Medicines & Healthcare products
Regulatory Agency

MHRA Annual Report and Accounts

2023–2024

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Medicines and Healthcare products Regulatory Agency

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Table of contents

1 Performance report 6

1.1 Performance overview 8

Interim Co-Chairs' foreword 9

Chief Executive's perspective on the year 11

About the MHRA 15

Our vision, mission and values 15

Our structure 16

Our role 16

Quality management 17

How we are funded 19

Our goals and deliverables 19

Performance summary at a glance 20

1.2 Performance analysis 35

Progress against our strategic objectives 36

Performance against our public health targets 41

Transparency 53

Risk Profile 54

Sustainability report 56

Climate Related Disclosure report 65

Health and safety report 67

Financial review 69

2 Accountability report 72

2.1 Corporate governance report 75

2.2 Statement of Accounting Officer's responsibilities 88

2.3 Governance statement 90

2.4 Remuneration and staff report 104

2.5 Parliamentary accountability and audit report 128

3 Financial statements 137

1.0 Performance report

1.1 Performance overview

This section describes the role of the Medicines and Healthcare products Regulatory Agency (MHRA), explains our purpose, goals and strategic objectives and provides a summary of our performance in 2023/24.

Interim Co-Chair's foreword

It is our privilege to have been able to support the MHRA this year as interim Co-Chairs following the departure of Stephen Lightfoot in July 2023. On behalf of the MHRA Board, we extend sincere thanks to Stephen for his expert leadership of the Board over the preceding three years. As interim Co-Chairs, we each bring a unique focus to our roles, whether chairing the Board, facilitating cross-government or stakeholder engagement or contributing to organisational development. We have worked closely together using our combined expertise to ensure continuity of leadership throughout the year.

The MHRA has a unique capability worldwide, bringing together regulatory responsibilities with scientific expertise from the bench to bedside and access to longitudinal, real-world data. These strengths create a platform for unrivalled benefit for the UK and public health in the fast-moving landscape of medicine and medical technology product development. This year has seen the MHRA deliver on that promise, with the delivery of expert research, assessment of life-changing products, regulatory action to prevent harm and creation of a trusted environment for safe data usage. The MHRA has built on its strong international relationships to enable rapid access to safe new medicines and healthcare products, as well as with domestic partners. As a part of the wider health ecosystem the agency does not work alone and as we grapple with the challenges of developing science and technology, we understand that we have greatest impact through working with others.

The MHRA has a unique capability worldwide, bringing together regulatory responsibilities with scientific expertise from bench to bedside and access to longitudinal, real-world data.

There have been performance challenges in some areas of the MHRA's activities this year, and as Co-Chairs we have supported the Chief Executive Officer and the Board to address these. The Board has encouraged the MHRA to review the services that it provides, emphasising quality and efficiency to deliver the best for patients and the public. We are pleased to see sustainable performance restored in some areas, with substantial improvement work on those that remain outstanding well underway.

The Board has also seen unequivocal improvements in performance monitoring, enabling clear oversight and rapid action where issues start to develop. There is more to do, and a clear path ahead. We are confident that the MHRA will rise from these challenges stronger than ever.

This year has seen a focus on ensuring that the MHRA attracts and retains the talent and expertise it needs to operate as a world class regulator. We are pleased to welcome graduates to the MHRA through the

new graduate scheme, enabling medicines regulation to form a fundamental part of the career development of talented individuals at the start of their careers. The MHRA is also ensuring that existing staff are supported in their career development through a new leadership programme and training opportunities. Similarly, the MHRA has worked hard to cement its progress in recent years on an effective governance, risk and control environment.

As an essential part of the national health infrastructure, the MHRA remains committed to independence, objectivity, and evidence-based decision-making to uphold and protect patient safety and public health as our highest priority. These principles underpin our culture and are the foundations on which the agency operates in everything it does. We would like to close by offering our thanks to the executive team, to all our staff and non-executive directors for their commitment to MHRA and its work to keep patients safe and enable access to high quality safe and effective medical products.

Professor Graham Cooke, Michael Whitehouse and Amanda Calvert – Interim Co-Chairs

Professor Graham Cooke

Michael Whitehouse OBE

Amanda Calvert

Chief Executive's perspective on the year

As I complete my fifth year as Chief Executive, I reflect on another year of important change for our organisation, as we continue to establish the agency's 'lifecycle' model reflecting the development pathway of healthcare products. It is my privilege to lead the MHRA and to bear witness to the tireless commitment of our staff to fulfil our critical public health responsibilities. I am sincerely grateful for the efforts of every person in the MHRA and proud to reflect on what we have achieved.

I would also like to express my thanks to Amanda Calvert, Professor Graham Cooke and Michael Whitehouse, our Non-Executive Directors who have generously given their time and expertise as interim Co-Chairs after Stephen Lightfoot stepped down in July 2023.

Our responsibilities to public health demand the best of us and we remain dedicated to acting in the best interests of patients. Our safety activities are our first priority, ranging from the value we place on every single report of an adverse event relating to the use of a medicine or healthcare product, whether from a patient or a healthcare professional, to innovative ways of using real-world data. This year has seen further investment in our new signal detection system, SafetyConnect, which enables better, swifter identification of potential safety signals and provides much greater information back to the original reporter. We are delighted to have established our Yellow Card Biobank pilot in partnership with Genomics England, testing the ability to identify potential adverse drug reactions from a patient's genetic makeup.

Our responsibilities to public health demand the best of us and we remain dedicated to acting in the best interests of patients.

We know the public and patients rely on a robust, effective regulator and where safety issues are identified, that appropriate action is taken, including when such issues are identified over time in clinical use. This year, following

carefully listening to the patient voice, we have taken action to restrict the prescribing of the antiepileptic valproate and the acne treatment isotretinoin in new patients without careful safeguards, and have strengthened safety measures for those already on treatment. Following a public consultation, we have also reclassified codeine linctus to a prescription-only medicine given the risks of dependence, addiction and overdose.

Robust, responsive safety systems capable of rapidly refining our benefit-risk understanding underpin our ability to bring innovation to patients in the shortest time. The agency was the first medicines regulator to approve a gene therapy for sickle cell disease and β-thalassemia. The first medicine to be licensed that uses the innovative gene-editing tool CRISPR. I am extremely grateful to those living with sickle cell disease who gave their time to provide us with a patient perspective as we rigorously reviewed its safety, quality and efficacy. We have been guided by population health priorities, such as for anti-obesity medicines, and the importance of preventive healthcare, such as a new formulation for pre-exposure HIV prophylaxis.

We are equally committed to recognising and supporting the benefits for both patients and the healthcare system of innovative medical devices. This year we launched a new pathway to accelerate access to innovative medical devices which meet an unmet clinical need. Developed and operated with a range of partners, this new pathway will support the route to market for eight pilot products, ranging from diagnostic devices linked to stroke and sepsis, to accurate detection of oxygen levels in people with darker skin tones, to a biomarker test for Alzheimer's disease. Each product could make a real difference to the experience and health of patients.

These new offers sit alongside our efforts to enable rapid access to new medicines by recognising the licensing decisions of other respected regulators. This is a core element of enabling rapid access to new drugs which can bring life-saving or outlook-changing benefits to patients. Our new legislation on international recognition for medicines means that, subject to appropriate checks, we can also minimise the need for duplicative scrutiny and avoid unnecessary approval delays. We have also published our policy intent to progress work on international recognition of medical technology. Both initiatives together pave the way to the exciting opportunity to define the agency's future unique regulatory contribution.

Our world-leading research and innovation capability is a critical foundation of our regulatory function, enhancing our scientific expertise as we keep pace with global innovations. It continues to enable us to serve the life sciences sector through development of new standards and reagents, supporting access to effective and quality medicines and diagnostics globally. Importantly, the polio vaccine co-developed by our scientists was pre-qualified by WHO for poliovirus type 2 outbreaks, contributing to global polio eradication. In partnership with Innovate UK and the Office for Life Sciences we are creating a network of Centres of Excellence in Regulatory Science and Innovation, which will provide greater access to the UK research and innovation community, generating research-based evidence to strengthen our decision-making across a range of health and technical priorities.

Despite these significant successes, this year has seen under-performance in some of our core services. We have rapidly implemented improvements in clinical trials assessment and have sustained this performance while introducing a new system for the lowest risk trials. Our approval times for established medicines have been below the performance that patients, the public and industry can rightly expect. We are implementing a range of measures, including considering the appropriate regulatory oversight for medicines whose benefit risk is well understood, making full use of our sovereign regulator status and the benefit of improved technology through the successful launch of our new information management system, RegulatoryConnect.

Throughout the year, we have built on the improvements in our risk, governance and control environment that we have initiated over recent years. I am confident that our organisation is operating more effectively as a result, meeting the standards expected of us in operating on behalf of the UK public. We equally attach great importance to our responsibility in supporting the Covid Inquiry and are ensuring we provide the information needed to allow the Inquiry to fulfil its task effectively.

Recent years have been a time of profound change for MHRA and there has been much for the agency to grapple with. While our recent transformation was the beginning of a more continual approach to change, ensuring and further developing best practice in all we do, the wider seismic shifts we have needed to respond to have been far greater. Whether the UK's exit from the European medicines system, the findings of the Cumberlege report or resource replacement following the Covid pandemic, all have taken time to work through. While there is still more work to do, I am confident that the agency is securing its foundation for an agile, effective and successful future, putting patients first in all it does.

25 July 2024

Dr June M Raine, DBE
Chief Executive and Accounting Officer

About the MHRA

The Medicines and Healthcare products Regulatory Agency (MHRA) is an Executive Agency of the Department of Health and Social Care (DHSC). Our primary responsibility is to ensure that medicines and medical devices work as intended and are acceptably safe. We regulate medicines, medical devices and blood components for transfusion in the UK.

Our Framework Agreement includes further details about the MHRA and our relationship with the DHSC: https://www.gov.uk/government/publications/dh-and-mhra-framework-agreement/framework-agreement-between-dhsc-and-the-medicines-and-healthcare-products-regulatory-agency.

Our vision

Our vision is 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

Keeping patients safe and enabling access to high-quality, safe and effective medical products.

Our values

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 2023/24, our structure included seven operating groups, consisting of three core functions supported by corporate and platform services.

Our workforce

Our talented workforce of 1416 staff operate tirelessly from our suite of offices in Canary Wharf, London and our specialised Science Campus in South Mimms, Hertfordshire. Our dedicated expert compliance and enforcement teams are deployed remotely across the UK, inspecting and investigating across the medical product lifecycle and support chain. We are also delighted to work with the Laboratory of the Government Chemist (the LGC Group) in Teddington, who host and operate the British Pharmacopoeia Commission Laboratory on our behalf.

Our role

We protect the safety of patients and the public through the regulation of medicines, medical devices and blood components intended for transfusion in the UK. Using science and data to inform our decisions, we enable medical innovation and ensure that the medical products available in the UK are safe and effective.

We are responsible for carrying out the functions of the Secretary of State for DHSC as prescribed by UK legislation related to the regulation of medicinal products, blood components, e-cigarettes and traditional herbal and homeopathic remedies.

More details about our statutory responsibilities can be found on our website: https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/about

Our specialist services

Our specialist expertise and scientific resources within the agency add significant value to our regulatory role.

British Pharmacopoeia

The MHRA manages the British Pharmacopoeia (BP), the national pharmacopoeia of the United Kingdom. The BP is a comprehensive collection of published quality standards for pharmaceutical substances and medicinal products. These are used by researchers, manufacturers, and testers in the pharmaceutical industry to ensure the safety and effectiveness of their products. To view our products and find out more about the BP please visit our website: https://www.pharmacopoeia.com

Clinical Practice Research Datalink

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

The National Institute for Biological Standards and Control (NIBSC) Biological Standards and Reference Materials

The MHRA is the world leader in the design, production and distribution of biological reference materials which are used to assure the quality of biological medicines and diagnostics. These are produced and marketed under the NIBSC brand, reflecting our substantial history and expertise in this area built at the MHRA Science Campus.

The extensive catalogue of biological reference materials includes World Health Organisation (WHO) International Standards and influenza reagents. We also provide reagents to advance research into a range of infectious and emerging diseases, with support from key partners including the World Health Organization (WHO), the Coalition for Epidemic Preparedness Innovations (CEPI), Innovate UK and the UK Vaccines Network. Further details can be found on our website: https://nibsc.org

UK Stem Cell Bank

The MHRA hosts the United Kingdom Stem Cell Bank (UKSCB), which is the UK designated repository for human embryonic stem cells. The UKSCB houses the world's largest collection of clinical-grade material for use in scientific research and the clinical development of stem cell therapies. The UKSCB was established in 2003 and is an important facility for ensuring the ethical use of human embryonic stem cell lines in the UK. Visit our website to find out more: https://nibsc.org/ukstemcellbank

Influenza Resource Centre and World Health Organisation 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 WHO holds biannual meetings, which include the MHRA, to review influenza virus activity and make scientifically informed decisions.

Through the IRC, we play a central role in supporting the selection of WHO-recommended viruses for influenza vaccine manufacture. Our scientists also contribute to the development of candidate vaccines and providing high-quality influenza virus strains and reagents for vaccine production and research. As one of the four global WHO

Essential Regulatory Laboratories, we carry the responsibility of supporting the global influenza vaccine programme. Further details are available on our website: https://nibsc.org/science_and_research/virology/influenza_resource_.aspx

Official Medicines Control Laboratory

Our Science Campus at South Mimms serves as the United Kingdom's Official Medicines Control Laboratory (OMCL) for biological medicines. The OMCL performs independent laboratory testing and certification of batches of licensed blood products, vaccines and other biotherapeutics 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.

Polio Specialised Laboratory

Our Science Campus hosts one of the seven WHO Global Specialised Laboratories (GSL) that sit at the top of the three-tiered structure of the global polio network laboratories (Specialised, Regional and National laboratories). Through this, our expert scientists support the eradication and post-eradication era to end poliovirus infections. We play an important role in environmental screening and investigation of virus isolates detected and in ensuring the quality of current and future vaccines. To find out more, please visit our website: https://nibsc.org/science_and_research/virology/polio.aspx

Quality management

Quality management is of critical importance to us in supporting the public health outcomes we deliver. We work under several formal quality standards:

We are:

- Certified to ISO 9001:2015 as the underpinning framework for our Quality Management System (QMS), covering our regulatory work, post-market surveillance, the design, manufacture and supply of standards, reference materials, research reagents and primary care data
- 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 our batch release testing of biological medicines

We also hold:

- Two Human Tissue Authority licences for the storage and use of human tissue for research purposes and a Human Application Licence held by the UK Stem Cell Bank for the storage, procurement, processing, testing and distribution of cells
- A documented QMS compliant with the requirements of Good Clinical Practice for testing clinical trial patient samples
- A QMS for ISO 17034:2016 to produce Certified Reference Materials. This is in the process of being formalised
- An internal QMS for the management of Standardisation projects, the Reference Materials Quality Manual

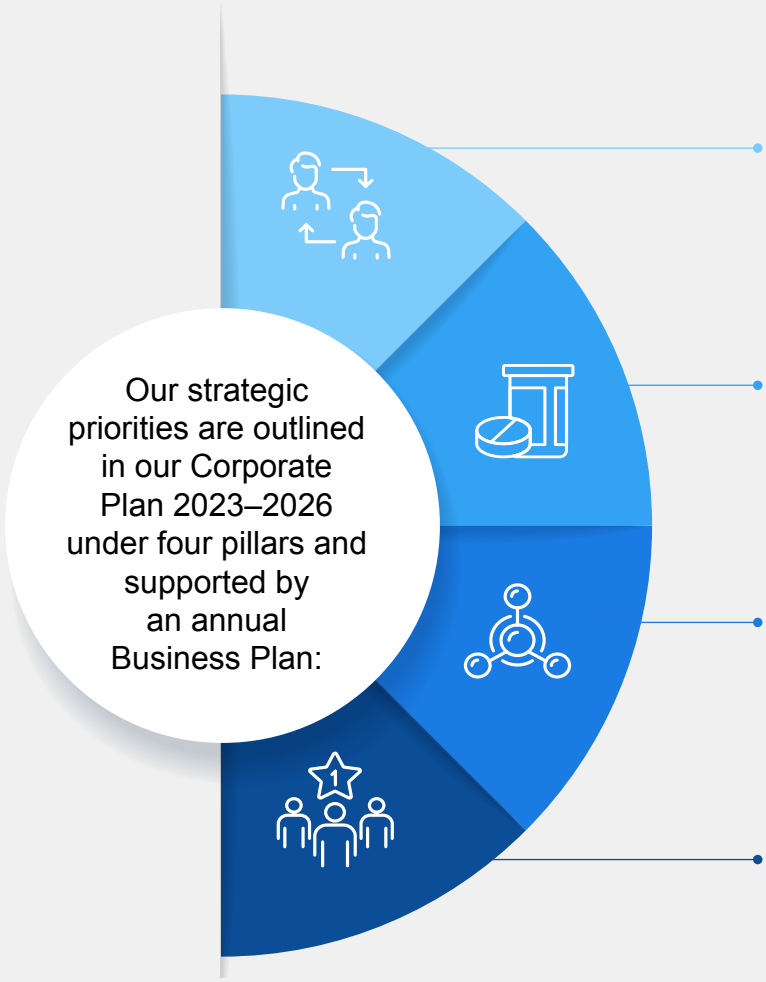
How we are funded

As an Executive Agency of the DHSC, Our finances are consolidated within the DHSC accounting boundary. Further details about our funding can be found in the 'Financial Review' section on page 69.

Last year most of our running costs were funded by statutory fees paid by industry for regulatory services or charges for non statutory goods and services. The DHSC provided the MHRA with £49.7m funding. Of this £8.1m was for the core delivery of devices regulation, £12.5m for our scientific work, £3.6m for other one off grants and £25.5m was capital.

Our goals and deliverables

We have outlined our strategic priorities in our Corporate Plan 2023 - 2026 and in our annual business plans.



https://www.gov.uk/government/publications/mhra-corporate-plan-2023-to-2026

Performance summary at a glance

This section highights some of the key achievements across our three core groups

Science, Research and Innovation Group

Healthcare, Quality and Access Group

Safety and Surveillance Group

Science, Research and Innovation Group

Our focus is on delivering public health impact through excellent scientifically-driven decisions and world leading regulatory science research innovation. The Science, Research and Innovation Group is led by our Chief Science and Innovation Officer. Our core activities are:

- Encouraging and enabling innovation
- Providing advice on, and taking decisions on applications for clinical trials and clinical investigations
- Assuring the quality of biological medicines and diagnostics
- Developing and providing biological reference materials for the purity and potency of biological substances, and designing test procedures for biologicals
- Performing independent batch release testing that assures the quality of biological medicines. This ensures that every batch that is manufactured meets the relevant requirements for safety and efficacy before it is allowed to enter the UK market
- Undertaking applied regulatory science research to enhance our activities

Our year in numbers:

>5,000 Clinical trial initial and amendment applications and 78 clinical investigation applications assessed	**>140** First-in-human clinical trials approved with an increase in both non-commercial and commercial trials	**81** Applications for our Innovative Devices Access Pathway (IDAP), with eight pilot products selected to receive support from IDAP partners (health technology and NHS bodies) at key stages of their product development
1,367 Vaccine and blood product batches tested and certified for safety and efficacy	**3,327** Plasma pools safety tested for the absence of blood-borne viruses and released for the manufacture of blood-derived medicines	**167,983** Biological standards, reference materials and reagents from our catalogue provided to customers globally to support the quality of biological medicines and research
81 New biological standards and reference materials developed and added to our catalogue	**>£4.5m** External competitively awarded research grants utilised in the year, supporting our regulatory science research programme	**75** Scientific publications published in peer reviewed journals reporting the public health impact of our science

Science, Research and Innovation successes

Clinical trials and investigations

The performance of our Clinical Investigations and Trials function is critical to the success of the UK life sciences ecosystem and is vitally important for the development of new treatments for patients. We have successfully improved service delivery for clinical trial applications assessment, eliminating all backlogs with sustained compliance with statutory timeframes from September 2023, and we have maintained performance for clinical investigations applications for medical devices assessment throughout the year. We have implemented a range of measures to improve our assessment performance for clinical trials including our innovative notification scheme for the lowest risk clinical trials. Applications submitted under this scheme will be processed by the MHRA within 14 days, instead of the statutory 30 days, safely accelerating the timeline for sponsors. Robust measures are in place to monitor and ensure continued performance and transparency of assessment timelines.

Innovative Devices Access Pathway pilot

A new Innovative Devices Access Pathway (IDAP) was launched in September 2023, which aims to accelerate the development of innovative medical devices which meet an unmet clinical need. The pathway will support

their route to market to facilitate rapid patient access.

We work extensively with the IDAP partners to deliver the pathway and seek the lived experience of patients and the public to support the development of innovative devices

The IDAP partners are:

- Medicines and Healthcare products Regulatory Agency
- Department of Health and Social Care
- Health Technology Wales
- National Health Service England
- National Institute for Health and Care Excellence
- Office of Life Sciences
- Scottish Health Technologies Group

Eight pilot products have been selected to receive advisory support from IDAP partners at key stages of their product development. Further details can be found on our website: The Innovative Devices Access Pathway (IDAP) - https://www.gov.uk/government/publications/the-innovative-devices-access-pathway-idap/the-innovative-devices-access-pathway-idap-pilot-phase

Innovative Licensing and Access Pathway

The ILAP is a flagship initiative in the UK as set out in the Life Sciences Vision and MHRA's corporate and business plans. It presents a unique opportunity to forge alignment across the life sciences ecosystem for key healthcare priorities and accelerate patient access for transformational and innovative medicines.

The MHRA is working with the ILAP partners to develop revised eligibility criteria for ILAP and improve the offer of ILAP in terms of efficient delivery of Target Development Profiles for products that gain an Innovation Passport.

The ILAP partners are:

- Medicines and Healthcare products Regulatory Agency
- Department of Health and Social Care
- All Wales Therapeutics and Toxicology Centre
- National Health Service England
- National Institute for Health and Care Excellence
- Scottish medicines Consortium

Control testing

We assessed and certified all batches of biological medicines used in the UK within the statutory timelines throughout the year. A dynamic approach was taken to decide whether and how laboratory testing was carried out. For some products, laboratory testing was 'switched on' to adapt to changes in external processes, whilst sufficient assurance was available to streamline testing regimens in other areas. Laboratory methods required updating and validation in response to modifications to existing products, e.g., COVID-19 vaccines, and new methods were set up at our Science Campus for the control testing of novel products in preparation for use in public health programmes, e.g., Respiratory Syncytial Virus (RSV) vaccines.

Standards and reference materials

We play a leading national and international role in assuring the quality of biological medicines and diagnostics. We provide reference materials including WHO International Standards, influenza standards and quality control reagents through our catalogue.

This year, we have developed 81 new materials, including 19 WHO International Standards and 43 influenza reagents. This included first generation International Standards and reference reagents for harmonising the measurement of human vascular endothelial growth factor-165, important in angiogenesis, anti-citrullinated peptide antibodies (ACPA) used in the diagnosis of rheumatoid arthritis, antibody reference materials for Rift Valley Fever, Nipah virus and Q Fever which supports both accurate diagnosis and vaccine development

of these escalating diseases and gut microbiome DNA extraction controls that will harmonise next generation sequencing of novel biologicals to help combat anti-microbial resistance.

Regulatory science research

This year, we utilised over £4.5m of external, competitively awarded research contract and grant funding to undertake additional regulatory science research that would not otherwise have been possible. Furthermore, our scientists secured more than £10m of new research contract and grant funding to be used in the 2023-2028 period.

This included a £5m National Institute for Health and Care Research grant to the Regulatory Science Research Unit to undertake research across themes highlighted in the UK Government Life Sciences Vision including pandemic preparedness, cancer and chronic inflammatory diseases, neurodegenerative disease, anti-microbial resistance (AMR) and assuring the quality of mRNA-based vaccines. A further £2.4m was secured to work specifically on establishing serological correlates of protection against Marburg and Nipah viruses, Q Fever and Plague.

The genetically stable polio vaccine nOPV2 previously co-developed by MHRA scientists has secured WHO Prequalification, the first Emergency Use Listing vaccine to achieve this important designation.

The circulating vaccine-derived polio Type 2 (cVDPV2) outbreak first detected in London wastewater samples in 2022, was declared over by the WHO in January 2024, meaning the UK is no longer considered a polio-infected country. The work of the MHRA Polio Laboratory was central and instrumental for this finding.

The impact of our programme of research has been communicated through publication of 75 Open Access peer-reviewed scientific papers.

Centres of Excellence in Regulatory Science and Innovation (CERSIs)

We are working with Innovate UK, the Office of Life Sciences and other partners to establish Centres of Excellence in Regulatory Science and Innovation (CERSIs). The discovery phase is underway, with applicants drawing together networks of collaborators to develop prospective CERSIs and linking with MHRA sponsors in Biotherapeutics, Cell and Gene Therapy and Diagnostics, Genomics and regulatory decisions.

The creation of CERSIs aims to help organisations to collaborate on the development of new tools, data sets and approaches which drive innovation.

Development of guidelines

Our scientists' expertise has been influential globally in the collaborative development of important scientific and regulatory guidelines. These include those focused on influenza testing and vaccine production, the regulation and safety testing of monoclonal antibodies and cell and gene therapies, vaccines and diagnostics for future pandemics and the implementation of Replacement, Reduction and Refinement (3Rs) toward improved animal welfare.

Scientists contributed to the drafting and revision of key documents of the European and British Pharmacopoeia that regulate the manufacture and quality assurance testing of vaccines and blood products. To encourage regulatory engagement of innovators working on novel biological medicines for antimicrobial resistance: workshops were held and exploratory guidelines on the regulation of microbiome and bacteriophage-based products were developed.

Healthcare, Quality and Access Group

Our Healthcare, Quality and Access Group works in increasingly complex scientific spheres to ensure patients and the public have safe access to medicines, vaccines and medical devices. The Group oversees the licensing and market access of medicines and medical devices as well as ensuring compliance with regulations and standards, while promoting patient safety and high quality healthcare.

Our year in numbers:

52 New medicinal substances were assessed and approved	**494** Generic medicinal products (those which have been in use for a certain period) were assessed and approved	**837** Compliance inspections were held to ensure the quality of licensed medicines produced
9 New approved bodies were designated which allows them to approve a range of medical devices for use in the UK	**15** New British Pharmacopoeia chemical reference standards were produced	**131** British Pharmacopoeia documentary standards were developed or revised

Healthcare, Quality and Access successes

Innovative medicines

During the year, a number of significant approvals for innovative medicines have been given including:

Tirzepatide (Mounjaro)

We approved a new indication for this diabetes medicine as a weight loss treatment for adults with obesity or who are overweight with weight-related health issues. This medication is a GLP-1 agonist which helps regulate appetite and should be used alongside a reduced-calorie diet and increased physical activity. This authorisation aligns with the Life Sciences Vision goal to address obesity, a significant public health challenge in the UK.

Epcoritamab (Tepkinly)

We authorised an innovative new medicine, epcoritamab, for the treatment of diffuse large B-cell lymphoma in adults. This is a bispecific antibody, which means it has two binding sites which help it to attach strongly to its target. The antibody binds to immune cells and cancer cells resulting in killing cancer cells.

Ritlecitinib (Litfulo)

We authorised a new medicine to treat severe alopecia areata (patchy hair loss) in adults and adolescents older than 12 years of age. Ritlecitinib works by reducing the activity of JAK3 and TEC kinases, which are involved in inflammation at the hair follicle.

Dostarlimab (Jemperli)

We approved a new indication via the US Food and Drug Administration (FDA) Project Orbis to treat advanced endometrial cancer in combination with chemotherapy. This monoclonal antibody is a checkpoint inhibitor and stimulates the immune system to kill tumour cells.

Exagamglogene autitemcel (Casgevy)

We approved the first gene therapy for sickle cell disease and transfusion-dependent beta thalassemia. Casgevy is the first medicine that uses innovative gene editing or "CRISPR" technology. Our engagement of patient representatives and the Sickle Cell Society was instrumental in providing valuable insights into the lived experience of individuals with sickle cell anaemia, which supported our assessment. The conditional approval of Casgevy marks a significant advancement in the treatment of these genetic conditions.

Lumacaftor and ivacaftor (Orkambi)

We approved a new lower-strength oral granule formulation of lumacaftor and ivacaftor (Orkambi) for treating cystic fibrosis in patients with the F580del mutation. We completed this approval alongside our access partners (Australia, Canada, Singapore and Switzerland), expanding the indication to include children aged one to less than two years, with the MHRA assessing the clinical data.

During the year, we assessed the safety of using UK-sourced plasma for the manufacture of albumin medicinal products with particular reference to the risk of variant Creutzfeldt-Jakob Disease. Based on current epidemiological data, manufacturing process capability, expert advice and information collected for previous reviews, we concluded that UK-sourced plasma can safely be used for the manufacture of albumin medicinal products, in addition to its already approved use for the manufacture of immunoglobulins.

COVID-19 vaccines

We have enabled supply of COVID-19 vaccines with the timely approval of the Pfizer and Moderna C19 vaccine variants (XBB.1.5) to ensure that the NHS could rollout the Autumn 2023 immunisation programme. We met with Forgotten Lives UK to discuss licensing pathways, hearing powerful testimony about the ongoing impact of COVID-19 on the lives of immunocompromised patients and their families, and the need for more effective prevention. We emphasised our commitment to putting the patient at the centre of everything we do and providing opportunities for patient involvement in our pre-authorisation activities.

Regulatory updates:

International Recognition Procedure

On 1 January 2024, the International Recognition Procedure (IRP) replaced the European Commission Decision Reliance Procedure (ECDRP). Under the new IRP, we can use the decisions of trusted reference regulators (those in Australia, the United States of America, Canada, Switzerland, Japan, Singapore, the European Union, EEA, and member states) to inform our own decision-making process. In support of 'Faster, Simpler, Fairer' principles, the IRP will benefit UK patients by facilitating earlier access to both new and established medicines. Applications assessed through this pathway have been approved 100% within target timelines.

Windsor Framework

We have worked closely with trusted advisors within Trade Associations and other areas of government on labelling and packaging of medicinal products for human use following agreement of the Windsor Framework, which sets out the long-term arrangements for the supply of medicines into Northern Ireland. This will ensure that we can approve and license medicines on a UK-wide basis, with medicines using aligned packaging and labelling. This enables the disapplication of European Union (EU) Falsified Medicines Directive (FMD) requirements for medicines marketed and supplied in Northern Ireland.

Advertising and the Promotion of Medicines

We continue to review advertisements and promotional material for new medicinal products ahead of UK marketing to ensure regulatory compliance and to support appropriate and

safe prescribing of a new medicine as it comes to market. We also consider complaints about the advertisement of medicines and take action against those who illegally promote prescription medicines to the public. A particular focus continues to be advertisements by treatment-service providers for prescription medicines for weight loss, aesthetics treatments, and hay fever. Summaries of our investigations are published on our website (https://www.gov.uk/government/collections/advertising-investigations-by-mhra).

Standards and compliance

Our compliance teams play a crucial role in regulating medicines worldwide. Their focus is on conducting regulatory inspections, supporting enforcement activities, and promoting compliance through stakeholder engagement and education. Additionally, our compliance teams have supported legislative reform efforts for medicines development and authorisation in the UK.

We have continued to collaborate and partner with regulators both nationally and internationally. This year, we:

- Co-hosted a joint symposium with the US FDA, and Health Canada on Good Clinical Practice (GCP) and Pharmacovigilance Compliance, attended by over 34,000 attendees (online and in-person) across 145 countries
- Participated in a marketing authorisation workshare pilot with the Australian Therapeutic Goods Agency to facilitate reduced regulatory burden on global manufacturers and introduced the pilot for the Good Manufacturing Practice single inspection programme with the Australian Therapeutic Goods Administration and Health Canada

British Pharmacopoeia

We continue to release our BP annual update every August with increased uptake, and this year, launched a new website with additional functionality. To supplement our work on monographs and reference standards, we also provided best practice downloads for emerging technologies and topics, including Advanced Therapy Medicinal Products (ATMP) guidelines and a new environmental hub showcasing flexibilities within the BP that enable users to reduce their carbon footprint and signposting best laboratory practice. The BP continues to support international pharmacopoeial convergence with its membership in the International Meeting of World Pharmacopoeias (IMWP).

Supporting supply of products

We have supported the DHSC throughout the year in its work on managing medicines supply by expediting assessment of new applications, variations, and batch-specific variations, notifications of imports of unlicensed medicines and inspections of manufacturers and wholesalers for medicines with supply challenges.

Safety and Surveillance Group

We protect public health using robust vigilance processes to quickly detect, monitor and evaluate the safety of medicines and medical devices once these are in clinical use, designing effective risk mitigation measures and supporting the patients, healthcare professionals and the healthcare system to implement these.

Our Safety and Surveillance Group is the engine room of signal detection and evaluation for all healthcare related products (medicines, medical devices, nicotine e- cigarettes, blood and blood components, and suspected defective or counterfeit products) supported by analysis of real world data through the Clinical Practice Research Datalink (CPRD), and is also home to our Criminal Enforcement Unit who take action to protect the public by preventing, detecting and disrupting the illegal trade in human medicines.

Our year in numbers:

87,566

Suspected adverse drug reaction reports for medicines and vaccines from patients, healthcare professionals and pharmaceutical companies were handled

31,364

Adverse incident reports for medical devices for medicines and medical devices

133

Safety signals for medicines and medical devices were identified

27

Benefit risk assessments for medicines resulted in communication of risk mitigations to health care professionals

45

Medicines recalls/notifications were actioned by the Defective Medicines Report Centre

308

Field Safety Notices for medical devices were reviewed by benefit risk evaluation assessors

76

Exceptional Use Authorisation applications for medical devices to fulfil an unmet clinical need were reviewed

£2.1m

In criminal profits were denied to offenders

4

Epidemiology CPRD studies were conducted independently

335

New research protocols were approved by the CPRD and 261 studies using CPRD data published in peer-reviewed journals

1,334

Threat reduction interventions were led by the Criminal Enforcement Unit

173

Months' imprisonment was handed down to 12 defendants in 6 criminal trials

115

Humanitarian medical device applications were reviewed by benefit risk evaluation assessors

Safety and Surveillance successes

Yellow Card

In September 2023, we launched a new Yellow Card regional centre in Northern Ireland, meaning we now have six MHRA-commissioned regional Yellow Card centres across the UK: Birmingham, Cardiff, Edinburgh, Liverpool, Newcastle, and Belfast.

The Yellow Card centres encourage patients and healthcare professionals to report suspected adverse incidents associated with medicines and medical devices, deliver training and education and promote safety messages from the MHRA to healthcare professionals and patient groups.

Yellow Card Biobank

In June 2023, in partnership with Genomics England we launched a pilot of the Yellow Card Biobank to investigate the role of genetics in certain severe adverse drug reactions. The aim of the Yellow Card Biobank is to better understand how a patient's genetic make-up can impact the safety of their medicines. The topics being studied are allopurinol, a highly prescribed gout treatment associated with severe (occasionally fatal) skin reactions and an important group of anticoagulant medicines used to prevent strokes (Direct Oral Anticoagulants), and their association with cases of severe bleeding.

Benefit Risk Evaluation (BRE)

We are committed to enabling patients to input into our benefit risk evaluation (BRE) reviews to ensure that the balance of benefits and risks reflects the perspectives of patients. Patients and patient groups shared their perspectives with the Pharmacovigilance Expert Advisory Group on montelukast, a medicine to prevent asthma and allergy symptoms, and fluoroquinolone antibiotics in our reviews of potential serious adverse effects.

Following a safety review, including more than 900 responses to our public consultation, we reclassified codeine linctus from pharmacy availability to prescription only, because of risk of opioid addiction. The Commission on Human Medicines advised that codeine linctus is likely, if incorrectly used, to present a substantial risk of medicinal abuse, to lead to addiction, or to be used for illegal purposes.

Following Yellow Card reports of addictive behaviour with the antipsychotic medicine aripiprazole, we reminded healthcare professionals to discuss this with patients and carers.

We advised on the strengthening of safety requirements for the use of isotretinoin, a medicine for the treatment of severe acne. This was accompanied by publication of the report of the Commission on Human Medicines (CHM) expert working group on isotretinoin safety. This recommended strengthened oversight of prescribing in under 18s in addition to the introduction of more stringent monitoring requirements for potential psychiatric and sexual side effects.

Strengthened oversight provisions were introduced for the antiepileptic sodium valproate, which is associated with serious harms in pregnancy, for all new patients (male or female) younger than 55 years. Our BRE team held meetings with patient charities and healthcare organisations to support safe implementation. We communicated to healthcare organisations via a National Patient Safety Alert, and the Valproate: review of safety data and expert advice on management of risks - GOV.UK (www.gov.uk) which covers the CHM expert advice on management of risks, as well as the CHM's Valproate Implementation Expert Working Group.

Safety warnings highlighting the risks were approved. Following a change in the legislation, all patients should receive their valproate-containing medicine in the manufacturer's original full pack so that they always receive all the information on the risks to the unborn baby.

Our collaboration to develop the digital pathfinder pregnancy prevention programme for lenalidomide, a myeloma treatment, received a high commendation in the category of Improving Medicines Safety at the HSJ Patient Safety Awards.

We launched the interim medical devices working group. This group meets monthly to provide independent expert advice regarding decisions on the safety, performance, benefits and risks of devices in use in the UK healthcare system.

We worked with health system stakeholders to evaluate and take action to mitigate risks with medical devices including NIDEK interocular lenses, batches of carbomer-lubricating eye gels, Sterifeed colostrum collectors and to reduce the risk of entrapment within bedrails following further reports of fatalities.

Criminal Enforcement Unit

The investigative work of the Criminal Enforcement Unit (CEU) led to multiple prosecutions relating to the illegal sale and supply of medicines. In one case, three defendants received custodial sentences totalling five years for their part in the illegal supply of controlled drugs and prescription-only medicines and associated money laundering. In parallel, the unit's financial investigators also denied offenders access to £2.1m in criminal profits.

Working with cross-sector partners, the CEU delivered more than 12,000 online disruptions of websites, social media profiles and marketplace listings illegally selling medical products to the public. Collaboration between the CEU and eBay resulted in the blocking of more than half a million prescription medicines, over-the-counter medicines, and medical devices before they could even be offered for sale.

The CEU led the UK contribution to Operation Pangea, a global operation, coordinated by Interpol, targeting the illegal trade in medicines. During November 2023, working with law enforcement partners, the CEU contributed to the seizures of more than two million doses of medicines to the global operational effort.

Clinical Practice Research Datalink

Our Clinical Practice Research Datalink (CPRD) completed the development of the first version of our new trusted research environment (TRE). The TRE will provide researchers with a secure environment and state-of-the-art analytical tools to support innovative research and analysis of CPRD datasets. The TRE will ensure alignment with data governance best practice, enabling key public health research whilst protecting the security of data and the anonymity of patients.

We also refreshed our CPRD data quality strategy to ensure that CPRD data continues to meet the data quality standards for regulatory requirements. The CPRD now has a dedicated data quality web page outlining our strategic objectives and approach to data quality. To support the implementation of the CPRD data quality strategy, we have established a Data Quality Advisory Group with external members who are experts in data quality.

In May 2023, we introduced CPRD ethnicity records which assign an ethnicity to patients in the CPRD databases, CPRD GOLD and CPRD Aurum, based on linked data. The ethnicity data is drawn from primary care databases and Hospital Episode Statistics (HES) datasets (where eligible). Ethnicity records are released quarterly and have been used in 36 studies. These are currently our most frequently requested algorithm-derived data, and can be used, along with area level data on deprivation and rural-urban classification to support health inequalities research. Work is ongoing to explore the recording of wider determinants of health in the CPRD primary care databases.

Public health campaign

We launched a public health campaign on adrenaline autoinjectors to give patients, healthcare professionals and the public information on the best use of these life-saving medicines in the event of an anaphylaxis event. This campaign was launched during World Allergy Awareness Week in 2023 and will continue until October 2024, leveraging influential voices across traditional and social media to engage target audiences.

Risk and performance summary

The role of the MHRA is to protect the safety of patients and the public through the regulation of medicines. The role of the MHRA is to protect and promote public health through the regulation of medicines, medical devices and blood components intended for transfusion in the UK. We take risk-proportionate decisions on new and existing medicines and medical devices and are agile and responsive in our safety surveillance systems. Our work pipeline is difficult to predict as much of what we do needs to be reactive.

We prioritise the safety of patients and the public and are proud that 100% of adverse drug reaction reports were acted on in the required timeframes (of 24–72 hours) throughout the year.

The MHRA has undergone significant change in recent years, with our response to the COVID-19 pandemic, the UK exiting the EU, and resulting changes in the regulatory landscape occurring alongside our transformation programme. During times of significant change, there is some inevitable loss of experienced staff. Resourcing challenges alongside an increase in workload resulted in the buildup of backlogs in some of our services, leading to our performance in some areas falling short of the required timeframes. We have taken decisive action in year to address areas of under-performance and ensure a sustainable and reliable return to statutory timelines across our services.

Key risks this year for the agency have been staff resourcing and performance against targets, as well as health and safety following an incident in the Science Campus laboratories and cyber security. These risks and their impacts, along with our handling, are discussed more fully in the performance analysis section on page 35 and the accountability report on page 73.

1.2 Performance analysis

This section considers the MHRA's performance against our key priorities, as set out in the Corporate Plan and Business Plan. It includes highlights of our achievements and detailed metrics against key targets.

Progress against our strategic objectives

Priority 1:
Maintain public trust through transparency and proactive communication

1.1 Embed patient involvement across our regulatory pathways that are meaningful, proportionate, and impactful to help ensure medical products reach patients without delay, accompanied by efficacy and safety information that better meets the needs of all patients.	• Developed new guidance on our support and safeguarding of patients, patient voices in safety reviews, data protection, and designing accessible and inclusive patient involvement activities • Developed a new Risk and Safety Communications Strategy to improve the safety communications we send to patients, the public and healthcare professionals
1.2 Enable diverse patient voices to provide evidence of safety concerns on specific medicines and medical products.	• Completed a review of women's health regulatory inequities and supported an independent review of inequity in medical devices led by Dame Margaret Whitehead • Sought input from under-served patient groups to inform handling of safety issues, such as our reviews of the cystic fibrosis drug Kaftrio and pulse oximeter guidelines, enabling the lived experience of patients to form part of the benefit and risk assessment • Broadened our communications channels to reach under-represented patient groups and continued to establish our presence on new direct and partner-led channels
1.3 Increase transparency of safety signals and the basis of our benefit-risk decisions by regularly publishing the safety signals on medical products and a public statement following approval of all new chemical entities within one week, plus a summary of the evidence for regulatory approval within one month.	• Published public statements within one week of approval for all new chemical entities and evidence summaries for the regulatory approval within one month • Commenced our pilot Yellow Card Biobank and enrolled our first participants. The Biobank aims to improve understanding of the link between a patient's genetics and the risk of harmful medication side effects • Published Yellow Card incident report data in a new interactive format first used in COVID-19. We continue to explore ways to further increase the transparency of our safety data

Priority 2:
Enable healthcare access to safe and effective medical products

2.1 Deliver predictable and reliable operational performance, having defined our priority improvements for our core services to ensure swift and robust decisions on medical products, safety signals and compliance.	• Returned clinical trial approval performance to statutory timelines by September 2023 with a new operating model to maintain performance • Addressed under-performance in service areas through increased resourcing and training, and improvement of processes. We continue to prioritise sustainable and improved performance • Completed phase one of our Medicines Compliance Strategy, supporting us to be innovation-enabling and risk-proportionate • Progressed development of a series of new digital tools to improve regulatory service delivery, including SafetyConnect, which will optimise our safety signal detection
2.2 Develop and embed system cooperation with UK partner organisations, including the NHS, to ensure the gap continues to be narrowed between regulatory and health technology approval with a clear path to patient deployment.	• Collaborated with UK partner organisations to establish UK healthcare system priorities for medicines and medical devices to support proactive supply chain management • Strengthened partnerships arrangements for the Innovative Licensing Access Pathway, bringing in new NHS partners to accelerate access to innovative products • Launched our new Innovative Devices Access Pathway (IDAP) pilot, to support development of transformative medical technologies to address unmet clinical needs. Eight new medical devices were selected to receive support from IDAP partners at key stages of product development, including a test for Alzheimer's disease

2.3 Launch the improved regulatory management system to make our services more streamlined as the first phase of replacing legacy IT systems, enabling all applications to be efficiently handled, maximising the use of self-service for low-risk decisions.	• Launched our new RegulatoryConnect portal, providing customer visibility of regulatory assessment timelines and enabling tracking of applications. Additional functionality and features will be delivered in our phase two release, including the ability to submit applications and variations through the service

Priority 3: Deliver scientific and regulatory excellence through strategic partnerships

3.1 Introduce the MHRA Science Strategy and establish and build on partnerships in key priority areas with national and international partners with measurable benefits that support prompt and robust regulatory decision-making.	• Commenced development of our new Science Strategy alongside a new Data Strategy, to grow our reputation for scientific excellence and help us use data more effectively to support decision-making • Developed and launched our Clinical Practice Research Datalink Data Quality Strategy to help ensure consistency in data quality for research • Enhanced resourcing of our Innovation Office to support the identification of opportunities in innovation, inform wider policy-making and increase our partnership working
3.2 Reprioritise standards, control testing and underpinning research to ensure support for priority areas of our MHRA Science Strategy and Corporate Plan.	• Developed our new strategy for the British Pharmacopoeia and associated laboratory services, setting out recommendations for service improvements for delivery in 2024/25 • Completed preparatory work to enable the creation of a network of Centres of Excellence in Regulatory Science and Innovation (CERSIs) to ensure regulatory decisions reflect the best science • Introduced a new risk-proportionate approach for control testing to ensure the quality of medicines

3.3 Legislate on Point-of-Care Manufacture and drive international regulatory progress in key scientific areas commensurate with scientific and technological advances such as mRNA technology, AI and in silico data generation.	• Continued work to develop the world's first regulatory framework for new point-of-care personalised medicines • Developed relationships and collaborations to support delivery of our priorities, including harmonisation and alignment in medicines and medical devices and promoting innovation • Prepared for implementation of the Windsor Framework and published guidance ahead of expected commencement in January 2025. This sets out arrangements for the supply of medicines to Northern Ireland • Launched our new International Recognition Procedure to help bring life-saving medicines to patients through consideration of decisions of trusted regulatory partners, enabling fast access to medicines whilst maintaining rigorous scrutiny • Continued work to reform the UK medical devices regulations to support the development of a new UK regulatory framework for medical devices

Priority 4:
Become an agency where people flourish, alongside a responsive customer service

4.1 Deliver a range of core and specialist learning opportunities and implement and review the agency leadership development plan to ensure we have the right capabilities across the organisation.	• Delivered a programme of learning and development opportunities to strengthen leadership capabilities • Progressed work on culture changes as set out in our Culture Action Plan • Continued to develop an agency-wide workforce plan to support proactive delivery of our workforce needs
4.2 Attract and develop talent by strengthening existing or creating new recruitment channels, such as a graduate scheme and increasing apprenticeships.	• Launched our graduate and apprenticeship schemes to help attract new talent into the MHRA, with eight new graduates and 40 apprentices joining the agency • Continued work on our wider talent management approach, supporting further delivery in 2024/25
4.3 Develop a new financial plan to ensure we continue to deliver value for money, invest in people, maintain our financial sustainability and recover the costs of all our services, with updates to our fees to be in force by 1 April 2025.	• Completed preparation for our anticipated fee uplift in April 2025, understanding the cost for our service delivery to enable cost recovery

Performance against our public health targets

This section considers our performance in 2023/24 against our key priorities for our statutory and non-statutory functions, which are essential for delivering our core purpose of keeping patients safe through efficient and risk-proportionate regulation.

We acknowledge that there is ongoing work required to fully address under-performance in certain service areas, resulting in unacceptable delays for our customers. Throughout 2023/24, we dedicated significant resources to tackle these performance challenges and return to sustainable performance. Notably, in September 2023 we successfully restored our clinical trial assessment performance to statutory timelines and have maintained a service which is faster than the statutory timeline. Additionally, we have made substantial progress to improving established medicines assessment timelines. Our ongoing Return To Green programme focusses on revitalising services, streamlining processes, and developing critical technology systems to ensure sustainable improvements in our performance.

Note:
Some of the measures do not have a target set. These are where we must remain reactive, for example safety recalls and criminal enforcement activities. For these measures we do all that is required, and our response is agile. These measures have " - " in the target and met positions. The Trajectory shows the direction of travel since the 2022/23 reporting period.

Performance Metric 1 (PM1) — Clinical trials and investigations

	Measure	Target	Total 2022/23	Total 2023/24	Met / Not Met 2023/24	Trajectory
PM1a	Percentage of clinical trial applications assessed within 30 days of submission	98%	25.9%	40%	Not Met	▲
PM1b	Percentage of Clinical investigations decision letters (objection/no objections) issued within 60 calendar days of submission	100%	100%	100%	Met	▶

PM1: The clinical trials applications target was not met in the last year due to a backlog of assessments which affected our assessment times. The backlog was successfully eliminated by September 2023, and applications were returned to statutory timelines.

Performance Metric 2 (PM2) — Licensing of medicinal products						
	Measure	**Target**	**Total 2022/23**	**Total 2023/24**	**Met / Not Met 2023/24**	**Trajectory**
PM2a	Percentage of medicines assessed via national route which contain a new active substance within 210 days (excluding the time awaiting applicant responses)	97%	88%	25%	Not met	▼
PM2b	Percentage of medicines assessed via recognition within published recognition pathway timeline (excluding the time awaiting applicant responses)	80%	29%	12%	Not met	▼
PM2c	Percentage of established products assessed via national route within 210 days (excluding the time awaiting applicant responses)	80%	13%	17%	Not met	▲
PM2d	Percentage of products approved via recognition of another regulator's decision:					
	New Active Substance (NAS)	80%	70%	84%	Met	▲
	Established products, Reliance	80%	19%	38%	Not met	▲
PM2e	Percentage of Type 1B and Type II variations assessed within the following timelines (excluding the time awaiting applicant responses):	Variations assessments – Type IB changes include simple 'tell and do' changes, such as changing location of manufacture. Type 2 changes are complex changes with changes of formulation, such as new or replacement excipients.				
	I. 30 days (Type 1B)	90%	60%	65%	Not met	▲
	II. 30 days (Type II expedited timetable)	90%	97.5%	92%	Met	▼
	III. 90 days (standard or complex Type II timetable)	90%	82.4%	53%	Not met	▼

	IV. 120 days (extended complex Type II timetable)	90%	77.8%	36%	Not met	▼
PM2f	Number of Parallel Imports determined:	Parallel Imports — Where a product is available in an EEA country and 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	-	375	876	-	▲
	II. Parallel Imports — Number of variation applications determined	-	7,573	9,638	-	▲
PM2g	Unlicensed Medicines	We review and verify medical items imported for supply to patients under prescriber oversight, where no UK licence exists. The MHRA's 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	-	109,068	173,477	-	▲

PM2: Work has progressed to clear backlogs in licensing applications, with performance metrics for established medicines published monthly on the gov.uk website: https://www.gov.uk/government/publications/mhra-performance-data-for-assessment-of-clinical-trials-and-established-medicines. A significant reduction in the backlog has been achieved with work ongoing through our Return to Green programme.

Performance Metric 3 (PM3) — Innovative Licensing Access Pathway (ILAP)						
	Measure	**Target**	**Total 2022/23**	**Total 2023/24**	**Met / Not Met 2023/24**	**Trajectory**
PM3	Innovative Licensing Access Pathway performance:					
	I. Total number of applications for Innovation Passports (IPs)	-	178	57	-	▼
	II. Number of IPs awarded	-	129	31	-	▼
	III. Number of IPs not awarded	-	19	32	-	▲
	IV. Total number of Target Development Profile (TDP) applications	-	40	15	-	▼
	V. Number of Target Development Profiles awarded / TDP roadmaps issued	-	26	5	-	▼

PM3: The ILAP partners are currently working to refine and refresh the ILAP. As a result, we have seen both a lower number of applications and throughput as companies await the announcement of the refresh. New targets will be defined as part of the refreshed programme.

Performance Metric 4 (PM4) — Medical device regulation

	Measure	Target	Total 2022/23	Total 2023/24	Met / Not Met 2023/24	Trajectory
PM4a	Number of approved bodies designated	Increase on 2022/23	4	9	Met	▲
PM4b	Initial review of applications for designation completed within 2 weeks	100%	66%	33%	Not met	▼
PM4c	Required surveillance and witnessed audits of designated Approved Bodies have been completed as required by UK Medical Devices Regulations 2002 (UKMDR 2002)	100%	100%	100%	Met	▶

PM4: The target for metric PM4b was missed routinely by one week throughout the year. We will revise this target for 2024/25 to 3 weeks. This is the first step in the designation process, and overall timelines show we are currently performing this function significantly faster than our counterparts in the European Union.

Performance Metric 5 (PM5) — Inspectorate inspections						
	Measure	**Target**	**Total 2022/23**	**Total 2023/24**	**Met / Not Met 2023/24**	**Trajectory**
PM5	Number of routine inspections completed for:					
	I. Good Manufacturing Practice (GMP)	-	274	223	-	▼
	II. Good Distribution Practice (GDP)	-	437	387	-	▼
	III. Good Clinical Practice (GCP) and GMP Quality Consultations (GCP/ GMPQC)	-	14	16	-	▲
	IV. Good Laboratory Practice (GLP)	-	53	33	-	▼
	V. GCP, including Bioequivalence (GCP/ BE)	-	38	58	-	▲
	VI. Good Pharmacovigilance Practice (GPvP)	-	21	16	-	▼

Performance Metric 6 (PM6) — Post marketing surveillance activity						
	Measure	**Target**	**Total 2022/23**	**Total 2023/24**	**Met / Not Met 2023/24**	**Trajectory**
PM6a	Total number of safety signals identified for further assessment	-	103	133	-	▲
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 73 hrs & 5 days	Met	▶
	III. 85% of potential signals evaluated within 5 working days	85%	94.16%	95.03%	Met	▲
PM6c	Defective medicinal product recalls:					
	I. Total number of defective medicinal product recalls	-	59	49	-	▼
	II. National Patient Safety Alerts (NatPSA) / Class 1 recalls	-	2	1	-	▼
	III. Class 2, 3, 4 recalls or company-led recalls	-	57	48	-	▼

Performance Metric 7 (PM7) — Criminal Enforcement Unit (CEU)

	Measure	Target	Total 2022/23	Total 2023/24	Met / Not Met 2023/24	Trajectory
PM7	Interventions conducted by the CEU that are assessed to have disrupted or degraded an identified criminal threat					
	I. Total number of CEU interventions	-	1,131	1,334	-	▲
	II. Major interventions	-	3	7	-	▲
	III. Moderate interventions	-	22	31	-	▲
	IV. Minor interventions	-	1,106	1,296	-	▲

Performance Metric 8 (PM8) — Batch release / control testing

	Measure	Target	Total 2022/23	Total 2023/24	Met / Not Met 2023/24	Trajectory
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	▶

Performance Metric 9 (PM9) — Science Research & Innovation (SR&I) standards

	Measure	Target	Total 2022/23	Total 2023/24	Met / Not Met 2023/24	Trajectory
PM9a	Numbers of products sold from the following product groups:					
	I. Reference Standards and reagents (including British Working Standards)	Increase from previous year	32,929	37,033	Met	▲
	II. WHO International Standards, Reference reagents and Reference Panels	Increase from previous year	33,326	44,030	Met	▲
	III. CE-marked diagnostic reference materials	Increase from previous year	28,309	20,466	Not met	▼
	IV. Influenza reagents	Increase from previous year	60,541	66,156	Met	▲
PM9b	Numbers added to portfolio:					
	I. Reference Standards and reagents (including British Working Standards)	Increase portfolio	51	6	Met	▼
	II. WHO International Standards, Reference reagents and Reference Panels	Increase portfolio	30	19	Met	▼
	III. CE-marked diagnostic reference materials	Increase portfolio	10	3	Met	▼
	IV. Influenza reagents	Increase portfolio	28	43	Met	▲

PM9: The demand for SARS CoV-2 CE marked materials has continued to decline this year, which has affected our sales figures for this product line. We reviewed the portfolio and discontinued some of products no longer required by the community in a year. Additionally, some of the CE-marked materials were converted to WHO International Standards during the year and are now monitored through the PM9b II metric.

Performance Metric 10 (PM10) — British Pharmacopoeia (BP)

	Measure	Target	Total 2022/23	Total 2023/24	Met / Not Met 2023/24	Trajectory
PM10a	Number of new BP standards developed and added to the 2023 BP publication:					
	I. Documentary standards (monographs)	Increase portfolio	81 (23 UK & 58 Ph.Eur)	131	Met	▲
	II. Physical standards (BP Chemical Reference Standards — BPCRS)	Increase portfolio	13	15	Met	▲
PM10b	Sales of BP standards	5% increase	36,442 vials	37,353 vials	Not met (2.5% increase)	▲

PM10: Sales of BP standards increased in 2023/24, but in line with year-on-year variances in the sales, figures did not meet the targeted 5% increase. The BP 5-year strategy aims to increase our understanding of buyer habits and levers to purchase to support our marketing strategy.

Performance Metric 11 (PM11) — Clinical Practice Research Datalink (CPRD)

	Measure	Target	Total 2022/23	Total 2023/24	Met / Not Met 2023/24	Trajectory
PM11a	Percentage of applications to the CPRD for access to data for research studies receiving first moderated review feedback within 30 working days of a valid application	90%	83.54%	98.9%	Met	▲

Performance Metric 12 (PM12) — Research and development

	Measure	Target	Total 2022/23	Total 2023/24	Met / Not Met 2023/24	Trajectory
PM12a	Number of scientific research publications from the Science Campus	Not Applicable	90	75	-	▼
PM12b	External grant and research contract funding	£4m minimum	£4m	£4.8m	Met	▲

Performance Metric 13 (PM13) — Working towards NetZero

	Measure	Target	Total 2022/23	Total 2023/24	Met / Not Met 2023/24	Trajectory
PM13a	Percentage of electricity generated through solar panels.	50% increase in savings due to use of solar panels	5.5%	5.6%	Not Met	▲
PM13b	Savings in water wastage on the Science Campus through a programme of works to reduce water loss	20% reduction in water usage on Science Campus	56.9% reduction	57.1% reduction	Met	▲
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	N/A	100%	Met	N/A

Note: PM13a new solar panels were bought in to operation at the end of the financial year savings will be seen in 2024/25.

Performance monitoring improvements

In 2023/24, we updated our reporting processes and established a new set of eight key performance indicators. These act as a health check that the agency is regulating medicines and healthcare products within its statutory timelines. Further work is planned this year to improve the transparency of our performance reporting. We will move to reporting on the new key performance indicators below in our annual report next year.

Our key performance indicators (KPIs) are:

	Key Performance Indicator	Performance*
KPI1	We will assess 95% of all initial Clinical Trial Authorisation (CTA) and Clinical Investigation applications within their category's statutory timeline.	100% On Target
KPI2	We will certify 95% of vaccine batches within 43 days and 99% of blood product batches within 15 days of submission.	100% On Target
KPI3	We will determine 95% of medicines licence applications within 210 days via the national route.	13% Off Target
KPI4	We will determine 95% of medicines licence applications within 60 days via recognition Route A and within 110 days via Route B through the International Recognition Procedure.	100% On Target
KPI5	We will assess 95% of all national variations within their category's statutory timeline.	75% Off Target
KPI6	We will grant, vary or refuse 95% of manufacturing and distribution authorisations within their category's statutory timeline.	54% Off Target
KPI7	We will process 90% of Fatal Adverse Drug Reaction (ADR) reports for medicines within 24 hours,100% within 72 hours, and 95% of serious ADR reports for medicines within 72 hours and 100% within 5 days (interim KPI).	100% On Target
KPI8	We will offer scientific advice to 95% of requests within 70 days of the request being made.	9% Off Target

*These new KPIs were established during the year and therefore we do not have access to full-year figures. This year, we measured performance in quarter four. Next year, we will report on performance over the full financial year.

Performance targets that were not met for KPI1-8 are under additional scrutiny and subject to an executive-led programme called Return to Green, driving sustainable improvements to our performance through targeted resourcing and process improvement.

Transparency

Freedom of Information requests

Under the Freedom of Information Act (FOIA), we must respond to Freedom of Information (FOI) requests within 20 working days of receipt and requests for internal review within 20 working days (or 40 working days if they are complex). The information rights regulator, the Information Commissioner's Office (ICO), advises that 'Good' performance is responding to 95% or more of the requests within the recommended timescales.

The number and types of requests have increased over the past few years, resulting in a backlog. This led to delays in our responses and complaints to the ICO about our performance on FOI requests. The ICO issued a Practice Recommendation in August 2023 outlining the steps required to improve our compliance with a deadline of 31 December 2023.

We developed an action plan to clear the backlog, implement improvements to our systems, deliver training to raise awareness of the requirements and return the MHRA to "Good" performance.

Compliance improved month by month, and by December 2023 the backlog was cleared and timelines had returned to the required timeframes. Performance continues to improve, and our specialist team is currently exceeding the requirements.

The publication and disclosure of FOI requests is now available on our website, including MHRA FOI performance data and information about the steps taken within our action plan to improve transparency and maintain public trust. https://www.gov.uk/government/publications/mhra-foi-performance-data

In 2023/24, we received 1,076 FOI requests and completed 1,120 requests, which included requests held up by the backlog. This compares to 975 requests received in 2022/23. Performance on FOI responses was returned to the required timescales by 31 December 2023.

Enquiries and complaints

During 2023/24 the MHRA Customer Experience Centre received 5,005 enquiries from the public and 430 complaints. This compares to 6,663 enquiries and 486 complaints received in 2022/23.

Parliamentary Questions

During 2023/24, we responded to 161 Parliamentary Questions and contributed to other questions answered by the DHSC. A significant range in topics was covered, including patient safety, COVID-19 vaccines, MHRA regulatory processes and performance. This compares to 61 Parliamentary questions responded to in 2022/23.

Risk profile

Our key risks this year have been staff resourcing, performance against targets, health and safety at the Science Campus laboratories and cyber security.

Following our transformative restructure we saw a high voluntary turnover rate, with the loss of some of our specialist skilled and experienced resource. The challenge of identifying and attracting applicants with the right skills has meant that resource gaps have endured longer than we would have wished.

The resourcing challenges, coupled with an increase in workload over recent years, have meant our performance in some of our operational areas has fallen short of statutory duties, as shown in the performance table on page 52. Delays in our assessments and timely provision of scientific advice have a direct impact on the speed with which medicines can be developed and made available for patients. Ensuring timely access to high quality medicinal products is of the utmost importance to us and we took decisive action in year to address these performance timelines.

We have given precedence to improving performance of our statutory deliverables, which has meant making some difficult decisions on prioritisation.

At the start of the year, we identified that a backlog had built up in our clinical trials applications and amendments assessment service. We prioritised this as an issue through our corporate risk management, with specific mitigations including prioritisation of trial applications by risk stratification, the use of internal and external staff resource and process re-engineering.

In September 2023, our performance in clinical trial assessments was returned to statutory timeframes in September 2023, and we have maintained performance above target since then.

Other performance challenges were identified in established medicines applications assessments and some other areas of service delivery, which led to the development of an executive-led improvement programme called ‘Return to Green’, which is driving the identification and systematic clearance of backlogs, optimisation of processes and systems and the development of new performance indicators and increased monitoring. Good progress has been made in the high-priority areas, including established medicines assessments and variations during the year.

Key mitigations for our staff resourcing risk throughout the year have been:

- Movement of staff internally, where possible, to support work in priority areas.
- Recruitment of new specialist resource
- Development of new training programmes, including our graduate scheme, to enable us to develop and retain talented staff

As we have made progress in filling vacant roles throughout the year, the focus of our recruitment risk is changing to the need to right-size the agency and ensure a long-term view on resource requirements to enable efficiency through workforce planning.

Key mitigations for our performance risks throughout the year have been:

- Prioritisation and focus on statutory deliverables and patient safety
- Process redesign and improvement to enable optimised processes

- Development of new IT systems to replace legacy systems and enable simplified processes and increased customer self-service
- Communication with stakeholders on performance and expected waiting times
- Working with industry to drive up the standard of applications and increase the number of right first-time applications, reducing re-work

Management and mitigation of our health and safety risks have also been a high priority throughout the year. The nature of the work we carry out at our Science Campus carries an inherently higher risk to our staff, so we have increased monitoring and taken swift action to address recommendations made by the Health and Safety Executive. We are continually analysing and learning from incidents to drive a strong health and safety culture.

Cyber security is a key risk for most organisations, with threats becoming increasingly sophisticated, complex and frequent. Throughout the year, we have forensically explored the strength of our cyber and information security controls through a series of audits and benchmarking with similar organisations, with a focus on ensuring robust controls.

Further details on our risk management approach and the risks we have managed in the year, can be found in the accountability report on page 73.

Sustainability report

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

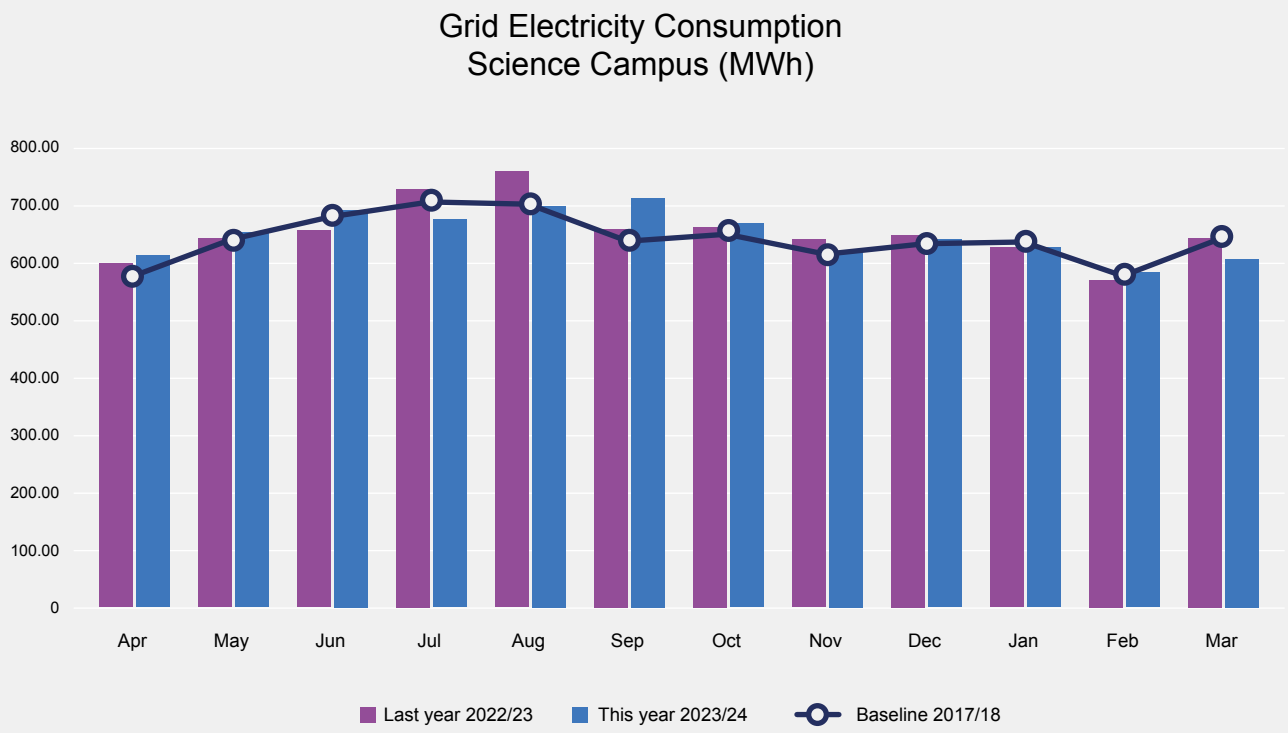
Energy management performance

Our Science Campus in South Mimms reports against a baseline of 2017/18 in accordance with Greening Government Commitments (GGC).

Our administrative office sites in Canary Wharf reports against a baseline of 2019/20, as that was the first full year of occupancy. This is a Government Property Agency (GPA) managed site with multiple occupants.

Electricity

Science Campus site: 7,798.61 MWh



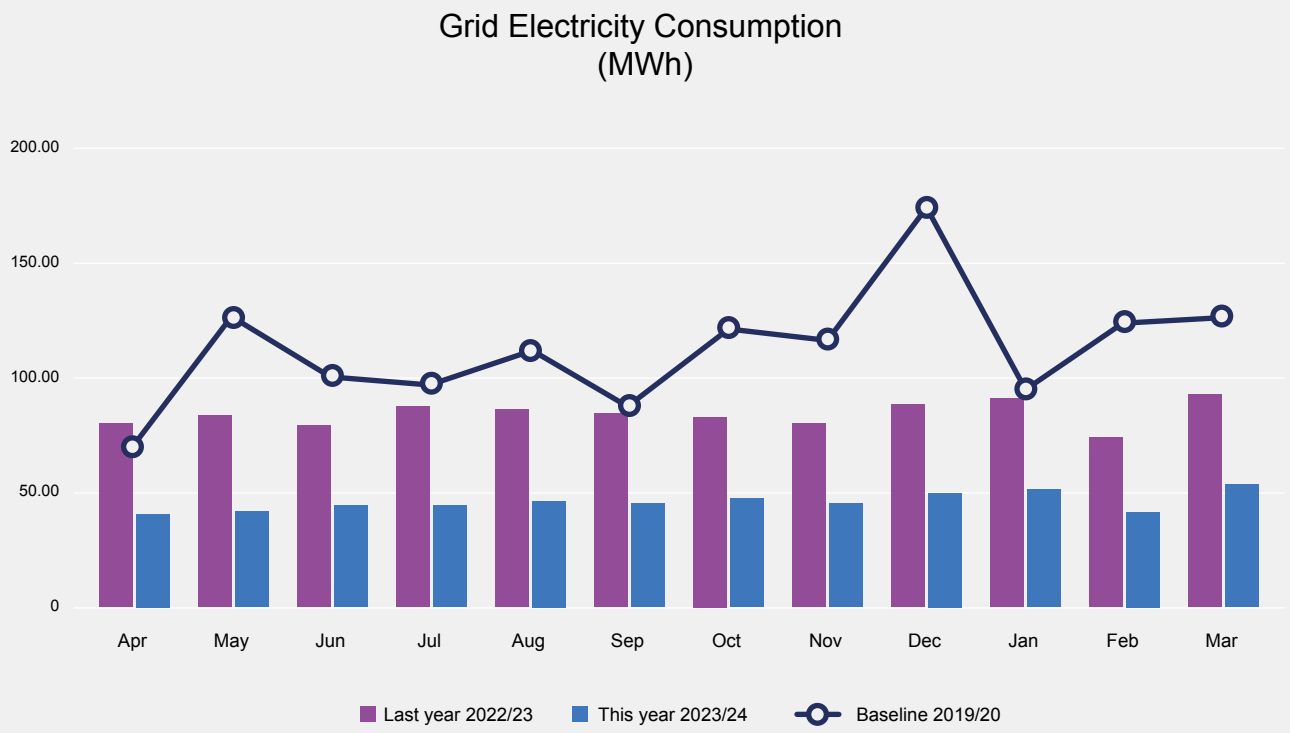
▲ 1.2% increase vs baseline (2017/2018)

▼ 0.8% decrease vs 2022/23

At our Science Campus grid electricity consumption this year was similar to last year. There was a slight reduction in July and August as the temperature was cooler (requiring less cooling). The new solar panels came online in December, and we generated 0.8% more electricity[1] than last year. Solar generation will increase significantly as we move into the longer daylight months.

1. 22/23 solar PV 430.53 MWh vs. 23/24 solar PV 433.85 MWh.

Canary Wharf office: 551.85 MWh



▼ 59.0% decrease vs baseline (2019/20)

▼ 45.3% decrease vs 2022/23

At our Canary Wharf office site, electricity consumption is still significantly lower than the baseline, and lower than last year. Building occupancy is was lower in January and February 2024.[1] The large drop in electricity consumption is due to the MHRA now only occupying 6.3%[2] of the building, which is approximately half last year's occupancy. As the site uses electricity for heating and cooling, consumption increases as building occupancy increases.

Note:

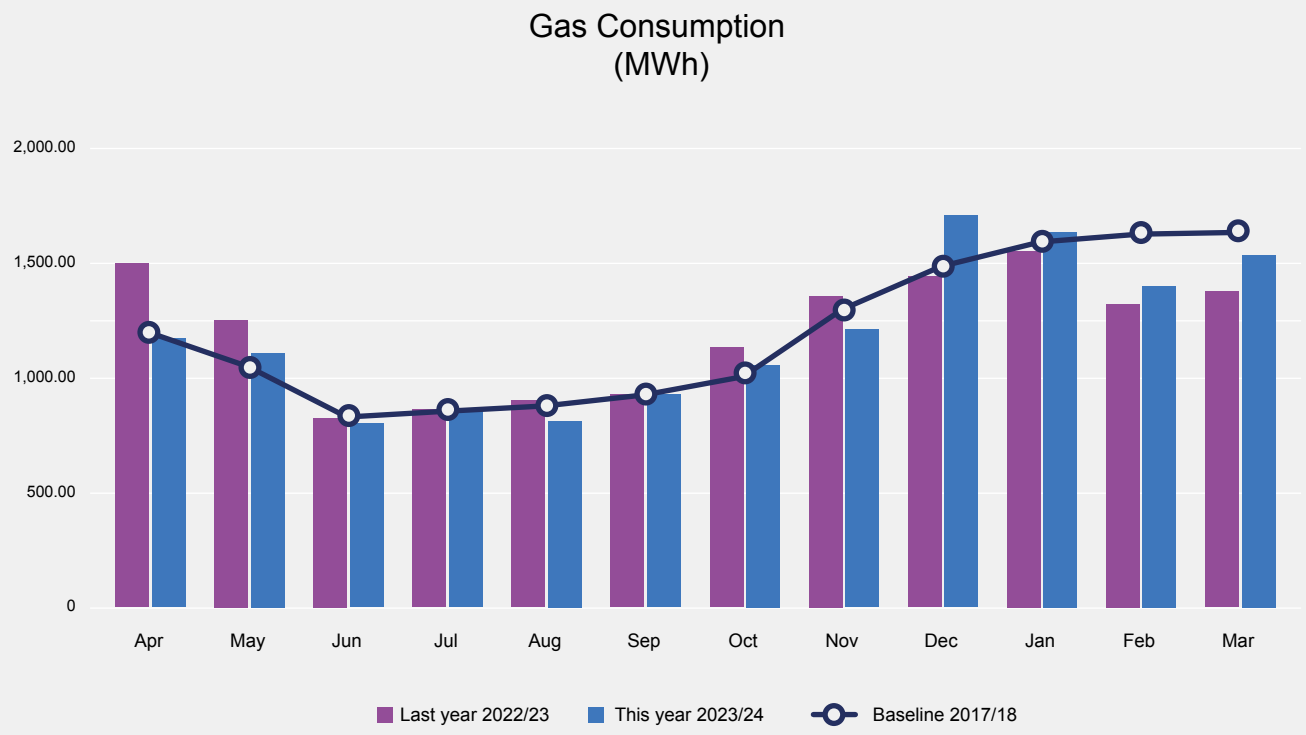
- The virtually identical consumption patterns at our Science Campus from one year to the next, with the high point being in summer; indicating our increased need for cooling. The solar panels support this requirement and the summer peak would be far more significant without the solar panels.
- The erratic baseline chart pattern for our Canary Wharf office shows the link between electricity consumption and occupancy levels, so this is very low during summer and Christmas holidays due to increased staff taking annual leave. The Canary Wharf office has electric heating, so both cooling and heating impact on electricity consumption.

Our Canary Wharf office is a GPA-managed building. The MHRA forms a small part of the total building occupancy. Canary Wharf figures were reported as 6.3% of the total building figures for the financial year 2023/24, as this is the registered MHRA occupancy of the office building.

1. There was a sharp drop in occupancy in January 2024 due to the building being fumigated.
2. Canary Wharf office occupancy figures according to GPA, 11.1% 2022/23 vs. 6.3% 2023/24.

Gas

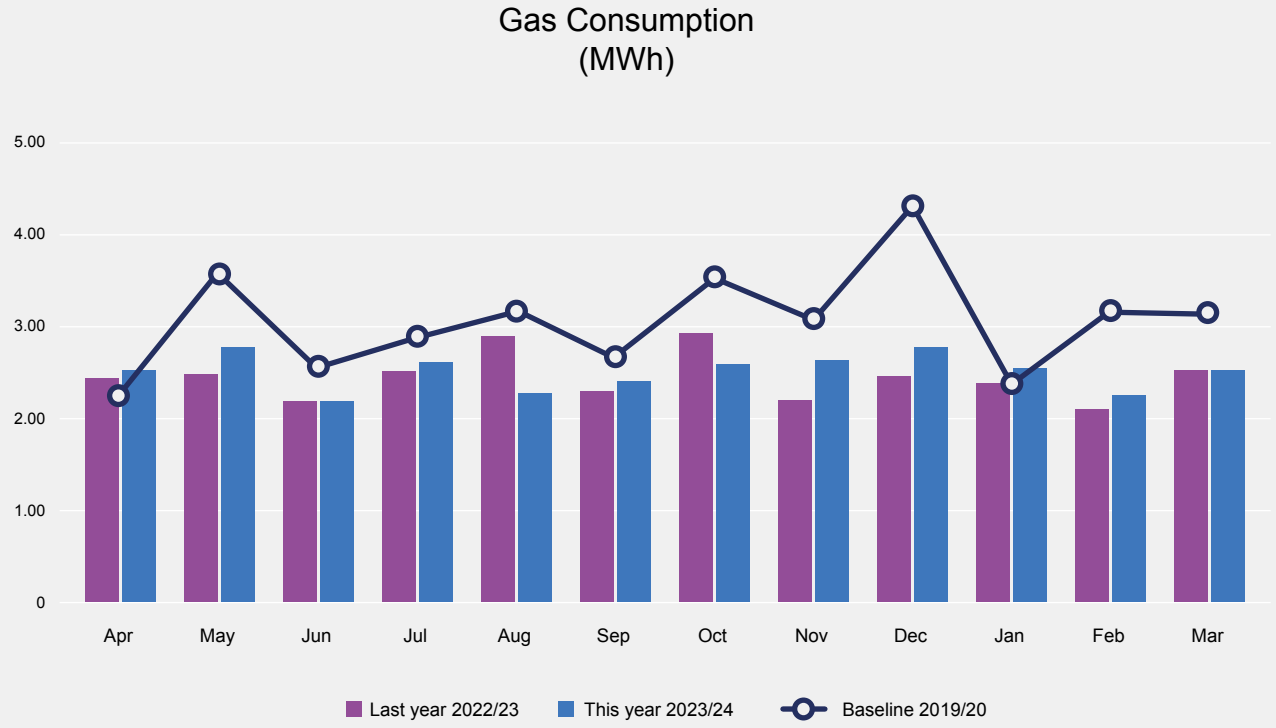
Science Campus: 14,476.27 MWh



- 0.2% increase vs baseline (2017/18)
- 1.5% increase vs 2022/23

Gas consumption at our Science Campus site is marginally increased from last year and the baseline year. This change is not significant and could be due to slight changes in weather, meaning that the building required more heating on specific days.

Canary Wharf office: 18.01 MWh



▼ 51.5% decrease vs baseline

▼ 40.1% increase vs last year

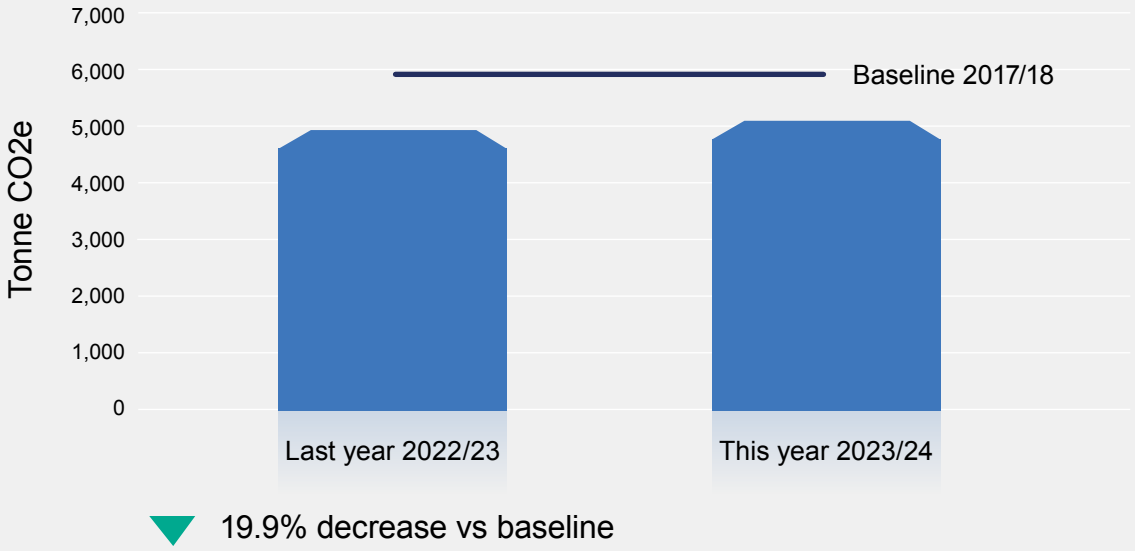
Gas consumption at our Canary Wharf office shows a reduction from last year as MHRA building occupancy has reduced. Gas at the Canary Wharf office is only used for heating water. The higher the number of people in the building, the higher the demand for hot water; however, the MHRA occupancy is limited to the available space.

Carbon emission performance

Note: tCO2e is a measurement for emissions of greenhouse gases, “tonnes of carbon dioxide equivalent”, where carbon dioxide equivalent is a standard unit for counting greenhouse gas emissions regardless of whether they are from carbon dioxide or another gas such as methane.

Science Campus

Footprint

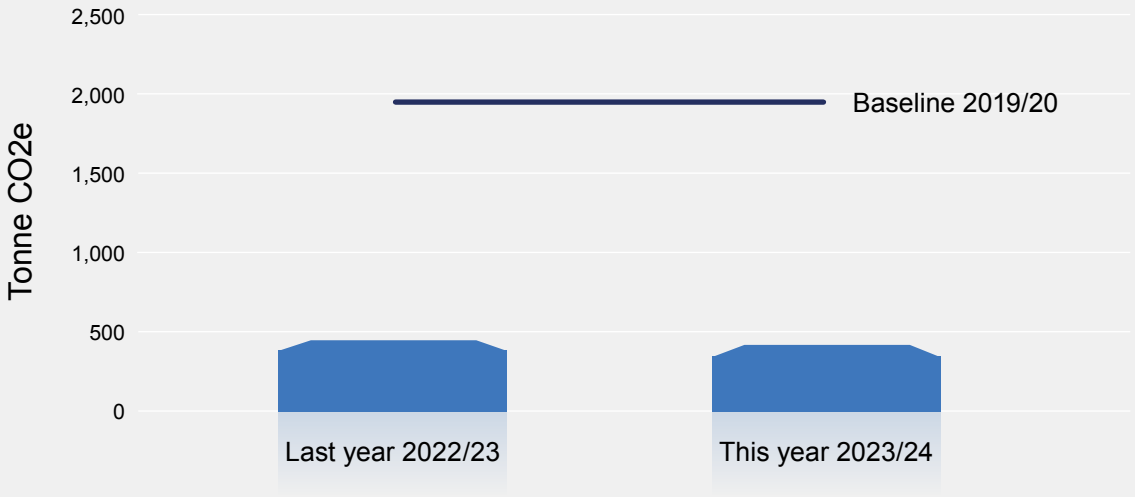


▼ 19.9% decrease vs baseline

Carbon emissions have fallen from 5,917 tCO2e in 2017/18 to 4,738 tCO2e this year at our Science Campus.

Canary Wharf office

Footprint



▼ 82.7% decrease vs baseline

Carbon emissions have fallen from 1,954 tCO2e in 2019/20 to 339 tCO2e this year in our Canary Wharf office.

The carbon footprint has fallen at both our sites since the baseline years. The carbon intensity of UK grid gas[1] has fallen slightly and electricity has increased[2], mainly due to an increase in the use of gas to compensate for lower renewables (notably wind). Carbon intensity is a measure of how many kilograms of CO_2 are released to produce each kilowatt hour of electricity or gas.

The amount of business travel has a greater impact on emissions from our Canary Wharf office site as this is a shared building with a constant base load. The number of maintenance, cleaning and catering staff does not vary. The amount of energy for lighting, lifts, cooking, heating and cooling the building is very similar whether the building is a quarter or half full. The amount of water used at the Canary Wharf office increases with occupancy.

Our Science Campus has a much higher baseload. The emissions associated with freezers and boilers constantly running for scientific purposes overshadows the emissions from the office and non-science activities.

We cannot properly compare emissions across the different MHRA sites as these are significantly different working environments; however, normalising the data per person[3] gives the following result:

Canary Wharf office:
6.6 kg CO_2 per person per occupancy day

Science Campus:
94.0 kg CO_2 per person per occupancy day

1. Carbon emission factor for natural gas from the UK grid in 2022/23 was 0.18293 Kg CO2e. In 20223/24, it was 0.18254 kg CO2e.
2. The combined transmission and generation factor grid electricity has increased from 2022 figure of 0.21107 kg CO2e per kWh to 0.22499 kg CO2e per kWh (a year-on-year increase of 7%).
3. Canary Wharf office emissions/occupancy per day from September 2023 building report. Science Campus data from March 2024.

Sustainability reporting requirements

Mitigating climate change: Working towards Net Zero

We are optimising our estate and operations to help safeguard a healthy 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.

- We are continuing to use Renewable Energy Guarantee of Origin backed grid electricity from 100% clean renewable sources
- The solar panels, which were installed at our Science Campus in 2016, have once again generated around 6% of our total electricity requirement. In doing so, they saved over £100k of supply costs and reduced our carbon footprint by 110 tonnes CO2e
- The new solar array, which was activated in December 2023 at the Science Campus, has already reduced our carbon footprint by a further 11 tonnes and supply costs by £11.7k
- We are currently installing solar carports at the Science Campus
- Biodiversity improvements at the Science Campus have continued throughout the year. The trees that were planted at the beginning of the year are now well established, and we have further enhanced the woodland area through the addition of a new hedgerow and the introduction of beehives
- We are refurbishing an outside space at our Science Campus which was previously used by staff and had fallen into disrepair. Once completed, the area will have improved mobility access and energy-efficient lighting, providing staff with a green space to relax and recharge. Many of the existing flowers and shrubs will be replanted, and we will be adding some climate-resilient plants. The area will also include bird boxes, insect houses and squirrel tables

Minimising waste and promoting resource efficiency

We are applying the waste hierarchy by prioritising prevention and designing out waste from internal policies and processes to avoid creating waste where possible.

- The waste contract for our Science Campus has included zero waste to landfill since 2016/17, any redundant equipment and waste that cannot be reused or recycled, is incinerated to generate energy
- In 2023/24, we sent nearly 10 tonnes of pallets and wood for reuse, and we also sent over six tonnes of furniture and equipment and one tonne of solid ice packs for reuse
- In addition to the standard “household” recycling streams, we continue to recycle polystyrene, old lab coats, baled cardboard, glass Winchester bottles and WEEE (waste electrical and electronic equipment)
- Food waste from the Science Campus canteen and tea points are composted on site. The compost is used on our staff-managed allotments on site
- When the waste contract for the Science Campus was re-tendered, we included plastic film recycling to facilitate recycling of the packaging from water treatment and delivery packaging
- Our Science Campus has switched from single-use plastic cups and food packaging to cardboard and is now considering introducing returnable food and beverage packaging[1]

Finite resource consumption and reducing water use

Due to the laboratory work performed at our Science Campus, it is difficult to reduce our demand for water at the site. We constantly measure and record our water use so that we can assess the impact of water efficiency measures. However, we can do better and our environmentally conscious team is constantly working on new ideas to reduce wastage.

- Water butts capture rainwater for use by grounds maintenance teams and on the allotments managed by staff
- During the first quarter of 2023, the hydrant pipework which runs under the Science Campus was checked and leaks were repaired. System efficiencies together with leak repairs and other remedial work carried out on the steam and water system have resulted in the site using over 40% less water this year than in 2022/23

Procuring sustainable products and services

Sustainable procurement 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).

Climate-Related Disclosure Report 2023–2024

The UK government formally endorsed the Task Force on Climate-Related Financial Disclosures (TCFD) framework and has mandated TCFD-aligned disclosure for large private entities in the UK. This is intended to improve the quality and breadth of climate-related information in annual reports in central government and align climate-related reporting.

Climate change commitments

As a world-leading regulator we understand the importance of managing Environmental, Social and Corporate Governance ("ESG") issues and recognise the growing urgency to respond to long-term sustainability issues, particularly climate change.

We have built-in ESG considerations as part of our development strategy. We have also aligned our net zero ambitions with the DHSC's ambitions to achieve a "net zero emissions" building estate by 2030 and are implementing necessary actions to enable us to achieve this.

We recognise the commitments made by countries, regions, organisations and individuals in relation to climate change. Climate change (and other long-term sustainability issues) presents opportunities and risks that increasingly require explicit consideration.

We are committed to:

- Reducing emissions to Net Zero by 2030. Eliminating direct scope 1 emission from gas and fluorinated gas, minimising indirect scope 2 emissions and embedding sustainability appraisals into procurement and project processes
- Significantly reducing emissions from business travel and supporting the transition away from fossil fuel-powered vehicles
- Prioritising waste prevention, improving reuse and recycling rates and annually reducing the proportion of waste being sent for incineration and to landfill. Removing single-use plastics from offices and embedding paperless 'digital by default' ways of working
- Identifying opportunities to improve water efficiency across our estate while raising awareness amongst our workforce on the importance of responsible water consumption
- Incorporating full life costs into the procurement process. Ensuring that new suppliers seek to achieve comparable goals on Net Zero and 'circular economy' and prioritising the most sustainable options for products and services
- Improving and encouraging biodiversity on our estate. Protecting the existing natural environment and helping staff to support nature recovery more broadly within local communities
- Assessing the risks of changing environments on the business and on staff and making the business climate resilient
- Applying the business rules of Greening Government: Information and Communications Technology (ICT) and Digital Services Strategy to all new ICT procurements
- Promoting healthy and sustainable foods and ensuring catering practices are sustainable

Governance

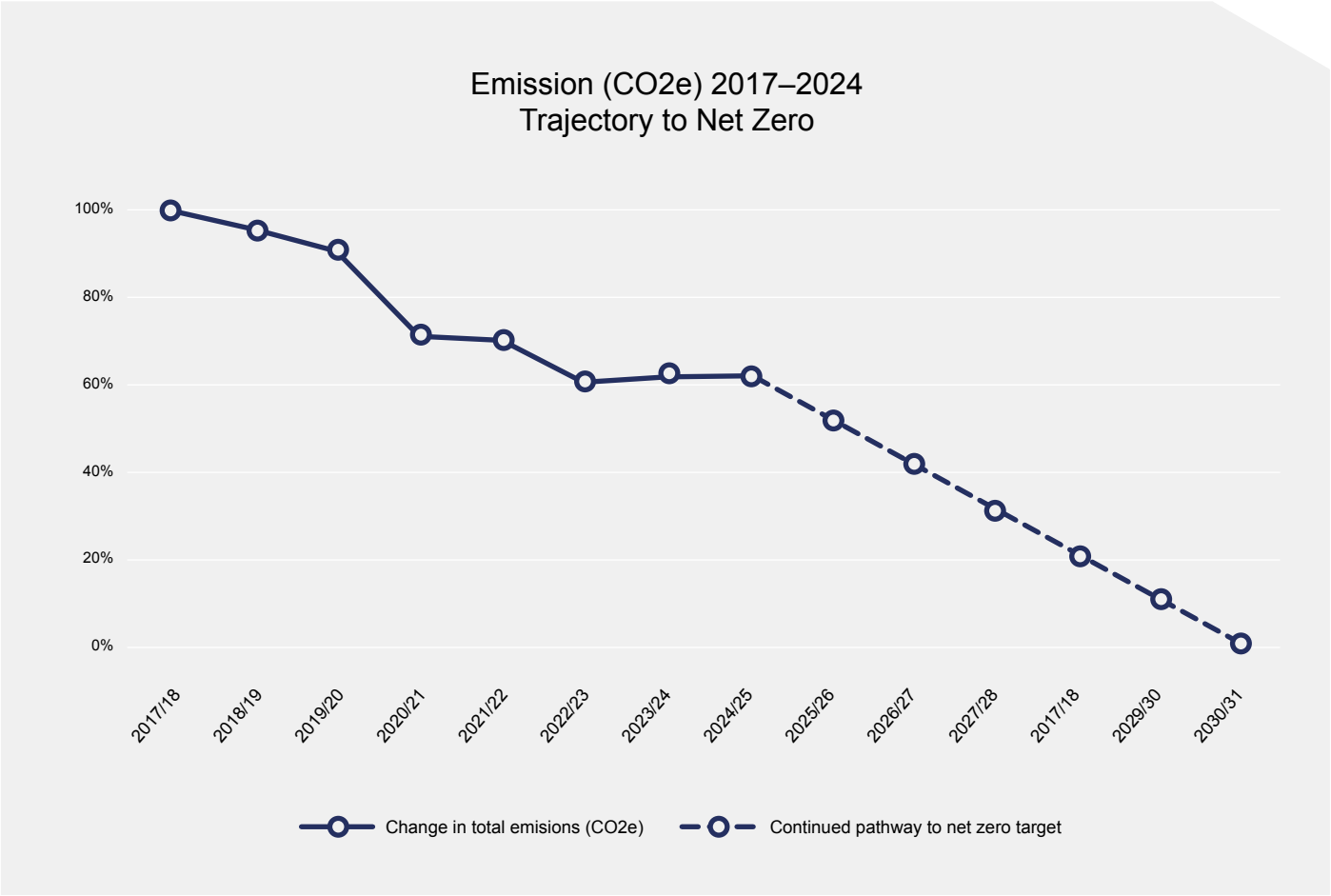
Climate-related risks and opportunities are reported to our Executive Committee as the decision-making body for MHRA, through our Business Continuity group, a subgroup of our Executive Committee management committees. We are developing this reporting line and the maturity of our risk-based discussions through close working with our Head of Risk and Audit and aligning with the requirements of the TCFD. We are currently developing an environmental policy which will include our ESG governance.

Metrics and Targets

We have carried out an analysis of our most significant carbon emissions at our primary locations (Canary Wharf offices and Science Campus), using 2017 as our baseline year[1]. The analysis, along with a range of other inputs, is being used to generate an informed review; helping us to better understand our current position, the impact of climate change-related improvements, and the carbon reduction trajectory required to meet a carbon net zero building estate by 2030.

In addition to analysing our current impact, we have commissioned a heat decarbonisation report assessing the viability of reducing our reliance on fossil fuels and better understand the financial and environmental impact of reducing our direct greenhouse gas emissions.

We recognise that greater transparency and disclosure will only serve to enhance the ability of our organisation to assess and monitor our exposure to climate-related risks and opportunities to build into our strategy and risk management process. As this is our first TCFD report in an uncertain period of climate change, the methodologies and approaches will evolve over the coming year.



We have analysed our progress in reducing significant emissions for our primary locations (measured in tonnes of Carbon Dioxide equivalents, tCO2e). On an absolute basis, these have reduced by approximately 38% over the past seven years, from 2017 to 2024.[2]

1. Aligned with the baseline year for the Greening Government Commitments for 2021 to 2025.
2. 2017/18 – 8213 tonnes, 2023/24 – 5078 tonnes.

Health and safety report

Effective health and safety management is vitally important the MHRA and we are committed to providing a safe workplace for our staff, visitors and contractors. Our suite of laboratories at our Science Campus 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.

Following significant organisational changes across the Agency in recent years, work has continued to map key resource requirements and ensure adequate staffing is in place for key health and safety requirements. The focus on health and safety priorities has remained a top priority and is subject to review by external regulators. In March 2024 the MHRA received one improvement notice following the Health and Safety Executive (HSE) intervention on auditing and inspection. Findings from the intervention, in conjunction with findings from an incident investigation, led to a notice from the HSE highlighting the failure in arrangements for the effective monitoring and review of preventative and protective measures required for the adequate control of the risk from activities with hazardous biological agents. Actions are being taken to address the improvement notice before the deadline of December 2024.

Health and safety governance

Responsibility for health and safety lies with the Chief Executive, with leadership assigned to the Chief Science and Innovation Officer (from 25 March 2024 this responsibility has been delegated to the Interim Executive Director of Science and Research following changes in the leadership team). The central Health and Safety Team, which sits within the Science and Research 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 Science Campus, 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.

We manage health and safety in line with the Health and Safety Executive's 'Managing for Health and Safety' Guidance Document (HSG 65).

Health and Safety Executive

The HSE provides an 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.

Four main inspections were undertaken in 2023/24:

- Human Factors baseline/scoping inspection
- A review of audit and inspection arrangements
- Containment and control systems at Containment Level 4, which is an annual inspection
- WHO Global Action Plan IV (GAPIV) for future Polio work

Accidents and incidents

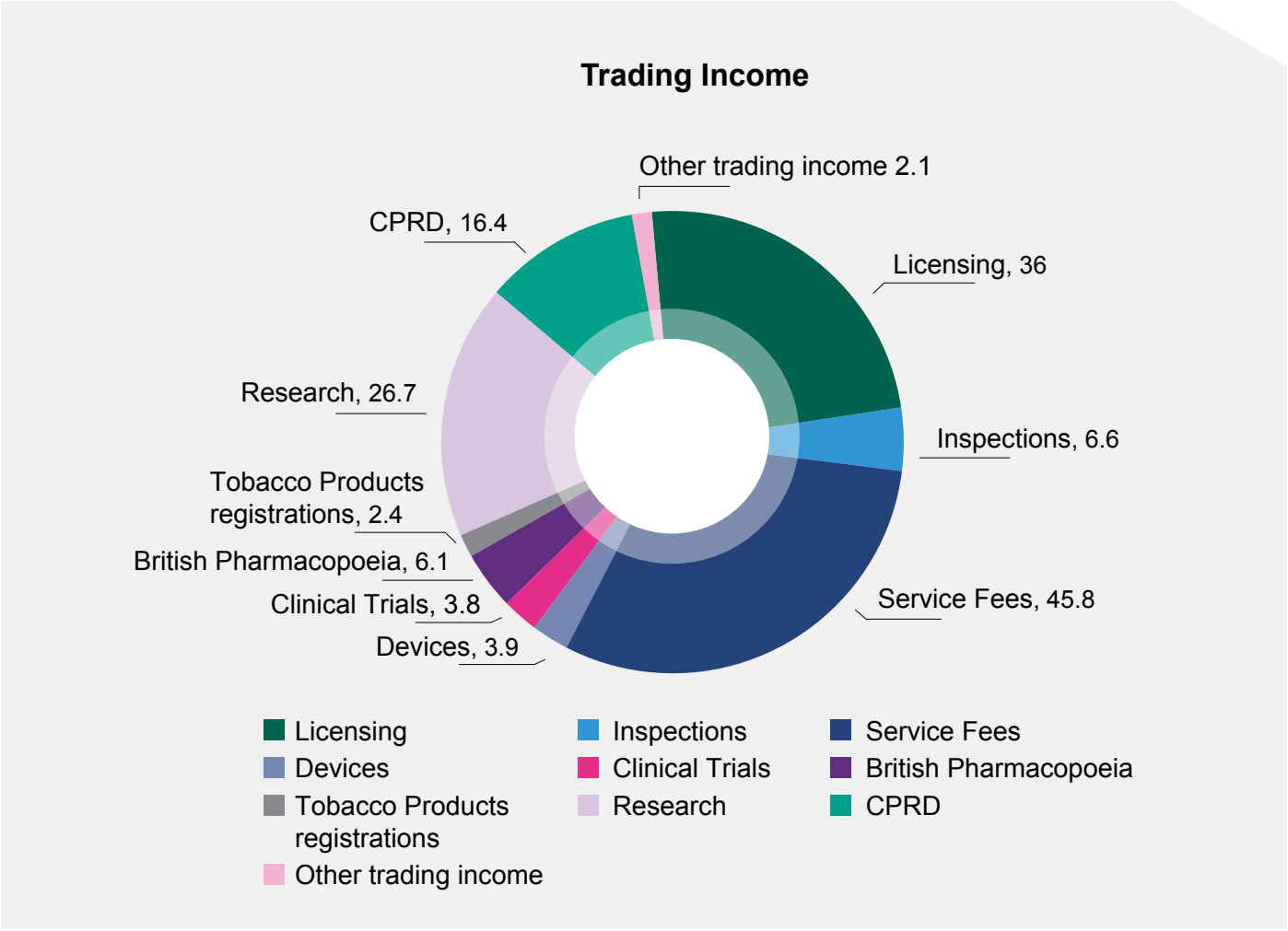
In 2023/24 there was one incident reported under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 (RIDDOR) at the Science Campus. The RIDDOR related to a spill in a Containment Level 3 (CL3) laboratory and was investigated by HSE with follow up actions to be completed by the end of June 2024

Our internal trend analysis for the past ten years indicates an increase in incidents reported in 2023/24 from previous years. The numbers are mostly related to the Science Campus due to the nature of the work performed there, compared to lower numbers at the Canary Wharf office, a reflection of the different environment. The accident statistics have remained consistent.

Analysis of all accidents and incidents is carried out to ensure that they are being reported appropriately, and to ensure underlying causes are fully understood and followed up where applicable. The significant increase in incidents (near misses) reported in 2023/24 is largely due to staff being encouraged to report these types of incidents to enable early investigation and corrective actions to be taken (preventing future accidents). A significant proportion of the incidents in 2023/24 relate to facilities-type issues that were being reported under the quality system.

Financial review

As an agency, we aim to recover our full costs through fees and charges for the services and goods that we provide. However, there is some work that we undertake for which we do not have a legal basis to recover the cost from customers. Although the DHSC funds this work, it is not shown as income in the Statement of Comprehensive Net Expenditure (SoCNE) on page 138. The DHSC funding of £49.7m is shown in the Statement of changes in Tax payers' Equity (SoCTE) on page 141. This means the Agency is showing negative comprehensive expenditure, of £31.5m for the financial year.



Where our funding comes from

The majority of the MHRA's running costs come from trading income, which is a combination of statutory fees paid by the industry for regulatory services and charges paid by customers for non-statutory services and goods. During 2023/24, the MHRA generated £150.0m of trading income.

The largest element of our trading income during 2023/24 was £45.8m from the vigilance risk management and enforcement activities. These are periodic fees charged to pharmaceutical companies for holding a marketing authorisation to market their products in the UK. The charges vary depending on the nature of the medicine being marketed, the length of time it has been sold and the value of the sales. The MHRA income from service

fees revenues covers the costs of monitoring medicines following marketing, including vigilance, risk management and enforcement activities where the cost of activities cannot be recouped through charging direct fees. The next largest income was £36.0m (as shown in the Fees and Charges table page 150) from the pharmaceutical industry for marketing authorisation applications, renewals and variations that provide the companies with market access for products in the UK. The MHRA earned £26.7m income from scientific research work, which includes grants, sales of biological standards and control testing of a wide range of medical products. Income from CPRD data access licence fees raised a further £16.4m. All fees are set based on the cost of delivering the service in line with Managing Public Money.

The DHSC provides baseline funding to support the provision of services for which the agency does not have the legal powers to levy fees or charges. This includes £12.5m for the scientific work that we do to deliver regulation and £8.1m for work on regulating devices. The DHSC also provided an additional £2.8m grant funding to support the continuing work on COVID-19 vaccine safety, including the COVID inquiry.

The MHRA is only able to use capital provided by either the DHSC or other Government sources. The DHSC provided £25.5m of capital funding in 2023/24. This was used for the maintenance of the Science Campus, to deliver the first release of the replacement of our regulatory casework IT management systems, to continue development of the SafetyConnect safety surveillance IT system, and further development of CPRD's Trusted Research Environment.

Our financial performance

More than half of the cost of running the agency relates to staff including pay, national insurance and pension costs. These increased in 2023/24 as the agency recruited into its new structure and pay rates increased by 5% in line with the Civil Service Pay Remit set by the Cabinet Office.

Computing costs increased by £2.2m (8%) due mostly to an increase in the cost of infrastructure services, additional software and licences in year. The Agency also invested in significant improvements in cyber and information security in order to protect its critical systems and data in response to the increasing global cyber security threat.

Our efficiencies

In our commercial work, the MHRA has delivered financial benefits of £4.9m for the financial year of 2023/24. This has been achieved by reducing expenditure through competitive procurement exercises and commercial activity to reduce spend against budgets for goods and services.

25 July 2024

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

2.0 Accountability report

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

2.1 Corporate governance report which provides an overview of the MHRA's leadership and our risk management approach, including the Director's report.
2.2 Statement of Accounting Officer's responsibilities
2.3 Governance statement
2.4 Remuneration and staff report which details remuneration and staff expenses and policies
2.5 Parliamentary accountability and audit report

2.1 Corporate governance report

The purpose of the corporate governance report is to explain our governance structures and how they have supported the achievement of our objectives.

Director’s report

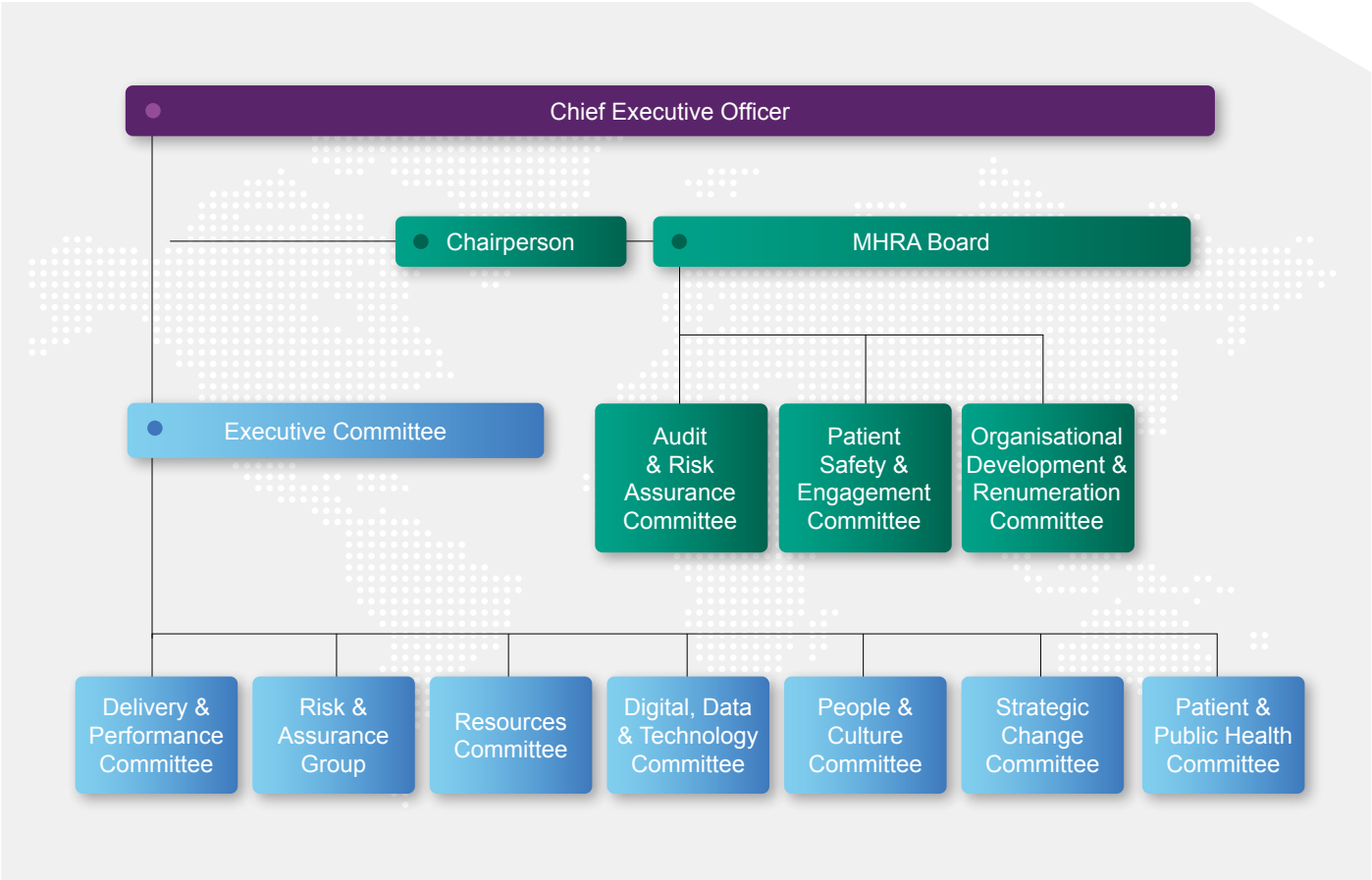
Governance structure overview

The MHRA is led by Dr June M Raine DBE, our Chief Executive Officer (CEO) and Accounting Officer. The CEO is directly accountable to ministers and Parliament and the Permanent Secretary for the operation and management of the MHRA and for the delivery of its functions. The CEO is supported by an advisory board (the Board), led by a Non-Executive Chair (the Chair), and the Executive Committee (ExCo). The Chair role is currently being performed by three interim Co-Chairs whilst a new Chair is recruited.

The CEO of the MHRA is designated as the Accounting Officer by the Principal Accounting Officer of the DHSC, Sir Chris Wormald, on behalf of the Secretary of State for Health and Social Care, The Rt Hon Steve Barclay MP (Oct 2022 to Nov 2023) and The Rt Hon Victoria Atkins MP (Nov 2023). Our senior Departmental Sponsor at the DHSC is the DHSC Medicines Director.

Our relationship with the DHSC and our accountabilities to each other are described in the DHSC and MHRA Framework Agreement; which has been refreshed this year and is published on our website: https://www.gov.uk/government/publications/dh-and-mhra-framework-agreement/framework-agreement-between-dhsc-and-the-medicines-and-healthcare-products-regulatory-agency

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.



MHRA Chair

The Chair, Stephen Lightfoot, stood down from the Board in July 2023. Since July 2023, we have had an interim arrangement with three existing MHRA Non-Executive Directors acting as interim Co-Chairs with specific responsibilities:

Professor Graham Cooke chairing of the MHRA Board meetings
Michael Whitehouse supporting cross-government engagement
Amanda Calvert supporting external stakeholder meetings and organisational development

We are extremely grateful for the support and expertise of the Co-Chairs this year. Their generous commitment, following Stephen Lightfoot's departure in July 2023, has been invaluable. Recruitment of a new Chair is progressing through ministerial appointment.

The Board

Our Board operates as unitary, comprising an equal number of Executive and Non-Executive Directors, along with a Non-Executive Chair. It serves in an advisory capacity, providing support to our CEO in overseeing the MHRA operations and ensuring the effective delivery of services.

More information can be found in the Board's Terms of Reference. https://assets.publishing.service.gov.uk/media/6682cbc6c7f64e23420901e4/Board_ToR_V3.0.pdf

The Board plays a critical role in scrutinising and challenging the Chief Executive and the Executive Team, focusing specifically on:

- Advising on and aligning with MHRA's strategic priorities within established financial and resource constraints
- Ensuring the establishment of a robust governance framework that incorporates effective internal controls for managing risks
- Reviewing the agency's strategic performance and offering constructive support and challenge where necessary

It is important to note that the Board does not participate in regulatory decisions concerning medicines, medical devices or any other products or services delivered by the MHRA. These decisions fall under the purview of the CEO, supported by the Executive Committee. The ultimate responsibility and accountability for such decisions lies with the CEO as the MHRA Accounting Officer.

Members of the Board in 2023/24

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

The Non-Executive Directors who served on the Board in 2023/24 were:

Stephen Lightfoot
September 2020–July 2023
Board Chair

Professor Graham Cooke
September 2021—Present
Board Deputy Chair September 2021–July 2023
Acting Co-Chair July 2023–Present
Member of Patient Safety and Engagement Committee

Michael Whitehouse OBE
September 2018–Present
Acting Co-Chair July 2023–Present
Chair of Audit Risk and Assurance Committee

Amanda Calvert
September 2018–Present
Acting Co-Chair July 2023–Present
Chair of Organisational Development Remuneration Committee
Member of Audit Risk and Assurance Committee

Dr Paul Goldsmith
September 2021–Present
Member of Audit Risk and Assurance Committee

Haider Husain
September 2021–Present
Member of Organisational Development Remuneration Committee

Mercy Jeyasingham MBE
May 2020–Present
Chair of Patient Safety and Engagement Committee

Raj Long
September 2021–Present
Member of Patient Safety and Engagement Committee

Dr Junaid Bajwa
September 2021–Present
Member of Organisational Development Remuneration Committee

The Executive Directors who served on the Board in 2023/24 were:

Dr June M Raine, DBE
September 2019–Present
Chief Executive Officer

Dr Marc Bailey
September 2021–March 2024
Chief Science and Innovation Officer

Dr Alison Cave
July 2021–Present
Chief Safety Officer

Dr Laura Squire
November 2021–August 2023
Chief Healthcare, Quality and Access Officer currently leading work on health technology regulation reform

Dr Glenn Wells
November 2021–Present
Chief Partnerships Officer

Claire Harrison
October 2021–Present
Chief Digital and Technology Officer

Rose Braithwaite
February 2023–Present
Chief Finance Officer

Liz Booth
October 2023–Present
Chief People Officer

Julian Beach
August 2023–Present
Interim Executive Director, Healthcare, Quality and Access

Board skills matrix — Non-Executive Directors

Board members bring a balance of skills and experience which underpins the support they can offer to the CEO in the successful operation of the MHRA.

	Stephen Lightfoot (Chair until July 2023)	Professor Graham Cooke	Michael Whitehouse, OBE	Amanda Calvert	Dr Junaid Bajwa	Dr Paul Goldsmith	Haider Husain	Mercy Jeyasingham, MBE	Raj Long
Public Health	●	●		●	●	●	●	●	●
Pharmaceutical/Life sciences Industry	●			●	●	●	●		●
Charities/Voluntary Sector			●					●	
Medicines Regulation	●					●			●
Infectious Disease Research		●							
Development/Manufacturing of Medicines & Medical Devices	●	●		●		●			●
Clinical Trials		●		●		●			
General Medical/Clinical Practice					●	●			
Government/Policy			●					●	
Digital/Technology				●	●	●	●		
Patient and Public Engagement								●	
Governance			●	●		●		●	
Finance/Accounting			●			●			
Change Management	●		●	●					
Consultancy/Advice		●		●					●
Equality and Diversity								●	
Global Health		●							●

Board meetings

In line with our commitment to prioritising patient and public interests, we conducted six Board meetings in public this year. These meetings were broadcast online, allowing members of the public to observe the Board's proceedings and pose questions related to the agenda. Minutes of these meetings are accessible on the MHRA's website — https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/about/our-governance#agency-board-minutes

The MHRA Board also held six Board meetings in Committee, enabling members' contribution to the development of new strategies and participation in Board training and development activities.

During each meeting, the Board considered papers from the CEO, finance group and Board Assurance Committees. In the 2023/24 period, specific issues addressed by the Board included:

- Development of the MHRA's strategies such as science, sustainability, data, fees, business plans and those set out in the Corporate Plan
- Strategic development of the MHRA's services, technology, legislative reforms, and partnerships
- Health and safety strategy, compliance and performance
- Risk management and key strategic risks
- Agency performance

Board declarations of interest

All members of the MHRA Board, both Non-Executive and Executive, must follow clear rules for disclosing interests in the sectors that the MHRA regulates. These rules ensure transparent management and maintain the Board's independence. Members declare interests upon appointment and annually, updating as needed. They also declare relevant interests at each Board meeting, with decisions on the management of these documented in the minutes.

The rules are outlined in our policy on declaring and managing interests for members of the MHRA Unitary Board https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/about/our-governance#board-members-declarations-of-interest, and are available on our website.

A register of Board member interests is published on our website to uphold transparency: https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/about/our-governance#board-members-declarations-of-interest

Board effectiveness

We have continued to implement improvements to Board effectiveness identified in Board development sessions held in 2022 and in our review of the assurance committees in 2023, including alignment and cohesion of the Board and Board Assurance Committees. A full and substantial review of the Board and its Assurance Committees is planned for 2024/25 following appointment of the new MHRA Chair.

Data Quality to Support the Needs of the Board

All papers to the Board comply with a required structure which ensures the decision requested is clear, that all relevant information is provided and appropriate clearance has been obtained. Finance and performance reports are provided in a clear and consistent manner, enabling comparison over time. Reports on both finance and performance are scrutinised by the Executive Committee prior to discussion at Board, to consider financial and performance implications, including risks. The Chief Finance Officer is the senior Executive with responsibility for Finance.

Board Assurance Committees

The Board is supported by three Board Assurance Committees.

Audit and Risk Assurance Committee (ARAC)

- Membership: Three Non-Executive members, chaired by Michael Whitehouse OBE
- Responsibilities: Oversight and advice on risk management, control, governance, audit, and financial reporting
- Focus 2023/24: Met seven times and addressed various areas, including risk management framework, internal and external audits, anti-fraud policies, cyber security, and engagement with health system partners

Patient Safety and Engagement Committee (PSEC)

- Membership: Three Non-Executive members, chaired by Mercy Jeyasingham MBE, along with three Executive members and two independent lay members
- Responsibilities: Providing independent advice, assurance, and recommendations on patient safety and engagement
- Focus 2023/24: Met three times and provided assurance on items such as the Patient Involvement Strategy, Sodium Valproate, safety reviews, and the Yellow Card Biobank consent process

Organisational Development and Remuneration Committee (ODRC)

- Membership: Three Non-Executive members, chaired by Amanda Calvert, along with three Executive members
- Responsibilities: Providing advice on the development of the MHRA's services, people, and culture strategies
- Focus 2023/24: Met four times, providing assurance on items such as delivering the "One Agency" model, Executive remuneration, leadership, values and culture, the agency's People Strategy, recruitment, talent management and succession, diversity, equality and wellbeing, business performance management, and service delivery

Board and Board Assurance Committee attendance table

Member	Role	Board attended/ eligible	ARAC* attended/ eligible	ODRC** attended/ eligible	PSEC*** attended/ eligible
Stephen Lightfoot[1]	Chair	4 (4)	-	-	-
June Raine	CEO/AO	12 (12)	6 (7)	4 (4)	3 (3)
Graham Cooke[2]	NED	12 (12)	-	-	3 (3)
Michael Whitehouse[2]	NED	12 (12)	7 (7)	-	-
Amanda Calvert[2]	NED	12 (12)	7 (7)	4 (4)	-
Paul Goldsmith	NED	12 (12)	7 (7)	-	-
Haider Husain	NED	7 (12)	-	4 (4)	-
Mercy Jeyasingham	NED	11 (12)	-	-	3 (3)
Raj Long	NED	8 (12)	-	-	3 (3)
Junaid Bajwa	NED	8 (12)	-	4 (4)	-
Marc Bailey[3]	Chief Science and Innovation Officer	12 (12)	-	-	2 (2)
Alison Cave	Chief Safety Officer	10 (12)	-	-	3 (3)
Laura Squire[4]	Chief Healthcare, Quality and Access Officer	7 (7)	-	-	3 (3)
Julian Beach[5]	Interim Executive Director, Healthcare, Quality and Access	8 (8)	-	-	-
Glenn Wells	Chief Partnerships Officer	12 (12)	-	-	-
Claire Harrison	Chief Digital and Technology Officer	12 (12)	-	4 (4)	-
Rose Braithwaite	Chief Finance Officer	12 (12)	5 (7)	3 (4)	-
Liz Booth[6]	Chief People Officer	6 (6)	-	-	-

[1] Stephen Lightfoot stepped down on 12 July 2023.
[2] Graham Cooke, Michael Whitehouse and Amanda Calvert commenced a Co-Chair arrangement on 12 July 2023.
[3] Marc Bailey stepped down on 25 March 2024.
[4] Laura Squire is currently focussed on future Health Technology regulation reform since 14 August 2023
[5] Julian Beach took on role of Interim Executive Director, Healthcare, Quality and Access on 14 August 2023
[6] Liz Booth commenced the Chief People Officer role on 16 October 2023.

Executive Committee

The CEO is supported by the Executive Committee, in the effective day-to-day leadership and management of the MHRA. The Executive Committee is responsible for:

- Optimising agency resources, structures and controls
- Making operational and regulatory decisions
- Developing strategic corporate and business plans and ensuring performance against objectives
- Managing key strategic risks
- Cultivating an enabling culture which prioritises patients

The Executive Committee is chaired by the CEO. Members of Executive Committee in 2023/24 were:

- **Chief Science and Innovation Officer (until 25 March 2024)**
- **Chief Healthcare, Quality and Access Officer**
- **Interim Executive Director, Healthcare, Quality and Access (from 14 August 2023)**
- **Chief Safety Officer**
- **Chief Partnerships Officer**
- **Chief Finance Officer**
- **Chief Digital and Technology Officer**
- **Chief People Officer (from 16 October 2023)**
- **Director of Governance**
- **Director of Communications and Engagement**
- **Director of Delivery**

The Executive Committee is supported by seven management committees arranged across the MHRA's operational and corporate businesses. Each committee has clearly defined delegated authority and decisions or recommendations are escalated to the Executive Committee when the decision exceeds the management committee's delegated authority or is of such a nature that it demands urgent consideration directly from the Executive.

Changes in leadership

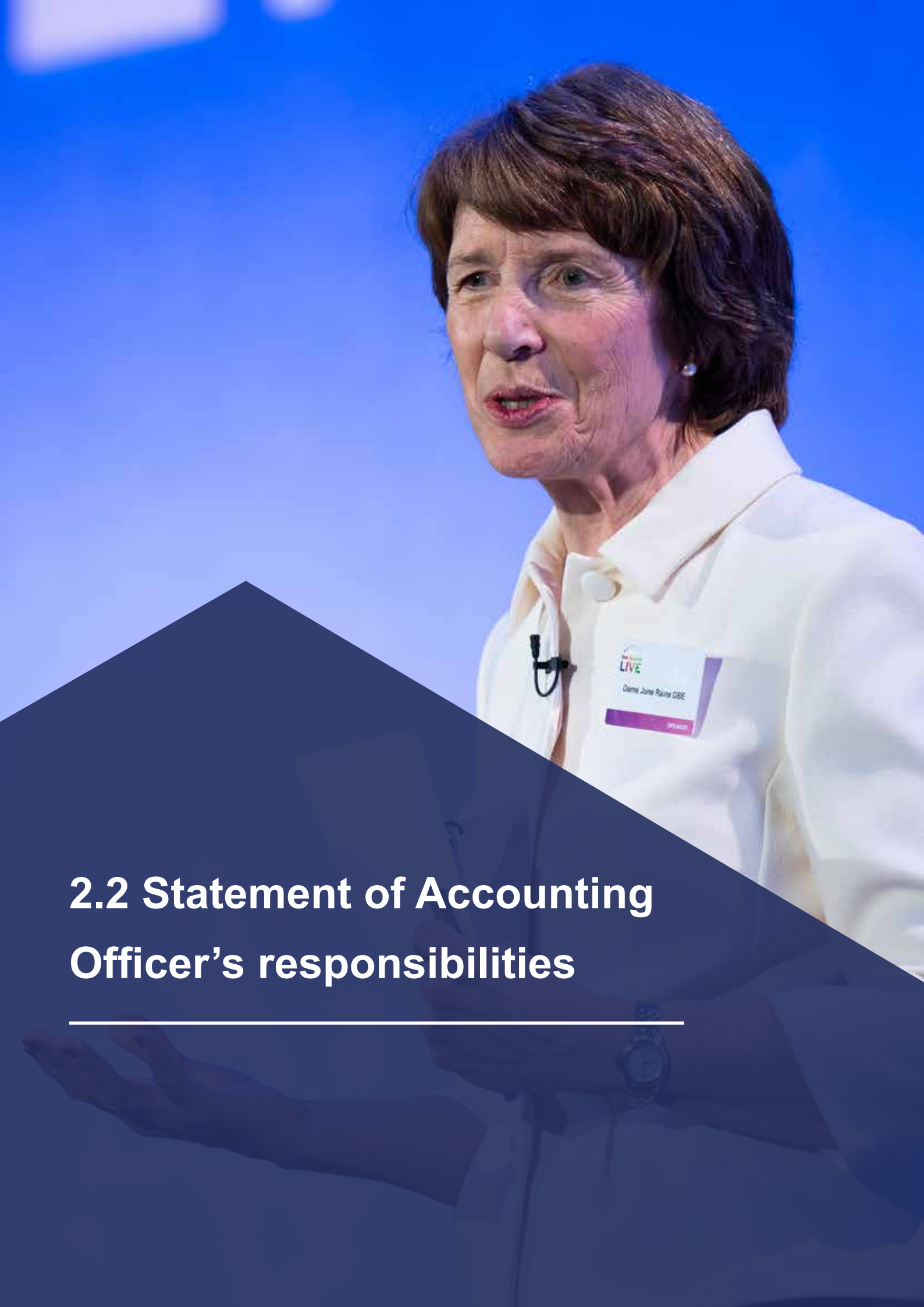
From 14 August 2023, the Chief Healthcare, Quality and Access Officer Laura Squire accepted a time-limited refocused role to lead on health technology regulation reform, and Julian Beach was appointed Interim Executive Director for Healthcare, Quality and Access.

On 25 March 2024, the Chief Science and Innovation Officer Marc Bailey stood down and two interim Executives were appointed to cover the responsibilities of the role. These are Nicola Rose, Interim Executive Director, Science and Research and James Pound, Interim Director, Innovation and Compliance.

The Executive Committee meeting attendance:

Member	Role	Executive Committee meetings attended / eligible
June Raine	Chief Executive Officer (Chair)	18 (23)
Marc Bailey[1]	Chief Science and Innovation Officer	21 (22)
Alison Cave	Chief Safety Officer	20 (23)
Laura Squire[2]	Chief Healthcare, Quality and Access Officer	19 (23)
Julian Beach[3]	Interim Executive Director Healthcare, Quality and Access	13 (15)
Glenn Wells	Chief Partnerships Officer	19 (23)
Claire Harrison	Chief Digital and Technology Officer	18 (23)
Rose Braithwaite	Chief Finance Officer	20 (23)
Liz Booth[4]	Chief People Officer	10 (12)
Carly McGurry	Director of Governance	21 (23)
Mick Foy	Director of Delivery	21 (23)
Rachel Bosworth	Director of Communications and Engagement	19 (23)
Nicola Rose[5]	Interim Executive Director Science and Research	1 (1)
James Pound[6]	Interim Executive Director Innovation and Compliance	1 (1)

[1] Marc Bailey stepped down on 25 March 2024.
[2] Laura Squire has been on health technology regulation reform since 14 August 2023.
[3] Julian Beach took role of Interim Executive Director, Healthcare, Quality and Access on 14 August 2023.
[4] Liz Booth commenced the Chief People Officer role on 16 October 2023.
[5] Nicola Rose took the role of interim Executive Director Science and Research on 25 March 2024.
[6] James Pound took the role of interim Executive Director, Innovation and Compliance on 25 March 2024.



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 the 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 an ongoing concern basis

HM Treasury has appointed the Chief Executive Officer, Dr June M 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.

As the Accounting Officer I confirm that the annual report and accounts as a whole are fair, balanced, and understandable. I take personal responsibility for the annual report and accounts and the judgements required to determine that they are fair, balanced and understandable.

2.3 Governance statement

As Accounting Officer, working with the MHRA Board and supported by the Executive Committee, I ensure effective governance and robust internal controls to enable us to achieve our objectives. My responsibilities include safeguarding public funds and assets, ensuring propriety and value for money, ensuring regulatory compliance, and overseeing day-to-day operations.

Improvements to our internal control environment

We have undertaken significant work to strengthen our internal control environment this year, including:

- Enhancing our risk management approach, resulting in a Substantial assurance rating from the Government Internal Audit Agency (GIAA) for our risk management audit
- Creating a comprehensive assurance map to evaluate control effectiveness across key MHRA activities, in line with the Orange Book
- Implementing an Executive Committee-led initiative, "Return to Green," to address under-performance in key service areas
- Improving the timeliness of responding to Freedom of Information (FOI) requests, to address an Information Commissioner's Office Practice Recommendation received in August 2023, achieving compliance by December 2023
- Increasing scrutiny of health and safety management and addressing recommendations from a Health and Safety Executive RIDDOR reportable incident in November 2023
- Substantially enhancing the closure timeliness of management actions from GIAA audits
- Refreshing our performance monitoring system for early issue identification and aligned reporting

Risk and Internal Control Framework

Risk management

The MHRA adheres to the principles outlined in the Government's Orange Book (https://www.gov.uk/government/publications/orange-book). Our approach to risk management seeks to:

- Identify risks
- Prioritise their management
- Implement an appropriate treatment strategy
- Monitor and report on them to enhance the quality of decision-making

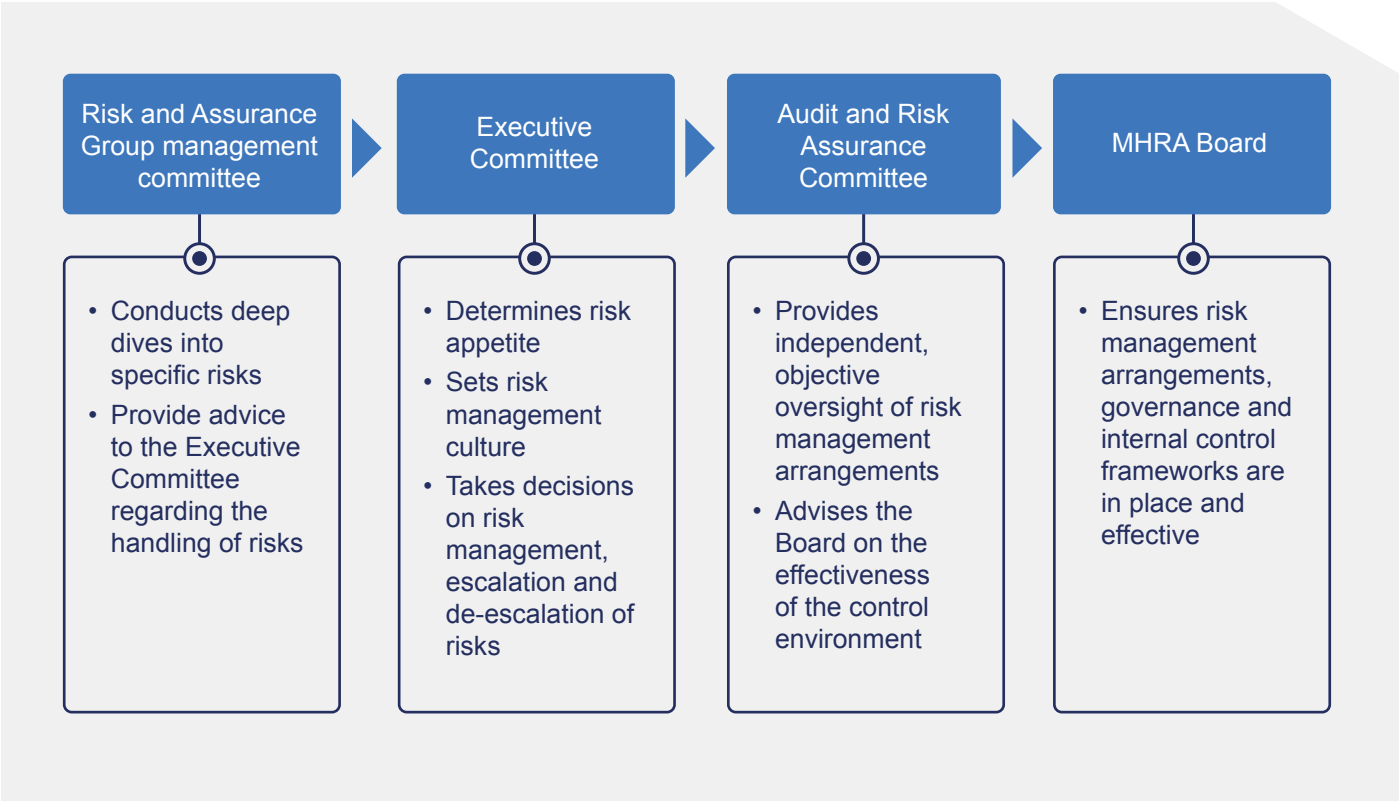
We recognise that it is not possible to eliminate all risks, particularly given the constraints on resourcing, budgets and the hazardous nature of the work we undertake at our Science Campus. Therefore, we seek to manage risk to a reasonable level.

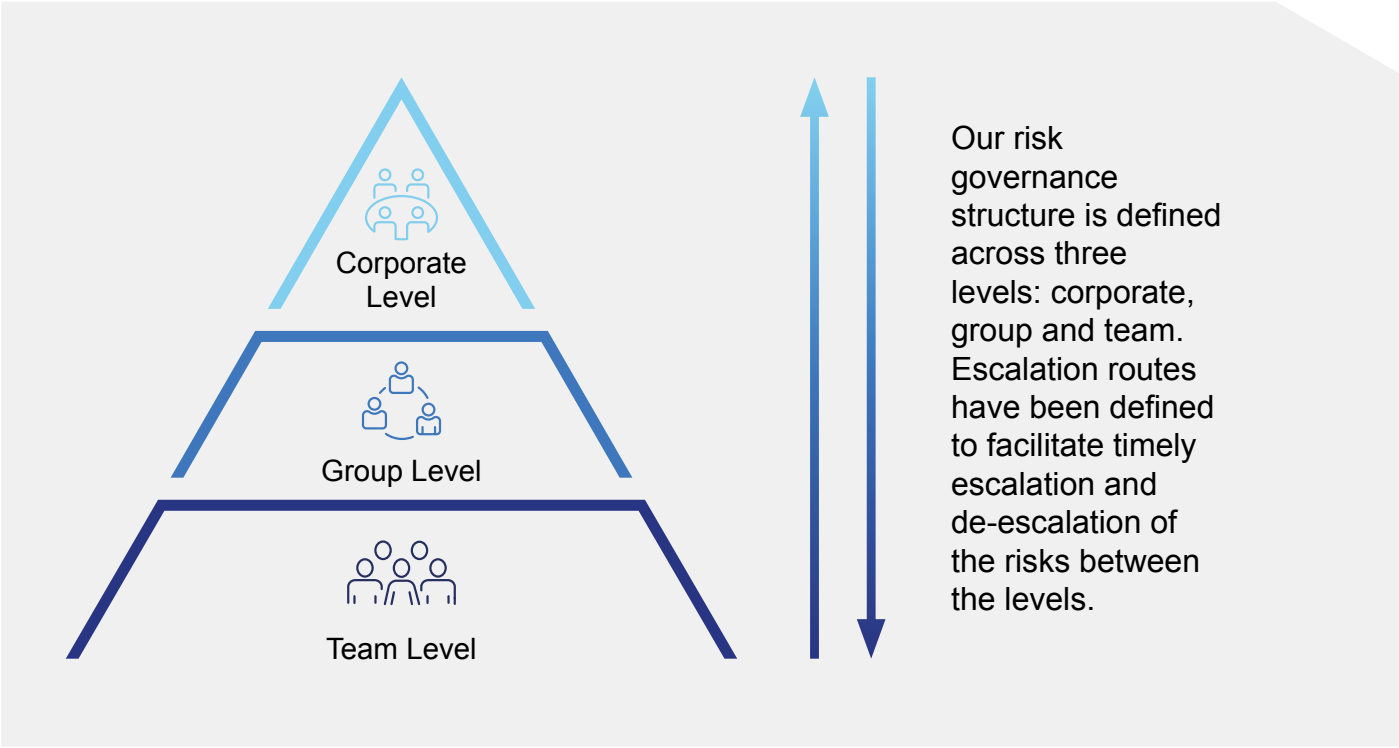
We will continue to embed new risk management processes and mature our risk management approach across the agency during 2024/25.

Key changes made during 2023/24 include:

1. Definition of a new risk governance structure and escalation process

Risks are identified through regular review and discussions as well as horizon scanning sessions at the ARAC, with escalation from group level risk registers as needed.





Our risk governance structure is defined across three levels: corporate, group and team. Escalation routes have been defined to facilitate timely escalation and de-escalation of the risks between the levels.

2. Development of a new risk assessment matrix

We launched a new Probability Impact (PI) matrix and assessment tool assessing risks against six key impact categories:

3. Establishment of risk appetite

Our new risk management framework includes defining the level of risk exposure we can tolerate to achieve strategic objectives. This supports effective decision-making and risk escalation. With Executive Committee agreement to a new appetite which is now in place for most of our impact areas, the final elements of our risk appetite will be operational within the first quarter of 2024/25.

Risk management practice 2023/24

We manage risks and issues using an online reporting system, with the Executive Committee reviewing full reports monthly to make decisions on risk movement, handling of emerging risks, and assessing the overall risk environment. The ARAC scrutinises and challenges the risk and issues register quarterly, providing assurance to the Board. The Board, in turn, considers the risk management approach twice yearly. A GIAA audit in February 2024 awarded our risk management approach a Substantial assurance rating, indicating adequacy and effectiveness of the governance, risk management, and control framework.

Key corporate risks and issues faced in 2023/24

We recognise the complexity and interconnectivity of the corporate risks and issues the agency has handled this year. We have highlighted below the key risks and issues considered during 2023/24, with the arrow showing the overall trajectory of the risk throughout the year:

Recruiting and retaining the right people with the right skills remained our primary operational issue during 2023/24 as it underpins our ability to deliver for public health and links to our risk on performance. This issue was also impacted by the challenging employment market and competition from the private sector. We mitigated this issue by improving our recruitment process, deploying expert staff across the agency's business and launching a new graduate scheme. The agency's turnover is now within the healthy range (as defined by the Chartered Institute for Personnel and Development [CIPD]).

Health and Safety

The work of the MHRA, especially at our Science Campus, carries an inherently high risk, necessitating additional heightened health and safety requirements to protect our staff. Health and safety remained one of the top risks throughout 2023/24 and was escalated to an issue in March 2024 following receipt of an enforcement notice from the HSE related to a reported incident. We are mitigating this issue through a forensic review of the current processes, provision of extra training and additional monitoring to support our steadfast commitment to the safety of our staff.

Cyber security and upgrading of agency systems

This is a key risk for many organisations due to the increasing sophistication of the cyber threat against the UK government. We manage critical data related to the medicinal products we regulate, necessitating a focus on information security and safeguarding against cyber threats. We have completed a comprehensive set of reviews of our cyber resilience and established a roadmap of improvements. We are replacing systems to bring in new, modern, scalable solutions with benefit to our customers through increased ability to self-serve. These have reduced the risk however it remained high during the year due to the complexity of delivery and the ongoing nature of the cyber threat.

Performance

This year, we have taken decisive action to address underperformance in some of our service areas where our timely decisions are needed to enable patients and the public to have rapid access to safe and effective medicines. We used a targeted approach to eradicate assessment backlogs in clinical trial applications and have used the lessons learned from this exercise to inform work underway to reduce waiting times for decisions on established medicines licence applications. Our key mitigations have been the introduction of new efficient processes, the use of skilled external and internal resource and ensuring open, transparent communication with our customers. We successfully returned clinical trial assessments to statutory timelines by September 2023 and by year end have reduced the established medicines assessment backlog by more than 50%. We are on track to resume successful performance on established medicines assessments by Q3 2024/25 and have a dedicated, Executive Committee led programme of work across key services to ensure that these performance improvements are sustainable over the longer term. This programme (Return to Green) and our wider approach was given a Moderate assurance rating by the GIAA in March 2024.

Appropriate and proportionate engagement with patients and public

We strive to place the patient at the heart of everything we do in regulating medical products for the UK. We are working to optimise patient engagement in our key decision areas and are building relationships with stakeholders across the health system. Actions defined in our Patient Involvement Strategy 2021–25 are our key mitigations for this risk, and we have included the patient perspective in the risk-benefit reviews of medicines this year such as the cystic fibrosis treatment, Kaftrio.

Assurance

In line with the Orange Book, the MHRA has adopted the “Three Lines” model for assurance, to provide oversight on our governance, risk management and control environment:

First-line assurance
Ensuring managerial and supervisory controls are in place and effective.

Second-line assurance
Supporting first-line management controls through cross-agency oversight, providing expertise and scrutiny one step removed from delivery across our decision-making and processes.

Third-line assurance
Third line assurance - Primarily provided by the independent audit function of the GIAA as well as oversight by the DHSC and external sources of assurance such as the HSE audits and external independent inspections.

In 2023/24, we refreshed the mapping of our control environment, using a process-based approach in line with the Orange Book. We have created a comprehensive map to help us to understand the sources of assurance over all of our services and activities, enabling us to proactively identify control weaknesses and develop an action plan to address these in 2024/25.

Health and safety

The MHRA health and safety policy commits to protecting our staff from harm and safeguarding their health and wellbeing. We undertake a wide range of activities, including some higher risk scientific activities and our health and safety programme recognises the need for additional measures in our Science Campus.

We have implemented a planned intervention programme with the HSE to support our compliance with health and safety legislation related to our laboratory work. The actions resulting from our planned intervention programme have been a key focus throughout the year, as well as responding to a laboratory incident reportable under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 (RIDDOR) in November 2023, which resulted in an Improvement Notice from the HSE. No staff were harmed in this incident, and we have taken robust action to address the causes and prevent a reoccurrence.

Financial governance framework

The MHRA has a financial governance framework with appropriate policies and procedures to ensure compliance with the requirements of Managing Public Money, government spending controls, relevant legislation and accounting standards. Further details of our financial governance and a detailed analysis of our accounts can be found on pages 69, 137–163 of this report.

Preventing fraud, bribery and corruption

We are committed to preventing and deterring cases of fraud, bribery and corruption and where they do occur, investigating cases and learning from them in line with our Anti-Fraud and Bribery Policy.

We use the Cabinet Office process and format for our assessment of fraud risk. Setting actions to mitigate and reduce these. Our annual action plan, aligned with our Fraud Strategy, sets out our activities and supports continual improvement. In 2023/24, we were peer-assessed as fully meeting the requirements of the Counter Fraud Functional Standard.

Raising a concern/whistleblowing

We encourage our employees to raise a concern when they believe there may have been a wrongdoing or if something does not feel, look or sound right. This aligns with our agency value of 'we work together with respect'. We remind staff of the process for raising concerns or whistleblowing throughout the year and through targeted activities such as Civil Service Speak Up week.

Our Non-Executive Director Mercy Jeyasingham is our Raising Concerns Champion, providing independent oversight and challenge of our approach to raising concerns and individual cases where necessary. Our Nominated Officers signpost staff to the appropriate place to address their concerns, and other sources of support for staff including Wellbeing Champions and Fair Treatment Ambassadors.

Staff approached the MHRA's Nominated Officers throughout the year for support and advice, but there were no formal whistleblowing cases. This compares with one formal concern case being raised and investigated in 2022/23.

Conflicts of interest

We have robust processes to manage conflicts of interest in order to protect the effectiveness and independence of our decision making. Our staff are required to uphold the highest standards of integrity, ensuring no conflicts of interest or apparent conflicts of interest arise between their official positions and the agency's work. Our policy is clear that staff are prohibited from holding interests in the industries regulated by the agency.

Board members are permitted to hold some interests but must adhere to clear rules on disclosing these as set out in our Policy on Declaring and Managing Interests for Members of the MHRA Unitary Board. The Board does not participate in any regulatory decisions concerning medicines, medical devices or any other products or services delivered by the MHRA. Further details about the Board and its operation can be found on pages 77–85 of this report.

Corporate conflicts of interest are rigorously addressed to prevent any conflict with our regulatory role, as outlined in our policy for handling conflicts of interest. Our dedicated Conflict of Interest Group evaluates and implements mitigations for potential conflicts, allowing us to maintain transparency while ensuring vital public health work continues uninterrupted.

Details of any transactions involving organisations connected to Executive or Non-Executive Directors, as key management personnel, are disclosed in the Related Parties note of the Annual Report and Accounts (page 163).

Human rights and staff well-being

We value our workforce and prioritise their well-being, striving to be an employer of choice. Our commitment to protecting the human rights of our staff is evident through the implementation and support of various policies and practices, including the 'Dignity at Work', 'Grievance', and 'Whistleblowing' policies. We actively promote diversity, inclusion, and well-being through a range of initiatives. Recognising the importance of staff representation, we support trade unions and staff-led networks, providing platforms for staff to voice concerns and advocate for specific issues. Our network of well-being champions and trained mental health first aid personnel further supports staff well-being. Additionally, our employee assistance programme offers comprehensive support, including legal advice, debt management guidance, and counselling services, ensuring our staff can access the assistance they need.

Information governance

The MHRA Chief Technology Officer oversees information governance and cyber security, both critical aspects of our operations. We continually benchmark ourselves to ensure robust controls are in place and effective.

In 2023/24, our efforts included:

- Completing the Data Security Protection Toolkit, benchmarking our compliance against the National Data Guardian's data security standards
- Participating in DHSC Information Governance meetings for cross-government alignment
- Engaging in the Joint Cyber Unit, comprising representatives from DHSC and arms-length bodies, facilitating collaboration on emerging security issues and best practice
- Undertaking GIAA audits on information and cyber security, enabling insights into threats and the strength of our defences
- Evaluating alignment with the National Cyber Security Centre (NCSC) Cyber Assessment Framework to gauge our cyber risk management effectiveness

Despite facing a high volume of cyberattacks and phishing attempts, our robust preventative controls detected and resisted threats effectively. A detailed Security Improvement Plan addresses the timely implementation of audit recommendations, ensuring full alignment with the NCSC Cyber Assessment Framework.

Information security statistics

In 2023/24, two information security incidents were reported: one cyber-attack on our website that caused some disruption and an attempted attack on a file-sharing software that was interrupted by a swift incident response.

This year, we have seen a significant increase in phishing, malware and spam emails.

- **4,626 Malware emails blocked** (compared with 300 in 2022/23)
- **113,542 Phishing emails blocked** (compared with 9,000 in 2022/23)
- **2,475,455 Spam emails blocked** (compared with 35,000 in 2022/23)

Personal data incidents

The MHRA has formally reported three data breaches to the ICO. Each was reported within the required 72 hours of becoming aware of the breach. No further actions were required beyond the remedial work and mitigation measures implemented. Incidents which did not require reporting to the Information Commissioner are recorded centrally within the MHRA.

Compliance with Government Functional Standards

The MHRA adheres to best practices and guidance as set out in the Government Functional Standards. We have assessed our compliance with the standards as meeting the minimum elements in five of the standards, with the majority of elements being met in the other nine standards. We have a programme of work across the agency to address the elements not yet fully met.

Internal control issues 2023/24

We described in our annual report last year, the journey we were on to address the challenges and opportunities in our systems of internal control which afforded us a Limited assurance rating from the GIAA. We knew that 2023/24 would be a further period of intense change with multiple, competing priorities and this has meant that our route to a Moderate assurance rating is taking longer than hoped.

Our operating environment remains challenging – from continuing to enable innovation in our regulated sectors, to pursuing effective international alignment and driving the efficiencies and productivity expected of a public body – yet we are deeply encouraged by the clear improvements we have seen throughout the year and reflected in the carefully balanced audit opinion.

At the start of 2023/24, we had a clear set of priorities, detailed in our Corporate Plan, related to our commitment to operate as a trusted and transparent regulator, deliver reliable performance and build a more responsive customer service. Detailed actions were outlined in our Business Plan to realise these strategic ambitions, which we report on in the Performance Analysis section of this report (pages 35–55).

We recognise there is still work to do to fully address the under-performance in some service areas, leading to some timelines becoming unacceptably long for our customers. Addressing these performance challenges consumed significant resource this year as we worked to resolve them sustainably. We successfully returned our performance on clinical trial decisions to statutory timeframes by September 2023 and have made significant improvements in our established medicines decision timelines. We are continuing to address under-performance across the MHRA through our Return to Green programme, which is driving the re-development of services, refresh of processes and design of critical new technology systems to support sustainable improvements. The GIAA rated this work as Moderate assurance following an audit on backlog handling in February 2024.

In June 2023, we received a Practice Recommendation from the ICO regarding our response times to FOI requests. We prioritised efforts to rectify this issue, successfully restoring performance on FOI requests by December 2023. Further details on our actions to bring our responses into compliance can be found in the Performance Analysis section (pages 35–55)

As described in the corporate risks section on page 91, our health and safety compliance has again been an area of significant focus over the course of this year. We have worked hard to address recommendations from our planned HSE surveillance programme, with the MHRA Board, Executive Committee and ARAC retaining close oversight over our health and safety provisions. A laboratory incident reportable under the RIDDOR in November 2023 led to us receiving an improvement notice from the HSE in March 2024. We are taking robust actions in response to the improvement notice.

In response to the Limited assurance rating assigned to the GIAA audit on recruitment we are implementing a new recruitment system and a new, embedded employer brand that will ensure that future talent is attracted to our employment offer, taking a more strategic approach to talent acquisition in a highly competitive market.

We have driven progress this year on our critical underpinning infrastructure in the form of our new regulatory IT system, RegulatoryConnect. The mid-year audit found a need to better define the vision and scope of the programme and to ensure governance arrangements supported effective decision-making. Much of the recommended change was delivered, alongside a refreshed business case. Phase one of our RegulatoryConnect release was completed as planned in March 2024, with new critical functionality that provides applicants with the ability to track their case in real time and check their data. This has received excellent feedback from users. This is the first deliverable of significant process improvement, and we are excited to build on its success.

The RegulatoryConnect IT infrastructure replacement is just one area of change in the organisation that has benefitted from our action this year to grow our capacity and capability in driving change through the recruitment of appropriate expertise, greater integration of the three lines of defence across all change initiatives, and clearer Executive direction. We expect this to continue to grow and develop into the coming year, learning from the work to secure sustainable improvements in our performance and understanding how we can better optimise our systems to anticipate and act rapidly in the face of an always changing environment.

During the year we have grappled with both new and existing challenges within an overall positive trajectory and clear signs of approaching a more Moderate assurance rating. It takes time to realise meaningful, sustainable change, with many smaller improvements needing to come together to deliver the whole. I am grateful to GIAA for their support of our work in resuming Moderate rating status to protect our vital public health outcomes. Their analysis has helped to inform our next set of priorities for methodically extending and embedding the control environment across all areas of the MHRA. To that end, we will strengthen our spotlight on the implementation of audit actions over 2024/25, with a direct line of sight to me as Accounting Officer. All areas will be supported to set SMART actions, balancing realistic delivery timelines with the need for rapid action to improve upon any weaknesses identified. We will combine this with our pre-planned controls alignment exercise to capture the benefits of co-ordinated action.

Building on the first phase of RegulatoryConnect and the launch of SafetyConnect, we will also continue to deliver tangible improvements in our digital environment, with an embedded plan taking a clearly prioritised approach to tackling legacy technologies and maximising the benefit of innovation, while complying with cross-government cyber resilience activities. This focused approach will also inform our ongoing business change.

Through internal checks the agency is aware of an issue where some workers have been appointed through service contracts which are not subject to the status determination controls. We have assessed the risk and estimated a provision in the accounts for the unpaid PAYE, National Insurance, interest and penalties, and will commence discussions with HMRC. Further details can be found on page 120-121 and page 162..

I am clear that the coming year will continue to demand excellence from the agency and I know I speak for all staff in saying that the MHRA is committed to delivering that excellence, both in our vital public health contribution and in all the operations of our organisation, capitalising on all of the hard work of recent years.

Head of Internal Audit (HIA) Opinion

The Government Internal Audit Agency (GIAA) provides the internal audit service for the MHRA, in line with Public Sector Internal Audit Standards to assess governance, risk, and controls. The GIAA focusses on business risks, drives improvements, and offer advice on changes. An Audit Plan is agreed with the Audit and Risk Assurance Committee (ARAC) and is updated regularly to target risks. The MHRA provides evidence to GIAA that agreed actions have been implemented, with progress reported to ARAC.

During 2023/24, the GIAA completed 13 audit engagements, of which one was advisory, three were rated as Substantial, five were Moderate, three were Limited and one was Unsatisfactory. The GIAA raised 68 recommendations for which action plans have been developed. The Annual Opinion for 2023/24 is Limited. Whilst this is the same overall Annual Opinion as the last two years, it reflects the complexity and varied levels of risk and controls maturity across the organisation. There is evidence that the embedding and further maturing of centrally orchestrated governance and oversight processes are on a positive trajectory and are strengthening the organisation.

In a subset of areas, management actions in response to reported weaknesses are not being addressed in a systematic manner. This relates mainly to the digital control environment, but is also apparent in delivering business change, and in some basic business processes (for example, recruitment).

GIAA's Annual Opinion for the 2023/24 report focused on four themes:

1. Digital Control Environment

The GIAA identified control deficiencies and the need for a structured approach to provide transparency around the improvement in the digital control environment. The audit of the Data Security Protection Toolkit (DSPT) in July 2023, received an Unsatisfactory opinion, noting a low confidence in the overall veracity of the self-assessment to NHS England against mandatory assertions across National Data Guardian standards. A Limited opinion was provided on Cyber Security arrangements, due to the absence of risk management arrangements and a functioning security oversight group, no detailed plans to address areas identified by the National Cyber Security Centre (NCSC) self-assessment, and the extended time taken to introduce mitigating controls from previously identified control weaknesses.

2. Operations and Performance

The GIAA found that the MHRA has prioritised ensuring delivery of core business functions, including meeting assessment targets for key services, and eliminating backlogs. Operational efficiency has been enhanced by addressing backlogs.

3. Corporate Functions

The GIAA found that the MHRA has well established arrangements and controls in place over its enabling finance, governance, and people-related corporate functions. Where widespread changes need to be actioned, the GIAA noted that the MHRA faces the challenge of being able to secure the resources to fully embed the improvements. On recruitment, a Limited opinion report was provided, noting sustained capacity and resilience issues, and gaps in second-line checks and management information.

4. Managing Change

The GIAA reinforced that efficient and effective delivery of change initiatives is vital if the MHRA is to fulfil its mission of protecting public health, ensuring compliance, fostering innovation, and maintaining its influence on the world stage in regulatory practices. A Limited opinion was provided on the reset and recovery arrangements for the RegulatoryConnect programme, identifying weaknesses in the management, delivery, and oversight.

In summary, the GIAA suggested that decisive steps should now be taken to show the evolution of MHRA's control environment. The progress made in specific areas needs to expand to cover all directorates. Adopting a systematic approach with collective senior responsibility will result in a more consistent application of actions to improve internal controls.

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 Executive Committee 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 the Executive Committee.

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 operational areas, completed by Executive Committee members
- The MHRA's internal audit coverage, which is established 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 (p.100)

The systems for corporate governance, risk management, internal control and assurance are monitored by the Board, ARAC and the Executive Committee, and have been in existence throughout the year to 31 March 2024 and up to the date of approval of the Annual Report and Accounts.

The Head of Internal Audit has given the MHRA a Limited assurance rating for the third consecutive year, with control weaknesses identified in our digital control environment, operations and performance, corporate functions and management of change. Decisive action has been taken to strengthen our control environment through an Executive owned Route to Moderate plan focussed on the core themes identified and driven through the timely closure of management actions and through maturing of the assurance and controls mapping activities already underway.

I have set out in the Internal Control Issues section of this report (page 98) details of the internal control matters which 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, we have undertaken significant reflection and engagement with both auditors and ARAC and I am confident that the specific matters to address these issues and the root causes of those matters have been identified,

management responsibility allocated and work is underway to resolve them. I am therefore sufficiently satisfied with our response to address these control weaknesses throughout the year. I am assured by the improvements made to the control framework this year, with specific improvements to our risk management and governance and plans to continually improve throughout 2024/25.

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 98).

While taking into account the specific weaknesses identified in earlier sections of this report and drawing on the improving trajectory recognised by the Head of Internal Audit opinion, my opinion is that the agency's overall governance and control structures have been appropriate for the agency's business and have been satisfactory throughout 2023/24.

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 the MHRA. 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 Executive Committee, 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.

25 July 2024

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

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 open-ended appointments. 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 agency has two performance development schemes for its staff. Senior Civil Servants (SCS) performance management is guided by the Cabinet Office scheme. A goal-setting plan that includes corporate goals mandated for all, quarterly conversations, a mid-year (September/November) and end of year (March/April) review as well as 360-degree feedback is also included. Aligned with this is potential to be awarded a mid-year or end of year performance bonus.

Our largest cohort of staff are in the Delegated Grades and the agency has a scheme called My Progress Review, which is based on a continuous quality conversation with quarterly 'check ins' on progress against goals. The scheme is underpinned by the agency values and includes the potential to be awarded an in-year award and/or recognition voucher, designed to reward exceptional performance 'in the moment', aligning the award with the value and behaviours that have been demonstrated.

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)

2023/24	Salary £'000	Performance pay and bonuses £'000	Pension related benefits* £'000	Total £'000
June Raine, DBE Chief Executive Officer	155–160	0–5	67	220-225
Rose Braithwaite Chief Finance Officer	125–30	Nil	54	175–180
Liz Booth[1] Chief People Officer	50–55	Nil	1	50–55
Alison Cave Chief Safety Officer	150–155	0–5	80	230–235
Marc Bailey[2] Chief Science, Research and Innovation Officer	125–130	Nil	78	200–205
Claire Harrison Chief Digital and Technology Officer	135–140	Nil	63	200–205
Glenn Wells Chief Partnerships Officer	120–125	Nil	48	170–175
Laura Squire, OBE Chief Healthcare Quality and Access Officer	115–120	Nil	67	185–190
Julian Beach[3] Interim Executive Director Healthcare Quality and Access	70–75	Nil	28	100–105
Nicola Rose[4] Interim Executive Director, Science and Research	0–5	Nil	1	0–5
James Pound[5] Interim Executive Director, Innovation and Compliance	0–5	Nil	1	0–5

*The value of the pension benefits accrued during the year is calculated as (the real increase in pension multiplied by 20) plus (the real increase in any lump sum) less (the contributions made by the individual). The real increases exclude increases due to inflation or any increases or decreases die to a transfer of pension rights.

[1] Liz Booth was appointed as Chief People Officer on 16 October 2023. Full year equivalent £110k–£115k.

[2] Marc Bailey stepped down as Chief Science and Innovation Officer on 25 March 2024. Full year equivalent £120k-–£125k.

[3] Julian Beach was appointed as Interim Executive Director Healthcare, Quality and Access on 14 August 2023. Full year equivalent £115k–£120k.

[4] Nicola Rose took on the role of Interim Executive Director Science and Research on 25 March 2024. Full year equivalent £100k–£105k.

[5] James Pound took on the role of Interim Executive Director Innovation and Compliance on 25 March 2024. Full year equivalent £95k–£100k.

2022/23	Salary £'000	Performance pay and bonuses £'000	Pension related benefits* £'000	Total £'000
June Raine, DBE Chief Executive Officer	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 , Research 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

*The value of the pension benefits accrued during the year is calculated as (the real increase in pension multiplied by 20) plus (the real increase in any lump sum) less (the contributions made by the individual). The real increases exclude increases due to inflation or any increases or decreases die to a transfer of pension rights.

[1] Jon Fundrey left the MHRA on 2 May 2022. Full year equivalent £140–£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 £260–£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.

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

2023/24	Salary £'000	Benefits in kind (taxable) to nearest £100	Total £'000
Stephen Lightfoot[1] Non-Executive Director, Chair	15–20	500	15–20
Junaid Bajwa Non-Executive Director	5–10	Nil	5–10
Amanda Calvert Non-Executive Director	15–20	4,800	15–20
Graham Cooke Non-Executive Director	15–20	100	15–20
Paul Goldsmith Non-Executive Director	15–20	4,500	15–20
Mercy Jeyasingham, MBE Non-Executive Director	5–10	100	5–10
Raj Long Non-Executive Director	5–10	1,600	5–10
Michael Whitehouse, OBE Non-Executive Director and ARAC chair	15–20	400	15–20
Haider Husain Non- Executive Director	5–10	Nil	5–10

[1] Stephen Lightfoot left the Board on 11 July 2023. Full year equivalent £60k–£65k.

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 NED from 1 September 2022. He was a non-voting associate NED from 1 September to 31 August 2022.

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 MHRA.

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 2023/24 relate to performance in 2022/23 and the comparative awards reported in 2022/23 relate to performance in 2021/22.

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 2024 was £155k–£160k (2022–23 was £150k - £155k). In 2023–24, no employee (2022–23, one employee) received remuneration in excess of the highest paid Chief Officer. Remuneration ranged from £8k to £156k (2022–23 £8k–£148k).

Total remuneration includes salary, non-consolidated performance-related pay, and 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
2023–24	4.44	3.50	2.46
2022–23	4.47	3.53	2.53

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:

	2023–24			2022–23		
	25th percentile	Median	75th percentile	25th percentile	Median	75th percentile
Total pay and benefits	£35,468	£44,974	£64,003	£34,102	£43,182	£60,172
Salary component	£35,010	£44,023	£61,841	£33,940	£42,176	£57,836

Percentage change from the previous financial year

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

% change — Highest paid Chief Officer	2023–24 Increase/(decrease) %
Salary and allowances	5.32
Performance pay and bonuses	0

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:

% change — Average for all employees taken as a whole	2023–24 Increase/ (decrease) %
Salary and allowances	7.73
Performance pay and bonuses	(1.39)

Pension benefits table (subject to audit)

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

2023/24	Real increase in pension and related lump sum at 60 £'000	Total accrued pension at age 60 on 31 March 2024 and related lump sum £'000	Cash Equivalent Transfer Value on 1 April 2023 £'000	Cash Equivalent Transfer Value on 31 March 2024 £'000	Real increase in Cash Equivalent Transfer Value £'000	Employers Contribution to stakeholder pension £'000
June Raine, DBE Chief Executive	2.5–5.0 plus Nil lump sum	75–80 plus a lump sum of 215 - 220	1,347	1.430	33	47
Rose Braithwaite Chief Finance Officer	2.5–5.0 plus Nil lump sum	5–10 plus Nil lump sum	40	93	43	38
Liz Booth[1] Chief People Officer	0–2.5 plus Nil lump sum	15–20 plus Nil lump sum	240	252	Nil	16
Alison Cave Chief Safety Officer	2.5–5.0 plus Nil lump sum	15–20 plus Nil lump sum	172	252	62	46
Marc Bailey[2] Chief Science, Research and Innovation Officer	2.5–5.0 plus Nil lump sum	15–20 plus Nil lump sum	218	293	58	38
Claire Harrison Chief Technology Officer	2.5–5.0 plus Nil lump sum	5–10 plus Nil lump sum	57	109	40	42
Glenn Wells Chief Partnerships Officer	2.5–5.0 plus Nil lump sum	10–15 plus Nil lump sum	99	149	30	37
Laura Squire, OBE Chief Healthcare, Quality and Access Officer	2.5–5.0 plus Nil lump sum	50–55 plus a lump sum of 110–115	1,057	1,171	43	36
Julian Beach[3] Interim Executive Director Healthcare, Quality and Access	0–2.5 plus Nil lump sum	0–5 plus Nil lump sum	22	47	19	34
Nicola Rose[4] Interim Executive Director Science and Research	0–2.5 plus Nil lump sum	15–20 plus Nil lump sum	249	249	1	32
James Pound[5] Interim Executive Director Innovation and Compliance	0–2.5 plus Nil lump sum	25-30 plus Nil lump sum	370	370	Nil	29

Note: Any members affected by the Public Service Pensions Remedy were reported in the 2015 scheme for the period between 1 April 2015 and 31 March 2022 in 2022–23 but are reported in the legacy scheme for the same period in 2023–24.

[1] Liz Booth was appointed on 16 October 2023.
[2] Marc Bailey stepped down on 25 March 2024.
[3] Julian Beach took on role of Interim Executive Director, Healthcare, Quality and Access on 14 August 2023.
[4] Nicola Rose took on the role of Interim Executive Director Science and Research on 25 March 2024.
[5] James Pound took on the role of Interim Executive Director Innovation and Compliance on 25 March 2024.

2022/23	Real increase in pension and related lump sum at 60 £'000	Total accrued pension at age 60 on 31 March 2024 and related lump sum £'000	Cash Equivalent Transfer Value on 1 April 2023 £'000	Cash Equivalent Transfer Value on 31 March 2024 £'000	Real increase in Cash Equivalent Transfer Value £'000	Employers Contribution to stakeholder pension £'000
June Raine, DBE Chief Executive	0 plus Nil lump sum	70–75 plus a lump sum of 200–205	1,267	1,254	(110)	45
Jon Fundrey[1] Chief Operating Officer	0–2.5 plus Nil lump sum	50–55 plus Nil lump sum	924	954	4	4
Rose Braithwaite[2] 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 plus Nil lump sum	5–10 plus Nil lump sum	85	133	33	43
Marc Bailey Chief Science, Research and Innovation Officer	2.5–5.0 plus Nil lump sum	10–15 plus Nil lump sum	152	197	29	36
Claire Harrison Chief Digital and Technology Officer	2.5–5.0 plus Nil lump sum	0–5 plus Nil lump sum	13	48	25	40
Glenn Wells Chief Partnerships Officer	2.5–5.0 plus Nil lump sum	5–10 plus Nil lump sum	49	82	21	35
Laura Squire, OBE Chief Healthcare, Quality and Access Officer	0–2.5 plus Nil lump sum	40–45 plus a lump sum of 85–90	781	863	(17)	34

[1] Jon Fundrey left the Agency on 2 May 2022
[2] Rose Braithwaite was appointed on 1 February 2023.

Civil Service Pensions

Pension benefits are provided through the Civil Service pension arrangements. Before 1 April 2015, the only scheme was the Principal Civil Service Pension Scheme (PCSPS), which is divided into a few different sections – classic, premium, and classic plus – these provide benefits on a final salary basis, whilst nuvos provides benefits on a career average basis. From 1 April 2015 a new pension scheme for civil servants was introduced – the Civil Servants and Others Pension Scheme or alpha, which provides benefits on a career average basis. All newly appointed civil servants, and the majority of those already in service, joined the new scheme.

The PCSPS and alpha are unfunded statutory schemes. Employees and employers make contributions (employee contributions range between 4.6% and 8.05%, depending on salary). The balance of the cost of benefits in payment is met by monies voted by Parliament each year. Pensions in payment are increased annually in line with the Pensions Increase legislation. Instead of the defined benefit arrangements, employees may opt for a defined contribution pension with an employer contribution, the partnership pension account.

In alpha, pension builds up at a rate of 2.32% of pensionable earnings each year, and the total amount accrued is adjusted annually in line with a rate set by HM Treasury. Members may opt to give up (commute) pension for a lump sum up to the limits set by the Finance Act 2004. All members who switched to alpha from the PCSPS had their PCSPS benefits 'banked', with those with earlier benefits in one of the final salary sections of the PCSPS having those benefits based on their final salary when they leave alpha.

The accrued pensions shown in this report are the pension the member is entitled to receive when they reach normal pension age, or immediately on ceasing to be an active member of the scheme if they are already at or over normal pension age. Normal pension age is 60 for members of classic, premium, and classic plus, 65 for members of nuvos, and the higher of 65 or State Pension Age for members of alpha. The pension figures in this report show pension earned in PCSPS or alpha – as appropriate. Where a member has benefits in both the PCSPS and alpha, the figures show the combined value of their benefits in the two schemes but note that the constituent parts of that pension may be payable from different ages.

When the Government introduced new public service pension schemes in 2015, there were transitional arrangements which treated existing scheme members differently based on their age. Older members of the PCSPS remained in that scheme, rather than moving to alpha. In 2018, the Court of Appeal found that the transitional arrangements in the public service pension schemes unlawfully discriminated against younger members.

As a result, steps are being taken to remedy those 2015 reforms, making the pension scheme provisions fair to all members. The public service pensions remedy is made up of two parts. The first part closed the PCSPS on 31 March 2022, with all active members becoming members of alpha from 1 April 2022. The second part removes the age discrimination for the remedy period, between 1 April 2015 and 31 March 2022, by moving the membership of eligible members during this period back into the PCSPS on 1 October 2023. This is known as "rollback".

[1] Jon Fundrey left the Agency on 2 May 2022.
[2] Rose Braithwaite was appointed on 1 February 2023. Full year equivalent £115k–£120k.

For members who are in scope of the public service pension remedy, the calculation of their benefits for the purpose of calculating their Cash Equivalent Transfer Value and their single total figure of remuneration, as of 31 March 2023 and 31 March 2024, reflects the fact that membership between 1 April 2015 and 31 March 2022 has been rolled back into the PCSPS. Although members will in due course get an option to decide whether that period should count towards PCSPS or alpha benefits, the figures show the rolled back position i.e., PCSPS benefits for that period.

The partnership pension account is an occupational defined contribution pension arrangement which is part of the Legal & General Mastertrust. The employer makes a basic contribution of between 8% and 14.75% (depending on the age of the member). 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 0.5% of pensionable salary to cover the cost of centrally provided risk benefit cover (death in service and ill health retirement).

Further details about the Civil Service pension arrangements can be found at the website 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 MHRA's contributions were as follows:

For 2023/24, employers' contributions for the MHRA employees of £16.8m were payable to the PCSPS (2022/23, £16.0m) at one of four rates in the range 26.6 per cent to 30.3 per cent of pensionable pay (2022/23, 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 £161k (2022/23, £146k) 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 (2022/23, 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 £5k (2022/23, £5k), 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 2023/24 (2022/23, Nil). No additional pension liabilities were accrued

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 The Occupational Pension Schemes (Transfer Values) (Amendment) Regulations 2008 and do not take account of any actual or potential reduction to benefits resulting from Lifetime Allowance Tax which may be due when pension benefits are taken.

Real increase in CETV

This reflects the increase in CETV that is funded by the employer. It does not include the increase in accrued pension due to inflation 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)

2023/24				2022/23
	Total	**Permanently Employed £'000**	**Other £'000**	**Total £'000**
Wages and salaries	**69,673**	66,412	3,261	60,901
Social security costs	**7,782**	7,782	-	6,820
Other pension contributions	**17,005**	17,005	-	14,403
Sub-total	**94,460**	91,199	3,261	82,124
Less recoveries in respect of outward secondment	**(5)**	(5)	-	(20)
Total	**94,455**	**91,194**	**3,261**	**82,104**

See the Remuneration and Staff Report on page 104.

During the year, an average of 1,416 staff were employed.

2023/24

	Total	Permanently Employed	Other*
Chair	-	-	-
Chief Executive/Directors	8	7	1
Senior Civil Servants	129	117	12
Other Civil Service Staff	1,279	1,042	237
Total	**1,416**	**1,166**	**250**

*Includes contingent workers.

2022/23

	Total	Permanently Employed	Other*
Chair	1	1	-
Chief Executive/Directors	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.

Reporting of Civil Service and other compensation schemes
Exit packages (subject to audit)

Cost band	Total Number of exit packages by cost band	
	2023/24	**2022/23**
<£10,000	**-**	**2**
£10,000–£25,000	**-**	**15**
£25,000–£50,000	**-**	**11**
£50,000–£100,000	**1**	**20**
£100,00–£150,000	**-**	**2**
£150,000–£200,000	**-**	**-**
Total number of exit packages	**1**	**50**
Total resource cost	**£95,000**	**£2,342,240**

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 for in full in the year in which the departure was agreed as binding. Where the DHSC has agreed to 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 £95k (2022/23, £2.342m) are included in wages and salaries and shown on the exit package table.

Spend on temporary staff

During 2023/24, expenditure on consultants was £310k (2022/23, £1.2m).
The MHRA continues to employ temporary staff where it is of operational necessity.
The MHRA temporary staff expenditure was £3.1m in 2023/24 (2022/23, £5.6m).

Off payroll engagements

For all off-payroll engagements as of 31 March 2024, for more than £245 per day	
Number of existing engagements as of 31 March 2024	58
Of which	
Number that has existed for less than one year at time of reporting	53
Number that has existed for between one and two years at time of reporting	5

Number of temporary off-payroll workers engaged between 1 April 2023 and 31 March 2024	**74**
Of which	
Number not subject to off payroll legislation	0
Number subject to off-payroll legislation and determined as in scope of IR35	74

For any off-payroll engagements of board members, and/or, senior official with significant financial responsibility, between 1 April 2023 and 31 March 2024	
Number of off-payroll engagements of board members, and/or, senior officials with significant financial responsibility, during the financial year	0
Number of individuals that have been deemed ‘board members, and/or, senior officials with significant financial responsibility’, during the financial year. This figure includes both off-payroll and on-payroll engagements	11

The Agency applies the off-payroll rules with diligence and care, taking a considered assessment of the status of each contingent worker using HMRC's online status determination tool. Through internal checks the Agency is aware of an issue where some workers have been appointed through service contracts which are not subject to the status determination controls. We have assessed the risk and estimated a provision for the unpaid PAYE, NI and estimated interest plus penalties and will commence discussions with HMRC.

The Government Apprentice scheme

The agency paid approximately £0.3m this year 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. In this respect, the agency currently falls short of full utilisation but continues to factor into workforce plans.

Aligning with the Government's Apprenticeship Strategy (published April 2022) and commitment to 1 in 20 Civil Servants being apprentices by 2025, we worked towards an appropriate action plan for 2023/24 supporting this aim. As well as launching a graduate scheme that onboarded a cohort of 8 recent graduates in September 2023 who will undertake the L7 Regulatory Affairs Apprenticeship.

It is recognised that entry-level apprenticeships are especially important in aiding social inclusion. This year, apprenticeship recruitment at entry-level has maintained the focus around our Corporate, Enablement and Digital and Technology groups. There are ongoing apprenticeships and apprenticeship recruitment at our Science Campus, supporting the development of in-house skills that are difficult to source in the local area. Similarly, the range of digital apprenticeships in the Digital and Technology group is 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. In addition to these activities, we recognise the utility of apprentices in upskilling and improving capability in our existing workforce.

There are 40 apprentices in the agency, a significant increase from the 21 from the previous year and the largest number of apprentices at the agency at any given time.

There are 40 apprentices in the agency, a significant increase to the 21 from the previous year and the largest number of apprentices at the agency at any given time. This is due to a larger uptake of in role apprenticeships, the launch of the MHRA's graduate scheme and recruitment of entry level apprentices.

The MHRA's Graduate Scheme

The MHRA's Graduate Scheme was launched this year to support the agency's talent pipeline and commitment to creating an agency where people flourish. Following a recruitment campaign and engagement with various institutions across the UK, the MHRA welcomed its first cohort of 8 recent graduates in September 2023 to pilot the scheme.

Participants of the scheme will rotate across the agency's three core operating groups over the course of three years; gaining insight into how the MHRA regulates throughout the product lifecycle and completing the Level 7 Regulatory Affairs Apprenticeship.

Other staff matters

Sickness absence

The sickness absence calculation includes all days lost to sickness absence, including those staff who left during the reporting year. The average annual sickness rate for the year was 5.7 working days per full-time equivalent employee (2022/23, 7.1 days).

The annual voluntary turnover for the MHRA in 2023/24 was 7.8 % (2022/23, 13.3 %).

Civil Service People Survey

The annual civil service people survey was live in September and October 2023 and 72% of our workforce took part in the survey. Our engagement score results were 58% (49% in the 2022 survey). The civil service benchmark score for 2023 is 64%.

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

Our senior leaders additionally pledge that wellbeing, workloads, and trust in leadership will inform thoughts and actions going forward.

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.

We also hold regular All Staff Meetings to which all staff are invited to attend either in person at either of our two sites, or virtually, to enable proposed key changes to be disseminated and views taken as well as successes shared.

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

Relevant Union Officials

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

Trade Union Percentage of time spent on facility time

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

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

Percentage of pay bill spent on facility time

Description	Figures
Total cost of facility time	£24,249
Total pay bill	£94,455,000
Percentage of the total pay bill spent on facility time*	0.000257

*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 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 wellbeing programme and information and signposting for sources of support. We have appointed four Board level Champions who will support Wellbeing, Sexual Orientation, Race and Disability.

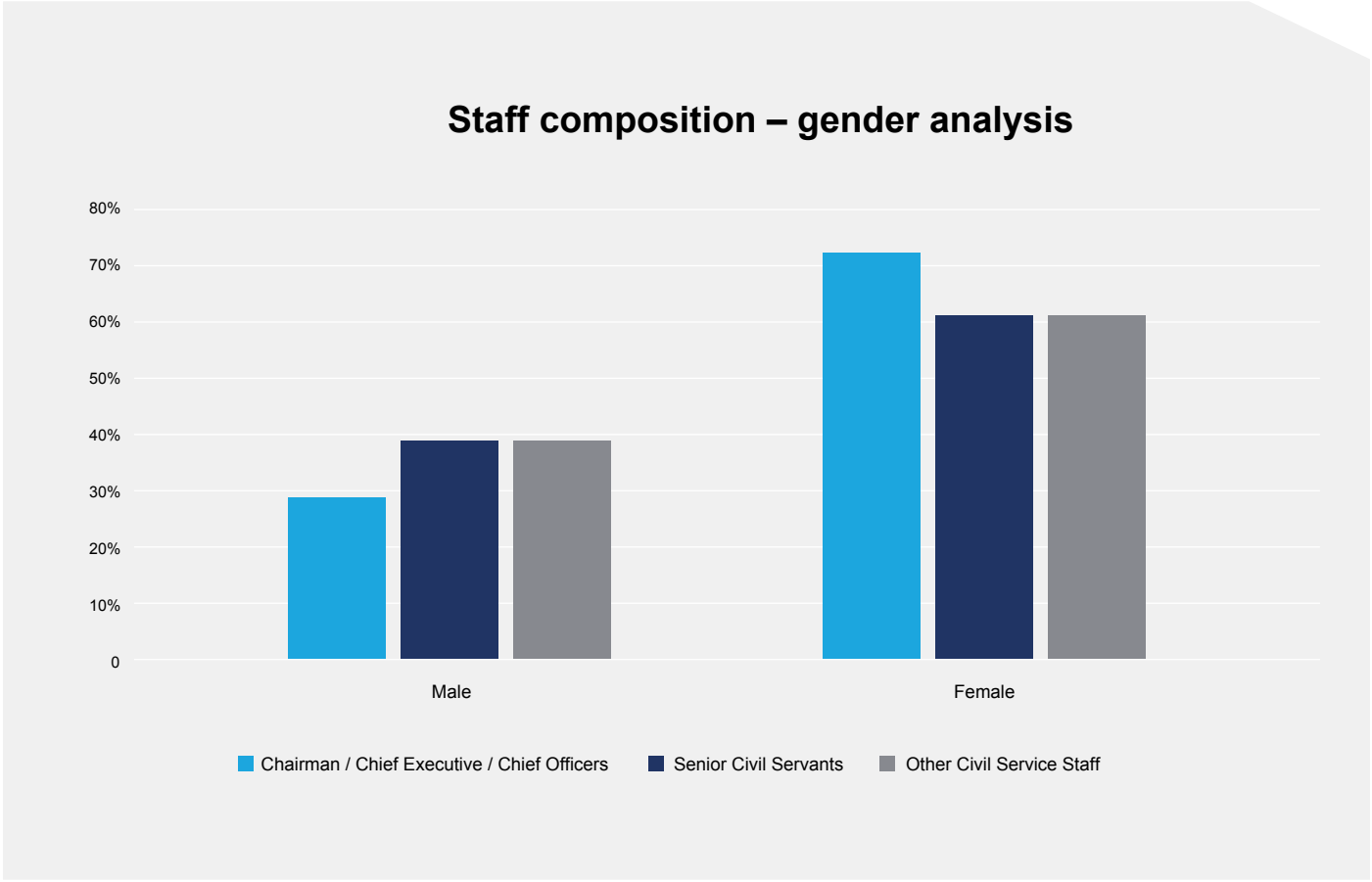
We have a Disability Confident Scheme (DCS) for job candidates with disabilities who meet the minimum selection criteria when applying for roles. We operate an open and fair recruitment process that is fully compliant with the Civil Service Commission Recruitment Principles.

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 our workforce. We are Disability Confident Level 2 and in line with the Civil Service Diversity and Inclusion Strategy, aim to become Disability Confident Level 3 as well as Carer Confident in 2024/25.

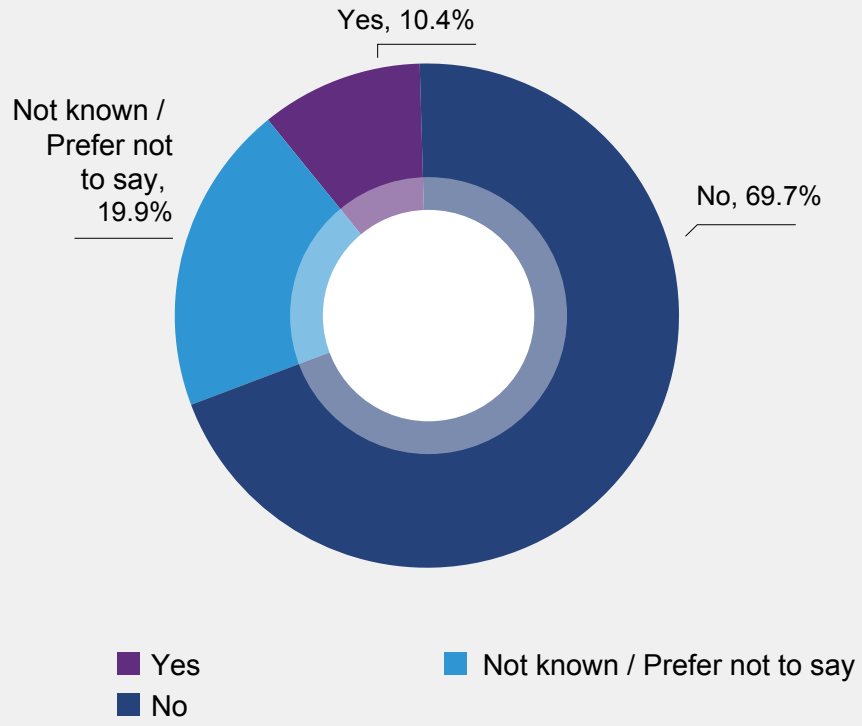
Staff composition

Gender analysis*	Male	Female
Chairman/Chief Executive/Chief Officers	29%	71%
Senior Civil Servants	39%	61%
Other Civil Service Staff	39%	61%
Total	**39%**	**61%**

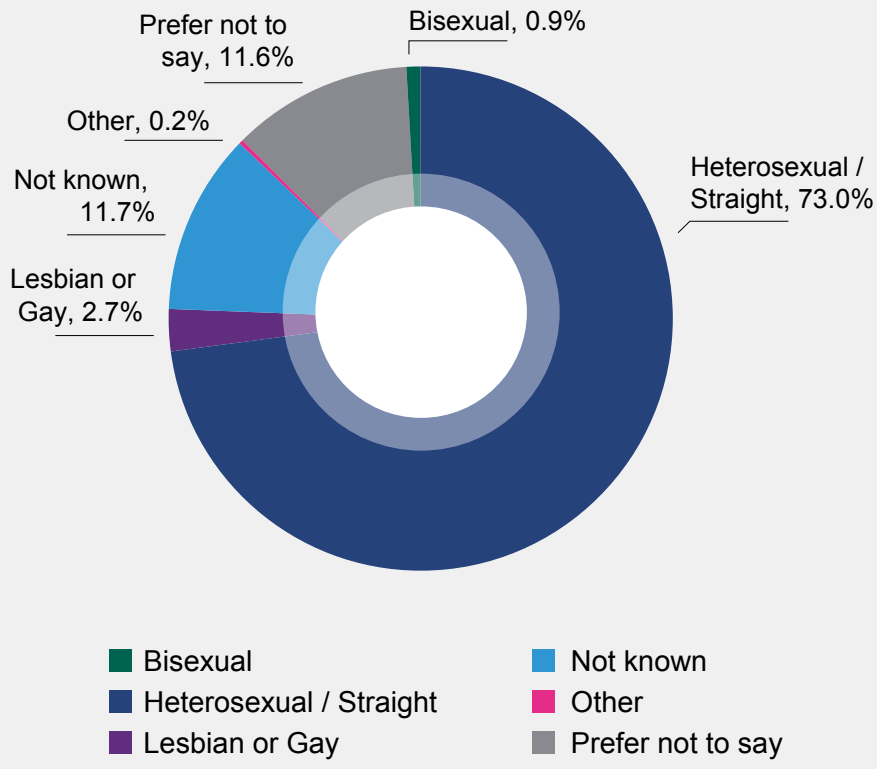
*Of those who declared.

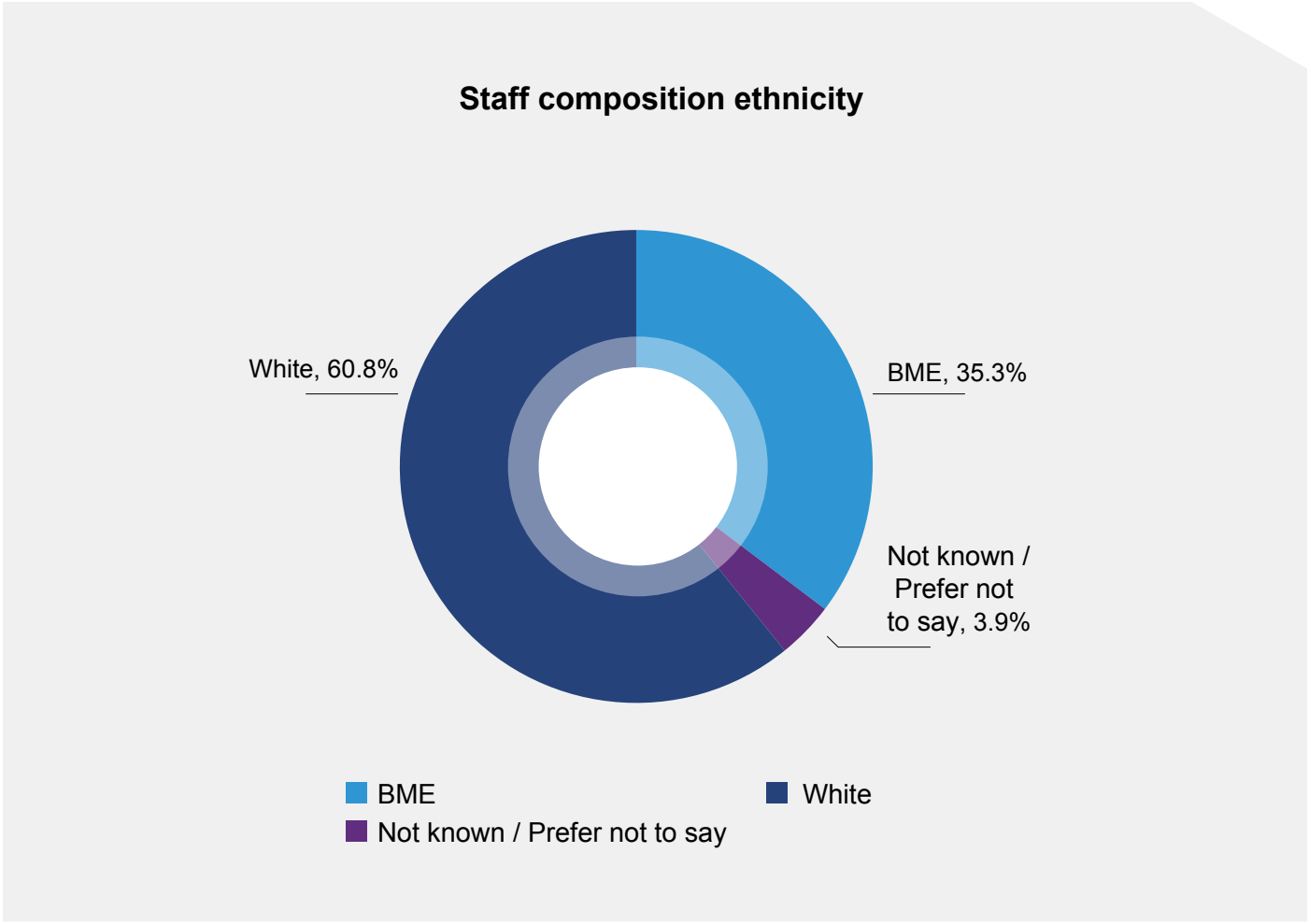


Staff composition disability



Staff composition sexual orientation





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.

Our action plan to help reduce these pay gaps focuses on using future awards to reduce pay ranges, managing the Pay Committee process to ensure all starting salary requests for above the minimum are considered and reviewed and continually reviewing policies to ensure fairness and equality in the recruitment process, continuing to scrutinise and review the recruitment journey from job posting to a job offer, ensuring a diverse mix of delegates on Talent Management initiatives and monitoring their impact, supporting parents returning to work following parental leave or career breaks and refreshing our networks to link with the Diversity and Inclusion framework.

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. The majority of fees are set to recover the full cost incurred in delivering the services by the MHRA. 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. MHRA is supported by £49.7m of funding from DHSC, reported in the Statement of changes in taxpayers' equity. After consideration of DHSC funding on the deficit below, a surplus of £12.3m is made.

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

2023/24	£'000 Income	£'000 Expenditure	£'000 Surplus/ (Deficit)
Licensing	36,022	(40,566)	(4,544)
Inspections	6,634	(14,781)	(8,147)
Vigilance, Risk Management and Enforcement	45,820	(40,108)	5,712
British Pharmacopoeia	6,050	(5,766)	284
Devices	3,908	(6,371)	(2,463)
Clinical Trials	3,825	(2,224)	1,601
Tobacco Products Directive	2,401	(1,252)	1,149
CPRD	16,400	(19,486)	(3,086)
Research	26,684	(56,065)	(29,381)
Other non-attributable	2,092	(624)	1,468
Total	**149,836**	**(187,243)**	**(37,407)**

2022/23	£'000 Income	£'000 Expenditure	£'000 Surplus/ (Deficit)
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)**

Losses and special payments

Managing Public Money requires a statement showing losses and special payments by value and type where they exceed £0.3m in total and those individually that exceed £0.3m. There were no special payments in excess of £0.3m during the financial year.

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

25 July 2024

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

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 2024 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 2024;
- 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 2024 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

- 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 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 inquired 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.

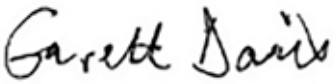
Other auditor's responsibilities

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.



29 July 2024

Gareth Davies
Comptroller and Auditor General

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

3.0 Financial statements

Statement of comprehensive net expenditure for the year ended 31 March 2024	Note	2023/24 £'000	2022/23 £'000
Income			
Trading income	3	**149,836**	122,904
Total income		**149,836**	122,904
Expenditure			
Staff costs	4	**(94,455)**	(82,104)
Operating costs	5	**(92,788)**	(79,860)
Total expenditure		**(187,243)**	(161,964)
Net operating expenditure		**(37,407)**	(39,060)
Finance income		**14**	1,352
Finance costs		**(278)**	(99)
Net expenditure for the year		**(37,671)**	(37,807)
Transfers under absorption accounting		**-**	789
Other comprehensive income			
Realised (gain) on inventories		**(211)**	(92)
Net gain on revaluation of property, plant and equipment*	6	**6,437**	4,804
Total comprehensive expenditure for the year		**(31,455)**	(32,306)

*All gains and losses arise from continuing operations.

The notes on pages 137–163 form part of these accounts.

Statement of financial position as of 31 March 2024	Note	31 March 2024 £'000	31 March 2023 £'000
Non-current assets			
Property, plant and equipment	6	**147,581**	140,208
Right of use assets	7	**6,993**	11,770
Intangible assets	8	**30,338**	18,722
Inventories	9	**10,132**	8,942
Total non-current assets		**195,044**	179,642
Current assets			
Inventories	9	**839**	645
Trade and other receivables	10	**26,210**	23,943
Cash and cash equivalents	11	**85,460**	77,822
Total current assets		**112,509**	102,410
Total assets		**307,553**	282,052
Current liabilities			
Trade and other payables	12	**(33,913)**	(29,211)
Lease liabilities	13	**(1,010)**	(1,002)
Other liabilities	14	**(24,079)**	(30,202)
Provisions	15	**(6,333)**	-
Total current liabilities		**(65,335)**	(60,415)
Total assets less current liabilities		**242,218**	221,637
Non-current liabilities			
Lease liabilities	13	**(6,098)**	(7,813)
Other liabilities	14	**(16,188)**	(12,147)
Provisions	15	**(1,998)**	(1,998)
Total non-current liabilities		**(24,284)**	(21,958)
Net assets		**217,934**	199,679
Taxpayers' equity			
Reserves			
Revaluation reserve		**128,540**	122,314
Income and expenditure reserve		**954**	954
General fund		**88,440**	76,411
Total taxpayers' equity		**217,934**	199,679

25 July 2024

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

The notes on pages 137–163 form part of these accounts.

Statement of cash flows for the year ended 31 March 2024

	Note	31 March 2024 £'000	31 March 2023 £'000
Cash flows from Operating activities			
Net operating expenditure		**(37,407)**	(39,060)
Depreciation and amortisation	6/7/8	**13,699**	13,831
Loss on disposal of assets	6/8	**36**	62
Impairment of personal protective equipment (PPE) and intangible assets	6/8	**-**	28
Reversal of PPE and intangible assets	6/8	**104**	-
Disposal of ROU asset	7	**11,770**	-
Disposal of lease liability	13	**(8,815)**	-
Realised (gain) on inventories	9	**(211)**	(92)
(Increase)/Decrease in inventories	9	**(1,384)**	547
(Increase)/Decrease in trade and other receivables	10	**(2,267)**	16,479
Increase/(Decrease) in trade and other payables	12	**4,702**	(2,293)
(Decrease)/Increase in other liabilities	14	**(2,082)**	8,250
Increase in provisions	15	**6,333**	-
Net cash (outflow) from operating activities		**(15,522)**	(2,248)
Cash flows from investing activities			
Purchase of property, plant & equipment	6	**(9,306)**	(8,887)
Right of use assets	7	**-**	(2,857)
Purchase of intangible assets	8	**(16,235)**	(5,541)
Net cash (outflow) from investing activities		**(25,541)**	(17,285)
Cash flows from financing activities			
Interest received		**14**	1,352
Interest paid		**(3)**	-
Funding from the DHSC		**49,700**	50,700
Capital repayments made under lease liabilities		**(735)**	(1,618)
Interest payments made under lease liabilities		**(275)**	(99)
Repayment of PDC		**-**	(1,329)
Dividend paid		**-**	(2,413)
Net cash inflow from financing		**48,701**	46,593
Transfers under absorption accounting		**-**	(285)
Net increase in cash and cash equivalents in the financial year	11	**7,638**	26,775
Cash and cash equivalents at the beginning of the financial year	11	**77,822**	51,047
Cash and cash equivalents at the end of the financial year	11	**85,460**	77,822

The notes on pages 137–163 form part of these accounts.

Statement of changes in taxpayers' equity for the year ended 31 March 2024

	PDC	General Fund	Reval. reserve	I & E reserve	Total
	£'000	£'000	£'000	£'000	£'000
Balance on 1 April 2022	**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 the DHSC	-	50,700	-	-	50,700
Net gain on revaluation of property, plant and equipment	-	-	4,804	-	4,804
Realised (loss) on inventories — biological standards	-	-	(92)	-	(92)
Transfers under absorption costing	-	789	-	-	789
PDC repayment	(1,329)	-	-	-	(1,329)
Sub total	(1,329)	51.489	4,712	-	54,872
Balance on 31 March 2023	**-**	**76,411**	**122,314**	**954**	**199,679**
Changes in taxpayers' equity for 2023/24					
Net expenditure for the year	-	(37,671)	-	-	(37,671)
Other changes					
Funding from DHSC	-	49,700	-	-	49,700
Net gain on revaluation of property, plant and equipment	**-**	**-**	**6,437**	**-**	**6,437**
Realised (gain) on inventories - biological standards	**-**	**-**	**(211)**	**-**	**(211)**
Sub total	**-**	**49,700**	**6,226**	**-**	**55,926**
Balance at 31 March 2024	**-**	**88,440**	**128,540**	**954**	**217,934**

The notes on pages 137–163 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 14 December 2023 https://assets.publishing.service.gov.uk/media/666ada1f50dca4553304f32a/DAO_02-24_-_Dear_Accounting_Office_letter.pdf

Where the FReM permits a choice of accounting policy, the policy that is judged to be most appropriate to the particular circumstances of the Medicines and Healthcare products Regulatory Agency for the purpose of giving a true and fair view has been selected.

The particular policies adopted by the Medicines and Healthcare products Regulatory Agency are described below. They have been applied consistently in dealing with items that are considered material to the accounts.

1.1.2 Accounting standards that have been issued but have not yet been adopted

HM Treasury's FReM does not require the following Standards and Interpretations to be applied in 2023/24.

- IFRS 17 Insurance Contracts: This standard is not yet adopted by FReM and is not expected to have any effect on MHRA's accounts

1.2 Accounting convention

The accounts have been prepared under the historical cost convention and 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 calculate our liability using an employee-by-employee breakdown of the actual leave balance and the average salary for the grade. The principal uncertainty is in respect of when the leave balance will be used. In the absence of information on the timing of staff members' future use of their leave, we neither discount the liability nor include any forecast of future salary increases.

- **Valuation of Property, Plant and Equipment**
  Plant and Equipment have been revalued in line with Office of National Statistics indices.

  A desktop valuation of the Science Campus was carried out by the Valuation Office Agency on 31 March 2024. 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 a valuation in these financial statements.

- **Inventory valuation**
  In line with the specialist knowledge of managers and senior staff, the historical cost is estimated by calculating the average sales over the last four years, 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 desktop valuation took place on 31 March 2024. 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 the 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	5–25 years
Vehicles	3–7 years
Fixtures and fittings	Up to 20 years
Computer systems	5–10 years
Office refurbishment costs	10–15 years

During the annual asset verification exercise, the MHRA 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 MHRA 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

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

The CPRD architecture is the application developed to manage the collection of patient data including features required to support clinical trials.

Risk-based Inspection (RBI) is a Risk Data Repository that houses intelligence information and processes 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 (VAT)

All statutory activities of the MHRA are outside the scope of VAT, and, in general, output tax does not apply and input taxes on some purchases are recoverable. The MHRA 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

Following the end of the joint arrangement in March 2022, NIHR funding has been retained by MHRA for the purpose of ongoing business development and continuous improvement of CPRD with specific performance obligations. When these performance obligations have been successfully delivered, the CPRD will be able to draw down from these funds in line with expenditures incurred during the year.

1.7 Income

The MHRA's 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 MHRA has the following income streams:

The agency has the following income streams:

- 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
- 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.
- British Pharmacopoeia income is recognised at the point where orders are fulfilled.
- Tobacco Products Directive 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 MHRA's website
- Miscellaneous income: This is non-statutory income and is recognised as earned when the service has been 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 is treated as a contribution rather than income. Departmental 'supply' funding is credited to reserves when received rather than recognised as income in line with IAS 20. Payment for marketing authorisations, variations, clinical trials and e-cigarette notifications is due on invoicing. The proportion of the fees receivable for marketing authorisation applications, and variation applications 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-cigarette 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 the 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 cost or net realisable value. Net realisable value is based on the estimated selling price minus 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 historical 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.

The 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.

When lease payments become payable, VAT may be chargeable and may not be recoverable, even where not recoverable such payments are not included in the valuation of the lease liability or the associated Right of Use asset in line with accepted accounting practice.

Recognition and initial measurement

At the commencement of a lease (or the IFRS 16 effective date), the 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, the MHRA's incremental cost of borrowing. For the MHRA, the incremental cost of borrowing is the rate advised by HM Treasury for that calendar year (2023/24: 3.51%). The lease term is 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 (p132).

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

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.

Lease expenditure

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.

1.10 Segmental Reporting

In accordance with IFRS 8, the MHRA's operating segments reflect information provided to Executive Committee and the MHRA 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 MHRA are enshrined in current legislation and will continue to be funded as they are an essential part of HMG's public services. The legislation required to operate the MHRA'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 MHRA 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 which is used to report to Executive Committee and the MHRA Board. An analysis of assets and liabilities is not provided as these are not regularly reported internally.

2023/24	Science, Research and Innovation £'000	Healthcare Quality and Access £'000	Safety & Surveillance £'000	Total £'000
Income from external customers	64,465	53,754	31,617	149,836
Total income	**64,465**	**53,754**	**31,617**	**149,836**
Direct costs	(33,442)	(31,187)	(25,160)	(89,789)
Indirect costs	(33,108)	(28,407)	(35,939)	(97,454)
Total expenditure	**(66,550)**	**(59,594)**	**(61,099)**	**(187,243)**
Net operating deficit	**(2,085)**	**(5,840)**	**(29,482)**	**(37,407)**

2022/23	Science, Research and 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 deficit	**(27,786)**	**(8,028)**	**(3,246)**	**(39,060)**

3 Trading Income

	2023/24 £'000	2022/23 £'000
Licenses and Inspections	**42,656**	27,650
Vigilance, Risk Management and Enforcement	**45,820**	41,749
Devices	**3,908**	2,072
Clinical trials	**3,825**	3,462
British Pharmacopoeia	**6,050**	5,989
Tobacco Products Directive	**2,401**	2,204
Research	**26,684**	24,016
CPRD	**16,400**	13,211
Other trading income	**2,092**	2,551
Total	**149,836**	122,904

4 Staff costs

	2023/24 £'000	2022/23 £'000
Wages and salaries	**69,673**	60,901
Social security costs	**7,782**	6,820
Other pension contributions	**17,005**	14,403
Sub total	**94,460**	82,124
Less recoveries in respect of outwards secondment	**(5)**	(20)
Total	**94,455**	82,104

See staff report on page 104.

5 Operating costs

	2023/24 £'000	2022/23 £'000
Computing	**28,847**	26,691
Depreciation and amortisation	**13,699**	13,831
Accommodation	**11,190**	11,475
Medicines testing and Laboratory expenses	**10,818**	8,801
Travel and subsistence	**1,335**	865
Other operating costs	**26,899**	18,196
Total	**92,788**	**79,860**
Other operating costs include:	**£'000**	**£'000**
Contracted out services	**14,562**	12,145
Legal services	**1,488**	1,677
Printing and stationary	**1,637**	1,404
Notional audit fees	**153**	140

6 Property, plant and equipment

2023/24	AUC	Land and Build-ings	Computer and Telecom Equip-ment	Plant and Equip-ment	Fittings, Furniture and Office Equip-ment	Total
	£'000	£'000	£'000	£'000	£'000	£'000
Cost or valuation						
At 1 April 2023	**5,765**	**118,546**	**11,687**	**34,988**	**140**	**171,126**
Additions	9,306	-	-	-	-	9,306
Transfers	(12,106)	3,306	3,017	3,813	1,970	-
Reclassification	184	-	-	-	-	184
Reversal	(98)	-	-	-	-	(98)
Revaluation	-	1,346	-	340	1	1,687
Disposals	-	-	(2,955)	(247)	-	(3,202)
At 31 March 2024	**3,051**	**123,198**	**11,749**	**38,894**	**2,111**	**179,003**
Accumulated Depreciation						
At 1 April 2023	-	-	8,648	22,160	110	30,918
Charge for the year	-	4,908	1,253	2,222	37	8,420
Revaluation	-	-	-	158	-	158
Elimination of accumulated depreciation	-	(4,908)	-	-	-	(4,908)
Disposals	-	-	(2,955)	(211)	-	(3,166)
At 31 March 2024	**-**	**-**	**6,946**	**24,329**	**147**	**31,422**
Net book value						
At 31 March 2024	**3,051**	**123,198**	**4,803**	**14,565**	**1,964**	**147,581**
Net book value at 31 March 2023	5,765	118,546	3,039	12,828	30	140,208
Owned	**3,051**	**123,198**	**4,803**	**14,565**	**1,964**	**147,581**

Land and buildings

A professional valuation of land and buildings was carried out on 31 March 2024, which resulted in a net increase of £6,254k. 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.

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	-
Impairment	(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 2023	1,514	119,322	1,837	11,928	25	134,626
Owned	**5,765**	**118,546**	**3,039**	**12,828**	**30**	**140,208**

7 Right of use assets

2023/24	Land and Buildings £'000	Total £'000
Cost or valuation		
At 1 April 2023	**13,290**	**13,290**
Addition	**7,843**	7,843
Disposal*	**(13,290)**	(13,290)
At 31 March 2024	**7,843**	7,843
Depreciation		
At 1 April 2023	**(1,520)**	(1,520)
Charge for the year	**(850)**	(850)
Disposal	**1,520**	1,520
At 31 March 2024	**(850)**	**(850)**
Carrying value		
At 31 March 2024	**6,993**	6,993
At 1 April 2023	**11,770**	11,770

***The original lease with GPA was terminated and a new lease for half the office space was signed with DHSC.**

8 Intangible assets

2023/24	Computer Systems £'000	AUC £'000	Software Licences £'000	Total £'000
Cost or valuation				
At 1 April 2023	**46,245**	**5,153**	**3,445**	**54,843**
Additions	14	16,221	-	16,235
Transfers	7,430	(7,499)	69	-
Reclassification	-	(184)	-	(184)
Reversal	-	(6)	-	(6)
Disposals	(2,373)	-	(115)	(2,488)
At 31 March 2024	**51,316**	**13,685**	**3,399**	**68,400**
Amortisation				
At 1 April 2023	**32,779**	**-**	**3,342**	**36,121**
Charge for the year	4,398	-	31	4,429
Disposals	(2,373)	-	(115)	(2,488)
Amortisation at 31 March 2024	**34,804**	**-**	**3,258**	**38,062**
Net book value at 31 March 2024	**16,512**	**13,685**	**141**	**30,338**
Net book value at 31 March 2023	13,466	5,153	103	18,722
Owned	**16,512**	**13,685**	**141**	**30,338**

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**

9 Inventories

	31 March 2024 £'000	31 March 2023 £'000
Current		
Biological Standards	**685**	506
Laboratory consumables and other stores	**154**	139
Total current	**839**	645
Non-current		
Biological Standards	**10,132**	8,942
Total	**10,971**	9,587

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 2023/24 was £211k (2022/23, £92k). Inventories consumed during the year amounted to £1,311k (2022/23 £2,170k).

10 Trade and other receivables

	31 March 2024 £'000	31 March 2023 £'000
Amounts falling due within one year		
Trade receivables*	**7,849**	10,338
Other receivables	**1,475**	1,024
Contract assets	**6,145**	5,499
Accrued income	**6,340**	4,385
Prepayments	**4,401**	2,697
Total	**26,210**	23,943

***Trade receivables are shown net of a provision for bad debts of £2,171k (2022/23, £318k) and credit notes for all unpaid periodic fees at year end of £860k (2022/23, £1,242k).**

11 Cash and cash equivalents

	31 March 2024 £'000	31 March 2023 £'000
Balance at 1 April	**77,822**	51,047
Net change in year	**7,638**	26,775
Balance at 31 March	**85,460**	77,822
Made up of		
Government Banking Service	**85,460**	77,822

12 Trade and other payables

	31 March 2024 £'000	31 March 2023 £'000
Amounts falling due within one year		
Payments received on account	**4,137**	5,268
Taxation and social security	**4,030**	3,354
Contract liabilities	**2,220**	1,015
Other trade payables	**3,426**	1,494
Other payables	**4**	14
Accruals	**20,096**	18,066
Total	**33,913**	29,211

13 Lease liabilities

	Land and Buildings £'000
Operating lease commitments at 1 April 2023	**8,815**
Interest accrued during the year	**275**
Payments	**(1,010)**
Disposals	**(8,815)**
Additions	**7,843**
At 31 March 2024	**7,108**
Current	**1,010**
Non-current	**6,098**
At 31 March 2024	**7,108**
Obligations under leases	
Within one year	**1,010**
Between two to five years	**4,040**
Over five years	**3,260**
Less interest	**(1,202)**
At 31 March 2024	**7,108**
Cash outflow for leases	
Cash outflow – interest	**275**
Cash outflow – capital	**1,010**
Total cash outflow for leases	**1,285**

14 Other liabilities

	Current		Non-current	
	31 March 2024 £'000	31 March 2023 £'000	**31 March 2024 £'000**	31 March 2023 £'000
Deferred revenue:				
Other fees	**3,931**	6,172	**40**	62
Contract liabilities	**16,528**	14,339	**11,104**	12,085
Others:				
DHSC Contribution to CPRD	**3,620**	9,691	**5,044**	-
Total	**24,079**	30,202	**16,188**	12,147

15 Provisions

	Current		Non-current	
	31 March 2024 £'000	31 March 2023 £'000	**31 March 2024 £'000**	31 March 2023 £'000
Dilapidations	**-**	-	**1,998**	1,998
Others*	**6,333**	-	**-**	-
Total	**6,333**	-	**1,998**	**1,998**

***Other provisions established during the year are in respect of: A provision in lieu of unpaid PAYE, NI and interest plus penalties relating to incorrect application of IR35 regulations. Further details have been provided within the annual Governance Statement on page 99. This is an estimate and pending discussions and settlement agreement with HMRC. The provision has been prepared based on the best assumptions available to management but could change due to assumptions materialising differently. In particular relating to the level of expenditure incurred that is in-scope and the level of taxes that could be offset. a range of possible outcomes has not been calculated at the time of preparing the accounts due to further work being required to assess the expenditure incurred by the agency and the need to engage with suppliers and HMRC.**

Movement in provisions

	Total £'000
At 1 April 2023	**1,998**
Arising during the year	**6,333**
At 31 March 2024	**8,331**

Expected timing of cash flows:

Within one year	**6,333**
Between two to five years	**-**
Over five years	**1,998**
Total	**8,331**

16 Capital commitments

Contracts entered into not provided for in the accounts	31 March 2024 £'000	31 March 2023 £'000
Property, plant and equipment	**2,507**	606
Intangible assets	**1,449**	1,755
Total capital commitments	**3,956**	2,361

17 Related party transactions

The MHRA is an Executive Agency of the DHSC. The DHSC is regarded as a related party. During the year, the MHRA has had a number of material transactions with DHSC and with other entities for which the DHSC is regarded as the parent Department, notably various NHS Trusts.

In addition, the MHRA 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 2023/24, none of the Board members, members of the key management staff or other related parties had undertaken any material transactions with the Agency or with other organisations that the Board members and members of the key management staff may hold. Details of compensation for key management staff are disclosed in the remuneration and staff report.

18 Events after the reporting period

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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