Medicines & Healthcare products
Regulatory Agency

MHRA Annual Report and Accounts

2022-2023

Medicines and Healthcare products Regulatory Agency

Annual Report and Accounts 2022 / 2023

For the period from 1 April 2022 to 31 March 2023

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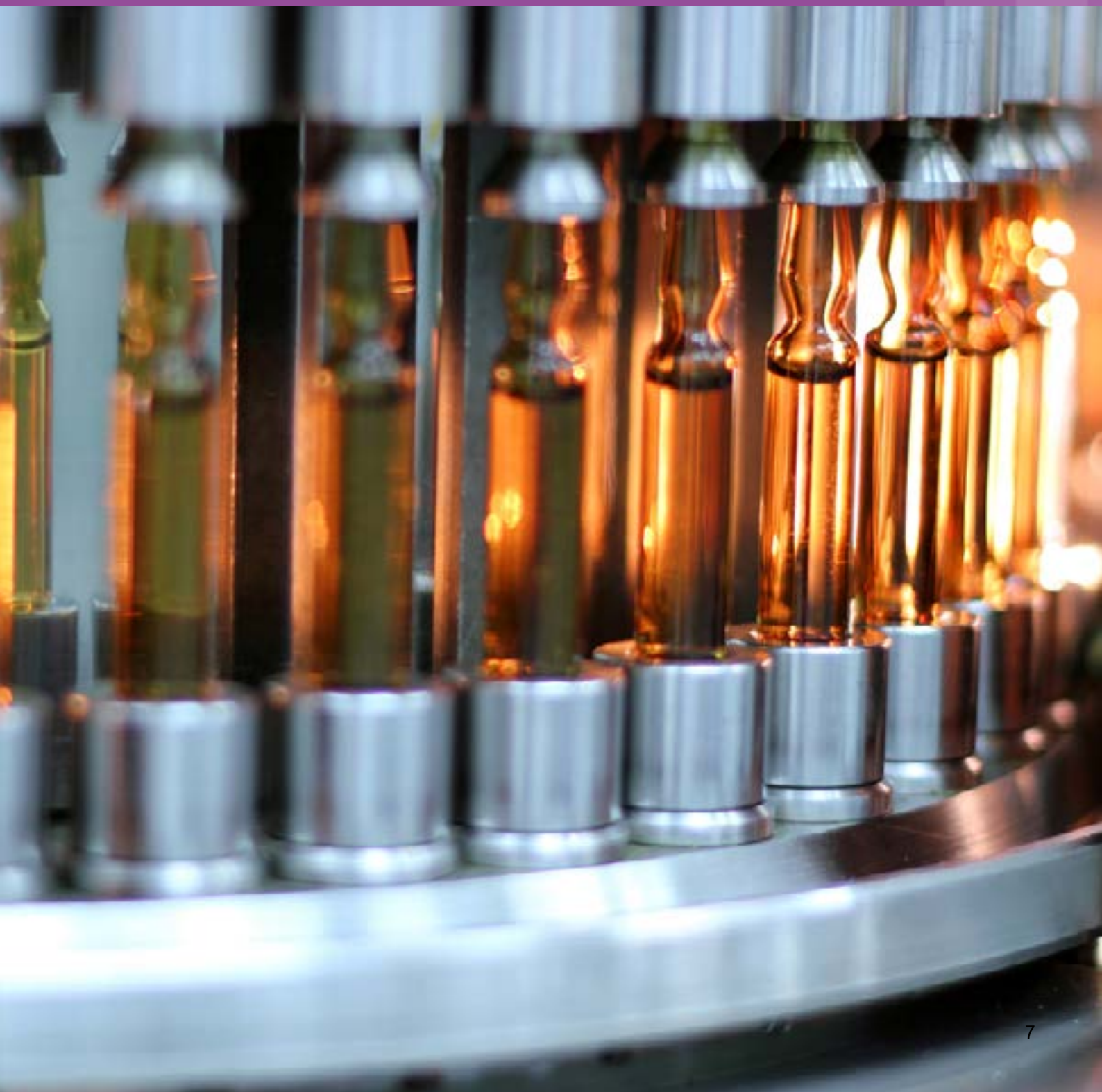
1.1 Performance overview

This section describes the role of the Medicines and Healthcare products Regulatory Agency (MHRA), explains our purpose, strategic objectives and goals and provides a summary of our performance in 2022/23.



Chair's foreword

This is my final foreword to the MHRA Annual Report as I will be stepping down as Chair of the MHRA in July 2023. It has been my privilege to Chair the MHRA for the last three years and work with talented people in the agency who are committed to their role in public health, whether enabling innovation, accelerating patient access to new treatments, maintaining the safety of medical products or working to deliver the agency's supporting functions.

The past few years have involved a period of extreme change for the MHRA. They included a time for reflection as we listened and responded to the outcomes of the of the Independent Medicines and Medical Devices Safety Review (Cumberlege Review). A time to embrace change, as we navigated the UK's exit from the EU and embarked on the largest and most dynamic transformation programme in the MHRA history, restructuring the agency around the product life cycle to best align our service offering to the development of new medical technologies. A time for action, as we embraced agile approaches to regulation to protect UK patients and the public through the COVID-19 pandemic and the vaccination programme, which has enabled us to learn to live with the virus and return to some degree of normality.

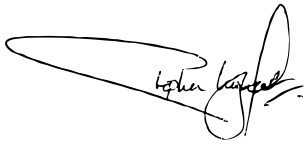
While I will be sorry to leave the MHRA after eight years in total as a member of the Board, it feels like the right time for me to step down. Our new organisational structure has been populated, our financial budgets have been balanced, our new approach to governance that the Board has been instrumental in developing is working and the benefits from our new 'One Agency' approach are starting to be realised.

As the MHRA emerges from this period of great change, a new Chair will bring a fresh perspective as the MHRA embarks on the next chapter of its evolution.

> **The agency's strength remains its unwavering commitment to protecting public and patient health.**

There is much still to do. Changes of the magnitude described above take time. We know that we need to deliver predictable performance across all our many services, and we are committed to bringing our performance back in line with statutory timelines. We then need to go further and work with patients, partners and developers to maximise the benefits of risk-proportionate regulation.

I am confident that the MHRA will continue to bring the required agility and alertness to anticipate and meet the demands of an ever-changing regulatory landscape. It is a substantial task. The agency's strength remains its unwavering commitment to protecting public and patient health, while seeking opportunities to lead, develop and collaborate with national and international partners to leverage innovation for the benefit of patients and the public. We are very fortunate and privileged in having an agency that is staffed by highly capable individuals who have the expertise to deliver their specialist roles. I am grateful to all my colleagues at the MHRA for supporting me and contributing to our shared mission.



Stephen Lightfoot
Chair

Chief Executive's perspective on the year

It has been my privilege to lead for a fourth year an agency whose work touches lives right across the UK and beyond, as the world continues to emerge from the most challenging public health emergency of modern times. As CEO, I am proud to lead an organisation that continues to evolve and expand its range of responsibilities while delivering effective regulation and applying scientific knowledge to improve health outcomes.

My perspective as CEO on the year is one of strong, steady progress, as seen by the accomplishment of the majority of the objectives in the agency Delivery Plan 2021-23. Before reflecting on our achievements, I wish to start by recording my profound thanks to every member of our staff. It is absolutely clear that we can only succeed in our mission to protect patients and the public by virtue of the dedication and hard work of all our teams.

This year has been a landmark in our evolution as an agency, with the move to our new 'One Agency' organisation. The launch event, 'One Agency Live', brought together experts from various sectors to discuss the expectations and opportunities for our agency. A new leadership team has been established and we are now well-positioned to benefit from our integrated operating model and related cultural change. We have made substantial progress in addressing legacy IT systems and establishing a sustainable operating model, with new fees approved by Parliament, a major step to enhance financial stability and strategic financial planning.

During this year of agency organisational evolution, we have not taken our eye off the ball. We have maintained as a top priority our strategy to facilitate patient access to innovative healthcare products, in full alignment with the Life Sciences Vision. A new pathway for access to innovative medical technology has been devised and is moving to the pilot stage, building on the learnings of the Innovative Licensing and Access Pathway for medicines. New products which blur definitional boundaries are being presented, and technologies which support personalised treatments such as cancer vaccines challenge the traditional regulatory approaches.

> **We have maintained as a top priority our strategy to facilitate patient access to innovative healthcare products.**

We have also driven forward a far-reaching programme of regulatory reform, such as overhauling clinical trials legislation with new provisions for point-of-care manufacturing and major revision of medical devices legislation to accommodate technological advancements. Public consultations have shown strong support for these flexible regulatory frameworks. Furthermore, we have enshrined the Early Access to Medicines Scheme in legislation to ensure timely and safe access to later-stage innovative medicines.

Our commitment to patient involvement has gained real momentum. The patient voice has been incorporated throughout the product lifecycle, from study designs to benefit-risk assessments and post-authorisation safety issues. Our Patient Engagement team works closely with scientific teams to involve patients systematically, enabling us to critically assess the impact of this new approach.

Maintaining patient safety has remained a constant priority, with the recommendations of the Independent Medicines and Medical Devices Safety Review (Cumberlege review) constantly front of mind. The launch of the SafetyConnect programme has improved our surveillance capabilities by allowing better interaction with Yellow Card reporters, enhancing our ability to respond promptly to emerging signals.

Our new Partnership Group has fostered meaningful and productive relationships with organisations in the healthcare and regulatory sectors, both domestically and internationally. Collaborations have yielded tangible outcomes, such as the Yellow Card biobank launched in partnership with Genomics England, which holds promise for identifying genetic factors contributing to adverse reactions.

On the international stage, our Chairmanship of the Access Consortium has enabled us to promote innovation and expedite approvals across a population of 150 million people.

> **The patient voice has been incorporated throughout the product lifecycle, from study designs to benefit-risk assessments and post-authorisation safety issues.**

Full membership in the International Medical Device Regulators Forum and the International Conference on Harmonisation, allows us to contribute to global work on medical devices and influence the development of guidelines to the benefit of UK patients.

It would be remiss not to acknowledge that this has come with challenges. We have seen a high level of turnover in staff during 2022/23. Whilst this has now returned to normal levels, it had an impact on our ability to ensure predictable levels of operational performance. Our work to address legacy systems and processes to embed best practice continues. With our new structures, processes and technology being implemented, we continue to challenge, critique and evolve our culture to meet our vision of becoming a world-leading, proactive and enabling regulator. All of this and more is captured in our new Corporate Plan 2023-2026.

I conclude by reflecting on the success of our new product lifecycle operating model exemplified by our response to COVID-19. Scientists and assessors working together approved both additional vaccines, boosters and therapeutics for new variants, use in new age groups and for those more vulnerable to the virus due to their limited immune response. These regulatory decisions, weighing the balance of risk and benefit, were informed by expertise from the independent Commission on Human Medicines. In support of our commitment to transparency on the decisions we make, we introduced new, interactive adverse reaction reporting presentations for COVID-19 vaccines, making safety data more transparent and accessible than ever before.

This in a nutshell is ‘One Agency’ in action, delivering for patients and the public. The commitment of the agency, and every member of staff, to supporting and protecting patient and public health remains as steadfast as ever.

My heartfelt thanks to you all.

Dr June M Raine DBE

> **The commitment of the agency to supporting and protecting patient and public health remains as steadfast as ever.**

About the MHRA

We are the UK regulatory body responsible for overseeing medical products, medicines, medical devices and blood components for transfusion. As an Executive Agency operating under the Department of Health and Social Care (DHSC), we are held accountable for our performance by the DHSC.

Our primary goal is to ensure the safety and effectiveness of medical products within the UK. In partnership with the DHSC, we work diligently to fulfil our obligations to patients, public, ministers and Parliament.

If you are interested in learning more about our relationship with the DHSC you can find detailed information in our Framework Agreement available on the Gov.uk website: https://www.gov.uk/government/publications/dh-and-mhra-framework-agreement. This agreement is currently being refreshed and a new agreement will be published shortly.

At our core, we are committed to upholding the highest of standards in regulating medical products. In doing so, we aim to safeguard patient well-being and maintain public trust in the healthcare sector.

Our vision

To be a truly world-leading, enabling sovereign regulator that protects public health through achieving excellence in regulation and science, and delivering the right outcomes for patients.

Our mission

To deliver the MHRA's commitment to protect and improve public and patient health.

Our values

Our values are the foundation of our organisational culture.

We focus on **patients** and **public health**

We **work together** with **respect**

We take **responsibility** and are **accountable**

We create an environment where **learning** and **innovation** thrive

Our structure

During 2022/23 we completed our agency restructure to bring together our regulatory work, our research and standards function and our clinical data service from three centres into 'One Agency'.

Our new organisational structure reflects the core functions within the regulatory lifecycle of medicines and medical devices and the services needed to support those.

We have seven operating groups including three core functions supported by corporate and platform services.

Core functions:
- Science, Research and Innovation (SR&I)
- Healthcare Quality and Access (HQ&A)
- Safety and Surveillance (S&S)

Corporate and platform services:
- Partnerships
- Digital and Technology
- Corporate (People, Finance, Commercial, Infrastructure & Laboratory Services)
- Enablement (Communications & Engagement, Governance, Strategic Delivery)

Last year, our workforce consisted of 1,285 staff working from our suite of offices in Canary Wharf, London and our specialised laboratory site in South Mimms, Hertfordshire. A small number of desks are also provided in a shared office facility in York for our inspectors. We also have a contract with LGC Group in Teddington, who host and operate the UK's Official Medicines Control Laboratory (OMCL) for chemical testing and British Pharmacopoeia Commission Laboratory on behalf of the MHRA.

Our role

We protect the safety of patients and the public by regulating medicines, medical devices and blood components for transfusion in the UK. We rigorously use science and data to inform our decisions, enable medical innovation and to make sure that medicines and healthcare products available in the UK are safe and effective.

Our responsibilities are to:
- Ensure medicines, medical devices and blood components for transfusion meet applicable standards of safety, quality and effectiveness
- Ensure secure safe supply chains for medicines, medical devices and blood components
- Promote international standardisation and harmonisation to ensure the effectiveness and safety of medical products
- Educate the public and healthcare professionals about the risks and benefits of medicines, medical devices and blood components, leading to safer, more effective use
- Enable innovation and research and development which is beneficial to public health
- Collaborate with partners in the UK and internationally to support our mission to enable the earliest access to safe medicines and medical devices to protect public health

We are responsible for carrying out the functions of the Secretary of State for Health and Social Care as prescribed by UK legislation. These functions relate to the regulation of:

- Medicines and vaccines
- Medical devices
- Blood components
- E-cigarettes
- Traditional herbal and homeopathic remedies

For more detailed information about our statutory responsibilities, please visit our website: https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/about

We have a wealth of specialist expertise and scientific resource within the agency, which adds significant value to our regulatory role.

British Pharmacopoeia

Since its inception in 1864, the British Pharmacopoeia (BP) has been instrumental in safeguarding the well-being of patients. The MHRA is responsible for managing the BP, which is the official guide for medicines in the United Kingdom. The BP plays a vital role in protecting public health by providing a collection of quality standards for pharmaceutical substances and medicinal products. These standards are used by researchers, manufacturers, and testers in the pharmaceutical industry to ensure the safety and effectiveness of medicines.

Clinical Practice Research Datalink

The Clinical Practice Research Datalink (CPRD) is a real-world data research service which supports public health research and clinical studies. CPRD makes available anonymised patient data collected from a network of GP practices across the UK, links the data to a range of other health-related data to provide a UK population health dataset for research into drug safety, health policy and disease risk factors. For more than thirty years, research using CPRD data has informed clinical guidance and best practice. CPRD is supported by the National Institute for Health and Care Research (NIHR).

UK Stem Cell Bank

The UK Stem Cell Bank, established in 2003, is housed within the MHRA. Its purpose is to facilitate the use and sharing of high-quality stem cell lines to support scientific research and clinical development of stem cell therapies. The UK Stem Cell Bank acts as a repository for human embryonic stem cells and holds the world's largest collection of clinical grade material. Our scientists conduct research into cell banking and the characterisation of stem cells, with the aim of improving standards, quality and safety. We offer guidance and advice to the UK stem cell community across healthcare, pharma and academia.

The UK Stem Cell Bank has received support from the Medical Research Council (MRC) and is currently supported by the National Institute for Health and Care Research (NIHR). We have recently taken responsibility for the secretariat function of the independent national steering committee for use of stem cells, which oversees the use of human embryonic stem cell lines in the UK and ensures that research is conducted within a transparent ethical framework.

Official Medicines Control Laboratory

The MHRA laboratories in South Mimms serve as the United Kingdom's Official Medicines Control Laboratory (OMCL) for biological medicines, performing independent laboratory testing and certification of batches of licensed blood products, vaccines and other biotherapeutics. The main role of the UK OMCL is to control the quality of these medicines and ensure that every batch that is manufactured meets the relevant requirements for safety and efficacy before it is allowed to enter the UK market.

Influenza Resource Centre and WHO Essential Regulatory Laboratory

The Influenza Resource Centre (IRC) plays a vital role in the standardisation and control of influenza vaccines. The influenza virus changes and adapts continuously and the vaccine produced each year must match the circulating strains. To determine which virus strain should be included in the annual vaccine, the World Health Organisation (WHO) convenes biannual meetings to review influenza activity and make informed decisions.

Through the IRC, we play a central role in supporting the selection of WHO-recommended viruses for influenza vaccine use. We also contribute to the development of candidate vaccines and provide high-quality influenza virus strains and reagents for vaccine production and influenza research. As one of the four global WHO Essential Regulatory Laboratories, we carry the responsibility of supporting the global influenza vaccine program.

Quality management

We value quality and work under a number of quality standards:

We are:

- Certified to ISO 9001:2015. This standard provides the framework for our Quality Management System and covers our regulatory work, post-market surveillance, the design, manufacture and supply of standards, reference materials and research reagents
- Certified to ISO 13485:2016 for the design and manufacture of our liquid and freeze-dried biological materials regarding in vitro Diagnostic Devices (IVDs)
- Accredited to ISO 17025:2017 for defined testing activities related to batch release of biological medicines under UK law

We also:

- Hold two Human Tissue Authority (HTA) licences for the storage and use of human tissue for research purposes and a Human Application Licence held by UK Stem Cell Bank (UKSCB) for the storage, procurement, processing, testing and distribution of human tissue
- Have a documented Quality Management System (QMS) compliant to the requirements of Good Clinical Practice (GCP) for testing clinical trial patient samples
- Have a quality management system for ISO 17034:2016 to produce Certified Reference Materials (CRMs) which is in the process of being formalised
- Have an internal quality management system for the management of Standardisation projects - the Reference Materials Quality Manual (RMQM)

How we are funded

As an Executive Agency of DHSC the MHRA's finances are consolidated within the DHSC accounting boundary. Further details about our funding can be found in the 'Financial review' section on page 50.

Last year most of the MHRA's running costs were funded by statutory fees paid by industry for regulatory services or charges for non-statutory goods and services. DHSC provided the MHRA with £50.7m grant-in-aid. Of this £8.1m was for the core delivery of devices regulation, £12.5m for our scientific work and £7m to support our transformation. DHSC also provided us with £17.5m of capital funding.

Our goals and deliverables

Our strategy was set out in our two-year Delivery Plan 2021-2023, 'Putting patients first - A new era for our agency'. This was published in July 2021 and covered the period to 31 March 2023. Our Delivery Plan set out an ambitious roadmap to ensure we put patients first, become a truly world leading regulator and that we continue to protect public health through excellence in regulation and science.

The Delivery Plan set out the following priorities:

- Patient and Public Involvement
- Scientific Innovation
- Healthcare Access
- Patient Safety
- Dynamic Organisation
- Collaborative Partnerships
- Financial Sustainability

We refreshed the plan in 2022/23 and included focus on the following areas of activity:

- Patient and Public Involvement
- Equity in Healthcare
- Embedding Innovative Ways of Working

Performance summary at a glance

We have reached the conclusion of the second and final year of our ambitious and transformative Delivery Plan. A substantial amount has been achieved, both in fulfilling the goals as outlined in our Delivery Plan and addressing additional priority work which emerged during the year. These successes were achieved while upholding our essential core activities arising from our crucial public health role to protect the safety of patients and the public through regulation and our statutory responsibilities.

We have much to celebrate. In 2022/23 we have:

- Achieved a positive shift in how we engage and involve patients, delivering our commitment to putting patients first
- Worked closely with partners to ensure the supply of vital medicinal products
- Delivered new access pathways
- Made progress on legislative reform, including taking steps to promote equality in healthcare through our legislative change work
- Continued to deliver cutting-edge science to accelerate the development of new products for patients and demonstrate our worldwide influence.
- Strengthened our ability to manage safety issues by modernising our systems and ensuring greater involvement of patients
- Deepened our position as a sovereign regulator, developing our national and international partnerships to drive our priorities for the UK, yielding new products and access routes and furthering our ability to protect public health
- Taken important steps to improve our leadership capability, governance functions, culture and systems
- Put the MHRA on a financially sustainable footing since we transitioned from being a trading fund to operating within the annual accounting boundary of the Department of Health and Social Care on 1 April 2022

This year, we have achieved many successes. However, we must also recognise that we have faced challenges. One of the main challenges has been maintaining the timelines for our core operational performance in the face of significant vacancies and during a period of extensive redevelopment of our services and systems. We have been working hard to address the wait times for some of our services, by prioritising vacancy filling and streamlining training, increasing resource in key areas, simplifying our processes and through ruthless prioritisation. We are also increasing our communications with stakeholders to ensure visibility of the timelines and progress being made to reduce these.

Further details of our achievements and an analysis of our performance can be found in the ‘performance analysis’ section (page 23).

Some highlights of our year:

‘One Agency Live’

At the start of the year, we launched our new organisational structure with a staff engagement event, ‘One Agency Live’. This event was an exciting opportunity for colleagues to meet each other face to face, with some new teams meeting in person for the first time, and to hear leading thinkers in the healthcare family reflecting on the important role we play in protecting public health in the UK and internationally.

The opportunity to engage with patient representatives really brought the event to life and many staff reflected that it helped them to better understand the impact of our work at the patient level.

Four inspiring themes emerged from the event:

- Patient involvement
- Innovation
- Diversity and equality
- Partnerships

We have continued to build on the positive momentum generated by the event through the year, with the refresh of our delivery plan and through team development activities.

Accelerating patient access to new medicines

Authorisation of new medicines is an essential part of our role as the UK licensing authority. We assess the safety, manufacturing quality and efficacy before deciding if the medicine can be sold in the UK.

When a company produces a totally new medicine, this will be supported by a patent, giving them the exclusive right to make and sell the medicine for a period of time. Once the patent expires other companies can start to manufacture and sell their own versions of the medicine (a medicine with the same active pharmaceutical ingredients or which is clinically similar). These are called generic medicines. Generic medicines typically reduce the cost of treatments and the NHS relies on these to help control costs.

During 2022/23 we:

- Approved **729** new generic medicines to go on to the market in the UK
- Approved over **100,000** notifications to enable patients to access essential drugs not otherwise available in the UK
- Inspected over **700** factories, labs and trial sites to keep patients safe

We have also been instrumental in mitigating the impact of drug shortages, e.g. antibiotics for treatment of Strep A infection during the winter outbreak.
We are committed to reducing the time it takes for new medicinal products to safely reach patients. We are working in partnership with other healthcare bodies to achieve this aim:

Innovative Licensing and Access Pathway

The Innovative Licensing and Access Pathway (ILAP) aims to accelerate the approval process for new medicines and repurposed medicines for life threatening or seriously debilitating conditions, so that patients can access them faster. This is achieved in partnership with other health bodies, supporting the manufacturer through the licensing process, while still ensuring these are safe and fit for purpose.

Our partners in ILAP are All Wales Therapeutic and Toxicology Centre (AWTCC), the National Institute for Clinical Excellence (NICE), and the Scottish Medicines Consortium (SMC).

Medicines on the ILAP pathway, which fulfil the criteria, are awarded an Innovation Passport designation initially. They can then progress to a Target Development Profile, if they are intending to progress to market, which sets out a regulatory roadmap for delivery to patients.

To date we have received **178** applications from a range of pharmaceutical companies and awarded **129** Innovation Passports, including one for a ground-breaking immunotherapy for the treatment of Alzheimer's disease. **40** products have progressed to a TDP with **26** TDP regulatory roadmaps issued.

Project Orbis

Project Orbis is a collaborative programme, led by the US Food and Drug Administration (FDA), which reviews and approves promising cancer drugs, enabling patients to access these treatments more rapidly. MHRA is a partner in Project Orbis alongside regulatory authorities from Australia, Canada, Singapore, Switzerland, and Brazil.

In **2022/23**, through Project Orbis, the MHRA approved four new medicines and new uses for three existing cancer medicines, including nivolumab (Opdivo) for use in non-small cell lung cancer in adults, darolutamide (Nubeqa) for the treatment of certain prostate cancers and durvalumab (Imfinzi) for the treatment of metastatic biliary tract cancer.

Medicines intended for use in Great Britain must meet the qualifying criteria for ILAP in order to be considered for Project Orbis.

Early Access to Medicines Scheme

The Early Access to Medicines Scheme (EAMS) aims to provide patients with life threatening or seriously debilitating conditions early access to medicines, where there is a clear evidenced need to do so. We assess the benefit-risk balance of these medicines based

on a comprehensive evaluation of the data and issue a scientific opinion. This opinion outlines the risks and benefits of the medicine, empowering prescribers and patients to make informed decisions on the use of the medicine prior to official licensing.

In **2022/23** we have established the EAMS in law under the Medicines and Medical Devices Act, improving the safe supply of innovative medicines to patients in the UK.

Under the scheme we have provided 47 scientific opinions from a total of 65 applications received, with four scientific opinions refused, 12 withdrawn and two in progress.

Ensuring the safety of patients and the public

We protect public health through robust vigilance processes, which quickly detect, monitor and evaluate safety signals for medicines, medical devices, electronic cigarettes, blood / blood components, clinical trials and defective or counterfeit products. These processes enable us to develop effective risk mitigations and support the healthcare system in implementing them.

SafetyConnect

The implementation of improved IT systems for vigilance through our SafetyConnect programme is one of our highest priorities. Delivery of this programme will enable us to have a more responsive safety surveillance system and support us to act quickly on concerns.

The SafetyConnect programme will:

- Transform how we manage safety monitoring
- Improve our ability to interact with patients and follow up reports of adverse events
- Enable new approaches to gathering and analysing data
- Deliver a common vigilance platform for collection and assessment of adverse incidents for medicines and medical devices

In 2022/23 we have implemented phase one of the SafetyConnect programme which has included:

- Launch of the HALO case management system for devices, which facilitates greater automation and use of Artificial Intelligence to assist with case processing
- Launch of the new Manufacturers Online Reporting Environment (MORE) reporting platform for device manufacturers and their representatives
- Integration of the Yellow Card reporting system with the HALO and MORE systems

Yellow Card scheme

The Yellow Card scheme encourages both the public and healthcare professionals to report suspected side effects and adverse incidents associated with medicines, vaccines, e-cigarettes, medical devices, and counterfeit products. Reporting concerns can be done online through the dedicated website, using the Yellow Card application available on Android and Apple devices, directly through primary care systems, some secondary care systems, or by telephone. Patient information leaflets and instructions accompanying medications and medical devices routinely provide details on the Yellow Card scheme and how to report concerns.

The MHRA collates and investigates reports of side effects and adverse incidents reported via the Yellow Card scheme. Investigations are carried out in a risk-proportionate way and MHRA acts where we need to protect public health.

In 2022/23 we made several enhancements to the Yellow Card scheme platform, including:

- The ability for MHRA to ask tailored questions to the reporter based on the information provided, allowing us to gather additional information at the point of reporting
- Introducing the ability for reporters to update the information they have submitted for medicine and vaccines, to enable them to provide additional information as time progresses
- Functionality to enable the MHRA to schedule long term follow up for registered users where relevant to the report they initially submit
- The ability to allow users to upload attachments for medicines and vaccine reports (devices reporting forms already have this capability)
- Improvements in data collection for device incidents and updates to device incident reporting form wording and structure

In 2022/23 we have:

- Promoted the use of the Yellow Card scheme through social media and activities during international Med Safety Week
- Translated our web pages on how to engage with the Yellow Card scheme into a range of the most commonly spoken languages in the UK to improve inclusion and accessibility

Criminal Enforcement Unit

The MHRA protects the public from criminal threats through the work of its dedicated Criminal Enforcement Unit (CEU). The CEU leads, supports and coordinates a range of interventions to address the illegal global trade in medicines and medical devices. In addition to compromising the safety and efficacy of the products patients need, this criminality can also erode confidence in regulation and bring about financial detriment to individuals and the economy. The CEU works hard to protect the UK from these harms by preventing offending where it can, disrupting offending where it cannot, and bringing offenders to justice where it should.

In 2022/23, CEU criminal threat reduction activity resulted in:

- The removal of 8000 illegally trading web pages
- The removal of nearly 7 million doses of illegally traded medicines from circulation
- Successful prosecutions leading to custodial sentences of 216 months
- The denial of £850,000 in criminal profits

Regulatory reform

During 2022/23, we made significant progress in a program of legislative reform aimed at making the UK an attractive place to develop and deploy medical products.

This has included the following achievements:

- Achieving the Life Sciences Council agreement to refocus the delivery of the future UK health tech regulatory framework, to ensure we take full advantage of the opportunities of being outside the EU and respond to the rapid evolution of the sector since we consulted in 2021. We are now progressing the delivery of Statutory Instruments (SIs) guidance and best practice advice to form the new framework
- Publishing our roadmap to reform the legislation for Software and AI as a Medical Device and pushing forward the delivery, including ensuring we take account of wider moves to regulate AI both in the UK and internationally
- Completing our Compliance Strategy, which will enable innovation and access in the regulated supply chain via more risk-proportionate compliance approaches
- Publishing the responses to two significant consultations, on the reform of the clinical trials regulations and the regulation of manufacturing at the point of care

Clinical trials legislation

A public consultation was conducted to guide the reform of UK clinical trials legislation, with proposals aimed at encouraging representation of underserved populations and increasing diversity in clinical research. In March 2023, the government published its response to the public consultation, representing the most significant overhaul of clinical trials legislation in over two decades. These reforms position the UK as a leading country for conducting clinical research. We have published our plans to enhance and strengthen the UK legislation in preparation for laying the Statutory Instrument.

The key outcomes of the clinical trial legislation overhaul include:

- Enabling more proportionate, streamlined, and flexible clinical trial processes without compromising safety
- Establishing a regulatory framework that accommodates different types of trials and innovative designs
- Increasing transparency by requiring trial registration in the World Health Organisation public register, publication of result summaries, and sharing trial findings with participants

Public access: Freedom of Information requests, enquiries and complaints

From 1 April 2022 to 31 March 2023 there were 975 statutory access requests received by the MHRA. The majority of these were handled under the Freedom of Information Act; and others being handled under General Data Protection Regulation (GDPR).

In the same period the MHRA Customer Experience Centre received 6,663 enquiries from the public. We are committed to providing a high-quality service to everyone we interact with. Where complaints arise, we want to resolve them promptly and constructively. During the financial year we received 486 complaints, with a third of these received from members of the public.

Parliamentary questions

During the 2022/23 financial year, the MHRA responded directly to 61 parliamentary questions and contributed to other questions answered by the Department of Health and Social Care. There was a significant range in topics covered, and themes included patient safety, COVID-19 vaccines and MHRA regulatory processes.

Forward look 2023/24

Following completion of our Delivery Plan, we will shortly be publishing our Corporate Plan (MHRA Corporate Plan 2023-26) which sets out our strategic priorities and ambitions for the next three years.

The Corporate Plan outlines the actions we will take each year under four new strategic priorities and will be supported by annual business plans:

1 Maintain public trust through transparency and proactive communication

2 Enable healthcare access to safe and effective medical products

3 Deliver scientific and regulatory excellence through strategic partnerships

4 Become an agency where people flourish alongside a responsive customer service culture

1.2 Performance analysis

This section considers in more depth the MHRA's performance against our key priorities, as set out in the 2022/23 Delivery Plan, including highlights of our achievements and detailed metrics against key targets.

Progress against our Delivery Plan objectives

Our delivery plan has been our roadmap for change, underpinning our commitment to putting patients first, supporting our ambition to become a truly world leading, enabling sovereign regulator and ensuring that we continue to protect public health through excellence in regulation and science.

Significant progress has been made this year in engaging and involving patients. We have collaborated closely with our national and international partners to ensure the availability of essential medical products, established new access pathways, and made strides in legislative reform. Through cutting-edge scientific work, we've accelerated the development of new treatments and solidified our global influence. Additionally significant efforts have been made to enhance leadership capabilities, governance functions, culture, and systems within the MHRA.

During a period of significant change and amidst the challenges posed by the UK departure from the EU and the ongoing COVID-19 response, substantial progress has been achieved over the past two years. Any outstanding items from the previous period will be addressed in the development of the new Business Plan to ensure continuous monitoring of their delivery.

The following sections provide more detail on the progress made against the themes of our Delivery Plan:

Patient and public involvement

This strategic theme was added to our Delivery Plan in 2022/23 to underpin our commitment to delivering the step-change needed in patient and public involvement in our work.

We have achieved a major shift in how we engage and involve patients, with the following accomplishments.

During 2022/23 we:

- Improved our support for the public in responding to our consultations to ensure their insight better informs our decisions
- Listened to the public through our consultation on proposals to streamline and strengthen UK clinical trials, using the results to inform the new legislative framework
- Piloted patient listening sessions on software as a medical device and risk communications to understand the patient perspective and how decisions affect them
- Piloted a Patient and Public Reference Group for the Innovative Licensing and Access Pathway to incorporate patient expertise and insight in the operation of the pathway
- Launched a shared commitment to improve public involvement in research, with other regulators, funders and research organisations to support the research community to increase public involvement through shared guidance, policies, systems and incentives
- Engaged with the public on our new pilot Yellow Card biobank project, aimed to facilitate research on adverse drug reactions, using the public input to inform the design and set-up of the biobank
- Supported our staff to put the patient first through tailored patient and public involvement training and the establishment of a new Patient Champion Network
- Developed plans to increase patient representation and contribution to our committees and groups

We continue to prioritise work in this area in 2023/24 with a focus on recruiting lay representatives to our committees and developing patient engagement guidelines to ensure we are including the needs of different population groups. We are working to increase our understanding of patient perceptions of benefit and risk to enhance our regulatory decision making, with incorporation of patient views and their lived experience in our benefit-risk reviews and defining the deliverables on Patient Reported Outcome Measures to better understand the impact of regulation on patients.

Equity in healthcare

To ensure that we, and our regulatory frameworks, deliver for all patients we are working to increase diversity, representation, and inclusivity in healthcare regulation. We are increasing the insight we gather from patients, with a particular focus on including patients from groups which the MHRA has historically engaged with less.

In 2022/23 we have:

- Engaged with the public using a range of different engagement strategies, on proposals to increase diversity and representation of under-served populations in clinical trial populations. Outputs of this engagement informed plans to overhaul the UK's clinical trial legislative framework
- Defined deliverables for integrating our suspected side effect data with NHS healthcare records to deepen our understanding of the representativeness of our data and the impact of demographics in patient adverse drug reactions
- Expanded the Clinical Practice Research Datalink (CPRD) Pregnancy Register to increase the data available to support research into rare exposures in pregnancy and their outcomes
- Improved our ethnicity data by using a new algorithm and integrating a more accurate and updated ethnicity record into the anonymised patient records within our databases. This has been used to confirm CPRD data has good representation across a range of ethnic categories and will be launched as a value-added product to the wider research community in 2023/24
- Improved UK regional representativeness of our CPRD service to include at least 10% of GP practices across all UK regions
- Developed a web-based tool which detects and corrects biases due to under-represented populations for Artificial Intelligence applications; market research is now underway to consider how this can be developed further
- Provided translated web pages on how to engage with our Yellow Card scheme into the most spoken languages in the UK to improve inclusion and accessibility
- Enhanced diversity of our patient group consultative forum to increase its contribution to regulatory decision-making
- Completed an initial review of women's health regulatory inequities, with further work planned for 2023/24

Work to increase equity in healthcare will continue in 2023/24, including:

- Work on better evidence-based dosing for medicines used in pregnancy and to support associated training for obstetricians, supported by grant funding from the Bill and Melinda Gates Foundation

- Building on progress made this year on the review of teratogen use during pregnancy, including in depth independent patient and stakeholder input. An understanding of patient and stakeholder perspectives will inform our development of updated guidance and actions to protect public health
- Improving medical device legislation to increase the requirement for more representative product clinical data, to reduce bias and increase appropriateness for different populations

Embedding innovative ways of working

We have made progress this year on embedding the changes and improvement to our ways of working following the completion of our transformational change programme.

During 2022/23 we have:

- Embedded new ways of working to make the MHRA more dynamic, including refreshed values, a new workforce planning framework, a culture action plan, new people strategy and refreshed inclusive hybrid working policy
- Completed the actions in our 2022/23 Leadership Action Plan, including work to set expectations and to evaluate and develop capability
- Updated our talent management model to ensure we can attract, develop and retain world-class scientific and regulatory capacity
- Appointed a new Director of Delivery to support and drive the aligned and focused delivery of our services. We have identified our key ambitions for service redesign which will be progressed in 2023/24
- Worked with industry via a task force focusing on performance to identify opportunities to work together to improve the service we offer and increase the proportion of 'right first time' applications

Scientific innovation

We have continued to deliver cutting-edge science to accelerate the development of new medical products for patients.

Highlights of our achievements in 2022/23 for research and development include:

- Active global involvement in a range of high-profile scientific areas e.g., assessing new SARS-CoV-2 variants, work on polio eradication and ongoing work on the development of new standards and replacement standards
- Recognition of our leading role in the development and post-use evaluation of a novel oral polio vaccine by the World Health Organization (WHO) Director General following the global milestone of 500 million doses deployed
- Rapid development of a research reagent for Mpox (previously named Monkeypox) for global distribution to assist with the evaluation of methods to detect anti-Mpox antibody and authorisation of a clinical trial (Platinum trial) of an antiviral drug in patients with Mpox
- Detection of poliovirus through our wastewater surveillance programme, in collaboration with the UK Health Security Agency, prompting a vaccine catch up programme to be undertaken. This surveillance programme has now been expanded to identify and assess local and national poliovirus transmission

- Development of a pilot Biobank project, to be jointly delivered with Genomics England in 2023/24, to investigate the role of genetics in the development of adverse drug and vaccine reactions

We have made progress in our plans to improve our management of clinical trials and investigations, including:

- Publishing our plans to improve and strengthen the UK legislation that underpins the regulation of clinical trials in preparation for laying the Statutory Instrument
- Improving our IT platforms to support delivery of an enhanced clinical trials service by moving our clinical investigations service onto our clinical trials platform
- Working with our Access Consortium partners to set up a working group to increase harmonisation for clinical trials, with further work planned in 2023/24

We have continued to support rapid and safe patient access to innovative medicines, by:

- Launching our Innovation Accelerator service, following consultation with stakeholders, to help provide innovators better access to our scientific expertise and regulatory guidance
- Continued operation and development of the Innovative Licensing Access Pathway (ILAP). The ILAP was recognised at The Organisation for Professionals in Regulatory Affairs (TOPRA) Human Medicines Symposium 2022 as a good example of how to create an end-to-end approach from discovery to deployment, involving both the regulator and health technology assessment bodies
- Creating a cross-agency team to rapidly deliver an end-to-end regulatory pathway for personalised cancer vaccines
- Developing guidelines, via an NHS programme, for acute myeloid leukaemia detection and creating better informatics tools for analysing patients' genomic data
- Contributing to a scientific programme focusing on developing better tools to analyse the microbiome, to improve patient access to personalised treatments
- Developing a proposal and strategy for a risk-based approach to batch release testing to assure the quality of biological medicines, while maintaining the capability to independently monitor the quality of biological medicines not traceable by the risk-based approach

Healthcare access

Throughout 2022/23 we have worked closely with our partners to ensure a continued and safe supply of vital medicines and medical products.

This has included:

- Continuing to increase access to therapeutics, vaccines and diagnostics for COVID-19 and to maintain a focus on future pandemic preparedness. We continue to expedite approvals where there is a public health need to do so, including approving the Novavax COVID-19 vaccine for use in adolescents aged 12 to 17 years, as well as the first bivalent COVID-19 booster vaccine which targets two different coronavirus variants to enable the delivery of the NHS Autumn 2022 campaign to vaccinate twenty million of the most vulnerable UK citizens.

The World Health Organisation (WHO) has now declared that COVID-19 is no longer a public health emergency, however it continues to take priority in the MHRA as vaccines are updated for new variants, new formulations and new populations. In 2022/23 we dealt with 76 substantial changes to COVID-19 vaccine licences requiring involvement of our medical assessors and a further 54 drawing on the skills of our quality assessors

- Working with pharmaceutical companies to support access to suitable vaccines and treatments for Mpox in the UK
- Approving new uses for existing cancer medicines through Project Orbis, an international programme led by the US Food and Drug Administration to accelerate access to new cancer medicines
- Granting the first Innovation Passport under the Innovative Licensing and Access Pathway. This product (belzutifan) was approved via the Project Orbis initiative for treatment of adults with von Hippel Lindau disease

We have laid the foundations for a raft of legislative changes to facilitate safe and rapid access to medicines and medical devices.

This has included:

- Establishing the Early Access to Medicines Scheme in law under the Medicines and Medical Devices Act, improving safe supply of innovative medicines to UK patients
- Achieving the Life Sciences Council agreement to refocus the delivery of the future UK health tech regulatory framework to ensure we take full advantages of the opportunities of being outside the EU and respond to the rapid evolution of the sector since we consulted in 2021. We are progressing the delivery of Statutory Instruments (SIs), guidance and best practice advice to form the new framework
- Publishing our roadmap to reform the legislation for Software and AI as a Medical Device and pushing forward the delivery of the roadmap deliverables
- Completing our Compliance Strategy, which will enable innovation and access in the regulated supply chain via more risk-proportionate compliance approaches

In recognition of the importance of our work to bring innovative new medicines and medical technologies to UK patients more quickly we have been awarded £10million in the UK Budget, for use to boost our support to innovators and deliver pathways for international recognition of approvals by other regulators. We have also received a grant award from the Regulators' Pioneer Fund, established by the Department of Business, Energy and Industrial Strategy, to support three projects that aim to unlock regulatory innovation.

Our work to ensure the safe and efficient supply of medicinal products has included:

- Holding a workshop on licensing electronic cigarettes as medicines, to encourage safe, high-quality and effective e-cigarette products to be made available in the UK

- Publishing guidance on the manufacture of cannabis-based products for medicinal use to clarify the MHRA and Home Office requirements and how these interrelate
- Holding educational workshops held to inform industry and pharmacists on meeting regulatory requirements to support access to hormone replacement therapy
- Continuing to develop remote and hybrid inspection approaches, using lessons learned during the COVID-19 pandemic. Embedding visual technology capabilities as a standard part of inspections

We have taken forward actions for 2023/24 to ensure integrated UK regulatory pathways for products that combine medicinal products and devices; and to establish a new medical devices framework to support safe innovation and ongoing access to products. These are included in our Corporate Plan.

Patient safety

We continue to protect public health by monitoring and responding to important patient safety issues related to the use of medicines and by prompt action to deal with faulty medicinal products and combat trade in non-compliant and illegal health products.

Achievements in 2022/23 include:

- Announcement of new safety measures for the use of sodium valproate in the light of data on established and evolving risks, using patient evidence to inform the approach and improve risk materials and working with stakeholders to safely implement these measures
- Recalling medicinal products which were found to be faulty, including insulin pumps, mexiletine hydrochloride and pholcodine, naloxone and contaminated perfusion solutions
- Involvement of our dedicated Criminal Enforcement Unit in Operation Pangea, an international initiative co-ordinated by Interpol, to combat trade in non-compliant and illegal health products
- Leading a successful global social media campaign, MedSafetyWeek, to encourage people to report suspected adverse effects from healthcare products via the Yellow Card Scheme
- Providing support and training for the Gates Foundation African Union Smart Safety Surveillance project, which has strengthened safety monitoring of priority medical products, including COVID-19 vaccines
- Launching a consultation exercise with healthcare professionals on how we can strengthen our communications on medicines and devices safety
- Reviewing the available evidence on pelvic mesh benefit-risk and results of engagement sessions, included in our Business Plan for completion of delivery in 2023/24
- Progressing our review of teratogen use during pregnancy, taking the decision to increase the independent patient and stakeholder involvement in 2023/24 to better understand stakeholder perspectives and choices

We have strengthened our ability to manage safety issues by modernising our systems and increasing engagement and involvement of patients to support our decision making.

This has included:

- Making our systems more effective, accessible and transparent through the SafetyConnect programme. This programme is delivering on our response to the Independent Medicines and Medical Devices Safety (Cumberlege) Review by introducing a new vigilance service to detect and respond to safety signals more quickly and comprehensively
- Launching an interactive adverse reaction reporting format for COVID-19 vaccines for reports received through the Yellow Card scheme, as a key milestone of the SafetyConnect programme. This will be expanded during 2023/24 to include all reports on medicines and medical devices
- Upgrading the Clinical Practice Research Datalink (CPRD) observational research infrastructure to deliver the second iteration of a Trusted Research Environment (TRE). This is now ready for testing by external users so we can improve our delivery of research data services
- Completing the development of the CPRD GOLD synthetic dataset in preparation for launch in the Summer of 2023 and launching a new synthetic data generation service which provides clients with bespoke synthetic data based on non-CPRD datasets
- Delivering an expanded scope of the NHSX-funded synthetic data research project and launching the synthetic data service
- Making good progress in setting up the UK's statutory committee on the safety of medical devices, which will strengthen our ability to manage safety issues, with an interim committee created to provide advice and support until the statutory committee is fully established
- Progressing the agreement of a policy for an enhanced devices transparency regime in preparation for delivery in 2023/24

Dynamic organisation

During 2022/23 we completed establishment of our new 'One Agency' structure to create a cohesive and agile organisation, populating the majority of the core roles, and establishing new ways of working. We have started work to redefine and optimise our core services.

This year we have:

- Launched our new 'One Agency' structure with an engaging and energising launch event "One Agency Live", in which staff were able to hear from Ministers, leading scientists, key stakeholders and patient representatives on the importance of the work of the MHRA
- Launched our new People Strategy 2022-2026 which sets out commitments and targets against five themes to support us to attract, develop and retain exceptional people, value diversity, promote wellbeing and inclusion, and enable great performance and delivery. These commitments have also been placed at the heart of the new Corporate Plan
- Improved and invested in our leadership capability, governance, culture and systems
- Launched our first in-house graduate scheme, aimed at attracting new talent to the organisation. This will offer a three-year programme for up to eight science graduates
- Commenced development of our data strategy, including data sharing, underpinned with robust security standards and privacy by design. This strategy will be published in 2023/24
- Progressed the replacement of legacy IT systems to improve our ability to deliver for patients and the public
- Reviewed our use of expert and advisory committees, safeguarding

their important advisory role and ensuring the best use of expertise and the application of consistent high-quality standards of operation

Collaborative partnerships

During 2022/23 we have established our position as a sovereign regulator, developing international and national partnerships to drive our priorities, yielding new products and access routes.

Achievements include:

- Becoming a full participant in the FDA's Project Orbis, a programme to accelerate access to new cancer medicines. In June 2022, the first medicine to be awarded an Innovation Passport was authorised via the Orbis initiative for cancer medicines
- The MHRA has taken over the Chair of the Heads of Agencies of the Access Consortium of regulators of the UK, Australia, Canada, Singapore and Switzerland. The group oversees working groups that are undertaking work-sharing to continue to build international reliance
- Working with Access Consortium partners and supporting the 'New Active Substance Work Sharing Initiative' of the Access Consortium, with Faricimab becoming the first treatment approved in the UK via this initiative
- Initiating the first phase in the creation of an international recognition framework working closely with Australia, Canada, Switzerland, Japan, Singapore and the United States Food and Drug Administration (FDA)
- Participating in the Life Sciences Council stakeholders' group on the development of a roadmap for the new regulatory regime for medical devices. We have responded to the findings of the group, and Dame Angela McLean's review of Pro-Innovation Regulation by temporarily assigning one of our Chief Officers to strengthen the leadership of this work, building a blended team supported by expertise from across government and industry to deliver a framework for Med Tech regulation which protects patients and enables innovation
- Adopting international standards to improve our ability to exchange data with health partners and consulting on engaging with healthcare professionals
- Our memberships of the International Council for Harmonisation (ICH) and the International Medical Device Regulators Forum (IMDRF) were approved, providing us with opportunities to play a more active role in shaping international frameworks and achieving greater harmonisation

Work continues in 2023/24 to complete a consultation for a new national Great Britain scheme to replace the Falsified Medicines Directive safety features regulation and agreement of the position on the Falsified Medicines Directive for Northern Ireland post 3-year EU derogation.

Financial sustainability

During 2022/23 we have established the MHRA on a financially sustainable footing, successfully balancing our annual budget as we have moved within DHSC's accounting boundary.

Achievements this year have included:

- Creating a new leaner organisational structure based around the product lifecycle
- Finalised plans to overhaul legacy IT systems and secured investment in the Spending Review for new systems including SafetyConnect programme and the regulatory management system
- Developed, consulted on, and launched a new fees structure, to enable us to fully recover costs for the services we offer in line with the requirements of Managing Public Money

We are working towards additional savings through reduction of our corporate costs and technology costs in 2023/24.

Performance against our public health targets

This section considers our performance against our key priorities for our statutory and non-statutory functions, essential for delivery of our core purpose of keeping patients safe through efficient and risk proportionate regulation.

Following the restructure of our organisation we have developed new reporting metrics for this year, aligned to our priorities and services. These will be further matured during the coming year as we complete the refinement of our services and performance improvement. Due to metrics being newly defined not all have a comparator figure from 2021/22.

PM1 – Clinical trials and investigations

	Measure	Target	Total 2022/23	Total 2021/22	Met / Not Met 2022/23
PM1a	Percentage of clinical trial applications assessed within 30 days of submission	98%	25.9%	99.6%	Not met
PM1b	Percentage of Clinical investigations decision letters (objection/no objections) issued within 60 calendar days of submission	100%	100%	100%	Met

PM1a – Target for assessment of clinical trial applications was not met due to resourcing challenges. We have committed to meeting our timelines for clinical trial approvals by 1 September 2023. We have increased capacity by recruiting and training new staff, we are clearing backlogs and improving communications to help provide companies with more certainty on the timelines.

Our performance metrics for clinical trials are published monthly on the gov.uk website: https://www.gov.uk/government/publications/mhra-performance-data-for-assessment-of-clinical-trials-and-established-medicines

PM2 – Licensing of medicinal products

	Measure	Target	Total 2022/23	Total 2021/22	Met / Not Met 2022/23
PM2a	Percentage of medicines assessed via national route which contain a new active substance within 210-days (excluding time awaiting applicant responses)	97%	88%	New metric	Not met
PM2b	Percentage of medicines assessed via recognition within published recognition pathway timeline (excluding time awaiting applicant responses)	80%	29%	New metric	Not met
PM2c	Percentage of established products assessed via national route within 210-days (excluding time awaiting applicant responses)	50% (Target increasing for 2023/24)	13%	New metric	Not met
PM2d	Percentage of products approved via recognition of another regulator's decision:				
	New Active Substance (NAS) Reliance	Establishing baseline	70%	New metric	N/A
	Established products Reliance	Establishing baseline	19%	New Metric	N/A
PM2e	Percentage of Type 1B and Type II variations assessed within the following timelines (excluding time awaiting applicant responses):	Variations assessments – Type IB changes include simple 'tell and do' changes such as changing location of manufacture, with Type 2 changes being complex changes with changes of formulation such as new or replacement excipients			
	I. 30 days (Type 1B)	50% (Target increasing for 2023/24)	60%	New metric	Met
	II. 30 days (Type II expedited timetable)	50% (Target increasing for 2023/24)	97.5%	New metric	Met
	III. 90 days (standard or complex Type II timetable)	50% (Target increasing for 2023/24)	82.4%	New metric	Met
	I. 120 days (extended complex Type II timetable)	50% (Target increasing for 2023/24)	77.8%	New metric	Met
PM2f	Number of Parallel Imports determined:	Parallel Imports – Where there is a product available in an EEA country which is needed in the UK, provided the product has no therapeutic difference from a licensed product in the UK, subject to certain other conditions we can allow it to be imported			
	I. Parallel Imports – Number of initial applications determined	Establishing baseline	375	New Metric	N/A
	II. Parallel Imports – Number of variation applications determined	Establishing baseline	7573	New Metric	N/A
PM2g	Unlicensed Medicines	We review and verify medical items imported for supply to patients under prescriber oversight, where no UK licence exists. MHRA role is to determine if there are any issues where we would object to importation, e.g., issues with controls in place for distribution to a patient or concerns about adequate controls in the supply chain			
	Unlicensed Medicines – Total number of notifications determined	Establishing baseline	109068	New metric	N/A

We are working hard to improve our performance timelines for licensing of medicines. Recruitment to vacant roles, changes in practices and service redevelopment, along with industry awareness have been critical themes in ensuring our performance improves.

PM2a – We are undertaking assessor recruitment and training to support improvement against this metric and bring performance back into target for 2023/24.

PM2b – We are developing new business processes for this regulatory route to support improvement of our performance against this metric during 2023/24.

PM2c – To improve our performance timelines for assessment of established products we have undertaken the Established Medicines Task and Finish Group to work collaboratively with industry. We have committed to meeting our timelines for established medicines by 1 January 2024. Phased targets have been set to take account of current challenges and provide a realistic estimation of expected performance, with a target of 80% for 2023/24 and 90% for 2024/25.

PM2e – Although our internal target is met, we aim to improve our performance timelines for assessment of variations. We have committed to improving our timelines for Type 1B variations by 1 July 2023. Phased targets have been set to take account of current challenges and provide a realistic estimation of expected performance, with a target of 90% for 2023/24 and 97% for 2024/25.

Our performance metrics for established medicines are published monthly on the gov.uk website: https://www.gov.uk/government/publications/mhra-performance-data-for-assessment-of-clinical-trials-and-established-medicines

PM3 Innovative Licensing Access Pathway (ILAP)

	Measure	Target	Total 2022/23	Total 2021/22	Met / Not Met 2022/23
PM3	Innovative Licensing Access Pathway performance:	Medicines on the ILAP pathway, which fulfil the criteria, are awarded an Innovation Passport designation initially. They can then progress to a Target Development Profile, if they are intending to progress to market, which sets out a regulatory roadmap for delivery to patients			
	I. Total number of applications for Innovation Passports (IPs)	Establishing baseline	178	New metric	N/A
	II. Number of Innovation Passports awarded	Establishing baseline	129	New metric	N/A
	III. Number of Innovation Passports not awarded	Establishing baseline	19	New metric	N/A
	IV. Total number of Target Development Profile (TDP) applications	Establishing baseline	40	New metric	N/A
	V. Number of Target Development Profiles awarded / TDP roadmaps issued	Establishing baseline	26	New metric	N/A

PM4 – Medical device regulation

	Measure	Target	Total 2022/23	Total 2021/22	Met / Not Met 2022/23
PM4a	Number of approved bodies designated	Establishing baseline	4	New metric	N/A
PM4b	Initial review of applications for designation completed within 2 weeks	100%	66%	New metric	Not met
PM4c	Required surveillance and witnessed audits of designated Approved Bodies have completed as required by UK Medical Devices Regulations 2002 (UKMDR 2002)	100%	100%	New metric	Met

PM4b – Target for the initial review of applications for designation has not been met due to resourcing challenges due to vacancies in the team during the year. Vacancies have now been filled and the performance is improving.

PM5 – Inspectorate inspections

	Measure	Target	Total 2022/23	Total 2021/22	Met / Not Met 2022/23
PM5	Number of routine inspections completed for:				
	I. Good Manufacturing Practice (GMP)	Establishing baseline	274	New metric	N/A
	II. Good Distribution Practice (GDP)	Establishing baseline	437	New metric	N/A
	III. Good Clinical Practice (GCP) and Good Manufacturing (GMP) Quality Consultations (GCP/GMPQC)	Establishing baseline	14	New metric	N/A
	IV. Good Laboratory Practice (GLP)	Establishing baseline	53	New metric	N/A
	V. Good Clinical Practice GCP, including Bioequivalence (GCP/BE)	Establishing baseline	38	New metric	N/A
	VI. Good Pharmacovigilance Practice (GPvP)	Establishing baseline	21	New metric	N/A

PM6 – Post marketing surveillance activity

	Measure	Target	Total 2022/23	Total 2021/22	Met / Not Met 2022/23
PM6a	Total number of safety signals identified for further assessment.	Establishing baseline	103	New metric	N/A
PM6b	Adverse Drug Reaction (ADR) reports processed within the following timescales:				
	I. Fatal ADR 90% in 24 hours 100% in 72 hours	90% in 24 hrs 100% in 72hrs	100% in 24 hrs & 72 hrs	100% in 24 hrs & 72 hrs	Met
	II. Serious ADR 95% in 72 hours 100% in 5 days	95% in 72 hrs 100% in 5 days	100% in 72 hrs & 5 days	100% in 72 hrs & 5 days	Met
	III. 85% of potential signals evaluated within 5 working days	85%	94.16%	93%	Met
PM6c	Defective medicinal product recalls:	NatPSA / Class 1 recalls – The defect presents a risk of death or disability. Class 2,3,4 recalls – The defect may cause non-life-threatening harm, is unlikely to cause harm, has a minor defect not likely to impair the product. Company led recalls – the licence holder has identified all affected customers			
	I. Total number of defective medicinal product recalls	Establishing baseline	59	New metric	N/A
	II. National Patient Safety Alerts (NatPSA) / Class 1 recalls	Establishing baseline	2	New metric	N/A
	III. Class 2, 3, 4 recalls or company led recalls	Establishing baseline	57	New metric	N/A

PM7 Criminal Enforcement Unit (CEU)

	Measure	Target	Total 2022/23	Total 2021/22	Met / Not Met 2022/23
PM7	Interventions conducted by the CEU that are assessed to have disrupted or degraded an identified criminal threat	The grading of the intervention as minor, moderate or major is determined by assessing the immediate impact on threat and its likely duration			
	I. Total number of CEU interventions	Establishing baseline	1131	New metric	N/A
	II. Major interventions	Establishing baseline	3	New metric	N/A
	III. Moderate interventions	Establishing baseline	22	New metric	N/A
	IV. Minor interventions	Establishing baseline	1106	New metric	N/A

PM8 – Batch release / control testing

	Measure	Target	Total 2022/23	Total 2021/22	Met / Not Met 2022/23
PM8	Percentage of independent batch assessments completed within target times for:				
	I. Vaccine batches – Certified within 43 working days	95%	100%	100%	Met
	II. Blood products – Certified within 15 working days	99%	100%	100%	Met

PM9 – Science Research & Innovation (SR&I) standards

	Measure	Target	Total 2022/23	Total 2021/22	Met / Not Met 2022/23
PM9a	Numbers of products sold from the following product groups:				
	I. Reference Standards and reagents (including British working standards)	Establishing baseline	32,929	20,390	N/A
	II. WHO International Standards, Reference reagents and Reference Panels	Establishing baseline	33,326	34,673	N/A
	III. CE-marked diagnostic reference materials	Establishing baseline	28,309	33,580	N/A
	IV. Influenza reagents	Establishing baseline	60,541	85,743	N/A
PM9b	Numbers added to portfolio:				
	I. Reference Standards and reagents (including British working standards)	Establishing baseline	51	New metric	N/A
	II. WHO International Standards, Reference reagents and Reference Panels	Establishing baseline	30	New metric	N/A
	III. CE-marked diagnostic reference materials	Establishing baseline	10	New metric	N/A
	IV. Influenza reagents	Establishing baseline	28	New metric	N/A

PM10 – British Pharmacopoeia (BP)

	Measure	Target	Total 2022/23	Total 2021/22	Met / Not Met 2022/23
PM10a	Number of new British Pharmacopoeia (BP) standards developed and added to the 2023 BP publication:	The British Pharmacopoeia protects public health by providing chemical standards for the quality checking of UK pharmaceutical substances and medicinal products as well as monographs which detail the way a product should be tested and analysed to ensure it is the correct formulation and activity			
	I. Documentary standards (monographs)	Establishing baseline	81 (23 UK & 58 Ph.Eur)	New metric	N/A
	II. Physical standards (British Pharmacopoeia Chemical Reference Standards – BPCRS)	Establishing baseline	13	New metric	N/A
PM10b	Sales of British Pharmacopeia standards	5% increase	36442 vials	New metric	N/A

PM11 – Clinical Practice Research Datalink (CPRD)

	Measure	Target	Total 2022/23	Total 2021/22	Met / Not Met 2022/23
PM11a	Percentage of applications to CPRD for access to data for research studies receiving first moderated review feedback within 30 working days of a valid application	90%	83.54%	89.17%	Not met

PM11a – In June 2021 we launched a new research data governance process to manage CPRD data in response to an independent review. The new process relies on volunteer external reviewers undertaking approximately 70% of the application reviews. While the target has not been met the average feedback time is under 15 working days. Going forwards, while CPRD cannot enforce feedback times for external reviewers, we will work towards streamlining our internal processes and guidance to provide additional support to external reviewers.

PM12 – Research and development

	Measure	Target	Total 2022/23	Total 2021/22	Met / Not Met 2022/23
PM12a	Number of scientific research publications	Establishing baseline	90	New metric	N/A
PM12b	External grant and research contract funding	Establishing baseline	£4 Million	New metric	N/A

PM13 – Working towards NetZero

	Measure	Target	Total 2022/23	Total 2021/22	Met / Not Met 2022/23
PM13a	Increased solar panel savings in electricity costs on the South Mimms Site	50% increase in savings due to use of solar panels	New metric for 2022/23	New metric	N/A
PM13b	Savings in water wastage on the South Mimms Site through a programme of works to reduce water loss	20% reduction in water usage on South Mimms Site	New metric for 2022/23	New metric	N/A
PM13c	Heat Decarbonisation Plan production and application for Public Sector Decarbonisation Scheme funding to support our ambition of NetZero by 2030	Funding application submitted by December 2023	New metric for 2022/23	New metric	N/A

Sustainability report

We monitor and report on sustainability at our primary sites which are our office site in Canary Wharf, London and our laboratory site in South Mimms, Hertfordshire.

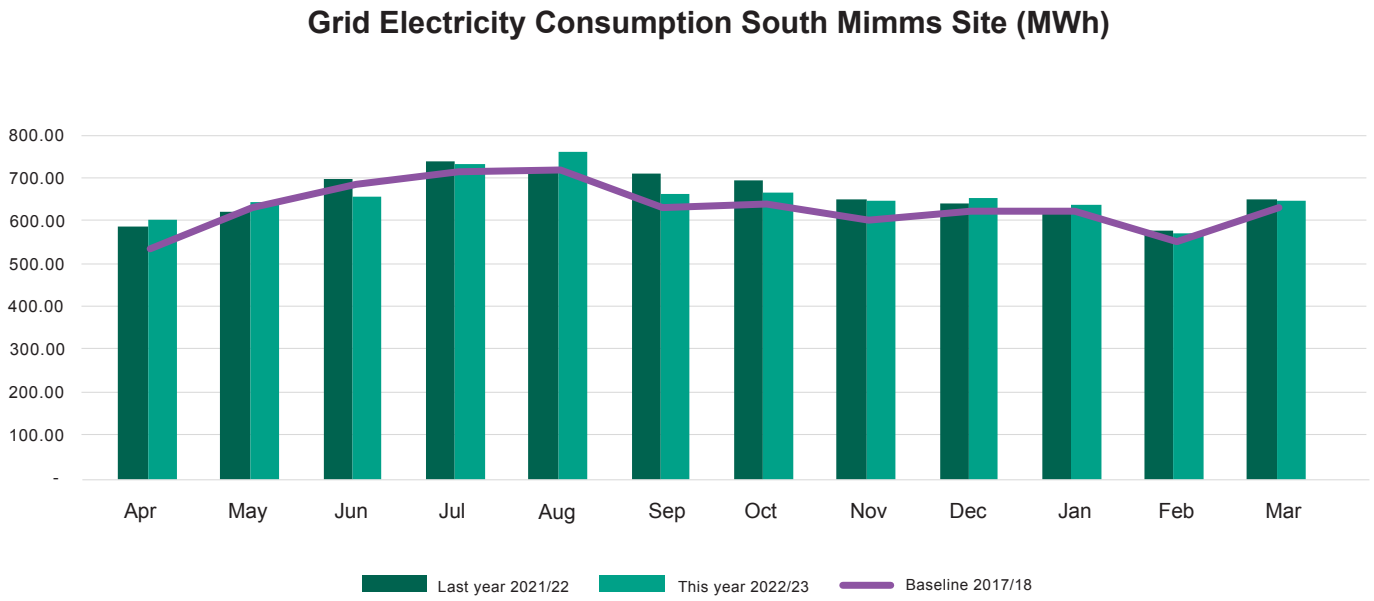
Energy management performance

Our site in South Mimms, which houses our laboratories, reports against a baseline of 2017 to 2018, in accordance with Greening Government Commitments (GGC).

Our administrative office site in Canary Wharf reports against a baseline of 2019 to 2020 as that was the first full year of occupancy of the site.

Electricity

South Mimms site 7,863.67 MWh



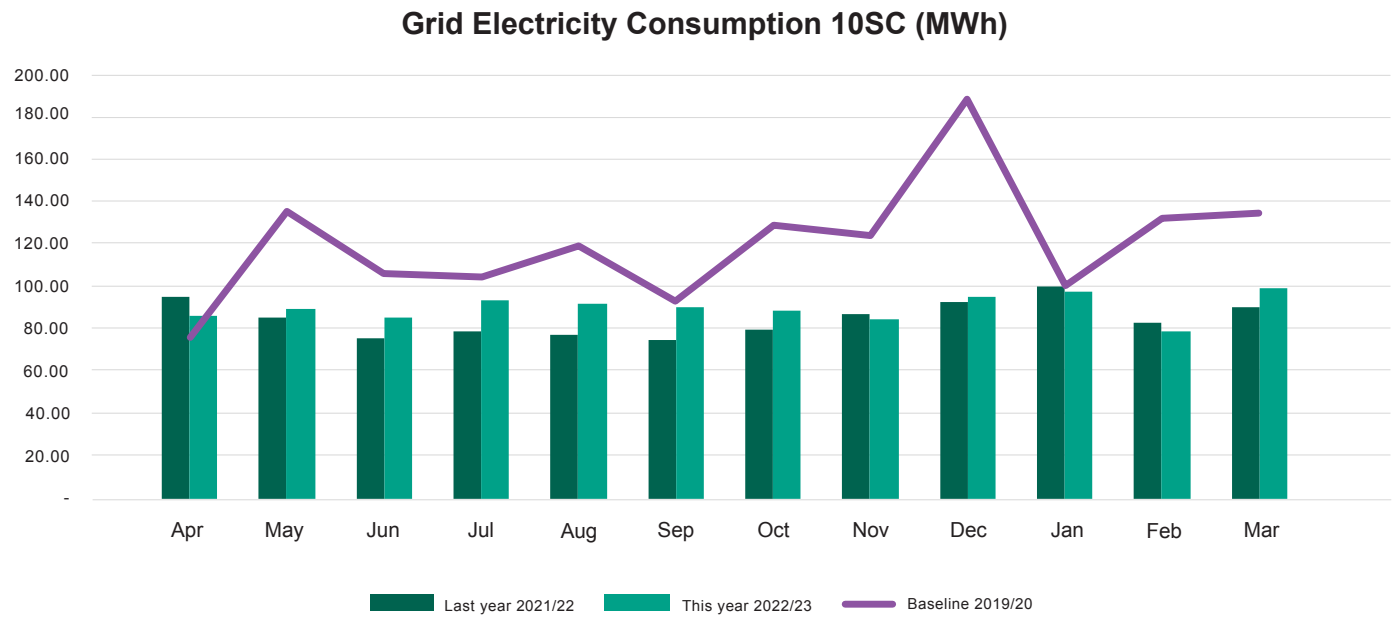
0.4% decrease vs last year

2.1% increase vs baseline

This year the electricity consumption at our South Mimms site has stayed at a similar level to last year. Despite 2022/23 having been warmer (requiring more cooling), the solar panels generated 7.4% more electricity[1] and site efficiencies negated the need to purchase any additional electricity. Our South Mimms site uses electricity for cooling and gas for heating.

[1] 22/23 solar PV 430.53 MWh vs. 21/21 solar PV 400.99 MWh

Canary Wharf offices 1,000.18 MWh



25.1% decrease vs baseline

5.8% increase vs last year

The electricity consumption at our site in Canary Wharf this year is still well below the baseline, but higher than last year. Building occupancy has increased since 2021/22 but is still much lower than the (pre-COVID) baseline. As the site uses electricity for heating and cooling, consumption increases as building occupancy increases.

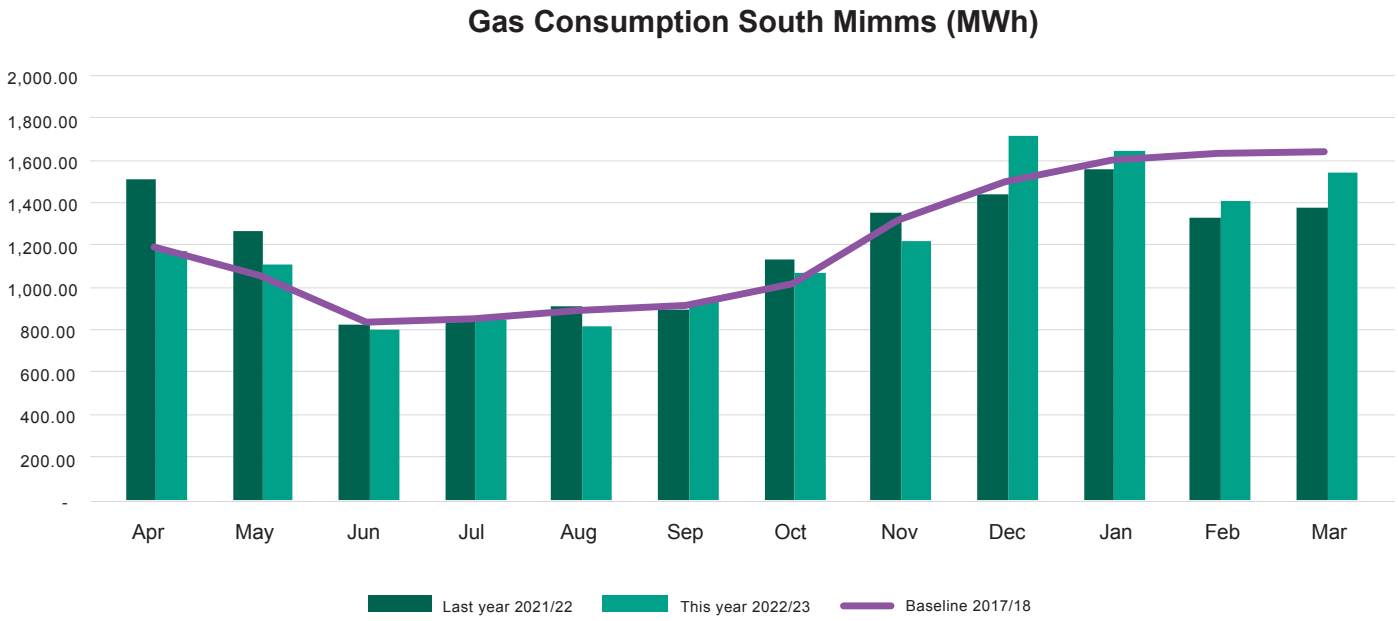
Note:

- The electricity consumption patterns at our South Mimms site are virtually identical between 2021/22 and 2022/23, with a peak in summer indicating an increase in the need for cooling, required to ensure the laboratories are retained at a stable temperature
- The erratic baseline chart pattern for our offices in Canary Wharf demonstrates the close link between electricity consumption and occupancy levels, dropping low during summer and in January to coincide with an increase in staff taking leave. Our Canary Wharf offices have electric heating, so both cooling and heating impact on electricity consumption

Our site in Canary Wharf is a Government Property Agency building and the MHRA represent 11.10% of the total building occupancy for 2022/23, as the formal figure from Government Property Agency.

Gas

South Mimms site 14,263.70 MWh

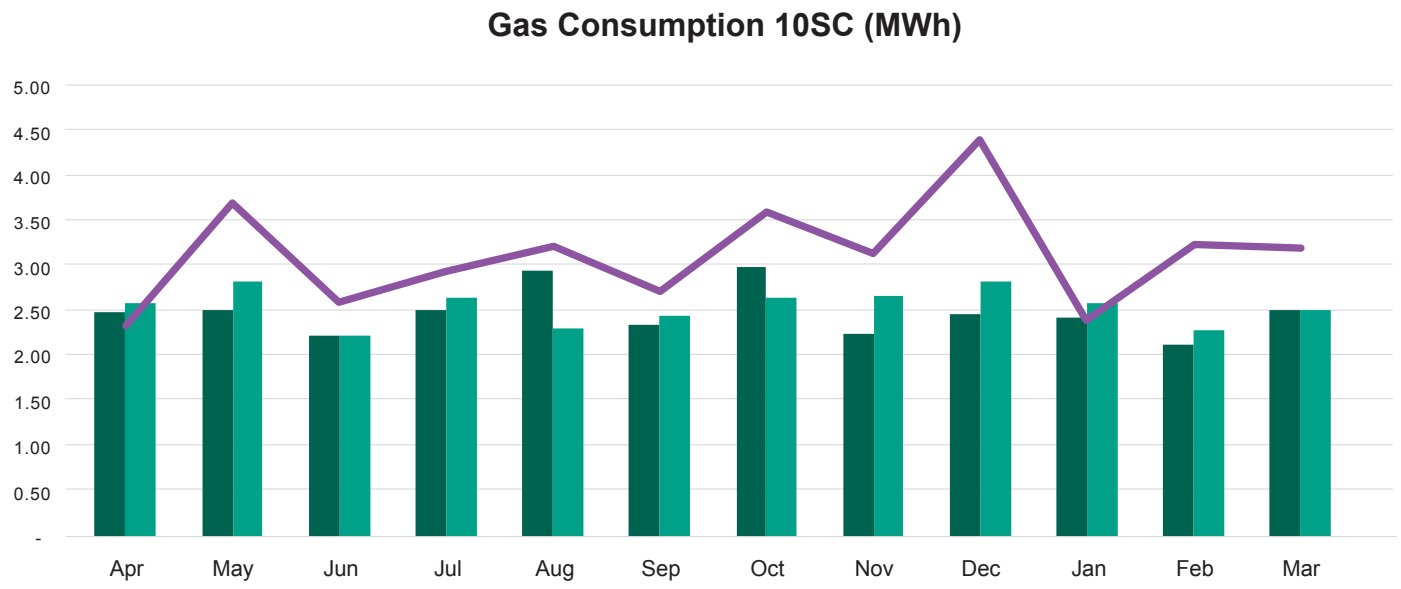


1.3% decrease vs baseline

1.3% decrease vs last year

Gas consumption at our South Mimms site for this year was marginally lower than 2021/22 and the baseline year, mainly due to milder weather meaning that the building required less heating.

Canary Wharf offices 30.09 MWh



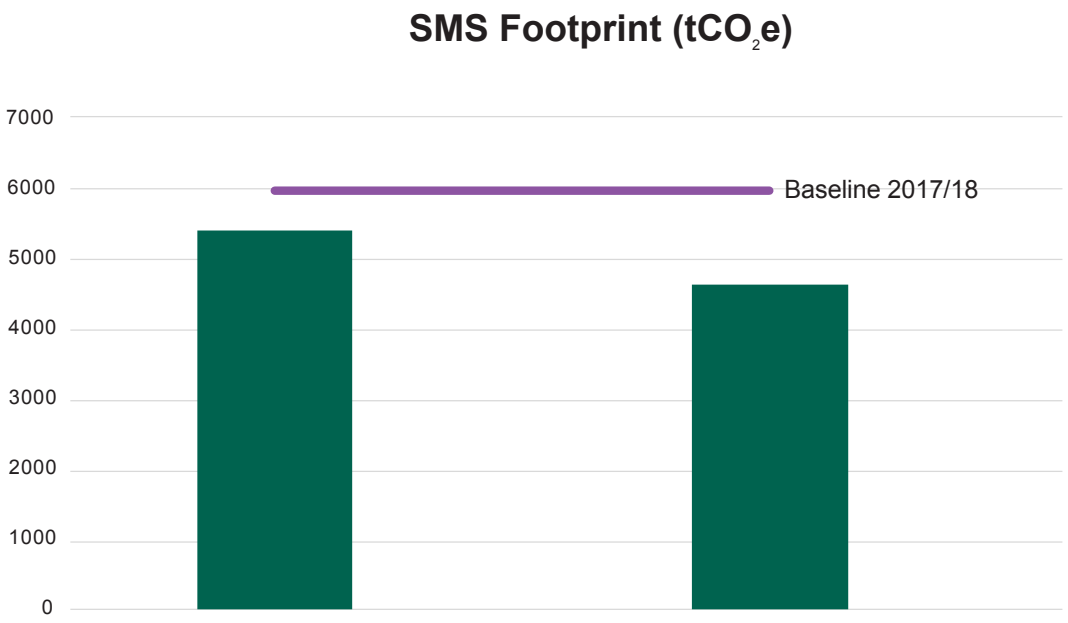
18.2% decrease vs baseline

2.2% increase vs last year

Gas consumption in our Canary Wharf offices increased this year compared with 2021/22 due to building occupancy being slightly higher. Gas in our Canary Wharf offices is only used for heating water, therefore the increase in 2022/23 was due to a higher number of people in the building increasing the demand for hot water.

Carbon emission performance

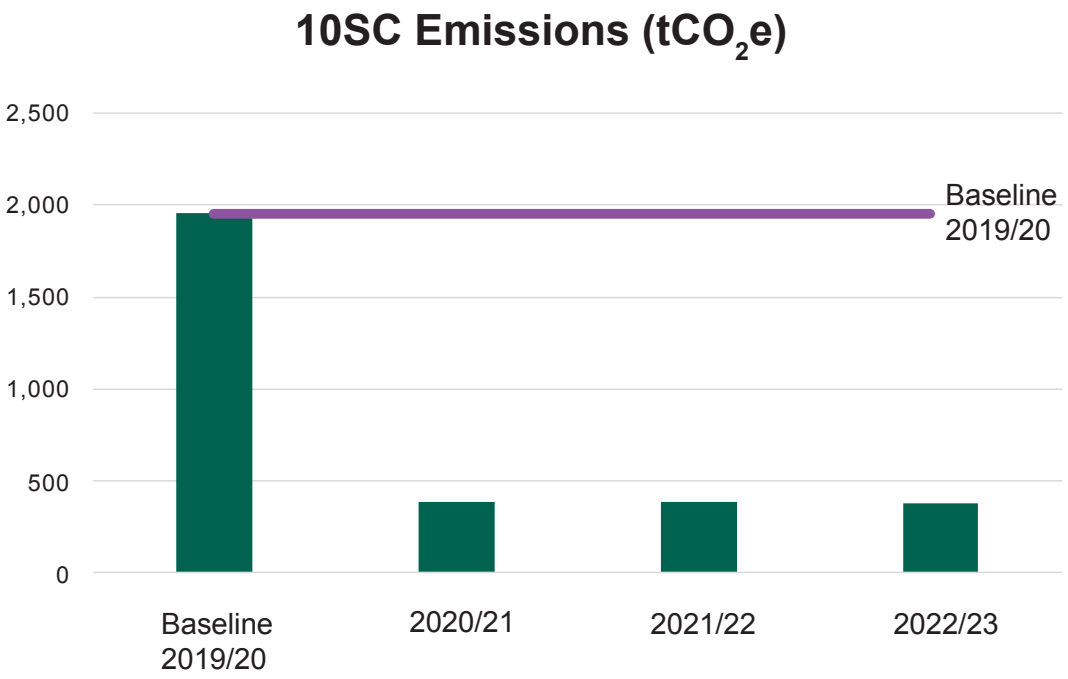
South Mimms site carbon emissions



22.5% decrease vs baseline

Carbon emissions at our South Mimms site have reduced from 5,917 tCO_2e in 2017/18 (baseline) to 4,588 tCO_2e in 2022/23.

Canary Wharf offices carbon emissions



80.6% decrease vs baseline

Carbon emissions in our Canary Wharf offices have reduced from 1,954 tCO_2e in 2019/20 (baseline) to 378 tCO_2e in 2022/23.

The carbon footprint of both our South Mimms laboratory site and the Canary Wharf office site have fallen considerably compared with the baseline years. A significant contributor to the decrease is the reduction in carbon intensity of grid gas[2] and electricity[3]. Carbon intensity is a measure of how many grams of CO_2 are released to produce each kilowatt of electricity or gas.

Our Canary Wharf offices are housed in a shared tenancy building, with a constant base load. The number of maintenance staff, cleaning staff and catering staff remains relatively stable and the energy usage for lighting, operating lifts, cooking, heating and cooling remains at a similar level regardless of building occupancy. Higher occupancy increases the amount of water used in our Canary Wharf offices and there is an increased use of gas to heat the water. The greatest impact on emissions for our Canary Wharf site is associated with business travel.

Our South Mimms site has a much higher baseload. The emissions associated with freezers and boilers constantly running for scientific purposes masks the emissions from the office/non-science-based activities.

Due to the differences between the sites, with our South Mimms site consisting primarily of scientific laboratories and our Canary Wharf site being office space, we cannot directly compare emissions across the two sites.

However, normalising the data per person gives:

- South Mimms site 144.4 $kgCO_2$ per person per occupancy day
- Canary Wharf offices 10.4 $kgCO_2$ per person per occupancy day

[2] Carbon intensity of UK gas in 2022/23 0.20227 $kgCO_2e$. In 20221/22 it was 0.2071 $kgCO_2e$

[3] Carbon intensity of UK electricity in 2022/23 0.19338 $kgCO_2e$. In 20221/22 it was 0.2445 $kgCO_2e$

Mitigating climate change: Working towards Net Zero

We are optimising our operations and estate to safeguard the environment for current and future generations. We will be led by science, aligned with the expert consensus on action needed during this decade to avert climate catastrophe (IPCC, 2018). As such, we are committed to reaching net zero greenhouse gas emissions by 2030. Recent initiatives during 2022/23 include:

Decarbonisation
Appointing a consultancy for Heat Decarbonisation Plan (HDP): Quantifying resources to reduce gas dependence, supporting our application to BEIS in 2023/24.

Switching to 100% clean renewable energy sources with Renewable Energy Guarantee of Origin (REGO)[4]

Solar energy
Increasing onsite solar energy generation at our South Mimms Site:
Roof panel installation (1560 panels) nearly complete, solar carports (486 panels) by the end of 2023/24.
Installed solar panels at our South Mimms site (installed in 2016) generated 6% of the site's electricity, saving £100,000 and reducing our carbon footprint by 110 tonnes CO_2e.
Replacing fluorescent lighting with occupancy and daylight sensing LED lights, reducing electricity usage in amenities by 40%.

Environmental
Supporting biodiversity through habitats for hedgehogs, bats, owls, and insects.
Clearing and replacing trees affected by ash dieback on our South Mimms site estate, planting 117 native trees.

Minimising waste and promoting resource efficiency
Reducing waste and promoting resource efficiency is our top priority. By prioritising prevention and designing out waste from internal policies and processes we apply the principles of the waste hierarchy:

At our South Mimms Site, we have taken several actions to minimise waste:

1. Zero landfill waste. Non-recyclable waste is incinerated to generate energy
2. Reused over 10 tonnes of pallets, 6 tonnes of furniture and equipment, and 1 tonne of solid ice packs
3. In addition to the standard 'household' recycling streams, we recycle polystyrene, baled cardboard, glass Winchester bottles from laboratory chemicals, and WEEE (waste electrical and electronic equipment)
4. Phased out plastic cups at our South Mimms site canteen and promoted water bottle fill points
5. Composted food waste from canteen and tea points
6. Renegotiating waste contract for broader recycling scope, including plastic film

By implementing these measures, we promote sustainability and set an example for efficient resource usage.

Whilst most waste reduction efforts focus on our South Mimms site, our offices in Canary Wharf also have initiatives like promoting recycling. Our printing reduced as offices transitioned to paper-free.

By implementing these measures, we promote sustainability and set an example for efficient resource usage.

Finite resource consumption and reducing water use
Due to the intense level of laboratory work undertaken in our laboratories at our South

[4] Renewable Energy Guarantees of Origin (REGO) | Ofgem - https://www.ofgem.gov.uk/environmental-and-social-schemes/renewable-energy-guarantees-origin-rego

Mimms site, it is difficult to reduce our demand for water on that site. We constantly measure and record our water use so that we can assess the impact of water efficiency measures as well as working on reducing wastage.

- Water butts capture rainwater for use by grounds maintenance teams and on the allotments managed by staff
- Steam and water leaks are identified and fixed promptly
- During 2023/24 the hydrant pipework which runs under all of our South Mimms site will be checked to ensure that it is not leaking

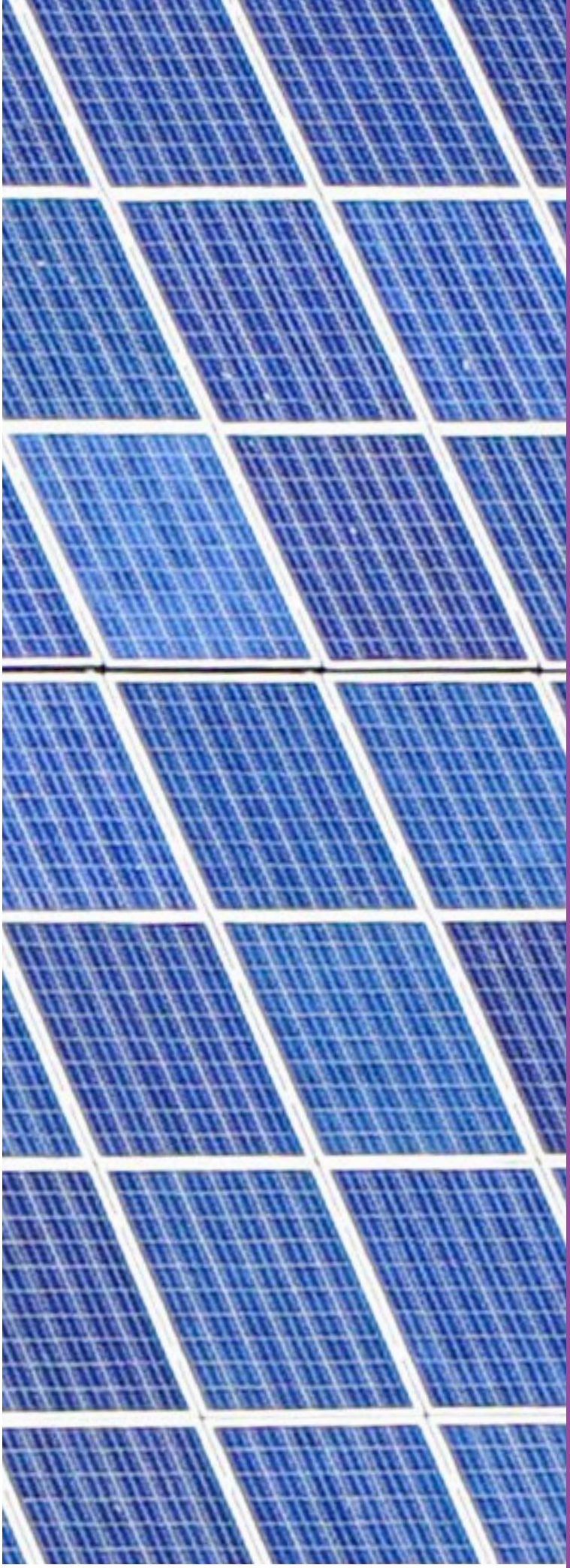
Procuring sustainable products and services

Sustainable procurement at the MHRA is crucial if we are to maintain an environmentally responsible and transparent supply chain, and drive reductions in our indirect (scope 3) emissions. We are already required to report publicly on our efforts to buy more sustainable and efficient products and services, in line with the Greening Government Commitments, and to adhere to relevant public procurement policy notes (PPNs).

Forward look 2023/24 sustainability projects

We have several exciting sustainability plans for 2023/24, including:

- The introduction of beehives to the conservation area at our South Mimms site which will bring biodiversity benefits and support preservation of the species, which is declining
- The introduction of Electric Vehicle (EV) charging points in the staff carpark at our South Mimms site to promote the use of ultra-low and zero emission vehicles and provide cleaner air
- Increasing the use of captured water from rainwater harvesting at our South Mimms site
- Implementing a robust plan for reducing our use of Fluorinated gas (Fgas), with a focus on capturing global warming potential (GWP) data from refrigerants



Health and safety report

Health and safety management is important to the MHRA and we are committed to providing a safe workplace for our staff and visitors and contractors. Our suite of laboratories at our South Mimms site operates at a range of biological containment levels, requiring us to implement robust controls and a strong health and safety culture to ensure we adhere to the required standards and legislation.

There have been significant organisational changes across the agency over the past year, which have required a detailed mapping exercise to ensure adequate resource is in place for key health and safety roles. However, the focus on health and safety priorities has been maintained and subject to review by external regulators. During a routine, planned intervention with the HSE, some areas concerning our management of health and safety during major change programmes were highlighted as requiring improvement, and these are currently being addressed. Additionally, actions to address two improvement notices relating to incidents reported to the Health and Safety Executive (HSE) in 2021/22 have required significant work this year to address. These have been satisfactorily completed.

At the close of 2022/23, we have addressed the HSE recommendations and have a fully resourced health and safety team focussed on continuing to embed and monitor improvements in the coming year.

Health and safety governance
Responsibility for health and safety lies with the Chief Executive, with leadership assigned to the Chief Science and Innovation Officer. The central Health and Safety Team, which sits within the Science, Research and Innovation Operating Group, provides competent advice regarding health and safety management and oversight for the whole agency. There is a network of safety support roles across the organisation to raise safety issues, provide advice and co-ordinate specific work activities and champion roles to support staff locally in their groups. There are Biological Safety Officers at the South Mimms site, who focus on ensuring safe working with biological agents, alongside a variety of strategic and operational oversight groups focussed on health and safety.

The Executive Committee and management committees support health and safety and provide challenge to ensure controls are effective. The Board and Board Assurance Committees support the Chief Executive in maintaining high standards of corporate governance and health and safety risk management.

Health and safety for the MHRA is managed in line with the Health and Safety Executive's 'Managing for Health and Safety' Guidance Document (HSG 65).

Health and Safety Executive (HSE)
The HSE provides external review of our health and safety management procedures through a planned intervention programme and we maintain a regular and open dialogue throughout the year.

Two main inspections were planned for 2022/23:

- A topic-based inspection on 'Management of Change – Organisational Restructure'
- An inspection to prepare for the licence renewal of our work under the Specified Animal Pathogens Order (SAPO)

These inspections resulted in actions for us to strengthen our processes for managing organisational change to ensure the risk of changes to safety critical roles and responsibilities are considered early in the

process. We are working towards the renewal of the SAPO licence for our biosafety level four (BSL4) facility in 2023/24, with all requirements already met for our biosafety level three (BSL3) facility (SAPO3 activities).

Accidents and incidents

There were three incidents reported under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 (RIDDOR) in 2022/23 at the South Mimms site. Two incidents relating to autoclaves were investigated by the HSE, and the MHRA received three verbal instructions as a result. This has led to a review of our control of contractors' policy.

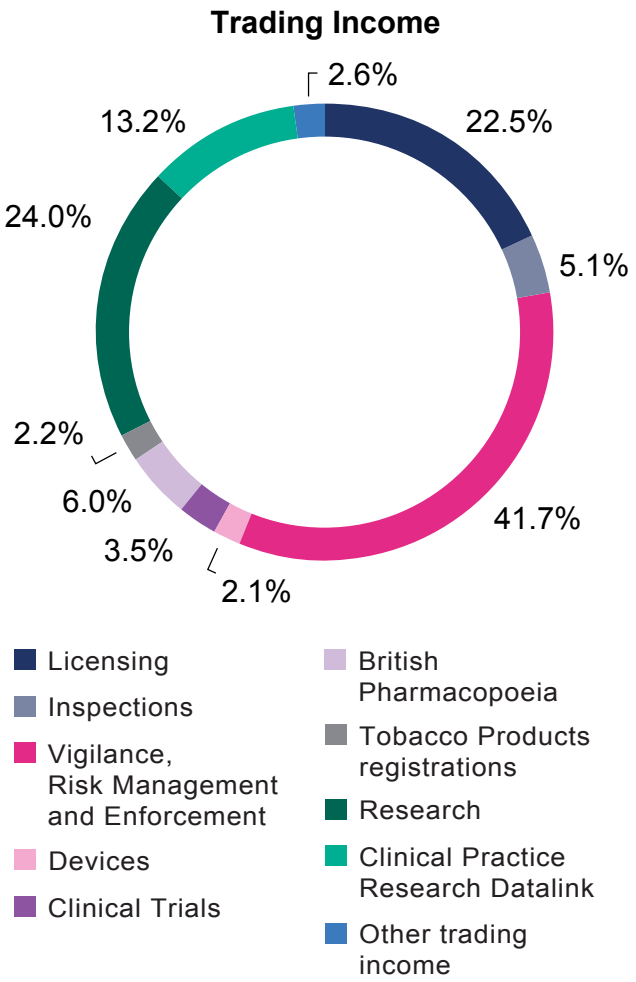
The final RIDDOR, relating to a minor spill in a CL3 laboratory, was initially reviewed by HSE, and was downgraded to non-reportable due to the hazard group of the agent involved.

There was also work completed in 2022/23 to close improvement notices received for incidents in the 2021/22 financial year. This has included strengthening our risk assessment procedures and policies, including delivering additional training for risk assessors and risk authorisers. We have also made significant improvements to our emergency procedures for high containment areas.

Overall trend analysis for the past five years indicates a general decrease in accidents and incidents at both the South Mimms site and London offices. At South Mimms the number of incidents (including near misses) remains proportionally higher than the number of accidents over the five-year period, indicating a healthy reporting culture is being maintained. The number of accidents and incidents reported at our office site remains lower than at the South Mimms site, which reflects the different working environments.

Financial review

Following the MHRA's reclassification from a trading fund the agency is now within the accounting boundary of the Department for Health and Social Care (DHSC). As a result, the funding from DHSC is no longer shown as income in our Statement of comprehensive net expenditure (SOCNE on page 119) but instead is included as a reserves movement in the general fund within the Statement of financial position (page 120). It is shown as a separate line in our Statement of changes in taxpayers' equity which provides details of how our balance sheet reserves have moved during the year. This means we are showing negative comprehensive expenditure in the SOCNE, equivalent to a loss of £32.3m, which are costs in the year in excess of our trading income. However, this loss is covered by the £33.2m of DHSC resource funding or 'grant-in-aid' that we have received during the year.



Where our funding comes from

The majority of the MHRA's running costs comes from trading income which are a combination of statutory fees paid by industry for regulatory services and charges paid by customers for the non-statutory services and goods. During 2022/23 the MHRA generated £122.9m of trading income.

The largest element of this during 2022/23 was £41.7m from the annual service fees. These are periodic fees charged to pharmaceutical companies for holding a marketing authorisation to sell products in the UK. The charges vary depending on the nature of the medicine being sold, the length of time it has been sold and the value of the sales. The income covers the costs of monitoring medicines following licencing including vigilance, risk management and enforcement activities where the cost of activities cannot be recouped through charging direct fees. MHRA earned £24m income from our scientific research work which includes, grants, the sales of biological standards and control testing of a wide range of products. The next largest income was £22.5m of licensing fees from the pharmaceutical industry for market authorisation applications, renewals and variations that provide the companies with market access for products in the UK. Income from CPRD data access licence fees raised a further £13.2m. All fees are set based on the cost of delivering the service in line with Managing Public Monies.

The Department for Health and Social Care (DHSC) provide baseline funding to support the provision of services for which we do not have the legal powers to levy fees or charges. This includes £12.5m for the science work that we do to deliver regulation and £8.1m for work on regulating devices.

As part of the 2022 Spending Review DHSC provided £7m of additional grant in aid to support the MHRA through its transformation. DHSC also provided £17.5m of capital funding. This was used for the maintenance of the South Mimms site, to start work on the replacement of our regulatory casework management systems (RMS), further develop the key SafetyConnect programme to support more responsive safety surveillance system and start developing CPRD's Trusted Research Environment.

The DHSC also provided an additional £3.4m grant funding to support the continuing work on COVID-19 vaccine safety.

During the year the Office of Life Sciences (OLS) awarded MHRA £5m of funding over a three year period to support the development of an Innovative devices access pathway.

Our financial performance

More than half of the cost of running the agency relate to staff including pay, national insurance and pension costs. The transformation of the agency reduced headcount but the reduction in pay costs was mostly driven by higher than planned vacancies as recruitment into the new structure took longer than anticipated.

Computing costs increased by £5.3m due mostly to an increase in the cost of infrastructure services and additional software and licences in year.

In line with the rest of government, the MHRA adopted IFRS 16 – Lease accounting at the start of this financial year. The only lease not already accounted for on the Statement of Financial Position was the lease for the main office building in Canary Wharf. This means that in 2022/23 the rental costs no longer go through the SOCNE under rental costs but instead are considered as depreciation. The prior year comparatives still retain the rental costs in the accommodation line as we are not required to restate them. Despite this accommodation costs increased by £2m from last year because the fit-out costs of £4.1m for the ground, fifth and half of the tenth floor had to be expensed when the space was vacated during the year (see efficiencies below). At the end of the year, we occupied half a floor of this Government Property Agency managed building on a 14-year lease.

Within other operating costs, contracted-out services reduced by over £9.3m as the transformation work was completed in the first quarter of the year and the contract with EY, who supported the programme, came to an end.

Our efficiencies

MHRA Commercial has delivered financial benefits of £1.16m for the financial year of 2022/23, equating to 1.6% of the MHRA's third-party spend. This has been achieved by reducing expenditure through competitive procurement exercises and commercial activity to reduce spend against budgets for goods and services. As the commercial team seeks to achieve value for money and support small businesses £27m of spend has been with Small and Medium Enterprises. As part of our commitment to deliver commercial best practice across the agency we have seen our Government Commercial Continuous Assessment Framework increase from 86.9% in 2022 to a current score of 93.2%.

The MHRA has reviewed and reduced office estate requirements during the year. The office footprint was reduced in Canary Wharf during 2022/23 by handing back 830m^2 on the ground floor in August and 1,985m^2 on the 10th floor in December which delivered in-year cash savings of c£1m. The reduction in office footprint should generate approximately £2.9m of cash savings per annum going forwards.

June M. Raine

Dr June M Raine DBE
Chief Executive and Accounting Officer
17 July 2023

02

2.0 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 MHRA's leadership and our risk management approach

2.2 Statement of Accounting Officer responsibilities

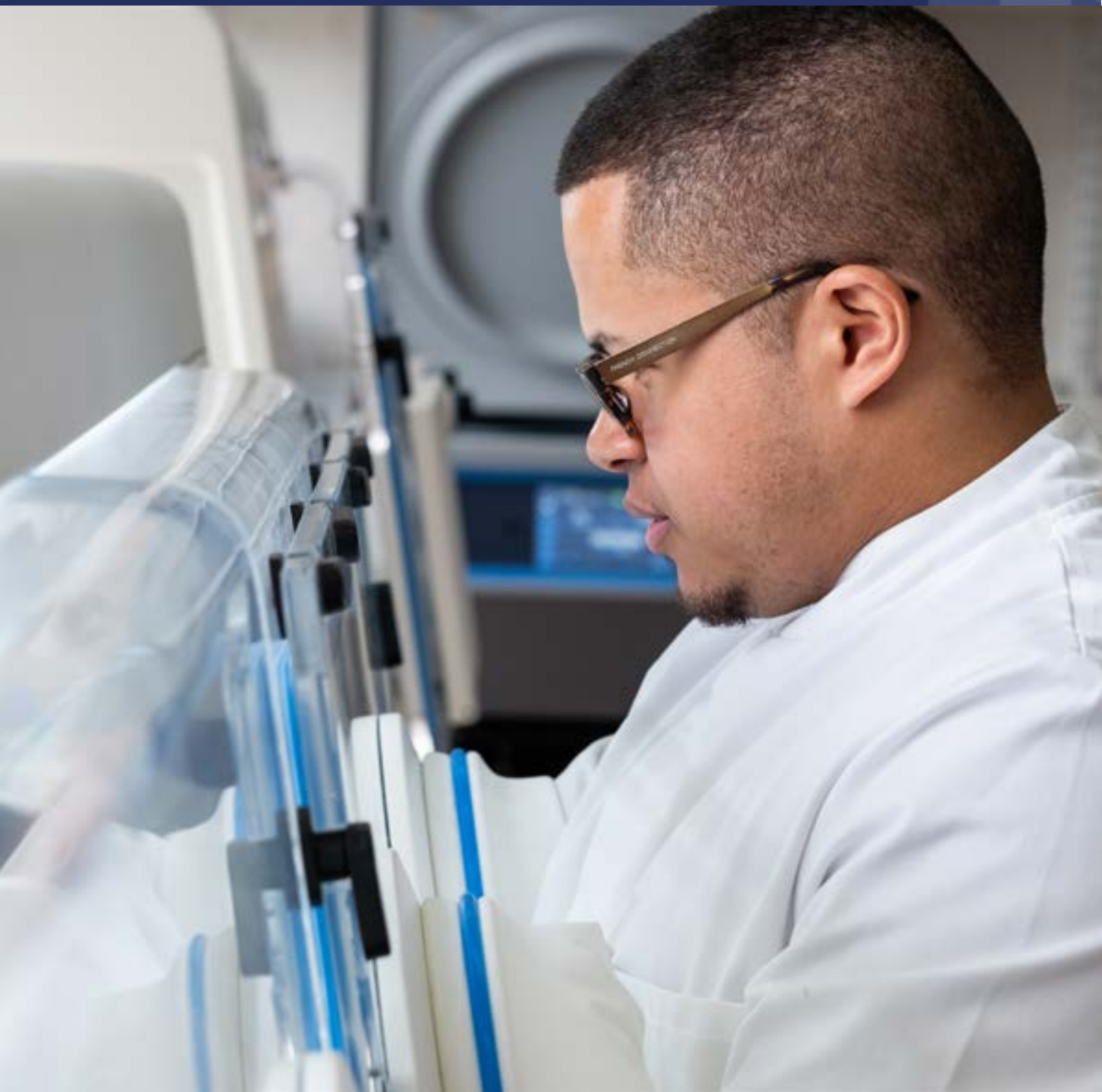
2.3 Annual governance statement

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

This section explains the governance structures at the Medicines and Healthcare products Regulatory Agency (MHRA), our internal controls and how these support the achievement of our objectives.

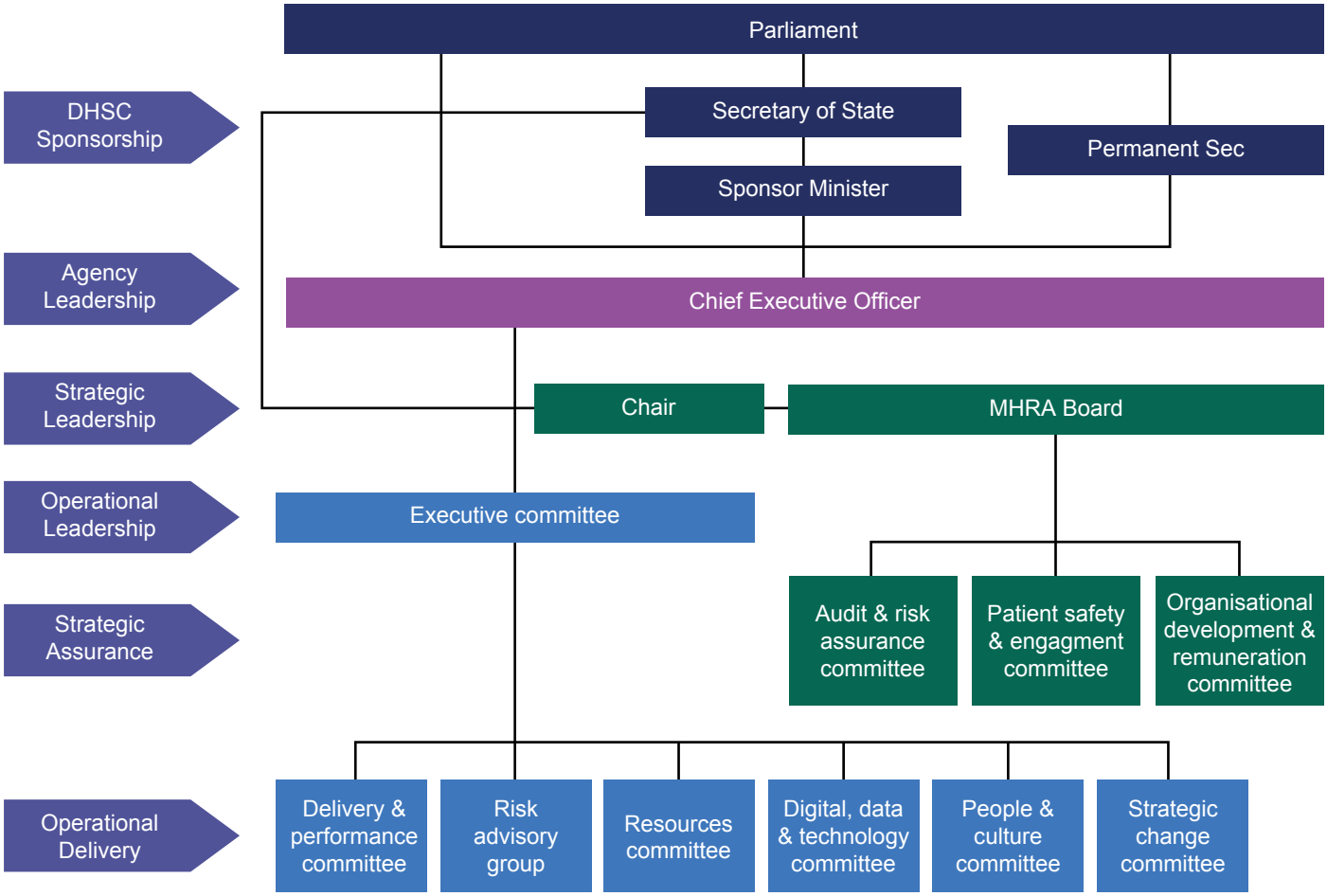


Directors report

Governance structure overview

The MHRA is led by the Chief Executive Officer, Dr June M Raine DBE, who is also the Accounting Officer. The Chief Executive is directly accountable to ministers and Parliament and DHSC Permanent Secretary for the operation and management of the organisation and for the delivery of its functions. The Chief Executive is supported by an advisory board (the Board), which is led by a Non-Executive Chair, Stephen Lightfoot (the Chair), and the Executive Committee (ExCo).

MHRA governance structure:



The Board

Our Board is a unitary board, with an equal number of Executive and Non-Executive Directors, plus a Non-Executive Chair. It is an advisory board and supports the Chief Executive in the effective delivery of services and overall performance of the organisation.

The Board provides scrutiny and challenge to the Chief Executive and executive team, with a specific focus on:

- Advising on and agreeing the strategic priorities of the MHRA, 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 Board has no involvement in regulatory decisions affecting medicines, medical devices or any other products or services delivered by the MHRA. These are the responsibility of the Chief Executive, supported by the Executive Committee (ExCo). Final decisions, and the responsibility and accountability for these, rest with the Chief Executive as the Accounting Officer of the MHRA. Board collectively does not exercise any line management or executive functions, nor does it have a legal or constitutional role or any liability in respect of decisions of the Executive.

The Board operation is consistent with the principles and supporting provisions of good corporate governance and aligns with Model 2, as set out in Cabinet Office guidance Public Bodies Handbook – Part 3. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/690636/Executive_Agencies_Guidance.PDF

In support of our commitment to putting patients and the public at the heart of all we do, the Board held six of its meetings in public last year and are planning to do the same this year. This enables members of the public to observe the Board conducting its business via an online broadcast and to ask questions directly of the Board on the agenda it is considering. Minutes of these meetings are published on the MHRA's website.

The Board is supported by three Board Assurance Committees:

- Audit and Risk Assurance Committee (ARAC)
- Patient Safety and Engagement Committee (PSEC)
- Organisation Development and Remuneration Committee (ODRC)

Board Assurance Committees

The Board Assurance Committees are Chaired by Non-Executive Directors (NEDs), with at least two further NEDs appointed as committee members.

Audit and Risk Assurance Committee

The Audit Risk and Assurance Committee (ARAC) operates in an independent advisory capacity, providing advice to the Board and the Accounting Officer on the management of risk, control, governance and financial reporting.

Membership of the ARAC is made up of three Non-Executive members, with one appointed as the Chair. The ARAC meetings are also attended by the Chief Executive, the Chief Finance Officer, Director of Governance, Head of Internal Audit (HIA) and a representative of External Audit.

The Non-Executive members of ARAC during 2022/23 were:
Michael Whitehouse, OBE – ARAC Chair
Dr Paul Goldsmith – Member
Amanda Calvert – Member

The role of the ARAC is to provide advice on:

- Assurances relating to the effectiveness of processes for identification and management of risk, the operation of controls and governance, the governance statement and achievement of value for money
- The accounting policies, the accounts, and the annual report of the organisation, including the process for review of the accounts prior to submission for audit, levels of error identified, and management's letter of representation to the external auditors
- The planned activity and results of both internal and external audit.
- Adequacy of management response to issues identified by audit activity, including external audit's management letter
- Anti-fraud policies, whistle-blowing processes, management of Conflicts of Interest and arrangements for special investigations

ARAC meets a minimum of four times each year and carries out its role in line with HM Treasury's ARAC Handbook (Audit committee handbook, HM Treasury, March 2016) https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/512760/PU1934_Audit_committee_handbook.pdf.

ARAC focus 2022/23

Throughout the year ARAC has met eight times, including a joint meeting with the Organisational Development and Remuneration Committee dedicated to a deep dive into the implementation of the new regulatory management system (RMS). The increase in meeting frequency this year has supported the risk management journey, in recognition of the high rate of change within the MHRA.

ARAC focus this year has been on the full risk profile of the agency, including targeting specific risks to the delivery of our objectives, including Health and Safety, RMS, financial risk and the delivery of our future operating model. ARAC has also supported the refresh of the Corporate Risk Register and risk management approach, through hosting the first MHRA Horizon Scanning Risk Meeting in September 2022 and by reviewing our risk management journey and providing strategic challenge to support planning and monitoring of our risk change programme.

In recognition of the importance of health and safety to our operation, in particular the additional health and safety requirements due to our work with biological agents, ARAC has closely monitored the health and safety incidents, and response to Health and Safety Executive actions, providing supportive challenge to ensure effective grip in this important area.

The ARAC Chair has met with members of internal and external audit in private, and with NEDs in private in advance of each scheduled meeting, as well as holding ad-hoc meetings throughout the year. Since February 2023 the ARAC Chair has met with the Head of Internal Audit to monitor progress of the Internal Audit Programme in order to support closure of the audits prior to the end of the financial year.

A review of the effectiveness of ARAC was undertaken in March 2023. Further details of this can be found in the Board and Assurance Committees' Effectiveness section of the report (page 75)

Assurance, through an ARAC meeting brief outlining key discussions and decisions, has been provided to the Board following each ARAC meeting.

Patient Safety and Engagement Committee

The Patient Safety and Engagement Committee (PSEC) provides independent, objective advice, assurance and recommendations to the Board to support their responsibilities relating to patient safety and patient engagement.

Membership of the PSEC includes three non-executive members, one appointed as the Chair, three executive members, including the Chief Executive, the Chief Healthcare Quality and Access Officer, the Chief Safety Officer and two independent lay members, who hold non-voting positions. The inclusion of lay members in the committee enables a robust lay perspective to be included in discussions.

The non-executive members of PSEC during 2022-23 were:
Mercy Jeyasingham, MBE – PSEC Chair
Professor Graham Cooke – Deputy Chair
Raj Long – Member

The role of the PSEC is to:

- Examine, scrutinise and challenge the management and operation of increased patient engagement, to deliver outcomes in line with the accepted recommendations of the Independent Medicines and Medical Devices Safety Review
- Provide challenge to the Executive on the delivery of the MHRA's statutory duties in a way that is responsive to the needs of patients and their concepts of risks and benefits and in its consideration of patient safety
- Consider and advise on the extent to which processes are in place to encourage the acquisition, analysis and decision-making based on information from patients and the public at all stages of the agency's regulation of medicines, medical devices and blood products
- Scrutinise the systems in place to ensure information is shared effectively with patients and the public on the outcome of their involvement in MHRA decisions, and on wider activities and operations of the agency

The PSEC has a particular focus on how the agency embeds the recommendations of the Independent Medicines and Medical Devices Safety (IMMDS) review report.
First do no harm: the report of the IMMDS review https://www.immdsreview.org.uk/Report.html

PSEC Focus 2022/23

Throughout the year PSEC met four times, including a joint meeting with the Organisational Development and Remuneration Committee for a deep dive into equality, diversity and inclusion.

PSEC provided the board with assurance on a range of items, including:

- Deliverables of the IMMDS review
- The Patient Involvement Strategy
- The use of real-world data and the use of signals to detect health risks.
- Consideration of safety issues in-depth, reporting these to the board
- Ensuring that the MHRA continues to focus on patient safety throughout everything we do

Similarly, items on benefit-risk communication and patient involvement have enabled PSEC to provide assurance to the board on how we are informing and involving patients on a range of issues and how we handle complaints.

A review of the effectiveness of PSEC was undertaken in March 2023. Further details of this can be found in the Board and Assurance Committees' Effectiveness section of the report (page 75).

Organisational Development and Remuneration Committee

The Organisational Development and Remuneration Committee (ODRC) provides independent and objective advice, assurance and recommendations to the Board and the Chief Executive on their responsibilities relating to the development of the MHRA and its services and its people and culture strategies.

Membership of the ODRC includes three Non-Executive members, one appointed as Chair, and three executive members including the Chief Executive, the Chief People Officer and the Chief Digital and Technology Officer.

The Non-Executive members of ODRC during 2022/23 were:
Amanda Calvert – ODRC Chair
Dr Junaid Bajwa – Member
Haider Husain – Member

The role of the ODRC is to:

- Examine, scrutinise and challenge the management and delivery of change and transformation in the MHRA, in order to provide advice to the Chief Executive and assurance to the Board that the development of the agency will equip it to adequately meet its strategic objectives
- Scrutinise the processes, systems and structures in place within the agency to attract, retain, and develop staff capabilities and retain talent in a changing environment
- Provide challenge to the Executive on the development and implementation of the People Strategy
- Provide assurance to the Board that the MHRA has appropriate culture and procedures in place for managing and developing its workforce capabilities and delivering change
- Provide a formal and transparent process for determining Executive remuneration

ODRC Focus 2022/23

Throughout the year the ODRC met six times, including a joint meeting with PSEC for a deep dive into equality, diversity and inclusion, and a joint meeting with ARAC for a deep dive into the implementation of our new regulatory management system.

The ODRC has provided the Board with assurance on a range of items, including a number of reviews of the effectiveness of the new organisational structure and operating model, and development of our key services to deliver our 'One Agency' ambitions.

Additionally, there was a focus on developing our leadership and culture, including:

- A review of the internal audit on culture
- A review of our People Strategy, to enable the MHRA to attract and retain key talent to build our capability
- Initiatives such as the Competency Development Framework to support delivery of the new operating model, and provide staff with opportunities to progress their careers; and
- Employee satisfaction and motivation

A review of the effectiveness of the ODRC was undertaken in March 2023. Further details of this can be found in the Board and Assurance Committees' Effectiveness section of the report (page 75).

Board register of interests

Members of the Board are bound by clear rules related to holding and declaring interests in the pharmaceutical and medical devices industry, as well as other relevant interests. These are set out in our policy 'Policy on Declaring and Managing Interests for Members of the MHRA Unitary Board' which can be found on our website via the Conflicts of Interest Policy link. https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/about/our-governance#board-members-declarations-of-interest.

The policy supports a culture in which we are transparent about the interests of Board members and ensures that these are understood and managed. Both Non-Executive Directors and Executive Directors as Board members are bound by this policy in relation to Board meetings. A full declaration of interests must be made on appointment and annually, with any changes or updates raised throughout the year. Further declarations of relevant interests related to items for discussion are declared at the start of each Board meeting, with decisions on management of these included in the minutes.

The following interests must be declared:

- Financial interests in the pharmaceutical and medical devices industry or other relevant industries, held by themselves or their immediate family (spouse or partner and any members of family living in the same household)
- Business interests or positions of authority outside of their role in the MHRA, regardless of whether they are linked to the health sector
- Any other matter which could affect, or be perceived as affecting, their impartiality

The Chair is responsible for taking the final decision on how declared interests should be handled, with the Deputy Chair taking responsibility for any interest declared by the Chair. A register of interests of Board members is maintained to record declarations to enable appropriate and transparent management of these and ensure independent operation of the Board. The register is available on the MHRA's website, under Board members' declarations of interest. https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/about/our-governance.

Information on any transactions with organisations with whom Executive or Non-Executive Directors are connected as key management personnel are detailed in the Related Parties note in the Annual Report and Accounts (page 141).

MHRA staff are not permitted to hold any interests in the industries the agency regulates. We have policies for declaration of staff interests and interests arising from members of expert committees, as well as separate policies on management of Corporate Conflicts of Interest. Further information on our management of Corporate Conflicts of Interest can be found on page 80 of this report.

Members of the Board in 2022/23

Board members bring a balance of skills and experience which underpins the support they can offer to the Chief Executive in the successful operation of the MHRA. The Non-Executive Directors who served on the Board in 2022/23 were:

Full biographies and details of all declared interests can be found on the MHRA website at: https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/about/our-governance

Stephen Lightfoot
Board Chair
September 2020 - present

Stephen has been a Non-Executive Director of the MHRA since 2015 and was appointed as agency Chair in September 2020.

He has extensive experience in the life sciences industry, working on the development and commercialisation of medicines and medical devices within UK and global healthcare companies. Stephen also holds the position of Chair of the NHS Sussex Integrated Care Board.

Dr Junaid Bajwa
Member of ODRC
September 2021 - present

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

Junaid currently holds the role of Chief Medical Scientist at Microsoft Research and is a practising General Practitioner in London. He also holds Non-Executive Director roles at University College London Hospital NHS Foundation Trust and Nahdi Medical Corporation in Saudi Arabia.

Amanda Calvert
Chair of ODRC, Member of ARAC
September 2018 - present

Amanda has extensive experience in the Life Sciences sector gained through senior operational roles at ICI, Zeneca and AstraZeneca, and has experience of leading major change programmes.

Amanda set up Quince Consultancy Ltd., providing consultancy services to companies including those in the healthcare sector. Amanda is currently a Non-Executive Director for High Value Manufacturing Catapult and a member of the Advisory Board for Cambridge Judge Business School.

Professor Graham Cooke
Board Deputy Chair, Member of PSEC
September 2021 - present

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

Graham currently is NIHR Professor of Infectious Diseases at Imperial College London and leads the translational infectious research within the NIH Biomedical Research Centre with a particular interest in precision medicine and diagnostics.

Graham is a consultant advisor for 30 Technology Ltd., DNAnudge Ltd., and Seventh Sense Biosystems. He is also the Chair of the End Point Review Committee for vaccine trials for Sanofi CoV and Chair of the Committee for the Committee for the Selection and Use of Essential Medicines for the World Health Organisation.

Dr Paul Goldsmith
Member of ARAC
September 2021 - present

Paul has a breadth of clinical, drug development, digital health and governance experience. He is a serial innovator who has co-founded four healthcare businesses.

Paul has a particular interest in applying evolutional neuroscience insights to the problems of modern life. Paul is currently the Director and Co-Founder of Closed Loop Medicine Limited, Director of MDU Ltd. and MDU Investments Ltd. and a Trustee of the Big Tent Foundation. He is also a Clinical Senate Member in the NHS.

Haider Husain
Member of ODRC
September 2021 - present

Haider is an experienced international healthcare IT business leader with a strong technology background and experience of partnership working.

Haider is currently Chief Operating Officer for Health Innova Ltd., Non-Executive Director of Milton Keynes University Hospital NHS Foundation Trust and Associate Non-Executive Director of NHS Buckinghamshire, Oxfordshire and Berkshire West Integrated Care Board. Haider is Panel Chair for the Safe and Effective Use of AI in Healthcare at the British Standards Institute.

Mercy Jeyasingham MBE
Chair of PSEC
May 2020 - present

Mercy has extensive experience gained through working in the voluntary health and social care sector as well as multiple Government appointments.

Mercy is a management consultant specialising in managing charities, health and social care policy and promoting equalities. She also holds volunteer roles. Mercy is a Non-Executive Member of the NHS South West London Integrated Care Board.

Raj Long
Member of PSEC
September 2021- present

Raj 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 and Social Care, European Union, Gates Foundation and Word Health Organisation (WHO).

Raj is currently the Deputy Director for safety and pharmacovigilance at the Gates Foundation. Raj provides advice to a number of projects and is also an Associate Non-Executive Board Member for the UK Health Security Agency.

Michael Whitehouse OBE
Chair of ARAC
September 2018 - present

Michael is a qualified accountant and auditor with over 30 years' experience as an external auditor of central government on behalf of Parliament.

Following his retirement in 2017 Michael now holds the position of Deputy Chair and Senior Independent Non-Executive Director of the South East Coast Ambulance Services NHS Foundation Trust and Chairs their Audit Committee and Charities Committee.

The Executive Directors who served on the Board in 2022/23 were:

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

June trained in medicine in Oxford after completing a Master's degree by research in Pharmacology. June's interest in drug safety led to a career in medicines regulation which has spanned a number of roles in assessment, management and strategic development within the UK national authority.

June was elected, in 2012, as the first Chair of the European Pharmacovigilance Risk Assessment Committee and is also co-Chair of the WHO Advisory Committee on Safety of Medicinal Products.

Dr Marc Bailey
Chief Science & 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 MHRA in 2017 at the South Mimms Laboratory initially as 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 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 Medicines Group at the MHRA and the European Medicines Agency (EMA).

In addition, Alison was Head of Cellular, Developmental and Physiological Science at the Wellcome Trust and most recently an Industrial Strategy Challenge Fund Director at UK Research and Innovation.

Dr Laura Squire
Chief Healthcare Quality and Access Officer
November 2021 - presentt

Laura started her career as a post-doctoral research assistant looking at 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 operational transformation through her wider policy and operational work in other major government departments. She joined the MHRA from the DHSC where she worked on the COVID-19 vaccine deployment programme.

Dr Glenn Wells
Chief Partnerships Officer
November 2021 - present

Glenn joined the MHRA from the Medical Research Council (MRC) where he was Director of Strategy and 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 the 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.

Claire Harrison
Chief Digital and Technology Officer
October 2021 - present

Claire has had a varied career with extensive experience gained through engineering, data and architecture roles in the private sector and senior public sector roles focussed on digital and organisational transformation, legacy technology, data and digitalisation.

Claire holds a Masters in Technology Management. She has held senior roles in a variety of government organisations such as NHS Digital, Department for Work and Pensions and Homes England. More recently Claire was part of the senior leadership team responsible for merging NHS Test and Trace, Public Heath England and Joint Bio Security Centre to create the UK Health Security Agency.

Rose Braithwaite
Chief Finance Officer
February 2023 - Present

Rose is a qualified chartered accountant who trained with the National Audit Office. She has extensive experience as a finance leader across government and as a non-executive board member of a housing association and mental health charity.

Rose joined the MHRA as Finance Director in January 2022 and successfully led the revision of our agency statutory fees, supported our transition from a trading fund and laid the foundations for the MHRA's Corporate Plan 2023-26, working closely with 'One Agency' Leadership Group (OALG) colleagues. She was promoted to Chief Finance Officer at the beginning of February 2023.

Previous Executive Directors

- Jon Fundrey, Chief Operating Officer, February 2016 – April 2022
- Joann Passingham – Chief Finance Officer (Interim), May 2022 – June 2022
- John Taylor – Chief Finance Officer (Interim), August 2022 – February 2023

Attendance at Board and Assurance Committees in 2022/23

Member	Role	Board attended/ eligible	ARAC* attended / eligible	ODRC** attended/ eligible	PSEC*** attended/ eligible
Stephen Lightfoot	Chair	11 (11)	-	-	-
June Raine	CEO/AO	11 (11)	5 (8)	6 (6)	3 (4)
Marc Bailey	Chief Science & Innovation Officer	10 (11)	-	-	4 (4)
Junaid Bajwa	NED	10 (11)	-	6 (6)	-
Rose Braithwaite	Chief Finance Officer	2 (2)	8 (8)	1 (1)	-
Amanda Calvert	NED	11 (11)	7 (8)	6 (6)	-
Alison Cave	Chief Safety Officer	11 (11)	-	-	-
Graham Cooke	NED	11 (11)	-	-	4 (4)
Jon Fundrey	Chief Operating Officer (until April 2022)	1 (1)	-	1 (1)	-
Paul Goldsmith	NED	11 (11)	5 (8)	-	-
Claire Harrison	Chief Digital and Technology Officer	11 (11)	-	-	-
Haider Husain	NED	10 (11)	-	6 (6)	-
Mercy Jeyasingham	NED	11 (11)	-	-	4 (4)
Raj Long	NED	8 (11)	-	-	2 (4)
Joann Passingham	Chief Operating Officer (interim from May 2022 to June 2022)	3 (3)		-	-
Laura Squire	Chief Healthcare Quality and Access Officer	10 (11)	-	-	4 (4)
John Taylor	Chief Operating Officer (interim from August 2022 to February 2023)	3 (4)	-	3 (3)	-
Glenn Wells	Chief Partnerships Officer	9 (11)	-	-	-
Michael Whitehouse	NED	10 (11)	8 (8)	-	-

The MHRA Board met in public six times during the year and in private committee five times during the year. This approach enabled the Board to fulfil its Terms of Reference, contribute to the early development of new strategies and participate in Board training and development activities.

Executive Committee and management committees

The Chief Executive is supported by the Executive Committee (ExCo), which is responsible for the effective day-to-day leadership and management of the MHRA. The ExCo is responsible for ensuring optimal use of resources, structures and controls within the agency as well as being responsible for operational and regulatory decisions.

The ExCo works with the Board to develop strategic and corporate plans to deliver the MHRA objectives and enable performance monitoring against targets. The ExCo takes evidence-based and informed decisions to enable the MHRA to deliver and to manage risks to our performance. The ExCo relies on advice from officials and effective decision making throughout the organisation.

The ExCo is formed of the Chief Executive, who Chairs the Committee, and:

- Chief Science and Innovation Officer
- Chief Healthcare Quality and Access Officer
- Chief Safety Officer
- Chief Partnerships Officer
- Chief Finance Officer
- Chief Digital and Technology Officer
- Chief People Officer (in recruitment)

Additional advisory members are the Directors of Governance, Director of Communications and Engagement, Director of Human Resources and Director of Transformation, with the role replaced by Director of Delivery during the year.

The Chief Operating Officer role was vacated in April 2022 and the financial aspects of this role have been held by interim Chief Finance Officers for the majority of the financial year, with the people aspects of the role being covered by the Director of Human Resources as an interim arrangement. The Chief Operating Officer held the role of senior executive with oversight of Finance, Human Resources, Estates and Laboratory Services, Procurement and Commercial. A decision was taken in October 2022 to formally separate the role of Chief Operating Officer into two new posts of Chief Finance Officer and Chief People Officer. The new permanent Chief Finance Officer was appointed in February 2023 and leads the development of our new Fees Strategy and retains responsibilities for our Finance, Commercial and Infrastructure Laboratory Services functions. The Chief People Officer will lead the development of our new People Strategy and will be responsible for our Human Resources and Organisational Development function. Recruitment of the new Chief People Officer is underway.

Key responsibilities of the ExCo include:

- Taking public health and regulatory decisions, particularly where decisions are novel, complex or could have significant strategic, public health or reputational impact
- Developing strategic corporate and business plans for approval by the Board
- 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
- Setting and driving an enabling culture, which centres patients at the heart of the MHRA's responsibilities

The ExCo is supported by management committees, each with a different focus across the MHRA's operational and corporate business. The management committees are Chaired by senior leaders and provide assurance to the ExCo. Decisions and recommendations are escalated to the ExCo if the decision exceeds the management committee's delegated authority or is of such a nature that it demands urgent consideration by the ExCo directly.

The ExCo meeting attendance:

Member	Role	ExCo meetings attended/eligible
June Raine	Chief Executive (Chair)	21 (21)
Marc Bailey	Chief Science and Innovation Officer	19 (21)
Alison Cave	Chief Safety Officer	18 (21)
Laura Squire	Chief Healthcare Quality and Access Officer	21 (21)
Glenn Wells	Chief Partnerships Officer	19 (21)
Claire Harrison	Chief Digital and Technology Officer	18 (21)
Rose Braithwaite	Chief Finance Officer	6 (6)
John Taylor	Chief Finance Officer (interim)	8 (8)
Joann Passingham	Chief Finance Officer (interim)	5 (5)
Jon Fundrey	Chief Operating Officer	1 (1)
Carly McGurry	Director of Governance	18 (21)
Davinder Virdi	Director of Transformation	6 (8)
Rachel Bosworth	Director of Communications and Engagement	16 (21)
Vanessa Birchall-Scott	Director of Human Resources	15 (21)
Mick Foy	Director of Delivery	9 (11)

Role of the Accounting Officer

The Chief Executive of the MHRA has been designated as the Accounting Officer by the Principal Accounting Officer of the Department for Health and Social Care, Sir Chris Wormald, on behalf of the Secretary of State for Health, The Rt Hon Steve Barclay MP (25 October 2022-current and 5 July 2022 – 6 September 2022), The Rt Hon Therese Coffee MP (6 September 2022 – 25 October 22), The Rt Hon Sajid Javid MP (26 June 2021- 5 July 2022). The Principal Accounting Officer DHSC has appointed a senior Departmental Sponsor, Elizabeth Woodeson, as the MHRA's designated consistent point of contact within the Department.

The Chief Executive of the MHRA is responsible for the leadership and management of the agency, the delivery of its objectives and for ensuring that there are effective governance arrangements and systems of internal control. The Chief Executive is supported by the unitary Board in the effective delivery of services and overall performance of the organisation. Further information about our Governance structure can be found in on page 55 of this report.

Specific responsibilities of the Chief Executive as the Accounting Officer for the agency include:

- Safeguarding the use public funds
- Ensuring propriety, regularity, value for money and feasibility in the handling of public funds
- Responsibility for the day-to-day operations and management of the MHRA
- Ensuring governance, decision-making and financial management operates as set out in Managing Public Money (Managing Public Money, Box 3.1 - standards expected of the accounting officer's organisation) https://www.gov.uk/government/publications/managing-public-money
- Ensuring the discharge of statutory functions and ensuring clarity about the legislative requirements associated with them

The MHRA complies with Managing Public Money, Principles of the Corporate Governance set out in Annex A of Part 3 of Cabinet Office Public Bodies Handbook and the DHSC Code of Business Conduct, the Civil Service Code and the Civil Service Management Code. Our relationship with the Department of Health and Social Care and our accountabilities to them are described in the DHSC and MHRA Framework Document; which can be accessed on the Gov.uk website: https://www.gov.uk/government/publications/dh-and-mhra-framework-agreement

The framework document is currently being refreshed and a new agreement will be published shortly.

2.2 Statement of Accounting Officer's responsibilities

Under Section 7(1), (2) and (5) of the Government Resources and Accounts Act 2000, HM Treasury has directed the Medicines and Healthcare products Regulatory Agency ('the MHRA') to prepare for each financial year a statement of accounts in the form and on the basis set out in the Accounts Direction.

The accounts are prepared on an accruals basis and must give a true and fair view of the state of affairs of MHRA and of its income and expenditure, Statement of Financial Position and cash flows for the financial year.

In preparing the accounts, the Accounting Officer is 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 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 the Chief Executive, Dr June Raine DBE, as the Accounting Officer of the MHRA. The responsibilities of an Accounting Officer, including responsibility for the propriety and regularity of the public finances for which the Accounting Officer is answerable, for keeping proper records and for safeguarding the agency's assets, are set out in 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 MHRA's auditors are aware of that information. So far as I am aware, there is no relevant audit information of which the auditors are unaware.

2.3 Governance statement

Development of our Governance Framework

This year we have continued to embed robust governance systems within our new 'One Agency' structure to underpin our operational framework. Although different elements are at different stages of development, we are already benefitting from an increasing maturity within our risk management and in the operation of the Board and Committees. As we further mature our systems we are defining, aligning and refining our Governance Framework to better support decision making and accountability within the MHRA.

This year the Governance Office team has completed recruitment of key roles and is now operating close to full capacity. The focus this year has been:

- Redefining our Framework Agreement with Department for Health and Social Care
- Embedding and maturing our Risk Management systems, ensuring that we are managing the right risks in our new 'One Agency' structure
- Defining our decision-making structures and ensuring clarity of decision-making processes within the Committees
- Revising our approach to management of Conflicts of Interest within our new 'One Agency' structure
- Improving the way we work with Government Internal Audit Agency to ensure greater value from audit outcomes and timely provision of evidence to support audit closure

Getting our governance structures right is fundamental to ensuring the successful operation of the MHRA as a whole. The agency is working through significant change in multiple areas of its operation and continues to be stretched across many delivery priorities as a result. Many of these are long-term changes, whether tackling legacy technology or establishing new regulatory frameworks in legislation. This report sets out the progress we have made in implementing improvements during 2022/23 as one year of a multi-year programme.

Board and Board Assurance Committees – performance and effectiveness

The Board undertook development sessions in March 2022 and August 2022 with some external input to continue to improve its performance. In these development sessions the Board was found to be making good progress with clear impact, and we have built upon this foundation throughout the year through a programme of governance work to increase cohesion of the Board and the Board Assurance Committees and to create a forward plan which enables the Board to consider issues at the appropriate stage in their development.

In January 2023, the Governance Office conducted a light-touch review of the effectiveness of the Board Assurance Committees and gathered feedback from members on joint working and improvements to the assurance provision. This was the first joined-up review of the Board Assurance Committees.

The review found that the Board Assurance Committees have facilitated a wide range of work to be considered by the Board from across the agency. For example, the PSEC has been instrumental in helping the MHRA to navigate our priorities in response to the IMMDS review report. The ODRC has supported the MHRA's Transformation Programme, bringing substantial benefit to the clarity of delivery and desired outcomes. The ARAC has been instrumental in helping the agency to address our financial sustainability as well as providing constructive challenge across the range of our essential functions, such as risk and internal audit.

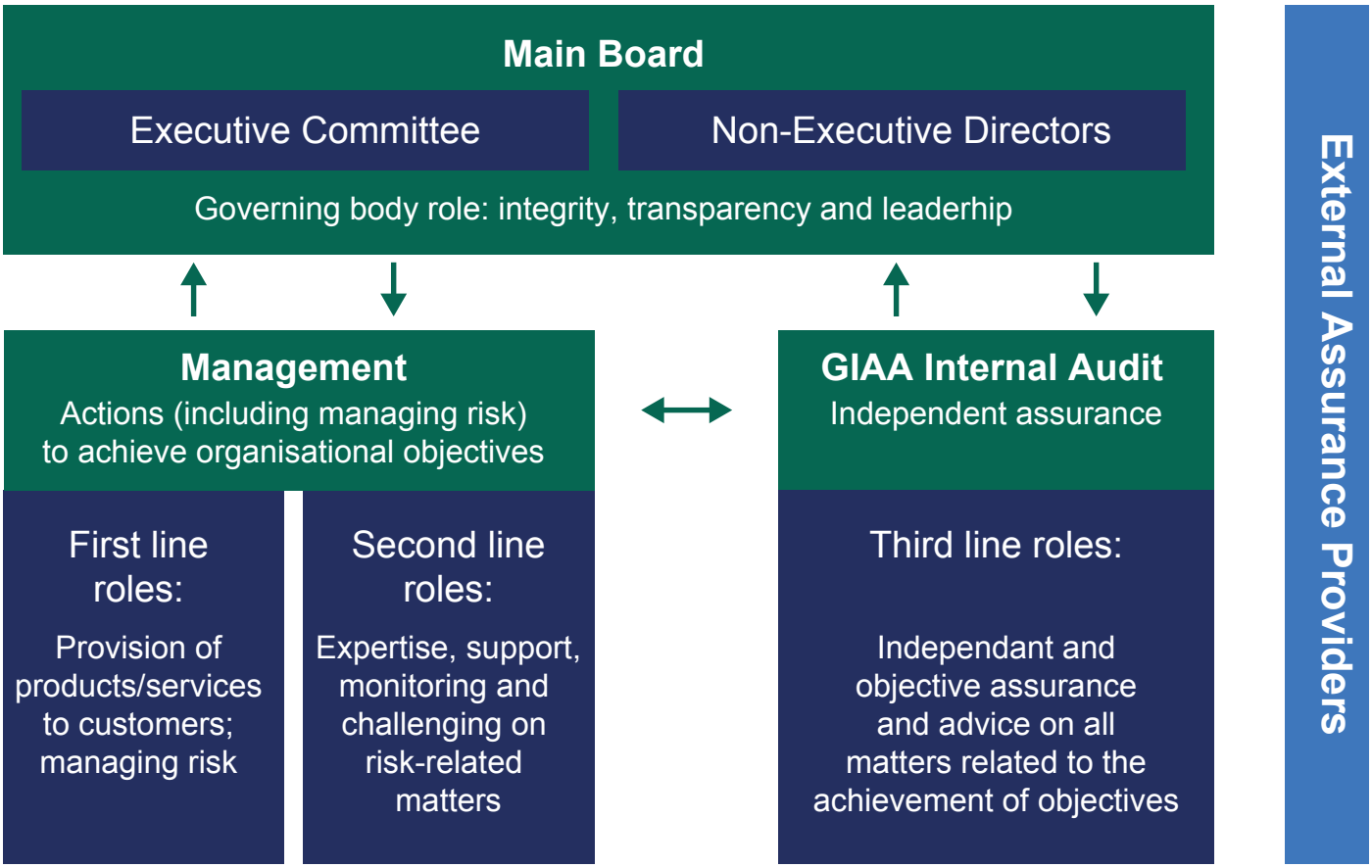
The Board Assurance Committee review highlighted that members felt all three Board Assurance Committees were operating successfully, with a higher level of impact recorded for the ARAC, which has been established the longest and therefore had more established ways of working.

The Governance Office has worked throughout the year on increasing the visibility of the work plan for the Board and the Board Assurance Committees through development of a Board forward schedule and aligned forward schedules for each of the Board Assurance Committees. This has enabled a more effective flow of information between the Board Assurance Committees, enabling active assurance monitoring and significantly reducing instances of inadvertent duplication.

Additionally, as part of the development programme, the Governance Office has performed a full revision of Terms of Reference for the Board, Assurance Committees and Executive Committee, leading to the inclusion of increased clarity on the roles of the Board in support of the Chief Executive, and the addition of aligned schedules of reserved matters which provide clarity on delegation and decision making between the Board, the Board Assurance Committees and the Executive Committee. The management of Conflicts of Interest has been strengthened in all Terms of Reference, in recognition of the importance of the appropriate and robust management of these to the agency.

Risk and Internal Control Framework

We use the Institute of Internal Auditors 'Three Lines Model' as a framework to provide a structure around risk management and internal controls within the agency. This framework defines roles and responsibilities in different areas and the relationship between those different areas. It also outlines the role of Government Internal Audit Agency and the audit programme in assuring the effective management of risk.



Key:

- Accountability, reporting
- Delegation, direction, resources, oversight
- Alignment, communication, collaboration and coordination

The first line of control sits in the operational areas where we manage risks and deal with issues on a daily basis. We use our risk registers to record, review, discuss and manage risks across the organisation. Risks are recorded on local risk registers in operational areas with a Corporate Risk Register at the corporate level to manage key strategic risks.

The second line of control is delivered through our committees and our dedicated teams, who support managers to help ensure risk and controls are effectively managed. Those teams oversee risks, controls and compliance, for example our Quality Team, our Risk Management team, and management committees which review risks and issues and support the MHRA to manage them.

The third line of control provides independent assurance on the operations, functions and activities of the agency and relevant risks. Government Internal Audit Agency perform this role for the MHRA through the programme of audits which is planned to align with our risks and controls framework and aims to identify and support improvement of areas of control weakness. This is supplemented by additional external review as necessary, such as with the Security Threat and Risk Assessment (STARA) review of our cyber security.

Risk management

The MHRA follows the principles and good practice outlined in the Government's Orange Book https://www.gov.uk/government/publications/orange-book. Our approach to risk management seeks to identify risks, assess them and mitigate to the appropriate level. It recognises that it is not possible to eradicate all risk, particularly given the challenging objectives the MHRA seeks to deliver and the resource limitations.

Risks are managed through the risk management governance framework outlined above, supported by the Head of Risk and Audit. This year the Head of Risk and Audit has begun a full refresh of the risk management framework and implementation of new risk management processes.

The Corporate Risk Register and the process which supports its development continue to be scrutinised and challenged by the Risk and Assurance Group (RAG) management committee and Audit Risk and Assurance Committee (ARAC) Board Assurance Committee on a regular basis. ARAC provides independent challenge to the agency's management in order to assure the Accounting Officer and the Board that risks are being appropriately identified and mitigated. The Chairs of ARAC and RAG both provide regular assurance reports to the MHRA Board and Executive Committee (ExCo), covering specific risks and the process for risk identification and mitigation. Additionally, the Board has discussed risk three times during the year, as well as supporting the refresh of the Corporate Risk Register.

Our risk journey

Throughout 2022/23 the Governance Office has undertaken a comprehensive review and refresh of the strategic risks on the Corporate Risk Register to ensure these are appropriate and enable effective grip on the risks, issues, and opportunities the MHRA faces.

The key strategic risks were monitored and reviewed regularly throughout the first half of the year by all risk leads and Chief Officers to ensure mitigations remained effective and appropriate and to provide updates on risk movement. The Risk and Assurance Group and ExCo monitored the full risk profile at least quarterly.

In parallel, the Governance Office commenced a programme of review to explore the focus of the risks on the Corporate Risk Register, identify new risks emerging and facilitate the total refresh of the risks and mitigations. This was approached through dedicated risk conversations with Chief Officers and use of a risk planning tool with senior staff across the agency, designed to support the purposive identification of risks, issues and opportunities across operational areas, and to assist review of local risk registers. This risk harvesting exercise informed discussions in our Agency Horizon Scanning Risk meeting attended by ARAC and ExCo members in September 2022.

In October 2022 recruitment of a new Head of Risk and Audit completed, coinciding with agreement by the Board, ARAC and RAG members of the focus and risk themes for our new refreshed Corporate Risk Register. The new Head of Risk and Audit continued the journey to refresh our risk management approach with the introduction of regular risk meetings with Chief Officers and risk leads to agree the detailed focus and mitigations of each of our new corporate risks. Alongside the design of our new Corporate Risk Register, work commenced to increase the maturity of risk management across the organisation, adding the bottom-up approach for identification and management of the risks to our existing top-down approach, facilitating identification of risks at source and enabling faster mitigation.

There have been variances in the local risk management approach within operational areas throughout the year. Operational areas which have been brought together in the new MHRA structure have continued to use historic local risk registers, with a spectrum of maturity in their risk approach. In recognition of the need to embed a single risk approach across the MHRA, and a desire to better link the local risks with the corporate risks to ensure effective risk

flow, a new Local Risk Template and scoring matrix was provided to all operating groups in January 2023 and the Head of Risk and Audit has begun working across the agency to support a single approach to management and scoring of risks.

During 2022/23 we have also procured a new dedicated risk management software tool which will improve visibility of risks across the agency by providing a single tool for managing risks and mitigations across the new operating model and structure. This is due to go live in early 2023/24.

A lot of work has been done to maintain and improve our risk management approach. It has been evident that, throughout the year, we have continued to manage our risks effectively, but there was a need for a new aligned approach within the new 'One Agency' structure. We are confident that the coming year will see continued benefits from our efforts to align, refresh and mature our approach to risk management.

Our risk ambition

The refresh of the risk management framework will continue into next year and is due to complete in September 2023. The endpoint of the journey aims for alignment of risk assessment with agency's strategic objectives and an established risk appetite across different risk areas, with effective escalation routes which facilitate appropriate visibility of risks and the speedy implementation of mitigations.

Key corporate risks 2022/23

We recognise the complexity and interconnectivity of the corporate risks the agency has handled this year. Key risks considered this year include

COVID operational delivery - Risk to the timely assessment of COVID-19 vaccines and medical products was mitigated and closed as the MHRA approved five vaccines for UK deployment and several therapeutic treatments for COVID, as well as monoclonal antibodies and antivirals.

Future operating model - The risk of future operating model failure was one of the highest risks at the beginning of 2022/23 as we completed the first phase of our Transformation Programme. As we approached the second phase focused on refining the design of our core service delivery, this risk has been closed off and a new risk around the development of the new services and design of our ways of working has been created in the register. Areas of focus for this risk have been identified and projects are being initiated to mitigate this risk.

People, culture and capability - Having the right people, with the right capability in the right roles is important. Therefore, people, culture and capability remains our primary operational risk and issue following the restructure of the MHRA. Although the agency's high turnover is now on a downward trajectory, some key resource gaps have existed throughout the year. A challenging employment market across all sectors/roles, our ability to match private sector salaries and the increasing cost of living have made recruitment to some of our specialist vacancies difficult. In parallel, we are working hard to develop our culture to help us to retain staff, create a sense of purpose and belonging, foster a positive work environment and support employee engagement and satisfaction.

Patient and public engagement - Appropriate, proportionate, and meaningful engagement of patients and public is a key priority of the MHRA and therefore the risk of us not delivering on this commitment is one we are managing closely. We are addressing this risk through multiple workstreams, based on our Patient Involvement Strategy which was published last year. We have increased the size and capability of our internal patient engagement team during this year and introduced a mandatory patient engagement e-learning for all staff to develop greater knowledge of and confidence in patient engagement. We have supported groups across the agency in patient engagement and have led engagement on a number of safety issues. We have started to build stronger relationships and networks with other patient involvement players across the health system, and with key external organisations.

Technology and cyber security - Technology and cyber security both remain in our corporate risk register from last year, driven by the higher levels and sophistication of cyber threat against the UK Government with well-resourced and competent threat actors seeking to disrupt national infrastructure and services. We are currently replacing legacy 'end –of-life' technology to improve our resilience. A comprehensive series of cyber security reviews are being developed for 2023/24 to support us in strengthening our defences.

Health and safety - The risk of the MHRA breaching Health and Safety legislation was escalated to the strategic level during 2022/23, due to the receipt of a series of recommendations from the Health and Safety Executive resulting from planned inspections and reported incidents. Effective management of health and safety is essential for the MHRA, with additional heightened requirements due to the scientific laboratory work which we undertake at our South Mimms laboratory site. This year this risk, and its mitigations, have been closely monitored by the Board, Executive Committee, Risk and Assurance Group and Audit Risk and Assurance Committee. Extra funding has been approved and allocated to train additional health and safety resource, as well as targeted training for other key roles. The risk has decreased slightly at the end of the year, with the closure of several HSE actions and work ongoing to ensure robust health and safety systems are in place. We have welcomed the HSE guidance and take confidence from the awareness and willingness of our laboratory staff to highlight safety issues and rapidly report accidents and dangerous occurrences, as this enables us to address risks and mitigate future occurrences. We are committed to ensuring that the right mitigations are in place to protect our staff from harm in the critical roles they deliver.

Additional controls

Counter-fraud, bribery and corruption

The MHRA is committed to preventing and deterring cases of fraud, bribery and corruption and, where they do 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 to increase compliance with the Counter Fraud Functional Standard.

When assessing fraud risks, we identify actions to mitigate and reduce these risks. We now use the Cabinet Office format for risk-assessing fraud and will continue to move our fraud risks over to this format in the coming year to help strengthen the robustness of our mitigations.

We report to, and receive assistance from, the DHSC Anti-Fraud Unit, who provide specialist expertise to support our investigation of 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, the Audit Risk and Assurance Committee receives notification of all fraud and error cases. The ARAC also receives and reviews an annual report setting out counter fraud activities, risk assessment processes, a summary of cases and a proposed action plan for the following year.

Raising a concern / whistleblowing

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

As part of their induction, new 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. There are links on our internal staff 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.

We received one formal concern that was raised under the Raising Concerns Policy and Procedure in this year, which we investigated in accordance with our stated policies and subsequently found no evidence of wrongdoing but identified some improvements to increase visibility of decision making. Staff approached the MHRA's Nominated Officers under the Civil Service Code throughout the year and were provided with support and advice on how to proceed. This compares with no formal concerns being raised in 2021.

We are committed to ensuring that staff feel safe and able to speak up about any concerns that they may have. We raise awareness through targeted activities throughout the year such as Civil Service Speak Up week and, in 2023/24, we will be engaging with operational teams to increase awareness of how to raise a concern and how these would be handled.

Corporate Conflicts of Interest

Corporate Conflicts of Interest (COIs) can arise where one part of the MHRA has worked on an activity, such as creating data which could be included in a regulatory submission, on which another part of the agency is then required to make a decision. We are committed to ensuring we identify and mitigate any corporate Conflicts of Interests appropriately and transparently.

We have refreshed our management of corporate Conflicts of Interest this year to ensure an aligned approach across our new 'One Agency' structure, by renewing the membership and revising the terms of reference of our COI Management Group. This COI Management Group considers and agrees mitigations for potential corporate COIs to enable, where possible, important public health work to continue. We are reviewing the Corporate COI Policy and Procedure, which will be published on our website in 2023/24. As part of our commitment to transparency, details of the management of our Conflicts of Interest and our policy are published on our website, with cases redacted to protect any sensitive or identifiable data: https://www.gov.uk/government/publications/mhra-policy-for-handling-conflicts-of-interest

Human rights and staff wellbeing

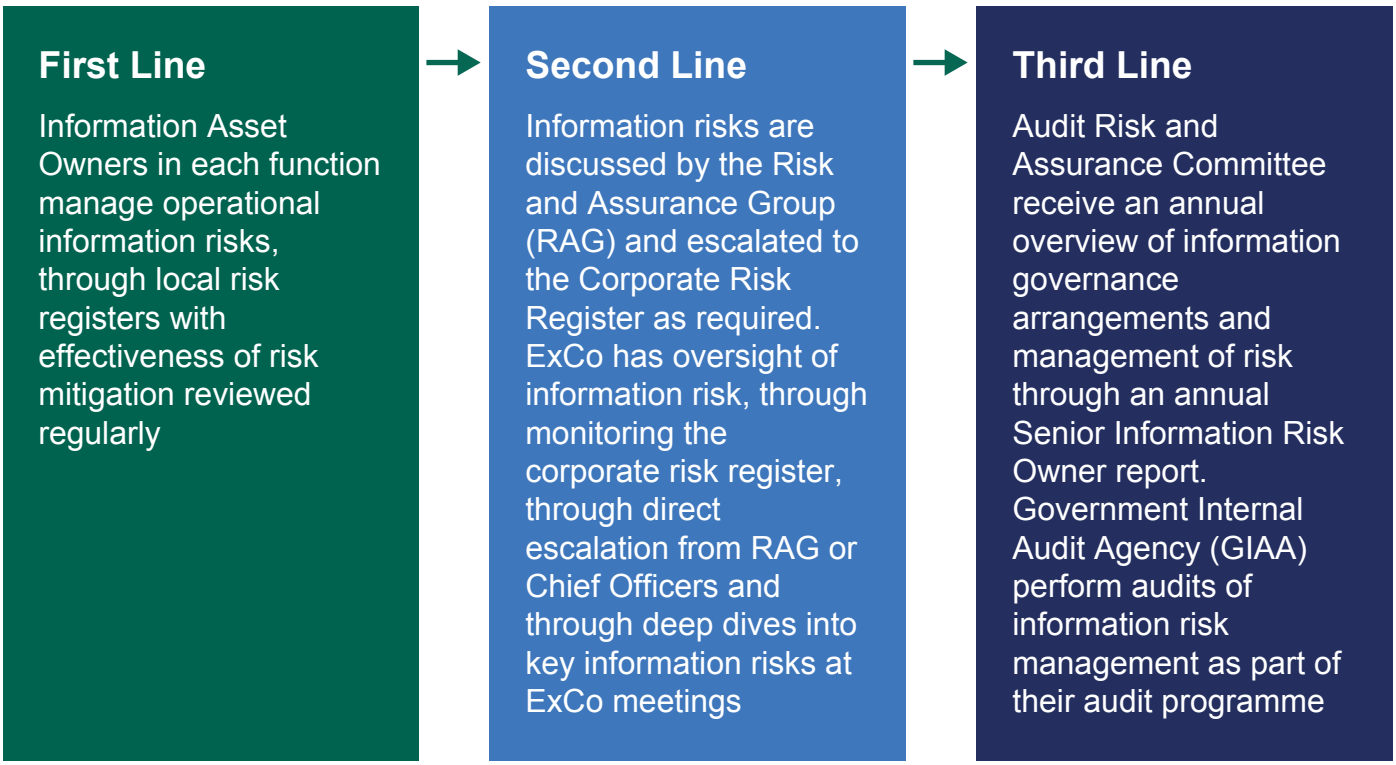
We recognise that we deliver our excellent services through a talented and developed workforce and we strive to be an employer of choice. We implement and support a range of policies and practices that aim to protect the human rights of our staff, including policies on Dignity at Work, Grievance and Whistleblowing. We offer a wide range of initiatives to support diversity, inclusion and wellbeing. We have recognised trade unions for staff, and we also support a range of staff-led 'networks', designed to support and give a voice to staff on particular issues.

We have a network of mental health champions and mental health first aid personnel who are trained to support staff with their wellbeing, and we are currently working to ensure that all staff are aware of how to access support when they need it. Additionally, staff have access to a range of support through our employee assistance programme, including legal advice, advice on debt management and counselling support.

Information governance

The MHRA 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 provides assurance to the Senior Information Risk Owner (SIRO), Digital, Data and Technology Board, and the MHRA Board that information and data assets and associated risks are effectively managed.

Management of information risk is based around the three lines model:



MHRA staff also attend the Department of Health and Social Care Information Governance meetings to enable cross-government alignment.

The MHRA continues to prioritise cyber risk management and has taken positive steps to improve data security against a background of ongoing and increasingly sophisticated cyber threat. These cyber-attacks are expected to increase in intensity and sophistication than those seen previously, as nation state actors and well-resourced criminal groups seek to disrupt our business.

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 the cyber security alerts from the NHS Digital and National Cyber Security Service and have taken proactive mitigating actions. This year there have been no significant successful cyber security attacks on the agency.

The MHRA has undergone a Security Threat and Risk Assessment (STARA), commissioned by Department of Health and Social Care and carried out by British Aerospace. This comprehensive review of information security across the agency has given us a clearer idea of the capabilities of the threats we face and the strength of our controls to defend against them. We have included actions to implement the recommendations of the STARA review in our security improvement plan, which has given the MHRA a foundation to align to the Cyber Assessment Framework (CAF) that will be required of all ALBs under the government security strategy.

in 2022/23 no security incidents were reported. There were 842 reports from staff of phishing emails. Our security systems have ensured that on average the number of suspicious emails blocked every 30 days was:

- 300 Malware emails
- 9000 Phishing emails
- 35000 Spam emails

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 completed the Data Security Protection Toolkit and continue to perform well against the National Data Guardian's data security standards.

We have worked hard to improve compliance and raise awareness of our obligations under UK data protection legislation and to embed data protection by design. Over the past year, we have developed a cross-agency data sharing agreement template for use with non-Crown independent data controllers and have mitigated risks through the completion of data protection impact assessments and updating security management plans with our core IT suppliers. We have continued to handle all subject access requests and data breaches in a timely manner.

All new starters in the MHRA are required to complete our Digital Ways of Working training and all staff must complete the Civil Service Learning Security and Data Protection 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.

Personal data incidents

The MHRA has formally reported two data breaches to the Information Commissioner's Office (ICO). These were 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 one complaint referred to it by the ICO in relation to a subject access request handled over the past year. Following an internal review conducted by the MHRA Data Protection Officer, the ICO advised that the agency had complied with data protection law as required.

Internal control issues identified 2022/23

We set out in our annual report last year that we had begun to identify and resolve a series of challenges and opportunities in our systems of internal control as part of our MHRA transformation programme. We knew that we were just at the beginning of a journey and that we would learn more as we progressed. We also knew that 2022/23 would be a further period of intense change with multiple, competing priorities right across the agency. This has certainly proven to be correct and has added further complexity to our work to develop and maintain sound systems of governance and control.

There is no doubt about the criticality of the work underway to identify and, where necessary, address historic approaches to our internal controls and governance processes which are not now reflective of best practice. The MHRA Board and the Executive Committee understand that solid foundations of governance and control create the framework for the agency to deliver on its public health aims at a global level. This is reflected in the amount of work underway across the organisation to address these challenges, dismantling systems and ways of working that no longer deliver for us and for the UK and building better, more effective approaches in their place. Despite the level of resource and commitment to successfully concluding this work, we know that this is not an overnight fix.

We began 2022/23 with a clear set of priorities from last year relating to our legacy systems and associated processes, effective use of data across the agency and cultivating a new culture to support the proactive and enabling regulator that the MHRA is set to be. These priorities sat alongside another full year of anticipated transformation, notably in redesigning our core operational services to eliminate inefficiencies and ensuring we were delivering maximum public health value. In turn, progress on these endeavours depended on progress with our other priorities – completing recruitment to our new organisational structure with appropriate expertise and capability, alongside rapid development of new supporting regulatory technology systems to automate and simplify service delivery in keeping with our aim to be a world-leading regulator. While juggling all of these priorities, we needed to continue to deliver on other strategic commitments, such as a wealth of new legislation to embrace the opportunities presented by a stand-alone regulatory system and development of programmes and initiatives to support the government's commitment to capturing and implementing cutting edge innovation for the benefit of patients and the healthcare system.

This level of change, within a highly condensed time frame and following a significant change in both our financial status (ceasing to operate as a Trading Fund) and in our regulatory systems (following EU exit), not to mention the ongoing effects of the COVID-19 pandemic, is far from ideal. It means the MHRA is trying to effect change in all directions and all areas of the organisation at the same time, with limited resources and staff whose resilience has been, at best, severely tested. It can also mean that the time it takes to effect sustainable change is lost in the overwhelming need to achieve change now. As a result, we have continued to recognise and grapple with a number of control issues over the course of this year, as set out throughout this report, and a number of underlying challenges:

- Our ability to rapidly implement priority commitments. Whether establishing the underpinning economic, legal and partnership arrangements for Innovative Licensing and Access Pathway (ILAP) or making progress across our service redesign work, speedy implementation remains a challenge. DHSC called attention to the need for sufficient clarity about decision-making arrangements in their stage-gate review of our transformation programme
- Our ability to maintain our core operational performance in the face of significant vacancies over the course of the year, while simultaneously redeveloping services and supporting the design of critical new technology systems. This is an unsurprising

consequence of multiple competing priorities but also speaks to the need for exacting prioritisation and cool appraisal of difficult options
- The pace of culture change remains a source of concern, particularly in relation to roles, responsibilities, ownership and authority. This connects profoundly to the challenges above of being able to drive performance and implementation while taking tough priority decisions on our most valuable contributions to public health
- As described in the corporate risks section on page 78, our health and safety compliance has also been an area of significant focus over the course of this year. Stemming primarily from the need to have the right expertise in place in critical health and safety roles, there has also been a clear need to ensure that other agency policies, such as the management of organisational change policy, also support our commitment to protecting the health and safety of all our staff
- Issues with payroll control are yet to be fully resolved. The NAO management letter and this year's audit have identified that further work is needed to clarify roles and responsibilities and appropriate operation of checks on payroll variances

Despite this, and fully acknowledging that we have further to travel, the MHRA has dedicated significant effort to tackling these issues this year. Highlights of these efforts include:

- Process improvements in our core financial controls, in advance of technological solutions that will follow, connected to our new regulatory systems. These improvements, coupled with clear ownership of relevant roles and responsibilities, have seen improvements to our order to cash systems and substantially addressed our historic debt profile
- Significant engagement across government and externally on the development of our data strategy and continued process improvement on corporate data flows
- Relentless focus on supporting culture change across the MHRA through development and implementation of both our Culture Action Plan and Leadership Strategy, including roll out of leadership training to all level-3 staff in the agency, focused specifically on how to build high performing teams. We have also redeveloped our organisation values through staff consultation to continue to support the evolution of our culture, as well as embedding our senior leadership network to address and consider agency priorities, both operational and corporate, and implement actions throughout their teams. Ahead of a launch in early 2023/24, we have also drawn on good practice across government to support us in establishing our first Shadow Executive Committee, comprised of members of staff in grades below SCS, drawn from across the organisation. The Shadow group will join formal monthly meetings of the Executive Committee to provide insight of the staff perspective to factor into decision-making
- We have succeeded in recruiting new employees into the majority of our critical roles in our new organisational structure, despite a notably challenging labour market. We have made the most of our flexibilities to bring in the right expertise and we have launched our first graduate scheme. We will grow this scheme over the coming year to ensure we build capacity and meaningful succession planning into MHRA operations
- We have moved to the next phase of our transformation programme, with a new Director of Delivery to drive progress in the redevelopment of our services. To address the findings of the stage gate review, we have redeveloped the governance framework for the programme to bring greater clarity to the decision-making structures and accountabilities

- In a similar vein, we have made further changes to our membership of the Executive Committee's sub-groups to make better use of the expertise of the next management layer in the corporate management of the MHRA. This has significantly increased the capacity of those forums, which over time will free the Executive Committee to focus on the most strategic challenges and decisions in support of our ambition to operate with agility. We are already seeing the benefit of this change in bringing people together to tackling the organisational challenges, as well as benefitting from genuine cross-agency input
- We have worked to improve our risk management approach, building on last year's Internal Audit review of assurance mapping. As we have set out in the risk journey section (page 77) we have completely overhauled our approach at the corporate level and are now working to support all areas of the business at differing levels of maturity in advance of redefining our risk appetite in 2023/24. The significant strengthening of our approach to risk, building on the work of recent years, is again already bearing fruit, enabling the right discussions about how to balance the many competing priorities
- We have equally improved our utilisation of internal audit, both by improving the alignment between areas of focus with our areas of risk and through developing much tighter management of management actions to minimise the time that the MHRA is exposed to any weaknesses in its internal controls. As set out above, some of the issues are not a quick fix but we will continue to track and monitor progress appropriately until all actions are complete and our systems, controls and processes meet the necessary standard
- Finally, our work to meet the Government's Functional Standards is well underway as set out on page 87

This work, and our commitment to continue to address areas where our historic or legacy approaches are no longer meeting expectations or exemplifying best practice, continues seamlessly into the next financial year, building on the significant work undertaken since the beginning of our transformation programme. Looking to the year ahead, our Corporate Plan reflects our commitment to operate as a trusted and transparent regulator, deliver reliable performance and build a more responsive customer service. Our supporting business plan sets out the actions we will take this year to begin to deliver on the strategic ambitions in our Corporate Plan as well as our expected performance across our core operational services. For the first time, our business plan brings together our strategic ambitions with our core operational services and our supporting activities, such as operating a quality system or ensuring effective health and safety systems to protect staff. This one amalgam of agency objectives and commitments for the year ahead will support effective prioritisation, effective risk management and effective monitoring of our achievements. It will enable a continuing and resolute focus on the progress we have made so far and the areas we continue to develop and improve.

We are under no illusions that 2023/24 will be of equal challenge and will continue to demand excellence and resilience from all areas of the agency to get to our desired state. I am grateful for all the commitment of staff in continuing to work so hard to grasp our opportunities and accumulate our progress as we continue our journey through this challenging change landscape.

Government Functional Standards

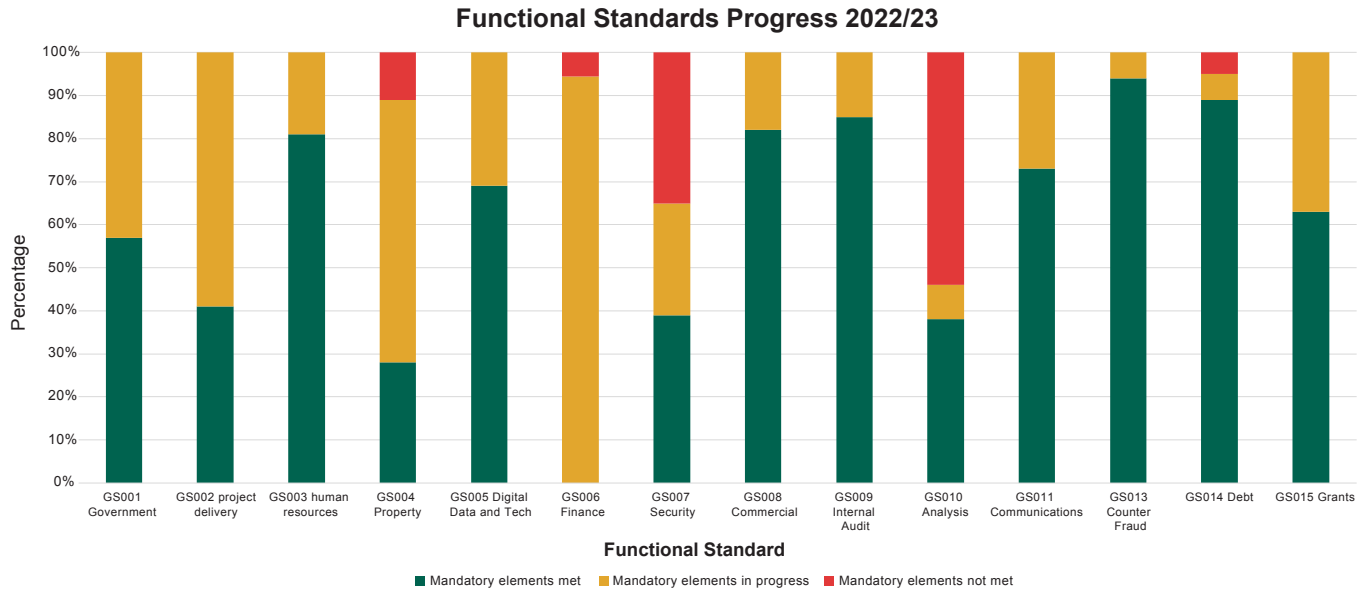
The UK government has created a suite of management standards and associated documentation to create a coherent, effective and mutually understood way of doing business within government organisations and across organisational boundaries, and to provide a stable basis for assurance, risk management, and capability improvement. Further information on the Functional Standards can be found on the gov.uk website: https://www.gov.uk/government/collections/functional-standards

Compliance with the Government Functional Standards is now mandated across government since March 2022. The standards contain mandatory and advisory elements which support governance, planning and assurance of our delivery. Meeting the government standards enables us to focus on continuous improvement and ensure we are aligned with best practice across other Arm's Length Bodies.

Work is underway to enable us to meet all the ten Functional Standards, with variation in maturity across the MHRA. This year each area has undertaken a self-assessment against the mandatory elements, which has then been sense-checked by the Head of Risk and Audit to ensure consistency. Each area has, or is developing, a detailed plan to meet the outstanding elements over the coming year. Some areas, such as the Counter Fraud function, are more advanced in progress towards meeting the functional standards. Four of our functional standards have been peer assessed during 2022/23.

During 2023/24 the Governance Office will perform a full assessment of progress to each of the standards and review the plans to achieve compliance. When areas feel they are meeting the majority of the mandatory and advisory elements we will seek peer assessment as a second line check.

Progress towards meeting the mandatory elements of the Functional Standards at end of 2022/23:



Internal audit

During 2022/23 we have worked hard to increase our engagement and collaboration with the Government Internal Audit Agency (GIAA).

This year we identified that there was an increase in the number of recommendations from internal audit which were not being closed by the due date. Further to this, some recommendations were closed internally without Government Internal Audit Agency receiving evidence to support the closure, leading to a disparity between the registers held at MHRA and GIAA. Governance Office have worked closely with GIAA to address this during the year, working to align the registers, establish new due dates and review open recommendations to ensure they are still current and valid.

Governance Office are leading a programme of engagement aimed at increasing awareness within the agency of the audit processes and the role of GIAA in managing our control environment. Helping staff to understand GIAA's role in supporting the MHRA to identify risks and improve our ability to deliver our strategic objectives is already leading to increased engagement. This was evidenced by the high-quality contributions to the development of proposals for the content of the draft Internal Audit Plan for 2023/24.

Internal audit programme 2022/23

The audit programme was designed to focus on key areas of risk identified in the 2021/22 audit programme, including the MHRA's financial controls, and delivery of key strategic projects essential to the agency's delivery of services in support of patients.

Audit	Focus	Assurance rating
Innovative Licensing and Access Pathway (ILAP)	To provide assurance over the delivery of the ILAP programme including governance arrangements, approval of the business case, finance and resource requirements, patient engagement arrangements and how these inform decision making. The outcome of this audit reflects the findings of the operational environment in place on the 31 March 2022 as this review originally formed part of the 2021/22 audit programme and closure was delayed in 2022/23	Limited
Payroll	To provide assurance that MHRA has effective process in place for payroll activities, including whether there is a robust control environment which allows the accurate and timely payment of staff	Limited
Agency Fees	To provide assurance over the methodologies and processes used to implement the MHRA revised fee structure	Substantial
Core Financial Controls	To provide assurance over the effectiveness of core financial controls in operation over a range of areas fundamental to the delivery of accurate and robust financial reporting, including accruals and prepayment, payment controls, bank and balance sheet reconciliations and assurance mechanisms	Moderate
Cabinet Office Spend Controls	To provide assurance on spending control compliance by Arm's Length Bodies to DHSC. Work conducted as part of cross Health Group assurance activity	Moderate
RMS	To provide assurance over a broad range of programme governance, planning, reporting and assurance arrangements	Moderate
Information Security Awareness - mandatory training	Review of the information security control framework with a focus on education and awareness of staff to latest security threats and how to respond	Limited
Conflict of Interest	Assurance review of policies and procedures in place for management and reporting of Conflicts of Interest for staff and Board members as a core element of the agency's corporate governance framework	Moderate
Patient Engagement (Advisory)	Evaluating the agency's progress towards implementing its Patient Engagement Strategy and assessing the maturity of supporting systems in place	Advisory
Backlogs	A high-level review of the identification and management of backlogs in the MHRA to provide assurance on the processes for managing these and to inform further audits for 2022/23	Advisory

Head of Internal Audit opinion

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

This opinion is based primarily on the work conducted during the year, but also incorporates our cumulative audit knowledge, observations made during attendance at Audit Risk and Assurance Committee (ARAC) and Risk and Assurance Group (RAG) meetings, access to risk registers and other key documentation (including reports and updates produced by second-line assurance teams within the agency and other assurance providers), as well as discussions with management and non-executives.

I am providing a '**Limited**' opinion on the adequacy of the framework of governance, risk management and control within the Medicines and Healthcare products Regulatory Agency (MHRA) for the reporting year 2022/23. This is consistent with that provided in 2021/22. There is evidence of an improving picture in some key areas across the MHRA, although work to properly address all key areas for improvement previously highlighted needs to conclude before I can provide a positive opinion on the strength of risk control and governance arrangements.

My opinion is set within the context of significant structural and operational changes that occurred across MHRA in previous years which have continued to impact its operations during 2022/23, including the loss of its Trading Fund status and the resulting pressures on resources, the impact of EU Exit on the regulatory framework, and the ongoing need to develop and embed new systems and ways of working to fully realise the benefits associated with the MHRA's Transformation Programme.

- The MHRA has been building its **risk management** capacity and capability during 2022/23, and some positive actions have been put in place to ensure that there are solid foundations through which it can mature its risk management approach. The positive work at a strategic level will need to be replicated and embedded across all corporate and functional areas and sufficiently resourced. Work has commenced to assess risk management maturity across the agency and results from this work will help inform a roadmap of activities to support more effective management of risk at all levels of the organisation. Key areas such as articulation of risk appetite across the range of MHRA functions and a more structured approach to horizon scanning to identify emerging risks that could impact the agency's operations will need to be put in place if the MHRA is to optimise the benefits and build on the activity completed to date.
- On the **effectiveness of controls and compliance with required controls** I have seen some improvement in the control environment within finance directorate this year, but there are still weaknesses evident in other areas such as HR where the design and application of controls associated with maintaining the payroll function are not appropriately risk-focused or not operating effectively. We also identified weaknesses in ensuring compliance with completion of key mandatory training for staff to ensure that they are aware of their responsibilities with regards to information security. Some recommendations to improve control weaknesses identified in earlier years have not been implemented and this has resulted in these issues impacting the effectiveness of the agency's control framework across multiple years. Compliance with Government Functional Standards is also a mixed picture across the MHRA and the self-assessment completed by the MHRA highlights a number of areas where there is much work to do for the agency to be able to demonstrate full compliance with all mandatory elements of the frameworks.

- Throughout the year we have engaged with stakeholders across MHRA in our work and as part of Risk and Assurance Group. This has enabled us to understand some of the pressures within the agency in maintaining adequate **governance structures and processes**. Post-Transformation a number of key activities associated with Health and Safety and Quality Assurance have been subject to resourcing pressures which have resulted in some material risks to the agency's operations emerging and have required significant efforts to take corrective action and allow the agency to operate some of its high-risk laboratory-based functions in a safe and legally compliant way. There have also been delays in implementing a number of internal audit recommendations associated with our 2020/21 review of Corporate Governance, and whilst some initial activity to create an Assurance Map was conducted following our advisory work in 2021/22, because of resourcing pressures and the need to focus on refreshing the MHRA's risk management this has not been taken forward and developed further. Additionally, a significant number of policies and procedures across a broad range of MHRA activities are overdue a formal review, increasing the risk that they are out of date and do not reflect the current operating environment or best practice across Government.
- Other key themes identified and contributing to my opinion include the **challenges associated with delivering and implementing change and ensuring associated benefits are realised**. This has impacted MHRA in a number of key areas including Transformation Programme, the Innovative Licensing and Access Pathway (ILAP), the new regulatory management system (RMS) and in the embedding of a more patient centric approach to how the MHRA operates in response to the Independent Medicines and Medical Devices (IMMDS) review.

Graham Smith
Government Internal Audit Agency

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 MHRA's governance structures, risk management and internal control framework. My review 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 control framework includes the following:

- The MHRA'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 MHRA'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 MHRA's internal control framework, which is reported in this annual report (page 89)

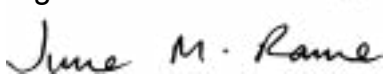
The systems for corporate governance, risk management, internal control and assurance are monitored by the Board, ARAC and ExCo, and have been in existence throughout the year to 31 March 2023 and up to the date of approval of the Annual Report and Accounts. As set out on in the Internal Control Issues section of this report (page 83) some internal control matters have arisen during the year.

Where specific weaknesses were identified within the year, rapid action was taken to address these and restore control. Where an issue required longer-term action, 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 to resolve them. I am therefore satisfied with our response to address control weaknesses throughout the year. I am assured by the improvements made to the control framework this year and plans to continually improve throughout 2023/24.

I have considered the evidence provided for the production of the Governance Statement. The conclusion of my review is that this has been a year of considerable progress but we have more to address, as set out in my statement on internal controls (page 83). With the exclusion of the specific weaknesses identified in earlier sections of this report, the agency's overall governance and internal control structures have been appropriate for the agency's business and have been satisfactory throughout 2022/23.

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 Board, the ARAC and the ExCo, that on balance there are adequate and effective risk management, corporate governance and internal control systems to manage the achievement of the MHRA's objectives.

Signed



Dr June M Raine DBE
Chief Executive and Accounting Officer
17 July 2023

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 board members and the directors who regularly attend board meetings. The content of the tables is subject to audit, where indicated.

Remuneration policy

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

Service contracts

Civil Service appointments are made in accordance with the Civil Service Commissioners' Recruitment Principles, which requires appointments to be based on fair and open competition but also includes the circumstances when appointments may otherwise be made as exceptions to the principles. 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 Chief Officers and 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/.

The Chair and non-executive directors are appointed by the Secretary of State for Health and are on fixed term contracts.

Performance appraisal

The MHRA 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 a mid-year or end – of-year performance bonus.

For our largest cohort of staff in the Delegated Grades, the MHRA 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., Executive Committee and Board members) of the MHRA. Executive Team members' salary and bonus awards were decided by the Organisational Development and Remuneration Committee; salary and bonus awards are set by a DHSC Pay Committee in accordance with the Department's senior salaries review processes. Remuneration for non-executive directors is determined by DHSC in accordance with the Departmental review process.

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

2022/23	Salary £'000	Performance pay and bonuses £'000	Pension related benefits £'000	Total £'000
June Raine, DBE Chief Executive	145 – 150	0 – 5	Nil	150 – 155
Jon Fundrey[1] Chief Operating Officer	10 – 15	Nil	5	15 – 20
Joann Passingham[2] Chief Finance Officer (Interim)	50 – 55	Nil	Nil	50 – 55
John Taylor[3] Chief Finance Officer (Interim)	170 – 175	Nil	Nil	170 – 175
Rose Braithwaite[4] Chief Finance Officer	15 – 20	Nil	7	20 – 25
Alison Cave Chief Safety Officer	140 – 145	Nil	50	190 – 195
Marc Bailey Chief Science and Innovation Officer	115 – 120	Nil	47	160 – 165
Claire Harrison Chief Digital and Technology Officer	130 – 135	Nil	51	180 – 185
Glenn Wells Chief Partnerships Officer	115 – 120	Nil	46	160 – 165
Laura Squire, OBE Chief Healthcare Quality and Access Officer	105 – 110	Nil	46	150 – 155

1. Jon Fundrey left the MHRA on 2 May 2022. Full year equivalent £140k-£145k.
2. Joann Passingham was appointed as Interim Chief Finance Officer on 2 May 2022 and left the MHRA on 4 July 2022. Full year equivalent £260k-£265k.
3. John Taylor was appointed as Interim Chief Finance Officer on 15 August 2022 and left the MHRA on 1 February 2023. Full year equivalent £315k-£320k.
4. Rose Braithwaite was appointed as Chief Finance Officer on 1 February 2023. Full year equivalent £115k-£120k.

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

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

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

2022/23	Salary £'000	Benefits in kind (taxable) to nearest £100*	Total £'000
Stephen Lightfoot **Non-Executive Director, Chair**	60 – 65	800	60 – 65
Junaid Bajwa **Non-Executive Director**	5 – 10	100	0 – 5
Amanda Calvert **Non-Executive Director**	5 – 10	1,000	5 – 10
Graham Cooke **Non-Executive Director**	5 – 10	700	0 – 5
Paul Goldsmith **Non-Executive Director**	5 – 10	3,500	5 – 10
Mercy Jeyasingham, MBE **Non-Executive Director**	5 – 10	100	5 – 10
Raj Long **Non-Executive Director**	5 – 10	700	5 – 10
Michael Whitehouse, OBE **Non-Executive Director and ARAC Chair**	10 – 15	100	10 – 15
Haider Husain[1] **Non- Executive Director**	5 – 10	Nil	5 – 10

1. Haider Husain was appointed as a full voting Non-Executive Director from 1 September 2022. He was a non-voting associate NED from 1 September 2021 to 31 August 2022.

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[2] **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

1. Junaid Bajwa, Graham Cooke, Paul Goldsmith and Raj Long joined the MHRA on 1 September 2021. Full year equivalent £5k-£10k.
2. Barbara Bannister, MBE; Bruce Campbell and David Webb, CBE and Anne-Toni Rodgers left the MHRA on 31 August 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 MHRA and thus recorded in these accounts.

Benefits: The MHRA'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: Performance awards are based on performance recognised through the SCS performance management scheme and the My Progress Review performance development scheme. The awards reported in 2022/23 relate to performance in 2021/22 and the comparative awards reported in 2021/22 relate to performance in 2020/21.

Fair pay disclosures (subject to audit)

Reporting bodies are required to disclose the relationship between the remuneration of the highest-paid Chief Officer 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 Chief Officer in the MHRA as at 31 March 2023 was £150k-£155k (2021-22 was £145k-£150k). In 2022-23 one employee (2021-22, no employees) received remuneration in excess of the highest paid Chief Officer. Remuneration ranged from £8k to £148k (2021-22 £9k-£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 Chief Officer's pay and benefits (excluding pension benefits) to the 25th, 50th and 75th percentile of pay and benefits of the MHRA's employees is disclosed in the table below:

Year	25th percentile pay ratio	Median pay ratio	75th percentile pay ratio
2022-23	4.47	3.53	2.53
2021-22	4.35	3.14	2.38

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:

	2022-23			2021-22		
	25th percentile	Median	75th percentile	25th percentile	Median	75th percentile
Total pay and benefits	£34,102	£43,182	£60,172	£33,915	£46,908	£62,066
Salary component of total pay and benefits	£33,940	£42,176	£57,836	£33,086	£45,586	£61,455

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 Chief Officer	2022-23 Increase/ (decrease)%
Salary and allowances	3.79
Performance pay and bonuses	100.00

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 MHRA taken as a whole is as follows:

%age change – Average for all employees taken as a whole	2022-23 Increase/ (decrease)%
Salary and allowances	(1.95)
Performance pay and bonuses	65.34

Pension benefits table (subject to audit)

Neither the Chair nor Non-Executive Board directors have any pension entitlement arising from their service with the MHRA.

The following table provides details of the pension entitlements of Executive Committee members:

2022/23	Real increase in pension and related lump sum at 60 Bands of £2,500	Total accrued pension at age 60 at 31 March 2023 and related lump sum Bands of £5,000	Cash Equivalent Transfer Value at 1 April 2022. To nearest £1,000	Cash Equivalent Transfer Value at 31 March 2023* 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, DBE Chief Executive Officer	0 plus a lump sum of 0	70 - 75 plus a lump sum of 200 - 205	1,267	1,254	(110)[1]	45
Jon Fundrey[2] Chief Operating Officer	0 – 2.5	50 - 55	924	954	4	4
Rose Braithwaite[3] Chief Finance Officer	0 - 2.5 plus a lump sum of 0 - 2.5	45 - 50 plus a lump sum of 50 - 55	989	1,039	9	33
Alison Cave Chief Safety Officer	2.5 – 5.0	5 - 10	85	133	33	43
Marc Bailey Chief Science and Innovation Officer	2.5 – 5.0	10 - 15	152	197	29	36
Claire Harrison Chief Digital and Technology Officer	2.5 – 5.0	0 - 5	13	48	25	40
Glenn Wells Chief Partnerships Officer	2.5 – 5.0	5 - 10	49	82	21	35
Laura Squire, OBE Chief Healthcare Quality and Access Officer	0 - 2.5 plus a lump sum of 0	40 - 45 plus a lump sum of 85 - 90	781	863	(17)	34

*CETV figures are calculated using the guidance on discount rates for calculating unfunded public service pension contribution rates that was extant at 31 March 2023. HM Treasury published updated guidance on 27 April 2023; this guidance will be used in the calculation of 2023-24 CETV figures.

1. Taking account of inflation the CETV funded by the employer has decreased in real terms.
2. Jon Fundrey left the MHRA on 2 May 2022.
3. Rose Braithwaite was appointed on 1 February 2023.

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 2023 and related lump sum Bands of £5,000	Cash Equivalent Transfer Value at 1 April 2022. To nearest £1,000	Cash Equivalent Transfer Value at 31 March 2023* 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, DBE Chief Executive Officer	0 plus lump sum of 0	65 – 70 plus lump sum of 195 -200	1,269	1,267	(14)	38
Jon Fundrey Chief Operating Officer	0 – 2.5 plus Nil lump sum	50 – 55 plus Nil lump sum	840	924	45	42
Christian Schneider[1] Interim Chief Scientific Officer	0 – 2.5 plus Nil lump sum	15 – 20 plus Nil lump sum	205	214	9	14
John Quinn Interim Chief Digital and Technology Officer	0 – 2.5 plus Nil lump sum	45 – 50 plus lump sum of 85 - 90	780	827	5	29
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
Alison Cave[2] Chief Safety Officer	0 – 2.5 plus Nil lump sum	10 – 15 plus Nil lump sum	51	85	22	30
Marc Bailey Chief Science and Innovation Officer	2.5 – 5.0 plus Nil lump sum	10 – 15 plus Nil lump sum	113	152	27	34
Glenn Wells[3] Chief Partnerships Officer	0 – 2.5 plus Nil lump sum	0 – 5 plus Nil lump sum	40	49	7	12
Laura Squire, OBE[4] Chief Healthcare Quality and Access Officer	0 – 2.5 plus Nil lump sum	35 – 40 plus lump sum of 85 - 90	732	781	15	13

1. Christian Schneider left the MHRA on 31 July 2021
2. Alison Cave was appointed on 16 July 2021
3. Glenn Wells was appointed om 29 November 2021
4. Laura Squire was appointed on 1 November 2021

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)

	2022/23 £'000	2021/22 £'000
Wages and salaries	**60,901**	68,307
Social security costs	**6,820**	7,172
Other pension contributions	**14,403**	15,705
Sub total	**82,124**	91,184
Less recoveries in respect of outwards secondment	**(20)**	(180)
Total	**82,104**	91,004

Note: 2021/22 staff costs are higher than 2022/23 due to inclusion of included £4.5m exit costs. Staff numbers reduced in 2021/22 due to departure prior to year-end. Staff numbers increased in 2022/23 due to recruitment to vacant roles, with new employees starting positioned at the lower end of the pay scales

During the year an average of 1,285 staff were employed

Number of staff employed as at 31 March 2023 (not subject to audit)

	2022/23		
	Total	Permanently Employed	Other*
Chair	1	1	-
Chief Executive/Chief Officers	7	7	-
Senior Civil Servants	124	119	5
Other Civil Service Staff	1,153	997	156
Total	**1,285**	**1,124**	**161**

*Includes contingent workers

	2021/22		
	Total	Permanently Employed	Other*
Chair	1	1	-
Chief Executive/Chief Officers	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.

SCS by salary band (not subject to audit)

Senior Civil Servants by salary band	2022/23	2021/22
£65,001 - £70,000	-	-
£70,001 - £75,000	19	23
£75,001 - £80,000	23	20
£80,001 - £85,000	27	24
£85,001 - £90,000	20	15
£90,001 - £95,000	12	13
£95,001 - £100,000	6	8
£100,001 - £105,000	6	6
£105,001 - £110,000	1	1
£110,001 - £115,000	1	4
£115,001 - £120,000	3	-
£120,001 - £125,000	-	-
£125,001 - £130,000	-	1
£130,001 - £135,000	1	1
£135,001 - £140,000	-	7
£140,001 - £145,000	1	4
£145,001 - £150,000	1	-
Total	**121**	**127**

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 13½ years to retirement at 1 April 2012 joined alpha and those with less than ten years remained in their current scheme. Those within ten to thirteen and a half years to normal pension age on 1 April 2012, were given the option to join alpha or remain in their existing scheme. The service to date of employees in their old scheme who transferred to alpha was frozen, therefore past and present employees of the MHRA are covered by the provisions of the Principal Civil Service Pension Schemes (PCSPS). Since 1 April 2023 all other pension schemes were closed and all employees are now members of the alpha scheme.

Civil Service Pensions

The PCSPS is an unfunded multi-employer defined benefit scheme and alpha is a defined benefit scheme worked out on a career average basis. The agency is unable to identify its share of the underlying assets and liabilities. A full actuarial valuation was carried out on 31 March 2016. Details can be found in the resource accounts of the Cabinet Office: Civil Superannuation www.civilservicepensionscheme.org.uk.

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

For 2022/23, 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	Alpha contribution rate
£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%

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 the 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. 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 benefits in closed Civil Service schemes cover Classic, Premium, Classic plus and Nuvos schemes. In Classic, benefits 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. In 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.

Employees are entitled to receive their accrued pension from a closed scheme when they reach pension age, or immediately on ceasing to be an active member of the scheme if they are already at or over pension age. Pension age is 60 for members of Classic, Premium and Classic plus and 65 for members of Nuvos. Normal Pension Age is the later of age 65 or State Pension age for members of Alpha.

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

The NHS Pension Scheme (NHSPS)

Some employees in the MHRA 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 Civil Service Pension scheme. Since 1 April 2015 all employees are covered by the provisions in the Civil Service Pension scheme, as detailed above.

Employer contributions

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

For 2022/23, employers' contributions for the MHRA employees of £16,048,353 were payable to the PCSPS (2021/22, £16,048,353) at one of four rates in the range 26.6 per cent to 30.3 per cent of pensionable pay (2021/22, 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, which is a stakeholder pension with an employer contribution. Employers' contributions of £146,096 (2021/22, £135,642) were paid to the appointed stakeholder pension provider. 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 £4,953 (2021/22, £4,817), 0.8 per cent of pensionable pay, were payable to the Civil Service Pension scheme 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 2022/23 (2021/22, 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	
	2022/23	2021/22
<£10,000	**2**	**2**
£10,000 - £25,000	**15**	**24**
£25,000 - £50,000	**11**	**35**
£50,000 - £100,000	**20**	**37**
£100,000 - £150,000	**2**	**-**
£150,000 - £200,000	**-**	**-**
Total number of exit packages	**50**	**98**
Total resource cost	**£2,342,240**	**£4,269,604**

Redundancy and other departure costs were paid in accordance with the provisions of the Civil Service Compensation Scheme, a statutory scheme made under the Superannuation Act 1972. Exit costs are accounted in full in the year in which the departure was agreed as binding. Where the department has agreed early retirements, the additional costs are met by the agency and not the Civil Service Pension scheme. Ill health retirement costs are met by the pension scheme and are not included in the table.

Termination benefits of £2,342k (2021/22, £4,270k) 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 2023.

Spend on temporary staff

During 2022/23, expenditure on consultants was £1,163k (2021/22, £6,443k).

The MHRA continues to employ temporary staff where it is of operational necessity. The MHRA temporary staff expenditure was £5,594k in 2022/23 (2021/22, £5,890k).

The Government Apprentice scheme

The MHRA currently pays approximately £258,000 per annum as an Apprenticeship Levy and recognises that this money is lost to the organisation unless used to pay for apprenticeship learning provision. There remains a commitment to this scheme, but also a recognition that apprenticeships need to be appropriate in terms of current and future roles and in this respect the agency currently falls short of full utilisation but continues to factor into workforce plans.

There are 21 apprentices in the MHRA, a significant increase to the fourteen from the previous year and a return to 2020/21 numbers. This is due to a take up of apprenticeships internally and recruitment of entry level apprentices. 12 apprenticeships were started in the agency in 2022/23.

It is recognised that entry level apprenticeships are especially important in aiding social inclusion. Apprenticeship recruitment at entry level this year have been undertaken in our Corporate, Enablement and Digital and Technology groups. 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 the Digital and Technology group 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 Apprentice Strategy (published April 2022) commits to one in twenty Civil Servants being apprentices by 2025. The MHRA has produced an appropriate apprenticeship action plan for 2023/24 to continue to contribute to this aim. The agency has also launched recruitment on a graduate scheme that aims to onboard a cohort of eight recent graduates to undertake the Regulatory Affairs degree apprenticeship.

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 legislative and agency safety requirements, and the agency's Health and Safety Policy statement. Accidents and incidents reported during the year were logged, investigated and appropriate remedial action was taken.

Overall trend analysis for the past five years indicates a general decrease in accidents and incidents at both our South Mimms site and our

offices in Canary Wharf. At our site in South Mimms the number of incidents (including near misses) remains proportionally higher than the number of accidents over the five-year period, indicating a healthy reporting culture is being maintained. The number of accidents and incidents reported at our site in Canary Wharf remains lower than at our South Mimms site, which is a reflection of the different working environments.

There were seven working days lost as a result of two accidents involving injury at work during the year. Further details about our health and safety can be found in the Health and Safety Report (page 48).

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 7.1 working days per full time equivalent employee (2021/22, 4.5 days). The annual voluntary turnover for the MHRA was 13.3% (2021/22, 12%).

Civil Service People Survey

The annual Civil Service People Survey was live for 6 weeks during September to October 2022. 70% of our workforce took part in the survey, and our engagement score results were 49% (51% in the 2021 survey). The Civil Service benchmark score for 2022 is 65%.

We have an agency-wide action plan owned by the Executive Committee to deliver three key priorities in response to the survey feedback:

1. Improving engagement within the MHRA
2. A focus on making the MHRA a great place to work
3. Improving the accessibility of our senior leaders

In addition, the Chief Executive and each Chief Officer has made personal commitments to deliver change, designed to improve engagement and supporting this are local action plans to more effectively drive engagement within Groups and their teams.

Employee consultation

The MHRA 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, PCS, UCU and the FDA) through monthly Staff Partnership Meetings and quarterly formal Employee Relations Liaison Group meetings.

The MHRA 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[1]. It is for this reason that the information discloses the trade union facility time utilised by MHRA 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.

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

Relevant union officials

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

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	£28,877
Total pay bill	£82,104
Percentage of the total pay bill spent on facility time*	0.04%

* 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 MHRA 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 all members of staff with occupational health referrals, a confidential employee assistance programme, a formal reasonable workplace adjustment policy and a support process for any colleague experiencing significant life change. We have a comprehensive mental health and wellbeing offer to support staff at all times and, in particular through learning and development and through our promotion of mental health champions and information and signposting for sources of support. We have appointed three Board level Champions who will support Mental Health, Race and Disability.

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 and wellbeing issues on our intranet as part of a planned programme to increase awareness of diversity, inclusion and wellbeing across the workforce. We are Disability Confident Level two and in line with the Civil Service Diversity and Inclusion Strategy, aim to become Disability Confident Level three as well as Carer Confident in 2023/24.

We deliver learning and development in a variety of formats to ensure it is accessible to all staff and during 2021/22 all cross-organisation 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, mentoring and reverse mentoring for staff are also offered via our network of qualified MHRA coaches

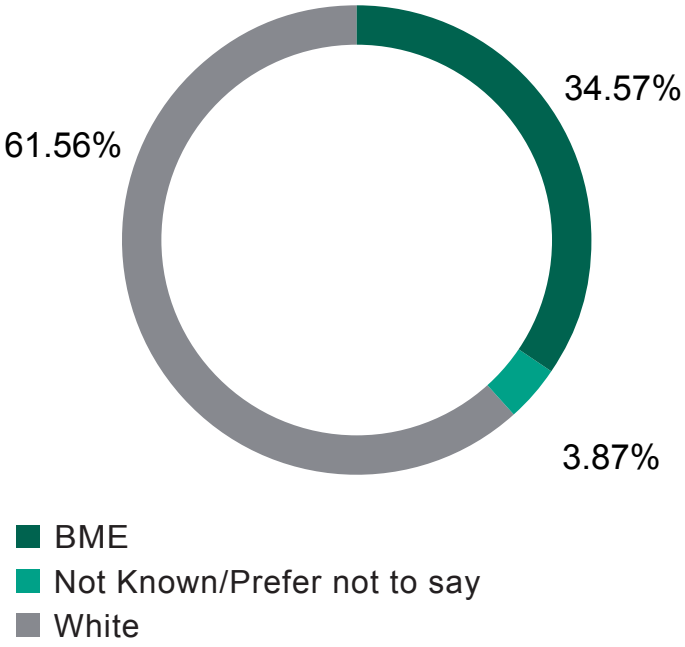
Staff composition

Gender analysis*

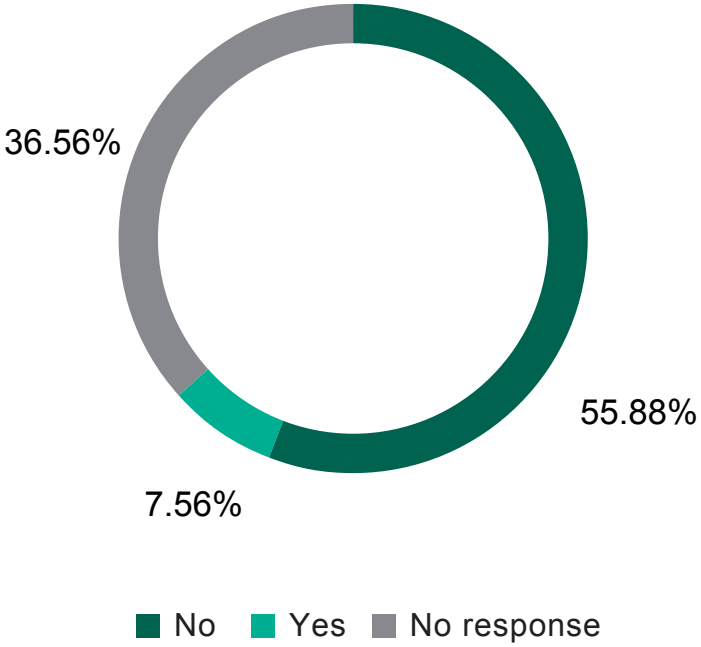
	Male	Female
Chairman/Chief Executive/Chief Officers	30%	70%
Senior Civil Servants	37.8%	62.2%
Other Civil Service Staff	39%	61%
Total	**38.9%**	**61.1%**

*Of those who declared

Staff Composition – Ethnicity



Staff Composition – Disability

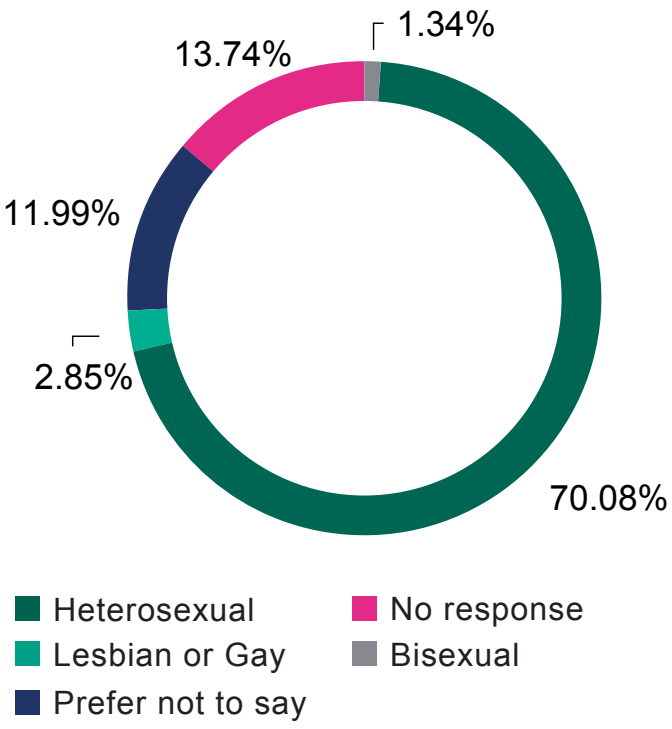


Gender pay gap

The MHRA produces pay gap reporting on gender and ethnicity. Gender pay gap reporting can be found at: https://www.gov.uk/government/publications/mhra-gender-pay-gap-report and ethnicity pay gap reporting can be found at: https://www.gov.uk/government/publications/mhra-ethnicity-pay-gap-report.

Our action plan to help reduce these pay gaps focus on using future awards to reduce pay ranges, managing the Pay Committee process to ensure all starting salaries above the minimum are considered and reviewed, continually reviewing policies to ensure fairness and equality in recruitment process, continuing to scrutinise and review the recruitment journey from job posting to job offer, monitoring the uptake on mandatory training on Civil Service Learning for Diversity and Inclusion modules, ensuring a diverse mix of delegates on Talent Management initiatives and monitoring their impact, supporting women returning to work following maternity leave and refreshing our networks to link with the Diversity and Inclusion framework.

Staff Composition – Sexual Orientation



2.5 Parliamentary accountability 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 MHRA 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 MHRA's income is derived from its regulatory function in achieving its objectives of protecting, promoting, and improving public health.

2022/23	£'000 Income	£'000 Expenditure	£'000 Net income/ (expenditure)
Licensing	**22,530**	**(33,244)**	**(10,714)**
Inspections	**5,120**	**(13,945)**	**(8,825)**
Vigilance, Risk Management and Enforcement	**41,749**	**(32,055)**	**9,694**
British Pharmacopoeia	**5,989**	**(3,618)**	**2,371**
Devices	**2,072**	**(5,341)**	**(3,269)**
Clinical Trials	**3,462**	**(1,444)**	**2,018**
Tobacco Products Directive	**2,204**	**(882)**	**1,322**
CPRD	**13,211**	**(16,930)**	**(3,719)**
Research	**24,016**	**(54,007)**	**(29,991)**
Other non-attributable	**2,551**	**(498)**	**2,053**
Total	**122,904**	**(161,964)**	**(39,060)**

2021/22	£'000 Income	£'000 Expenditure	£'000 Net income/ (expenditure)
Licensing	**25,254**	**(34,476)**	**(9,222)**
Inspections	**5,376**	**(11,221)**	**(5,845)**
Vigilance, Risk Management and Enforcement	**36,297**	**(35,859)**	**438**
British Pharmacopoeia	**6,029**	**(1,796)**	**4,233**
Devices	**1,862**	**(9,728)**	**(7,866)**
Clinical Trials	**3,757**	**(3,581)**	**176**
Tobacco Products Directive	**1,155**	**(568)**	**587**
CPRD	**6,750**	**(8,729)**	**(1,979)**
Research	**28,310**	**(56,674)**	**(28,364)**
Other non-attributable	**6,435**	**(10,075)**	**(3,640)**
Total	**121,225**	**(172,707)**	**(51,482)**

Losses and special payments

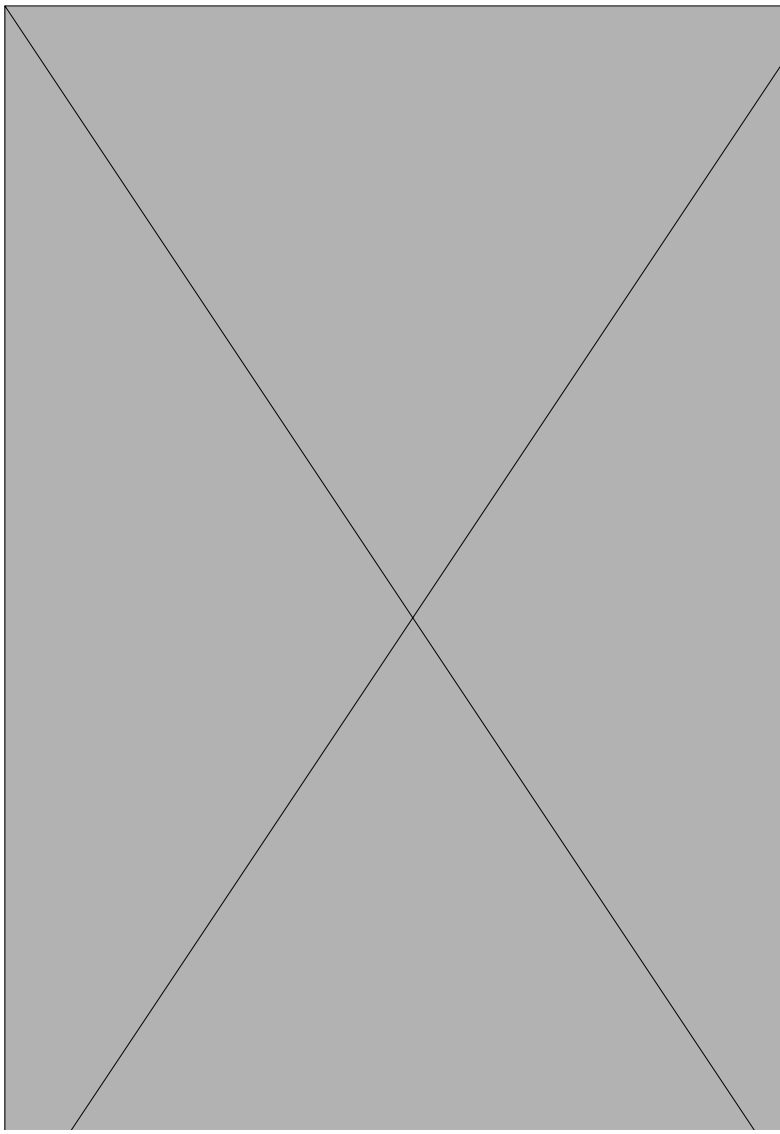
Managing Public Money requires a statement showing losses and special payments by value and type where they exceed £300k in total, and those individually that exceed £300k. There were no special payments in excess of £300k during the financial year.

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

The Accounting Officer authorised these financial statements for issue on 17 July 2023.

Dr June M Raine DBE
Chief Executive and Accounting Officer
Medicines and Healthcare products Regulatory Agency

17 July 2023



The certificate and report of the comptroller and auditor general to the house of commons

Opinion on financial statements

I certify that I have audited the financial statements of the Medicines and Healthcare products Regulatory Agency for the year ended 31 March 2023 under the Government Resources and Accounts Act 2000.

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

- Statement of Financial Position as at 31 March 2023;
- Statement of Comprehensive Net Expenditure, 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 Medicines and Healthcare products Regulatory Agency's affairs as at 31 March 2023 and its net expenditure for the year then ended; and
- have been properly prepared in accordance with the Government Resources and Accounts Act 2000 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 and Regularity of Public Sector Bodies in the United Kingdom (2022). 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 am independent of the Medicines and Healthcare products Regulatory Agency in accordance with the ethical requirements that are relevant to my audit of the financial statements in the UK. My staff and I have fulfilled our other ethical responsibilities in accordance with these requirements.

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

Conclusions relating to going concern

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

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

My responsibilities and the responsibilities of the Accounting Officer with respect to going concern are described in the relevant sections of this certificate.

The going concern basis of accounting for the Medicines and Healthcare products Regulatory Agency is adopted in consideration of the requirements set out in HM Treasury's Government Financial Reporting Manual, which requires 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 and my auditor's certificate and report thereon. 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.

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 part of the Remuneration and Staff Report to be audited has been properly prepared in accordance with HM Treasury directions made under the Government Resources and Accounts Act 2000.

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 Resources and Accounts Act 2000;
- 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 Medicines and Healthcare products Regulatory Agency and its environment obtained in the course of the audit, I have not identified material misstatements in the Performance and Accountability Reports.

I have nothing to report in respect of the following matters which I report to you if, in my opinion:

- Adequate accounting records have not been kept by the Medicines and Healthcare products Regulatory Agency or returns adequate for my audit have not been received from branches not visited by my staff; or
- I have not received all of the information and explanations I require for my audit; 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 is not in agreement with the accounting records and returns; or
- the Governance Statement does not reflect compliance with HM Treasury's guidance.

Responsibilities of the Chief Executive/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;
- providing the C&AG with access to all information of which management is aware that is relevant to the preparation of the financial statements such as records, documentation and other matters;
- providing the C&AG with additional information and explanations needed for his audit;
- providing the C&AG with unrestricted access to persons within the Medicines and Healthcare products Regulatory Agency from whom the auditor determines it necessary to obtain audit evidence;
- ensuring such internal controls are in place as deemed necessary to enable the preparation of financial statements to be free from material misstatement, whether due to fraud or error;
- ensuring that the financial statements give a true and fair view and are prepared in accordance with HM Treasury directions made under the Government Resources and Accounts Act 2000;
- ensuring that the annual report, which includes the Remuneration and Staff Report, is prepared in accordance with HM Treasury directions made under the Government Resources and Accounts Act 2000; and
- assessing the Medicines and Healthcare products Regulatory Agency's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the Accounting Officer anticipates that the services provided by the Medicines and Healthcare products Regulatory Agency will not continue to be provided in the future.

Auditor's responsibilities for the audit of the financial statements

My responsibility is to audit, certify and report on the financial statements in accordance with the Government Resources and Accounts Act 2000.

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, I:

- considered the nature of the sector, control environment and operational performance including the design of the Medicines and Healthcare products Regulatory Agency's accounting policies, key performance indicators and performance incentives.
- inquired of management, the Medicines and Healthcare products Regulatory Agency's head of internal audit and those charged with governance, including obtaining and reviewing supporting documentation relating to the Medicines and Healthcare products Regulatory Agency's policies and procedures on:
  - identifying, evaluating and complying with laws and regulations;
  - detecting and responding to the risks of fraud; and
  - the internal controls established to mitigate risks related to fraud or non-compliance with laws and regulations including the Medicines and Healthcare products Regulatory Agency's controls relating to the Medicines and Healthcare products Regulatory Agency's compliance with the Government Resources and Accounts Act 2000 and Managing Public Money;
- inquired of management, the Medicines and Healthcare products Regulatory Agency's head of internal audit and those charged with governance whether:
  - they were aware of any instances of non-compliance with laws and regulations;
  - they had knowledge of any actual, suspected, or alleged fraud,
- discussed with the engagement team and the relevant internal specialists, including IT and property valuation specialists, 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 Medicines and Healthcare products Regulatory Agency for fraud and identified the greatest potential for fraud in the following areas: posting of unusual journals, complex transactions, and bias in management estimates. In common with all audits under ISAs (UK), I am required to perform specific procedures to respond to the risk of management override.

I obtained an understanding of the Medicines and Healthcare products Regulatory Agency's framework of authority and other legal and regulatory frameworks in which the Medicines and Healthcare products Regulatory Agency operates. I focused 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 Medicines and Healthcare products Regulatory Agency. The key laws and regulations I considered in this context included Government Resources and Accounts Act 2000, Managing Public Money, employment law and tax legislation.

Audit response to identified risk

To respond to the identified risks resulting from the above procedures:

- I reviewed the financial statement disclosures and tested to supporting documentation to assess compliance with provisions of relevant laws and regulations described above as having direct effect on the financial statements;
- I enquired of management and the Audit Committee concerning actual and potential litigation and claims;
- I reviewed minutes of meetings of those charged with governance and the Board; and internal audit reports; and
- in addressing the risk of fraud through management override of controls, I tested the appropriateness of journal entries and other adjustments; assessed whether the judgements on estimates are indicative of a potential bias; and evaluated the business rationale of any significant transactions that are unusual or outside the normal course of business.

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

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

Other auditor's responsibilities

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

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 I identify during my audit.

Report

I have no observations to make on these financial statements.

Gareth Davies
Comptroller and Auditor General
18 July 2023

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

03

3.0 Financial statements

Statement of comprehensive net expenditure for the year ended 31 March 2023

	NOTE	2022/23 £'000	2021/22 Restated** £'000
Income			
Trading income	3.1	**122,904**	121,225
Total income		**122,904**	121,225
Expenditure			
Staff costs	4	**(82,104)**	(91,004)
Operating costs	5	**(79,860)**	(81,703)
Total expenditure		**(161,964)**	(172,707)
Net operating expenditure		**(39,060)**	(51,494)
Finance income		**1,352**	35
Finance costs		**(99)**	(47)
Net expenditure for the year		**(37,807)**	(51,482)
Transfers under absorption accounting		**789**	-
Other comprehensive income			
Realised (gain) on inventories		**(92)**	(85)
Net gain on revaluation of property, plant and equipment*	6	**4,804**	6,054
Total comprehensive expenditure for the year		**(32,306)**	(45,525)

*All gains and losses arise from continuing operations.

**Further information on the restatement of 2021/22 comparatives is shown in note 18.

The notes on pages 123 to 143 form part of these accounts.

Statement of financial position as at 31 March 2023

	NOTE	31 March 2023 £'000	31 March 2022 Restated* £'000	1 April 2021 Restated* £'000
Non-current assets				
Property, plant and equipment	6	**140,208**	134,626	128,464
Right of use assets	7	**11,770**	-	-
Intangible assets	8	**18,722**	16,402	13,389
Inventories	9	**8,942**	9,473	9,379
Trade and other receivables	10		6,330	7,291
Total non-current assets		**179,642**	166,831	158,523
Current assets				
Inventories	9	**645**	661	184
Trade and other receivables	10	**23,943**	34,092	31,517
Cash and cash equivalents	11	**77,822**	51,047	79,601
Total current assets		**102,410**	85,800	111,302
Total assets		**282,052**	252,631	269,825
Current liabilities				
Trade and other payables	12	**(29,211)**	(33,920)	(43,029)
Lease liabilities	13	**(1,002)**	-	-
Other liabilities	14	**(30,202)**	(26,206)	(14,135)
Provisions		**-**	-	(1,781)
Total current liabilities		**(60,415)**	(60,126)	(58,945)
Total assets less current liabilities		**221,637**	192,505	210,880
Non-current liabilities				
Lease liabilities	13	**(7,813)**	-	-
Other liabilities	14	**(12,147)**	(7,893)	(4,602)
Provisions	15	**(1,998)**	(1,998)	(1,998)
Borrowings		**-**	-	(1,328)
Total non-current liabilities		**(21,958)**	(9,891)	(7,928)
Net assets		**199,679**	182,614	202,952
Taxpayers' equity				
Public dividend capital		**-**	1,329	1,329
Reserves				
Revaluation reserve		**122,314**	117,602	111,633
Income and expenditure reserve		**954**	954	954
General fund		**76,411**	62,729	89,036
Total taxpayers' equity		**199,679**	182,614	202,952

*Further information on the restatement of 2021/22 comparatives is shown in note 18.

The notes on pages 123 to 143 form part of these accounts.

June M. Raine

Dr June M Raine DBE
Chief Executive and Accounting Officer
Medicines and Healthcare products Regulatory Agency
17 July 2023

Statement of cash flows for the year ended 31 March 2023

	NOTE	2022/23 £'000	2021/22 Restated* £'000
Cash flows from Operating activities			
Operating (deficit)		**(39,060)**	(51,482)
Depreciation and amortisation	6/8	**13,831**	11,423
Loss on disposal of assets	6/8	**62**	182
Impairment of PPE and intangible assets	6/8	**28**	26
Realised (gain) on inventories	9	**(92)**	(85)
Decrease/(Increase) in inventories	9	**547**	(571)
Decrease/(Increase) in trade and other receivables	10	**16,479**	(1,625)
(Decrease)/Increase in trade and other payables	12	**(2,293)**	2,041
Increase in other liabilities	14	**8,250**	4,637
(Decrease) in provisions	15	**-**	(1,781)
Net cash (outflow) from operating activities		**(2,248)**	(37,235)
Cash flows from investing activities			
Purchase of property, plant & equipment	6	**(8,887)**	(7,813)
Right of use assets	7	**(2,857)**	-
Purchase of intangible assets	8	**(5,541)**	(6,939)
Net cash (outflow) from investing activities		**(17,285)**	(14,752)
Cash flows from financing activities			
Interest received		**1,352**	35
Interest paid		**-**	(47)
Funding from DHSC		**50,700**	27,600
Capital repayments made under lease liabilities		**(1,618)**	-
Interest payments made under lease liabilities		**(99)**	-
Repayment of PDC		**(1,329)**	-
Repayment of borrowings		**-**	(1,328)
Dividend paid		**(2,413)**	(2,827)
Net cash inflow from financing		**46,593**	23,433
Transfers under absorption accounting		**(285)**	-
Net increase/(decrease) in cash and cash equivalents in the financial year	11	**26,775**	(28,554)
Cash and cash equivalents at the beginning of the financial year	11	**51,047**	79,601
Cash and cash equivalents at the end of the financial year	11	**77,822**	51,047

The notes on pages 123 to 143 form part of these accounts.

Statement of changes in taxpayers' equity for the year ended 31 March 2023

	PDC £'000	General Fund £'000	Reval. reserve £'000	I & E reserve £'000	Total £'000
Balance at 1 April 2020 previously reported	**1,329**	**104,303**	**115,155**	**954**	**221,741**
Balance at 1 April 2021	**1,329**	**89,036**	**111,633**	**954**	**202,952**
Changes in taxpayers' equity for 2021/22 Restated					
Net expenditure for the year	-	(51,494)	-	-	(51,494)
Other changes					
Funding from DHSC	-	27,600	-	-	27,600
Net gain on revaluation of property, plant and equipment	-	-	6,054	-	6,054
Realised (loss) on inventories - biological standards	-	-	(85)	-	(85)
Dividend payable	-	(2,413)	-	-	(2,413)
Sub total	-	25,187	5,969	-	31,156
Balance at 31 March 2022 Restated	**1,329**	**62,729**	**117,602**	**954**	**182,614**
Changes in taxpayers' equity for 2022/23					
Net expenditure for the year	-	(37,807)	-	-	(37,807)
Other changes					
Funding from DHSC	-	50,700	-	-	50,700
Net gain on revaluation of property, plant and equipment	-	-	4,804	-	4,804
Realised (gain) on inventories - biological standards	-	-	(92)	-	(92)
Transfers under absorption accounting	-	789	-	-	789
PDC repayment	(1,329)	-	-	-	(1,329)
Sub total	(1,329)	51,489	4,712	-	54,872
Balance at 31 March 2023	**-**	**76,411**	**122,314**	**954**	**199,679**

The notes on pages 123 to 143 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 HM Treasury's Financial Reporting Manual (FReM) issued by HM Treasury and under an accounts direction issued by HM Treasury on 15 December 2022 DAO__22__06_Non_bespoke_accounts_direction_2022-23.pdf (publishing.service.gov.uk)

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.

Following the revocation of its Trading Fund status on 1 April 2022, MHRA remained an executive agency of DHSC and has been consolidated into DHSC group reporting. As part of this, accounting policies have been reviewed to ensure alignment with DHSC group accounting policies. Additional changes include the adoption of IFRS 16 Leases. Under IFRS 16, MHRA has recognised the right of use assets and corresponding lease liabilities, and these have been disclosed in notes 7 and 13. Changes to recognition of departmental funding are detailed in note 1.7 and note 18.

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 2022/23.

- IFRS 17 Insurance Contracts: Effective 1 January 2021 but not yet adopted by FReM. This is not expected to have any effect.

1.2 Accounting convention

The Accounts have been prepared under the historical cost convention, modified to allow for the revaluation of non-current assets (excluding IT equipment and assets in the course of construction) at their value to the business by reference to their current costs.

1.3 Critical accounting judgements and estimates

The preparation of the financial statements requires the use of estimates and assumptions. Although we base judgements and estimates on our best knowledge of current events and actions, actual results may differ from our assumptions. The most significant estimates and areas of management judgement made in the preparation of the financial statements relate to:

- **Measurement of the accrual for employee leave liability**
  We use an employee-by-employee breakdown of actual leave balance and average salary for the grade to calculate our liability. The principal uncertainty is in respect of when the leave balance will be used. In the absence of information on the timing of staff members' future use of their leave, we neither discount the liability nor include any forecast of future salary increases.

- Valuation of Property, Plant and Equipment
  Plant and Equipment have been revalued in line with Office of National Statistics indices. A full valuation of the South Mimms site at 31 March was carried out by the Valuation Office Agency. The valuation of properties is prepared based on building cost indices in order to reflect the cost of building a replacement asset in the same location. The indices utilised in preparing the valuation are subject to a 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 values in the report have been used to inform the measurement of property assets at valuation in these financial statements.

- **Inventory valuation**
  In line with specialist knowledge of managers and senior staff, the historic cost 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 the year of production.
  There are no other judgements or estimates made by management that have a significant impact on the financial statements.

1.4 Non-Current Assets

1.4.1 Property, Plant & Equipment

Property, Plant & Equipment are capitalised if:

- they are held for use in delivering services or for administrative purposes;
- it is probable that future economic benefits will flow, or service potential will be supplied;
- they are expected to be used for more than one financial year;
- individually have a cost equal to or greater than £5,000; or
- collectively have a cost of at least £5,000;

Computer and telecom equipment are stated in the Statement of Financial Position at cost less subsequent accumulated depreciation and any impairment in value. This carrying amount closely approximates with fair value due to the short economic life of these assets.

The fair value of freehold land and buildings is determined by an independent valuation carried out every five years in accordance with guidance issued by the Royal Institute of Chartered Surveyors (RICS). A full valuation took place at 31 March 2023. Valuation is on an open market (existing use) basis except for buildings of a specialised nature, where a market value is not readily obtainable, which are valued on a depreciated replacement cost basis.

Other property, plant and equipment and furniture & fittings are revalued annually using Office of National Statistics cost indices. These indices reflect the upward or downward movements in valuation of these assets and are broadly consistent with fair values. The difference between the carrying value, net of accumulated depreciation, of property, plant and equipment at the date of the statement of financial position and the net book value at historic cost is credited (in the case of a surplus) or debited (in the case of a deficit) to the revaluation reserve. Reductions in value are only taken to the revaluation reserve to the extent that they reverse a previous upward valuation of the same asset, any other downward valuations would be charged to the Statement of Comprehensive Income. All other assets held for operational use are carried at depreciated historic cost, as a proxy for fair value, as they have short lives, or low values (or both).

1.4.2 Depreciation, amortisation and impairments

Assets under construction are not depreciated. Otherwise, depreciation and amortisation are charged on a straight-line basis over the estimated useful life of the asset as follows:

Freehold buildings	Up to 90 years
Laptops and associated applications	3 years
Plant and equipment	5 to 25 years
Vehicles	3 to 7 years
Fixtures and fittings	Up to 20 years
Computer systems	5 to 10 years
Office refurbishment costs	10 to 15 years

During the annual asset verification exercise, the agency checks whether there is any indication that any of its tangible or intangible non-current assets has suffered an impairment loss. If there is indication of an impairment loss, the recoverable amount of the asset is estimated to determine whether there has been a loss and, if so, its amount. If an asset meets the impairments criteria the value is restated to the underlying recoverable amount.

Impairment losses that arise from a clear consumption of economic benefit are taken to expenditure. Where an impairment loss subsequently reverses, the carrying amount of the asset is increased to the revised estimate of the recoverable amount but capped at the amount that would have been determined had there been no initial impairment loss. The reversal of the impairment loss is credited to expenditure.

1.4.3 Intangible assets

Intangible assets are capitalised if:

- They are held for use in delivering services or for administrative purposes;
- it is probable that future economic benefits will flow to, or service potential will be supplied;
- they are expected to be used for more than one financial year;
  - individually have a cost equal to or greater than £5,000; or
  - collectively have a cost of at least £5,000.

Intangible assets acquired are initially recognised at cost and amortised over the life of the assets. Following initial recognition, they are carried at cost less accumulated amortisation and any impairment in value.

Intangible assets in the course of construction are carried at cost, less any impairment loss. Cost includes professional fees required to bring the asset into a usable state. Amortisation commences in the month after they are brought into use.

The useful lives of intangible assets are assessed to be either finite or indefinite. The Agency holds no assets with indefinite life.

The estimated useful lives are:

Computer software	3 -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
Sentinel architecture	15 years
CPRD architecture	8 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)

The joint arrangement ended on 31 March 2022 when the Memorandum of Understanding expired. NIHR have confirmed the funding balance held by MHRA on the 31st of March 2022 (£10.8m) can be retained by MHRA for the purpose of ongoing business development and continuous improvement of CPRD with specific performance obligations and deliverables including the introduction of new value added features to the database, improving data quality, transitioning to a trusted research environment (TRE) model of data access, developing or enhancing data-enabled clinical trial services and expansion of available primary care data (specifically, the onboarding of TPP data) and new linkages (specifically, streamlining the linked data approvals and processing, validating the new linkage model from NHS England, onboarding of dispensing data, prescribing data, onboarding of linkages for TPP data). When these performance obligations have been successfully delivered, CPRD will be able to draw down from these funds in line with expenditure incurred during the year. Total assets of £3.142m and total liabilities of £2.355m were transferred to the Agency on that date. This has been incorporated in the agency financial statements under absorption accounting in line with guidance from DHSC with a net value of £789k.

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-cigarettes income is based on the number of notified products. Income is recognised when the performance obligation is complete; this is when the application has been validated and published on the Agency's website.
- Miscellaneous income: This is non-statutory income and is recognised as earned when the service has provided.
- Standards income is recognised when an order has been fulfilled.
- 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.
- Departmental funding: following the revocation of the trading fund status, and joining DHSC group, departmental funding is treated as a contribution rather than income. Departmental 'supply' funding is now credited to reserves when received rather than recognised as income in line with IAS 20. The comparatives have been restated as a result. See note 18 for further details.

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). 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 or net realisable value. Net realisable value is based on estimated selling price less any 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 been classified as current where expected sales are within the next twelve months, with the balance classified as non-current.

1.9 Leases

Scope and classification

Contracts that convey the right to use an asset in exchange for consideration are classified as leases and are accounted in accordance with IFRS 16 leases. For the MHRA this is the main office building at Canary Wharf.

MHRA excludes low value contracts defined as items costing less than £5,000 when new, provided they are not highly dependent on or integrated with other items; and contracts with a term shorter than twelve months.

Recognition and initial measurement

At the commencement of a lease (or the IFRS 16 effective date) MHRA recognises a right-of-use asset and a lease liability.
The lease liability is measured as the payments for the remaining lease term net of irrecoverable value added tax, discounted either by the rate implicit in the lease, or, where this cannot be determined, MHRA's incremental cost of borrowing. For MHRA, the incremental cost of borrowing is the rate advised by HM Treasury for that calendar year (2022/23: 0.95%). The lease term is as reflected in the lease agreements. The liability is based on payments that are fixed in the lease. The lease liability is presented within note 13.

The right-of-use asset is initially measured at the value of the liability. The liability is adjusted for the accrued interest and repayments.

Expenditure includes interest and straight-line depreciation. Lease payments reduce the lease liability. Rental payments for leases of low value items or shorter than twelve months are expensed.

Subsequent measurement

The asset is subsequently measured using the fair value model. The MHRA considers the cost model to be a reasonable proxy for this. The liability is adjusted for the accrued interest and repayments.

MHRA has made the following determinations which have been mandated by HM Treasury

- To adopt IFRS 16 retrospectively' without restatement of comparative balances. As such, the Statement of Comprehensive Income and Statement of Financial Position for 2021-22 reflect the requirements of IAS 17;
- For leases previously treated as operating leases:
  - To measure the liability at the present value of the remaining payments, discounted by the incremental cost of borrowing as at the transition date;
  - To measure the asset at an amount equal to the liability, adjusted for any prepayment or accrual balances previously recognised for that lease;
  - To use the practical expedient to exclude leases whose whole term ends within twelve months of first adoption;
  - To use the practical expedient to use hindsight in assessing remaining lease terms.

1.10 Segmental Reporting

In accordance with IFRS 8, MHRA's operating segments reflect information provided to ExCo and the Board. Details are disclosed in Note 2.

1.11 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.

1.12 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 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

Income and expenditure are analysed and reported in line with management information as used to report to ExCo and the Board. An analysis of assets and liabilities is not provided as these are not regularly reported internally.

2022/23	Scientific, Research & Innovation £'000	Healthcare Quality and Access £'000	Safety & Surveillance £'000	Total £'000
Income from external customers	29.623	47,543	45,738	122,904
Total income	**29,623**	**47,543**	**45,738**	**122,904**
Direct costs	(21,828)	(28,954)	(25,404)	(76,186)
Indirect costs	(35,581)	(26,617)	(23,580)	(85,778)
Total expenditure	**(57,409)**	**(55,571)**	**(48,984)**	**(161,964)**
Net operating expenditure	**(27,786)**	**(8,028)**	**(3,246)**	**(39,060)**

2021/22	Scientific, Research & Innovation £'000	Healthcare Quality and Access £'000	Safety & Surveillance £'000	Total £'000
Income from external customers	34,540	48,691	37,994	121,225
Total income	**34,540**	**48,691**	**37,994**	**121,225**
Direct costs	(27,653)	(31,513)	(19,961)	(79,127)
Indirect costs	(34,370)	(31,836)	(27,374)	(93,580)
Total expenditure	**(62,023)**	**(63,349)**	**(47,335)**	**(172,707)**
Net operating expenditure	**(27,483)**	**(14,658)**	**(9,341)**	**(51,482)**

3 Income

3.1 Trading income

	2022/23 £'000	2021/22 Restated £'000
Licences and Inspections	**27,650**	30,630
Service fees	**41,749**	36,297
Devices	**2,072**	1,862
Clinical trials	**3,462**	3,757
British Pharmacopoeia	**5,989**	6,029
Tobacco Products Directive	**2,204**	1,155
Research	**24,016**	28,310
Other trading income	**2,551**	6,435
CPRD	**13,211**	6,750
Total	**122,904**	121,225

4 Staff costs

	2022/23 £'000	2021/22 £'000
Wages and salaries	**60,901**	68,307
Social security costs	**6,820**	7,172
Other pension contributions	**14,403**	15,705
Sub total	**82,124**	91,184
Less recoveries in respect of outwards secondment	**(20)**	(180)
Total	**82,104**	91,004

See staff report page 92

5 Operating costs

	2022/23 £'000	2021/22 £'000
Computing	**26,691**	21,406
Depreciation and amortisation	**13,831**	11,423
Accommodation	**11,475**	9,501
Medicines testing and Laboratory expenses	**8,801**	10,546
Travel and subsistence	**865**	351
Other operating costs	**18,196**	28,476
Total	**79,860**	81,703
	£'000	**£'000**
Other operating costs include:	**£'000**	**£'000**
Contracted out services	**12,145**	**21,453**
Statutory audit fees	**140**	**130**

6 Property, plant and equipment

2022/23	AUC	Land and Buildings	Computer and telecom equipment	Plant and equipment	Fittings, furniture and office equipment	Total
	£'000	£'000	£'000	£'000	£'000	£'000
Cost or valuation						
At 1 April 2022	**1,514**	**119,322**	**9,473**	**31,844**	**129**	**162,282**
Transfers under absorption accounting	-	-	143	-	-	143
Additions	8,887	-	-	-	-	8,887
Transfers	(4,608)	41	2,095	2,466	6	-
Reversals	(28)	-	-	-	-	(28)
Revaluation	-	4,295	-	957	5	5,257
Elimination of accumulated depreciation	-	(5,112)	-	-	-	(5,112)
Disposals	-	-	(24)	(279)	-	(303)
At 31 March 2023	**5,765**	**118,546**	**11,687**	**34,988**	**140**	**171,126**
Accumulated Depreciation						
At 1 April 2022	**-**	**-**	**7,636**	**19,916**	**104**	**27,656**
Transfers under absorption accounting	-	-	101	-	-	101
Charge for the year	-	5,112	933	2,011	4	8,060
Revaluation	-	-	-	451	2	453
Elimination of accumulated depreciation	-	(5,112)	-	-	-	(5,112)
Disposals	-	-	(22)	(218)	-	(240)
At 31 March 2023	**-**	**-**	**8,648**	**22,160**	**110**	**30,918**
Net book value						
At 31 March 2023	**5,765**	**118,546**	**3,039**	**12,828**	**30**	**140,208**
Net book value at 31 March 2022	1,514	119,322	1,837	11,928	25	134,626
Owned	**5,765**	**118,546**	**3,039**	**12,828**	**30**	**140,208**

Land and buildings

A professional valuation of land and buildings was carried out on 31 March 2023 which resulted in a net increase of £4,295k. 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.

6 Property, plant and equipment (cont.)

2021/22	AUC	Land and Buildings	Computer and telecom equipment	Plant and equipment	Fittings, furniture and office equipment	Total
	£'000	£'000	£'000	£'000	£'000	£'000
Cost or valuation						
At 1 April 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	-
Revaluation	-	481	-	473	-	954
Reclassification	(50)	-	-	-	-	(50)
Impairment	(26)	-	-	-	-	(26)
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
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**

7 Right of use assets

Right of use assets	Land and Buildings £'000	Others	Total £'000
Right of use assets recognised under IFRS 16 at 1 April 2022	**10,433**	**-**	**10,433**
Prepayments*	7,027	-	7,027
Right of use assets recognised under IFRS 16 at 1 April 2022	17,460	-	17,460

*Prepayments for fit out costs included in ROU assets in line with IFRS16

Right of use assets	Land and Buildings £'000	Total £'000
Cost or valuation		
At 1 April 2022	**17,460**	**17,460**
Release of prepayment	**(4,170)**	**(4,170)**
At 31 March 2023	**13,290**	**13,290**
Depreciation		
At 1 April 2022	**-**	**-**
Charge for the year	**(1,520)**	**(1,520)**
At 31 March 2023	**(1,520)**	**(1,520)**
Carrying value		
At 1 April 2022	**-**	**-**
At 31 March 2023	**11,770**	**11,770**

8 Intangible assets

2022/23	Computer systems £'000	AUC £'000	Software licences £'000	Total £'000
Cost or valuation				
At 1 April 2022	**37,118**	**3,684**	**3,445**	**44,247**
Transfers under absorption accounting	5,055	-	-	5,055
Additions	-	5,541	-	5,541
Transfers	4,072	(4,072)	-	-
At 31 March 2023	**46,245**	**5,153**	**3,445**	**54,843**
Amortisation				
At 1 April 2022	**24,529**	**-**	**3,316**	**27,845**
Transfers under absorption accounting	4,025	-	-	4,025
Charge for the year	4,225	-	26	4,251
Amortisation at 31 March 2023	**32,779**	**-**	**3,342**	**36,121**
Net book value at 31 March 2023	**13,466**	**5,153**	**103**	**18,722**
Net book value at 31 March 2022	12,589	3,684	129	16,402
Owned	**13,466**	**5,153**	**103**	**18,722**

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**

9 Inventories

	31 March 2023 £'000	31 March 2022 £'000
Current		
Biological Standards	**506**	522
Laboratory consumables and other stores	**139**	139
Total current	**645**	661
Non-current		
Biological Standards	**8,942**	9,473
Total	**9,587**	10,134

When first recorded in the NIBSC balance sheet at 31 March 2010 an unrealised gain of £3,958k 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 2022/23 was £85k (2021/22, £85k). Inventories consumed during the year amounted to £2,170k (2021/22 £2,916k).

10 Trade and other receivables

	31 March 2023 £'000	31 March 2022 Restated £'000	1 April 2021 Restated £'000
Amounts falling due within one year			
Trade receivables**	**10,338**	12,956	17,520
Other receivables	**1,024**	2,099	601
Contract assets	**5,499**	7,056	6,948
Accrued income	**4,385**	8,583	3,683
Prepayments	**2,697**	3,398	2,765
Total	**23,943**	34,092	31,517
Amounts falling due after more than one year:			
Prepayments	**-**	6,330	7,291
Total	**23,943**	40,422	38,808

**Trade receivables are shown net of a provision for bad debts of £318k (2021/22, £2,373k) and credit notes for all unpaid periodic fees at year end of £1,242k (2021/22, £1,020k).

11 Cash and cash equivalents

	31 March 2023 £'000	31 March 2022 £'000
Balance at 1 April	**51,047**	79,601
Net change in year	**26,775**	(28,554)
Balance at 31 March	**77,822**	51,047
Made up of		
Government Banking Service	**77,822**	51,047

12 Trade and other payables

	31 March 2023 £'000	31 March 2022 Restated £'000	1 April 2021 Restated £'000
Amounts falling due within one year			
Due to DHSC	**-**	2,500	2,875
Payments received on account	**5,268**	5,396	6,081
Taxation and social security	**3,354**	3,213	3,568
Contract liabilities	**1,015**	1,386	12,761
Other trade payables	**1,494**	6,238	2,680
Other payables	**14**	3	379
Accruals	**18,066**	15,184	14,685
Total	**29,211**	33,920	43,029

13 Lease liabilities

	Land and Buildings £'000	Others £'000	Total £'000
Operating lease commitments at 31 March 2022	**24,972**	**16**	**24,988**
Total leases reported under IAS 17 at 31 March 2022	**24,972**	**16**	**24,988**
Impact of discounting	**(534)**	**-**	**(534)**
Other Adjustments	**(14,005)**	**(16)**	**(14,021)**
Lease liabilities recognised under IFRS 16 at 1 April 2022	**10,433**	**-**	**10,433**

	Land and Buildings £'000
Operating lease obligations at 1 April 2022	**10,433**
Interest accrued during the year	**99**
Payments	**(1,717)**
At 31 March 2023	**8,815**
Current	**1,002**
Non current	**7,813**
At 31 March 2023	**8,815**
Obligations under leases	
Within one year	**1,002**
Between two to five years	**4,008**
Over five years	**4,239**
Less interest	**(434)**
At 31 March 2023	**8,815**

14 Other liabilities

	Current		Non-current	
	31 March 2023 £'000	31 March 2022 £'000	31 March 2023 £'000	31 March 2022 £'000
Deferred revenue:				
Other fees	**6,172**	3,051	**62**	30
Contract liabilities	**14,339**	12,322	**12,085**	7,863
Others:				
DHSC Contribution to CPRD	**9,691**	10,833	**-**	-
Total	**30,202**	26,206	**12,147**	7,893

15 Provisions

	Current		Non-current	
	31 March 2023 £'000	31 March 2022 £'000	31 March 2023 £'000	31 March 2022 £'000
Dilapidations	**-**	-	**1,998**	1,998
Total	**-**	-	**1,998**	1,998

Movement in provisions

	Total £'000
At 1 April 2022	**1,998**
At 31 March 2023	**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	Tangible	Intangible	Tangible
	31 March 2023 £'000	31 March 2023 £'000	31 March 2022 £'000	31 March 2022 £'000
Contracted	**1,755**	**606**	381	705
Total	**1,755**	**606**	381	705

17 Related party transactions

The MHRA is an Executive Agency of the Department of Health and Social Care (DHSC). DHSC is regarded as a related party. During the year, the agency has had a 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 2022/23, 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 Prior period restatement on joining DHSC group

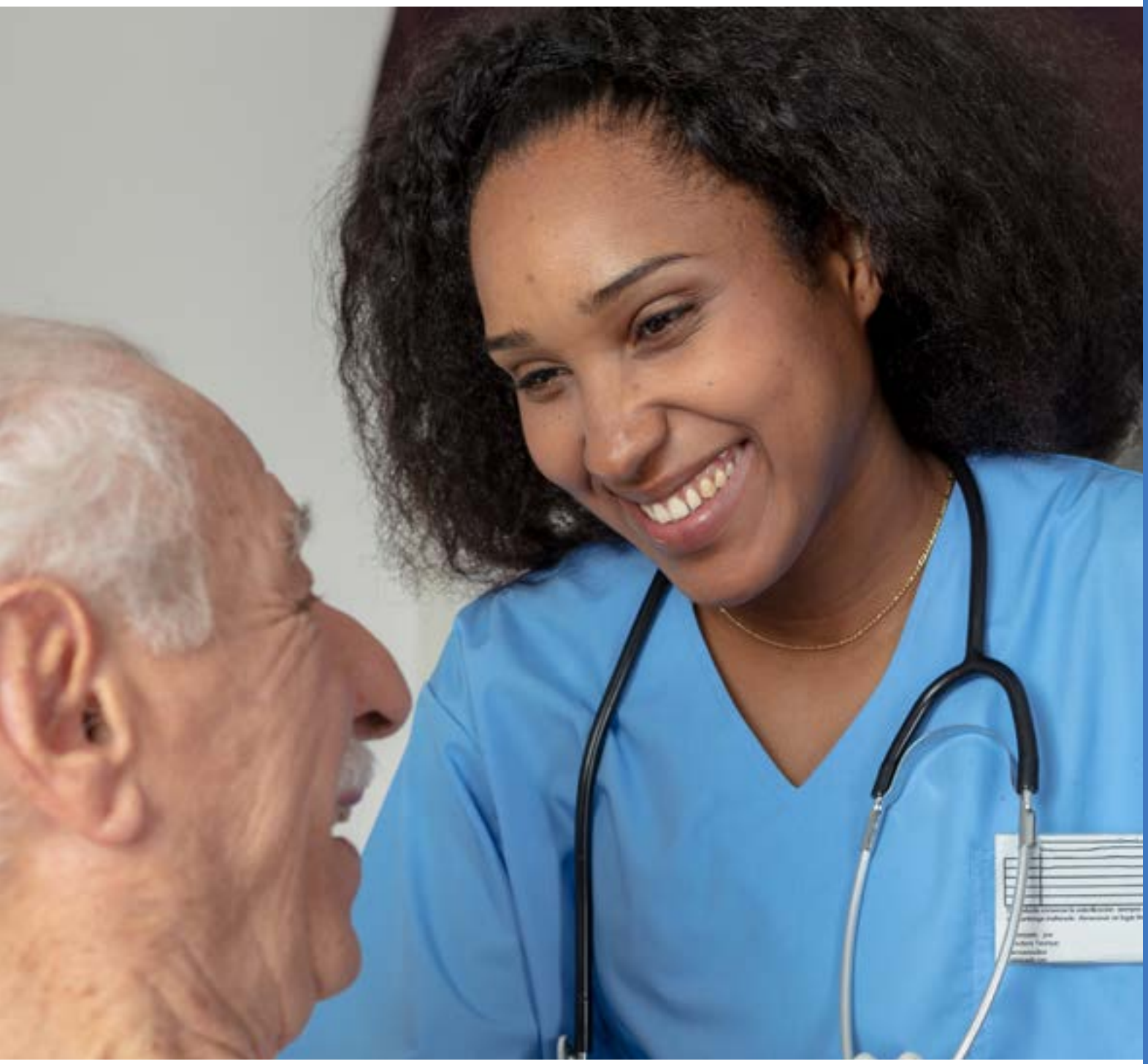
Following the revocation of the trading fund status and joining DHSC group with effect from 1 April 2022, DHSC are no longer invoiced for funded activities. These activities are instead funded through 'supply funding'. Prior to 1 April 2022, department funding was recognised as income. After joining DHSC group, departmental funding is now credited to reserves at the time of receipt. Additional funding to cover the cost of NIBSC depreciation and dividend has stopped in 2022/23. Both changes cause issues of comparability and given the material change, prior year comparatives have been restated in line with IAS 8, with adjustments in the Statement of comprehensive net expenditure, Statement of financial position, Statement of cash flows and Statement of changes in taxpayers' equity.

	Balance in 2021/22 accounts £'000	Restatement £'000	Revised balance in 2021/22 accounts £'000
Statement of comprehensive net expenditure			
Income			
Trading income	148,825	(27,600)	121,225
Other income	12,436	(12,436)	-
Total income	**161,261**	**(40,036)**	**121,225**
Operating expenditure	(172,707)	-	(172,707)
Net expenditure for the year	(11,446)	(40,036)	(51,482)
Total comprehensive expenditure for the year	**(5,489)**	(40,036)	(45,525)
Statement of Financial Position			
Trade and other receivables	46,528	(12,436)	34,092
Total current assets	**98,236**	**(12,436)**	**85,800**
Trade and other payables	(46,356)	12,436	(33,920)
Total current liabilities	**(72,562)**	**12,436**	**(60,126)**
Total assets less liabilities	**182,614**	**-**	**182,614**
Total taxpayer's equity	**182,614**	**-**	**182,614**
Statement of cash flows			
Net expenditure for the year	(11,446)	(40,036)	(51,482)
Decrease in trade and other payables	(10,395)	12,436	2,041
Funding from DHSC	-	27,600	27,600
Statement of changes in taxpayer's equity			
Balance at 1 April 2021	202,952	-	202,952
Net expenditure for the year	(11,446)	(40,036)	(51,482)
Dividend payable	(14,849)	12,436	(2,413)
Funding from DHSC	0	27,600	27,600
Balance at 1 April 2022	**182,614**	**-**	**182,614**

19 Events after the reporting period

These accounts are laid before the Houses of Parliament by the Department of Health and Social Care. IAS10 requires the MHRA 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.

There have been no significant events between the Statement of Financial Position and the date of authorising these financial statements.



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