle, shifting the Agency's focus to proactive, risk-proportionate and patient-centred regulation, pulling scientific innovation through the system and seeking opportunities to add value at every step of the process

1. Medicines & Healthcare products regulatory agency. Patient Involvement Strategy 2021-25. 2021. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1022370/Patient_involvement_strategy.pdf?fbclid=IwAR20fuPuHv-t_JglsHNFnhmv4wB_5sbkWLKHpGeyXTc33j_LEPEoW6WCy3k. Accessed July 2022.

Highlights 2021/22

Here are some ways we have made a positive difference to public health in 2021/22

Certified over 220 batches of COVID-19 vaccines for use in the UK health system equivalent to **> 220 million doses**

COVID-19

Approved **3 new COVID-19 vaccines** (taking the total approved for use in the UK to 5), and approved new therapeutics and treatments

Speedy Patient Recruitment into Trials (SPRINT) tool launched to enable rapid recruitment and increased diversity in clinical trials

Changing Clinical trials

Polio - **nOPV2**
New Oral Polio vaccine developed at NIBSC approved by WHO SAGE for wider use

Global health

Public consultation launched to help shape the future of **clinical trials** and to help put patient participation at the heart of trial regulation

Enforcement group and online marketplace collaboration resulted in the removal of **100 illicit adverts** for unlicensed medicines, including a class B drug, and millions of illegal medicines seized at UK entry points ensuring the quality and safety of UK medicines

Patient Safety

Launched a **public consultation** on the future legal framework for medical devices in the UK, to ensure the highest standards of safety and accuracy for diagnostic **tests and innovative medical technologies**

Our future

The Agency's transformation

This year, we have embarked upon a journey of ambitious transformation to create a compelling future for the Agency in response to a number of drivers and opportunities for change. These range from the opportunities of EU Exit, the recommendations of the Independent Medicines and Medical Devices Safety Review (IMMDS) and the rapid pace of innovation in life sciences to addressing inefficient legacy technology and a siloed organisational culture. The potential synergies of working across our three key assets of cutting-edge science, innovative regulatory approaches and real-world evidence, to deliver the best outcomes for public health, needed to be maximised.

To embrace all that these challenges and opportunities have to offer, we have developed a number of key principles that establish our new operating model and are informing the detail of our transformation programme:

- We will move from a reactive approach to become a proactive, agile and patient-centred regulator, pulling scientific innovation through the regulatory system and seeking out opportunities to add value in new, innovative ways
- We will orientate our work around the lifecycle of the healthcare products we regulate to dispense with old, siloed approaches and fully capture the benefits of operating as one Agency across our different functions
- We will differentiate between mature and innovative healthcare products and regulate in a risk-proportionate way, with a clear focus on where and how we add value
- We will work with partners to best deliver our purpose, but we will at all times maintain our sights on the rationale for our existence which is to protect and benefit patients and public health

Over the course of this year, we have been implementing our new organisational structure to deliver our new operating model in line with the above principles. We have also developed a path to financial sustainability, through a reduction in non-pay spend and technology investment, a reduction in staff roles where appropriate and in proportion to inherent risk, and work to refresh our fees policy, which will require amendments to our existing regulations.

In line with the Delivery Plan 2021-2023[1], our transformation will deliver a wide range of tangible improvements to the regulatory processes including:

- Improved patient safety through the introduction of more efficient and effective safety systems, enabling us to take rapid action on safety concerns
- Better use of real-world data in regulatory decision making to identify and verify safety concerns, connecting into our improved safety systems to enable rapid action
- Rapid provision of advice on clinical trial design and regulation to academia and industry, supporting the Government's commitment to make the UK the best place to develop and run clinical trials and develop new healthcare products
- Reduction in time to market for innovative medicines and medical devices through a full end-to-end pathway of product development, with the aim of reducing the time to market
- Enhanced partnerships nationally and internationally to ensure rapid, safe access to new healthcare products for UK patients through collaboration including work-sharing
- Streamlined, automated and standardised processes delivering greater value through new modernised technology

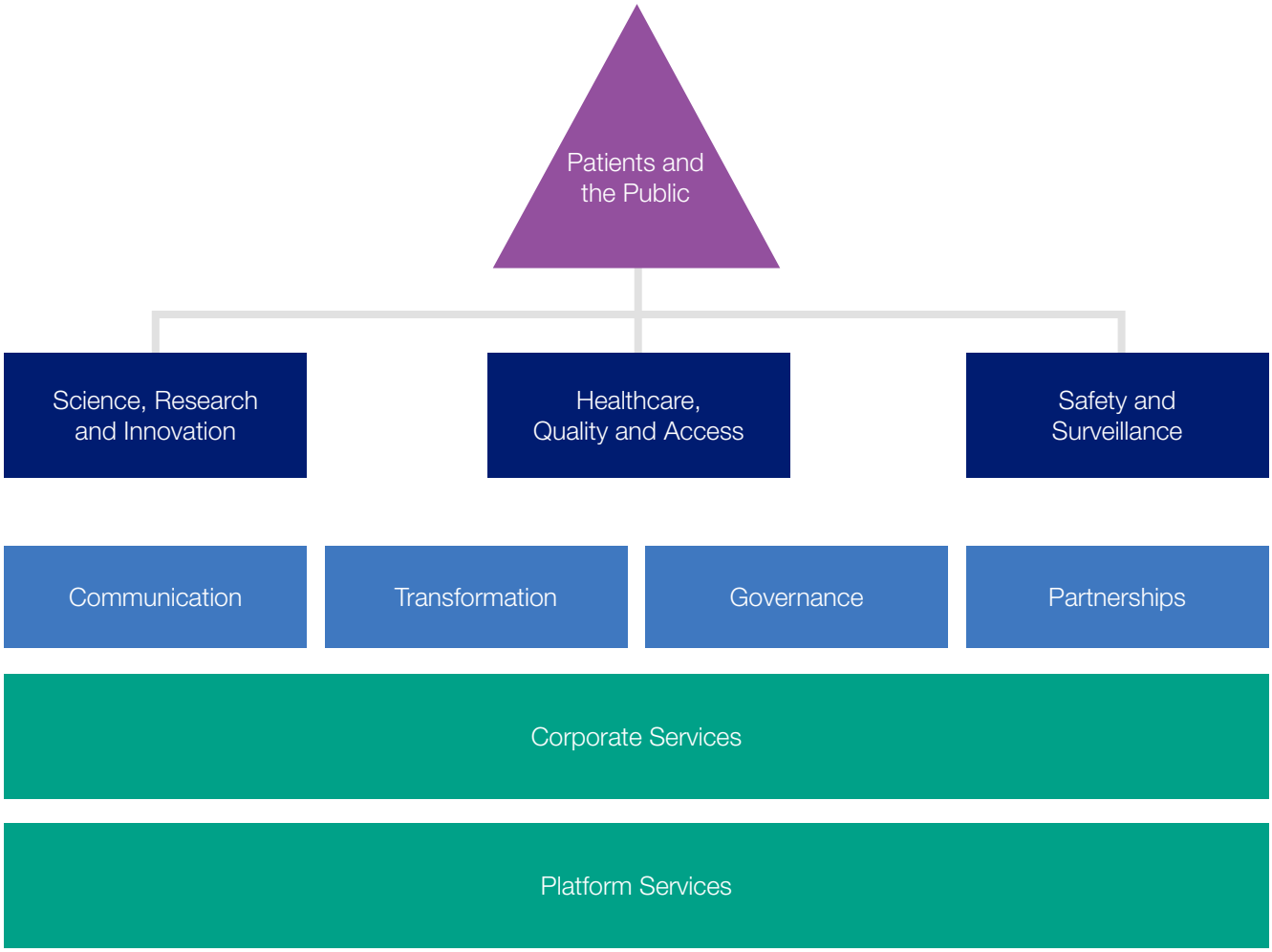
The new Agency operating model is being supported by a substantial technology investment programme which includes upgrading our support systems, replacing legacy systems and investing in new technology. In addition to supporting improvements in our regulatory processes, our investment in technology will:

- Deliver significant cost reductions and increase efficiencies within the Agency's technology estate
- Enable our staff to work effectively by providing underpinning platforms and enhancing collaborative opportunities across the new Agency structure
- Improve access to the Agency's services for patients, the public, industry and our many other stakeholders, ensuring information is provided in a user-friendly way

1. GOV.UK. The Medicines and Healthcare products Regulatory Agency Delivery Plan 2021-2023. July 2021. Available at: https://www. gov.uk/government/publications/the-medicines-and-healthcare-products-regulatory-agency-delivery-plan-2021-2023. Accessed July 2022.

Our new One Agency structure

Our new operating model is based around three core functions, underpinned by communication, transformation, governance and partnership groups and supported by corporate and platform services. This operating model is designed around the product lifecycle with a focus on patients and the public who we are delivering for:



1.2 Performance Analysis

This section considers in more depth the Agency's performance against our key priorities as set out in the 2021/22 Business Plan, including highlights of our achievements and detailed metrics against key targets.

Highlights of our 2021/22 achievements

COVID-19 Pandemic response

The Agency played a key role in leading the UK out of the pandemic through support and regulation of the world-leading COVID-19 vaccination program, through facilitating access to antivirals and treatments for vulnerable people, through collaboration on access to COVID-19 tests, and by working to increase public understanding and trust in vaccination by applying rigorous analysis and excellent science to support our decision making and risk communication.

In 2021/22, we approved three new COVID-19 vaccines for use in the UK, taking the total number to five, and certified over 220 vaccine batches, equivalent to over 220 million vaccine doses.

We released a weekly publication on suspected Adverse Drug Reactions to COVID-19 vaccines, which set out trends in reporting, with over 2,000 Yellow Card reports per day. CPRD data enabled us to monitor COVID-19 vaccines and treatments and carry out rapid evaluation of adverse events.

Our scientific research program led to the development of the first International Standard for COVID-19, endorsed by the World Health Organisation, as well as the production of a large selection of reference materials for COVID-19 virus variants. These are highly characterised biological materials, which are used by manufacturers of vaccines, treatments and diagnostic test kits to ensure that the tests they use to assess their products are accurate, measurable and reproducible.

We also participated in analysis of new COVID-19 variants alongside UK Health Security Agency (UKHSA) in a program funded by the Centre for Emergency Preparedness Innovations (CEPI) to further understanding of the pathogenicity of new variants.

Patient involvement

In 2021/22 we published the Agency *Patient Involvement Strategy 2021-2025*[1], detailing how we will increase engagement and involvement of the public and patients throughout the regulatory journey.

We consulted with patients and the public on a number of topics:

- As part of our safety review of an acne treatment, isotretinoin, we consulted extensively with patients, their families and the public on the nature of the adverse drug reactions reported and the patients' and families' views on how risks should be communicated and managed
- We met with patient representatives who had experienced adverse events as a result of surgery with urogenital mesh, to further understand the nature and impact of these events and their views on the future role of mesh
- As part of our benefit / risk review of insulin pumps, we consulted with manufacturers and patients, in collaboration with Diabetes UK, to understand the perspective of those living with diabetes and using insulin pumps
- We received helpful insights from the IMDDS Safety Review's Patient Reference Group to inform our Patient Involvement Strategy and improve our adverse event reporting system; several members of the group also joined our Patient Group Consultative Forum
- We held a workshop with patients and patient representative groups with an interest in Assistive Technology and improved our guidance based on their feedback and input
- We launched a public consultation on new proposals for the future of clinical trial legislation in the UK which will put active patient participation at the heart of the regulation of trials and help us to support innovation and reduce time of approval
- We launched a broad-ranging public consultation on the future legal framework for medical devices in the UK including in vitro diagnostics and innovative medical technology including software as a medical device

We also began enhancing our Customer Service Centre to support effective engagement with patients and customers, providing a single point of contact within the Agency to facilitate access to information.

1. Medicines & Healthcare products regulatory agency. Patient Involvement Strategy 2021-25. 2021. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1022370/Patient_involvement_strategy.pdf?fbclid=IwAR20fuPuHv-t_JglsHNFnhmv4wB_5sbkWLKHpGeyXTc33j_LEPEoW6WCy3k. Accessed July 2022.

Scientific innovation

Throughout 2021/22, the Agency led or participated in over 50 grant-funded research projects in support of public health. Importantly, in July 2021 the Agency was designated as a Public Sector Research Establishment (PSRE) enabling us to be eligible to receive funding from the UK Research Councils.

NIBSC designation as a WHO Collaborating Centre and International Laboratory for Biological Standards was renewed by the Director-General of the WHO for a further 4-year period, in recognition of our role as a global leader in the standardisation and control of biological medicines.

Our scientific experts from our WHO Essential Regulatory Laboratory for Influenza participated in the WHO Influenza Vaccine Composition Consultation Meeting to support discussions to decide the composition of Influenza vaccines for the 2022/23 season.

The UK Stem Cell bank was awarded a £1.2m NIHR grant to support development of novel advanced therapy medicinal products.

A new oral polio vaccine, nOPV2, developed within the Agency, was endorsed by the WHO Strategic Advisory Group of Experts on Immunization to transition to wider use, supporting our agenda to help eradicate poliovirus worldwide.

CPRD launched a new service Speed Patient Recruitment INto Trials (SPRINT) which assists the rapid recruitment of patients into commercial clinical trials and we delivered two NIHR funded real world pragmatic clinical trials through our innovative data-enabled clinical trials platform. Expansion of our CPRD population coverage, means that one in every four GP practices across the UK are now contributing anonymised patient data.

We published guidance on the use of real-world data in clinical studies to support regulatory decisions and a guideline on randomised controlled trials using real-world data to support regulatory decisions.

Healthcare access

The Innovative Licensing and Access Pathway (ILAP), a collaboration between the Agency and Health Technology Assessment bodies, received 77 applications for Innovation Passport designation in 2021/22, exceeding expectations. In 2021/22 we welcomed the All Wales Therapeutics and Toxicology Centre (AWTTC) as a new ILAP partner and as a member of the steering group. The ILAP provides an integrated UK approach to accelerating time to market for new treatments by delivering tools and advice for companies on clinical trial design and providing support along the development pathway to ensure there is clarity on the data and evidence required for licensing.

We announced a Multi-Agency Advisory Service for Artificial Intelligence (AI) and digital technologies to reduce time for innovations to reach healthcare (in collaboration with the National Institute for Health and Care Excellence (NICE), the Care Quality Commission (CQC) and the Health Research Authority (HRA).

Through the Early Access to Medicines Scheme (EAMS) we continued to make new medicines and new indications available to patients prior to their regulatory approval. Since May 2021, we have awarded 18 Promising Innovative Medicine designations and five EAMS scientific opinions.

Through our participation in Project Orbis with the U.S. Food and Drug Administration we have approved new cancer treatments and extended the indications for other cancer medicines, increasing patient rapid access to treatments.

Oral contraceptives containing desogestrel were reclassified from prescription only to pharmacy medicines, increasing access for patients to a method of continuous hormonal contraception.

We published updated guidance on requirements for licensing e-cigarettes as medicines to support smoking cessation.

Patient safety

This year we developed an enhanced and more responsive safety reporting system through a number of safety initiatives including SafetyConnect and integration of the Yellow Card App into the NHS App for ease of patient reporting. By making it easier for patients to report adverse events and provide patient safety insights, this enables us to respond rapidly to new signals to protect public health.

We created the Medicines and Pregnancy Registry for anti-epileptic drug sodium valproate, enabling us to rapidly identify pregnancy in women taking sodium valproate using NHS records. This register will allow us to manage the safety of sodium valproate and is being used to build data collection for all girls and women prescribed any antiepileptic drugs in pregnancy.

We also created a new expanded CPRD Pregnancy Register. This is an algorithmic pregnancy register based on electronic healthcare records which includes anonymised data on 17 million pregnancy episodes across seven million women, greatly increasing our ability to study rare exposures and outcomes and helping us to be able to provide timely healthcare advice to women.

Our enforcement teams worked with enforcement partners around the world to dismantle criminal networks involved in the illegal sale and supply of medicines, seizing more than 500,000 doses of unlicensed medicines in the UK (including those containing controlled drugs). In collaboration with WHO, the Operation Pangea[1] enforcement team seized millions of illegal medicines at UK entry points and coordinated the arrest of several suspected organised criminals, as well as working with the online marketplace to remove 100 illicit adverts for unlicensed medicines including an advert for a class B drug.

1. GOV.UK. Over 3 million medicines and devices seized in UK as part of global crackdown. June 2021. Available at: https://www.gov.uk/government/news/over-3-million-medicines-and-devices-seized-in-uk-as-part-of-global-crackdown. Accessed July 2022.

Dynamic organisation

This year we launched our ambitious transformation programme to create our new One Agency operating model focussed on the product lifecycle with a shift in our focus and culture to enable us to become a proactive, risk-proportionate and patient-centred regulator.

We finalised the design of our new One Agency structure in October 2021, following formal staff consultation, and in January 2022 started the process of creating the new structure, populating new roles from our existing experienced staff and commencing external recruitment to bring in new skills and capabilities. We started embedding new ways of working and creating new governance and operational frameworks to reflect changes in the Agency's structure and focus as well as recognising the need to adapt to new ways of working developed during the pandemic.

In preparation for the end of the Agency operation as a Government Trading Fund on 31 March 2022, and in recognition of changes to our income from fee generating activities as a result of the UK exit from the EU, we have remodelled our financial operations to enable the Agency to operate in a sustainable cash position.

We have:

- Commenced the remodelling of the Agency fees structure
- Reduced the Agency's staff costs through headcount reduction, contributing to the corporate cost reduction target outlined in our Delivery Plan 2021-23[1]
- Commenced reduction of our technology costs through contract renegotiation and contract management, through our technology review which is a core part of the Agency's Digital, Data and Technology Strategy
- Minimised contingent labour spend in line with government controls established by the Cabinet Office in November 2021

The Agency's technology estate has grown organically over the years, and we recognise that part of the work of transformation is renewing our technology and making sure we have the capacity and infrastructure to deliver for the patient and the public as well as reducing our costs to make us more sustainable. To this end we are taking an Agency-wide view of our digital, data and technology infrastructure in order to ensure that it is fit for purpose and to significantly reduce our operational and investment costs from the Agency's technology estate. We are reducing our IT costs through contract renegotiation and contract management and will be undertaking a substantial technology investment programme, including upgrading our support systems, replacing legacy systems and investing in new technology, to provide a more user-friendly service and enable staff to deliver optimal solutions with integration across the health system.

1. GOV.UK. The Medicines and Healthcare products Regulatory Agency Delivery Plan 2021-2023. July 2021. Available at: https://www.gov.uk/government/publications/the-medicines-and-healthcare-products-regulatory-agency-delivery-plan-2021-2023. Accessed July 2022.

Significant progress has been made on core Technology projects such as:

- Implementation of our SafetyConnect vigilance system - an enhanced, integrated, vigilance service for medicines and medical devices enabling us to rapidly detect and respond to safety signals
- Launch of a new Innovative Licensing and Access Pathway (ILAP) digital solution enabling more efficient application and enhanced digital functionality for applications to the ILAP pathway for innovative medicines, reducing the time to market and increasing patient access to new medicines
- Launch of new Clinical Trials Combined Ways of Working case management functionality, creating a single online location for clinical trial applications in the UK and simplifying the submission process for our customers

Collaborative partnerships

Collaborative partnerships, both national and international, have been a key focus for us since the United Kingdom (UK) left the EU, enabling us to redesign our organisation in relation to its regulatory activities and move towards becoming a proactive, agile regulator focussing on innovation.

We continued to work closely with central government to deliver for the NHS and the UK as a sovereign regulator, ensuring the supply of medicines into the UK, driving evolution of the UK's regulatory regime, in line with the Medicines and Medical Devices Act 2021 and ensuring the continued supply of medicines into Northern Ireland through the new regulation, the Northern Ireland MHRA Authorised Route.

We also began to further develop our international strategy which builds on global partnerships with the Access Consortium (Australia, Canada, Singapore and Switzerland) to enable patients to benefit from timely access to high quality, safe and effective medicines.

Via our collaboration with the U.S. FDA on Project Orbis we approved new cancer treatments; a significant number of ILAP products have progressed to patient access though Project Orbis.

We published *"Good Machine Learning Practice for Medical Device Development"*,[1] a joint publication with U.S. FDA and Health Canada, setting out 10 guiding principles for the development of Good Machine Learning Practice (GMLP) to advance high quality artificial intelligence / machine learning enabled medical device development.

We established a clinical trials working group of the International Coalition of Medicines Regulatory Authorities (ICMRA) to take forward recommendations of the G7 health summit in relation to trials on COVID-19 medicines and vaccines.

1. GOV.UK. Good Machine Learning Practice for Medical Device Development: Guiding Principles. October 2021. Available at: https://www.gov.uk/government/publications/good-machine-learning-practice-for-medical-device-development-guiding-principles/good-machine-learning-practice-for-medical-device-development-guiding-principles. Accessed July 2022.

Performance against targets 2021/22

Target Description	Target	2021/22 Total (2020/21 total)	Met/ Not Met	Comments
PM1		**Medicines licensing, validation of applications**		
a) Type 1B and Type II variations - 97% of scientific validation process completed within 14 days of case creation	97% completed within 14 days	97.5% (100%)	Met	
b) New Marketing Authorisation applications - 97% of validation reports produced within 14 days of case creation	97% produced within 14 days	83.4% (91%)	Not Met	Embedding Centrally Authorised Products (CAP) grandfathering transition activities resulted in backlogs in Q1 and a missed target. Performance was recovered in Q2 and returned to target in Q3-4.
c) Change of Ownership applications and Request for Information (RFI) requests - 97% validated or issued within 42 days of receipt	97% validated of issued within 42 days	97.9% (100%)	Met	

Target Description	Target	2021/22 Total (2020/21 total)	Met/ Not Met	Comments
PM2		**Medicines licensing, assessment of applications**		
a) The assessment of applications for New Active Substances (NAS) Marketing Authorisations for UK/ GB - 97% assessed within 80 days (National including Orbis and Access Consortium)	97% assessed within 80 days	92% (100%)	Not Met	This target was missed due to 3 assessments exceeding the 80-day limit. 1 NAS application was very complex due to the rarity of disease. This application was also affected by the prioritisation of assessment for antiviral products to treat COVID-19 due to the pandemic. 2 other applications went marginally beyond the 80-day timeline because of scheduling issues and resource constraints. The new organisational structure will address the resourcing issues and this will be back on target by end Q2 2022/23.

Target Description	Target	2021/22 Total (2020/21 total)	Met/ Not Met	Comments
b) The assessment of applications for New Marketing Authorisations in Europe, Decentralised and Mutual Recognition Procedures (DCP and MRP) - 97% assessment within designated timeframe. [does not include European Commission Decision Reliance Procedure ECDRP]	DCP 97% assessed within designated timeframe	90% (98%)	Not Met	These targets were missed due to resource constraints and will be addressed by reallocation of activities within our new operating structure, with the aim to be back in target by end Q2 2022/23.
	MRP 97% assessed within designated timeframe	54%	Not Met	
c) Type 1B Minor and Type II Major Variation Applications in National and European (MRP) Procedures. [Does not include ECDRP only National (NAT) and Concerned Member States (CMS) variations]	IB 97% assessed within designated timeframe	84% (98%)	Not Met	These targets were missed due to resource constraints and will be addressed by reallocation of activities within our within our structure.
	II 97% assessed within designated timeframe	93%	Not Met	

Target Description	Target	2021/22 Total (2020/21 total)	Met/ Not Met	Comments
PM3		**Assessment of clinical trials and investigations**		
a) 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 1 trials)	98% in 30 days	99.6% (100%)	Met	
	14-day average	13.41 days average (12.2 days average)	Met	Note: figures relate to standard applications and not those submitted through the piloted combined (MHRA/ethics) review service. This will be included in future metrics
b) Clinical Investigation Notifications for Medical Devices – Initial assessment of applications within a maximum of 60 days	100% within 60 days	100% (100%)	Met	
PM4		**Capturing and analysing adverse event reports – making reports available, issuing alerts and acting on signals**		
a) Medical Device Alerts - 95% issued within 10 days, 100% within 15 days	95% within 10 days	N/A (100%)	N/A	The last MDA was issued in July 2020 followed by the MHRA being credentialed for National Patient Safety Alerts (NatPSAs). These do not have a target timeline due to the significant stakeholder engagement required to agree system wide actions. A timescale metric is no longer appropriate.
	100% within 15 days	N/A (100%)	N/A	

Target Description	Target	2021/22 Total (2020/21 total)	Met/ Not Met	Comments
b) Alerts for Fatal UK Adverse Drug Reactions - 90% issued within 24 hours, 100% within 72 hours	90% within 24 hours	100% (100%)	Met	
	100% within 72 hours	100% (100%)	Met	
c) Alerts for serious UK Adverse Drug Reactions - 95% issued within 72 hours, 100% within 5 days	95% within 72 hours	100% (100%)	Met	
	100% within 5 days	100% (100%)	Met	
d) Prompt Action on UK Potential Signals (Relating to Medicines) from All Sources - 85% initially evaluated within 5 working days	85% initially evaluated within 5 working days	93% (95%)	Met	
PM5		**Publication of UK assessment reports for new Marketing Authorisations**		
UK Assessment Reports - 98% published within 60 net calendar days of grant of new authorisations	98% published within 60 days	98.4% (99%)	Met	This target was met despite an 87% increase in the number of Safety Public Assessment Reports (UKPARS) from the previous year. (2021/22 - 419 UKPARS published, 2020/21 - 224 published).

Target Description	Target	2021/22 Total (2020/21 total)	Met/ Not Met	Comments
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	99% within agreed timeframes	99.8% (100%)	Met	
b) Plasma Pools Batch Release - 8 days	100% within 8 days	100% (100%)	Met	
c) Molecular Immunology Batch Release - 10 days	100% within 10 days	99% (100%)	Not Met	Human error led to this KPI being narrowly missed. The procedure has been changed to ensure a second operator independently verifies paperwork, to prevent reoccurrence. This is expected to be back in target at the start of 2022/23.
d) Haemostasis Batch Release - 15 days	100% within 15 days	100% (100%)	Met	

Target Description	Target	2021/22 Total (2020/21 total)	Met/ Not Met	Comments
e) Official Control Authority Batch Release (OCABR) - 95% of all requested OCABR and non-EU testing completed within agreed timelines: (60 days for vaccines)	95% within agreed timeframes (60 days for vaccines)	100% (100%)	Met	
PM7		**Clinical Practice Research Datalink (CPRD) activity**		
a) Research Applications - 90% to receive initial feedback from Independent Scientific Advisory Committee (ISAC) review within 30 working days	90% within 30 working days	89.17% (97%)	Not Met	CPRD launched a new Research Data Governance process in June 2021 increasing the number of external reviewers for CPRD and providing more robust assurance and longer-term resilience. For 2021/22 CPRD was embedding the process and there were also resourcing issues leading to this target being narrowly missed. This is being rectified and is anticipated to be back in target by end Q2 2022/23 once the new organisational structure is completed.

Target Description	Target	2021/22 Total (2020/21 total)	Met/ Not Met	Comments
b) Expand CPRD database coverage to 25% of the total UK population	25%	24.55% (25%)	Not Met	Due to the continued workload pressures in primary care the recruitment of new practices was slowed down in 2021/22. This led to this target being missed. Additionally, there has been a change in data for 2021/22 to only include research acceptable patients whose records meet our data quality checks. This target will be reviewed and considered against the external requirements of primary care in Q1/Q2 2022/23.
c) 1 new routine linkage available for observational research studied	1 new linkage	1 (2)	Met	

Target Description	Target	2021/22 Total (2020/21 total)	Met/ Not Met	Comments
PM8		**Answering Freedom of Information (FOI) requests, letters and parliamentary questions (PQs)**		
a) Respond to all requests under the Freedom of Information Act within 20 working days (or within permitted extension)	100% requests responded to within 20 working days	76% (99%)	Not Met	There was a significant increase in FOI requests this year. In 2021/22 we received 1609, in 2020/21 we received 753, and in 2019/20 we received 609. A significant proportion of the late cases were part of a series of similar requests for which additional work was required to determine handling.
b) Aim to return all responses to Parliamentary Questions (PQs) to the DHSC by noon on the date specified	100% responses to Parliamentary Questions (PQs) by noon on the date specified	64% (97%)	Not Met	There was an increase in PQs in 2021/22 (118 directly responded to plus 41 additional contributions in 2021/22, 88 were responded to in 2020/21). Many of the PQs contained sensitive information, extending clearance processes and times. From January 2022, our response time has been 86% showing a clear improvement. This is anticipated to be back in scope by end Q2 2022/23 once the new organisational structure is completed.

Target Description	Target	2021/22 Total (2020/21 total)	Met/ Not Met	Comments
c) Return Ministerial correspondence (POs) drafts to the DHSC within 4 working days of receipt in at least 90% of cases	90% returned within 4 working days of receipt	81% (98%)	Not Met	A record number of POs were received in 2021/22 against resource pressures due to work prioritisation. The sensitive nature of POs also led to extended clearance times. From January 2022, our response time has been 90%, showing improvement. This is already back in scope at the start of 2022/23 financial year.
PM9		**Summary Evaluation Report Reviews –Transmissible Spongiform Encephalopathies (TSE)**		
a) Medical Devices utilising starting materials for which a TSE certificate of suitability is available. Opinion must be provided within 12 weeks from the date in which the UK Approved Body informed MHRA	100% within 12 weeks	N/A (100%)	N/A	None received in 2021/22

Target Description	Target	2021/22 Total (2020/21 total)	Met/ Not Met	Comments
b) Medical Devices utilising starting materials for which a TSE certificate of suitability is not available - Opinion must be provided within 12 weeks from the date in which the UK Approved Body informed MHRA	100% within 10 days	N/A (100%	N/A	None received in 2021/22
c) Summary Evaluation Reports (SERs) received from other Member States. 100% responses must be provided within required timeframe to ensure timely response back to the Notified Body	100% within 15 days	N/A (100%	N/A	Due to the UK departure from the EU the Agency no longer receives SERs for review from EU member states
PM10		**IT operations**		
a) Major IT Incidences (Category – Priority 1 and 2) - 10% reduction from 2020/21	10% reduction	22.7% reduction (43%)	Met	
b) Major IT Incidences (Category priority 1 and 2 caused by change) - Fewer than 5 major incidents	Less than 5	4 (0)	Met	
c) IT Incidents - No major problem tickets open for more than 6 weeks	0 major tickets open more than 6 weeks	0 (0)	Met	

Target Description	Target	2021/22 Total (2020/21 total)	Met/ Not Met	Comments
PM11		**Information management**		
a) Cyber Security: Information Security Incidents – 95% resolved within 15 days of being reported	95%	82% (81%)	Not Met	The information security team has dealt with a 42% increase in number of incidents in 2021/22 (224 in 2021/22 compared with 158 on 2020/21). These have required investigation and response from users, which has meant that some of the larger investigations exceeded the 15 days target. This target will be reviewed in Q1/Q2 2022/23 to bring it back into scope.
b) Data Protection: Individual Rights Requests (IRR) – 95% provided with a response within GDPR timescales.	95%	99% (100%)	Met	

Sustainability Report

The Agency's buildings covered in this report are:

- three floors of offices at 10 South Colonnade (10SC), the building owned and maintained by the Government Property Agency
- the entire 20-acre site at South Mimms (SMS), which is comprised of laboratories and offices and is owned by the Agency

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.

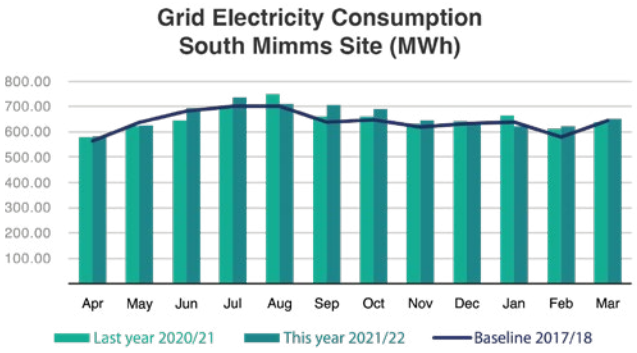
Energy Management Performance

As part of the Greening Government Commitments 2021-2025[1] (GGCs) it was decided that the target baseline year would be changed from 2009/10 to 2017/18, to more accurately reflect the current government estate and ensure government builds on the progress it has already achieved since 2009 to 2010. The GGCs apply to the office and non-office estate of central government departments and their Executive Agencies (EAs), Non-Ministerial Departments (NMDs) and executive Non-Departmental Public Bodies (NDPBs).

10SC reports against a baseline of 2019/20 as that was the first full year of occupancy.

Electricity

South Mimms (SMS) 7,950.23 MWh

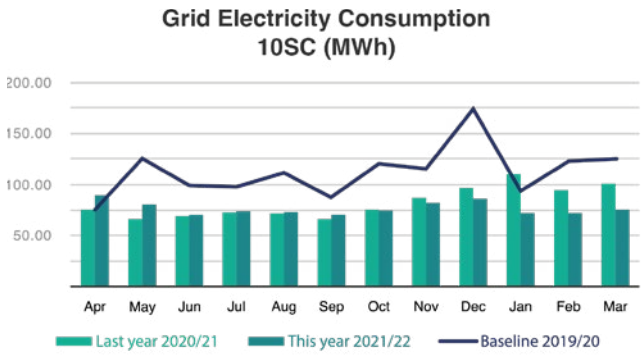


3.2% increase vs baseline

1.4% increase vs last year

Electricity consumption is marginally up from last year, reflecting an increase in the number of people on site since COVID-19 restrictions have decreased. SMS required staff onsite during lockdowns due to essential COVID-19 laboratory work. Having more people on site necessitates more cooling and ventilation was increased due to our COVID-19 response.

10SC 918.00 MWh



31.8% decrease vs baseline

6.7% decrease vs last year

Down from last year, partly due to lower building occupancy due to staff working remotely and partly due to changing set points at which building heating and cooling is activated. Consumption is significantly down on the baseline as building occupancy was significantly higher prior to COVID-19 restrictions.

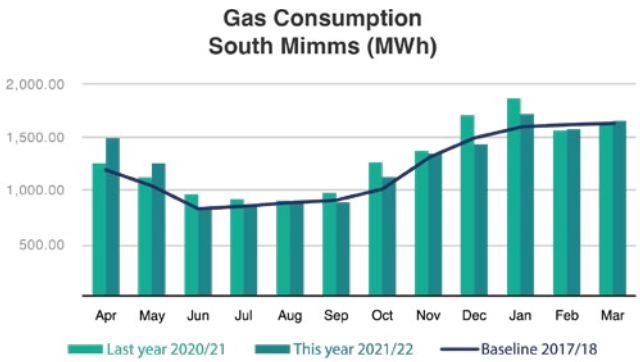
1. GOV.UK. Greening Government Commitments 2021 to 2025. October 2021. Available at: https://tinyurl.com/yc38d48u. Accessed June 2022.

Note the erratic baseline chart pattern for 10SC shows how much electricity consumption is linked to occupancy levels, so is very low during summer and Christmas holidays. 10SC has electric heating, so both cooling and heating impact on electricity consumption.

The Agency's figures for 10SC were reported as 11.10% of the total building for financial year 2021/22.

Gas:

SMS 15,150.24 MWh

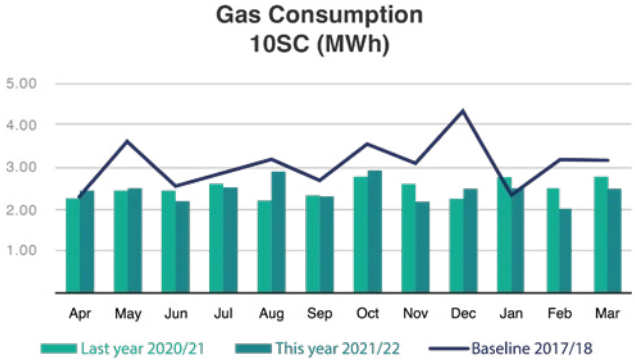


4.9% increase vs baseline

2.9% decrease vs last year

Gas consumption is marginally down from last year, mainly due to milder weather meaning that the building required less heating. There was higher than usual gas use at the beginning of the year due to a leak in the steam return system, once this was fixed, we returned to a normal pattern of consumption.

10SC 33.34 MWh

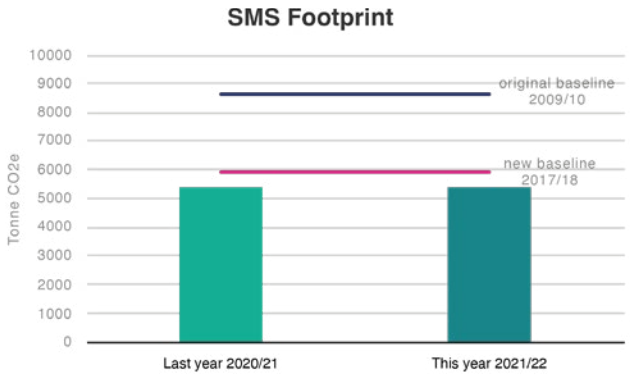


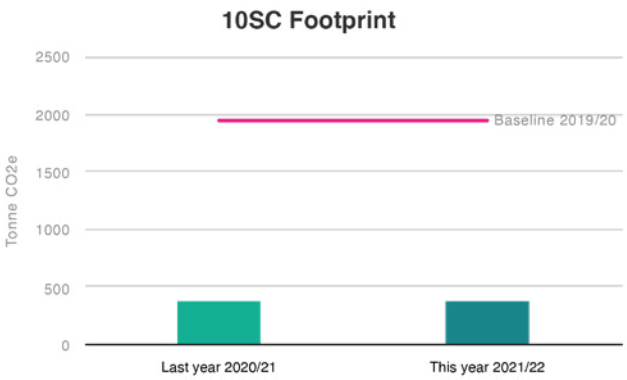
20% decrease vs baseline

1.7% decrease vs last year

Gas consumption is slightly down from last year due to the milder weather meaning that the water required less gas to heat. Gas at 10SC is only used for heating water; the Agency's use of hot water at 10SC is calculated as a percentage of leased floorspace, not based on the number of people in the building.

Carbon Emission Performance





9.4% decrease vs baseline

Carbon emissions have fallen from 5,917 TCO2e in 2017/18 to 5,361 TCO2e this year

80.1% decrease vs baseline

Carbon emissions have fallen from 1,954 TCO2e in 2019/20 to 389 TCO2e this year

Both sites' carbon footprints have fallen since the baseline years. It must be noted that as we are now reporting against a new baseline year, this report cannot be directly compared to previous reports.

The impacts are different for the two sites, with 10SC's change being from building occupancy and business travel and SMS from energy consumption, due to the nature of the work at each site.

The significant reduction in the carbon footprint for the 10SC site is partially due to the travel restrictions in place with the pandemic, and partly due to reduced building occupancy. The reduction for the SMS site is much lower as the site had to remain fully operational.

New GGC's targets were set in 2021, and although the Agency was exempt from direct reporting due to its Trading Fund status[1], it still adopted Net Zero ambitions to meet those targets:

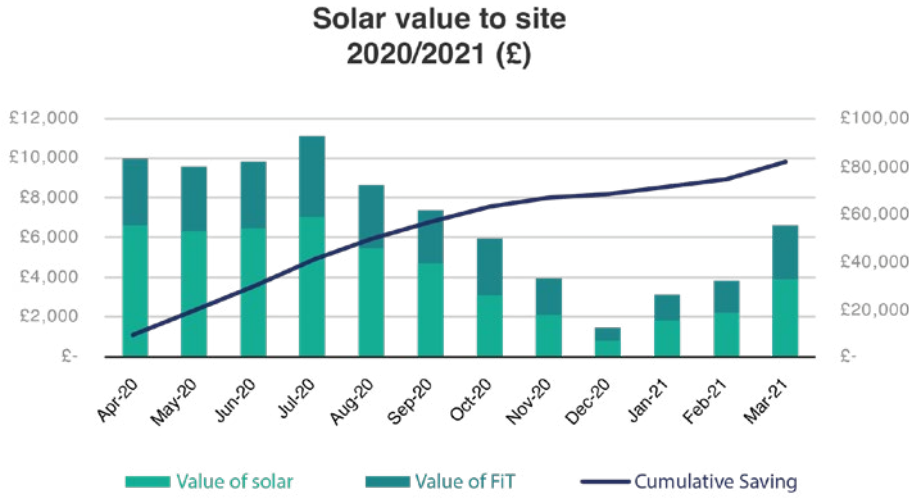
- Achieve a net zero building estate by 2030
- Reach net zero business travel by 2025 and empower staff to work and commute more sustainably
- Minimise waste and embrace a 'circular economy' approach by 2025
- Significantly reduce water consumption by 2025
- Adopt a sustainable procurement approach by the end of 2022
- Implement a measurable biodiversity gain and contribute to nature recovery by 2025
- Adapt to protect our staff, estate and operations from the impacts of the climate crisis by 2030

1. From April 2022 the Agency is no longer a Trading Fund so is no longer exempt from reporting.

- Align with the 'Greening Government: ICT and Digital Services Strategy' by 2025
- Work closely with catering providers to minimise the environmental impacts of our food by 2025

Renewable technology performance

The existing array of 1,490 solar panels that were installed at SMS in 2016, have a net benefit of nearly £80,000 a year for the Agency, a figure likely to increase as the cost of electricity increases. These generate about 6% of the electricity required by SMS, reducing our energy consumption and carbon footprint, demonstrating the Agency's green commitment to keep reducing its impact on the environment.



In 2022/23, we are intending to take advantage of the latest advances in solar panel technology at the SMS site. Even though there is no longer a Feed in Tariff[1], new panels are 20% more efficient than they were 7 years ago; they rely on daylight rather than direct sunlight. This means that it is now viable to use east, west and north facing roofs. By also installing solar car ports, this project is intended to supply a further 8% of SMS electricity requirement and provide a similar yearly financial benefit.

Building management at 10SC is also looking to install solar panels. As 10SC does not have a large roof the panels would only supply a fraction of the electricity required by the building, however a combination of reduced costs and the recent steep rise in the price of electricity has significantly reduced the return on investment of solar panels.

1. The Feed in Tariff (FIT) scheme was a government initiative designed to promote the adoption of renewable and low-carbon electricity generating technologies, by paying producers for the renewable electricity they generated. The scheme was introduced in April 2010 and closed to new applicants in March 2019.

Health and safety report

The Agency is committed to promoting a positive health and safety culture across the organisation, with the aim of reducing risks associated with the Agency's activities. Responsibility for health and safety lies with the Agency's Chief Executive, with Agency leadership assigned to the Chief Scientific Officer, and cascading down through the Executive Committee to Centre and Divisional management. The Agency 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 incident information and lessons learnt with external partners. Health and safety 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 2021/22 included: achieving excellence in leadership and culture, continued regulatory compliance, continued compliance to ISO45001 certification at our London site, delivering overseas travel safety requirements, fire safety management and continued staff engagement with a focus on staff health and wellbeing. In addition, work has been focussed on assessing the health and safety requirements for organisational change as a result of the Agency transformation.

High standards of health and safety are essential to protect staff and prevent disruption to the Agency's work in protecting and improving public health. The Agency staff continued to work within the health and safety measures implemented during the COVID-19 pandemic which enabled critical work to continue, both on site and from home, whilst ensuring the safety of all staff and others involved in supporting the Agency's work. Health and safety training courses and procedures for auditing were adapted to continue 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 and applications for travel increased towards the later part of the year when COVID-19 restrictions started to lift. 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 SMS on existing new or emerging pathogens, at appropriate biological containment levels and in adjusting to legislative changes. This included approval from HSE for the continued work on SARS-CoV-2 virus.

Two accidents occurred this year in work with live SARS CoV-2 virus resulting in internal investigations to assess the root cause and ascertain if any risk of exposure to the staff members had occurred. Both accidents occurred due to failure of equipment, one leading to the potential release of live virus into the laboratory and the other leading to the potential release of live virus within the microbiological safety cabinet. Both accidents were investigated thoroughly and no exposure of staff to the virus was found.

The Agency prioritises the safety of staff and has robust procedures in place to ensure that work is appropriately controlled and risk-assessed. Incidents and accidents are investigated thoroughly to ensure continuous improvement and the Agency worked closely with the HSE to ensure any actions from their investigations were acted upon to reduce the risk of similar events occurring. As a result of these accidents, new procedures have been put in place to ensure extra precautions are taken to check equipment prior to use.

Financial review

Accounts preparation and overview

The MHRA was a trading fund until the end of March 2022 and these accounts detail the financial performance of the organisation for the final year of trading fund status. As a trading fund the Agency was required by a HM Treasury Minute (reproduced in section 3 of this report) 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. Over the five-year period prior to the closure of the trading fund the average surplus was £6.586m representing an average return of 3.6%, based on the total equity as at 31st March 2022.

How is the Agency funded?

The Agency is funded mostly by income from fees for both statutory and non-statutory sales of products and services (further details of our funding can be found in the "Performance Overview" section on page 13). Trading income from external customers from fee charging statutory activities and commercial activities in 2021/22 was £150.3m which was £3.8m higher than in 2020/21. The increase in revenue was due to an increase in volume of service fees as more licences were needed following the UK exit from the EU and the increase in our sales of pharmaceutical standards. Income from our medical devices work was also higher due to a change in legislation that increased the products requiring registration.

How the funding was used

This year 2021/22 has seen a net cash outflow from operating activities of £9.6m compared to an outflow of £2.9m in 2020/21. The current year operating cash outflow was driven by the operating deficit of £11.4m adjusted for non-cash items (add back depreciation of £11.4m less DHSC non-cash funding of £12.4m) along with a £2.5m cash inflow from a decrease in working capital.

Cash for purchases of tangible and intangible assets was a further outflow of £14.8m and there was a net cash outflow of £4.2m from financing activities, mainly the payment to DHSC of a cash dividend of £2.8m and the repayment of the loan of £1.3m. As a result, cash and cash equivalents at the end of the 2021/22 financial year were £28.6m lower than at the end of 2020/21.

Summary of financial outturn

The Agency's financial performance in 2021/22 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 continued to be impacted by the COVID-19 pandemic.

The DHSC provides funding for a range of Agency services that are either not commercial or for which we do not have the legal basis to charge. This year funding for activities from DHSC was £30.0million, £13.4million lower than last year due to the phasing out of the EU exit support and the end of additional pension funding paid over the last two years. Staff costs, excluding redundancies, decreased by £5.6m (6%) reflecting a 7.8% decrease in the average number of employees, both permanently and temporarily employed.

The resulting 2021/22 operating deficit before interest and dividends was £11.4m compared to a surplus of £0.03m in 2020/21. The main reason for this deficit was the investment made in transforming the agency following the UK exit from the EU. We spent £11.8million on transformation during the year. This includes £4.2million on redundancies through a voluntary exit and a voluntary redundancy scheme. The cost of the transformation was paid for out of the Trading Fund reserves. The completion of the transformation, including improvements in our technology and processes, is being supported by the DHSC.

After dividends payable of £14.9m the net deficit of £26.3m has resulted in a reduction to reserves.

Financial sustainability

A key aim in our Delivery Plan 2021-23[1] is ensuring the Agency's financial sustainability. In 2021/22 we have been working to reduce our operational costs, establishing a robust future business model and remodelling the Agency's fees structure to ensure we correctly recover the costs of our statutory services.

A key focus has been to target reductions in pay (headcount reduction) and non-pay spend (operating cost reduction) to balance the budget in-year to ensure the Agency is operating in a financially sustainable cash position as described in our Delivery Plan 2021-23[1]. Details of the financial outturn for the year can be found in the summary of financial outturn (page 49).

In 2021/22, we made improvements to the way we manage our income through our Finance Transformation Programme, including:

- Automation of payment processes via the gov.uk service, enabling easier payment and better income realisation
- Improving the integration between our finance systems and other subsidiary systems to address the cause of the accumulation of aged debt
- Implementing technology development of procure-to-pay automated matching software to improve efficiency and accuracy of invoice matching.

Better payment practice code

The Agency has signed up to the Government's Prompt Payment Policy. We undertake to pay 90% of undisputed and valid invoices from SMEs within five days and 100% of all undisputed and valid invoices to be paid within 30 days.

This year, we achieved 94% (2021: 96%) of all invoices paid within 30 days with 53% (2021: 70%) of all SME invoices paid within five days. Work is currently underway to improve Agency-wide processes to enable better payment performance.

Dr June Raine DBE

Chief Executive and Accounting Officer

Medicines and Healthcare products Regulatory Agency

14 July 2022

1. GOV.UK. The Medicines and Healthcare products Regulatory Agency Delivery Plan 2021-2023. July 2021. Available at: https://www. gov.uk/government/publications/the-medicines-and-healthcare-products-regulatory-agency-delivery-plan-2021-2023. Accessed July 2022.

2 Accountability report

The accountability report sets out how we meet the key accountability requirements to Parliament. It is broken down into five areas:

2.1 Corporate Governance Report which provides an overview of the Agency's leadership and our risk management approach

2.2 Statement of Accounting Officer responsibilities

2.3 Annual Governance Statement

2.4 Remuneration and Staff Report which details remuneration and staff expenses and policies

2.5 Parliamentary Accountability and Audit Report

2.1 Corporate Governance Report

The purpose of this section is to explain the composition and organisation of the Agency's governance structures and how they support the achievement of our objectives.

It has three parts:

- Director's report
- Statement of the Accounting Officer's responsibilities
- The annual governance statement

Director's Report

The Director's Report, as per the requirements of the Government Financial Reporting Manual (FReM), requires certain disclosures relating to those having authority or responsibility for directing or controlling the entity, including details of their remuneration and pension liabilities.

Governance Structure Overview

The Agency is led by the Chief Executive Officer (Chief Executive) who is directly accountable to ministers for the operation and management of the organisation and for the delivery of its functions. The Chief Executive is also directly accountable to Parliament as the Accounting Officer for the Agency. The Chief Executive is supported by the Agency Board, which is led by a Non-Executive Chair (the Chair).

The Agency Board supports the Chief Executive in the effective delivery of services and overall performance by providing leadership, advising on strategy and the deliverability of policies as well as scrutinising performance and acting as the forum for self-challenge.

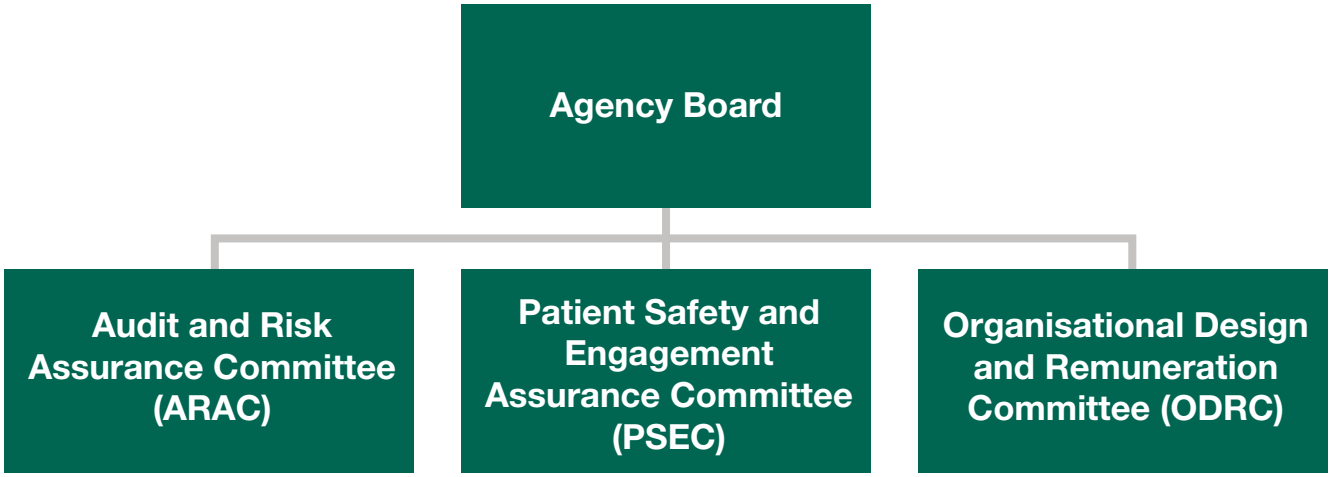
The Chair is responsible for the leadership of the Agency Board and for ensuring its overall effectiveness. The Chair is responsible for ensuring that the Agency Board, carries out its business efficiently and effectively and is undertaking an annual assessment of Non-Executive Directors' (NEDs) performance.

NEDs provide independent and constructive challenge in their role as Agency Board members. All NEDs must be properly independent of management and are expected to become a member of at least one assurance committee.

Executive Committee (ExCo) supports the Chief Executive in the operational and executive leadership of the Agency with responsibility for optimal use of resources, structures and controls to achieve Agency objectives, as well as responsibility for operational and regulatory decisions. ExCo in turn relies on quality advice from officials and effective decision making at all levels throughout the organisation.

The Role of the Agency Board and its Committees

The Agency has a unitary Board - the Agency Board, with an equal number of Executive and Non-Executive Directors, plus a Non-Executive Chair, supported by three Board assurance committees.



Agency Board

The role of the Agency Board is:

- Supporting the Chief Executive in the effective delivery of services and successful operation of the Agency as a whole
- Advising on and agreeing the strategic priorities of the Agency, in keeping with the key financial and resource limits placed upon it
- Ensuring an appropriate framework of governance which embeds suitable internal control and enables risk to be well managed
- Reviewing the strategic performance of the Agency and providing constructive support and challenge to the Executive

The Agency Board has no involvement in regulatory decisions affecting medicines, medical devices or any other products or services delivered by the Agency. These are the responsibility of the Chief Executive, supported by ExCo. Final decisions (and the responsibility and accountability for those) rest with the Chief Executive as the Accounting Officer of the Agency.

Board Sub-committees

The three Board Sub-committees enable independent scrutiny of core activities of the Agency, providing robust assurance and allowing recommendations for improvement to be reported back to the Agency Board. Each committee is chaired by a Non-Executive Director (NED) with at least two further NEDs appointed as members. Details of each committee's area of focus are set out below.

Audit and Risk Assurance Committee (ARAC)

The role of the Audit Risk Assurance Committee is:

- Providing independent advice and assurance to support the Agency Board and Accounting Officer in their responsibilities on issues of risk, control and governance
- Reviewing the Annual Report and Accounts and presenting it to the Board
- Overseeing internal and external audit activities and response to findings
- Reviewing the development of the risk management framework

ARAC meets a minimum of four times each year and carries out its role in line with HM Treasury's ARAC Handbook.

Patient Safety and Engagement Committee (PSEC)

The role of the Patient Safety and Engagement Committee is:

- Providing independent consideration of patient safety, involvement and engagement in the operation of the Agency's activities
- Ensuring that patient views are consistently considered in decision making
- Overseeing how the Agency engages with and responds to patients and the wider public

PSEC has a particular interest in how the Agency is embedding the recommendations of the the Independent Medicines and Medical Devices Safety (IMMDS) review report.

Organisational Design and Remuneration Committee (ODRC)

The role of the Organisational Development and Remuneration Committee (ODRC) is:

- Providing independent and objective strategic advice to the Chief Executive on their responsibilities relating to workforce planning, development and rewards
- Providing assurance to the Agency Board that the Agency has the right culture and procedures in place to manage and develop the Agency's workforce and capabilities

ODRC has a particular interest in the development and implementation of the Agency's transformation programme.

Data quality to support the needs of the Agency Board

The Chief Operating Officer is the senior executive with responsibility over Finance. Finance reports containing clear consistent and comparable performance information are discussed at the regular monthly meetings of the Resource Committee prior to submission to the Agency Board and any resource or financial implications are highlighted.

The Agency Board receives reports at their meetings to support their discussions. All papers to the Board are first reviewed at ExCo. All papers comply with a required structure which ensures the decision requested is clear, that all relevant information is provided and appropriate clearance has been obtained.

The Agency Board

Members of the Agency Board and its committees in 2021/22

The Non-Executive directors (NEDs) who served on the Agency Board in 2021/22 were:

Stephen Lightfoot, Board Chair
The Chair
(September 2020 - present)

Stephen Lightfoot became the agency's Chair on 1 September 2020, having been a Non-Executive Director of the agency since September 2015. He has also been appointed as Chair Designate of the future Integrated Care Board (ICB) for the NHS in Sussex, following the completion of his eight-year term as Deputy Chair of Sussex Community NHS Foundation Trust.

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.

Dr Junaid Bajwa, Non-Executive Director
Member of ODRC
(September 2021 - present)

Dr Junaid Bajwa has a wide range of global digital health experience from a software and pharmaceutical perspective, combined with his ongoing clinical, academic and non-executive experience around the world.

Junaid is the Chief Medical Scientist at Microsoft Research, a practising GP in London, Non-Executive Director at University College London Hospitals NHS Foundation Trust, Non-Executive Director of Nahdi Medical Corporation in Saudi Arabia and a Visiting Scientist at the Harvard School of Public Health in the USA. He was previously an Executive Director in the Digital Centre of Excellence for the global pharmaceutical company Merck Sharp & Dohme, where he helped shape the global digital strategy of the company and then led the academic and technology partnerships to implement it.

Amanda Calvert, Non-Executive Director
Chair of ODRC, member of ARAC
(September 2018 - present)

Amanda 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.

She set up Quince Consultancy to help businesses to add value through creating a supportive culture for people to grow and develop, simplifying processes and utilising technology effectively. She 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 Graham Cooke, Non-Executive Director
and Deputy Chair
Member of PSEC (September 2021 - present)

Professor Graham Cooke has extensive experience of international clinical research, innovative clinical trial design, World Health Organisation (WHO) Committees and expert groups.

Graham is NIHR Professor of Infectious Diseases at Imperial College in London and leads the translational infection research within the NIHR Biomedical Research Centre with a particular interest in precision medicines and diagnostics. He has been a Principal Investigator for the REACT study of COVID-19 home testing with over 3 million participants and has been involved in several other COVID-19 studies and expert committees. Graham's international experience also includes being Chair of the WHO Committee on the Selection & Use of Essential Medicines, which has led to globally recognised recommendations on the use of innovative therapies and antibiotics. Graham's experience also includes being a founding Principal Investigator for viral hepatitis in the National Health Informatics Collaborative collecting secondary care data to complement our Clinical Practice Research Datalink (CPRD) primary care data and was Convenor of a Clinical Expert Group for the Infected Blood Inquiry.

Dr Paul Goldsmith, Non-Executive Director
Member of ARAC
(September 2021 - present)

Dr Paul Goldsmith has a breadth of clinical, drug development, digital health and governance experience, whilst also being a serial innovator who has co-founded 4 healthcare businesses.

He has extensive experience in frontline clinical medicine as a Consultant Neurologist and has held NHS Clinical Networks, Vanguard and Senate roles. He is also President, Chief Innovation Officer and Co-Founder of Closed Loop Medicine Limited, as well as being a Board Member of the MDU Ltd and MDU Investments Ltd, and trustee of the Big Tent Foundation. Paul's start-up companies have involved disease modelling, drug development, digital automated therapy provision, online cognitive behavioural therapy and drug optimisation by integrating the use of diagnostics, drugs and digital technologies. He has a PhD in developmental biology and has particular interest in applying evolutionary neuroscience insights to the problems of modern life.

Haider Husain, Associate Non-Executive Director
Member of ODRC
(September 2021 - present)

Haider Husain is an experienced international healthcare IT business leader with a strong technology background and experience of partnership working, combined with his work as a Panel Chair for the British Standards Institute (BSI) and non-executive experience within the NHS.

Haider is the Chief Operating Officer of an international healthcare technology consultancy called Healthinnova Limited, a Non-Executive Director of Milton Keynes University Hospital NHS Foundation Trust and is the Panel Chair for the Safe and Effective Use of AI in Healthcare at the British Standards Institute. Prior to this, Haider was the General Manager for Caradigm's European population health management business and has worked for other international companies such as Microsoft, GE Healthcare and Logica.

Mercy Jeyasingham MBE, Non-Executive Director
Chair of PSEC
(May 2020 - present)

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. Currently a management consultant specialising in managing charities, health and social care policy, and equalities she is also a local volunteer. 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.

Raj Long, Non-Executive Director
Member of PSEC
(September 2021 - present)

Raj Long has considerable experience as a senior international regulatory executive in the pharmaceutical industry, combined with strategic experience as an advisor to the Department of Health & Social Care, European Union, Gates Foundation and World Health Organisation (WHO).

Raj is currently a Deputy Director for safety and pharmacovigilance at the Gates Foundation and also supports the WHO COVID-19 vaccine manufacturing taskforce. Prior to that, Raj was Consultant Advisor to the Chief Scientist of the WHO, as well as being a WHO co-lead on the COVAX Task Force on COVID-19 vaccine manufacturing and supporting other WHO committees, Vice Chair of the World Dementia Council and has provided advice to numerous expert groups and government initiatives such as the G7 Global Action Against Dementia initiative and the Accelerated Access Review with NHS England. In her executive career, Raj held very senior international regulatory roles with responsibility for licensing innovative medicines in global pharmaceutical companies such as Bristol Myers Squibb, Novartis and GE Healthcare.

Michael Whitehouse OBE, Non-Executive Director
Chair of ARAC
(September 2018 - present)

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

Previous NEDs

Dr Barbara Bannister (September 2015 – August 2021)

Professor Bruce Campbell (September 2015 – August 2021)

Anne-Toni Rodgers (September 2018 – August 2021)

Professor David Webb (September 2013 – August 2021)

The Executive directors who served on the Board in 2021/22 were:

Dr June Raine DBE, Chief Executive CEO (September 2019 - present)

June qualified in medicine at Oxford University, and undertook postgraduate research leading to an MSc in pharmacology. After general medical posts and Membership of the Royal Colleges of Physicians (MRCP), she joined the then Medicines Division in 1985, and has worked in several licensing areas including the Review of Medicines, new drugs and abridged. Prior to becoming Chief Executive, June was Director of Vigilance and Risk Management of Medicines from 1999

Dr Marc Bailey Chief Science and Innovation Officer (September 2021 - present)

Marc is a molecular biologist with a PhD in Pathology. Marc has had a varied career starting with academic research on infectious diseases before establishing a team developing physical standards for biotechnology at the National Physical Laboratory and then leading research into Digital Health for a multinational corporation. Marc joined the Agency in 2017 at the South Mimms Laboratory initially as a Head of Division and then as interim Director of NIBSC

Dr Alison Cave, Chief Safety Officer (July 2021 - present)

Alison is a pharmacologist with a PhD in biochemistry. Her long career includes significant academic and regulatory experience, the latter initially at the Medicines Control Agency and then in senior roles within the Vigilance and Risk Management of Medicine Group at the MHRA and the European Medicines Agency (EMA). In addition she was Head of Cellular, Developmental and Physiological Sciences at the Wellcome Trust and most recently an Industrial Strategy Challenge Fund Director at UK Research and Innovation.

Jon Fundrey, Chief Operating Officer (February 2016 - April 2022)

Jon worked for the Medicines and Healthcare products Regulatory Agency (MHRA) as Chief Operating Officer from 2016 until May 2022. He joined the Civil Service in 2007 as Financial Controller at HM Revenue and Customs (HMRC), moving to the Department for Work and Pensions in 2014. Prior to joining the Civil Service Jon held a number of senior finance, IT and global programme management roles, over a 17 year period at the BOC Group Plc – a FTSE50 company. This year, he joined the Government Legal Department (GLD) as Finance, Operations and Digital Director.

Claire Harrison, Chief Technology Officer (October 2021 - present)

Claire Harrison has had a varied career extending across all aspects of digital transformation and technology leadership. Especially relevant to the MHRA is Claire's previous work on implementing the NHS Spine and delivering the technology transformation at the Care Quality Commission. Claire is currently the technical architect for the UK Health Security Agency which is bringing together a number of different systems and organisations

Dr Laura Squire, Chief Quality and Access Officer (November 2021 - present)

Laura oversees a large portfolio that is designed to ensure the quality and access of products to the UK market - this includes scientific advice, clinical trials/clinical investigations, licensing assessment, marketing authorisations and device registrations, inspections, enforcement and standard setting through for example the British Pharmacopoeia and Target Product Profiles.

Laura started her career as a post-doctoral research assistant looking at resistance to anti-malarial drugs at the Liverpool Institute of Tropical Medicine following her PhD and BSc in Biochemistry and Physiology. She has spent most of her career as a Civil Servant. After many years in operational work Laura moved into government policy in 2014. In parallel, she went back to university, gaining an Executive Master's degree in Public Policy from the London School of Economics. Laura has extensive experience of regulatory and organisational transformation through her wider policy and operational work in other major government departments.

She joined the Medicines and Healthcare products Regulatory Agency from the Department of Health and Social Care, where she worked extensively on the COVID-19 vaccine deployment programme.

Dr Glenn Wells, Chief Partnerships Officer (November 2021 - present)

Dr Glenn Wells joins the MHRA from the Medical Research Council where he is Director of Strategy and has developed national partnerships with academia, industry and across government, as well as building international relationships. Prior to the MRC, Glenn also built partnerships while working for the Oxford Academic Health Science Centre and Wellcome Trust. In addition, Glenn developed an extensive knowledge of legal frameworks for healthcare systems through his work as a Senior Civil Servant in DHSC delivering the Health and Social Care Act 2012.

Previous Executive Directors

Dr Samantha Atkinson, Interim Chief Quality and Access Officer
September 2020 – October 2021

John Quinn, Interim Chief Technology Officer
September 2020 – October 2021

Dr Christian Schneider, Interim Chief Science and Innovation Officer
September 2020 – July 2021

Agency Board performance and effectiveness

In the summer of 2020, we conducted a review of the Agency's governance, with a special focus on our decision-making processes. The review, which revealed that our Agency Board didn't fully function as intended as a unitary board, recommended the appointment of new 'chief officers' as executive board members to provide a balance on the Agency Board and to provide additional executive leadership in support of the CEO. This has helped to inform our redesign of the Board in 2021/22.

We have continued to implement the findings of the review throughout this year, as well as improving the supporting operations of the Agency Board, such as the Board Assurance Committees. Four NEDs, three of whom had served the Agency Board for at least two terms, left the Board in August 2021 at the end of their terms. Four new NEDs and one Associate NED joined the Agency Board in September 2021.

In March 2022, we held an externally supported Agency Board review and development session to assess how to maximise effectiveness as a unitary board. The external review concluded that, despite being a relatively new in membership and unitary status, the Agency Board was making good progress with clear impact. Further improvements will focus on ensuring the Agency Board looks at the right issues at the right stage in their development. Further development support is planned for 2022/23 and the Agency Board will regularly review progress against its identified development objectives.

Agency Board members' attendance

Attendance at Agency Board meetings and its committees in 2021/22:

Member	Board attended/ eligible	ARAC* attended/ eligible	ODRC** attended/ eligible	PSEC*** attended/
Stephen Lightfoot	11 (11)	-	-	-
June Raine	11 (11)	5 (5)	2 (2)	3 (4)
Sam Atkinson	3 (4)	-	-	1 (2)
Marc Bailey	7 (7)	-	-	3 (3)
Junaid Bajwa	6 (7)	-	2 (2)	-
Barbara Bannister	3 (4)	1 (1)	-	-
Amanda Calvert	10 (11)	5 (5)	2 (2)	-
Bruce Campbell	4 (4)	-	-	1 (1)
Alison Cave	8 (8)	-	-	4 (4)

Member	Board attended/ eligible	ARAC* attended/ eligible	ODRC** attended/ eligible	PSEC*** attended/
Graham Cooke	6 (7)	-	-	3 (3)
Jon Fundrey	10 (11)	5 (5)	2 (2)	-
Paul Goldsmith	7 (7)	4 (4)	-	-
Claire Harrison	5 (6)	-	-	-
Haider Husain	7 (7)	-	1 (2)	-
Mercy Jeyasingham	11 (11)	-	-	4 (4)
Raj Long	7 (7)	-	-	3 (3)
John Quinn	4 (4)	-	-	-
Anne-Toni Rodgers	4 (4)	-	-	-
Christian Schneider	3 (3)	-	-	0 (1)
Laura Squire	5 (5)	-	-	2 (2)
David Webb	4 (4)	-	-	1 (1)
Glenn Wells	4 (4)	-	-	-
Michael Whitehouse	10 (11)	5 (5)	-	-

*The following persons routinely attended all ARAC meetings:

- The Accounting Officer
- The Chief Operating Officer
- The Deputy Director of Finance
- The Financial Controller
- The Head of Internal Audit
- Representatives from the External Auditor
- Representatives from the DHSC
- Head of Risk and Audit

**The following persons also routinely attend all Organisational Development and Remuneration Committee (ODRC) meetings:

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

***The following persons routinely attend all Patient Safety and Engagement (PSEC) Committee meetings:

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

There was a joint PSEC and ARAC meeting in February 2022 which was held to review assurance of the SafetyConnect project on both patient safety and risk control aspects.

The Agency Board held a joint Board-to-Board meeting with NICE in October 2021.

Register of interests

A register of interests is maintained to record declarations of any interests of the Non-Executive Agency Board members so that such interests can be appropriately managed and public confidence in the independent operation of the Agency Board supported. NEDs must declare any potential conflicts upon application to join the Agency Board and declare any new interests or changes to existing interests as soon as possible. The register, which is continually updated and is available on the Agency's *website*[1], includes details of all directorships and other relevant and material interests which may relate to the Agency's work.

A separate policy governs the declaration and management of Agency staff interests which must be recorded on a central system. Staff are not permitted to hold any interests in the industries the Agency regulates. As with NEDs, Agency staff are required to reconfirm their declared interests annually, in addition to declaring any changes in-year as they arise.

Information on any transactions with organisations with whom Executive or Non-Executive Directors are connected with as key management personnel are detailed in the Related Parties note in the Annual Report and Accounts (page 159).

1. GOV.UK. MHRA Board Declarations of Interest. May 2022. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1076724/0522_MHRA_Board_Declarations_of_Interest_May_22__2_.pdf. Accessed July 2022.

The role of Executive Committee (ExCo) and its management committees

As noted above, the Chief Executive is supported by ExCo focused on the day-to-day effective leadership and management of the Agency. Key responsibilities of ExCo include:

- Generating strategic options and refining forward strategies (for discussion with the Board and for inclusion in the Corporate and annual Business Plans as appropriate)
- Deciding operational priorities and allocating resources accordingly
- Ensuring performance against strategic objectives, through the identification and removal of barriers and through holding business units to account
- Managing key strategic risks to the successful operations of the Agency; and
- Setting and driving an enabling culture which centres patients at the heart of the Agency's responsibilities

ExCo is supported by six management committees covering a range of the Agency's operational and corporate business. Each of these are chaired by a member of ExCo and discharge obligations of scrutiny and assurance on its behalf. Decisions may be escalated to ExCo with recommendations if the decision exceeds the management committee's delegated authority or is of such a nature that it demands urgent consideration by ExCo directly.

Executive Committee (ExCo) attendance

Member	ExCo meetings attended/eligible
June Raine	23 (23)
Samantha Atkinson	12 (13)
Marc Bailey	14 (17)
Alison Cave	15 (16)
Jon Fundrey	22 (23)
Claire Harrison	8 (10)
John Quinn	8 (13)
Christian Schneider	6 (6)
Laura Squire	10 (10)
Glenn Wells	7 (8)

Personal data incidents

The Agency has formally reported one personal data related incident to the Information Commissioner's Office. This was reported within the required 72 hours timeframe and no further action was required beyond the remedial work and mitigation measures agreed.

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 ('the agency') to prepare for each financial year a statement of accounts in the form and on the basis set out in the Accounts Direction. The accounts are prepared on an accruals basis and must give a true and fair view of the state of affairs of the Agency and of its income and expenditure, 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 Agency. The responsibilities of an Accounting Officer, including responsibility for the propriety and regularity of the public finances for which the Accounting Officer is answerable, for keeping proper records and for safeguarding the Agency's assets, are set out in the chapter under Accounting Officers in Managing Public Money, published by HM Treasury.

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 Annual Governance Statement

Section 2.1.1 above sets out the roles and responsibilities at Board and Executive level within the Agency's governance framework. This is an area that the Agency has reviewed and significantly improved over recent years and will continue to develop and embed best practice across our transformed organisation.

As Accounting Officer, I have overall responsibility for maintaining an effective system of internal control that supports the achievement of the Agency's policies, aims and objectives. The system of internal control has been in place at the Agency for the year ended 31 March 2022 and up to the date of approval of the Annual Report and Accounts and accords with HM Treasury guidance.

However, I have to report one irregular payment that was identified during the year, relating to 2020/21. There was a breach of the Civil Service exit rules relating to a special severance payment. Approval for the Compulsory Redundancy exit scheme (and for the Voluntary Redundancy scheme which preceded it) was secured from the Cabinet Office in January 2020 however approval was not sought from HMT. In addition, the notice period which was applied for the purposes of calculating compensation in lieu of notice was later advised by the Cabinet Office to have been inaccurate based on the application of section 11.1.4c of the civil service management code. The irregular payment was small and as a result HMT have not levied any penalties.

To prevent this occurring again, the process for agreeing redundancy payments has been revised and any special severance payments now require additional approvals within the agency before the case is submitted to DHSC. Internal training and improved guidance have also been implemented.

The Risk and Control Framework

Risk

The Agency follows the principles and good practice outlined in the HMG Orange Book[1]. Our approach to risk management seeks to identify and evaluate risks, agree an appropriate response and implement mitigations in such a way as to limit the Agency's exposure. It recognises that it is not possible to eradicate all risk, particularly given the complex and challenging objectives the Agency seeks to deliver.

Risks are managed through the risk management governance framework outlined below, supported by a corporate risk manager who drives the operation of the risk management process and provides specialist advice.

1. GOV.UK. Orange Book. May 2013. Available at: https://www.gov.uk/government/publications/orange-book. Accessed June 2022.

The Corporate Risk Register and the process which supports its development continue to be scrutinised and challenged by the ARAC on a regular basis and reviewed by the Agency Board. ARAC 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 assurance reports to the Agency Board, covering specific risks and the process for risk identification and mitigation.

We have seen a number of complex and interconnected risks over the course of this year. These have arisen primarily from pressures on staff capacity as a result of COVID-19 and the impacts of the transformation programme, and at a service level ongoing change to how we work to embed patient involvement throughout the organisation. At a strategic level, development of a key changes to secure our financial sustainability as we move away from Trading Fund status has also been a key priority throughout the year. Many of these risks have been considered through our internal audit programme, and although the precise nature of the risk has changed over the period, it is clear that many of these risks will continue into the next reporting year. Key risks to the success of year two of the Delivery Plan include:

- Impacts on capacity from the implementation of service redesign in the transformation programme
- Continued prioritisation of COVID-19 work in response to new vaccines or therapeutics, particularly in relation to new variants
- Timely implementation of improvements to internal financial systems to support the new Agency operating model and introduction of changes to our fee levels and structures via legislation

Given the scale of change in the Agency this year, we are undertaking work to align the operation of the risk process with the new operational structure. This will help to ensure that risks are being dynamically identified and managed across our new operating model and structure at the right level, with ExCo able to focus on the most strategic risks. This will also enable us to incorporate lessons identified in advisory work by the Government Internal Audit Agency (GIAA) on how to further strengthen our risk process.

Systems of internal control

As set out in the "Our future" section on page 19, this year has been the start of a significant journey for the Agency. It has also been a year of embracing opportunities and tackling challenges. We will no doubt learn more as we continue the journey we have started.

Amongst these are opportunities and challenges related to our systems of internal control, where we have focused substantial effort this year. As some of our audits have evidenced, we have identified some weaknesses this year. The audit of order to cash processes highlighted the need for improved integration of systems across the business, along with improved customer record management and training of staff. The audit of the change to the Agency's trading fund status set out the need for appropriate oversight, planning and scrutiny of the deliverables in scope. Management action has been agreed and rapidly implemented to improve the control of both issues.

Key themes arising from audits on organisational culture and our response to the Independent Medicines and Medical Devices Safety Review also highlight the need for clear ownership of and accountability for deliverables, with appropriate scrutiny at the correct governance forum. This is an issue that the Agency has been addressing over the course of this year as we continue to implement our governance changes, and the audit recommendations have added to that programme of work.

We have focussed in 2021/22, throughout our transformation process, on addressing the underlying cause of the weaknesses identified, and this critical work continues into next year.

One underlying cause is undeniably our legacy systems and associated processes, the complexity of which is a direct result of the organic growth of the Agency through several mergers over time. Our commitment through transformation to bring the Agency more closely together to better drive public health outcomes has helped to illuminate where our legacy systems are no longer adequately supporting the business or are not adequately integrated. While we have been working to address those legacy systems through our IT infrastructure plans, our work this year has allowed us to get more forensic about the changes needed in the accompanying processes.

Closely aligned to the issues of systems and process is our corporate data flows and their integrity. This is both cause and consequence of system and process challenges. While our work on the latter will begin to impact on how we assure, use and share our data, work is also underway in the Agency on our first data strategy. This considers how we leverage one of our most important assets both for the delivery of regulatory outcomes and to maximise the effective and efficient operation of our organisation.

Finally, our work on transformation includes a clear focus on our organisational culture. We are moving from a reactive gatekeeper to a pro-active, enabling and agile regulator, able to meet the expectations of the public in preventing harm, enabling rapid access to healthcare products and operating as a responsible public body. This change, and the accompanying culture shift, will embody grasping responsibility at individual staff level, with revised supporting protocols and a clear framework for delegation of decision-making. This in turn will be supported by our maturing governance, with improved oversight and reporting at the right level and frequency addressing the findings of this year's audits about our operational and project governance, so that we have clarity about delivery and accountability. We will continue to build on our approach to identifying strategic change that impacts across the organisation, particularly in the context of our move to a One Agency approach, in order that we avoid piecemeal or disconnected implementation. All of this will come together through improved prioritisation, with similarly improved business planning aligned to those priorities, so that we are better able to drive forward delivery of interventions which have the most critical impact on our operations.

In addition to these specific areas of focus, next year brings a continued programme of work across both the corporate and operational areas of the business. We will continue to build on our areas of strength in many aspects of our corporate governance and our public health response. We will also continue our process of implementing our transformation, with radical revision where

necessary to drive better outcomes for patients and the public. As part of this revolution in how we operate, we will continue to critically self-appraise how we do business and embrace new approaches where they are needed.

Audit and Risk Assurance Committee (ARAC)

In 2021/22, ARAC carried out its role in line with HM Treasury's ARAC Handbook covering the Committee's usual activities, including reviewing the Agency's Annual Report and Accounts, internal and external audit activities, and the development of the risk management framework. ARAC also focused on several specific areas over the year including financial performance, 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. Overall, 84% of all responses gave ARAC a grading of "Good" or "Excellent". Feedback was collected from ARAC members on improvements to be taken forward in the next year, including encouraging early discussions on potential new risks and introduction of a dedicated horizon scanning meeting to the annual meeting calendar.

During the year ARAC has provided oversight and challenge to support the Agency management of corporate risks, including deep dive analysis of financial, technical and resourcing risks. The Committee has supported the review and refresh of the corporate risk register to drive continual improvement and overseen the internal audit program, ensuring progress against the audit plan and reviewing responses to audit recommendations to ensure these are timely and effective.

Throughout 2021/22, ARAC has provided challenge to support improvements to the internal control framework and reviewed internal policies including the management of conflicts of interest policy and fraud and whistleblowing policies, as well as overseeing the Agency progress towards meeting the Cabinet Office Functional Standards. Through the meeting program, review of the Annual Report and Accounts and by monitoring the risk and audit activities of the Agency ARAC has sought assurance on behalf of the Board that critical corporate responsibilities have been properly discharged.

Internal audit

Internal audit services were provided by GIAA. The GIAA team operates to Public Sector Internal Audit Standards and the internal audit plan included the reviews listed in the table below.

As outlined in the “Systems of internal control” section of this report (page 73) we have taken action to critically appraise systems where we had reason to doubt their efficacy. We asked GIAA to look at those areas to help identify weaknesses that we must address. While we acknowledge the need to drive specific improvements, it was right that to first take the time to examine these issues, despite the exceptionally high workloads and challenging pace of transformation over the course of this year. We have shared the independent assessments and the improvements needed with ARAC and the Board and are content that the issues can be addressed in the short-medium term and that we have a sufficient plan in place to do so.

We have also improved the monitoring of audit outcomes over the course of this year in order to ensure we are capturing and meaningfully embedding change in response to audit recommendations. We will continue to build our maturity of approach in this area over the course of 2022/23.

Further, we have confidence in the audit plan agreed with GIAA for this coming year, which is built around areas of substantial risk, aligned to the second year of our Delivery Plan, informed by ARAC and focused on ensuring we have robust systems of internal control.

Audit	Areas reviewed	Assurance rating
COVID-19 Response	• Governance and accountability for monitoring and co-ordination of major incident response including incident escalation, the closure of the Incident Management Team, establishment of Task Force, and initiation of subsequent reviews • Lessons learned - identifying and sharing lessons learned from incidents and addressing common themes • Resourcing - capacity and capability to respond to major incidents while continuing to deliver day to day business activities and internal change programmes • Accurate accounting and allocation of financial costs • Plan for improving incident management capability, including strategy setting and capability planning • Plan to maintain relationships built up with interested parties during the pandemic, ensuring there is effective communication going forward	Moderate
Organisational culture	• Definition of baseline of current culture and setting clear objectives for cultural change • Ensuring Culture Change Action Plan addresses the identified drivers for culture change • Establishing the necessary activities with sufficient resources, defining accountability and monitoring progress, including oversight and reporting • Linking the Agency's strategy for culture change to other transformation work taking place within the Agency	Limited

Audit	Areas reviewed	Assurance rating
Order to Cash	• Test principles identified in Government Finance Function as: master data set up and maintenance; invoice generation; receipting and debt management • Activity of the central finance team engaged in accounts receivable processes and teams working in income generating services in NIBSC and CPRD	Unsatisfactory
Independent Medicines and Medical Devices (IMMDS)	• Action plan to address the recommendations of the IMMDS Review, including the resources provided, the timeframes and progress to date • Assessment of work so far completed to determine whether it has achieved the intended benefits • How progress against the plan is communicated to senior managers and stakeholders • Arrangements for engaging with stakeholders including any plans for engagement with the Patient Safety Commissioner	Limited

Audit	Areas reviewed	Assurance rating
Safety Connect Programme	• Programme Delivery Objectives - clarity of objectives, timescales, outcomes, budgetary control and intended benefits • Communications - suitable communication channels in place to keep key stakeholders informed of progress, ensuring delivery confidence and effective oversight • Governance - forums are held regularly with key personnel present resulting in effective decision making • Risks and issues - effectively captured, tracked and mitigated, with interdependencies from the Agency's transformation programme and other strategic developments across the Agency clearly identified and mitigated • Financial management information is accurate, correctly reconciled ensuring correct programme cost and minimising the risk of fraud or error	Substantial
Innovative Licensing and Access Pathway (ILAP)	Still being concluded	
Preparation for loss of trading fund status	• Roles and responsibilities and accountabilities in identifying and coordinating the changes required • Action planning to implement the changes required, including identification and allocation of appropriate resources • Arrangements for communicating the changes to staff • Arrangements for ensuring there is clarity of the financial implications of the change, including the role of Finance and the role of budget managers	Unsatisfactory

Audit	Areas reviewed	Assurance rating
Corporate governance	• Executive Committee terms of reference and delegated authorities to provide context for arrangements set out below Executive Committee and sub-committees • Operational level delegated authorities (financial and non-financial) • Key decisions implicated by the Agency's strategy and how these are considered in operational governance processes • Information flow and communication structures and systems supporting the Agency's governance processes (e.g., reporting timetable)	Moderate
Assurance mapping (advisory work)	Advisory work to consider potential additional improvements to the risk management framework	N/A

Head of Internal Audit (HIA) opinion

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

My overall opinion is that I can give **Limited** assurance to the Accounting Officer 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 2021-22.

The MHRA ("the agency") is an Executive Agency of the Department for Health and Social Care. The agency's purpose as set out in the 2021-23 Delivery Plan[1] is to protect and improve patient health by enabling the earliest access and high-quality supply of safe, effective and innovative medical products through proportionate, data-driven assessment of risks and benefits.

My opinion is set within the context of significant change across the agency during 2021/22, including preparation for the loss of its Trading Fund status on 1 April 2022 and therefore access to spend its reserves and resulting pressures on resources, the continuing response to the Independent Medicines and Medical Devices Safety (IMMDS) review, the impact of EU Exit on the regulatory framework, and the agency's response to the COVID-19 pandemic.

My opinion is derived from the internal audit work delivered over the year, together with my observations from attending Audit and Risk Assurance Committee (ARAC) and management's responses to internal audit reports and recommendations.

We have completed all but one of the planned audits from the 2021/22 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 Limited assurance with 1 Substantial, 2 Moderate, 2 Limited and 2 Unsatisfactory opinions issued.

1. GOV.UK. The Medicines and Healthcare products Regulatory Agency Delivery Plan 2021-2023. July 2021. Available at: https://www. gov.uk/government/publications/the-medicines-and-healthcare-products-regulatory-agency-delivery-plan-2021-2023. Accessed July 2022.

Governance

Audits undertaken in 2021/22 provided a mixed picture of the adequacy and effectiveness of the agency's governance arrangements. Some specific audits: SafetyConnect, COVID-19 Response and Corporate Governance provided positive assurance over the governance arrangements within the scope of these audits.

Other audits identified gaps in the governance and leadership arrangements, specifically;

- Preparations for change in Agency status where activities had been identified and led by operational teams with limited direction and oversight from senior leadership and limited discussion about the corporate nature of the change and input required from the wider agency
- The IMMDS audit identified that there was a need to clarify the role and responsibilities of the oversight forum for the delivery of the actions
- The audit of Organisational Culture identified that there was a lack of strategic direction for the activities identified, particularly when resources needed to be reallocated to other priorities. This had led to staff working on the actions taking their own decisions about the respective priorities without necessarily having regard for the wider agency picture. We also found there was a lack of a formal schedule of reporting to senior leadership and the Board sub-committee

Risk Management

Audits that specifically included risk management arrangements confirmed that these were working effectively; the audit of Safety Connect found that strong risk management arrangements were in place with risks and issues being effectively captured, tracked and mitigated, and the audit of the COVID-19 Response also found that there was a dedicated risk register for COVID related risks and that this was being reviewed and updated.

Through our attendance at ARAC and ExCo Risk group, we can confirm that the agency has effective arrangements in place to manage its strategic risks and reports on these at an appropriate level both at executive and non-executive levels. ARAC has received deep dives into particular areas of risk, including the Future Operating Model, Digital Implementation and Digital Supplier Contract and Future Staffing and Skills risks.

Through our advisory review of Assurance Mapping, we made recommendations for further strengthening the format of the risk registers to aid management's and ARAC's ability to assess the effectiveness of controls in mitigating the risks they relate to.

Internal controls

Due to the scale and pace of change taking place across the agency during 2021/22 together with ARAC's agreement to a smaller internal audit plan, much of the work undertaken by internal audit was necessarily focused on governance arrangements (e.g., SafetyConnect, ILAP, Corporate Governance, Preparations for Change in Agency Status). Where internal audit work focused on internal controls, these were not found to be adequately designed or effectively implemented. The audit of Order to Cash found that the systems in place were not effectively joined up, the processes were split between teams with no individual or team having oversight of the end-to-end processes, and manual processes were in place for example for approving write offs and credit notes with little supporting documentation available.

We were also asked to comment on an identified overpayment to a non-executive director after he had left the agency. Our initial observations were that the controls as explained to us were not sufficient to have identified an overpayment to a leaver that had not been processed by the payroll provider. The payroll provider was not providing an appropriate report to enable the agency to check that all expected leavers had been removed and the team were relying on checking a report showing variations to pay which would not have included unprocessed leavers. We provided responses detailing our recommendations and an audit of Payroll is currently underway as part of the 2022/23 audit plan.

Monitoring and Oversight of identified actions

In my annual reports for 2019/20 and 2020/21, I reported that several audits over the two-year period had identified a failure to properly assign actions to named postholders with target dates for completion. I considered that this may lead to a risk that actions identified by the Agency to address known issues may not be delivered in the absence of clear ownership and accountability. A small number of audits undertaken in 2021/22 have identified the same issue, in particular,

- The audit of COVID-19 response identified that whilst there was a comprehensive list of actions arising from an internal Lessons Learned review, not all actions were assigned to a named owner or given a date for completion,
- The Organisational Culture audit identified that there was an action plan in place, but again not all actions had owners and target dates and there was no formal schedule of reporting up to the relevant ExCo sub-committee and no evidence of monitoring of delivery of the actions,
- The audit of preparations for change in Agency status identified that activities to deliver the change had been identified by Finance colleagues who had developed their own workplans but these workplans had not been signed off by management and were not being monitored and reported on at a senior level.

Counter fraud, bribery and corruption

The Agency is committed to preventing and deterring cases of fraud, bribery and corruption and where it does occur, to investigating cases and learning from them in line with our Anti-Fraud and Bribery Policy. Our fraud strategy, from which annual action plans are drawn, sets out these aims and actions to improve further and achieve compliance with the Counter Fraud Functional Standard.

When assessing both our regulatory and non-regulatory fraud risks, we identify actions to mitigate and reduce these risks. In the next year, we will be reviewing our fraud assessment process and moving towards using the Cabinet Office format which should help strengthen the robustness of our findings.

We report to and receive assistance from the DHSC Anti-Fraud Unit which provides specialist expertise, if needed, to investigate suspected fraud against the Agency. The DHSC Anti-Fraud Unit runs regular Counter Fraud Liaison group meetings, of which we are part, and we share best practice and counter fraud briefings with relevant Agency colleagues.

At each meeting, ARAC receives notification of all fraud cases and from 2022/23 this will include errors, so it mirrors the quarterly information given to Cabinet Office via DHSC. ARAC also receives and comments on an annual report setting out counter fraud activities, risk assessment process, a summary of cases and a proposed action plan for the following year.

Human rights

We recognise that we deliver our excellent services through a talented and developed workforce and we strive to be an employer of choice. We implement and support a range of policies and practices that aim to protect the human rights of our staff, including policies on Dignity at Work, Grievance and Whistleblowing. We have a dedicated Diversity and Staff Engagement Team who deliver a wide range of initiatives to support diversity, inclusion and wellbeing. We have recognised trade unions and staff are welcome to join, and we also support a range of Staff led ‘networks’, designed to support and give a voice to staff on particular issues.

Raising a concern / whistleblowing

It is important that staff feel able to raise concerns, whether informally or formally under the Agency’s Raising Concerns Policy and Procedure and this chimes with one of the Agency’s three values which is “we work together with respect”.

Both the results of the 2021 Civil Service Staff Survey and a separate survey to find out the possible reasons why there had not been formal concerns raised in the last few years, showed that Agency needed to do more to raise awareness of the routes to raising concerns, what will happen when concerns are raised and the protections available. Actions taken in the last year to improve awareness included providing "Create a Speak Up Culture" sessions, articles and videos on the intranet as part of the Civil Service "Speak Up Week" in September and providing values and behaviour workshops to line managers. There is further to go, and plans have been developed, shared with the NED Raising Concerns Champion and ARAC in the annual report to them on raising concerns.

As part of induction, staff are made aware of the Civil Service Code, how to raise concerns and the role of the Nominated Officers in signposting to the best place to progress any concern. The intranet site includes a summary of the process, and a form staff can fill in if they wish, which was made available in 2021. There are links on the intranet site to the policy and associated guidance as well as to sources of other support including Mental Health Champions and Informal Employee Contacts.

With DHSC, we regularly share learning and best practice, and we report quarterly to Cabinet Office via DHSC on whistleblowing/raising concerns cases. The Agency was included in DHSC's whistleblowing internal audit in April 2021 which received a moderate assurance reflecting that there were adequate whistleblowing policies in place drawn from Civil Service model policy and reflecting best practice as outlined in the National Audit Office (NAO) *"Making a whistleblowing policy work[1]"* report (2014).

Information governance

The Agency prioritises good management of information and in 2021 created an Information Assurance Group, reporting into the Digital Delivery Data and Technology Committee. This group is responsible for the Agency's information and data governance arrangements, and providing assurance to the SIRO, Digital, Data and Technology Board, and the Agency Board that information and data assets and associated risks are effectively managed.

Management of information risk is based around three lines of defence. Information Asset Owners in each function manage operational information risks, through risk registers with effectiveness of risk mitigation reviewed regularly. As a second line of defence, ExCo has oversight of information risk, through monitoring of information risks on the corporate risk register, together with deep dives into key information risks at Exco meetings as required. Thirdly, ARAC commission's regular internal audits of information risk, and an annual Senior Information Risk Owner report provides ARAC with an annual overview of information governance arrangements and management of risk.

1. National Audit Office. Making a whistleblowing policy work. March 2014. Available at: https://www.nao.org.uk/wp-content/uploads/2015/03/Making-a-whistleblowing-policy-work.pdf. Accessed July 2022.

The Agency continues to prioritise cyber risk and has taken positive steps to improve data security against a background of ongoing cyber threat. These cyber-attacks are expected to increase in intensity and sophistication than those seen previously. To address these threats, we have embedded security by design into our project and change lifecycle. We continue to work closely with the National Cyber Security Centre to respond to new security threats. We have responded to a number of cyber security alerts from the NHS Digital and National Cyber Security Service, and have taken proactive mitigating actions, and this year has seen no significant successful cyber security attacks on the Agency.

This year, 22 security breaches have been reported and investigated, and 324 reports from staff of phishing emails. Our security systems have ensured that 165,173 suspicious emails were captured. We have carried out IT health checks throughout the year and are making steady progress in closing the high-level vulnerabilities that were identified. We have again successfully implemented the Data Security Protection toolkit and continue to perform well against the National Data Guardian data security standards.

We have worked to improve compliance and raise awareness of our obligations under the Data Protection Act and Law Enforcement Directive, to embed data protection by design. We completed and updated our register of personal data processing as required under Article 30 of the General Data Protection Regulation. We introduced additional technical measures to prevent accidental email breaches through implementing of data loss prevention technology.

We have continued to handle all subject access requests and data breaches in a timely manner. The Agency has formally reported one data-related incident to the Information Commissioner's Office. This was reported within the required 72 hours timeframe and no further action was required beyond the remedial work and mitigation measures agreed. The Agency has also had two complaints referred to it by the Information Commissioner's Office (ICO) in relation to two subject access requests handled over the past year. Following an internal review conducted by the Agency's Data Protection Officer, the ICO advised that the Agency had complied with data protection law as required.

All new starters in the Agency are now asked to complete Information Governance training and all staff must complete online information governance training every two years. In addition to this basic training, targeted training is offered to those handling sensitive information or with responsibilities for managing data protection requests. Regular information is published to remind staff of good information security practices.

Accounting Officer's review of the effectiveness of the 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.

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

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 2022 and up to the date of approval of the Annual Report and Accounts.

This year has been a year of significant change for the Agency, adapting to our new external environment as well as significant redesign of our operating model. Change is difficult and inevitably surfaces internal challenges, but it is also a positive opportunity to make improvements and to consciously address areas where weaknesses have been identified. I have particularly welcomed the support of internal and external auditors in highlighting areas of focus for the coming year.

As set out on in the “Systems of internal control” section of this report (page 73) some internal control matters have arisen during the year. Where specific weaknesses were identified within the year, rapid action was taken to address those and restore control. Where longer term action is required, following significant reflection and engagement with both auditors and ARAC, I am confident that the specific matters to address and the root causes of those matters have been identified, management responsibility allocated and work is underway. I am therefore satisfied that a plan of action to address control weaknesses and ensure continuous improvement of the control framework is in place.

I have considered the evidence provided for the production of the Governance Statement. The conclusion of my review is that although there are areas for improvement in the coming year; the Agency’s overall governance and internal control structures have been appropriate for the Agency’s business and have been satisfactory throughout 2021/22.

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.

I am therefore satisfied, based on the information set out above, the advice given to me by the Head of Internal Audit, the Agency Board, Audit Risk and Assurance Committee (ARAC) and Executive Committee (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

The Remuneration and Staff Report provides details of the remuneration (including any non-cash remuneration) and pension interests of Agency Board members and the directors who regularly attend Board meetings. The content of the tables is subject to audit.

Remuneration policy

It is the aim of the Agency to maintain levels of remuneration such as to attract, motivate and retain colleagues of a high calibre who can effectively contribute to the successful development of the business.

Service contracts

Civil Service appointments are made in accordance with the Civil Service Commissioners' Recruitment Code, which requires appointments to be based on fair and open competition but also includes the circumstances when appointments may otherwise be made. Unless otherwise stated below, the officials covered by this report hold appointments that are open-ended. Early termination, other than for misconduct, would result in the individual receiving compensation as set out in the Civil Service Compensation Scheme. The standard period of notice to be given by directors is 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 at: http://civilservicecommission.independent.gov.uk/.[1]

The Chair and NEDs are appointed by the Secretary of State for Health and are on fixed term contracts.

Performance appraisal

The Agency has two performance development schemes for its staff. Senior Civil Servants (SCS) performance management is guided by the Cabinet Office scheme, with a goal setting plan that includes corporate goals mandated for all, with a mid-year (September/November) and end of year (March/April) review. Aligned to this is potential to be awarded an in year or end of year performance bonus.

For our largest cohort of staff in the Delegated Grades, the Agency has a scheme called "My Progress Review", which is based on a continuous quality conversation with quarterly 'check ins' on progress against goals. The scheme includes in year awards with the potential to be awarded a performance bonus or recognition voucher, designed to reward exceptional performance 'in the moment'.

Remuneration and pension entitlements

The section below provides details of the remuneration and pension interests of the most senior management (i.e., ExCo and Agency Board members) of the Agency. Executive Team members' salary and bonus awards are decided by the Organisational Development and Remuneration Committee. Remuneration for NEDs is determined by DHSC in accordance with the Departmental review process.

1. Civil Service Commission. April 2022. Available at: https://civilservicecommission.independent.gov.uk. Accessed June 2022.

This table now reflects the new structure with only Executive Directors listed. This excludes Divisional Directors included in last year's table.

Executive Committee (ExCo) members' salaries, bonus and benefits table – (subject to audit)

2021/22	Salary £000	Performance pay and bonuses £000	Pension related benefits £000	Total £000
June Raine, CBE Chief Executive	140 – 145	5 – 10	Nil	145 - 150
Samantha Atkinson[1] Interim Chief Quality and Access Officer	90 – 95	Nil	34	125 – 130
Marc Bailey[2] Chief Science, Research and Innovation Officer	110 – 115	5 – 10	44	160 – 165
Alison Cave[3] Chief Safety Officer	100 – 105	Nil	36	135 – 140
Jon Fundrey Chief Operating Officer	140 – 145	Nil	52	190 – 195
Claire Harrison[4] Chief Technology Officer	50 – 55	Nil	Nil	50 – 55
John Quinn[5] Interim Chief Technology Officer	95 – 100	Ni	19	115 – 120
Christian Schneider[6] Interim Chief Scientific Officer	45 – 50	Nil	18	60 – 65
Laura Squire, OBE[7] Chief Healthcare Officer	40 – 45	Nil	26	65 – 70
Glen Wells[8] Chief Partnerships Officer	35 – 40	Nil	15	50 – 55

1 Samantha Atkinson's role as Interim Officer ended on 31 October 2021.
2 Marc Bailey was appointed on 1 September 2021. Full year equivalent is £115k-£120k.
3 Alison Cave was appointed on 16 July 2021. Full year equivalent is £135k-£140k.
4 Claire Harrison was appointed on 29 October 2021. Full year equivalent is £125k-£130k. Not a member of PCSPS.
5 John Quinn left the Agency on 31 January 2022.
6 Christian Schneider left the Agency on 31 July 2021. Full year equivalent £135k-£140k.
7 Laura Squire, OBE, was appointed on 1 November 2021. Full year equivalent is £100k-£105k.
8 Glen Wells was appointed on 29 November 2021. Full year equivalent is £110k-£115k.

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

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

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

2021/22	Salary £000	Benefits in kind (taxable) to nearest £100*	Total £000
Stephen Lightfoot Non-Executive Director, Chair	60 – 65	Nil	60 – 65
Junaid Bajwa[1] Non-Executive Director	0 – 5	100	0 – 5
Barbara Bannister, MBE[2] Non-Executive Director	0 – 5	Nil	0 – 5
Amanda Calvert Non-Executive Director	5 – 10	Nil	5 – 10
Bruce Campbell[2] Non-Executive Director	0 - 5	Nil	0 - 5
Graham Cooke[1] Non-Executive Director	0 – 5	100	0 – 5
Paul Goldsmith[1] Non-Executive Director	0 – 5	400	5 – 10
Mercy Jeyasingham, MBE Non-Executive Director	5 – 10	Nil	5 – 10
Raj Long[1] Non-Executive Director	0 – 5	Nil	0 – 5
Anne–Toni Rodgers Non-Executive Director	0 – 5	Nil	0 – 5
David Webb CBE[2] Deputy Chair Non-Executive Director	0 – 5	Nil	0 – 5
Michael Whitehouse, OBE Non-Executive Director and ARAC chair	10 – 15	100	10 – 15

*Agency Board Non-Executive Directors received no performance pay or bonus. Benefits in kind relate to travel expenses.

1 Junaid Bajwa, Graham Cooke, Paul Goldsmith and Raj Long joined the Agency on 1 September 2021.Full year equivalent £5k-£10k
2 Barbara Bannister, MBE; Bruce Campbell and David Webb, CBE left the Agency on 31 August 2021. Full year equivalent £5k-£10k

2020/21	Salary £000	Benefits in kind (taxable) to nearest £100*	Total £000
Michael Rawlins, GBE Kt[1] Chair (until 31 August 2020)	25-30	Nil	25 - 30
Stephen Lightfoot[2] Non-Executive Director, Chair (from 1 September 2020)	40 - 45	Nil	40 - 45
Barbara Bannister, MBE Non-Executive Director	5 - 10	Nil	5 - 10
Amanda Calvert Non-Executive Director	5 - 10	Nil	5 - 10
Bruce Campbell Non-Executive Director	5 - 10	Nil	5 - 10
Mercy Jeyasingham MBE[3] Non-Executive Director	5 - 10	Nil	5 - 10
Anne–Toni Rodgers Non-Executive Director	5 - 10	Nil	5 - 10
Liam Smeeth[4] Non-Executive Director	5 - 10	Nil	5 - 10
David Webb CBE Deputy Chair	5 - 10	Nil	5 - 10
Michael Whitehouse, OBE Non-Executive Director	10 - 15	Nil	10 - 15

*Agency Board NEDs received no performance pay, bonus or any pension related benefits.

1 Michael Rawlins GBE Kt left the Agency Board on 31sAugust 2020. Full year equivalent £60k-£65k.
2 Stephen Lightfoot was appointed Chair on 1 September 2020.Full year equivalent £60k-£65k.
3 Mercy Jeyasingham joined the Agency Board on 1 May 2020. Full year equivalent £5k-£10k.
4 Liam Smeeth joined the Agency Board on 1 July 2020 and left on 28 February 2021. Full year equivalent £5k-£10k.

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 2021/22 relate to performance in 2020/21 and the comparative awards reported in 2020/21 relate to performance in 2019/20.

Fair pay disclosures (subject to audit)

Reporting bodies are required to disclose the relationship between the remuneration of the highest-paid director in their organisation against the 25th percentile, median and 75th percentile of remuneration of the organisation's workforce. Total remuneration is further broken down to show the relationship between the highest paid director's salary component of their total remuneration against the 25th percentile, median and 75th percentile of salary components of the organisation's workforce. The banded remuneration of the highest paid director in the Agency in the financial year 2021/22 was £145k-£150k (2020/21, £145k-£150k). In 2021/22, no employees (2020/21, 0) received remuneration in excess of the highest paid director. Remuneration ranged from £9k to £150k (2020/21 £8k-£150k).

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

Pay ratio information

The ratio of the highest paid director's pay and benefits (excluding pension benefits) to the 25th, 50th and 75th percentile of pay and benefits of the Agency's employees is disclosed in the table below:

Year	25th percentile pay ratio	Median pay ratio	75th percentile pay ratio
2021/22	4.35	3.14	2.38
2020/21	4.48	3.50	2.44

The total pay and benefits and the salary component of total pay and benefits of the employees at each percentile is disclosed in the table below:

2021/22	25th percentile	Median	75th percentile
Total pay and benefits	£33,915	£46,908	£62,066
Salary component of total pay and benefits	£33,086	£45,586	£61,455

2020/21	25th percentile	Median	75th percentile
Total pay and benefits	£32,957	£42,224	£60,397
Salary component of total pay and benefits	£32,957	£41,004	£56,314

Percentage change from previous financial year

For each of salary and allowances and performance pay and bonuses payable, the percentage change from the previous financial year in respect of the highest paid director is as follows:

%age change – Highest paid director	2021/22 Increase/ (decrease%)
Salary and allowances	3.64
Performance pay and bonuses	(66.67)

The differences in these figures relate to a change in the highest paid Director from 2020/21 and 2021/22, due to the payment of bonus payments that were made in both years.

For each of salary and allowances and performance pay and bonuses payable, the percentage change from the previous financial year in respect of the employees of the Agency taken as a whole is as follows:

%age change – Average for all employees taken as a whole	2021/22 Increase/ (decrease%)
Salary and allowances	3.21
Performance pay and bonuses	(3.32)

The increase in these figures relate in the main to organisational changes which took place within the Agency in 2021/22, this includes a voluntary exit scheme that was implemented in 2021/22. In addition to this scheme over the course of 2021/22 the staff attrition rate was 17.2%, with a significantly higher attrition rate for staff at HEO and below. Both of these factors increased the average figure despite there being only a limited pay award in 2021/22.

Pension benefits table (subject to audit)

Neither the Chair nor NEDs have any pension entitlement arising from their service with the Agency. The following table provides details of the pension entitlements of ExCo members:

2021/22	Real increase in pension and related lump sum at 60 Bands of £2,500	Total accrued pension at age 60 at 31 March 2022 and related lump sum Bands of £5,000	Cash Equivalent Transfer Value at 1 April 2021. To nearest £1,000	Cash equivalent Transfer Value at 31 March 2022. To nearest £1,000	Real increase in Cash equivalent Transfer Value. To nearest £1,000	Employers Contribution to stakeholder pension. To nearest £1,000
June Raine, CBE Chief Executive	0 plus lump sum of 0	65 – 70 plus lump sum of 195 - 200	1,269	1,267	(14)	38
Samantha Atkinson Interim Chief Quality and Access Officer	0 – 2.5 plus Nil lump sum	30 – 35 plus Nil lump sum	422	462	13	29
Marc Bailey Chief Science, Research and Innovation Officer	2.5 – 5.0 plus Nil lump sum	10 – 15 plus Nil lump sum	113	152	27	34
Alison Cave[1] Chief Safety Officer	0 – 2.5 plus Nil lump sum	5 - 10 plus Nil lump sum	51	85	22	30

1 Alison Cave was appointed on 16 July 2021

2021/22	Real increase in pension and related lump sum at 60 Bands of £2,500	Total accrued pension at age 60 at 31 March 2022 and related lump sum Bands of £5,000	Cash Equivalent Transfer Value at 1 April 2021. To nearest £1,000	Cash equivalent Transfer Value at 31 March 2022. To nearest £1,000	Real increase in Cash equivalent Transfer Value. To nearest £1,000	Employers Contribution to stakeholder pension. To nearest £1,000
Jon Fundrey Chief Operating Officer	0 – 2.5 plus Nil lump sum	50 – 55 plus Nil lump sum	840	924	45	42
John Quinn[1] Interim Chief Technology Officer	0 – 2.5 plus Nil lump sum	45 – 50 plus lump sum of 85 - 90	780	827	5	29
Christian Schneider[2] Interim Chief Scientific Officer	0 – 2.5 plus Nil lump sum	15 – 20 plus Nil lump sum	205	214	9	14
Laura Squire, OBE[3] Chief Healthcare Officer	0 – 2.5 plus Nil lump sum	35 – 40 plus lump sum of 85 - 90	732	781	15	13
Glen Wells[4] Chief Partnerships Officer	0 – 2.5 plus Nil lump sum	0 – 5 plus Nil lump sum	40	49	7	12

1 John Quinn left the Agency on 31 January 2022
2 Christian Schneider left the Agency on 31 July 2021
3 Laura Squire was appointed on 1 November 2021
4 Glen Wells was appointed on 29 November 2021

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 2022 and related lump sum Bands of £5,000	Cash Equivalent Transfer Value at 1 April 2021. To nearest £1,000	Cash equivalent Transfer Value at 31 March 2022. To nearest £1,000	Real increase in Cash equivalent Transfer Value. To nearest £1,000	Employers Contribution to stakeholder pension. To nearest £1,000
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
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
Vanessa Birchall-Scott Director of Human Resources	0 – 2.5 plus Nil lump sum	10 – 15 plus Nil lump sum	169	209	26	29
Rachel Bosworth Director of Communi -cations	0 – 2.5 plus lump sum of 2.5 – 5.0	30 – 35 plus lump sum of 90 – 95	677	730	26	31
Sarah Branch Director of Vigilance and 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
Jon Fundrey Chief Operating Officer	2.5 – 5.0 plus Nil lump sum	45 – 50 plus Nil lump sum	752	837	43	42

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 2022 and related lump sum Bands of £5,000	Cash Equivalent Transfer Value at 1 April 2021. To nearest £1,000	Cash equivalent Transfer Value at 31 March 2022. To nearest £1,000	Real increase in Cash equivalent Transfer Value. To nearest £1,000	Employers Contribution to stakeholder pension. To nearest £1,000
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
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
Christian Schneider Interim Chief Scientific Officer	0 – 2.5 plus Nil lump sum	15 – 20 plus Nil lump sum	161	205	38	42
Boryana Stambolova[1] Deputy Director of Finance	0 – 2.5 plus Nil lump sum	0 – 5 plus Nil lump sum	60	77	12	29
Graeme Tunbridge Director of Devices	2.5 – 5.0 plus Nil lump sum	25 – 30 plus Nil lump sum	276	317	25	28
Janet Valentine Director of CPRD	2.5 – 5.0 plus Nil lump	20 – 25 plus Nil lump sum	270	316	27	33
John Quinn 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

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

Cash Equivalent Transfer Value (CETV)

A 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.

Staff costs (subject to audit)

2021/22	Total £000	Permanently Employed £000	Other £000
Wages and salaries	68,307	62,417	5,890
Social security costs	7,172	7,172	-
Other pension contributions	15,705	15,705	-
Sub-total	91,184	85,294	5,890
Less recoveries in respect of outward secondment	(180)	(180)	-
Total staff costs	91,004	85,114	5,890

2020/21	Total £000
Wages and salaries	69,745
Social security costs	7,067
Other pension contributions	15,873
Sub-total	92,685
Less recoveries in respect of outward secondment	(246)
Total staff costs	92,439

Number of staff employed as of 31 March 2022 (subject to audit)

2021/22	Total	Permanently Employed	Other*
Chair	1	1	-
Chief Executive/ Directors	10	10	-
Senior Civil Servants	103	100	3
Other Civil Service Staff	1,063	982	81
Total	1,177	1,093	84

*Includes contingent workers
1,177 full time equivalent staff were employed as of 31 March 2022.

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

SCS by grade

Senior Civil Servants by salary band (£000)	2021/22	2020/21
65 – 70	-	-
70 – 75	23	27
75 – 80	20	16
80 – 85	24	32
85 – 90	15	26
90 – 95	13	13
95 – 100	8	12
100 –105	6	5
105 – 110	1	4
110 – 115	4	3
115 – 120	-	1
120 – 125	-	1
125 – 130	1	-
130 – 135	1	-
135 – 140	7	1
140 – 145	4	3
Total	**127**	**144**

Pensions

Pension scheme participation

Employees who joined on or after 1 April 2015 are members of the Civil Service Pensions (CSP) alpha scheme. Current employees with over 13.5 years to retirement at 1 April 2012 joined Alpha scheme 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).

Civil Service pensions

The Civil Service Pension Scheme 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 *(https://www.civilservicepensionscheme.org.uk/)*[1].

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 2021/22, employees' contributions were payable at one of four 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 £23,100	4.60%
£23,001 to £56,000	5.45%
£56,001 to £150,000	7.35%
£150,001 and above	8.05%

1. Civil Service Pension Scheme. Civil Service Pensions. 2022. Available at: https://www.civilservicepensionscheme.org.uk/. Accessed July 2022.

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/.* [1]

1. Civil Service Pension Scheme. Civil Service Pensions. 2022. Available at: https://www.civilservicepensionscheme.org.uk. Accessed July 2022.

The NHS Pension Scheme (NHSPS)

Employees of NIBSC were covered by the provisions of the NHS Pensions Scheme. This scheme closed on 31 March 2015 and employees were given the opportunity to either preserve those awards or transfer them into the PCSPS. Since 1 April 2015 all NIBSC employees are covered by the provisions in the Civil Service Pension scheme, as detailed above.

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 2021/22, employers' contributions for the Agency employees of £15,704,919 were payable to the PCSPS (2020/21, £15,873,194) at one of four rates in the range 26.6 per cent to 30.3 per cent of pensionable pay (2020/21, 26.6 per cent to 30.3 per cent). 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 £80,261 (2021/22, £133,731) 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 (2020/21, 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 £4,817 (2021/22, £4,788), 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 2021/22 (2020/21, Nil). No additional pension liabilities were accrued.

Reporting of civil service and other compensation schemes

Exit packages (subject to audit)

Cost band	Total Number of exit packages by cost band	
	2021/22	2020/21
<£10,000	2	1
£10,000 - £25,000	24	-
£25,000 - £50,000	35	-
£50,000 - £100,000	37	9
£100,000 - £150,000	-	-
£150,000 - £200,000	-	-
Total number of exit packages	98	10
Total resource cost	**£4,269,604**	**£556,619**

In accordance with the civil service requirement when there is an intended reduction in workforce, the Cabinet Office approved the Agency's request for a multi-scheme exits package including voluntary early departure; voluntary redundancy and compulsory redundancy. The planned full consultation on agency wide organisational change in the context of the Agency's transformation programme then followed. In order to mitigate redundancy, an opportunity to consider a voluntary exit was provided to a number of staff in specified functions. Exits under this scheme concluded in early January 2022. Staff who did not secure a role in the new structure were placed at risk of redundancy from December 2021. The focus has remained on redeployment of those staff into vacant roles within the Agency and wider civil service for the remainder of this annual reporting period. However, a number of staff have been offered and accepted voluntary redundancy with a notice period occurring within the next annual report period and all staff at risk of redundancy are aware that we will continue to seek a suitable alternative role until their departure date. The requirement to consider exits under compulsory redundancy and appropriate consultation will also occur in the next annual reporting period and for these a suitable alternative will also be sought.

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 Agency 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 £4,270k (2020/21, £557k) 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 2022.

Spend on temporary staff

During 2021/22, expenditure on consultants was £6,443k (2020/21, £761k).

The Agency continues to employ temporary staff where it is of operational necessity. The Agency temporary staff expenditure was £5,890k in 2021/22 (2020/21, £5,743k).

The government apprentice scheme

The Agency currently pays approximately £294,000 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 were 14 apprentices in the Agency in 2021/22, a significant drop from the 22 in 2020/21. This drop was due to lower take up of apprenticeships internally, fewer recruitments and a significant number of resignations by current apprentices. Six apprenticeships were started in the Agency in 2021/22 compared to twelve in the previous year.

It is recognised that entry level apprenticeships are especially important in aiding social inclusion. Apprenticeship recruitment at entry level this year has been widely paused this year, however there are ongoing apprenticeships and apprenticeship recruitment in South Mimms, 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.

The Government's new Apprentice Strategy (published April 2022) commits to 1 in 20 Civil Servants being apprentices by 2025. The Agency will be guided by the DHSC on how this target impacts on the Agency and will produce an appropriate apprenticeship strategy towards the end of Q2 2022/23.

Other Staff Matters

Health and Safety

We are committed to providing a safe and secure workplace and adhering to the Health and Safety at Work Act 1974 and other related requirements, and the Agency's Health and Safety Policy statement. There were 15 accidents and 28 incidents reported during the year, which were logged, investigated and appropriate remedial action was taken. There were 14 working days lost because of the accidents involving injury at work during the year. Ensuring safety of staff during the continued pandemic has remained a key priority. Further details on our Health and Safety can be found on page 47 of this report.

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 4.5 working days per full time equivalent employee (2020/21, 3.7 days).

The annual turnover for the Agency was 22.9% (2020/21, 8.5%).

Civil Service People Survey

The annual Civil Service people survey was live for 6 weeks during September – November 2021. 48% of our workforce took part in the survey, and our engagement score results were 51% (67% in 2020). The civil service benchmark score for 2021 is 66%.

The Agency was undertaking a major organisational change programme at the time of the People Survey and staff were awaiting consultation outcomes following a proposed re-design of the organisation. As a result, it was anticipated staff engagement could be lower and that feedback may reflect uncertainty. The survey contained helpful indicators and regular PULSE surveys have since been being used to track staff perceptions throughout the change process.

Employee consultation

The Agency is committed to consulting and communicating effectively with its employees. There are policies in place to ensure that there is open and honest consultation with our recognised trade unions (Prospect, Unite, Public and Commercial Services Union (PCS), University and College Union (UCU) and the FDA Trade Union) through monthly Staff Partnership Meetings and quarterly formal Employee Relations Liaison Group meetings.

The Agency also holds regular All Staff Meetings to which all staff are invited, to enable proposed key changes to be disseminated and views taken as well as successes shared.

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

Relevant Union Officials

Number of employees who were relevant union officials during the relevant period	Full-time equivalent employee number
21	20.8

Trade Union Percentage of time spent on facility time

Percentage of time	Number of employees
0%	0
1-50%	21
51-99%	0
100%	0

Percentage of pay bill spent on facility time

Description	Figures
Total cost of facility time	£54,054
Total pay bill	£91,004
Percentage of the total pay bill spent on facility time*	0.06%

* 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

Equality and diversity

The Agency embraces diversity and promotes equal opportunities. 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 are seeking to appoint a Mental Health Champion at Agency Board level.

We run a Disability Confident Scheme (DCS) for job candidates with disabilities who meet the minimum selection criteria. We operate an open and fair recruitment process, fully compliant with the Civil Service Commission Recruitment Principles. We are committed to supporting staff through occupational health support, health and safety support and guidance, and in addition utilise our Workplace Adjustments Policy to enable staff who are, or 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 2021/22 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.

Staff composition - gender analysis*

	Male	Female
Chair/Chief Executive/ Directors	45%	55%
Senior Civil Servants	38%	62%
Other Civil Service Staff	40%	60%
Total	**40%**	**60%**

*Of those who declared

Staff composition - ethnic breakdown

Ethnic identity	Male
White	56%
BME	30%
No data/prefer not to say	14%

Gender Pay Gap

The mean gender pay gap for 2021/22 is 6.5% (7.9% in 2020/21) and the median pay gap for 2021/22 is 7.1% (8.7% in 2020/21).

The Agency's *gender pay gap report for 2020/21*[1] sets out targeted action on reducing the pay gap by:

- Focussing future pay awards on reducing specific pay ranges and on addressing specific pay issues that benefit the majority of our workforce, including factoring how the pay award effects staff covered by the provisions of the 2010 Equality Act
- Continuing to review recruitment policies and processes to ensure fairness and equality, including the diversity of the interview panel and starting salaries
- Scrutinising and reviewing the recruitment journey, including monitoring job advertisements to ensure that they are gender neutral and fully reflect the benefits of working for the Agency
- Monitoring and reporting on the uptake of mandatory modular training on Diversity and inclusion, complemented by providing bespoke in-house recruitment training
- Supporting women returning to work following maternity or adoption leave, linking this to our Diversity and Inclusion framework and supporting other Agency-wide initiatives
- Improving representation of female participants on talent development schemes that are either run by the Agency or the wider Civil Service; and
- Evaluating our existing development programmes to assure our Talent Management processes

The Agency also published an *ethnicity pay gap report for 2020/21*.[2]

1. GOV.UK. MHRA gender pay gap report: 2020 to 2021. January 2022. Available at: https://www.gov.uk/government/publications/mhra-gender-pay-gap-report/mhra-gender-pay-gap-report-2020-to-2021. Accessed July 2022.
2. GOV.UK. Ethnicity pay gap report: April 2020 to March 2021. January 2022. Available at: https://www.gov.uk/government/publications/mhra-ethnicity-pay-gap-report/ethnicity-pay-gap-report-april-2020-to-march-2021. Accessed July 2022.

2.5 Parliamentary acountability and Audit Report

This section is subject to audit

Remote contingent liabilities

There are no remote contingent liabilities.

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, DHSC and HM Treasury and are intended, taking one year with another, to cover the costs of the agency. Fees are set to recover the full cost incurred by the Agency. The Agency has complied with the cost allocation and charging requirements as set out in HM Treasury's guidance. DHSC funding in relation to devices activities is intended to cover the costs of providing this specific service. The Agency's income is derived from its regulatory function in achieving its objectives of protecting, promoting, and improving public health.

2021/22	£000 Income	£000 Expenditure	£000 Surplus/(Deficit)
Licensing	25,254	(33,000)	(7,746)
Inspections	5,376	(9,942)	(4,566)
Vigilance, Risk Management and Enforcement	37,452	(35,132)	2,320
British Pharmacopoeia	6,029	(1,671)	4,358
Devices	10,962	(16,042)	(5,080)
Clinical Trials	3,757	(3,484)	273
Regulator total	88,830	(99,271)	(10,441)
CPRD	13,500	(16,452)	(2,952)
DHSC share of joint venture	(6,750)	8,226	1,476
	6,750	(8,226)	(1,467)

2021/22	£000 Income	£000 Expenditure	£000 Surplus/(Deficit)
NIBSC	46,810	(55,169)	(8,359)
Total charging activities	**142,390**	**(162,666)**	**(20,276)**
DHSC Funding	12,436	-	12,436
Other non-attributable	6,435	(10,041)	(3,606)
Total deficit	**161,261**	**(172,707)**	**(11,446)**

The Agency received £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.

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)

2020/21	£000 Income	£000 Expenditure	£000 Surplus/ (Deficit)
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 deficit	**158,971**	**(158,945)**	**26**

Losses and special payments

Managing Public Money requires a statement showing losses and special payments by value and type 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.

The Agency's ability to recover debt from its customers has been adversely affected by weaknesses in the Agency's Order to Cash (O2C) processes, and unintegrated legacy income collection systems. These weaknesses were highlighted in a February 2022 internal audit report which gave an unsatisfactory rating. £2.4 million in aged debt has been deemed irrecoverable on the grounds that it is uneconomical to pursue or is not legally collectable under The Limitations Act 1980. The amount was written off during the financial year with approval from DHSC.

Management have undertaken a process improvement review and has a plan of action to deliver process and systems efficiencies, automation, and best practice to prevent future losses due to process failures.

In February 2022, as part of a business review, CPRD concluded that, due to significant integration issues with other Agency systems and the Citrix component of the customer service portal it would be prudent to impair the asset as it no longer had any value to the Agency. The asset was capitalised in January 2022 (cost £225k). The Net Book Value at the time of the review was £221k.

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

Dr June Raine DBE

Chief Executive and Accounting Officer

Medicines and Healthcare products Regulatory Agency

14 July 2022

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 Medicine and Healthcare products Regulatory Agency for the year ended 31 March 2022 under the Government Trading Funds Act 1973.

The financial statements comprise the Medicine and Healthcare products Regulatory Agency's

- Statement of Financial Position as at 31 March 2022;
- Statement of Comprehensive Income, Statement of Cash Flows and Statement of Changes in Taxpayers' Equity for the year then ended; and
- the related notes including the significant accounting policies.

The financial reporting framework that has been applied in the preparation of the financial statements is applicable law and UK adopted International Accounting Standards.

In my opinion, the financial statements:

- give a true and fair view of the state of the Medicine and Healthcare products Regulatory Agency's affairs as at 31 March 2022 and its deficit for the year then ended; and
- 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 for opinions

I conducted my audit in accordance with International Standards on Auditing (UK) (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 Medicine 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 Medicine 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 Medicine 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 Medicine and Healthcare products Regulatory Agency is adopted in consideration of the requirements set out in HM Treasury's Government Financial 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 financial statements or my auditor's certificate thereafter. The 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 Remuneration and Staff Report to be audited have been properly prepared in accordance with HM Treasury directions issued under the Government Trading Funds Act 1973.

In my opinion, based on the work undertaken in the course of the audit:

- the parts of the Accountability Report subject to audit have been properly prepared in accordance with HM Treasury directions made under the Government Trading Funds Act 1973;
- the information given in the Performance and Accountability Reports for the financial year for which the financial statements are prepared is consistent with the financial statements and is in accordance with the applicable legal requirements.

Matters on which I report by exception

In the light of the knowledge and understanding of the Medicine 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:
- I have not received all of the information and explanations I require for my audit; or
- adequate accounting records have not been kept by the Medicine and Healthcare products Regulatory Agency 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 subject to audit are not in agreement with the accounting records and returns; or
- certain disclosures of remuneration specified by HM Treasury's Government Financial Reporting Manual have not been made or parts of the Remuneration and Staff Report to be audited are not in agreement with the accounting records and returns; or
- the Annual 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:

- maintaining proper accounting records;
- the preparation of the financial statements and Annual Report in accordance with the applicable financial reporting framework and for being satisfied that they give a true and fair view;

- ensuring that the Annual Report and accounts as a whole is fair, balanced and understandable;
- internal controls as the Accounting Officer determines is necessary to enable the preparation of financial statement to be free from material misstatement, whether due to fraud or error; and
- assessing the Medicine 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 Medicine 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.

Extent to which the audit was considered capable of detecting non-compliance with laws and regulations including fraud

I design procedures in line with my responsibilities, outlined above, to detect material misstatements in respect of non-compliance with laws and regulations, including fraud. The extent to which my procedures are capable of detecting non-compliance with laws and regulations, including fraud is detailed below.

Identifying and assessing potential risks related to non-compliance with laws and regulations, including fraud

In identifying and assessing risks of material misstatement in respect of non-compliance with laws and regulations, including fraud, we considered the following:

- the nature of the sector, control environment and operational performance including the design of the Medicine and Healthcare products Regulatory Agency's accounting policies.
- Inquiring of management, The Medicine and Healthcare products Regulatory Agency's head of internal audit and those charged with governance, including obtaining and reviewing supporting documentation relating to the Medicine 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 Medicine and Healthcare products Regulatory Agency's controls relating to the Medicine and Healthcare products Regulatory Agency's compliance with the Government Trading Funds Act 1973, Managing Public Money.

- discussing among the engagement team regarding how and where fraud might occur in the financial statements and any potential indicators of fraud.

As a result of these procedures, I considered the opportunities and incentives that may exist within the Medicine and Healthcare products Regulatory Agency for fraud and identified the greatest potential for fraud in the following areas: revenue recognition, posting of unusual journals and potential manipulation of year-end transactions. In common with all audits under ISAs (UK), I am also required to perform specific procedures to respond to the risk of management override of controls.

I also obtained an understanding of the Medicine and Healthcare products Regulatory Agency's framework of authority as well as other legal and regulatory frameworks in which the Medicine and Healthcare products Regulatory Agency operates, focusing on those laws and regulations that had a direct effect on material amounts and disclosures in the financial statements or that had a fundamental effect on the operations of the Medicine 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.

Audit response to identified risk

As a result of performing the above, the procedures I implemented to respond to identified risks included the following:

- reviewing the financial statement disclosures and testing to supporting documentation to assess compliance with provisions of relevant laws and regulations described above as having direct effect on the financial statements;
- enquiring of management and the Audit Committee concerning actual and potential litigation and claims;
- reading and reviewing minutes of meetings of those charged with governance and the Board and internal audit reports;
- 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.*[1] This description forms part of my certificate.

Other auditor's responsibilities

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

Date
18 July 2022

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

1. Financial Reporting Council. Description of the auditor's responsibilities for the audit of the financial statements. December 2019. Available at: https://www.frc.org.uk/auditors/audit-assurance/auditor-s-responsibilities-for-the-audit-of-the-fi/description-of-the-auditor%e2%80%99s-responsibilities-for. Accessed July 2022.

3 Financial Statements

Statement of comprehensive income for the year ended 31 March 2022

	NOTE	2021/22 £000	2021/22 £000	2020/21 £000	2020/21 £000
Income					
Trading income	3.1		148,825		146,546
Other income	3.2		12,436		12,425
Total income			**161,261**		**158,971**
Expenditure					
Staff costs	5	(91,004)		(92,439)	
Operating costs	6	(81,703)		(66,506)	
Total expenditure			(172,707)		(158,945)
Operating (deficit)/ surplus			**(11,446)**		**26**
Finance income			35		6
Finance costs			(47)		(47)
Deficit for the financial year			(11,458)		(15)
Other comprehensive income					
Realised loss on inventories			(85)		(188)
Net gain/(loss) on revaluation of property, plant and equipment*	7		6,054		(3,334)
Total comprehensive loss for the year			**(5,489)**		**(3,537)**

*All gains and losses arise from continuing operations.

The notes on pages 133 to 160 form part of these accounts.

Statement of financial position as at 31 March 2022

	NOTE	31 March 2022		Restated 31 March 2021	
		£000	£000	£000	£000
Non-current assets					
Property, plant and equipment	7	134,626		128,464	
Intangible assets	8	16,402		13,389	
Inventories*	10	9,473		9,069	
Trade and other receivables	11	6,330		7,291	
Total non-current assets			**166,831**		**158,213**
Current assets					
Inventories*	10	661		494	
Trade and other receivables**	11	46,528		43,942	
Cash and cash equivalents	12	51,047		79,601	
Total current assets			**98,236**		**124,037**
Total assets			**265,067**		**282,250**
Current liabilities					
Trade and other payables***	13	(46,356)		(44,729)	
Other liabilities	14	(26,206)		(24,860)	
Provisions	15	-		(1,781)	
Total current liabilities			**(72,562)**		**(71,370)**
Total assets less current liabilities			**192,505**		**210,880**
Non-current liabilities					

	NOTE	31 March 2022		Restated 31 March 2021	
		£000	£000	£000	£000
Other liabilities	14	(7,893)		(4,602)	
Provisions	15	(1,998)		(1,998)	
Borrowings		-		(1,328)	
Total non-current liabilities			**(9,891)**		**(7,928)**
Assets less liabilities			**182,614**		**202,952**
Taxpayers' equity					
Public dividend capital			1,329		1,329
Reserves					
Revaluation reserve			117,602		111,633
Income and expenditure reserve			954		954
General fund			62,729		89,036
Total equity			**182,614**		**202,952**

*Inventories now split into current and non-current; see note 1.8
**In 2020-21 contract assets were shown separately on the face of the Statement of Financial Position. In 2021-22 they have been presented as part of trade and other receivables and are shown in note 11.
***In 2020-21 contract liabilities were shown separately on the face of the Statement of Financial Position. In 2021-22 they have presented as part of trade and other payables and are shown in note 13.

Dr June Raine DBE

Chief Executive and Accounting Officer

Medicines and Healthcare products Regulatory Agency

14 July 2022

The notes on pages 133 to 160 form part of these accounts.

Statement of cash flows for the year ended 31 March 2022

	NOTE	2021/22 £000	£000	Restated 2020/21 £000	£000
Cash flows from Operating activities					
Operating (deficit)/surplus		(11,446)		26	
Depreciation and amortisation	7/8	11,423		10,338	
Loss on disposal of assets	7/8	182		40	
Impairment of property, plant and intangible assets	7/8	26		462	
Realised loss on inventories	10	(85)		(188)	
(Increase) in inventories	10	(571)		(3,725)	
(Increase) in trade and other receivables*	11	(1,625)		(9,394)	
(Decrease) in trade and other payables**	13	(10,395)		(3,342)	
Increase in other liabilities	14	4,637		762	
(Decrease)/increase in provisions	15	(1,781)		2,068	
Net cash (outflow) from operating activities			(9,635)		**(2,953)**
Cash flows from investing activities					
Purchase of property, plant and equipment	7	(7,813)		(2,214)	
Purchase of intangible assets	8	(6,939)		(1,789)	
Net cash (outflow) from investing activities			(14,753)		(4,003)
Cash flows from financing activities					

	NOTE	2021/22 £000	£000	Restated 2020/21 £000	£000
Interest received		35		6	
Interest paid		(47)		(47)	
Repayment of borrowings		(1,328)		-	
Dividend paid		(2,827)		(2,687)	
Net cash (outflow) from financing			**(4,167)**		(2,728)
Net (decrease) in cash and cash equivalents in the financial year	**12**		**(28,554)**		**(9,684)**
Cash and cash equivalents at the beginning of the financial year	12		79,601		**89,285**
Cash and cash equivalents at the end of the financial year	**12**		**51,047**		79,601

*In 2020-21 a separate line was shown for the movement in contract assets. This has been presented as part of the increase in trade and other receivables.
**In 2020-21 a separate line was shown for the movement in contract liabilities. This has been presented as part of the decrease in trade and other payables.

The notes on pages 133 to 160 form part of these accounts.

Statement of changes in taxpayers' equity for the year ended 31 March 2022

	PDC £000	General Fund £000	Reval. reserve £000	I & E reserve £000	Total £000
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
Changes in taxpayer's equity for 2021/22					
Deficit for the year	-	(11,458)	-	-	(11,458)
Other changes					
Net gain on revaluation of property, plant and equipment	-	-	6,054	-	6,054
Realised loss on inventories - biological standards	-	-	(85)	-	(85)
Dividend payable	-	(14,849)	-	-	(14,849)
Sub total	-	(14,849)	5,969	-	(8,880)
Balance at 31 March 2022	**1,329**	**62,729**	**117,602**	**954**	**182,614**

The notes on pages 133 to 160 form part of these accounts.

NOTES TO THE ACCOUNTS

1 Accounting policies

1.1 General

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 2021/22 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 2021/22.

- IFRS 16 Leases: effective date 1 April 2022. 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 for National Statistics indices.

A desktop valuation of the NIBSC estate at 31 March 2022 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, adaptations in how space was provided may 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 and Equipment

Property, Plant and 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 closely approximates 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 2022. 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 and fittings are revalued annually using Office for 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 Bulidings	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
Computers 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 in accordance with IFRS11. Any surplus or deficit generated is 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 the two parties. This agreement was subsequently updated in April 2014 to reflect changes in the governance, funding and accounting for the joint arrangement. Details of the joint arrangement are included in note 4 CPRD. During the year £487k was invested in enhancing capability of the CPRD's Interventional Research Services Platform and the electronic Research Application Portal.

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 at the beginning of 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: 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 at the point where orders are fulfilled.
- E-cigarette's 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 and is recognised as earned when the service has been provided.
- Revenue grants from DHSC for the provision of services are treated as income when received.
- NIBSC standards income is recognised when order has been 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 and included in trade and other payables in the statement of financial position.
- Capital grants receivable from government 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 comprise biological standards and laboratory consumables. Biological standards incorporate a wide range of biological reference materials and reagents, including WHO international standards, influenza reagents and Quality Control Reagents Unit (QCRU) reagents. All biological reference materials, standards and reagents are available to buy online and meet the IAS 2 definition of inventories as assets held for sale in the ordinary course of business or in the process of production for such sale.

Inventories are valued at the lower of cost and 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. Inventories have previously been classified as current. These have now been reclassified as current and non current. Where expected sales are within the next twelve months, they have been classified as current with the balance classified as non-current. Prior year comparatives in the Statement of Financial Position have been restated to reflect the reclassification between current and non-current.

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.

As noted in 1.1.2 above, IFRS 16 Leases will replace IAS 17 Leases, IFRIC 4 (Determining whether an arrangement contains a lease) and other interpretations, and is applicable in the public sector for periods beginning 1 April 2022. The standard provides a single accounting model for lessees, recognising a right of use asset and obligation in the statement of financial position for most leases: some leases are exempt through application of practical expedients explained below. For those recognised in the statement of financial position the standard also requires the remeasurement of lease liabilities in specific circumstances after the commencement of the lease term. For lessors, the distinction between operating and finance leases will remain and the accounting will be largely unchanged.

IFRS 16 changes the definition of a lease compared to IAS 17 and IFRIC 4. The Agency will apply this definition to new leases only and will grandfather its assessments made under the old standards of whether existing contracts contain a lease.

On transition to IFRS 16 on 1 April 2022, the Agency will apply the standard retrospectively without restatement and with the cumulative effect of initially applying the standard recognised in the income and expenditure reserve at that date. For existing operating leases with a remaining lease term of more than 12 months and an underlying asset value of at least £5,000, a lease liability will be recognised equal to the value of remaining lease payments discounted on transition at the Agency's incremental borrowing rate. The Agency's incremental borrowing rate will be defined by HM Treasury. For 2022, this rate is 0.95%. The related right of use asset will be measured equal to the lease liability adjusted for any prepaid or accrued lease payments. For existing peppercorn leases not classified as finance leases, a right of use asset will be measured at current value in existing use or fair value. The difference between the asset value and the calculated lease liability will be recognised in the income and expenditure reserve on transition. No adjustments will be made on 1 April 2022 for existing finance leases.

For leases commencing in 2022/23, the Agency will not recognise a right of use asset or lease liability for short term leases (less than or equal to 12 months) or for leases of low value assets (less than £5,000). Right of use assets will be subsequently measured on a basis consistent with owned assets and depreciated over the length of the lease term.

The Agency has estimated the impact of applying IFRS 16 in 2022/23 on the opening statement of financial position and the in-year impact on the statement of comprehensive income and capital additions as follows:

Estimated impact on 1 April 2022 statement of financial position	
Additional right of use assets recognised for existing operating leases	23,687
Additional lease obligations recognised for existing operating leases	(23,687)
Changes to other statement of financial position line items	-
Net impact on net assets at 1 April 2022	-
Estimated in-year impact in 2022/23	
Additional depreciation on right of use assets	2,315
Additional finance costs on lease liabilities	225
Lease rentals no longer charged to operating expenditure	(2,441)
Estimated impact on surplus/deficit in 2022/23	**99**
Estimated increase in capital additions for new leases commencing in 2022/23	**-**

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 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.

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.

1.12 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. The Agency's trading fund status was revoked on 1 April 2022. The consolidation of the Agency into DHSC group accounts will have no effect on the Agency's financial status. The legislation required to operate the Agency's services is not subject to any change and there is no expectation of change. 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

Agency 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 NIHR and the Agency.
- **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 of 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.

2021/22

	CPRD* £000	NIBSC £000	Regulator £000	Total £000
Income from external customers	6,412	26,291	86,165	118,868
Income from DHSC	338	20,519	9,100	29,957
Sub total	6,750	46,810	95,265	148,825
Other income not attributable to segments	-	-	-	12,436
Total income	6,750	46,810	95,265	161,261
Direct costs	(5,462)	(40,651)	(53,759)	(99,872)
Indirect costs	(2,764)	(14,518)	(55,553)	(72,835)
Total expenditure	(8,226)	(55,169)	(109,312)	(172,707)
Segment operating (Deficit)/Surplus	(1,476)	(8,359)	(14,047)	(11,446)

* Represents the Agency's 50% share of joint arrangement

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	39,643	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 (Deficit)/Surplus	(2,355)	(9,232)	(812)	26

3 Income

3.1 Trading income

	2021/22 £000	2020/21 £000
Licenses and inspections	30,630	32,268
Service fees	37,452	30,952
European Medicines Agency (EMA)	-	122
Devices	10,962	9,856
Clinical trials	3,757	3,574
British Pharmacopoeia	6,029	5,388
Other trading income	6,435	19,203
NIBSC	46,810	39,463
CPRD	6,750	5,720
Total	**148,825**	**146,546**

3.2 Other income

The Trading Fund received financial assistance in the form of additional funding of £12.4m (2020/21, £12.4m) from DHSC to offset the additional costs of dividend £5.7m (2020/21, £5.5m) and depreciation £6.8m (2020/21, £6.9m), resulting from the transfer of NIBSC to the Agency on 1 April 2013.

4 Clinical practice research datalink

Joint arrangement memorandum account

CPRD is an observational and interventional research service, jointly supported by DHSC and the Agency.

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

	2021/22 £000	2020/21 £000
Income	13,500	11,440
Expenditure		
Operating costs	(11,255)	(11,080)
Staff costs	(5,158)	(5,070)
Operating (deficit)	**(2,913)**	**(4,710)**

Statement of financial position

	31 March 2022 £000	31 March 2021 *£000
Non-current assets		
Tangible assets	84	140
Intangible assets	2,062	3,319
Current assets		
Trade and other receivables	4,139	3,679
Current liabilities		

	31 March 2022 £000	31 March 2021 *£000
Trade and other payables	(1,143)	(990)
Other liabilities	(3,565)	(3,802)
Assets less liabilities	1,577	2,346
Reserves		
Reserves	1,577	2,346
Total Reserves	**1,577**	**2,346**

*The figures above have been represented to correct a casting issue in the prior year comparators.

Non-current assets

	2021/22 £000	2020/21 £000
Fixed Asset		
Cost		
At 1 April	10,062	9,642
Additions	560	420
Disposals	(224)	-
At 31 March	10,398	10,062
Amortisation		
At 1 April	6,603	5,029
Charge for the year	1,653	1,574
Disposals	(4)	-
At 31 March	8,252	6,603
Net Book Value at 31 March	**2,146**	**3,459**

5 Staff costs

	2021/22 £000	2020/21 £000
Wages and salaries	68,307	69,745
Social security costs	7,172	7,067
Other pension contributions	15,705	15,873
Sub total	91,184	92,685
Less recoveries in respect of outwards secondment	(180)	(246)
Total	**91,004**	**92,439**

See the “Remuneration and Staff Report” report page 89.

6 Operating costs

	2021/22 £000	2020/21 £000
Computing	21,406	23,228
Accommodation	9,501	8,951
Medicines testing and Laboratory expenses	10,546	9,487
Depreciation and amortisation	11,423	10,338
Travel and subsistence	351	72
Other operating costs	28,476	14,430
Total	**81,703**	**66,506**

Other operating costs include:	2021/22 £000	2020/21 £000
Contracted out services	21,453	12,767
Operating leases	2,673	2,463
VAT partial exemption refund	(1,567)	(1,013)
Statutory audit fees	130	105

7 Property, Plant and Equipment

2021/22	AUC £000	Land and Buildings £000	Computer and telecom equipment £000	Plant and equipment £000	Fittings, furniture and office equipment £000	Total £000
Cost or valuation						
At 1 April 2021	755	117,695	8,562	27,026	106	154,144
Additions	8,047	-	-	(234)	-	7,813
Transfers	(7,212)	1,146	911	5,132	23	-
Reclassification	(50)	-	-	-	-	(50)
Impairment	(26)					(26)
Revaluation	-	481	-	473	-	954
Disposals	-	-	-	(553)	-	(553)
At 31 March 2022	**1,514**	**119,322**	**9,473**	**31,844**	**129**	**162,282**
Accumulated Depreciation						
At 1 April 2021	**-**	**-**	**6,943**	**18,634**	**103**	**25,680**
Charge for the year	-	5,347	693	1,516	1	7,557
Revaluation	-	-	-	247	-	247

2021/22	AUC £000	Land and Buildings £000	Computer and telecom equipment £000	Plant and equipment £000	Fittings, furniture and office equipment £000	Total £000
Elimination of accumulated depreciation	-	(5,347)	-	-	-	(5,347)
Disposals	-	-	-	(481)	-	(481)
At 31 March 2022	**-**	**-**	**7,636**	**19,916**	**104**	**27,656**
Net book value at 31 March 2022	**1,514**	**119,322**	**1,837**	**11,928**	**25**	**134,626**
Net book value at 31 March 2021	755	117,695	1,619	8,392	3	128,464
Owned	**1,514**	**119,322**	**1,837**	**11,928**	**25**	**134,626**

Land and buildings

A professional desktop valuation of land and buildings was carried out on 31 March 2022 which resulted in a net increase of £481k. 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.

2020/21	AUC £000	Land and Buildings £000	Computer and telecom equipment £000	Plant and equipment £000	Fittings, furniture and office equipment £000	Total £000
Cost or valuation						
At 1 April 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 accumulated 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

8 Intangible assets

2021/22	Computer systems £000	AUC £000	Software licences £000	Total £000
Cost or valuation				
At 1 April 2021	33,591	456	3,323	37,370
Additions	(36)	6,975	-	6,939
Transfers	3,675	(3,797)	122	-
Reclassification		50		50
Disposals	(112)	-	-	(112)
At 31 March 2022	37,118	3,684	3,445	44,247
Amortisation				
At 1 April 2021	20,667	-	3,314	23,981
Charge for the year	3,864	-	2	3,866
Disposal	(2)	-	-	(2)
Amortisation at 31 March 2022	24,529	-	3,316	27,845
Net book value at 31 March 2022	**12,589**	**3,684**	**129**	**16,402**
Net book value at 31 March 2021	12,924	456	9	13,389
Owned	**12,589**	**3,684**	**129**	**16,402**

2020/21	Computer systems £000	AUC £000	Software licences £000	Total £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**

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	**2021/22 £000**	**2021/22 £000**	**2020/21 £000**	**2020/21 £000**
Minimum lease payments	24	2,441	24	2,439
Total	**24**	**2,441**	**24**	**2,439**
Total future minimum lease payments	**2021/22 £000**	**2021/22 £000**	**2020/21 £000**	**2020/21 £000**
Payable:				
Within one year	16	2,441	24	2,439
Between two to five years	-	9,764	13	9,757
Over five years	-	12,767	-	22,516
Total	**16**	**24,972**	**37**	**34,712**

10 Inventories

	31 March 2022 £000	Restated* 31 March 2021 £000
Current		
Biological Standards	522	355
Laboratory consumables and other stores	139	139
Total current	**661**	**494**
Non-current		
Biological Standards	9,473	9,069
Total	**10,134**	**9,563**

*Reclassified into current and non-current

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 2021/22 was £85k (2020/21, £188k).

11 Trade and other receivables

	31 March 2022 £000	31 March 2021 £000
Amounts falling due within one year		
Due from the Department of Health and Social Care	12,436	20,854
Trade receivables**	12,956	9,091
Contract assets	7,056	6,948
Other receivables	2,099	601
Accrued income	8,583	3,683
Prepayments	3,398	2,765
Total	**46,528**	**43,942**
Amounts falling due after more than one year:		
Prepayments	6,330	7,291
Total	**52,858**	**51,233**

*In 2020-21 contract assets were shown in a separate note. For 2021-22 they have been shown as part of trade and other receivables.
**Trade receivables are shown net of a provision for bad debts of £2,373k (2020/21, £33k) and credit notes for all unpaid periodic fees at year end of £1,020k (2020/21, £447k). A provision for bad debts was made after the Order to Cash internal audit report highlighted issues with aged debts over twelve months.

12 Cash and cash equivalents

	31 March 2022 £000	Restated 31 March 2021 £000
Balance at 1 April	79,601	89,285
Net change in year	(28,554)	(9,684)
Balance at 31 March	51,047	79,601
Made up of		
Government Banking Service	51,047	79,601
Cash and cash equivalents	51,047	79,601

13 Trade and other payables

	31 March 2022 £000	31 March 2021 £000
Amounts falling due within one year		
Due to Department of Health and Social Care	14,936	15,300
Payments received on account	5,396	6,081
Taxation and social security	3,213	3,568
Contract liabilities	1,386	2,036
Other trade payables	6,238	2,680
Other payables	3	379
Accruals	15,184	14,685
Total	**46,356**	**44,729**

*In 2020-21 contract liabilities were shown as a standalone note to the accounts. In 2021-22 they have been presented as part of trade and other payables.

14 Other liabilities

	Current		Non-current	
	31 March 2022 £000	31 March 2021 £000	31 March 2022 £000	31 March 2021 £000
Deferred revenue:				
Other fees	3,051	2,787	30	28
Contract liabilities	12,322	10,725	7,863	4,574
Others:				
DHSC Contribution to CPRD joint arrangement	10,833	11,348	-	-
Total	26,206	24,860	7,893	4,602

15 Provisions

	Current		Non-current	
	31 March 2022 £000	31 March 2021 £000	31 March 2022 £000	31 March 2021 £000
Other provisions	-	1,781	-	-
Dilapidations	-	-	1,998	1,998
Total	-	1,781	1,998	1,998

Movement in provisions

	Total £000
At 1 April 2021	3,779
Arising during the year	-
Used during the year	(1,387)
Released	(394)
At 31 March 2022	1,998
Expected timing of cash flows:	
Within one year	-
Between two to five years	-
Over five years	1,998
Total	**1,998**

16 Capital and other financial commitments

Contracts entered into, not provided for in the accounts

	Intangible 31 March 2022 £000	Tangible 31 March 2022 £000	Intangible 31 March 2021 £000	Tangible 31 March 2021 £000
Contracted	381	705	56	567
Total	381	705	56	567

17 Related party transactions

The Agency is a Government Trading Fund and an Executive Agency of DHSC. DHSC is regarded as a related party. During the year, the Agency has had a significant number of material transactions with DHSC and with other entities for which DHSC 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 2021/22, 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.

18 Events after the reporting period

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

The Agency's trading fund status is to be revoked with effect from 1 April 2022. The Agency will remain an executive Agency of DHSC and will be consolidated into DHSC group reporting from 2022-23. The main changes for the Agency's accounts from 2022/23 will be:

- Dividends will no longer be payable to DHSC following the repayment of the Agency's public dividend capital on 1 April 2022
- Departmental funding will be credited to the general fund in the SoCTE instead of being recognised as income in the SoCI to match related expenditure

Other than the above, there have been no significant events between the Statement of Financial Position and the date of authorising these financial statements.

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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