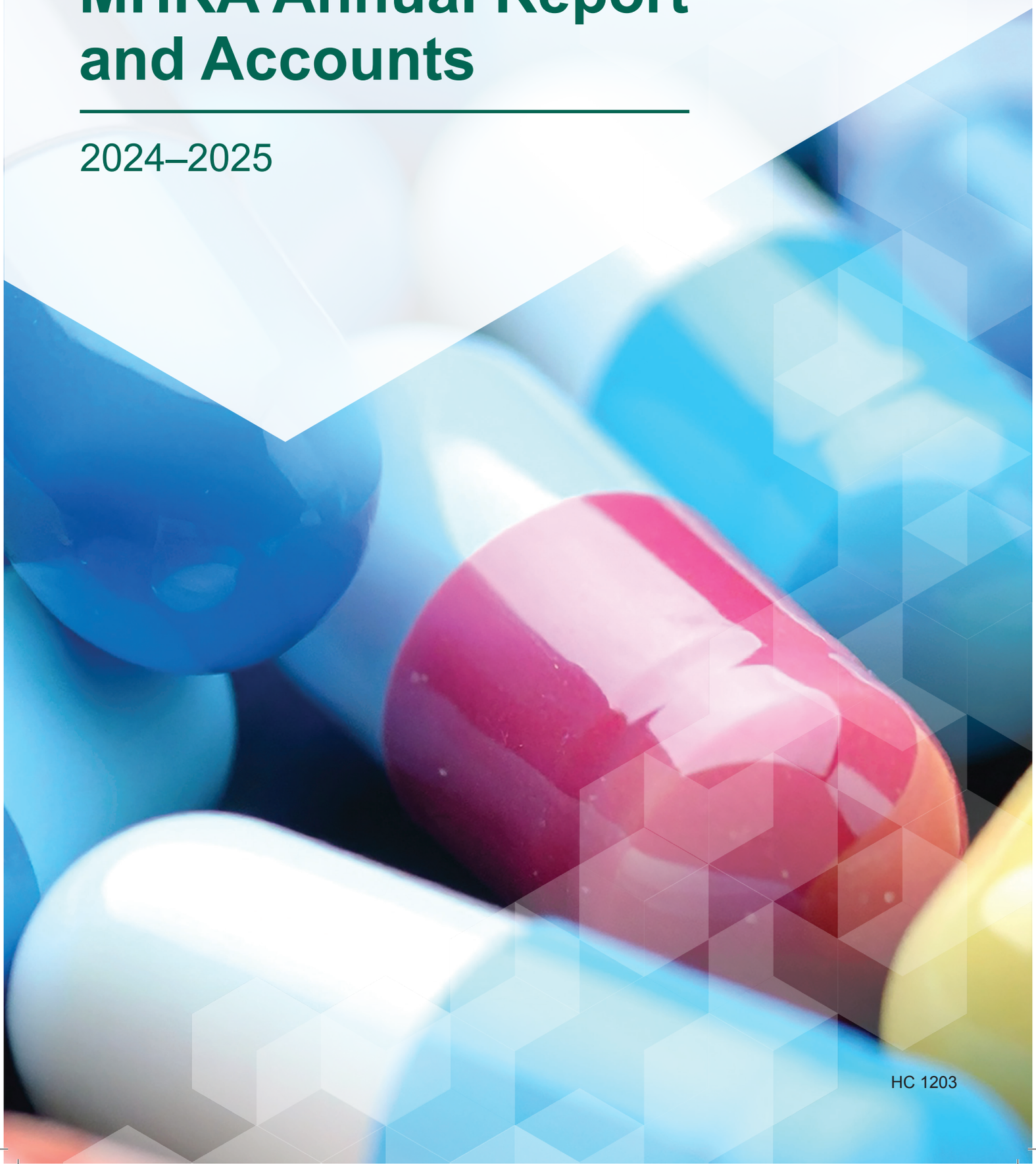
Medicines & Healthcare products
Regulatory Agency

MHRA Annual Report and Accounts

2024–2025



HC 1203

Medicines and Healthcare products Regulatory Agency

Annual Report and Accounts 2024 / 25

For the period from 1 April 2024 to 31 March 2025

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1.0 Performance report

Chair’s foreword

As Chair of the Medicines and Healthcare products Regulatory Agency (MHRA), I am pleased to present our annual report for the year 2024/25. This year has been marked by significant advancements and achievements in our mission to safeguard public health through the regulation of medicines, medical devices, and blood components for transfusion.

I assumed the role of Chair in January 2025, and I am deeply grateful for the leadership provided by the interim co-chairs, Amanda Calvert, Graham Cooke, and Michael Whitehouse, who performed the Chair role prior to my appointment. Their dedication and expertise have been instrumental in guiding the MHRA through a period of substantial change, and enabled the agency to build on the successes of previous years.

This year has been one of substantial improvement for the MHRA. We have focused on establishing dependable and sustainable performance whilst continuing to support innovation. Our efforts have laid a solid foundation for future growth and success.

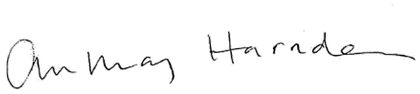
Our dedicated staff have maintained the highest standards of safety, efficacy, and quality in our regulation of healthcare products. We have continued to foster innovation, and supported the development of new treatments and technologies that promise to improve patient outcomes and enhance the quality of care. In addition to our regulatory responsibilities, we have placed a strong emphasis on patient and public engagement. By listening to the voices of patients and healthcare professionals, we have been able to tailor our approaches to better meet their needs and expectations.

Our dedicated staff have maintained the highest standards of safety, efficacy, and quality in our regulation of healthcare products. We have continued to foster innovation, and supported the development of new treatments and technologies that promise to improve patient outcomes and enhance the quality of care.

This commitment to inclusivity and responsiveness is at the heart of our work.

We remain deeply committed to harnessing our expertise and resources to drive meaningful progress in healthcare, ensuring that the MHRA continues to be a catalyst for positive change. As the healthcare landscape evolves, so too will we, adapting with agility and purpose to meet emerging challenges and seize new opportunities. Our vision is to be a world-leading regulatory agency that not only protects the public, but also propels the advancement of healthcare.

At the end of March 2025, our Chief Executive, Dr June Raine, concluded her remarkable tenure, leaving behind a legacy of profound impact and a solid foundation for the future. I extend my sincere gratitude to Dr Raine for her unwavering dedication and leadership. I would also like to express my heartfelt thanks to our exceptional staff, valued partners, and dedicated stakeholders whose continued support and collaboration are vital to our shared mission.



11 July 2025

Professor Anthony Harnden,
Chair, MHRA

Chief Executive's perspective on the year

Looking ahead, our growth agenda is focused on expanding our capabilities, accelerating innovation, and deepening partnerships across the UK health and life sciences ecosystem and beyond.

I am honoured to have joined the MHRA as Chief Executive on 1 April 2025. The agency's mission to protect public health and enable access to innovative treatments is one I deeply share, having witnessed the impact of the MHRA through my work in the NHS.

I would like to thank Dr June Raine DBE for her outstanding leadership. Her tenure saw the MHRA through some of the most challenging periods in recent history and laid a strong foundation for the future.

This year has been one of considerable progress for the MHRA, reaffirming our commitment to innovation, regulatory excellence, and public health. We have cleared the backlog of licensing activities, just as we did with clinical trials, restoring our performance and reaffirming our position as a world-leading regulator.

Patient safety remains our top priority, and we carefully consider every report of an adverse event, whether from a healthcare professional or a patient. We have further developed our advanced signal detection system, which enables faster identification of potential safety issues and improves engagement with those who report them.

We have strengthened the safety oversight of medicines in use through targeted regulatory actions. This includes the implementation of a Pregnancy Prevention Programme for women of childbearing age taking topiramate, in response to evidence of potential harm to unborn children. Additionally, we have issued safety alerts regarding the unprescribed use of GLP-1 receptor agonists, medicines intended for the treatment of diabetes and weight management.

We have approved several new groundbreaking medicines that mark significant progress in the treatment and diagnosis of serious conditions. These include innovative therapies for Alzheimer's disease, precision-targeted cancer treatments, and a novel therapy for Duchenne Muscular Dystrophy, offering renewed hope to patients affected by this rare and progressive genetic disorder.

This year, we made significant strides in modernising the UK's regulatory framework to foster innovation whilst upholding the highest standards of safety. We introduced new post-market surveillance legislation for medical devices, enhancing traceability and enabling quicker responses to safety concerns. We also advanced legislation to establish world-leading regulation for the point-of-care manufacture of medicines, ensuring that products made within healthcare settings consistently meet rigorous safety and quality standards. In a landmark move, we implemented the most substantial update to UK clinical trials legislation in over two decades, streamlining processes to make it easier, and safer, to test new medicines.

Additionally, in January 2025, we introduced new arrangements under the Windsor Framework, ensuring that medicines are available under the same licence and packaging across the UK. These reforms reflect a broader shift toward more risk-proportionate agile regulation, designed to support innovation, drive growth, and ensure patients continue to benefit from safe and effective medical products.

As I begin my tenure at the MHRA, two things immediately stand out: the exceptional expertise of our staff, and their unwavering dedication to public service. Their scientific and technical capabilities are a true national asset, and their commitment to patient safety, timely access to effective treatments, and fostering innovation is both inspiring and essential. Looking ahead, our growth agenda is focused on expanding our capabilities, accelerating innovation, and deepening partnerships across the UK health and life sciences ecosystem and beyond.

Together, we will continue to lead in advancing public health, delivering impact for patients, and supporting the UK's position as a global leader in life sciences.

11 July 2025

Lawrence Tallon
Chief Executive and Accounting Officer, MHRA

1.1 Performance overview

This section describes the role of the MHRA, explains our purpose, strategic objectives and goals and provides a summary of our performance in 2024/25.

A change of Chief Executive

Our Chief Executive Officer, Dr June M Raine DBE, stepped down from her role on 31 March 2025 following a remarkable forty years at the agency. Dr Raine led the agency as Chief Executive since 2019.

Under her leadership, we became the first regulator in the world to approve an mRNA vaccine for human use, the Pfizer-BioNTech COVID-19 vaccine, in December 2020. This was a groundbreaking achievement in the global fight against the COVID-19 pandemic. We also licensed the first ever treatments for sickle cell disease and Alzheimer's disease and took risk proportionate regulatory action to minimise exposure to sodium valproate in pregnancy and prevent harm to unborn children.

Dr Raine's commitment to drug safety and regulatory excellence was evident throughout her career. She played a pivotal role in enhancing our vigilance and risk management systems for the benefit of patients and the public in the UK and beyond.

She was elected as the first chair of the European Pharmacovigilance Risk Assessment Committee in 2012, where she contributed significantly to the safety monitoring of medicines across Europe.

Dr Raine also served as co-chair of the World Health Organization (WHO) Advisory Committee on Safety of Medicinal Products, furthering international collaboration on drug safety.

She championed patient involvement in the regulatory process and improved risk communication, ensuring that regulatory actions were transparent and patient-centric. Dr Raine's dedication and leadership have left a lasting impact on the field of medicine regulation, and her contributions will continue to benefit public health for years to come.

Message from our outgoing Chief Executive

As I step down from my role as Chief Executive of the MHRA, I am profoundly grateful for the privilege of leading the agency and working alongside our dedicated and talented staff.

I take immense pride in our collective accomplishments and have every confidence that the MHRA will continue to excel under new leadership. I am pleased to leave the MHRA in a stronger position, with a solid foundation for future changes and advancements. Our efforts have positioned the agency to continue its vital work and adapt to the evolving landscape of healthcare regulation. The principles of scientific excellence, innovation, and patient-centric regulation will remain the cornerstone of this agency's mission.

Introducing our new Chief Executive: Lawrence Tallon

We welcomed Lawrence Tallon as the new Chief Executive Officer of the agency on 1 April 2025. With extensive experience in the healthcare sector, Lawrence brings a wealth of knowledge and experience to our organisation.

Lawrence joined us from Guy's and St Thomas' NHS Foundation Trust, where he has served as Deputy Chief Executive since March 2020. His previous roles include Director of Strategy, Planning, and Performance at University Hospitals Birmingham NHS Foundation Trust and Managing Director of the Shelford Group, representing some of England's foremost NHS teaching hospitals.

Lawrence is committed to building on our strong foundation and leading the MHRA into its next phase of growth. He is passionate about innovation and growth and is dedicated to improving our operational efficiency and prioritising patient safety.

It is an honour to join the MHRA at such a pivotal time. My priority is to build on the agency's strong foundation, enhance regulatory frameworks, drive innovation, and ensure timely access to safe and effective medical products. Central to this will be deepening our partnerships across the health system and with international regulators, working collaboratively to protect and improve public health.

About the MHRA

The 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. This is available here: 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, protecting public health through 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 take **responsibility** and are **accountable**

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

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

Our structure

During 2024/25, our structure included eight operating groups, consisting of four core functions supported by corporate, enablement and platform services.

Our workforce

Our talented workforce of 1,553 staff operates from our 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 also work with the Laboratory of the Government Chemist (LGC Group) in Teddington, which hosts and operates 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 Health and Social Care 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

Quality management

Quality management is of critical importance to us in supporting the public health decisions and 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, PMS, the design, manufacture and supply of standards, reference materials, research reagents and primary care data

- Accredited to ISO 17025:2017 for the competence of testing and calibration laboratories, covering our work on vaccine and blood product control testing

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 (GCP) 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

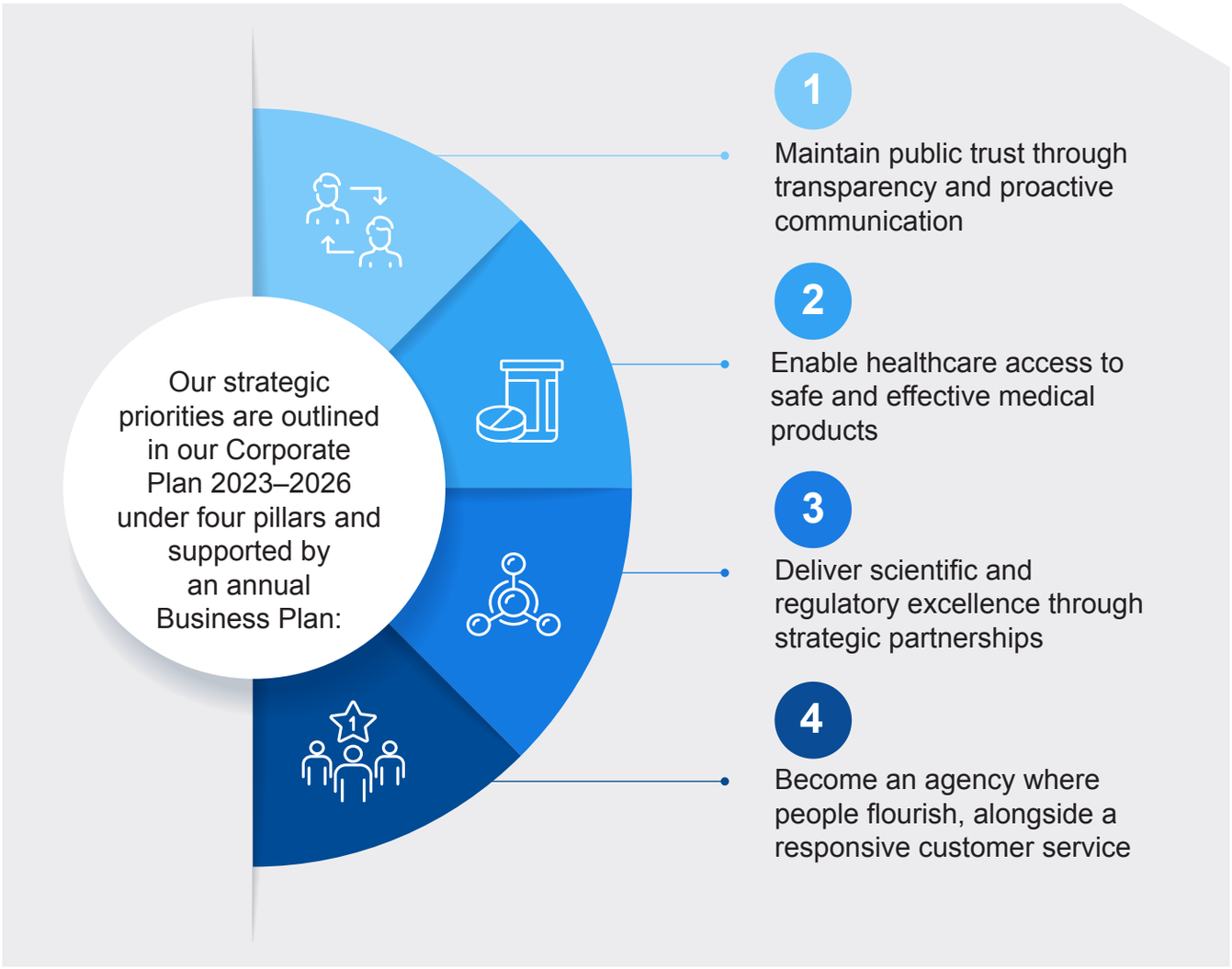
As an Executive Agency of the DHSC, our finances are consolidated within the DHSC accounting boundary. Further details about our funding can be found in the ‘Financial Review’ section on page 82.

Last year, most of the MHRA’s running costs were funded by statutory fees paid by industry for regulatory services or charges for non-statutory goods and services. The DHSC provided the MHRA with £64m funding. Of this, £8.1m was for the core delivery of devices regulation, £12.5m for our scientific work, £12.9m for other one-off grants and £30.5m was capital for investment in the agency.

We have robust processes to manage conflicts of interest, ensuring the effectiveness and independence of our decision-making. Staff are prohibited from holding interests in regulated industries, and board members must disclose any interests according to clear rules. Further details about our management of conflicts of interest can be found in the accountability report on page 113.

Our goals and deliverables

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



MHRA Corporate Plan: 2023 to 2026 and Business Plan: 2024 to 2025: https://www.gov.uk/government/publications/mhra-corporate-plan-2023-to-2026

Our specialist services

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

British Pharmacopoeia

We manage 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 more than 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

We are the world leader in the design, production, and distribution of biological reference materials that 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 the 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 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

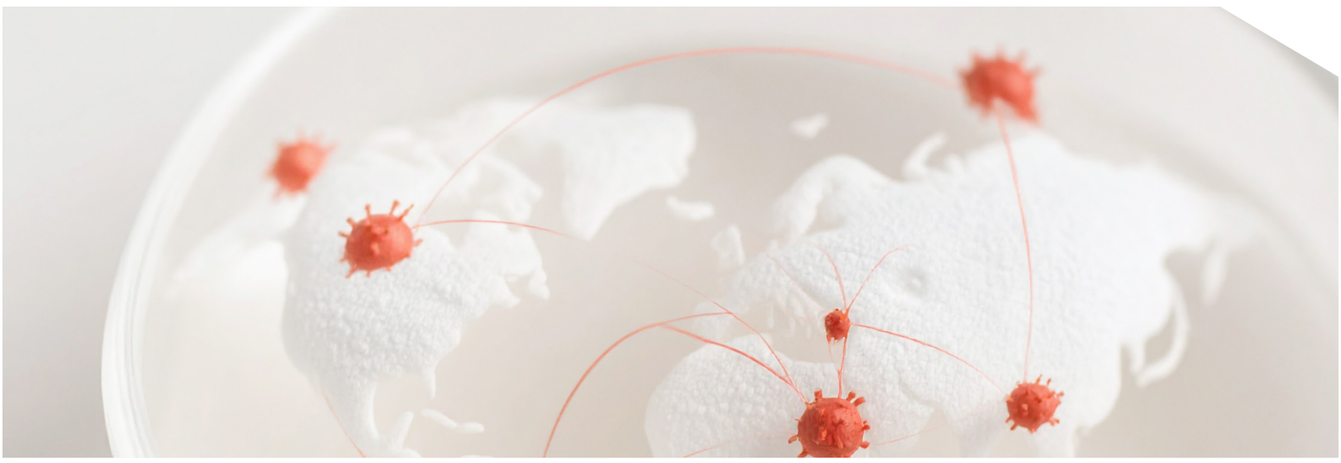
We host the United Kingdom Stem Cell Bank (UKSCB), which is the UK designated repository for human embryonic stem cells. The UKSCB houses the world's largest collection of clinical grade material for use in scientific research and the clinical development of stem cell therapies. The UKSCB was established 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.

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. The NIBSC, part of the MHRA, was a founding member of the international OMCL network established in 1994 and has long played a central role in safeguarding the quality of biological medicines. Each batch of vaccine, blood product, and plasma pools used in their production undergoes impartial scrutiny before use as a medicine. This ensures robust oversight from the development of biological medicines through to distribution.

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.



Spotlight: The MHRA Influenza Resource Centre

The MHRA Influenza Resource Centre (IRC) plays a vital role in global influenza preparedness and response. As one of the WHO Essential Regulatory Laboratories (ERLs), the IRC is part of the Global Influenza Surveillance and Response System (GISRS), a network of laboratories in over 130 countries that monitor influenza outbreaks and virus evolution.

Here are some of the ways that we ensure that effective, safe and timely influenza vaccines are available to the public:

- **Guiding vaccine composition:** Each year, our scientists support the WHO in recommending which influenza strains should be included in seasonal vaccines for the northern and southern hemispheres. These decisions are based on global surveillance data and are critical to ensuring vaccines are effective against the most prevalent virus strains
- **Creating Candidate Vaccine Viruses:** When vaccine compositions change, new candidate vaccine viruses (CVVs) must be

Influenza viruses are constantly changing; therefore, influenza vaccines need to be updated regularly to be effective. The MHRA plays an important part in ensuring that influenza vaccines match the circulating strains of the virus and that the vaccines are delivered to the public on time.

Othmar Engelhardt, Head of Seasonal Influenza, and the WHO Essential Regulatory Laboratory

developed. The MHRA, with our expertise in working with influenza viruses and creating biological standards, is one of only seven laboratories in the world equipped to create CVVs. Our scientists use advanced reassortment techniques to combine viruses with donor viruses in hen's eggs to produce CVVs, which are then distributed to vaccine manufacturers globally

- **Setting global standards:** As one of just four WHO-designated ERLs for Influenza, we develop and supply the reference materials and reagents used to test vaccine potency and for the standardisation of influenza vaccines. The Single Radial Immunodiffusion assay, developed by NIBSC (now part of the MHRA), has been recommended by the WHO since the 1970s to test vaccine potency

- **Ensuring vaccine safety and quality:** As the UK's OMCL, we rigorously evaluate all influenza vaccines, alongside other vaccines and medicinal products such as blood products, assessing that their safety, efficacy, and quality meet the licence specification before they are approved for public use in the UK. We ensure that all products meet the highest standards of patient safety

- **Pharmacovigilance:** We continuously monitor the safety of medicines and vaccines through various pharmacovigilance processes and identify and monitor side effects via the Yellow Card Scheme, taking action when needed to protect public health. This ensures that vaccines remain safe throughout their lifecycle

- **Pandemic preparedness:**Influenza viruses can cause pandemics when virus strains circulating in animals undergo a significant mutation (change), which enables them to infect humans (known as zoonosis) and transmit efficiently from person to person. Global travel accelerates their spread, which can lead to widespread outbreaks. Historical pandemics, like the 1918 Great Influenza pandemic (Spanish influenza), have caused millions of deaths, underscoring the potential severity of future outbreaks. We support pandemic preparedness in a number of significant areas. The Influenza Resource Centre contributes by monitoring outbreaks and staying abreast of real-time virus epidemiology via the WHO GISRS network. It also contributes to scientific evidence reviews for pandemic influenza preparedness. Our high-containment laboratories and experienced scientists can rapidly respond to pandemics, creating candidate vaccine viruses and reagents to support vaccine development and research

Performance summary

This section highlights some of the key achievements across our four core groups.

Science and Research Group

Innovation and Compliance Group

Healthcare, Quality and Access Group

Safety and Surveillance Group

Science and Research Group

Our focus is on delivering public health impact through scientifically driven and world-leading regulatory science. Our responsibility is to ensure the quality of biological medicines and diagnostics. We develop and provide biological reference materials that are designed to ensure the purity and potency of biological substances globally. We perform independent batch release testing to guarantee that every manufactured batch meets safety and efficacy requirements before entering the UK market. Our applied regulatory science research underpins and enhances these activities and improves global public health.

Dr Nicola Rose, Interim Executive Director, Science and Research

Our year in numbers:

1,342

Vaccine and blood product batches tested and certified for safety and efficacy

127,788

Units of biological standards, reference materials and reagents from our catalogue provided to customers globally to support quality testing of biological medicines and research. Including:

- 32,705 units of reference standards and reagents, including British Working Standards
- 35,739 units of WHO International Standards, reference reagents and reference panels
- 10,206 units of CE-marked diagnostic reference materials
- 49,288 units of Influenza reagents

3,409

Plasma pools safety tested for the absence of blood-borne viruses and released for the manufacture of blood-derived medicines

63

New biological standards and reference materials developed and added to our catalogue. Including:

- 34 reference standards and reagents, including British Working Standards
- 8 WHO International Standards, reference reagents and reference panels
- 5 CE-marked diagnostic reference materials
- 16 influenza reagents

£7.08m

External competitively awarded research grants utilised in the year, supporting our regulatory science research programme

57

Scientific publications published in peer-reviewed journals reporting the public health impact of our regulatory science research

Science and Research Group successes

In 2024/25, we have:

Achieved redesignation as a WHO Collaborating Centre for the Standardization and Evaluation of Biologicals. The designation is critical for the work we do on behalf of the WHO to develop, produce and distribute physical standards for biological medicines. The MHRA Group is one of seven such centres world-wide, and one of the four of this group that are custodians of WHO reference preparations.

Launched new and replacement International Standards which have been approved and endorsed by the WHO Expert Committee on Biological Standardisation (ECBS). These span a wide range of biologicals, including infectious disease agents, vaccines, biotherapeutics, cancer genomics, hormones and monoclonal antibodies, and contribute to programmes on pandemic preparedness, clinical virology and clinical diagnostics. International standards

ensure the quality, safety and efficacy of biological products by providing a common benchmark for testing and calibration of biological substances. They contribute to improved patient safety and facilitate regulatory compliance and scientific research.

Some examples of our new products include:

- **International reference material for lung cancer mutations**. Lung cancer is the leading cause of cancer-related deaths worldwide, and many of these cases are non-small cell lung cancer (NSCLC). Epidermal growth factor receptor (EGFR) mutations play a crucial role in the pathogenesis and treatment of NSCLC and targeted therapies such as EGFR tyrosine kinase inhibitors (TKIs) have revolutionised the therapeutic landscape for this type of cancer. However, many patients eventually develop resistance to these therapies due to the appearance of novel EGFR mutations. Molecular testing to identify these mutations is critical, and we have prepared the first WHO International References for specific individual mutations associated with cancer to monitor and control the performance of these molecular tests

- **Reference reagents for Group B streptococcus (GBS) serology assays**. GBS can cause serious infections in babies, albeit rarely, and there is a critical need for pregnancy vaccines to protect unborn and newborns against invasive GBS disease. We have strengthened our supporting role in the development of vaccines by developing biological reference reagents for serology immunoassays which are used to assess the performance of GBS vaccines currently in development

- **WHO International Standard for monoclonal antibody golimumab**. Golimumab monoclonal antibody targets tumour necrosis factor (TNF) and is used to treat a range of chronic immune conditions and inflammatory disorders, including rheumatoid arthritis, psoriatic arthritis and ulcerative colitis. There are a number of biosimilar versions of the product in development, and we have produced a WHO International Standard to support consistent measurement of biological activity throughout the product lifecycle and harmonisation across different versions of the product. Immunogenicity is a concern for anti-TNF monoclonal antibodies, thus there is a need to monitor levels of the drug in patients (therapeutic drug monitoring). This standard will be critical in facilitating the harmonisation of those assays in use for informing clinical decisions and treatment strategies

- **First WHO International Standard for HIV-1 p24 antigen**. To support improved HIV diagnostics, we have launched the first WHO International Standard for HIV-1 p24 antigen. This standard is used globally to define the analytical sensitivity of 4th Generation/Antigen-only and point-of-care diagnostic p24 immunoassays to HIV-1, thus improving the consistency of HIV-1 diagnosis

Commenced and progressed grant-funded projects in key public health and regulatory science areas, including:

- **Streptococcus A**. Infection with Group A streptococcus (Strep A; GAS) bacteria is associated with a range of diseases in humans and is responsible for over 500,000 deaths globally each year. Antimicrobial resistance is an emerging problem, and a GAS vaccine is a current global priority for the WHO. We have been working with collaborators to help develop novel approaches for GAS vaccine development, with the ultimate goal to prevent infection and minimise the risk of severe illness

- **Pandemic preparedness and priority pathogen research**. It is critical that there is early availability of materials that help to evaluate and compare the performance of diagnostic assays, increase the confidence

of diagnosis and accelerate vaccine development by facilitating the comparison of immune responses in vaccine clinical trials. The aim is to develop assays and supporting materials quickly and ensure that they all get the same results no matter which laboratory receives the clinical sample. Significant progress has been made this year in projects focused on Lassa Virus and Marburg Virus and this will continue with collaborations on other priority pathogens. Our Centre for Infectious Disease Reagents now has an expanded role in pandemic preparedness, acting as a repository for important reagents to support research into emerging priority pathogens

- **Tuberculosis (TB)**. *Mycobacterium tuberculosis*, the bacterium which causes tuberculosis, is a significant global health issue affecting millions of people worldwide. As part of global efforts to combat drug-resistant strains of TB, new TB vaccines are in development, and we are using our testing expertise to help evaluate these candidate vaccines at the pre-clinical stage

- **Methods for the replacement of animal tests by laboratory assays**. Tetanus vaccines contain tetanus toxoid and are currently safety tested for the absence and irreversibility of tetanus toxin activity by manufacturers and control laboratories. We are supporting the development and validation of a method that will remove the need for animals 'Organ-on-a-chip' technologies have the potential to transform the pre-clinical testing pipeline and accelerate the delivery of new medicines, enabling more accurate and reliable evaluation of drug candidates before they progress to human trials. We are a member of a consortium that is developing these technologies. Our regulatory expertise will support collaborators with valuable insights into the navigation of the complex landscape of pre-clinical testing regulations

- **Gene therapy vectors** development and standardisation to support the delivery of therapeutic genetic material directly into cells as an innovative tool for the prevention and treatment of diseases

- **Environmental surveillance of poliovirus**. The continuous wastewater testing for poliovirus can act as an early warning system for poliovirus transmission in the UK and inform public health authorities early so that adequate measures can be introduced in time. This enables a review of national vaccination coverage to identify vulnerable groups for targeted vaccination campaigns. We have supported the UK and other countries in the detection of vaccine-derived poliovirus in wastewater. Further, we have contributed improvements through a programme to harmonise sampling protocols and analysis methods to strengthen surveillance

- **Tackling antimicrobial resistance (AMR)**. AMR poses a significant threat to global public health. In addition to regulatory research focused on new vaccines targeting drug-resistant pathogens, we have made good progress in producing materials to assist in the characterisation of the microbial communities present in the human gut microbiome using high-throughput sequencing technologies. This is important with the emergence of new therapies targeting the manipulation of the microbiome, and work is ongoing to support other biological niches in addition to the gut. Building on our existing work, we have secured additional funding support to provide critical information on AMR products in early development, which allows us to target and prioritise early regulatory science research, draft appropriate guidelines and provide advice, and identify where public standards may assist in the measurement of critical quality attributes to assure safety and efficacy of these novel products

- **Supported reintroduction of UK plasma for production of medical blood products for NHS supply**. In our role as an OMCL, we played a crucial role in supporting the reintroduction of UK plasma for medical blood products. Following rigorous safety reviews, we approved its use for manufacturing immunoglobulins and albumin. This aims to reduce reliance on imported plasma, enhance the resilience of the UK's medical supply chain, and ensure patients have access to vital treatments

- **Introduced batch release testing for escalating pathogen vaccines**. Including the Respiratory Syncytial Virus (RSV) vaccine, ensuring that every batch manufactured for use in the UK is safe and effective before it can enter the UK market. This supported the UK immunisation schedule and the new RSV vaccination programme that was introduced in 2024

- **Regulatory science training**. Over the past 20 years, we have competitively awarded up to three PhD studentships per annum to applications submitted by our scientific staff. These studentships enable new regulatory scientific research projects to be initiated by young laboratory scientists. Two new awards this year will enable the supervisors to appoint students to work on projects studying the molecular basis underlying the cross-colonisation of Neisseria meningitidis and Neisseria gonorrhoea and the mechanism of action of mesenchymal stromal cell-derived extracellular vesicles, respectively. The projects are co-supervised with academic partners

Innovation and Compliance Group

The Innovation and Compliance group works to enable life sciences and health tech innovation across the product lifecycle from early-stage innovation advice through clinical research and innovation pathways. The integration of our compliance function enables compliance-by-design from the outset and across the product lifecycle.

James Pound, Interim Executive Director, Innovation and Compliance

Our year in numbers:

5,059

Clinical trial applications were assessed, including 761 initial applications and 4,298 substantial amendments. Combined reviews with the Health Research Authority (HRA) are now completed in an average of 40 days — 20 days faster than the statutory 60-day limit for regulatory and ethics approval of clinical trials

373

Clinical investigation applications were assessed, including 83 initial applications and 290 amendments

911,781

Non-compliant medical devices were seized, with 3 enforcement notices issued

46

New documentary standards were added to the British Pharmacopoeia 2025 edition (BP2025), including 14 of UK origin and 32 from the European Pharmacopoeia (Ph. Eur.)

105

Documentary standards of UK origin were revised for BP2025

15

New physical standards were developed and included in BP2025 (BP Chemical Reference Standards BPCRS)

39,143

Vials of BPCRS sold

98

Enquiries responded to by the Innovation Office

1,032

Wholesale dealer distribution authorisations and 974 manufacturing authorisations were issued

855

Routine inspections were conducted to ensure compliance with GxPs (quality guidelines and regulations used in the life sciences and pharmaceutical industries to ensure that products are safe, meet quality standards and are fit for their intended use). Specifically, we conducted:

- 353 Good Manufacturing Practice (GMP) inspections
- 321 Good Distribution Practice (GDP) inspections
- 12 GCP and GMP quality Control Laboratories (GCP/GMPQC)
- 57 Good Laboratory Practice (GLP) inspections
- 48 GCP, including Bioequivalence (GCP/BE) inspections
- 29 Good Pharmacovigilance Practice (GPvP) inspections

Innovation and Compliance Group successes

Clinical trials and investigations

This year, we have successfully maintained our performance on clinical trials and clinical investigation assessments with redesigned processes, maintaining sustainable timelines within statutory timelines for the full year.

Alongside the HRA, we consistently met the 60-day timeline for approval of clinical trial applications via our combined review process. The performance data for UK clinical trials is published and can be accessed here: https://sites.google.com/nihr.ac.uk/thefutureofukclinicalresearch/home/news-updates/performance-indicators-report. Throughout 2024/25, we have maintained an average time for combined review approval of 39.5 days. The UK's combined review enables safety and ethics to be reviewed together, facilitating efficient assessment timelines.

New legislation to reform the UK clinical trial regulations have now been signed into law, representing the most significant update to UK clinical trial regulation in two decades. These regulations aim to strengthen patient safety, accelerate approvals, enable innovation and help more people benefit from taking part in vital research.

Artificial Intelligence and Large Language Models

To support our ongoing sustainable performance and increase the efficiency of our clinical trials assessment processes, we have introduced new artificial intelligence (AI) and large language model (LLM) tools. These tools support assessors during their review of clinical trial applications and facilitate the training of new assessors. We are currently developing an additional AI web tool to support the management of enquiries about the grounds for non-acceptance.

UK Centres of Excellence for Regulatory Science and Innovation

There are seven UK Centres of Excellence for Regulatory Science and Innovation (UK-CERSIs), established in 2024 as a joint initiative with the Office for Life Sciences, Innovate UK and the Medicines Research Council. The aim of these CERSIs is to bring together multidisciplinary expertise in the UK to solve regulatory challenges through innovative thinking, including the use of AI, digitisation of processes and other emerging novel technology.

Our Clinical Investigations and Trials Unit sponsors and supports the Centre of Excellence on In-silico Regulatory Science & Innovation (CEiRSI). CEiRSI aims to advance regulatory science through in-silico methods, which are computer-based modelling and simulations. The use of in-silico methods in clinical trials enables the evaluation of the safety and efficacy of drugs and devices in a virtual environment. We are currently implementing the CERSI on In-silico Technologies (IST) which will play a critical role in the development of regulatory frameworks to support the evaluation and adoption of these new technologies.

Access Clinical Trials Working Group

Since 2020, we have been an active member of the Access Consortium, a collaborative initiative comprising regulatory authorities from Australia, Canada, Singapore, Switzerland, and the United Kingdom. The consortium works to streamline the review and approval of medicines and medical devices through joint assessments and harmonised regulatory approaches. By participating in Access, the MHRA strengthens international cooperation, reduces duplication of effort, and helps ensure faster access to safe and effective healthcare products for patients across member countries.

A key area of focus this year has been the Access Clinical Trials Working Group, which aims to enhance information sharing across member agencies to ensure patient safety. By fostering transparency and building trust in regulatory decisions, the group is helping to streamline the clinical trial authorisation process, enabling faster access to innovative

treatments for patients.

Introduction of Applied Evidence-Based Regulatory Science (AEBRS)

In 2024/25, the Clinical Investigations and Trials Unit launched a new strategic initiative, Applied Evidence-Based Regulatory Science (AEBRS). This programme leverages the extensive data held in the Unit's databank to generate insights that inform regulatory practice, policy, and research. A major milestone was achieved this year with the submission of our first scientific manuscript in November 2024 to the British Journal of Clinical Pharmacology, which was subsequently published in April 2025.

The study, conducted in collaboration with the University of Liverpool, represents the first comprehensive analysis of the UK clinical trial landscape. The study confirms the UK's position as a global leader in clinical research and identifies key opportunities to enhance patient access to innovative treatments. Key findings include:

- The UK is a hub for pioneering research, with one in eight trials testing treatments in humans for the first time. There is strong commercial investment in UK trials, with 85% industry sponsored. A smaller share (15%) comes from universities, hospitals, and charities

- Cancer trials dominate, making up nearly a third of all studies, but other major diseases lag behind. Heart disease, the world's biggest killer, receives just 5.2% of research focus. Trials for conditions such as chronic pain, respiratory conditions and mental health disorders were among the least common despite their major impact on public health

- Both sexes were included in most trials (90%) however male-only trials (6.1%) were nearly twice as common as female-only studies (3.7%). Pregnant and breastfeeding women were represented in 1.1% and 0.6% of trials, respectively, which could impact treatment suitability for these groups

- Cutting-edge treatments, such as gene and cell therapies, represent a growing clinical area but make up only 3.4% of trials, despite their potential to transform care for patients with limited treatment options

These findings are already shaping future regulatory priorities and underscore the value of data-driven approaches in advancing public health.

Supporting the development of innovative medicines and devices

In March 2025, we launched a refreshed Innovative Licensing and Access Pathway (ILAP) designed to be bolder, more efficient, and more impactful for patients and innovators. A key enhancement was the inclusion of the National Health Service as a full partner, enabling smoother integration of innovative medicines into routine care and accelerating system-wide adoption. The new ILAP strengthens our collaborative approach, offering coordinated advice and guidance with our partners to support the development of transformative treatments.

We also completed our Innovative Devices Access Pathway (IDAP) pilot, supporting eight breakthrough technologies with tailored tools and joint expert advice from across the healthcare system. The goal of the pathway is to accelerate the uptake of innovative devices to address unmet clinical needs. Evaluation is underway, with findings set to inform future device pathways and embed key learnings into standard regulatory processes.

Recognising the transformative potential of artificial intelligence in healthcare, we launched the AI Airlock, a world-first regulatory sandbox for AI as a medical device. This pilot created a safe space for four AI technologies to work alongside regulators, academics, and industry experts to explore and resolve key regulatory challenges. Participants reported significant benefits, including clearer regulatory pathways and valuable cross-sector engagement. Each project followed a bespoke testing plan, including virtual product testing and expert

roundtables. The success of the pilot has secured a second phase of funding, expanding its reach and informing the ongoing Medical Devices Regulatory Roadmap and software guidance updates.

This year we have also developed a long-term strategic approach to our Scientific Advice Meeting service to provide quality, risk-proportionate and impactful regulatory advice.

Legislative changes

Amendments to the Clinical Trials Regulations, anticipated to be implemented in 2026, will ensure patients and their safety are the focus of all clinical trials and bring the benefits of clinical trials to everyone; create a proportionate and flexible regulatory environment; cement the UK as a destination for international trials; and provide a framework that is streamlined, agile and responsive to innovation.

New legislation made in March 2024 fully implements the In Vitro Diagnostic Medical Device Regulation (IVDR) in Northern Ireland and designates the MHRA as the responsible authority. As a result, manufacturers and sponsors must now follow EU-aligned procedures for In Vitro Diagnostic (IVD) clinical investigations in Northern Ireland. This year, we have launched a new application process for IVD performance studies in Northern Ireland, developed in collaboration with Health and Social Care Northern Ireland and the DHSC.

New PMS regulations have introduced stronger requirements for manufacturers that will improve patient safety and support the continuous improvement of devices by manufacturers. These requirements include enhanced incident reporting and greater transparency around device performance. This strengthened oversight gives us greater confidence in our ability to detect and respond to safety issues promptly which in turn allows us to implement more agile pre-market regulatory approaches, such as International Reliance and early access pathways.

This year we have brought forward legislation to implement a regulatory framework for Point of Care and modular manufacturing of medicinal products, due to come into force in the summer of 2025. This will enable the manufacture of innovative medicines much closer to the patient and in line with ambitions to move treatment from the hospital to the community.

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 publication of guidance, stakeholder engagement and education. Additionally, our compliance teams have supported legislative reform efforts for medicines development and authorisation in the UK. In 2024/25, we conducted 849 compliance inspections across the medical product lifecycle: 820 inspections across medicines good practices (GxPs), 11 Approved Body audits, four ‘for cause’ manufacturer audits, 14 device inspections arising from investigations. This compares to 837 in 2023/24.

Our laboratory’s inspection team were successfully evaluated by representatives of the Organisation for Economic Co-operation and Development Working Party on Good Laboratory Practice, as part of the regular programme of On-Site Evaluations. We continue to be part of the Mutual Acceptance of Data scheme, meaning that data generated by UK GLP-compliant test facilities will be accepted by other member countries; this removes the need for multiple repeat studies, resulting in savings for industry and a reduction in animal testing.

As part of the Single Inspection programme, a joint initiative with Health Canada and the Australian Therapeutic Goods Administration, each agency has conducted a GMP inspection, avoiding seven separate inspections.

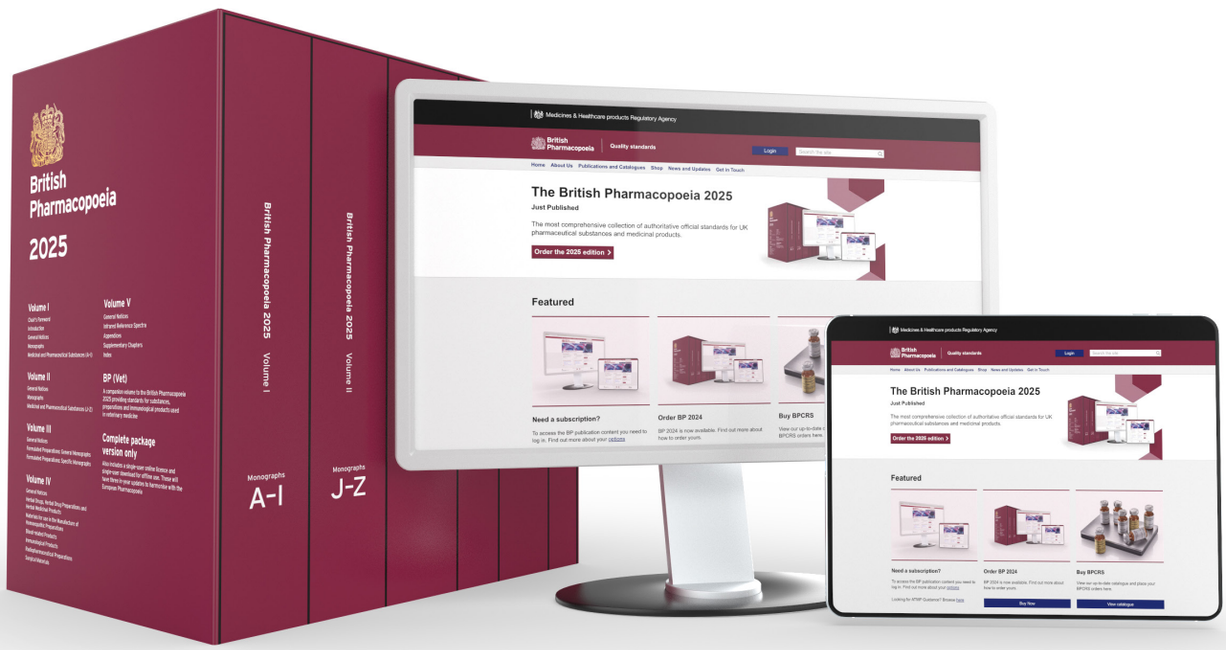
The compliance team are also engaging with the UK-CERSI network, in particular assisting with the implementation phase for the digitisation of the medicines manufacturing group “Digital CMC CERSI”.

British Pharmacopoeia

The BP has made an important contribution in protecting public health since 1864 and provides the only comprehensive collection of authoritative official standards for UK pharmaceutical substances and medicinal products (both human and veterinary).
We release our annual publication every August. The 2025 edition of the BP (BP2025) was published in August 2024, becoming effective on 1 January 2025, with 46 new documentary standards (monographs) added, of which 14 are of UK origin and 32 are from the European Pharmacopoeia. 105 documentary standards of UK origin were revised, and 15 new physical standards were developed.

This year we have launched a new BP website, which improves the user experience and allows us to better understand the user journey to support future developments. A market research exercise in July 2024 revealed a positive response from users. We have also published our first BP monograph which allows the user to tailor a testing method to adopt sustainability features that are appropriate for their laboratory, without compromising the quality of medicine under test.

To supplement our work on monographs and reference standards, we also provided best practice downloads for emerging technologies and topics, including 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 pharmacopeial convergence with its membership of the International Meeting of World Pharmacopoeias.



Healthcare, Quality and Access Group

The Healthcare, Quality and Access 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. We ensure patients and the public have safe access to medicines, vaccines and medical devices.

Julian Beach, Interim Executive Director, Healthcare, Quality and Access

Our year in numbers:

54

New medicinal substances were assessed and approved

805

Generic medicinal products (those which have been in use for a certain period) were assessed and approved

1,138

Parallel imports initial applications determined, providing UK access to medicines approved for use in selected European Economic Area countries, provided the product is not therapeutically different to a product already licensed in the UK

10,340

Parallel imports variations applications determined

176,475

Notifications of intent to import unlicensed medicines were processed by the MHRA import notification system. Unlicensed medicines are the last resort for ensuring medicine supply in the UK for situations where there is not a licensed available medicine capable of meeting the needs of patients. It is also the main route of access to cannabis-based products for medicinal use in humans which are yet to be licensed globally

Healthcare, Quality and Access successes

Performance improvements

After a significant collaborative effort from our assessors and industry, we are able to confirm that all statutory licensing backlogs are eliminated, as of 31 March 2025, and we are working well within statutory timelines for all new Marketing Authorisation and variations applications for innovative and established medicines. During our work to clear our backlogs, over 2,000 individual licences were decided.

Innovative medicines

During the year, we have approved several innovative medicines, following a rigorous assessment of their safety, quality, and effectiveness as well as consideration of the benefits and risks to the patients.

In July 2024, we approved:

Capivasertib (Trugap), for patients with advanced hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative breast cancer which has one or more abnormal “PIK3CA”, “AKT1”, or “PTEN” gene and does not respond to other anti-hormonal-based therapies. The active substance capivasertib is part of a group of medicines called AKT inhibitors, which block the effects of proteins called AKT kinases, which enable cancer cell growth and multiplication. By blocking their action, capivasertib can reduce the growth and spread of advanced breast cancer and help to destroy cancer cells. Capivasertib is given with fulvestrant, a hormonal therapy for the treatment of advanced breast cancer.

Raltegravir, the first generic raltegravir medicine to treat adult and paediatric HIV patients who weigh at least 40kg. The Human Immunodeficiency Virus (HIV) causes Acquired Immune Deficiency Syndrome (AIDS). HIV produces an enzyme called HIV integrase which enables multiplication of the virus in cells within the body. Raltegravir stops this enzyme from working, and when used with other medicines it may reduce the amount of HIV in the patient's blood and increase the patient's CD4-cell count (a type of white blood cell that plays an important role in maintaining a healthy immune system). Reducing the amount of HIV in the blood may improve the functioning of the immune system, meaning the body may fight infection better.

Semaglutide, a GLP-1 receptor agonist. This is the first weight loss drug approved in the UK to help prevent serious heart problems in overweight or obese adults with established cardiovascular disease (CVD). Already approved for the treatment of obesity and weight management alongside lifestyle changes, it is now also approved to reduce the risk of cardiovascular death, heart attack and stroke in individuals with a Body Mass Index (BMI) higher or equal to 27 kg/m2. CVD is one of the main causes of death and disability in the UK, but it can often be prevented by leading a healthy lifestyle. The drug is administered using a pre-filled pen. It works by mimicking the GLP-1 hormone, enhancing the insulin release in response to meals, lowering glucagon release and slowing the gastric emptying process. This helps to support weight loss.

In August 2024, we approved:

Lecanemab (Leqembi): the first treatment for Alzheimer's disease licensed to treat adults in the early stages of the disease who have one or no copies of the apolipoprotein E4 gene (ApoE4). A person can have no copies, one copy or two of this gene. Approximately 15% of those diagnosed with Alzheimer's have two copies of this gene, known as homozygous patients, and are at increased risk of developing Alzheimer's disease, while people with one copy also have an increased risk. Lecanemab is a monoclonal antibody that binds to a protein called amyloid beta In Alzheimer's disease, clumps of amyloid beta protein form plaques in the brain. Lecanemab works by binding to these clumps and reducing them, therefore slowing the progression of the disease.

In September 2024, we approved:

Fruquintinib (Fruzaqla), to treat adult patients with metastatic colorectal cancer (CRC). It is used when other treatments have not worked. CRC is an abnormal growth of cells that begins in a part of the large intestine called the colon. When the cancer is metastatic, this means that it has spread to other parts of the body.
In patients with metastatic CRC, fruquintinib stops tumours from making new blood vessels and therefore slows down the growth of cancer. Blood vessels would usually provide the tumour with nutrients and oxygen.

Leniolisib phosphate (Joenja), to treat a rare immune disease known as activated phosphoinositide 3-kinase delta syndrome or APDS in adults and adolescents aged 12-years-old and older who weigh 45kg or more. APDS is an inherited disorder where the patient is unable to fight infections because the immune system (the body's natural defences) does not work properly. The main symptoms usually occur in the first two years of life and include repeated lung infections and a failure to grow and develop normally. APDS is a long-term debilitating and life-threatening condition due to repeated lung infections that can lead to bronchiectasis (enlargement and inflammation of part of the airways). Patients with APDS are more prone to develop blood cell cancers, like lymphoma. This was the medicine we have approved via a fast-track approval process for medicines, known as the International Recognition Procedure (IRP) and follows an approval by the US Food and Drug Administration.

In October 2024, we approved:

Elafibranor (Iqirvo), to treat adult patients with a rare type of liver disease known as primary biliary cholangitis (PBC). PBC is a type of chronic liver disease in which the small bile ducts in the liver become injured and inflamed and are eventually destroyed. This leads to the buildup of bile and causes liver damage. This disease can get gradually worse over time and without treatment may lead to liver failure. Elafibranor helps to improve how the liver works by reducing the amount of bile acids the liver produces and reducing the buildup of bile. It also acts by reducing inflammation of the liver.

Eplontersen (Wainzua), to treat adults in the UK with polyneuropathy associated with hereditary transthyretin amyloidosis (ATTRv), a rare inherited condition where abnormal transthyretin (TTR) proteins clump together to form deposits called 'amyloid' which can build up, causing damage to nerves and organs. Polyneuropathy is damage to multiple nerves outside of the brain and central nervous system, resulting in pain, discomfort, progressive weakness and loss of sensation in the legs and arms, and mobility difficulties. The drug works by reducing TTR production in the liver therefore lowering amyloid build up, which can help reduce the effects of the disease. The drug is given as a monthly injection and requires patients to take vitamin A supplements during treatment due to reduced vitamin A levels.

In November 2024, we approved:

Flortaucipir (Tauvid), to be given to adults with memory problems so that doctors can perform a type of brain scan called a PET (Positron Emission Tomography) scan. Along with other brain function tests, flortaucipir may help the patient's doctor find the reason for their patient's memory problems by helping to determine whether they have abnormal forms of tau protein in their brain. Abnormal forms of tau protein are present in the brain of people with Alzheimer's disease, and therefore PET scans using this product can assist in the diagnosis of the condition.

In December 2024, we approved:

Givinostat (Duvyzat), to treat patients aged six and older with Duchenne Muscular Dystrophy (DMD). Givinostat is a nonsteroidal drug for the treatment of all genetic variants of DMD, which is a progressive muscle wasting condition affecting boys and those assigned male at birth. DMD is caused by alterations in a protein called dystrophin, which causes muscle fibres to break down and be replaced by fibrous or fatty tissues which cause the muscle to gradually weaken. Around 100 boys are born with DMD each year, and there are about 2,500 people living with the condition in the UK at any one time.

Tarlatamab (Imdyllta), to treat adult patients with small cell lung cancer (SCLC) that has spread throughout the lungs and/or to other parts of the body. This approval has been granted under Project Orbis, an innovative programme that allows participating regulators to review and approve applications for promising cancer treatments quickly and efficiently. SCLC is one of the two main forms of primary lung cancer, accounting for around one in seven of all lung cancers. It is less common than non-small-cell lung cancer and spreads more quickly. Tarlatamab belongs to a group of medicines called antineoplastic agents, which kill cancer cells that rapidly divide. Tarlatamab can only be prescribed to patients that have previously been treated with two other types of treatments and if those treatments did not work or are no longer working. Tarlatamab has shown encouraging results in phase 2 clinical trials with patients with extensive stage SCLC which has progressed or recurred following two previous lines of chemotherapy, with an overall response rate of 40%, and the median duration of response of 9.7 months. Overall, these results are encouraging in patients with advanced SCLC who have limited treatment options and for whom there is a high unmet need for effective treatment options.

In March 2025, we approved:

Lazertinib (Lacluze), for adults with non-small cell lung cancer that has spread to other parts of the body and has undergone specific changes in a gene called EGFR. It is to be used in combination with an approved cancer medicine called amivantamab. Lazertinib works by blocking EGFR and may help to slow or stop the lung cancer from growing. It may also help to reduce the size of the tumour.

Deutivacaftor / tezacaftor / vanzacaftor (Alyftrek), a triple combination medicine to treat cystic fibrosis (CF) in people aged six years and older who have specific mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that have been shown in trials to respond to the therapy. This includes F508del, which is the most common cystic fibrosis causing mutation. Cystic fibrosis is an inherited condition caused by a faulty CFTR gene, which helps regulate the flow of water and chloride in and out of the lungs and other organs. This causes sticky mucus to build up in the lungs and digestive system, which can lead to lung infections and problems with digesting food. The drug is a CFTR "modulator", meaning it is designed to correct the malfunctioning protein made by the CFTR gene in people with cystic fibrosis.

Trofolastat (RoTecPSMA), the first prostate-specific membrane antigen (PSMA)-targeting product authorised for UK use with technetium-99m to detect cancerous lesions in men with prostate cancer. Prostate cancer is one of the most common cancers in men in the UK, with one in eight men diagnosed in their lifetime. Diagnostic imaging plays an important role in identifying cancerous areas, which may help guide treatment decisions. Trofolastat is combined with the radioactive tracer technetium-99m to form Technetium (99mTc) trofolastat, which is administered as a single injection. It binds to a protein called PSMA found on prostate cancer cells, helping doctors identify cancerous areas during a medical imaging technique known as single photon emission computed tomography (SPECT).

Regulatory updates

We have successfully implemented the medicines arrangements of the Windsor Framework, providing guidance and support to industry. These changes ensure the appropriate sale and supply of medical products into the UK and ensure the stability of supply to Northern Ireland. This was a substantive cross-agency effort involving multiple different groups across the MHRA. We also worked in partnership with the DHSC to ensure that the changes did not lead to any shortage of medicines.

We have published the national assessment procedure for medicines, giving greater clarity and expectations for industry on the assessment procedure. This aims to ensure reliable timeframes for medical products approval and availability to patients. The International Recognition procedure has embedded well and we have approved in excess of 96% of applications in time against target. This offers an alternative service to our national procedures. The guidance can be found at: https://www.gov.uk/guidance/national-assessment-procedure-for-medicines.

Information sharing and system alignment

Partnership working continues across the health and life sciences ecosystem to ensure system-wide alignment that supports timely patient access to innovative technologies. The Medicines and Medical Devices (MMD) Access group, a partnership of key public sector bodies, including Health Technology Assessment organisations and the NHS, remains focused on horizon scanning and strategic information sharing. The MHRA continues to provide secretariat support for the group.

In January, the MMD Access group launched an 'open session' to the meetings to enable cross-ecosystem industry engagement, which will help coordinate discussions around the 10-Year Health Plan (10YP), an initiative launched by the UK government in 2025 with the aim of transforming the UK into a global leader in clinical research and innovation, and the life

sciences sector plan.

Operational information sharing, with company consent, is now well established, and a pilot has been conducted to facilitate the sharing of technical information with Health Technology Assessment bodies and NHS partners across the UK. Work is underway to extend this model to Northern Ireland following the finalisation of the Windsor Framework.

The growth commitments build on this work to identify further opportunities for alignment, including with joint scientific advice and joint pipeline meetings between the NICE and the MHRA, which will be piloted shortly.

Approval of the use of UK blood plasma derived albumin and immunoglobulin

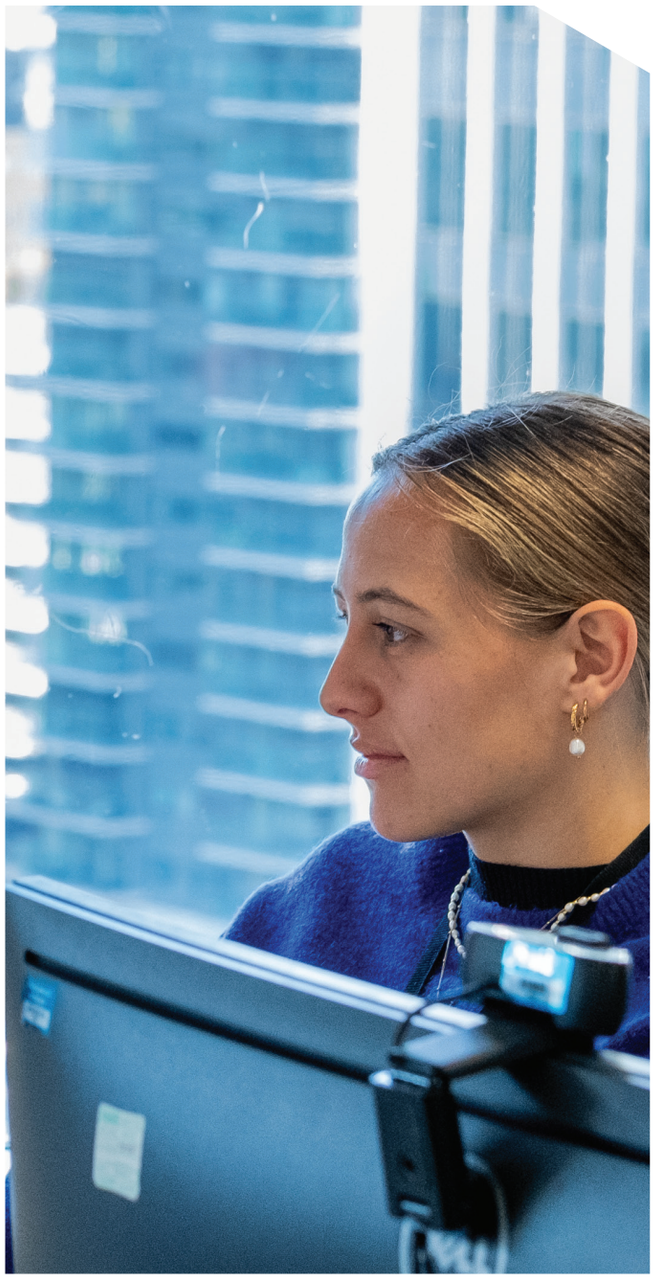
During this year we have started to review lifting the current ban on using UK plasma for manufacturing plasma-derived human clotting factors prothrombin complex concentrates (PCCs) and fibrinogen production. There were concerns that the use of UK blood plasma for the manufacturing of these products could increase cases of variant Creutzfeldt Jacob Disease, Following consideration of all of the evidence, including evidence from our own reviews in 2020 and 2022, we have lifted the ban on using UK-sourced plasma for immunoglobulins and albumins. We consulted with independent experts on the Committee for Human Medicines, who have advised us on specific actions we should take, and we will be working with manufacturers and stakeholders to develop this proposal over the coming year.

Advertising and the promotion of medicines

We 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 act 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.

Supporting supply of medical 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 the public by appropriately identifying, assessing and managing risks associated with medical products. Our ambition is to improve the safety of medical products by harnessing the excellent science, technology and professional practice to protect the public. We are informed by the very best data, evidence, information and intelligence, to benefit patients in new and impactful ways.

Dr Alison Cave, Chief Safety Officer

Our year in numbers:

Approximately
101,000

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

Around
56,000

Adverse incident reports assessed for medical devices since July 2024

146

Safety signals identified for further assessment

66

Defective medicinal product recalls

13

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

677

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

12

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

222

Humanitarian medical device applications were reviewed by benefit risk evaluation assessors

677

Type IB applications were granted to ensure that medicines remain safe and effective for patients

1,348

Type II applications were granted to ensure that medicines remain safe and effective for patients

1,091

Criminal Enforcement Unit (CEU) interventions conducted to disrupt or degrade an identified criminal threat. This included 6 major interventions, 17 moderate interventions and 1,068 minor interventions

118

Months' imprisonment was handed down to 5 defendants in 6 criminal trials

More than
£2.6m

In criminal profits were denied to offenders

77

Yellow Card Biobank participants were recruited, consented and provided blood samples for whole genome sequencing

Safety and Surveillance Group successes

Criminal Enforcement Unit

Throughout the year, the CEU worked with law enforcement partners and technology companies to tackle the illegal online trade in human medicines. CEU-led interventions included the taking down of 710 illegally trading websites and 393 social media posts. In a collaboration with eBay we provided support and advice that resulted in the creation of eBay's cutting-edge AI algorithm, successfully recognising and blocking more than 1.5 million unregulated prescription medicines, over-the-counter medicines and medical devices between 1 April 2024 and 31 March 2025 before they could be offered for sale to the public. Removing criminal routes to market in this way disrupts offenders, protecting the public from the significant harm associated with this pernicious trade.

Using the full range of its intelligence and investigative capabilities and legislative tools, the CEU denied organised criminal groups involved in medicines crime £2.6m in criminal profits. As part of the unit's multi-dimensional approach, denying criminals the proceeds of their crimes removes their motivation to offend, reducing the threat to the public.

During 2024/25, the CEU and its law enforcement partners removed more than 16 million doses of potentially harmful illegally traded medicines from circulation in the UK. The street value of the medicines removed is estimated at almost £37.5m. Every dose of illegally traded medicine can cause significant harm to the public, and their removal at volume also has a major disruptive impact on the criminal business model.

Clinical Practice Research Datalink (CPRD)

The CPRD was one of seven data partners that joined Health Data Research, UK's Real World Evidence Network led by the University of Oxford. The aim of this pilot is to demonstrate the potential of the Observational Medical Outcomes Partnership common data model as an enabler of efficient cross-nation federated research studies.

We launched the CPRD Trusted Research Environment (TRE), CPRD Safe, for Single Study Licences. CPRD Safe gives approved researchers with approved projects secure access to CPRD healthcare data. All patient information in CPRD Safe is anonymised, which means that any identifying (or personal) information such as names, addresses or NHS numbers are removed, and an individual cannot be identified by researchers.

We also launched the enhanced clinical trial recruitment platform, DART (Data Analytics Recruitment Tool), which acts as a link between CPRD electronic healthcare record data and GP practices involved in clinical studies. It allows for secure reidentification of patients within GP practices, GP review of patients, tracking of workflow across multiple studies and provision of metrics.

Scientific Data and Insight

This year we published our Data Strategy 2024-27, setting out our vision of how data, digital technology and real-world evidence can enable innovation and decisions that safeguard public health.

We also launched a Real-World Evidence Scientific Dialogue Programme to help innovators refine their evidence generation strategies and provide clear guidance on regulatory expectations. Real-world evidence is derived from the analysis of real-world data, which is data collected outside of a clinical study setting, predominantly through the delivery of normal clinical care. The pilot received 24 applications covering a wide range of disease areas and conditions. We are currently gathering data through meetings and workshops to support the preparation of a report in mid 2025/26.

Patient Safety Monitoring

We are committed to improving the way we proactively monitor and act on patient safety insights across the full-product lifecycle through joined-up systems, reporting and data. SafetyConnect, a comprehensive and transformative programme, was designed to improve our online systems to enable easier identification and detection of safety signals for medicines and devices. Throughout 24/25, work on SafetyConnect has progressed significantly to build a vigilance system that is fit for the future.

Historically, spontaneous reporting systems have collected data retrospectively through submission of a report of an adverse event that has already happened. This year we have improved the Yellow Card system so that it is now also proactive, with active follow up capability and the ability to conduct surveillance for products with specific safety concerns, conditional authorisations or specific innovations. We have continued activities to encourage and raise awareness of the importance of reporting.

The Defective Medicine Report Centre (DMRC) continues to provide an emergency assessment and communication system between manufacturers, distributors, wholesalers, pharmacies, regulatory authorities and users, cascading recall and safety information. The DMRC issued 66 recalls/notifications for the reporting period to support the statutory obligations of the Licence Holders. The DMRC report centre has assessed and evaluated cases originating from Licence Holders and also via safety signals raised by spontaneous Yellow Card reporting. More details on the recalls and notifications issued can be found here: https://www.gov.uk/drug-device-alerts.

We have continued to work in collaboration with Genomics England on the 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 provide information to support a better understanding of how a patient's genetic makeup 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. The pilot has recruited over 77 participants to date and has been approved to continue into 2025/26.

We have also collaborated with Serious Hazards of Transfusion to deliver blood training and blood awareness workshops. The first workshops were delivered to the Welsh and Southwest regions in January 2025, with further workshops planned in other regions. Additionally, we have enhanced the Yellow Card platform to increase the prominence of reporting of blood products in line with the recommendations of the Infected Blood Inquiry.

We have also continued to support the African Union Smart Safety Surveillance programme through grant funding from the Gates Foundation as a key technical partner. The MHRA has provided tools and training to the programme to support surveillance of priority medicinal products across the African continent. The MHRA's technical expertise is enabling the African Union Development Agency to work towards delivery of an African-owned and operated continental safety surveillance system, whilst also enabling expansion of the existing programme to additional countries. In the long term, these activities will also improve the diversity of global pharmacovigilance data, helping reduce global health disparities.

Benefit-risk evaluation

Our benefit-risk evaluation teams work across a wide spectrum of medicines and medical devices to make judgements on continued benefit versus risk and risk mitigations strategies for healthcare products.

A huge amount of effort from our benefit-risk evaluation teams has gone into clearing the agency backlogs as part of our performance improvement programme. We have processed large numbers of variations to medicines to ensure that they remain safe and effective for patients. Our Type 1B variation backlog was cleared at the end of September.

Some examples of our work this year include:

Our continued monitoring of the antiepileptic medication sodium valproate, which is associated with serious harm in pregnancy, for all new patients (male or female) younger than 55. Following a post-authorisation study that showed a small increased risk of neurodevelopmental disorders in children born to fathers taking sodium valproate compared to other medicines, we precautionarily advised men and their female partners to use contraception. The sodium valproate product information has been updated with the results of the study and advice for male patients, the result of robust considerations of data by the Commission on Human Medicines (CHM), which can be found at: https://www.gov.uk/government/publications/valproate-paternal-exposure-to-valproate-and-risk-of-neurodevelopmental-disorders-and-congenital-malformations-in-offspring.

We continued to ensure that accurate information regarding the benefits and risks of GLP-1 agonists for the treatment of diabetes and weight management is in the public domain and have published drug safety updates for the medicines to warn of potential side effects. GLP-1 agonists are Black Triangle medicines, which means that health professionals, patients and the public are encouraged to report any suspected adverse drug reactions, however minor, and ensures these medicines are more intensively monitored to ensure that any new safety issues are identified promptly.

We issued guidance for patients living with diabetes, including detailed information on how to report any safety concerns with their continuous glucose monitor or insulin pump to prevent the incorrect amount of insulin from being administered and causing potentially serious health consequences. This guidance provided examples of the types of issues which should be flagged and images to help guide users in their reporting.

We warned patients of the risks of using counterfeit and unbranded copies of LifeVac anti-choking devices that are being sold in the UK online without a valid UKCA or CE mark. These counterfeit devices may pose a significant risk of worsening choking if used and should not be used in the event of a choking emergency. We advised patients to dispose of these products once identified as counterfeit or non-compliant.

The CPT Hip System Femoral Stem 12/14 Neck Taper, cobalt chromium (a type of hip implant) was phased out in the UK by December 2024 following evidence that it carried a higher risk of postoperative periprosthetic femoral fracture compared to hips of a similar design but made of a different material.

We contributed substantially to the development of a comprehensive and robust risk management plan for lecanemab (Lequembi), the first treatment for Alzheimer's disease licensed for use in Great Britain.

We completed a safety review into finasteride, a medication used primarily to treat male pattern hair loss, following concerns from patients regarding a lack of awareness of psychiatric and sexual side effects among patients and healthcare professionals. As a result, the Pharmacovigilance Expert Advisory Group of the CHM recommended the inclusion of a patient card inside the pack to highlight the psychiatric and sexual side effects, including the potential for sexual dysfunction to persist after treatment has stopped, as these are not well known by prescribers and patients.

After a 2023 review of montelukast, a medication used to treat asthma and allergies with a known risk of neuropsychiatric reactions, the warnings of these side effects have been strengthened in the Patient Information Leaflet and the Summary of Product Characteristics for all montelukast products in the UK.

We reminded healthcare professionals and patients of the risk of severe asthma attacks and increased mortality associated with overuse of the asthma reliever SABA medications with or without anti-inflammatory maintenance therapy in patients with asthma.

We introduced information to the product label on the potency of topical steroids used as treatments for the management of a wide range of inflammatory skin diseases. This was in response to continued reports and concerns from patients regarding reactions to topical corticosteroids and their withdrawal, particularly when used to treat eczema.

Supporting the UK COVID-19 Inquiry

In 2024/25, we continued to fully and transparently support the ongoing UK COVID-19 Inquiry, contributing to a national effort to understand and learn from the pandemic response. To date, we have submitted over 450 pages of written statements, along with associated evidence, across multiple modules of the Inquiry. This includes written evidence for Modules 3 and 5, and both written and oral evidence for Modules 4 and 7.

Our contributions have drawn on the exceptional knowledge and corporate memory of colleagues across the agency, involving reviewing and coordinating approximately 20,000 internal documents. Notably, the MHRA was a core participant in Module 4, which focused on the development, regulation and deployment of the COVID-19 vaccines.

At the conclusion of the Module 4 evidence session in June 2024, Inquiry Chair Baroness Hallett shared remarks from Dame Kate Bingham, acknowledging the MHRA's critical role and expressing gratitude for the agency's dedication and flexibility.

Our active participation in the Inquiry has provided a unique opportunity to consolidate lessons learned, strengthen our responses to questions around vaccine safety and regulation, and contribute meaningfully to the UK's future pandemic preparedness.

Risk and performance summary

Our role is to protect and promote public health thorough 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 have taken decisive action this year to eliminate backlogs in key statutory services and ensure our performance is restored and sustainably returned to statutory timelines across our services.

This year's key risks and issues this year have been staff resourcing, performance, health and safety and cyber security. These risks and issues and their impacts and implications, along with their management strategies or mitigating tactics, are discussed more fully in the performance analysis section on page 63 and the accountability report on page 109.

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.

In March 2025, we welcomed Health Minister Karin Smyth to our Science Campus as part of British Science Week to demonstrate how innovations become safe, effective treatments for NHS patients.

1.2 Performance analysis

This section considers our performance in greater depth, outlining progress on 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

Performance against our Business Plan objectives for 2024/25 was strong, with 85% of our objectives delivered. Eight (15%) objectives were not delivered by March 2025, and these have been carried forward into our 2025/26 Business Plan with revised due dates. Our key achievements are summarised below.

Priority 1:
Maintain public trust through transparency and proactive communication

1.1 Embed our patient involvement strategy and begin implementation of our strategy for strengthened safety communications.	• Refreshed patient networks and established a new patient and public community to integrate patient voices in decision-making • Developed new guidance on patient and public involvement for a more transparent and responsive approach • Enhanced engagement with healthcare professionals through new systems • Redesigned our risk and safety communications, launching a new safety bulletin
1.2 Increase accountability and predictability by improving transparency of key information, including providing a more comprehensive overview of our core services..	• Expanded publication of our performance data, including key performance indicators (KPIs) and timescales, to improve transparency and set clearer customer expectations • Published the minutes of all non-exempt independent advisory bodies and expert groups within one month • Published FOI responses within the month that the FOI response was issued • Enhanced our web content to provide comprehensive information on regulation and decision-making processes
1.3 Strengthen regulatory approaches to tackling **health inequity** across the product lifecycle.	• Created guidance for equality, diversity, and inclusion in clinical trials and investigations. The HRA will launch the pilot in 2025/26

1.4 Pilot the introduction of a **single unified agency gateway** for customers to accelerate enquiry responses and enhance customer satisfaction.	• Launched an electronic case handling tool to centralise and automate Freedom of Information requests and complaint handling • Updated internal policies to enhance our knowledge hub and conducted workshops to improve enquiry handling and maintain consistent customer service standards

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

2.1 Improve and optimise regulatory services via development of new risk-proportionate regulatory pathways including international recognition of other stringent regulators' decisions.	• Cleared backlogs in statutory services, restoring reliable and predictable timeline • Met our commitment to process all licensing applications received from 1 September 2024 within statutory timelines, adhering to published assessment and decision points • Established the pathway for medicines licence applications via the IRP, with 98% approved on time in 2024/25, meeting our KPI
2.2 Deliver innovative pathways for access to transformative medicines and medical devices in co-ordination with health technology assessment and health service bodies.	• Launched a refreshed ILAP to accelerate access to innovative medicines, with comprehensive details and guidance published on our website. The new ILAP opened to applications on 31 March 2025 • Finalised the IDAP pilot, completing evaluations to determine the next steps to be implemented in 2025/26
2.3 Launch a range of **new digital tools** that improve delivery of regulatory services for all who use them.	• Enhanced the SafetyConnect programme to better detect and address safety issues for regulated health products. Phase 3 (haemovigilance) is live, with the signal detection component for medical devices expected by Q3 2025/26 • Implemented incremental changes to digital services supporting clinical trials, including updates to the Notification Scheme, Development Safety Update Reports, MicroStrategy, and a new Scientific Advice form • Secured Home Office accreditation, enabling full Police National Database integration in 2025/26 to enhance intelligence sharing with law enforcement and regulatory partners

2.4 Improve our **biotherapeutics laboratory capability and services**, especially for new cell and gene therapies and immunotherapies.	• Enhanced laboratory capabilities for assessing the safety and effectiveness of biologicals through new partnerships and co-authored three manuscripts • Evaluated novel reference materials, leading to the WHO ECBS adoption of three International Reference Reagents for standardising genomic assays for identification of EGFR genes frequently found in the most common type of lung cancer. These materials are available from our catalogue at www.nibsc.org • Facilitated a two-day international workshop on antimicrobial resistance innovation, to identify approaches to accelerate patient access to novel anti-microbial products, with a report to be published in early 2025/26 • Created guidance on regulatory best practices for microbiome and phage-derived medicinal products to support the design of novel antimicrobials, to be published in early 2025/26

Priority 3:
Deliver scientific and regulatory excellence through strategic partnerships

3.1 Implement our **regulatory science and data strategies**, establishing a network of CERSIs	• Implemented our data strategy to optimise our data usage for decision-making • Awarded seven CERSIs to support the advancement of regulatory science. Each will engage with the MHRA to share learning and evidence, ensuring our regulatory decisions reflect the best possible science
3.2 Improve and update **our UK regulatory frameworks** in line with evolving science and technology, to streamline our processes and remove unnecessary burdens.	• Prepared legislation for a new, risk-proportionate UK clinical trials regulatory framework. This will be implemented after a 12-month period following its debate in Parliament in February 2025 • Established a regulatory framework for point-of-care and modular manufacture, effective from 23 July 2025 • Implemented new arrangements for medicine access in Northern Ireland under the Windsor Framework, effective from 1 January 2025 • Published and completed consultation on a draft guideline on regulation of individualised mRNA cancer immunotherapies

3.3 Strengthen our **pandemic and escalating infectious disease programme**, contributing to the UK's pandemic preparedness.	• Enhanced our efforts to support vaccine development for priority pathogens, ensuring the reliability of diagnostic tests. We will continue to develop and distribute novel reference materials in collaboration with our partners, extending into 2025/26 • Created essential biological materials through our WHO ERL for Influenza, supporting readiness for a future influenza pandemic • Conducted regulatory research to identify immune correlates of protection or markers associated with four emerging diseases, aiding priority pathogen vaccine development and aligning with WHO International Standards
3.4 Strengthen our **strategic partnerships**, in the UK and internationally, to help us deliver our priorities.	• Advanced our system alignment with partners across the UK health family to facilitate the routine sharing of technical information. Feedback has been positive • Published our Access strategy and applied to become a WHO Listed Authority, aiming to enhance international co-operation and position consortium members as preferred regulators. The WHO committee will assess our application in June 2025 • Contributed significantly to global regulatory best practice and harmonisation through participation in an International Coalition of Medicines Regulatory Authorities Executive Committee meeting, attending the International Medical Device Regulators Forum Assembly in Japan, delivering a speech on Artificial Intelligence/MedTech, a regulatory update, and organising several bilateral discussions

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

4.1 Ensure that we recruit and develop people with the **right skills and capabilities** to deliver our current and future plans.	• Launched our new Oracle Recruit system, enhancing and streamlining user experience for candidates and hiring managers Combined with our LinkedIn recruiter profile, this enhances our ability to identify talented applicants for our roles • Updated our internal performance management systems, ensuring that staff receive clear guidance and support for their development. This includes setting challenging objectives, providing effective feedback, and offering coaching, mentoring, and development opportunities • Reinforced our commitment to diversity and inclusion in talent acquisition and staff development through our employee branding, our new Oracle Recruit system, and various development programmes
4.2 Promote **staff well-being** and help staff manage their workloads effectively, including through clarity on targets and with right-sized teams.	• Enhanced the agency-wide view of culture, with dedicated focus at internal leadership meetings and conferences, ensuring leaders understand its importance and their role in shaping it • Promoted and encouraged risk-proportionate decision-making in all activities. This initiative is ongoing and will continue to be strengthened throughout 2025/26 • Refreshed our performance development scheme for delegated grades to ensure all staff have meaningful objectives, focussed on productivity and well-being. A new Senior Civil Servant performance management scheme, managed by Cabinet Office, is in place for 2025/26 • Delivered a substantially improved control environment by targeting areas identified in the Government Internal Audit Agency annual opinion for 2023/24. We have increased compliance with the Government Functional Standards, with plans in place to fully meet these in the coming year

4.3 Deliver a **responsive service culture**, with robust and risk-proportionate decision-making, and achieve an improved internal control environment.	• Completed preparation for our anticipated fee uplift in April 2025, understanding the cost for our service delivery to enable cost recovery
4.4 Review and update our **service and product fees**, informed by activity recording data, so that the agency continues to be financially sustainable.	• Implemented our fee uplift for 2025–2027 through a phased implementation approach. Our fee uplift ensures our operating costs are covered, enabling us to be sufficiently resourced to fulfil our public health role

Performance against our public health targets

This section evaluates our performance in 2024/25 against KPIs and our key priorities for both statutory and non-statutory functions. These elements are crucial to fulfilling our core purpose of protecting patients through efficient, risk-proportionate regulation.

Throughout 2024/25, we concentrated on restoring our performance and bringing our statutory services back within statutory timescales, addressing the accumulated backlogs in some areas. As outlined in our 2023–26 Corporate Plan, we are dedicated to delivering predictable, optimised, and sustainable services across all functions. Our priority this year has been to embed long-term service sustainability and ensure our consistent performance within statutory timeframes.

Our strategy for clearing backlogs prioritised public health and the expedited assessment of products addressing unmet medical needs and supply shortages. Subsequently, we focused on clearing the oldest applications. While this approach was beneficial for patients and applicants, our KPIs measure progress based on total elapsed time per case. As a result, four of our KPIs missed their targets despite the significant progress made over the year (KPIs 3, 5, 6, and 8).

As of 31 March 2025, all backlogs related to our statutory functions have been cleared, with sustainable and effective processes established for our licence applications for innovative and established medicines, variations to licences, and manufacturing and distribution authorisations (KPI 3, 5 and 6). We, therefore, expect that the KPIs will show improved performance from April 2025 onwards.

We continue to report a positive trend in our performance on our scientific advice service (KPI 8), which is a non-statutory function. While a backlog remains, we are dedicating resources to clear this and working to develop and enhance our scientific advice service. We anticipate that we will have restored our performance by Autumn 2025.

As part of our commitment to greater transparency, we publish monthly data detailing progress against KPIs and processing times. This enhanced reporting will provide clearer insights into the impact of service optimisations, current expected processing times, and timelines across our key functions. This enables stakeholders, customers, and partners to plan with greater certainty. You can find our performance data here: MHRA Performance Data-GOV.UK https://www.gov.uk/government/publications/mhra-performance-data/mhra-performance-data.

Key performance indicators

Our KPIs serve as a health check, ensuring that we regulate medicines and healthcare products within statutory timelines. Our performance against these KPIs for the 2024/25 reporting year, with comparator data from the 2023/24 financial year, is summarised below.

These KPIs were newly established during 2023/24, meaning full-year data was not available for last year's annual report. Instead, performance was measured only in Q4 of 2023/24. The 2024/25 figures, however, reflect the entire reporting year.

Key performance indicator		Performance			Agreed backlog resolved
		2023/24	2024/25	Trajectory	
KPI 1	We will assess 95% of all initial **Clinical Trial Authorisation** and **Clinical Investigation** applications within their category's statutory timeline.	99%	100%	▲	Yes (Mar-25)
KPI 2	We will certify 95% of **Vaccine Batches** within 43 days and 95% of **Blood Product Batches** within 15 days.	100%	99%	▼	N/A
KPI 3	We will determine 95% of **Medicines Licence Applications** within 210 days via the **National Route**.	20%	8%	▼	Yes (Mar-25)
KPI 3a	[Interim from September 2024] Percentage of new Medicines Licence Applications determined within 210 days via the National Route.	N/A	100%	N/A	N/A
KPI 4	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%	98%	▼	N/A
KPI 5	We will determine 95% of all **National Variations** within their category's statutory timeline.	73%	78%	▲	Yes (Mar-25)
KPI 6	We will grant, vary or refuse 95% of **Manufacturing and Distribution Authorisations** within their category's statutory timeline.	51%	78%	▲	Yes (Mar-25)
KPI 7	[Interim] We will process 90% of fatal **Adverse Drug Reaction** reports for medicines and devices within 24 hours and 100% within 72 hours, and we will process 95% of serious ADR reports within 72 hours and 100% within 5 days.	100%	98%	▼	N/A
KPI 8	We will offer **Scientific Advice** to 95% of requests within 70 days of the request being made.	23%	24%	▲	No

KPIs 3, 5, 6, and 8 missed their targets due to backlogs that affected performance during parts of the year. The backlog for KPI 3 was cleared in September 2024 and for KPI 5 and 6 in March 2025, with performance returning to expected levels thereafter. KPI 3(a) was introduced in mid-2024/25 to improve transparency regarding the timeliness of licence assessments from 1 September 2024. A backlog remains for KPI 8 (scientific advice), with dedicated resources in place to clear it and refresh the service by Autumn 2025.

Performance metrics

In addition to our KPIs, we monitor a broader set of performance metrics to assess delivery across both our statutory and non-statutory functions. The performance metrics outlined below align directly with our KPIs and provide further insight into our operational effectiveness.

Performance metric 1: Clinical Trials and Investigations (KPI 1)

Measure	Target	2023/24	2024/25	Met / Not Met 2024/25	Trajectory
Percentage of **clinical trial** applications assessed within 30 days of submission	95%	40%	100%	Met	▲
Percentage of **clinical investigations** decision letters (objection/no objections) issued within 60 calendar days of submission	95%	100%	100%	Met	▶

Performance metric 2: Batch Release / Control Testing (KPI 2)

Measure	Target	2023/24	2024/25	Met / Not Met 2024/25	Trajectory
Percentage of independent batch assessments completed within target times for:					
Vaccine batches (non-COVID) — Certified within 43 working days	95%	100%	100%	Met	▶
Vaccine batches (COVID) — Certified within 43 working days	95%	100%	100%	Met	▶
Blood products — Certified within 15 working days	95%	100%	98%	Met	▼

Performance metric 3: Medicines Licensing: National (KPI 3)					
Measure	**Target**	**2023/24**	**2024/25**	**Met / Not Met 2024/25**	**Trajectory**
Percentage of **medicines licence** applications assessed via the **national route** (excluding the time awaiting applicant responses):					
Established Medicines — within 210 days	95%	17%	7%	Not Met	▼
New Active Substances — within 210 days	95%	25%	19%	Not Met	▼
From 1 September 2024: Percentage of medicines licence applications assessed via the national route (excluding the time awaiting applicant responses):					
Established Medicines — within 210 days	95%	N/A	100%	Met	N/A
New Active Substances — within 210 days	95%	N/A (not applicable) as no output during this period so cannot be measured			

KPI 3 was missed due to earlier backlogs, which were cleared by September 2024. KPI 3A was introduced to confirm that applications received from that point met required timelines.

Performance metric 4: Medicines Licensing: International Recognition Procedure (IRP) (KPI 4)					
Measure	**Target**	**2023/24**	**2024/25**	**Met / Not Met 2024/25**	**Trajectory**
Percentage of **medicines licence** applications assessed via the **international recognition procedure**:					
Route A — within 60 days	95%	N/A	98%	Met	N/A
Route B — within 110 days	95%	N/A	97%	Met	N/A

Performance metric 5: Variations (KPI 5)

Measure	Target	2023/24	2024/25	Met / Not Met 2024/25	Trajectory
Percentage of Type 1B and Type II **variations** assessed (excluding the time awaiting applicant responses):					
Type IB — within 30 days	95%	65%	83%	Not Met	▲
Type II — within 90 days	95%	53%	59%	Not Met	▲

Note: Type IB changes include simple 'tell and do' changes, such as changing the location of manufacture. Type II changes are complex changes with changes in formulation, such as new or replacement excipients.

KPI 5 was missed due to backlogs in both variation types. The Type 1B backlog cleared in September 2024, with timelines met from December 2024. The Type II backlog was cleared in March 2025, with on-time performance expected from April 2025.

Performance metric 6: Manufacturing and Distribution Authorisations (KPI 6)

Measure	Target	2023/24	2024/25	Met / Not Met 2024/25	Trajectory
Percentage of **Wholesale Dealer Licenses** completed on time	95%	N/A	81%	Not Met	N/A
Percentage of **Manufacturing Licenses** completed on time	95%	N/A	75%	Not Met	N/A

KPI 5 was missed due to backlogs in both variation types. The Type 1B backlog cleared in September 2024, with timelines met from December 2024. The Type II backlog was cleared in March 2025, with on-time performance expected from April 2025.

Performance metric 7: Adverse Drug Reaction (ADR) Reports (KPI 7)					
Measure	Target	2023/24	2024/25	Met / Not Met 2024/25	Trajectory
Fatal ADR: processed within 24 hours	90%	90%	90%	Met	▶
Fatal ADR: processed within 72 hours	100%	100%	100%	Met	▶
Serious ADR: processed within 72 hours	95%	95%	98%	Met	▲
Serious ADR: processed within 5 days	100%	100%	100%	Met	▶

Note: We have refreshed our performance monitoring this year. Any metrics included in the previous year's annual report that are not listed here are now covered elsewhere in this annual report, either within the narrative sections or under the relevant group summaries.

Transparency

Freedom of Information requests

Under the Freedom of Information Act (FOIA), we must respond to 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 publication and disclosure of our FOI requests is available on our website, MHRA Freedom of Information (FOI) disclosure log — GOV.UK. https://www.gov.uk/government/collections/mhra-freedom-of-information-foi-disclosure-log

In 2024/25, we received 940 FOI requests. This compares to 1,097 requests received in 2023/24. We delivered 99% of responses to these within the recommended timescales.

Enquiries and complaints

During 2024/25, the MHRA Customer Experience Centre received 60,385 enquiries and 467 complaints. This compares to 60,479 enquiries and 5,582 complaints received in 2023/24.

Of these, 3,245 enquiries and 187 complaints were from the public. This compares to 5,005 enquiries and 430 complaints received in 2023/24.

The significant reduction in complaints has been a result of the agency's focus on performance improvement initiatives and our commitment to enhance transparency of performance data. There were also fewer complaints regarding COVID-19 vaccines.

Parliamentary questions

During 2024/25, we responded to 90 parliamentary questions and contributed to 52 other questions answered by the DHSC. A significant range of topics were covered, including patient safety, COVID-19 vaccines, MHRA regulatory processes and selective serotonin reuptake inhibitors. This compares to 161 Parliamentary questions responded to in 2023/24.

Risk profile

Our key corporate risks and issues this year have been staff resourcing, improving our performance for various services, health and safety, particularly at the Science Campus laboratories, and cyber security.

Resourcing remained one of the highest scoring issues during 2024/25 due to the importance of having the right capability and capacity to support our effective delivery. This issue impacted colleagues across the agency, particularly those in the service areas faced with backlogs and performance challenges. We undertook an extensive exercise to assess our vacant posts and prioritise the roles to fill first. We refreshed our recruitment processes and systems and progressed our strategic workforce planning during the year which has led to the reduction of the impact of this issue as we ended the financial year.

Our performance was a key issue during the year as we worked to resolve the backlogs which had built up in some of our service areas. Through a targeted and focused plan, we are extremely pleased to have cleared all statutory backlogs by the end of 2024/25 and sustainably restored our services to their statutory timelines. This was achieved through a focussed executive-led improvement programme which drove the refresh of services, prioritisation of resources and enhanced performance monitoring to ensure sustainable ongoing performance. We will continue in 2025/26 to improve our performance across our non-statutory service areas including the delivery of scientific advice.

The nature of the work at our Science Campus carries an inherently higher risk to our staff. Following the receipt of an improvement notice from the Health and Safety Executive in 2023/24, the health and safety risk in our corporate risk register increased to be managed as an issue, which helped to ensure a targeted response to the improvements we needed to make. The management and mitigation of this health and safety issue was a high priority throughout the year. We have strengthened our health and safety capacity and capability through the recruitment of a specialist role and created a new Interim Executive level Health and Safety Committee to provide oversight and monitoring. We have also provided detailed training to staff during the year to ensure they are aware of and can comply with the health and safety requirements.

The Health and Safety Executive was satisfied with our response and the improvement notice was closed within the agreed timescales. Further details of our management of this risk can be found in our health and safety report on page 79.

Similar to many other organisations, cyber security remained a key risk for us this year. Cyber threats are becoming increasingly sophisticated, complex and frequent. Mitigations included continuously strengthening our systems, increasing staff awareness and ensuring our operational cyber and information security controls align with best practice through a series of audits and benchmarking exercises with similar organisations. We are in a strong position and remain focussed on continuous improvement.

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 109.

Sustainability report

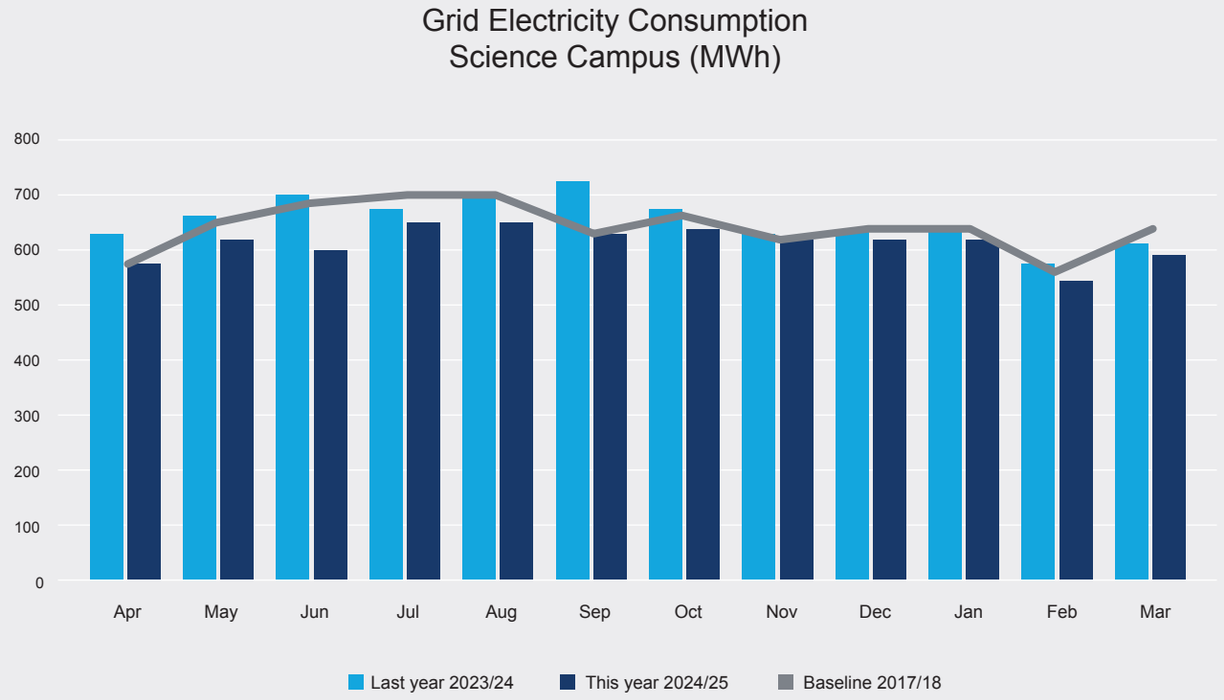
Energy management performance

- Our Science Campus, which is a mixed laboratory and office site, reports against a baseline of 2017 to 2018 in accordance with Greening Government Commitments (GGC)

- Our Canary Wharf office, which is a shared government office building, reports against a baseline of 2019 to 2020 as that was our first full year of occupancy in the government hub

Electricity

Science Campus 7,311.43 MWh

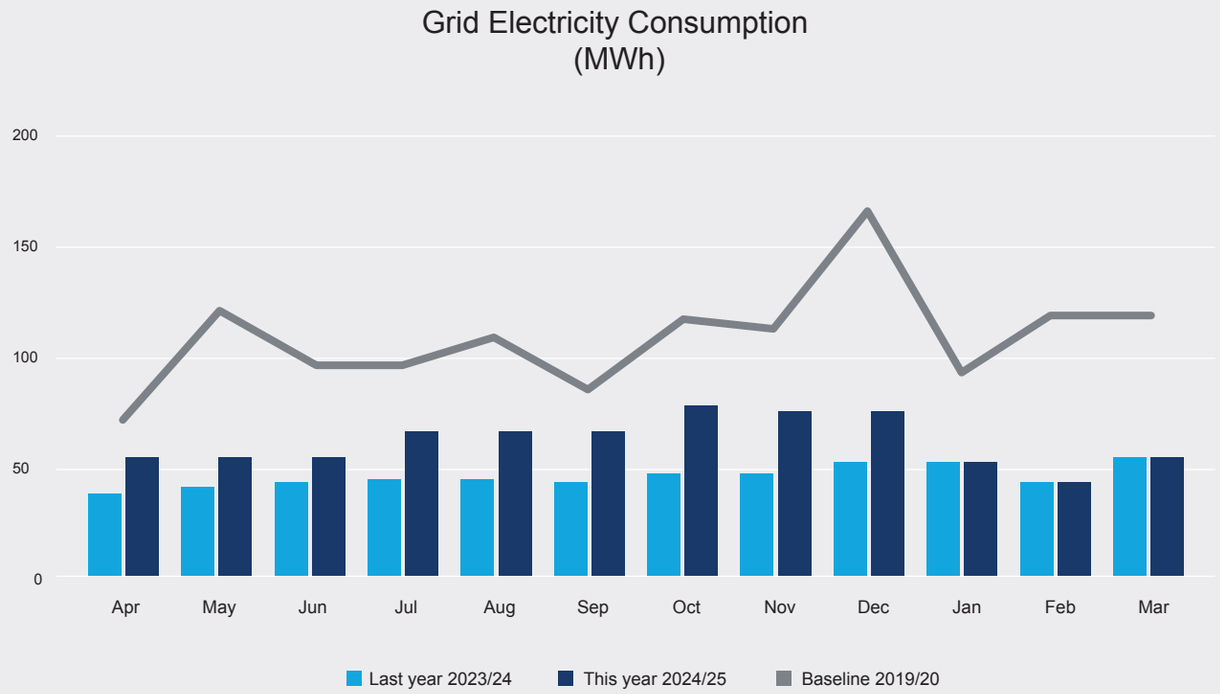


▼ 5.1% decrease vs baseline

▼ 6.2% decrease vs last year

Our Science Campus grid electricity consumption reduced slightly this year compared with last year, most notably from April 2024 to September 2024 where our new solar panels generated 13% of the electricity used on site. For the 2024/25 financial year, our Science Campus used 746MW of solar electricity compared to 435MW in 2023/24.

Canary Wharf office 734.32 MW



45.5% decrease vs baseline

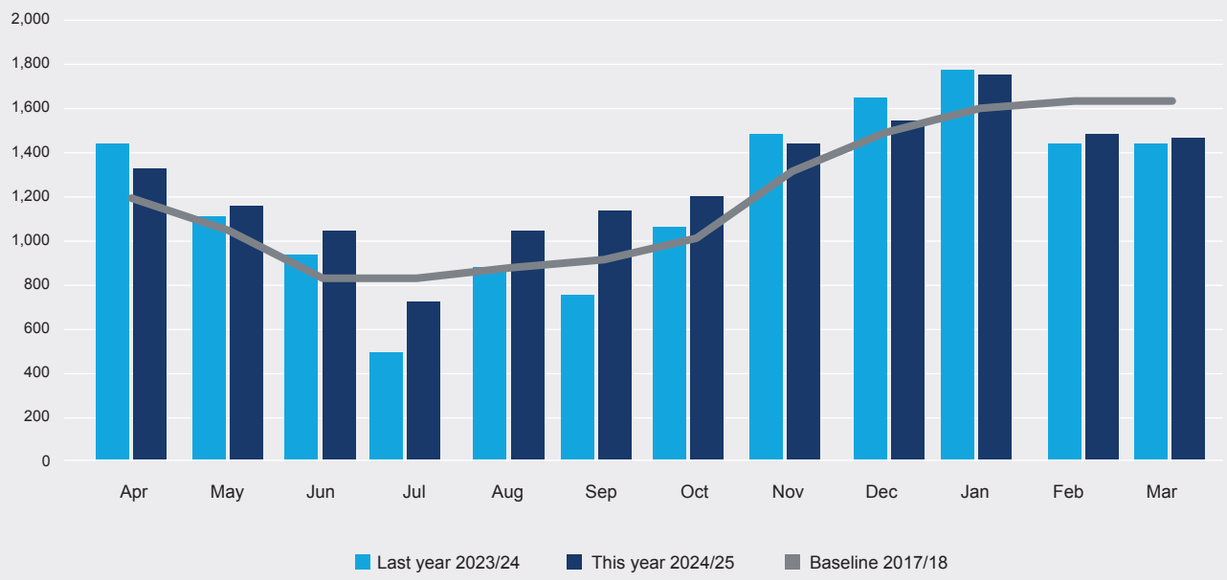
33.1% increase vs last year

The Canary Wharf office electricity consumption remained lower than the baseline, although it increased by 33% compared with last year. This is mainly due to higher building occupancy this year than last, and the office site water heating systems transitioning to electricity from gas.

- The electricity consumption at our Science Campus is significantly higher than at our Canary Wharf office site due to the higher requirement for electricity to support our specialist laboratory operations
- The electricity consumption patterns at our Science Campus are almost identical year on year. There is an increase in electricity usage in summer, corresponding with the need for cooling. Our solar panels offset this summer peak and it would be far more significant without them
- Our Canary Wharf office is a multi-occupancy Government Property Agency (GPA) building, and we occupy a small part of the total building. The MHRA Canary Wharf office figures were reported as 6.3% of the total building for the financial year 2024/25, as this is our occupancy reported by GPA
- As we are accountable for a portion of the total electricity consumption of the total building, the figures are not necessarily accurately representing the electricity used by our staff
- The Canary Wharf office building predominantly uses electricity for lighting, lifts, catering, heating and cooling. Therefore, it is likely that electricity consumption increases as building occupancy increases. As the data is provided to us on a quarterly basis, it is not currently possible for us to verify the link between building occupancy and electricity consumption

Gas

Science Campus: 15,233.30 MWh

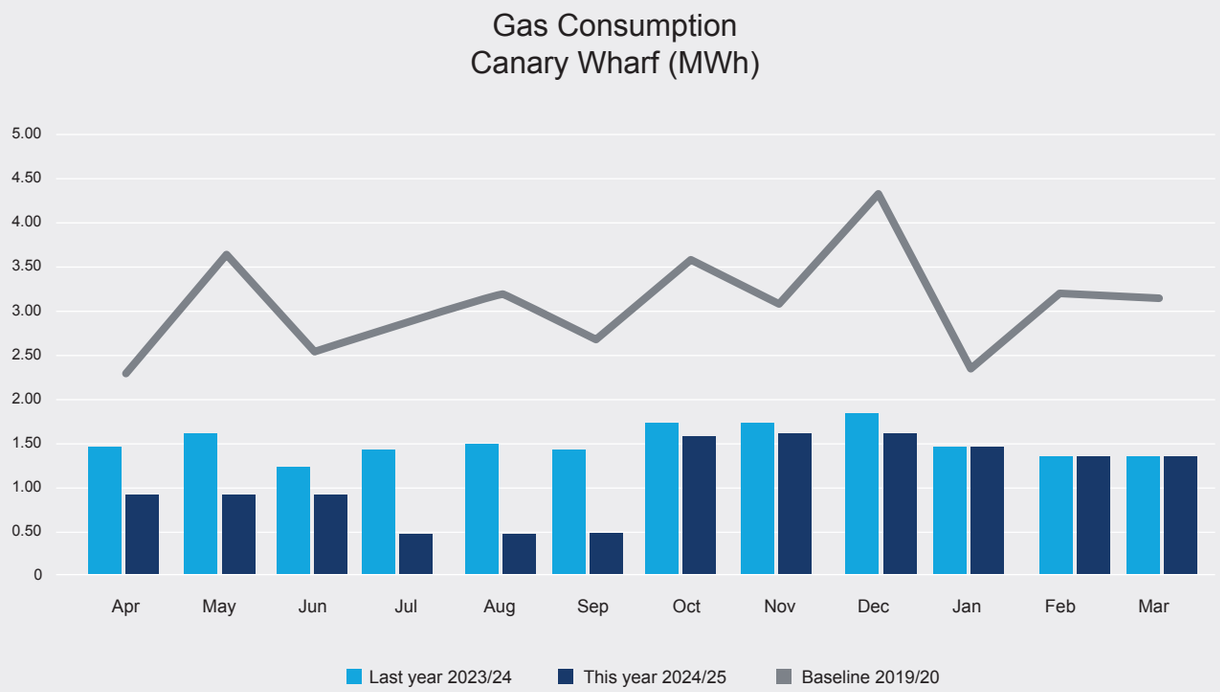


▲ 5.5% increase vs baseline

▲ 5.9% increase vs last year

Gas consumption at our Science Campus increased in 2024/25 compared with 2023/24 and the baseline year, mainly due to colder weather increasing the demand for heating.

Canary Wharf office 12.98 MWh



▼ 64.7% decrease vs baseline

▼ 28.0% decrease vs last year

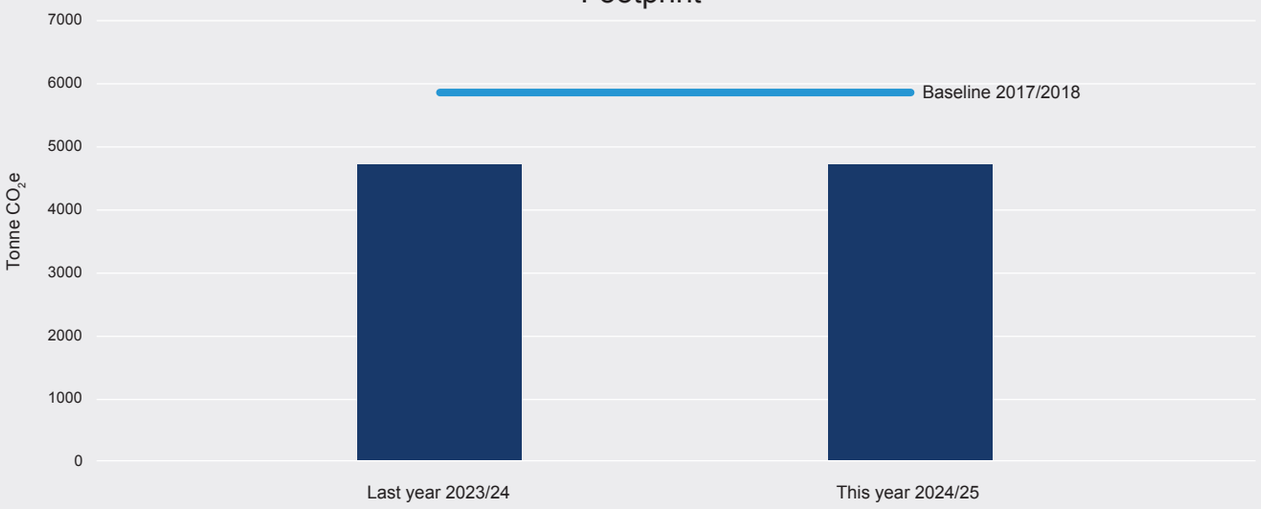
Gas consumption at our Canary Wharf office for 2024/25 is reduced from 2023/24 and the baseline year. Gas is now only used for some aspects of catering.

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

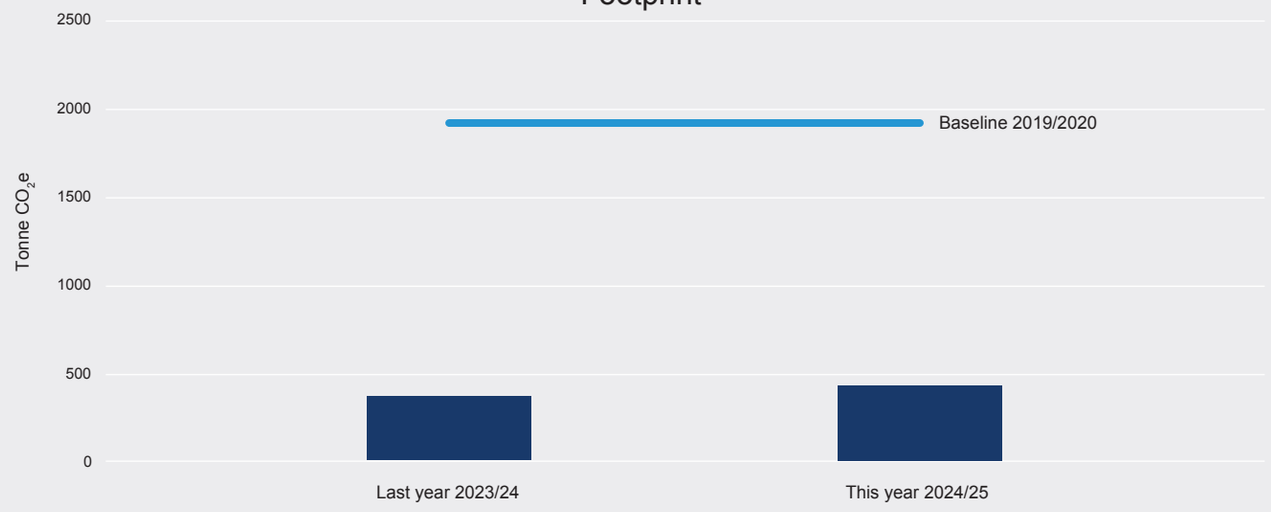


▼ 20.2% decrease vs baseline

Carbon emissions have been reduced at our Science Campus from 5,917 TCO2e in the baseline year (2017/18) to 4,722 TCO2e in 2024/25.

Canary Wharf office

Footprint



▼ 78.2% decrease vs baseline

Carbon emissions have been reduced at our Canary Wharf from 1,954 TCO2e in the baseline year (2019/20) to 425 TCO2e in 2024/25.

- Our carbon footprint at both of our sites has fallen compared with the baseline years. However, there has been no significant change in carbon emissions compared with 2023/24, with both the Science Campus and Canary Wharf office increasing slightly from 2023/24

- The carbon intensity has increased slightly for UK grid gas and grid electricity. The increase in electricity is mainly due to an increase in the use of natural gas within the grid mix for the second year running. Carbon intensity is a measure of how many kilograms of carbon dioxide gas is released to produce each kilowatt of electricity or gas

- Business travel has the greatest impact on carbon emissions associated with our Canary Wharf office function, as this is a shared building with a constant base load. The number of maintenance staff, cleaning staff and catering staff does not vary. The amount of energy used for lighting, lifts, cooking, heating and cooling the building is very similar regardless of building occupancy. However, the amount of water used at our Canary Wharf office increases with occupancy

- Our Science Campus operates with a much higher baseload. The emissions associated with the constantly running freezers, boilers and air handling equipment, necessary for our scientific purposes, mask the emissions from administrative and non-scientific activities

We cannot properly compare emissions across MHRA sites due to the very different nature of the work performed at each location. However, normalising the data per person gives:

Science Campus:
11.01kg CO^2 per person per occupancy day

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

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 are led by science and aligned with the expert consensus on action needed during this decade to avert climate catastrophe (IPCC, 2018). We aim to reach net zero greenhouse gas (GHG) emissions by 2030, which is in line with the ambitions and priorities of the DHSC.

Our progress includes:

- Use of Renewable Energy Guarantees of Origin (REGO) backed grid electricity generated from 100% clean renewable sources from April 2025
- Generation of 13% of our total electricity requirement for our Science Campus for 2024/25 through our solar panels, reducing our annual supply costs by over £200,000 and reducing our annual carbon footprint by approximately 170 tonnes CO2e
- Installation of solar carports to increase on-site clean electricity generation at our Science Campus
- Working to reduce our gas usage through a decarbonisation programme
- Increase in biodiversity at our Science Campus through the planting of hedgerows in our woodland area and the addition of a new beehive
- Enhancement of shared spaces at our Science Campus with climate-resilient planting, new bird boxes, insect houses and squirrel tables. Increased accessibility and new energy efficient lighting, providing staff a green space to relax and recharge

Minimising waste and promoting resource efficiency

We apply the waste hierarchy by prioritising prevention and designing out waste from our internal policies and processes.

Our progress includes:

- Zero waste sent to landfill since 2016/17, with any redundant equipment and waste that cannot be reused or recycled being incinerated to generate energy
- Sending nearly four tonnes of pallets and wood for reuse. Additionally, we enabled the reuse of over three tonnes of equipment, including furniture, office equipment, and solid ice packs. All food waste at the Science Campus is composted on-site for reuse on the site allotments
- Ensuring that our waste contract for our Science Campus is fully compliant with Simpler Recycling, a policy introduced in 2023 by the Department for Environment, Food and Rural Affairs with the ambition of making recycling easier and more consistent across different regions. Our glass, paper and plastic film waste are all segregated to facilitate recycling. We continue to recycle polystyrene, old lab coats, baled cardboard, glass Winchester bottles and waste electrical and electronic equipment

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. We constantly measure and record our water use so that we can assess the impact of our water efficiency measures and are working to reduce wastage.

Our progress includes:

- The use of water butts to capture rainwater for re-use by grounds maintenance teams and on the allotments managed by staff
- An ongoing programme of system efficiencies together with leak repairs and other remedial work carried out on the steam and water system. This programme has reduced water consumption at the Science Campus by 41% from 2023/24

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 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), including PPN 06/21, which sets out how suppliers' Carbon Reduction Plans and commitment to Net Zero can be taken into account in the procurement of in-scope central Government contracts. Where applicable, we include a minimum of 10% sustainability weighting in the tenders we issue to our supply chain partners.

Empowering staff to work and commute more sustainably

We promote active travel, including encouraging walking and cycling to work. Facilities to secure bikes, lockers and shower facilities are provided at both our Canary Wharf office and Science Campus. We are currently installing electric vehicle charging points to facilitate the transition to zero-emissions vehicles and support sustainable transport at the Science Campus.

Climate related disclosure report 2024/25

Compliance statement

We are committed to managing Environmental, Social and Governance (ESG) issues, including climate change. We also recognise that there is a growing urgency to respond to long-term sustainability issues, particularly climate change. Therefore, it is imperative that we consider and ensure ownership of ESG as part of our development strategy.

The Taskforce for Climate-Related Financial Disclosures (TCFD) provides a framework for organisations to analyse and disclose climate-related financial information. We report on climate-related financial disclosures consistent with HM Treasury's TCFD-aligned disclosure application guidance, which interprets and adapts the framework for the UK public sector. We comply with the TCFD-recommended disclosures around governance and metrics and targets in line with phase 2 of the central government's TCFD-aligned disclosure implementation timetable.

Climate change commitments

Our net zero ambitions, aligned with the DHSC net zero ambitions, aim to achieve a net zero emissions building estate by 2030. We are implementing a number of actions to enable these ambitions to be achieved. Climate change and other long-term sustainability issues present opportunities and risks that increasingly require explicit consideration.

We have the ambition to:

- **Achieve a carbon net zero building estate by 2030**, which we will achieve by eliminating direct scope 1 emissions from gas and F-gas, minimising indirect scope 2 emissions and embedding sustainability appraisals into our procurement and project processes. In 2024/25, we have removed gas usage from our Canary Wharf office. We are working to decarbonise our Science Campus and generate clean electricity through the use of solar panels. All purchased electricity is certified as zero carbon. We are working to replace our old refrigeration equipment containing refrigerant with a high global warming potential (GWP) with new low and zero GWP equipment as a rolling programme
- **Prioritise waste prevention, improve reuse and recycling rates and annually reduce the proportion of waste being sent to incineration and landfill.** In addition to our recycling and reuse programmes, we are working to remove single-use plastics from our offices and embed paperless 'digital by default' ways of working
- **Improve water efficiency across our estate while raising awareness of the importance of responsible water consumption.** We monitor our water consumption and have an ongoing programme to improve our water infrastructure at our Science Campus and a proactive maintenance programme
- **Drive sustainability through our contract management.** We consider sustainability through our procurement process; we comply with Procurement Policy Note 06/21 for our high-value contracts and encourage new suppliers to demonstrate their commitment to carbon reduction
- **Improve and encourage biodiversity on our estate**. We have an ongoing plan to protect our natural environment and support nature recovery

- **Consider climate risk to protect our buildings and workforce and increase our climate resilience.** We are building on our risk management approach through our business continuity processes to ensure effective management of climate risk

- **Enable our staff to make healthy and sustainable food choices.** Our catering contracts embed sustainability and promote healthy eating

TCFD pillar: Governance

The MHRA Board is responsible for ensuring that our risk management approach, including climate-related risk management, is both relevant and effective. This involves overseeing the risk management framework, ensuring that risks are properly identified, assessed, and managed, and verifying that appropriate policies and processes are in place to mitigate these risks. Additionally, the Board ensures that the Executive team is actively engaged in managing key risks. Further details of our Board and its operation can be found on page 91.

Our Audit and Risk Assurance Committee (ARAC) is responsible for supporting the Board and Accounting Officer by reviewing the comprehensiveness and reliability of assurances on governance and risk management. ARAC considers our corporate risks and issues on a quarterly basis, providing strategic challenges and oversight. Assurance is provided to the Board following each meeting. Further details of our ARAC can be found on page 99.

We are currently establishing formal governance structures for our climate and sustainability activities and will report on these in our next climate-related disclosure report.

TCFD pillar: Risk management

Our Risk Management Framework provides clear guidance for identifying, assessing and managing risks, including climate-related risks. Climate-related risks are managed through group-level risk registers and escalated to the corporate risk level if they exceed our risk appetite. The Executive Committee makes decisions on whether to escalate risks to the corporate level. We are currently working on the identification of climate related risks at the group level and there are currently no climate related risks escalated to the corporate risk level. Further details on our risk management approach can be found on page 109.

A climate change adaption plan is currently being developed, which includes a climate change risk assessment approach for assessing identified vulnerabilities at the Group level. We are assessing climate risk across the agency to understand the potential impact on our wider activities, including delivery of our strategic objectives, our procurement, and our supply chain.

TCFD pillar: Metrics and targets

We have analysed our most significant carbon emissions at our primary locations (Science Campus and Canary Wharf offices), using 2017 as our baseline year. This 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.

We have considered the viability of reducing our reliance on fossil fuels and assessed the financial and environmental impact of reducing direct GHG emissions. We have developed a heat decarbonisation plan in 2024/25 to support these activities.

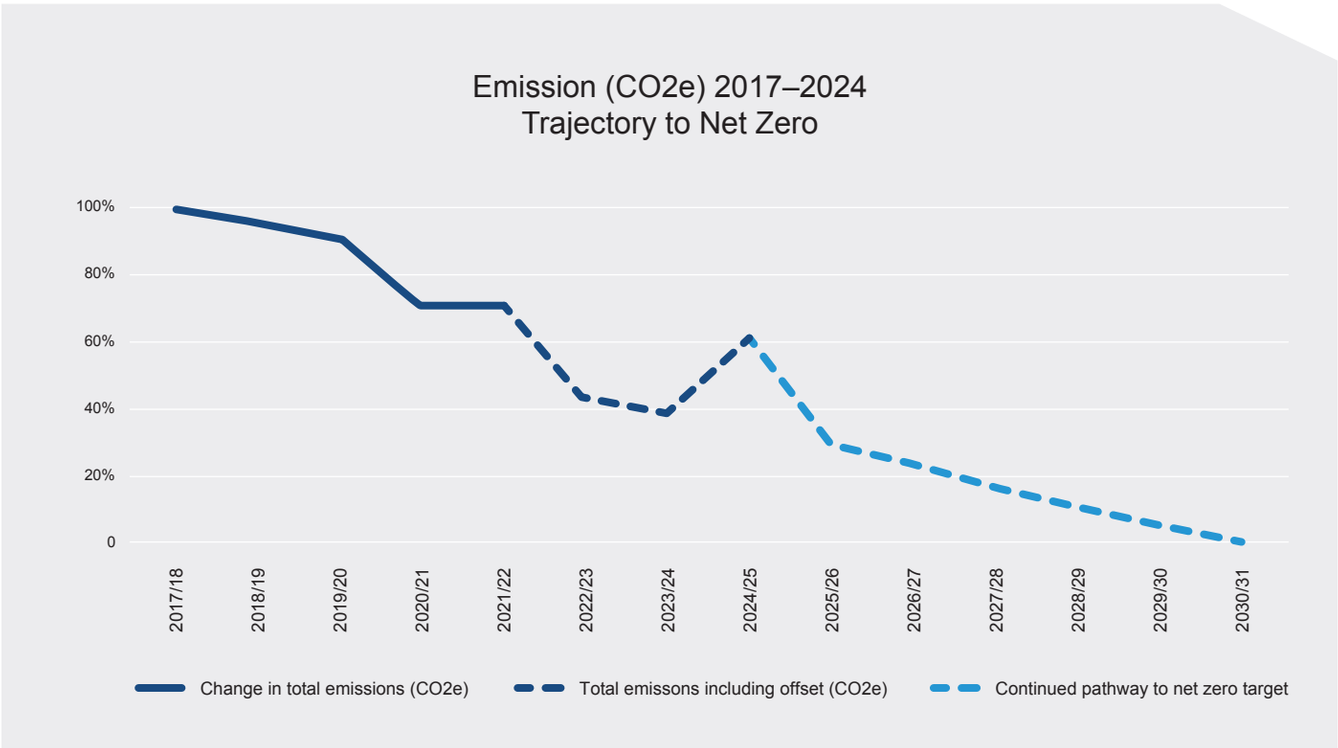
We recognise that greater transparency and disclosure will enhance our ability to assess and monitor our exposure to climate-related risks and support us in building these considerations into our strategy and risk management processes. This is our second TCFD report in an uncertain period of climate change; the methodologies and approaches may therefore evolve in the future.

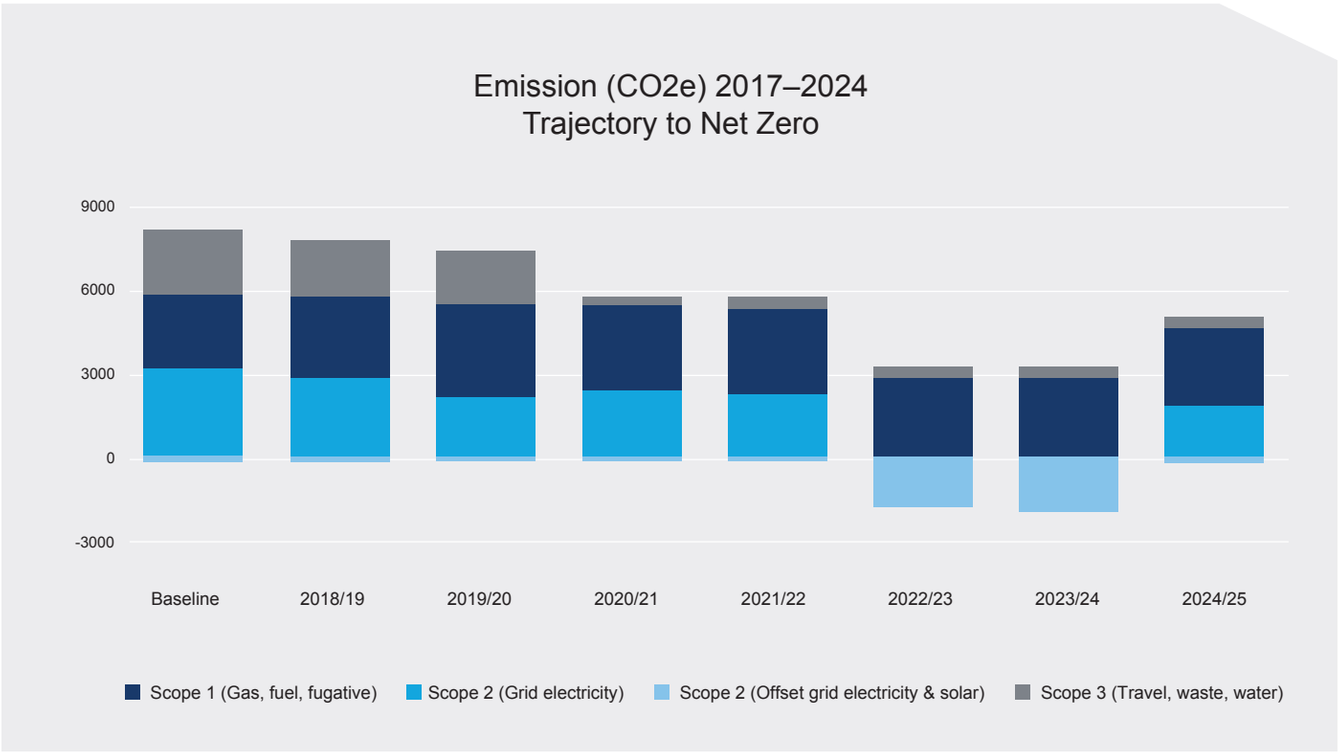
We have analysed our progress in reducing our significant emissions for our primary locations (measured in tonnes of carbon dioxide equivalents, tCO2e). On an absolute basis, these have reduced by approximately 35% since 2017.

Scope 1, Scope 2 and Scope 3 GHG emissions and the related risks

The carbon metrics being captured in this report by scope are:

- **Scope 1** — Direct GHG emissions from our organisational activities. These are:
  - Use of gas for the generation of heat and steam, catering and for incineration
  - Emissions from company fleet vehicles and on site (back-up) power generation
  - Accidental release of F-gas
- **Scope 2** — Indirect emissions from electricity purchased and used by our organisation. This includes our onsite plant and equipment, refrigeration, heating, ventilation, air conditioning, lighting, digital and technology equipment and vehicles
- **Scope 3** — Indirect emissions from activities and sources that the organisation does not directly own or control, including, but not limited to:
  - Business travel
  - Water and trade effluent management
  - Waste management
  - Outsourced data management
- **Absolute carbon footprint by scope** — This measurement refers to the total carbon emissions allocated to the MHRA in absolute terms





Our Scope 2 carbon emissions are offset by a combination of self-generated solar electricity and purchasing clean, renewable energy. Due to an administrative oversight, our grid electricity reverted to a standard electricity tariff in 2024/25 for the full financial year. This increased our carbon emissions for the year by approximately 2,000 tonnes. For 2025/26, we have ensured we are on a clean, renewable tariff, which will mean all our electricity emissions will be offset. Clean, renewable electricity with REGO certification is a credible offset as it provides transparency about the energy's renewable origin, helping to legitimise claims of environmental benefit.

At the MHRA, we take corporate responsibility seriously. We have made the proactive decision to generate and use clean, renewable electricity not only from our solar panels but also from the energy we purchase from the national grid. This benefits the environment and supports our longer-term sustainability agenda whilst also being a cost-effective future solution to our energy needs. While investing in renewable energy may require a higher initial outlay, the long-term financial benefits are substantial. By generating our own solar electricity, we eliminate fuel taxes and hidden costs including the climate change levy. Additionally, we are insulated from the volatility of fossil fuel prices and the political pressures that can cause fluctuations in energy costs. This ensures a more predictable, sustainable, and cost-effective energy solution for our operations.

Targets used by the organisation to manage climate-related risks and opportunities and performance against targets

We monitor our progress towards achieving our net zero and sustainability ambitions in line with the Government Greening Commitments and the requirements of the TCFD, and report our sustainability data to DHSC for centralised reporting to the Cabinet Office and the Department for Environment, Food & Rural Affairs. We are currently monitoring the following key sustainability metrics:

Measure	2023/24	2024/25	Trajectory
Percentage of electricity generated through solar panels at our Science Campus	5.6%	13%	▲
Percentage change in grid electricity usage at our Science Campus (from 2017 baseline year)	-1.2%	-5.1%	▼
Percentage change in grid electricity usage at our Canary Wharf office (from 2019 baseline year)	-59%	-45.5%	▲
Percentage change in gas usage at Science Campus (from 2017 baseline year)	-0.2%	-5.5%	▼
Percentage change in gas usage at our Canary Wharf office (from 2019 baseline year)	-51.5%	-64.7%	▼
Carbon emissions at our Science Campus (CO2 per person per occupancy day)	10.31kg	11.01kg	▲
Carbon emissions at our Canary Wharf office (CO2 per person per occupancy day)	1.65kg	1.57kg	▼
Percentage change in absolute carbon emissions from the 2017 baseline year	35%	35%	▶

Grid electricity usage at our Canary Wharf office increased in 24/25 due to greater building occupancy.

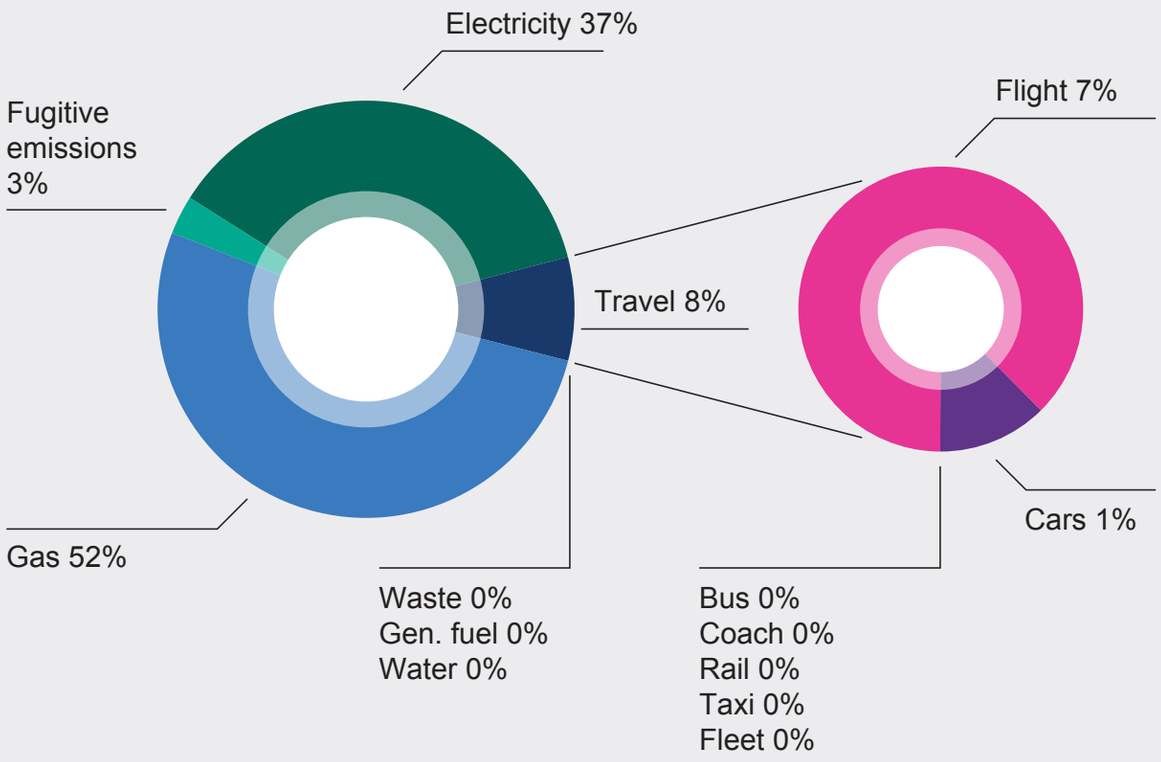
Carbon emissions at our science campus increased due to an administrative error leading to our grid electricity reverting to a standard electricity tariff for the 24/25 financial year.

We will be reviewing these sustainability metrics in the coming year.

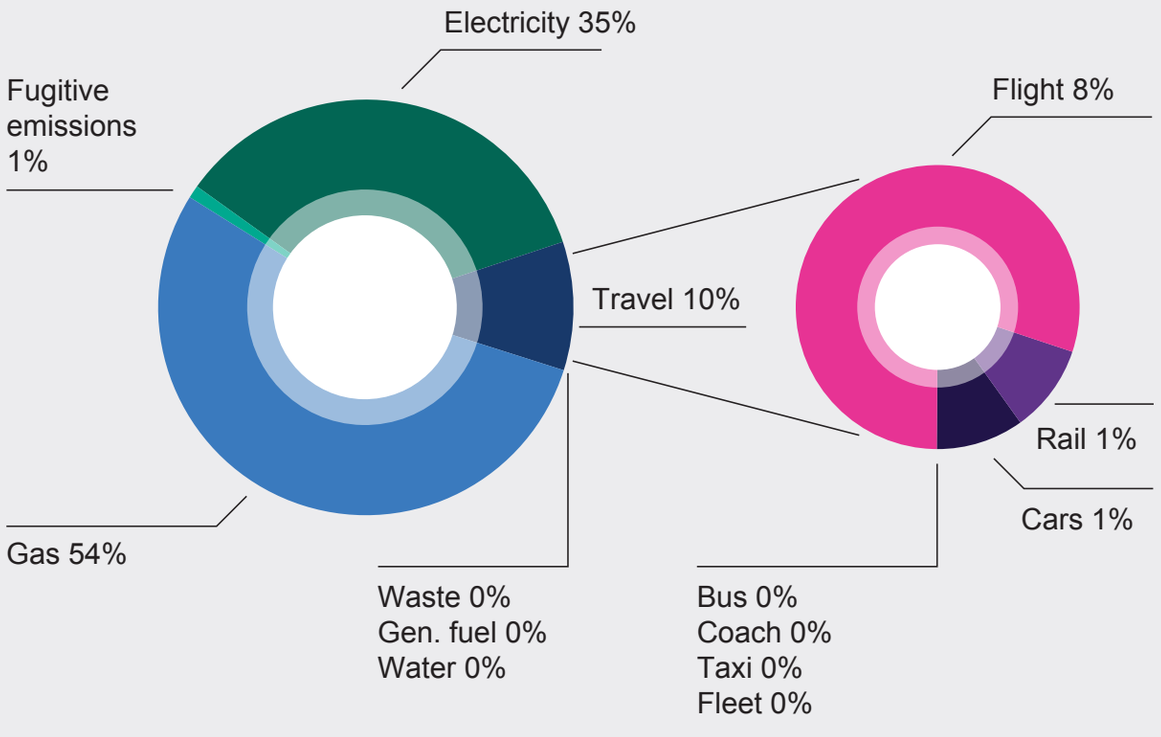
We have undertaken a series of significant projects in 2024/25 to increase our efficiency and support our sustainability ambitions. These include:

- Installation of solar panels
- Adding social value and sustainability targets into our significant projects and tenders

Emissions by Scope 2023/24



Emissions by Scope 2024/25



Business travel

We have reduced our Scope 3 emissions through increased hybrid working and encouraging online attendance at national and international meetings where appropriate and possible. There was a significant drop in Scope 3 emissions in 2020 as a direct result of the COVID-19 pandemic placing restrictions on travel. In recent years, we have seen the number of business journeys increase, but these remain less than a third of the number of business journeys in the baseline year (2017). Business travel is our most significant Scope 3 impact, and we are therefore calling this out in the TCFD report to enable our progress to be monitored.

Travel was responsible for 8% of our emissions in 2023/24, and this has increased to 10% in 2024/25. 80% of travel emissions are from air travel. Despite our ambitions to reduce our business travel, we recognise that this will always be an essential element of our operational activities due to our regulatory role requiring onsite inspections and the importance of networking to maintain our expert science base.

Health and safety report

Effective health and safety management is vitally important to 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 robust controls and a strong health and safety culture to ensure we adhere to the required standards and legislation to protect our people.

Our focus on health and safety has remained a top priority this year and we have strengthened our health and safety governance and processes significantly. The Health and Safety Executive (HSE) provides an external review of our health and safety management procedures through a planned annual intervention programme, and we maintain a regular and open dialogue throughout the year. Following the receipt of an improvement notice in March 2024 from the HSE in relation to our auditing and inspection, considerable work was undertaken to address the identified issues. This led to the development of our new and improved inspection audit programme and provided the opportunity to fully review the processes in place and identify where improvements could be made. Our new inspection and audit process combines existing quality system processes with health and safety requirements. This combined approach was approved by the HSE and is being embedded into our work programmes from early 2025.

Our process for risk assessment of our scientific procedures was enhanced in 2024 with the introduction of a more robust procedure for Safety Critical Task Analysis. This procedure allows detailed risk assessment by breaking an activity into smaller tasks and assessing how human factors may impact the risk to the process. Work on human factors is an area that is being developed further in the health and safety sector, and we work closely with similar organisations to share best practices in this work.

The Health and Safety team partnered with the HSE training division to deliver a specialised Biosafety training program for Containment Level 3 (CL3). The course enabled CL3 laboratory supervisors and their deputies to discuss local procedures, ensuring consistency and improvements in our processes. This cost-effective training enhanced staff understanding of CL3 operations, including equipment, person protective equipment, and working principles with biological agents. It covered design, management, maintenance, testing, and legislative requirements of CL3 laboratories, equipping delegates with the skills to handle high-hazard pathogens, assess risks, and manage incidents effectively.

Health and safety governance

Responsibility for health and safety lies with the Chief Executive, with leadership assigned to the Interim Executive Director of Science and Research throughout the year. 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, co-ordinate specific work activities and champion roles to support staff locally in their groups. Biological safety officers at the Science Campus, focus on ensuring safe working with biological agents, alongside a variety of strategic and operational oversight groups focussed on health and safety. The biosafety resource has been strengthened with the addition of a Biosafety Advisor who joined the agency in January 2025.

The Executive Committee and its management committees support health and safety and provide challenge to ensure controls are effective. At the start of the year, our health and safety governance has been strengthened with the implementation of a new interim Health and Safety Committee providing focussed strategic support which reports into the Executive Committee. 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) https://www.hse.gov.uk/pubns/books/HSG65.htm.

Accidents and incidents

Our internal trend analysis for the past ten years indicates a gradual increase in internally reported incidents over the decade; however, the number of such incidents reduced in 2024/25. Reported incidents in 2024/25 related primarily to our Science Campus, with lower numbers at the Canary Wharf office. This is a reflection of the different environments and the nature of the work performed at our Science Campus. Our reported accident statistics have also reduced this year from previous numbers.

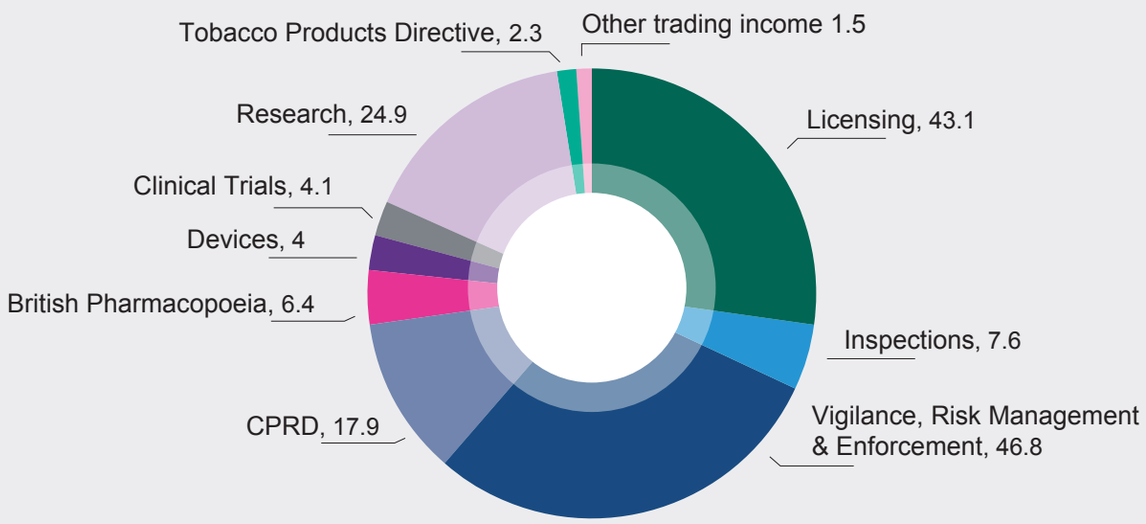
We carry out detailed analysis of all accidents and incidents to ensure they are being reported appropriately and that underlying causes are fully understood and followed up, where applicable, so that lessons are learned to prevent reoccurrence. We are confident that the reduction in accidents and incidents reported in 2024/25 is a positive reflection of the improvements made to our health and safety management.

In 2024/25, there were no accidents or incidents that met the requirements for reporting under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013.

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 154. The DHSC funding of £64.0m is shown in the Statement of Changes in Taxpayers' Equity (SoCTE) on page 157. This means the agency is showing comprehensive expenditure of £43.3m for the financial year, which is expected in line with the funding agreement in place with DHSC.

Trading income



Values rounded to the nearest million (£)

Our funding

The majority of the MHRA's running costs come from trading income, which is a combination of statutory fees paid by industry for regulatory services and charges paid by customers for the non-statutory services and goods. During 2024/25, the MHRA generated £158.5m of trading income.

The largest element of our trading income during 2024/25 was £46.8m 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 fee 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 £43.1m (as shown in the Fees and Charges table page 145) from the pharmaceutical industry for licensing (marketing authorisation applications, renewals and variations) that provide the companies with market access for products in the UK. The MHRA earned £24.8m in 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 £17.9m. 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 £8.0m grant funding to support Innovation. £1.0m for AI Airlock and £1.9m for the Innovative Licensing/Devices Access Pathways (ILAP/IDAP).

The MHRA is only able to use capital provided by either the DHSC or other Government sources. The DHSC provided £29.5m of capital funding in 2024/25. The majority of this was used for the maintenance of the Science Campus, to continue development of the replacement of our regulatory casework IT management systems, 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 2024/25 as the agency recruited and pay rates increased by 5% in line with the Civil Service Pay Remit set by the Cabinet Office.

Digital technology costs increased by £1.9m (6%) due mostly to an increase in the cost of infrastructure services, additional software and licences in the year. The agency also invested in significant improvements in cyber and information security 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 £3.7m for the financial year of 2024/25. This has been achieved by reducing expenditure through competitive procurement exercises and commercial activity to reduce spend against budgets for goods and services.

11 July 2025

Lawrence Tallon
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 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

Since 2019, the MHRA has been led by Dr June M. Raine DBE, who served as both Chief Executive Officer (CEO) and Accounting Officer. Dr Raine stepped down on 31 March 2025, and Lawrence Tallon assumed the roles of CEO and Accounting Officer for the MHRA from 1 April 2025.

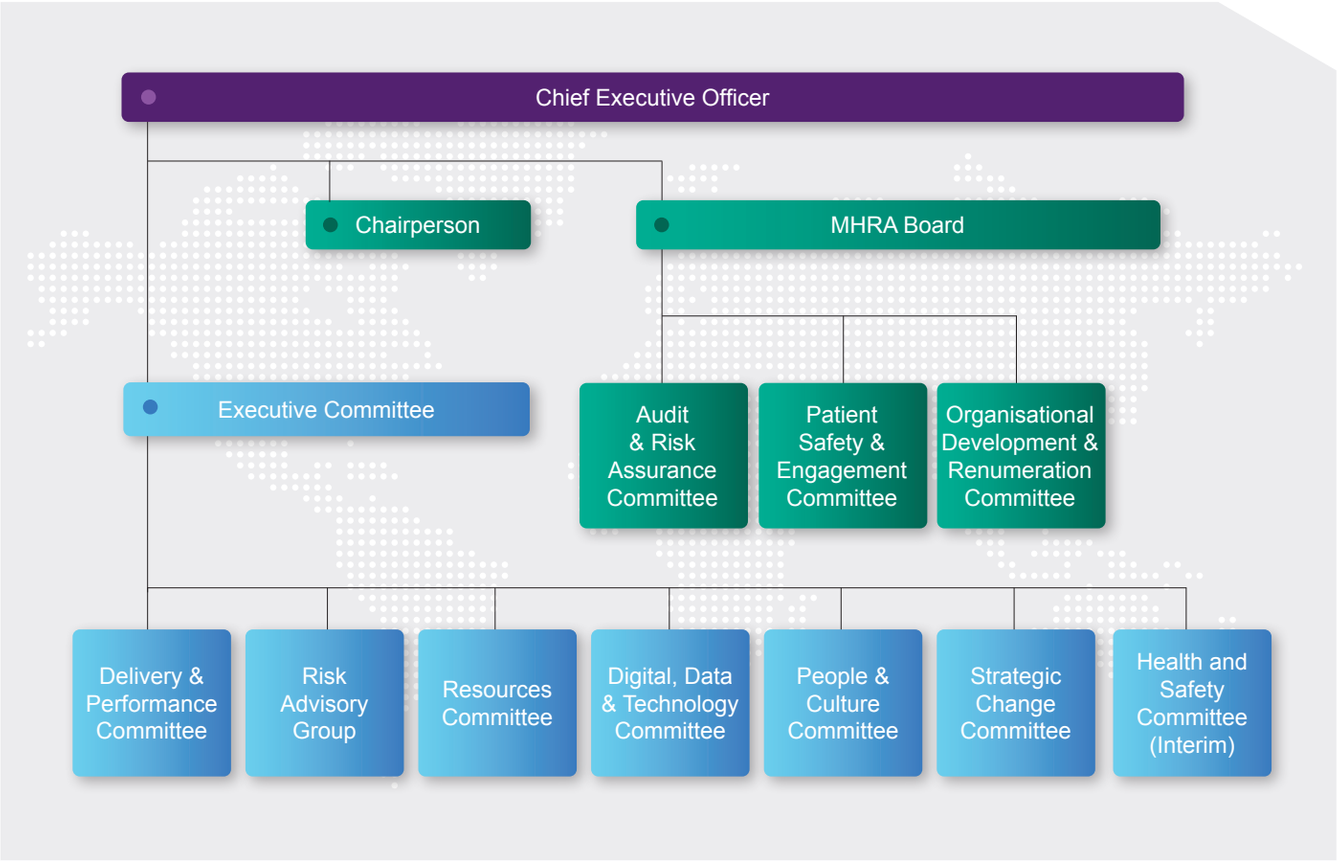
The CEO is directly accountable to Ministers, Parliament, and the Department of Health and Social Care (DHSC) Permanent Secretary for the operation and management of the MHRA and the delivery of its functions. The CEO is supported by an advisory board (the Board), led by a Non-Executive Chair (the Chair), and the Executive Committee (ExCo).

The CEO of the MHRA is designated as the Accounting Officer by the Principal Accounting Officer of the DHSC, Sir Chris Whitty, on behalf of the Secretary of State for Health and Social Care, The Rt Hon Wes Streeting MP. Our senior departmental sponsor in the DHSC is the DHSC Medicines Director, Gila Sacks.

Our relationship with the DHSC and our accountabilities to each other are described in our Framework Agreement; Framework agreement between DHSC and the Medicines and Healthcare products Regulatory Agency - GOV.UK (www.gov.uk) 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, Corporate Governance in Central Departments Code of Good Practice and the MHRA Code of Business Conduct, the Civil Service Code and the Civil Service Management Code.

Our governance structure:



MHRA Chair

From 12 July 2023 to 31 December 2024, the MHRA Chair role was managed through an interim arrangement with three existing MHRA Non-Executive Directors acting as interim co-chairs, each with specific responsibilities:

Amanda Calvert Supporting external stakeholder meetings and organisational development
Professor Graham Cooke Chairing MHRA Board meetings
Michael Whitehouse Supporting cross-government engagement

Our new Chair, Professor Anthony Harnden, joined the MHRA on 1 January 2025.

We are extremely grateful for the support and expertise of the co-chairs over the past 17 months. Their dedicated commitment, following Stephen Lightfoot stepping down as Chair in July 2023, has been invaluable.

Introducing our new Chair: Professor Anthony Harnden

We welcomed Professor Anthony Harnden as the new Chair of the Medicines and Healthcare products Regulatory Agency Board on 1 January 2025.

Professor Harnden worked for the NHS for 40 years and notably brings many years of experience working directly with patients including more than 33 years as a general practitioner in Wheatley, Oxfordshire. He has an academic interest in childhood infection and is a Professor of Primary Care at the University of Oxford and an Honorary Fellow of St Hugh's College.

Professor Harnden was a former registrant council member of the General Medical Council. He was also previously Deputy Chair of the Joint Committee on Vaccination and Immunisation and played a key role in ensuring public trust and patient safety during the distribution of the COVID-19 vaccine.

During his first 100 days with the MHRA, Professor Harnden's main priority was to engage with and listen to staff and partner organisations. This was so he could gain a strong understanding of how to drive forward the strategic direction of the MHRA to maintain the UK as a global centre of excellence in life sciences in the best interests of patients and the public.

As Chair of the MHRA Board, Professor Harnden's top priorities include:

- Protecting patient safety through robust safety surveillance systems
- Embracing risk-proportionate regulation
- Fostering an inclusive workplace where people flourish
- Improving engagement with the public

Another key focus that cuts across the priorities above is developing key strategic partnerships both within the UK and internationally.

I am excited to be joining at such a pivotal time for our work in the health and life sciences sectors, and I am grateful for the opportunity to connect with key stakeholders across the public sector and industry. I value the important role the MHRA plays, and it is well-positioned to achieve the realisation of our priorities through partnerships and working collaboratively. I want to continue to drive forward the strategic direction of the MHRA to maintain the UK as a global centre of excellence in life sciences in the best interests of patients and the public.

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The Board

Our Board operates as a unitary board, comprising an equal number of Executive and Non-Executive Director posts, along with a Non-Executive Chair. However, due to the vacant Chair post during the year, the number of Executives occasionally exceeded the number of Non-Executives at some of the Board meetings. The Board serves in an advisory capacity, providing support to our CEO in overseeing the MHRA's operations and ensuring the effective delivery of our 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, focusing specifically on:

- Advising on the agency's strategic direction and ensuring delivery of objectives set out in the business plan and agreed with ministers
- Supporting the CEO in delivering services effectively, scrutinising performance, and ensuring strong corporate governance and risk management
- Providing leadership, helping shape policy delivery, and maintaining high standards across the agency's operations

The MHRA Board does not participate in regulatory decisions regarding medicines, medical devices, or any other products or services delivered by the MHRA. These decisions are the responsibility of the Chief Executive, who is supported by the Executive Committee. As the MHRA's Accounting Officer, the Chief Executive holds ultimate responsibility and accountability for these decisions.

Members of the Board in 2024/25

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 2024/25 were:

Professor Anthony Harnden
January 2025–Present
Board Chair January 2025–Present

Amanda Calvert
September 2018–Present
Acting Co-Chair July 2023–December 2024
Chair of Organisational Development Remuneration Committee
Member of the Audit Risk and Assurance Committee

Professor Graham Cooke
September 2021–Present
Acting Co-Chair July 2023–December 2024
Member of the Patient Safety and Engagement Committee

Michael Whitehouse, OBE
September 2018–Present
Acting Co-Chair July 2023–December 2024
Chair of the Audit Risk and Assurance Committee

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

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

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

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

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

The Executive Directors who served on the Board in 2024/25 were:

Dr June M Raine, DBE
September 2019–March 2025
Chief Executive Officer

Dr Alison Cave
July 2021–Present
Chief Safety Officer

Dr Laura Squire
November 2021–February 2025
Chief Healthcare, Quality and Access Officer, currently leading work on health technology regulation reform

Dr Glenn Wells
November 2021–September 2024
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

Dr Nicola Rose
August 2024–Present
Interim Executive Director, Science and Research

Harriet Teare
November 2024–Present
Joint Interim Director, Partnerships Group

Rachel Arrundale
November 2024–Present
Joint Interim Director, Partnerships Group

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.

	Anthony Harnden (Chair)	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 five 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. Our governance - Medicines and Healthcare products Regulatory Agency - GOV.UK (www.gov.uk) https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/about/our-governance#agency-board-minutes.

The MHRA Board also held five Board meetings in committee and one seminar, enabling members to contribute to the development of new strategies and participate in training and development activities.

During each meeting, the Board considered papers from the CEO and the Executive Committee, and Board Assurance Committees. In the 2024/25 period, specific issues addressed by the Board included:

- Development of MHRA strategies such as data, fees, sustainability, health and safety, enforcement and patient and public involvement
- Strategic development of MHRA services, technology, legislative reforms, and partnerships
- Risk management, agreeing on the risk appetite and key strategic risks, including climate risk
- Agency performance, including financial, people and operational performance

Board declarations of interest

All members of the MHRA Board, both Non-Executive and Executive, must follow clear rules on 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 management of these documented in the minutes. While NEDs may hold other interests, members of MHRA staff are prohibited from holding any interests in the sectors that the MHRA regulates.

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: MHRA Governance https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/about/our-governance#board-members-declarations-of-interest.

Board effectiveness

Following the appointment of our new Chair, the Government Internal Audit Agency has conducted a review of the Board and subcommittee effectiveness. This received a Moderate rating, indicating that there is an appropriate governance arrangement to support the Board and its subcommittees in directing, informing and managing MHRA activities. The review highlighted good practice in the operation of the Board through the co-chair arrangement, the clarity of roles and responsibilities which supported the continued effective operations of the Board and in particular, arrangements in place to ensure the Board reviews its own effectiveness. The review noted the period of uncertainty throughout the lengthy process for recruitment of the new MHRA chair, with forward-looking recommendations including strengthening the support for the Board and enabling earlier circulation of Board papers to enable preparation ahead of meetings. The Board and its subcommittees are currently being reviewed by the new Chair to ensure they are optimally positioned to support the MHRA in the future.

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

During 2024/25, the Board has been 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 2024/25: Met five times and addressed various areas, including the risk management framework, internal and external audits, anti-fraud policies, cyber security, governance and the control environment

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 2024/25: Met two times and provided assurance on items such as the Patient Involvement Strategy, UK Electronic Patient Information Taskforce, Selective Serotonin Reuptake Inhibitors, women's health inequalities, a topiramate case study and clozapine

Organisational Development and Remuneration Committee (ODRC)

- Membership: Three Non-Executive members, chaired by Amanda Calvert, along with three Executive members
- Responsibilities: Providing advice on development of MHRA's services, people, and culture strategies
- Focus 2024/25: Met four times, providing assurance on items such as the performance and controls improvement programmes, RegulatoryConnect, risk appropriate decision making, workforce planning, recruitment processes, Executive remuneration, well-being survey results, equality and diversity, and occupational health services

Board and Board Assurance Committee attendance table

Member	Role	Board attended/ eligible	ARAC* attended/ eligible	ODRC** attended/ eligible	PSEC*** attended/ eligible
Anthony Harnden[1]	Chair	3 (3)	-	-	-
June Raine	CEO/AO	11 (11)	5 (5)	4 (4)	2 (2)
Graham Cooke[2]	NED	9 (11)	-	-	2 (2)
Michael Whitehouse[2]	NED	10 (11)	5 (5)	-	-
Amanda Calvert[2]	NED	11 (11)	5 (5)	4 (4)	-
Paul Goldsmith	NED	11 (11)	4 (5)	-	-
Haider Husain	NED	8 (11)	-	4 (4)	-
Mercy Jeyasingham	NED	11 (11)	-	-	2 (2)
Raj Long	NED	9 (11)	-	-	1 (2)
Junaid Bajwa	NED	7 (11)	-	4 (4)	-
Alison Cave	Chief Safety Officer	10 (11)	-	-	2 (2)
Laura Squire[3]	Chief Healthcare, Quality and Access Officer	6 (7)	-	-	2 (2)
Rose Braithwaite	Chief Finance Officer	11 (11)	4 (5)	4 (4)	-
Liz Booth	Chief People Officer	11 (11)			
Claire Harrison	Chief Digital and Technology Officer	10 (11)	2 (2)	4 (4)	-
Glenn Wells[4]	Chief Partnerships Officer	5 (5)	-	-	-
Julian Beach	Interim Executive Director, Healthcare, Quality and Access	10 (11)	-	-	-
Nicola Rose	Interim Executive Director Science and Research	10 (11)	-	-	2 (2)
Harriet Teare / Rachel Arrundale[5]	Joint Interim Director Partnerships	5 (5)	-	-	-

[1] Anthony Harnden was appointed as Chair on 1 January 2025
[2] Graham Cooke, Michael Whitehouse and Amanda Calvert served as co-chairs from 12 July 2023 to 31 December 2024
[3] Laura Squire stepped down from the Board on 7 February 2025
[4] Glenn Wells stepped down from the Board on 30 September 2024
[5] Harriet Teare and Rachel Arrundale attended alternative Board meetings as joint interim Director, Partnerships from 4 November 2024 following the departure of Glenn Wells

Executive Committee

The CEO is supported by the ExCo, in the effective day-to-day leadership and management of the MHRA. The ExCo 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 ExCo is chaired by the CEO. Members of Executive Committee in 2024/25 were:

- **Interim Science and Research Director (25 March 2024 – present)**
- **Chief Healthcare, Quality and Access Officer (until 7 February 2025)**
- **Interim Executive Director, Healthcare, Quality and Access (from 14 August 2023 - present)**
- **Chief Safety Officer**
- **Chief Partnerships Officer (until 30 September 2024)**
- **Chief Finance Officer**
- **Chief Digital and Technology Officer**
- **Chief People Officer**
- **Director of Governance**
- **Director of Communications and Engagement**
- **Director of Delivery (until 20 December 2024)**
- **Interim Executive Director, Innovation and Compliance**
- **Joint Interim Directors, Partnerships (from 4 November 2024 as a shared role)**

The ExCo is supported by seven management committees and an interim health and safety committee, arranged across the MHRA's operational and corporate businesses. Each committee has clearly defined delegated authority and decisions or recommendations are escalated to the ExCo 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 in 2024/25

This year, we have undergone notable leadership transitions.

Following the departure of our Chief Science and Innovation Officer in March 2024, two interim executive directors were appointed to support the senior leadership of the agency: Nicola Rose as Interim Executive Director of Science and Research, and James Pound as Interim Director of Innovation and Compliance. This restructuring created our new Innovation and Compliance group responsible for clinical trials and investigations, and this new structure was retained throughout 2024/25.

September 2024: Chief Partnerships Officer Glenn Wells left the agency for a new role. Harriet Teare and Rachel Arrundale were appointed as Interim Directors of Partnerships, jointly leading the Partnerships team in delivering national and international initiatives from 1 October 2024.

December 2024: Director of Delivery Mick Foy retired, and the Strategic Programme Delivery team was moved under the Director of Governance.

January 2025: Professor Anthony Harnden joined as the new Chair, ending the shared co-chair role previously held by Non-Executive Directors Amanda Calvert, Graham Cooke and Michael Whitehouse on an interim basis since July 2023.

Chief Healthcare, Quality and Access Officer Laura Squire left the organisation. Following Laura's departure, the Innovative Devices team was integrated into the Innovation and Compliance Group under the leadership of James Pound, Interim Executive Director of Innovation and Compliance.

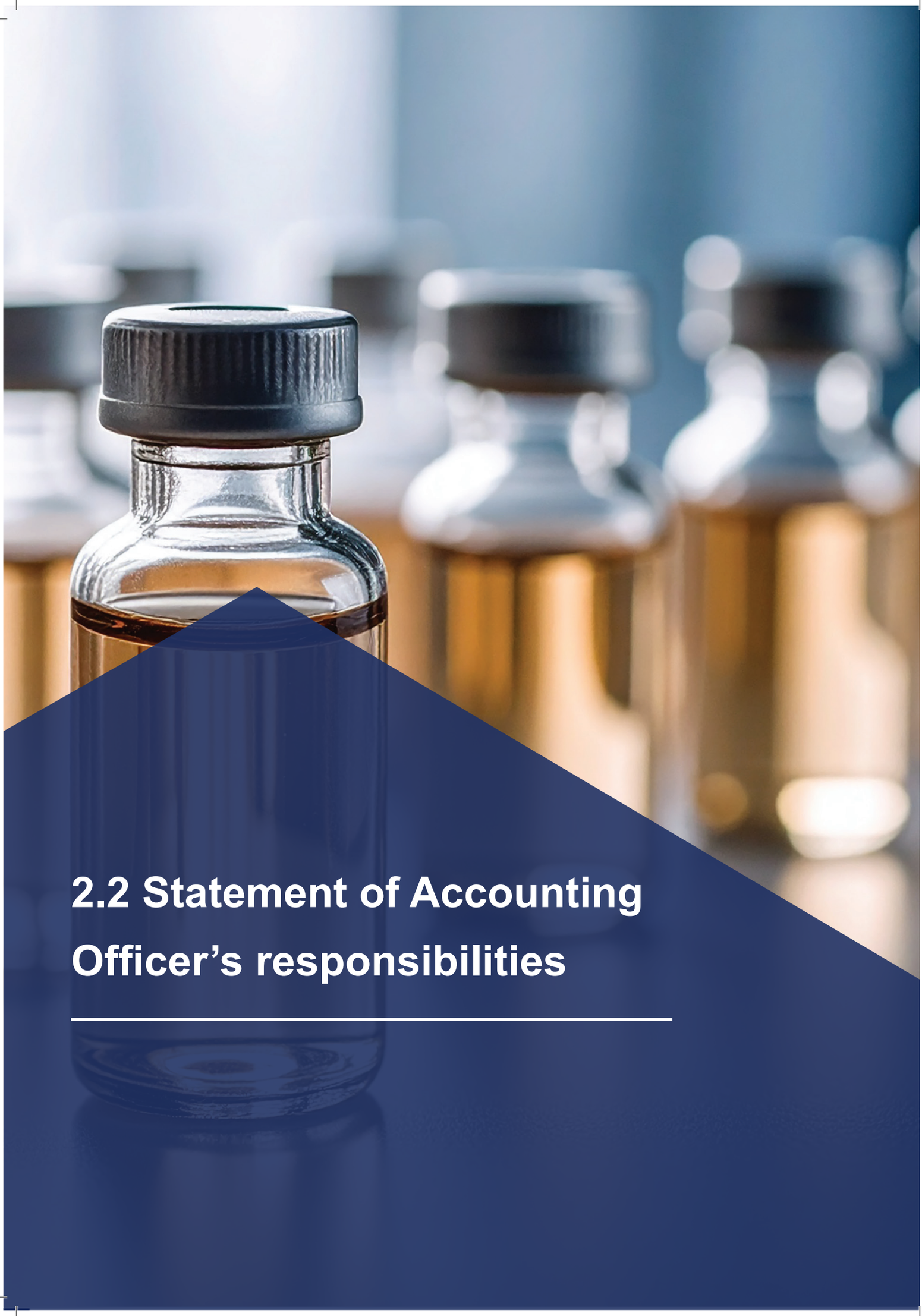
March 2025: Dr June Raine DBE stepped down as CEO on 31 March 2025, with Lawrence Tallon joining the MHRA as CEO on 1 April 2025.

Interim roles have been retained to ensure continuity of leadership, allowing the new Chief Executive and Chair to make informed decisions about the future leadership structure. These changes reflect a strategic approach to maintaining stability while positioning the agency for future growth and innovation.

The ExCo meeting attendance:

Member	Role	ExCo meetings Attended (eligible)
June Raine[1]	Chief Executive (Chair)	20 (25)
Alison Cave	Chief Safety Officer	16 (25)
Laura Squire[2]	Chief Healthcare, Quality and Access Officer	19 (25)
Julian Beach	Interim Executive Director Healthcare, Quality and Access	22 (25)
Glenn Wells[3]	Chief Partnerships Officer	9 (12)
Claire Harrison	Chief Digital and Technology Officer	17 (25)
Rose Braithwaite	Chief Finance Officer	24 (25)
Liz Booth	Chief People Officer	22 (25)
Carly McGurry	Director of Governance	23 (25)
Mick Foy[4]	Director of Delivery	15 (17)
Rachel Bosworth	Director of Communications and Engagement	21 (25)
Nicola Rose	Interim Executive Director Science and Research	20 (25)
James Pound	Interim Executive Director Innovation and Compliance	18 (25)
Harriet Teare and Rachel Arrundale[5]	Interim Director Partnerships (joint)	13 (13)

[1] June Raine stepped down on 31 March 2025.
[2] Laura Squire stepped down on 7 February 2025.
[3] Glenn Wells stepped down on 30 September 2024.
[4] Mick Foy stepped down on 20 December 2024.
[5] Harriet Teare and Rachel Arrundale took up a joint role as Interim Director, Partnerships from 4 November 2024 following the departure of Glenn Wells.



2.2 Statement of Accounting Officer's responsibilities

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

The accounts are prepared on an accruals basis and must give a true and fair view of the state of affairs of MHRA and 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 appointed the Chief Executive of the MHRA as Accounting Officer. This role was held by Dr June M Raine DBE until 31 March 2025 and Lawrence Tallon from 1 April 2025. 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 ExCo, 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.

As the new Chief Executive and Accounting Officer for the MHRA, effective from 1 April 2025, I have taken assurance from Dr June Raine to support my analysis of the strength and breadth of the internal control framework for the 2024/25 reporting year. I have received assurance on compliance with the controls and understand the control issues that were managed during the year. I extend my sincere thanks to Dr Raine for her significant contribution to improving patient outcomes and standards in public health.

Improvements to our internal control environment

This year, we have significantly improved performance across all service lines, strengthened our control environment, and enhanced communication channels. We have transitioned from reactive responses to a proactive approach, empowering staff to manage risks effectively and embed the three lines of defence. Our detailed analysis and mapping of controls has created a robust framework that continuously identifies and manages risks, ensuring effective delivery for patients and the public. Our enhanced communication channels ensure transparency and responsiveness. We will continue to build upon these improvements in the coming year.

Improved performance

Throughout 2024/25, we have maintained a relentless focus on performance. We have successfully addressed and eliminated backlogs in our statutory service areas and redesigned our services to ensure effective processes and enable sustainable performance.

All statutory service lines are now delivering within statutory timelines. As we move into 2025/26, we will continue to implement improvements, in line with the Government's growth agenda, to consistently refine and deliver high-quality services in the interests of patients and the public. Further details about our performance can be found in the performance analysis section on page 50 and on our website (https://www.gov.uk/government/publications/mhra-performance-data/mhra-performance-data).

Strengthened control environment

As a public body, we take our responsibilities to ensure optimal governance seriously. Following our third consecutive Limited assurance rating by Government Internal Audit Agency for 2023/24 we have delivered an Executive-owned improvement programme to strengthen our governance, risk and control. With an uncompromising approach to improving our overall control environment, we have built upon our assurance mapping of the agency, mapping controls across our activities and services, conducted a detailed analysis of the control environment across the three lines of defence and increased our compliance with the Government Functional Standards. Through the programme we have implemented measures to create a more robust and resilient control environment, better equipped to handle security challenges, protect data, ensure health and safety, manage risks, support compliance, maintain our operational integrity and ultimately achieve our objectives.

Enhanced communication channels

Under our commitment to transparency and maintaining public trust we have taken steps to further improve our correspondence handling and performance further. We have significantly improved our Freedom of Information (FOI) performance, maintaining compliance above 97% month on month and reaching 100% in September 2024 and January 2025, with an overall performance of 99% in target across the year. We have increased capability across the agency through dedicated training sessions to support our responses and established dedicated FOI resource, which included deploying a case management system earlier this year. We have worked collaboratively with partners across the Arm's Length Bodies network to share best practices. The publication and disclosure of requests are now available on the MHRA website, including the MHRA FOI performance data and information about the steps taken to improve transparency and maintain public trust (https://www.gov.uk/government/publications/mhra-foi-performance-data).

To support timely resolution of customer enquiries we are piloting approaches to promote increased self-service from the gov.uk website. We are reviewing and improving our guidance and information on our website on how to contact us. The effectiveness of these improvements is being monitored as part of our Customer Strategy, which will launch in 2025/26.

We have updated our Correspondence Handling policy this year to ensure that all staff who handle correspondence respond in a timely manner and maintain consistency in their approach. Our average response time for enquiries through the Customer Experience Centre is now seven working days (compared to ten days in 2023/24). In March 2025, we introduced a new telephony system, enabling us to more accurately track the speed and quality of service provided through our various helplines. We will continue to build on these improvements throughout 2025/26.

In 2024/25, we implemented a series of significant changes aimed at strengthening our control environment and enhancing overall performance. As we move forward, it is essential that these improvements are not only maintained but also embedded into our organisational culture. Sustaining this progress will require ongoing commitment, including the continuous education and engagement of staff at all levels. By fostering a shared understanding of the value these changes bring, we can build upon the foundations laid this year, ensuring that our governance framework remains robust, adaptive, and aligned with our strategic objectives.

Risk and Internal Control Framework

Risk management

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

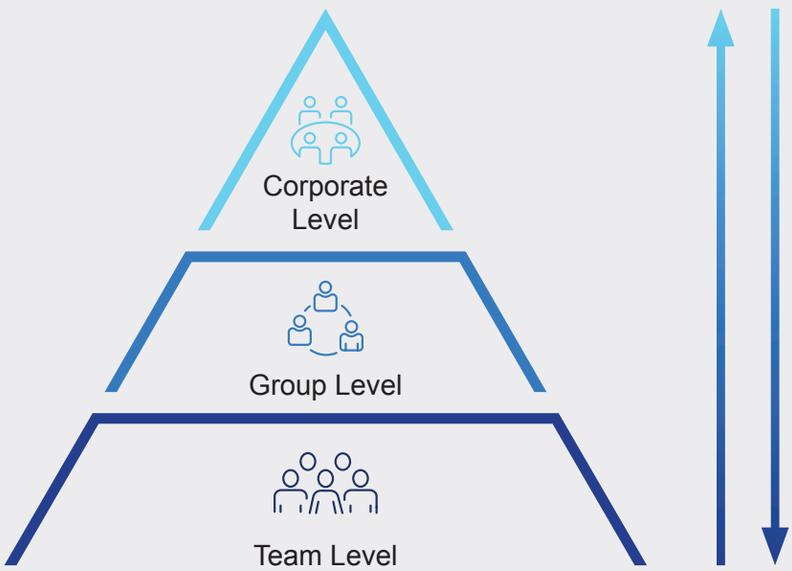
- Identify risks
- Prioritise their management
- Implement an appropriate treatment strategy
- Monitor and report on them to enhance the quality of decision-making

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

Highlights of 2024/25 include:

Publication of our Risk Management Framework

Our new Risk Management Framework provides guidance to staff on the management of risks across three levels and their escalation and de-escalation. Our new framework includes the application of our risk appetite, which supports our prioritisation and management of risks.



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.

This year, we have increased the maturity of our risk management at the group level (middle level), ensuring these risks are recorded and regularly reviewed using our dedicated risk management software and assessing them against our risk appetite to increase their visibility and understand those likely to escalate in the future, enabling us to prepare to mitigate them rapidly.

Risk management practice 2024/25

We manage our highest-level risks (corporate level) and issues using an online reporting system. The ExCo reviews our risk environment monthly, taking decisions on the escalation and de-escalation of risks and issues and developing strategies for risk reduction and the handling of emerging risks. The ARAC scrutinises and challenges our management of risk and issues quarterly, providing assurance to the Board. The Board, in turn, considers the overall risk environment and our risk management approach at least twice each year.

Key corporate risks and issues faced in 2024/25

We recognise the complexity and interconnectivity of the corporate risks and issues we have handled this year. We have highlighted below the key risks and issues considered during 2024/25, with the arrows showing the overall trajectory of the risk throughout the year:

Resourcing

Ensuring the capacity and capability of our staff remained our primary operational issue during 2024/25, as effective resource underpins our ability to deliver for public health and links to our performance risk. This issue is impacted by the requirement for specialist staff in many of our roles, the challenging employment market and competition from the private sector. To mitigate this risk, we have improved our recruitment process and resourcing model to increase the number of permanent staff recruited and reduced our use of contingent labour. We have launched a new graduate scheme, enabling us to equip graduates with the experience and expertise to be able to deliver for the future health environment. During the year, our staff turnover remained below the healthy range, (a maximum of 15%) as defined by the Chartered Institute for Personnel and Development. Risk score 15 (April 2024), risk score 20 (March 2025).

Health and Safety

The work our staff undertake, especially at our Science Campus, carries an inherently high risk, necessitating additional heightened health and safety requirements to protect their well-being. We have reduced the risk score during the year by addressing the recommendations made by the Health and by Safety Executive in March 2024 and by working closely with them through the annual compliance visit programme. The risk score remains high and to mitigate this risk, we continue to increase the capacity in the central team and the capability of staff through dedicated staff training. Risk score 25 (April 2024), risk score 20 (March 2025).

Data protection and information security

In response to the increasing sophistication and frequency of cyber threats against the UK government and given our responsibility for managing critical data related to medical products, it is essential that we prioritise information security and data protection. This year, we have continuously reviewed and enhanced our information security and data protection measures. To mitigate cyber risks, we are replacing our systems with modern, scalable solutions, that offer our customers improved self-service capabilities. Although these mitigations have controlled the risk, the score remained high throughout the year due to the complexity of the implementation of new systems and the persistent nature of cyber threats. Our new Data Protection Officer and specialist team have undertaken numerous initiatives to improve data protection within the agency, significantly reducing the risk likelihood and impact by March 2025. Risk score 16 (Nov 2024), risk score 9 (March 2025).

Performance

This year, we have addressed our performance challenges which were affecting the timeliness of our decisions in some of our service areas. A relentless focus on establishing sustainable performance improvements, through an Executive Committee-led programme, has returned our performance in our statutory services to their required timelines. Work continues into 2025/26 on our response to scientific advice requests and in areas aligned with our growth agenda. Key mitigations to our performance issue have been the optimisation of our processes, the use of skilled external and internal resource, and transparent communication with customers and other key stakeholders. Risk score 20 (July 2024), risk score 10 (March 2025).

Appropriate and proportionate engagement with patients and public

We strive to place the patient at the heart of every decision we make when we regulate medical products for the UK. This year we have worked with patients and their representatives to optimise their engagement in our key decision areas, and we continue to build relationships with stakeholders across the health system as part of our Patient and Public Involvement Strategy. The score for this risk was reduced during the year. Risk score 12 (April 2024), risk score 9 (March 2025).

Assurance

In line with the Orange Book, we have adopted the Three Lines model for assurance to oversee our governance, risk management, and control environment:

First-line assurance
Ensuring effective managerial and supervisory controls

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
Provided primarily by the independent audit function of the Government Internal Audit Agency, as well as oversight by the Department of Health and Social Care and external sources such as Health and Safety Executive compliance audits and independent inspections

This year, we have significantly evolved the mapping of our control environment using a process-based approach. Our comprehensive map has enhanced our understanding of our control environment, enabling us to proactively identify opportunities for improvement and develop aligned action plans to deliver these. We have developed a controls alignment approach for detailed analysis of the control environment in specific areas and services. This has been crucial in maturing controls within specific services and holds potential for enhancing controls across services that span multiple teams and involve handovers. Controls alignment activities will continue into 2025/26.

Health and safety

Our health and safety policy commits to protecting our staff from harm and safeguarding their health and well-being. We undertake a wide range of activities, including some higher risk scientific activities at our Science Campus, requiring some specific health and safety management processes to be in place.

At the start of the year, we redesigned our health and safety governance with the introduction of an executive-level interim health and safety committee responsible for reviewing, scrutinising and challenging our health and safety activities. We have undertaken an external review of our health and safety through a Government Internal Audit Agency audit, receiving a Moderate assurance rating. We were assessed as meeting a standardised/ predictable level on the Health and Safety Executive maturity model. In addition, the activities at the Science Campus are subject to an annual intervention plan that details visits by the Health and Safety Executive. This year we acted robustly to address the Improvement Notice issued to us in March 2024, making enhancements to our monitoring, inspection and auditing procedures, and improving the process for risk assessment and application of human factors. The Health and Safety Executive was satisfied with our improvements and have closed out the notice. We have enhanced our health and safety team, through the recruitment of a dedicated biological safety resource to provide further resilience in this area. Further information about our management of health and safety can be found in our health and safety report on page 79.

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 18, 82 and 153 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. We have fully met the requirements of the Counter Fraud Functional Standard since 2023/24 and are now working towards meeting the Continuous Improvement Assessment Framework.

Raising a concern/whistleblowing

We encourage our employees to raise a concern if they believe there may have been wrongdoing or 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 challenging 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 Well-being Champions and Fair Treatment Ambassadors. Staff approached the MHRA’s Nominated Officers throughout the year for support and advice, and there was one formal whistleblowing case that was investigated.

Anyone can raise concerns with the MHRA about the MHRA itself or the organisations that the MHRA regulates. Contact details are on our website: https://www.gov.uk/guidance/contact-mhra.

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 MHRA's work. Our policy is clear, staff are prohibited from holding interests in the industries regulated by the MHRA.

Non-Executive 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. https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/about/our-governance#board-members-declarations-of-interest. 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 page 91 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 (COI) evaluates and implements mitigations for potential conflicts, allowing us to maintain transparency while ensuring vital public health work continues uninterrupted. The COI Group's annual compliance report is available online (https://www.gov.uk/government/publications/mhra-policy-for-handling-conflicts-of-interest).

Details of any transactions involving organisations connected to any of our Executive or Non-Executive Directors, as key management personnel, are disclosed in the Related Parties note of the Annual Report and Accounts on page 181.

Human rights, staff well-being and the Modern Slavery Act

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 our implementation of various policies and practices, including 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.

We ensure that our supply chain complies with all legal requirements including the Modern Slavery Act (2015), which is aligned with the Cabinet Office PPN 02/23: Tackling Modern Slavery in Government Supply Chains guidance.

Information governance

Our Chief Digital and 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 2024/25, we have:

- Aligned our security risk management with industry and HM Government standards, including the National Cyber Security Centre Cyber Assessment Framework, and met the Data Security Protection Toolkit standards (DSPT), benchmarked against the National Data Guardian's standards, receiving a Moderate assurance rating for our DSPT audit from the Government Internal Audit Agency (GIAA). We have improved our GIAA rating, taking it from the lowest rating to the second highest rating in twelve months
- Strengthened our governance over security, including information security, cyber security and physical security, through creation of a new security risk working group to provide support and challenge
- Increased our compliance with GovS007 Security Functional Standard and introduced Secure by Design Principles as set out by the Cabinet Office
- Undertaken weekly information-sharing meetings with the DHSC Data Protection Office team, to align with best practice and provide assurance
- Engaged in the Joint Cyber Unit, comprising representatives from the DHSC and arm's length bodies, and worked closely with the NHS England Cyber Security Team, facilitating collaboration on emerging security issues and best practice
- Increased capacity in our information security team through the recruitment of additional specialist resource
- Provided cyber security and information security training to 97% of our staff

Despite facing a high volume of attempted cyberattacks and phishing attempts, our robust preventative controls have detected and resisted threats effectively. Detailed projects to ensure effective and robust controls are managed through our dedicated Cyber Programme aimed at improving our cyber security posture whilst reducing cyber security risk.

Information security statistics

In 2024/25, one cyber incident was reported, with no disruption to end users or customers, and there were no information security incidents.

This year, we have seen an increase in malware emails but a decrease in phishing and spam emails.

- **6,362 malware emails blocked** (compared with 4,626 in 2023/24)
- **90,506 phishing emails blocked** (compared with 113,542 in 2023/24)
- **1,816,502 spam emails blocked** (compared with 2,475,455 in 2023/24)

Personal data incidents

The MHRA has formally reported two data breaches to the Information Commissioner's Office (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 that did not require reporting to the ICO were recorded centrally within the MHRA.

Compliance with Government Functional Standards

We adhere to best practice and guidance as set out in the Government Functional Standards. We have assessed our compliance as fully meeting the mandated requirements in six of the standards (compared with four in 2023/24), and over 90% compliant with a further three standards. We have a programme of work in progress to address the elements not yet fully met, and this is being driven and monitored centrally. We are aiming for full compliance with the mandated elements of all relevant Functional Standards by March 2026.

Control environment

Control environment improvements

This year, we have made significant improvements in our performance, governance, risk management, and control environment, elevating our agency from a Limited assurance rating from GIAA in 2023/24 to a Moderate rating in 2024/25. This shift demonstrates our commitment to addressing identified weaknesses, as well as identifying potential for improvements before weaknesses materialise. Through establishing robust improvements in all corporate and operational areas, we have transitioned to a proactive control environment that delivers effective regulation in the interests of patients and the public.

We are dedicated to maintaining high ethical standards and transparency in our activities, and ensuring a responsive customer service culture. This year, we have improved our response times for freedom of information (FOI) requests and correspondence handling, maintaining compliance above 97% for FOI on-time responses, supported by our new electronic case management system. We have aligned our analysis of complaints and strengthened Executive-level scrutiny to ensure we maintain and further improve these performance levels.

In September 2024, we launched a three-year strategy to improve our safety communications, underpinned by meaningful consultation with healthcare professionals. This strategy is transforming the way we communicate about the risks and safety of medicines, medical devices, and healthcare products. Recognising that multiple entry points to communicate with the MHRA could create delays, we are consolidating phone lines into a single telephone contact centre system for 2025/26 to enhance responsiveness and call quality. We are also modernising our enquiry handling systems and standardising service delivery to continue putting customers at the heart of all we do

The health, safety, and well-being of our staff and stakeholders are of utmost importance. This year, we have made significant improvements to our health and safety governance. We have recruited new specialist resources and introduced enhanced Executive-level oversight of health and safety. We have provided staff with training to support their vigilance in identifying health and safety risks and promoting their positive well-being. Our new Code of Business Conduct has helped staff understand our expectations as part of our governance framework, and captures both civil service and MHRA values.

We are committed to improving our digital environment by addressing legacy technologies and maximising innovation benefits whilst adhering to cross-government cyber resilience activities. This year, we have significantly enhanced our digital control environment by aligning our security risk management with industry and HM Government standards, including the National Cyber Security Centre Cyber Assessment Framework. We have met the Data Security Protection Toolkit standards, benchmarked against the National Data Guardian’s standards, and increased compliance with the GovS007 Security Functional Standard, embedding Secure by Design principles aligned with the Cabinet Office requirements. We continue to address recommendations from” GIAA audits and other compliance reviews.

Our engagement across the health system has aligned with best practices and enabled a collaborative approach to emerging security issues. We have established a security risk working group to holistically oversee security risks and provided cyber security and information governance training to 97% of our staff. We have introduced new systems and enhancements to improve our digital infrastructure, enhancing user experience and enabling efficiencies across services. There have been some challenges in developing our new RegulatoryConnect system, which is taking longer than anticipated. However, we remain committed to delivering additional phases of the implementation programme during 2025/26.

Quality underpins everything we do, and we remain committed to operating an effective quality system. Our business plan signalled our commitment to quality management, and we demonstrated tangible improvements at our annual quality audit in January 2025. We have strengthened our central quality team and launched new electronic quality management system software to support whole enterprise aligned quality management. We have piloted the use of quality circles and peer review to support our decision-making. We are determined to build on these achievements in 2025/26, ensuring every decision and action aligns with our quality ambitions.

We have undertaken a substantial legislative reform programme, including the implementation of the medicines arrangements under the Windsor Framework in January 2025, new regulations to clarify and strengthen Post-Market Surveillance Requirements for medical devices coming into force in June 2025, and the extension of transitional arrangements for CE-marked devices. We are also adopting a phased approach to implement a new regulatory framework for medical devices, which will continue into 2025/26.

Additionally, we reformed the UK Clinical Trials Regulations, putting patients firmly at the centre whilst supporting more streamlined approvals, and introduced a new legislative framework for innovative manufacturing, enabling medicines to be made closer to where the patient receives their care.

Internal Control Issues 2024/25

In our 2023/24 annual report and accounts, we identified an issue involving workers appointed through service contracts who were not subject to status determination controls. During 2024/25 we have strengthened controls to prevent recurrence, including the embedding of preventative measures in our recruitment and procurement processes and targeted training for staff. While we have made significant progress in addressing the issue, resolution has taken longer than expected. A small number of contractors remain in highly specialised roles, where careful management of capacity and capability risks is essential. We are prioritising the resolution of these remaining non-compliant contracts and are actively engaging with HMRC to determine the financial implications and to gain assurance on the robustness of our controls.

Performance across several statutory service areas was below expected standards at the start of 2024/25, with known backlogs and delays. Recognising this as a critical control issue, we implemented a detailed improvement plan focused on clearing backlogs and redesigning service processes to ensure sustainable performance. This was a significant undertaking that required time, dedication, and coordinated effort across the agency. While performance remained a control concern for much of the year, we are pleased to report that by year-end, all statutory services were operating within required timelines. The improvements made have strengthened our operational controls and laid the groundwork for continued progress. We are now extending this work to non-statutory service areas, such as scientific advice, to ensure consistent delivery and further embed resilience across our operations.

Head of Internal Audit (HIA) Opinion

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

During 2024/25, the GIAA completed 10 audit engagements; one was rated as Substantial, eight were rated as Moderate, one was rated as Limited and there were no Unsatisfactory rated audits. GIAA made a total of 39 recommendations, of which 27 were medium priority and 12 were low priority. There were no high priority recommendations made. The themes identified through the audit programme were capability and training, policies and procedures and use of contractors and the impact of this on knowledge transfer. We have set management actions to address the recommendations, and these will be delivered over the coming months.

The GIAA Annual Opinion for 2024/25 was Moderate, indicating an improved governance, risk and control environment. This represents the huge amount of work undertaken to strengthen the control environment during the year. 90% of audits were given moderate or substantial assurance in 2024/25 compared with 62% positive assurance in 2023/24. GIAA noted the considerable progress made in developing our assurance maps, as part of our wider assurance framework.

Audit	GIAA Opinion
DSPT	Moderate
Budgeting and financial management	Moderate
Cost modelling	Moderate
Signals management	Substantial
Licensing	Moderate
Operational information sharing with cross-UK health system partners	Moderate
Board and subcommittee effectiveness	Moderate
Notification and recording of CPRD, research data quality issues	Moderate
Insider risk	Limited
RegulatoryConnect release 2 service readiness	Moderate

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. I have also received assurance from Dr June M Raine DBE, the outgoing CEO of the MHRA, of the effectiveness of the MHRA governance structures, risk management and internal control framework throughout 2024/25 to support my assessment of the year.

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 HIA's opinion on the overall adequacy of the MHRA's internal control framework, which is reported in this annual report (page 117)

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 2025 and up to the date of approval of the Annual Report and Accounts.

In the control environment section of this report (page 116), I have provided details of the internal control matters that 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 actions 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, satisfied with our response to address control weaknesses throughout the year. I am also assured by the improvements made to the control framework as a whole this year, with plans to build further on this throughout 2025/26.

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, and a firm foundation of controls has been established. However, the work to ensure a robust control environment cannot end here. Maintaining a robust and effective control environment will require a continuous cycle of proactive improvements alongside reactive responses, and this will be a continual focus for 2025/26.

While taking into account the specific weaknesses identified in earlier sections of this report and drawing on the improving trajectory recognised by the HIA's 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 2024/25.

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 June Raine as outgoing CEO, the HIA, 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.

11 July 2025

Lawrence Tallon
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 MHRA 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 is 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 must be in line with the values 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)

2024/25	Salary £'000	Performance pay and bonuses £'000	Pension related benefits* £'000	Single total for remuneration £'000
June Raine, DBE Chief Executive Officer	160–165	0–5	119	285–290
Rose Braithwaite[1] Chief Finance Officer	120–125	0–5	48	175–180
Liz Booth Chief People Officer	115–120	Nil	47	165–170
Alison Cave Chief Safety Officer	155–160	0–5	61	220–225
Claire Harrison Chief Digital and Technology Officer	145–150	Nil	57	200–205
Glenn Wells[2] Chief Partnerships Officer	60–65	Nil	25	85–90
Laura Squire, OBE[3] Chief Healthcare Quality and Access Officer	105–110	Nil	196	300–305
Julian Beach Interim Executive Director Healthcare Quality and Access	120–125	Nil	48	165–170
Nicola Rose Interim Executive Director, Science and Research	115–120	Nil	46	160–165
James Pound Interim Executive Director, Innovation and Compliance	110–115	0–5	44	160–165
Rachel Arrundale[4] Interim Director, Partnerships	40–45	Nil	38	80–85
Harriet Teare[5] Interim Director, Partnerships	40–45	Nil	15	55–60

[1] Rose Braithwaite moved to part time hours on 1st December 2024. Full time equivalent salary £130k–£135k.
[2] Glenn Wells left the MHRA on 30 September 2024. Full year equivalent £125k–£130k.
[3] Laura Squire OBE left the MHRA on 7 February 2025. Full year equivalent £120k–£125k.
[4] Rachel Arrundale was appointed Interim Director, Partnerships on a job share basis on 4 November 2024. Full year equivalent £90k–£95k.
[5] Harriet Teare was appointed Interim Director, Partnerships on a job share basis on 4 November 2024. Full year equivalent £90k–£95k.

2023/24	Salary £'000	Performance pay and bonuses £'000	Pension related benefits* £'000	Single total for remuneration £'000
June Raine, DBE Chief Executive Officer	155 –160	0–5	67	220–225
Rose Braithwaite Chief Finance Officer	125–130	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 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 increase or decrease due 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 £125k–£130k.
[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.

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

2024/25	Salary £'000	Benefits in kind (taxable) to nearest £100	Total £'000
Anthony Harnden[1] Non-Executive Director, Chair	15–20	Nil	15–20
Junaid Bajwa Non-Executive Director	5–10	Nil	5–10
Amanda Calvert Non-Executive Director	15–20	3,700	20–25
Graham Cooke Non-Executive Director	15–20	Nil	15–20
Paul Goldsmith Non-Executive Director	5–10	2,900	10–15
Mercy Jeyasingham, MBE Non-Executive Director	5–10	200	5–10
Raj Long Non-Executive Director	5–10	500	5–10
Michael Whitehouse, OBE Non-Executive Director and ARAC chair	15–20	200	15–20
Haider Husain Non-Executive Director	5–10	1,000	5–10

[1] Professor Anthony Harnden was appointed Chair on 1 January 2025. Full year equivalent £60k–£65k.

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	5–10	4,500	10–15
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.

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 2024/25 relate to performance in 2023/24 and the comparative awards reported in 2023/24 relate to performance in 2022/23.

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 of 31 March 2025 was £160k–£165k (2023/24 was £155k–£160k). In 2024/25 two employees (2023/24, no employee) received remuneration in excess of the highest paid Chief Officer. Remuneration ranged from £8k to £227k (2023/24 £8k–£156k).

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
2024/25	4.37	3.45	2.53
2023/24	4.44	3.50	2.46

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:

	2024/25			2023/24		
	25th percentile	Median	75th percentile	25th percentile	Median	75th percentile
Total pay and benefits	£37,198	£47,132	£64,196	£35,468	£44,974	£64,003
Salary component	£36,760	£46,224	£62,315	£35,010	£44,023	£61,841

Percentage change from the previous financial year

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

% change — Highest paid Chief Officer	2024/25 Increase/(decrease) %
Salary and allowances	4.85
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	2024/25 Increase/ (decrease) %
Salary and allowances	2.39
Performance pay and bonuses	(7.34)

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:

2024/25	Real increase in pension and related lump sum at 60 £'000	Total accrued pension at age 60 on 31 March 2025 and related lump sum £'000	Cash Equivalent Transfer Value on 1 April 2024 £'000	Cash Equivalent Transfer Value on 31 March 2025 £'000	Real increase in Cash Equivalent Transfer Value £'000	Employers Contribution to stakeholder pension £'000
June Raine, DBE Chief Executive	5.0–7.5 plus 2.5–5.0 lump sum	85–90 plus a lump sum of 220–225	1,430	1,504	82	47
Rose Braithwaite Chief Finance Officer	2.5–5.0 plus Nil lump sum	5–10 plus Nil lump sum	93	149	38	36
Liz Booth Chief People Officer	2.5–5.0 plus Nil lump sum	15–20 plus Nil lump sum	253	320	38	35
Alison Cave Chief Safety Officer	2.5–5.0 plus Nil lump sum	20–25 plus Nil lump sum	252	334	47	46
Claire Harrison Chief Digital and Technology Officer	2.5–5.0 plus Nil lump sum	10–15 plus Nil lump sum	109	165	36	43
Glenn Wells[1] Chief Partnerships Officer	0–2.5 plus Nil lump sum	10–15 plus Nil lump sum	149	181	16	19
Laura Squire, OBE[2] Chief Healthcare, Quality and Access Officer	7.5–10.0 plus 20.0–22.5 lump sum	60–65 plus a lump sum of 130–135	1,171	1,389	200	31
Julian Beach Interim Executive Director Healthcare, Quality and Access	2.5–5.0 plus Nil lump sum	5–10 plus Nil lump sum	47	92	33	35
Nicola Rose Interim Executive Director Science and Research	2.5–5.0 plus Nil lump sum	20–25 plus Nil lump sum	249	311	33	34
James Pound Interim Executive Director Innovation and Compliance	2.5–5.0 plus Nil lump sum	30–35 plus Nil lump sum	370	432	24	32
Rachel Arrundale[3] Interim Director, Partnerships	0–2.5 plus Nil lump sum	20–25 plus Nil lump sum	351	390	31	10
Harriet Teare[4] Interim Director, Partnerships	0–2.5 plus Nil lump sum	0–5 plus Nil lump sum	44	54	8	10

Note: Accrued pension benefits included in this table for any individual affected by the Public Service Pensions Remedy have been calculated based on their inclusion in the legacy scheme for the period between 1 April 2015 and 31 March 2022, following the McCloud judgment. The Public Service Pensions Remedy applies to individuals that were members, or eligible to be members, of a public service pension scheme on 31 March 2012 and were members of a public service pension scheme between 1 April 2015 and 31 March 2022. The basis for the calculation reflects the legal position that impacted members have been rolled back into the relevant legacy scheme for the remedy period and that this will apply unless the member actively exercises their entitlement on retirement to decide instead to receive benefits calculated under the terms of the Alpha scheme for the period from 1 April 2015 to 31 March 2022.

[1] Glenn Wells left MHRA on 30 September 2024.
[2] Laura Squire OBE left the MHRA on 7 February 2025.
[3] Rachel Arrundale was appointed on 4 November 2024.
[4] Harriet Teare was appointed on 4 November 2024.

2023/24	Real increase in pension and related lump sum at pension age £'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 plu 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 plu Nil lump sum	218	293	58	38
Claire Harrison Chief Digital and 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	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 was appointed 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.

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 pensions 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 the normal pension age. The 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 that 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".

For members who are in the 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 2024 and 31 March 2025 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 occupationally defined contribution pension arrangement that 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

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 2024/25, employer contributions for the MHRA employees of £20.5m were payable to the PCSPS (2023/24, £16.8m) at one of four rates in the range of 26.6% to 30.3% of pensionable pay (2023/24, 26.6% to 30.3%. 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 previous experience of the scheme.

Employees can opt to open a partnership pension account, which is a stakeholder pension with an employer contribution. Employer contributions of £177k (2023/24, £161k) were paid to the appointed stakeholder pension provider. Employer contributions are age-related and range from 3% to 12.5% of pensionable pay (2023/24, 3% to 12.5%). Employers can also match employee contributions up to a limit of 3% of pensionable pay. In addition, employer contributions of £5k (2023/24, £5k), 0.8% 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 2024/25, (2023/24: 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 into 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)

2024/25				2023/24
	Total £'000	**Permanently Employed £'000**	**Other £'000**	**Total £'000**
Wages and salaries	**79,055**	76,586	2,469	69,673
Social security costs	**8,581**	8,581	-	7,782
Other pension contributions	**20,489**	20,489	-	17,005
Sub-total	**108,125**	105,656	2,469	94,460
Less recoveries in respect of outward secondment	**(0)**	(0)	-	(5)
Total	**108,125**	**105,656**	**2,469**	**94,455**

See the Remuneration and Staff Report on page 120.

During the year, an average of 1,411 staff were employed and on 31 March 2025, the agency employed 1,553 staff.

2024/25

	Total	Permanently Employed	Other*
Chair	1	1	-
Chief Executive/Chief Officers	10	9	1
Senior Civil Servants	136	128	8
Other Civil Service Staff	1,406	1,171	235
Total	**1,553**	**1,309**	**244**

*Includes contingent workers.

2023/24

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

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

Cost band	Total Number of exit packages by cost band	
	2024/25	2023/24
<£10,000	-	-
£10,000–£25,000	1	-
£25,000–£50,000	-	-
£50,000–£100,000	-	1
£100,00–£150,000	-	-
£150,000–£200,000	-	-
Total number of exit packages	**1**	**1**
Total resource cost	**£15,709**	**£95,000**

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 upon 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 £16k (2023/24, £95k) are included in wages and salaries and shown on the exit package table.

Spend on temporary staff

During 2024/25, expenditure on consultants was £484k (2023/24, £310k).

The MHRA continues to employ temporary staff where it is of operational necessity. The MHRA temporary staff expenditure was £2.5m in 2024/25 (2023/24, £3.1m).

Off-payroll engagements

For all off-payroll engagements as of 31 March 2025, for more than £245 per day	
Number of existing engagements as of 31 March 2025	**43**
Of which, number that existed less than one year	36
for between 1 and 2 years	3
for between 2 and 3 years	0
for between 3 and 4 years	0
for 4 years or more	1
Number of temporary off-payroll workers engaged between 1 April 2024 and 31 March 2025	**103**
Of which	
Number not subject to off payroll legislation	0
Number subject to off-payroll legislation and determined as in scope of IR35	103
Number subject to off-payroll legislation and determined as out of scope of IR35	0
Number of engagements reassessed for compliance or assurance purposes during the year	30
Of which: number of engagements that saw a change to IR35 status following review	30

For any off-payroll engagements of board members, and/or, senior official with significant financial responsibility, between 1 April 2023 and 31 March 2025	
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	12

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 are in discussion with HMRC. During 2024/25 MHRA made an interim payment of £2m to HMRC towards the calculated liability.

The Government Apprentice scheme

The MHRA paid approximately £0.4m 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 and a recognition that apprenticeships need to be appropriate in terms of current and future roles. While there is still room for improvement, the agency has made meaningful progress towards ensuring that the use of the apprenticeship levy meets this end and continues to factor into workforce plans.

Aligning with the Government's Apprenticeship Strategy (published April 2022) and commitment to one in 20 Civil Servants being apprentices by 2025, we worked towards an appropriate action plan supporting this aim, as well as launching a development programme that enrolled a cohort of 22 colleagues from across the agency to undertake the L7 Senior Leader Apprenticeship.

It is recognised that entry-level apprenticeships are especially important in aiding social inclusion. This year, apprenticeship recruitment at entry level has maintained 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 acquire 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 long-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 63 live apprenticeships in the agency, a significant increase from the 40 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 and recruitment of entry-level apprentices.

The MHRA's Graduate Scheme

The MHRA's Graduate Scheme was launched in 2023 to support the agency's talent pipeline and commitment to creating an agency where people flourish. While the scheme is still in the pilot phase, the initial proof of concept has been positive, and a subsequent campaign was launched to recruit a further cohort of eight to start at the agency in September 2025.

Participants in the scheme rotate across the agency's four 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

Our 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 6.5 working days per full time equivalent employee (2023/24, 5.7 days).

The annual voluntary turnover for the agency was 5.8% (2023/24, 7.8%).

Civil Service People Survey

The annual Civil Service People Survey was live in September and October 2024 and 63% of the workforce took part in the survey. Our engagement score results were 59% (58% in the 2023 survey). The Civil Service benchmark score for 2024 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 well-being, workloads and trust in leadership will inform thoughts and actions going forward. Our approach is to recognise that a healthy workforce where workloads are manageable will enable our staff to flourish.

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 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 Medicines and Healthcare products Regulatory Agency staff only. The statutory reporting requirement is met through the entity's underlying Annual Report and Accounts, where an entity is in scope of this requirement.

Relevant union officials

Number of employees who were relevant union officials during the relevant period	Full-time equivalent employee number
19	18.7

Trade Union percentage of time spent on facility time

Percentage of time	Number of employees
0%	3
1–50%	16
51–99%	0
100%	0

Percentage of pay bill spent on facility time

Description	Figures
Total cost of facility time	£33,859
Total pay bill	£108,351,000
Percentage of the total pay bill spent on facility time*	0.03

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

Paid Trade Union activities

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

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

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 well-being offer to support staff at all times through learning and development, promotion of the well-being programme and signposting for sources of support. We have appointed four Board-level Champions who will support Well-being, Sexual Orientation, Race and Disability.

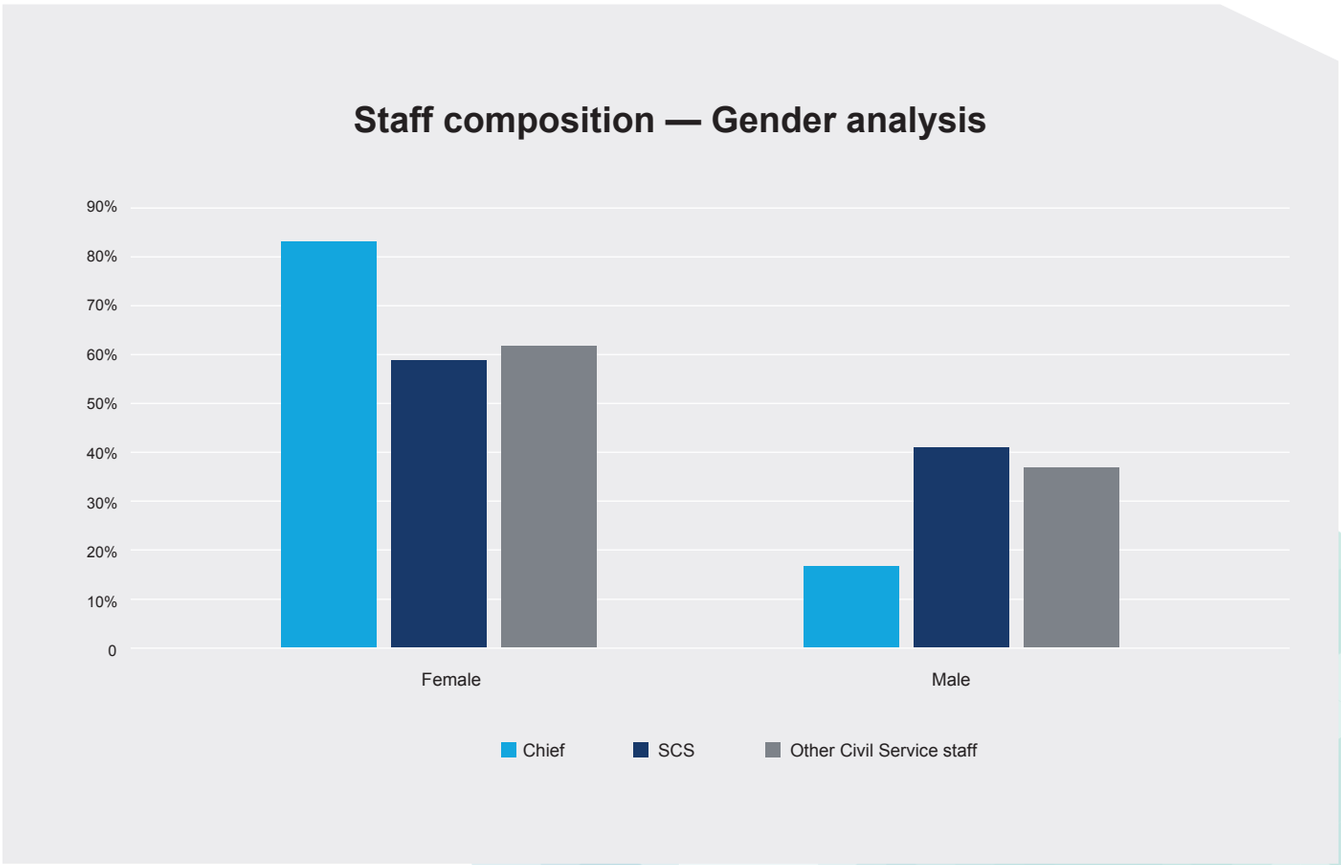
We have a Disability Confident Scheme (DCS) for job candidates with disabilities who meet the minimum selection criteria when applying for roles. We operate an open and fair recruitment process that is fully compliant with the Civil Service Commission Recruitment Principles.

We are committed to supporting staff through occupational health support, health and safety support and guidance. In addition to this, we 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 well-being issues on our intranet as part of a planned programme to increase awareness of diversity, inclusion and well-being 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 2025/26.

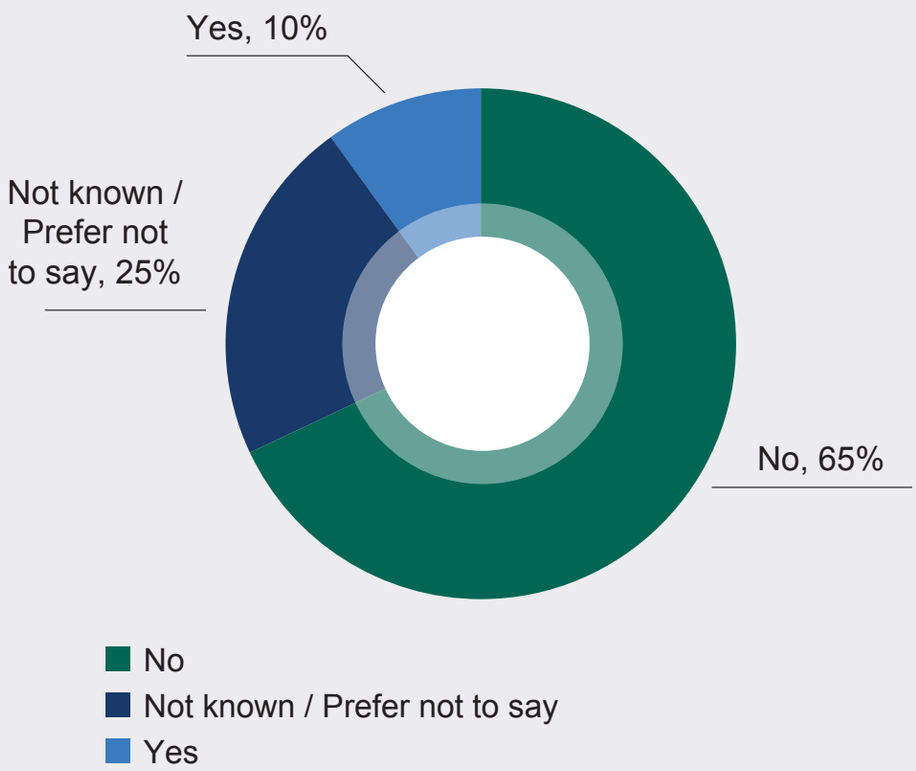
Staff composition

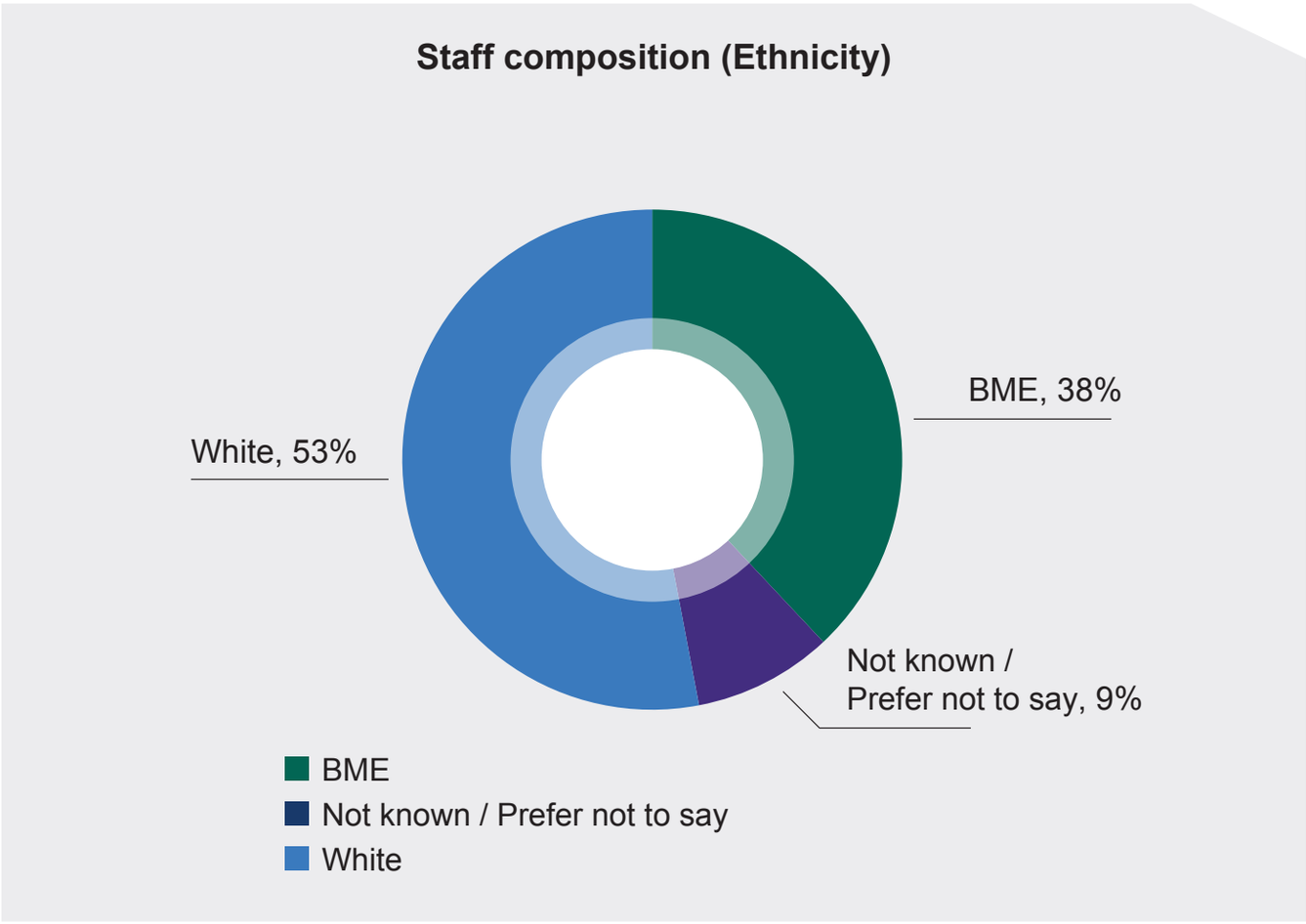
Gender analysis*	Male	Female
Chairman/Chief Executive/Chief Officers	17%	83%
Senior Civil Servants	41%	59%
Other Civil Service Staff	38%	62%
Total	**39%**	**61%**

*Of those who declared.



Staff composition (Disability)

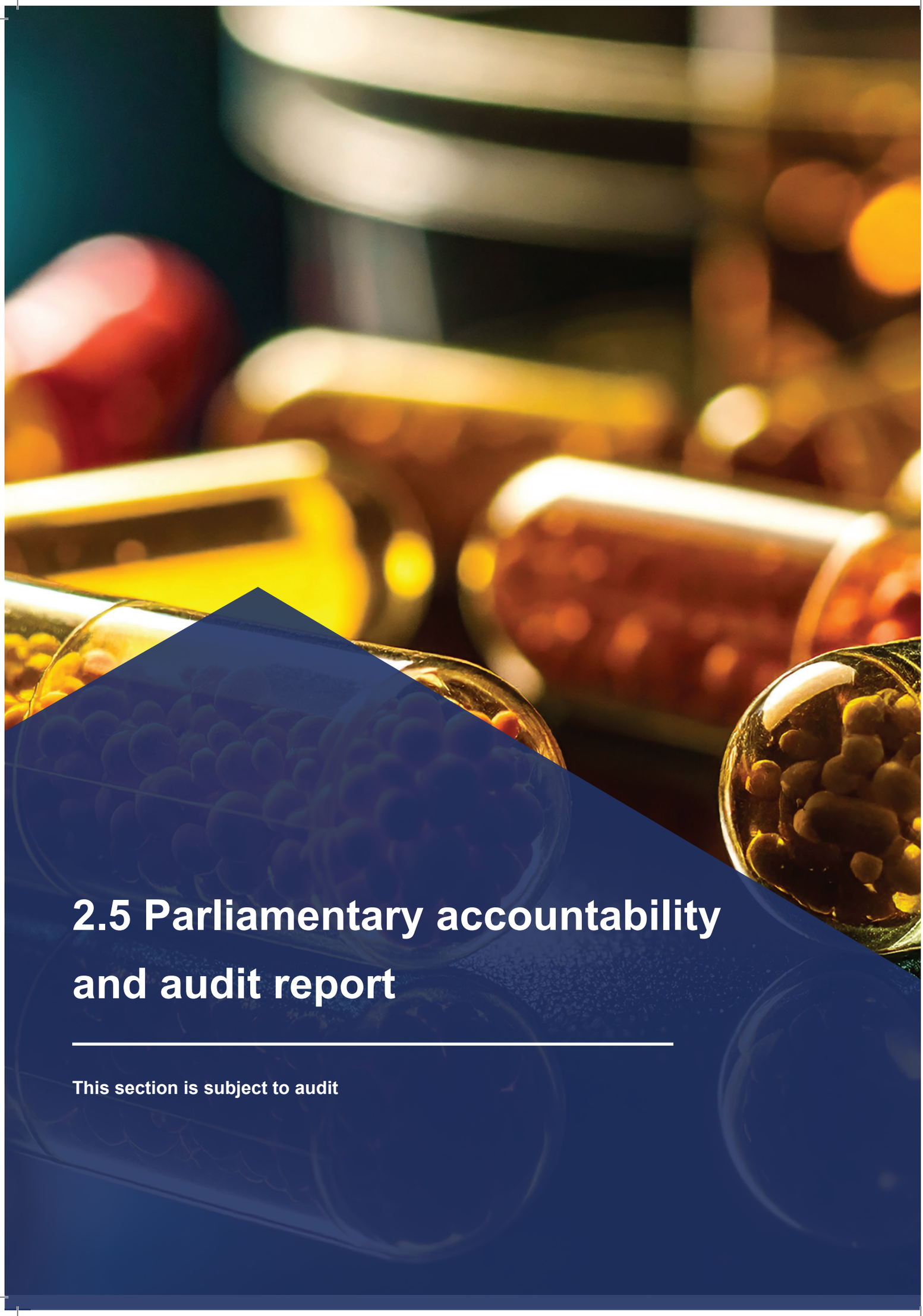




Gender pay gap

The gender pay gap shows the difference in the average pay between all men and women in a workforce. We produce an annual gender pay gap report, which is published on the DHSC website. Our 2024 gender pay gap was 7.7% (mean) and 13.9% (median). The full report can be found here: 2024 gender pay gap report — GOV.UK https://www.gov.uk/government/publications/dhsc-gender-pay-gap-report-and-data-2024/2024-gender-pay-gap-report

Our action plan to reduce pay gaps focuses on narrowing pay ranges through future pay awards and strengthening the Pay Committee process to ensure consistent review of all starting salary requests above the minimum. We continuously review recruitment policies to promote fairness and equality, and we closely monitor the entire recruitment journey—from job posting to job offer—to ensure inclusive practices. Talent Management initiatives are designed to include a diverse mix of participants, and we track their impact. We also support parents returning from parental leave or career breaks and have refreshed our staff networks in line with our 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. The MHRA is supported by £64.0m of funding from the DHSC, reported in the Statement of changes in taxpayers' equity. After consideration of DHSC funding on the deficit below, a surplus of £20.6m is made.

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

2024/25	£'000 Income	£'000 Expenditure	£'000 Surplus/ (Deficit)
Licensing	43,101	(51,078)	(7,977)
Inspections	7,606	(13,919)	(6,313)
Vigilance, Risk Management and Enforcement	46,757	(40,664)	6,093
British Pharmacopoeia	6,366	(6,715)	(349)
Devices	4,043	(8,066)	(4,023)
Clinical Trials	4,076	(2,944)	1,132
Tobacco Products Directive	2,326	(1,413)	913
CPRD	17,868	(20,604)	(2,736)
Research	24,847	(55,827)	(30,980)
Other non-attributable	1,510	(666)	844
Total	**158,500**	**(201,896)**	**(43,396)**

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)**

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 or losses in excess of £0.3m during the financial year.

11 July 2025

Lawrence Talon
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 (MHRA) for the year ended 31 March 2025 under the Government Resources and Accounts Act 2000.

The financial statements comprise the MHRA's:

- statement of Financial Position as at 31 March 2025;
- 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 MHRA's affairs as at 31 March 2025 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 (2024)*. 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 2024*. I am independent of the MHRA 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 MHRA'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 MHRA'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 MHRA 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 Performance and Accountability Reports. 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.

Opinions 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 issued under the Government Resources and Accounts Act 2000; and

- 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 MHRA 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 MHRA 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 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 MHRA 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;

- preparing financial statements which give a true and fair view and are prepared in accordance with HM Treasury directions made under the Government Resources and Accounts Act 2000;

- preparing annual report, which includes the Remuneration and Staff Report, is prepared in accordance with HM Treasury directions issued under the Government Resources and Accounts Act 2000; and

- assessing the MHRA'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 Chief Executive anticipates that the services provided by the MHRA 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 MHRA's accounting policies;
- inquired of management, the MHRA's Head of Internal Audit and those charged with governance, including obtaining and reviewing supporting documentation relating to the MHRA'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 MHRA's controls relating to the MHRA's compliance with the Government Resources and Accounts Act 2000 and Managing Public Money;
- inquired of management, the MHRA'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 MHRA 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 MHRA's framework of authority and other legal and regulatory frameworks in which the MHRA 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 MHRA. The key laws and regulations I considered in this context included Government Resources and Accounts Act 2000, Managing Public Money and employment law.

Audit response to identified risk

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

- I reviewed the financial statement disclosures and supporting documentation to assess compliance with provisions of relevant laws and regulations described above as having direct effect on the financial statements;
- I enquired of management and the Audit and Risk Assurance 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
- I addressed the risk of fraud through management override of controls by testing the appropriateness of journal entries and other adjustments, assessing whether the

judgements on estimates are indicative of a potential bias; and evaluating the business rationale of any significant transactions that are unusual or outside the normal course of business,

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.

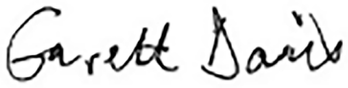
Other auditor's responsibilities

I am required to obtain sufficient appreciate evidence 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

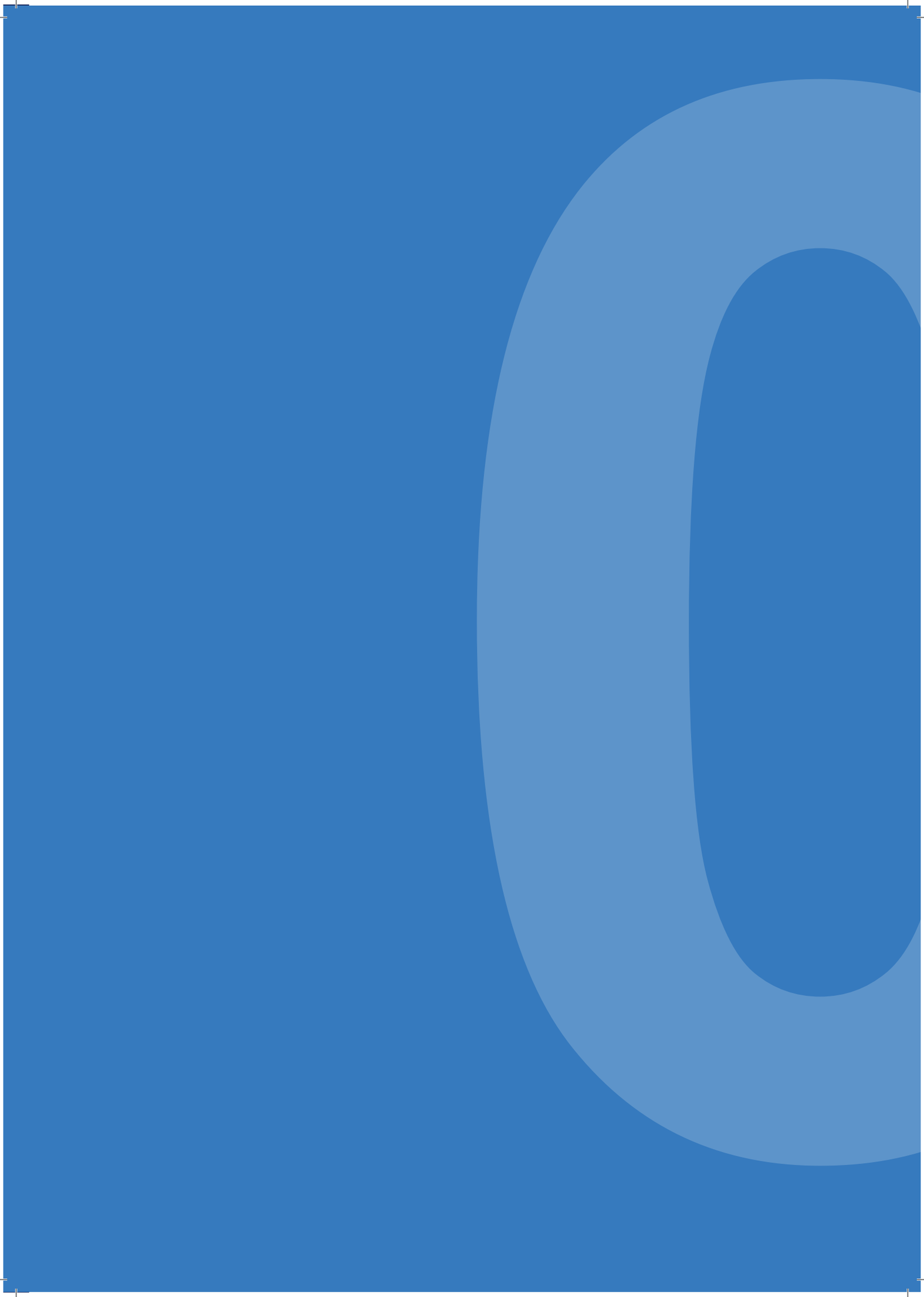
I have no observations to make on these financial statements.



15th July 2025

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 2025

	Note	2024/25 £'000	2023/24 £'000
Income			
Trading income	3	158,500	149,836
Total income		158,500	149,836
Expenditure			
Staff costs	4	(108,125)	(94,455)
Operating costs	5	(93,771)	(92,788)
Total expenditure		(201,896)	(187,243)
Net operating expenditure		(43,396)	(37,407)
Finance income		79	14
Finance costs		(270)	(278)
Net expenditure for the year		(43,587)	(37,671)
Other comprehensive income			
Realised (gain) on inventories		(63)	(211)
Net gain on revaluation of Property, Plant and Equipment*	6	386	6,437
Total comprehensive expenditure for the year		(43,264)	(31,445)

*All gains and losses arise from continuing operations.

The notes on pages 158–181 form part of these accounts.

Statement of financial position as of 31 March 2025	Note	31 March 2025 £'000	31 March 2024 £'000
Non-current assets			
Property, plant and equipment	6	148,869	147,581
Right of use assets	7	6,542	6,993
Intangible assets	8	46,598	30,338
Inventories	9	11,336	10,132
Total non-current assets		213,345	195,044
Current assets			
Inventories	9	928	839
Trade and other receivables	10	31,422	26,210
Cash and cash equivalents	11	66,876	85,460
Total current assets		99,226	112,509
Total assets		312,571	307,553
Current liabilities			
Trade and other payables	12	(34,183)	(33,913)
Lease liabilities	13	(1,093)	(1,010)
Other liabilities	14	(19,461)	(24,079)
Provisions	15	(3,725)	(6,333)
Total current liabilities		(58,462)	(65,335)
Total assets less current liabilities		254,109	242,218
Non-current liabilities			
Lease liabilities	13	(5,652)	(6,098)
Other liabilities	14	(7,347)	(16,188)
Provisions	15	(1,998)	(1,998)
Total non-current liabilities		(14,997)	(24,284)
Net assets		239,112	217,934
Taxpayers' equity			
Reserves			
Revaluation reserve		129,093	128,540
Income and expenditure reserve		954	954
General fund		109,065	88,440
Total taxpayers' equity		239,112	217,934

11 July 2025

Lawrence Tallon
Chief Executive and Accounting Officer
Medicines and Healthcare products Regulatory Agency

The notes on pages 158–181 form part of these accounts.

Statement of cash flows for the year ended 31 March 2025

	Note	31 March 2025 £'000	31 March 2024 £'000
Cash flows from operating activities			
Net operating expenditure		(43,396)	(37,407)
Depreciation and amortisation	6/7/8	15,518	13,699
Statutory audit fees	5	174	-
Loss on disposal of assets	6/8	11	36
Reversal of PPE and intangible assets	6/8	(2)	104
Disposal of ROU asset	7	-	11,770
Disposal of lease liability	13	-	(8,815)
Realised (gain) on inventories	9	(63)	(211)
(Increase)/Decrease in inventories	9	(1,293)	(1,384)
(Increase)/Decrease in trade and other receivables	10	(5,212)	(2,267)
Increase/(Decrease) in trade and other payables	12	270	4,702
(Decrease)/Increase in other liabilities	14	(13,459)	(2,082)
Increase/(Decrease) in provisions	15	(2,608)	6,333
Net cash (outflow) from operating activities		(50,060)	(15,522)
Cash flows from investing activities			
Purchase of property, plant & equipment	6	(10,368)	(9,306)
Right of use assets	7	-	-
Purchase of intangible assets	8	(21,184)	(16,235)
Net cash (outflow) from investing activities		(31,552)	(25,541)
Cash flows from financing activities			
Interest received		79	14
Interest paid		(3)	(3)
Funding from DHSC		64,038	49,700
Capital repayments made under lease liabilities		(819)	(735)
Interest payments made under lease liabilities		(267)	(275)
Net cash inflow from financing		63,028	48,701
Net (decrease)/Increase in cash and cash equivalents in the financial year	11	(18,584)	7,638
Cash and cash equivalents at the beginning of the financial year	11	85,460	77,822
Cash and cash equivalents at the end of the financial year	11	66,876	85,460

The notes on pages 158–181 form part of these accounts.

Statement of changes in taxpayers' equity for the year ended 31 March 2025

	General Fund	Reval. reserve	I & E reserve*	Total
	£'000	£'000	£'000	£'000
Balance on 1 April 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 on 31 March 2024	88,440	128,540	954	217,934
Changes in taxpayers' equity for 2024/25				
Net expenditure for the year	(43,587)	-	-	(43,587)
Other changes				
Notional audit fees	174	-	-	174
Funding from DHSC	64,038	-	-	64,038
Net gain on loss revaluation of property, plant and equipment	-	386	-	386
Net gain / (loss on revaluation of intangible)	-	230	-	230
Realised (gain) on inventories - biological standards	-	(63)	-	(63)
Sub total	64,212	553	-	64,765
Balance at 31 March 2025	**109,065**	**129,093**	**954**	**239,112**

*Income and Expenditure Reserve is a one-off capital grant from the Department of Health and Social Care and represents taxpayer's equity in the agency.

The notes on pages 158–181 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 10 January 2025 (DAO 03 24 2024 25 (19 February).docx) https://assets.publishing.service.gov.uk/media/67ed513c53fa8521c3248c09/DAO_03_24_2024_25__28_March___3_.pdf

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

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

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

HM Treasury's FReM does not require the following Standards and Interpretations to be applied in 2024/25.

- IFRS 17 Insurance Contracts: This standard is not yet adopted by FReM and is not expected to have any effect on the MHRA's accounts
- IRFS 18 Presentation and Disclosure in Financial Statements: This standard is not yet adopted by FreM
- IFRS 19 Subsidiaries without Public Accounting Disclosures: This standard is not yet adopted by FreM and will have no effect on the 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 use an employee-by-employee breakdown of actual leave balance and average salary for the grade to calculate our liability. The principal uncertainty is in respect of when the leave balance will be used. In the absence of information on the timing of staff members' future use of their leave, we neither discount the liability nor include any forecast of future salary increases.

- **Valuation of Property, Plant and Equipment**

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

  A desktop valuation of the agency's one Land and Buildings asset, the South Mimms Science campus was carried out by the Valuation Office Agency at 31 March 2025. The valuation of properties is prepared based on building cost indices in order to reflect the cost of building a replacement asset in the same location. The indices utilised in preparing the valuation are subject to a retrospective update and therefore may change. While the valuation provides an estimate of the cost of rebuilding the current estate, if a new property were to be built, adaptations in how space was provided may lead to changes in the final value. The values in the report have been used to inform the measurement of property assets at valuation in these financial statements.

- **Inventory valuation**

  Inventory is valued at the lower of cost and net realisable value. Significant judgements are made in line with specialist knowledge of managers and senior staff. Historic cost is estimated by calculating the average sales over the last four years and projecting this to a maximum of fifteen years and applying the unit cost for the year of production. Net realisable value is based on the estimated selling price minus any further selling costs expected to be incurred.

  The MHRA take a prudent view to adjust the inventory value for flu standards inventory over two years old as after this date the standard management consider this to be old, and that few requests will be received for it. A second prudent adjustment is made for stock whose sale in the current year was less than 24 units, as the judgement is that this is unlikely to increase. As a result, stock meeting either of these criteria is not included in the inventory valuation.

★ **IR35 Provision**

We have estimated a provision relating to incorrect application of IR35 regulations pending discussions and a 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 offset. Further engagement with HMRC and suppliers will be undertaken in 2025/26.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
- 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 by a Chartered Member of RICS took place at 31 March 2025. Valuation is on an open market (existing use) basis except for buildings of a specialised nature, where a market value is not readily obtainable, which are valued on a depreciated replacement cost basis.

Other property, plant and equipment and furniture and fittings are revalued annually using Office 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

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

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

During the annual asset verification exercise, the 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 an 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
    - 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, intangible assets are carried at current value in existing use by reference to an active market, or, where no active market exists, at the lower of amortised replacement cost or value in use where the asset is income generating.The amortised replacement cost in existing use is calculated by applying, annually, the producer price indices published by the Office of National Statistics (ONS). Management consider that these are the most appropriate indices for this purpose.

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 to 10 years
Sentinel architecture costs	15 years
Sentinel software	Remaining life of the Sentinel architecture

Intangibles include the following assets developed in house:

Description	Amortisation period
Sentinel architecture	15 years
Clinical Practice Research Datalink (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.

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 to house intelligence information and processing of this information via a statistical model (algorithm) to improve inspection planning.

Pharmacovigilance is the database for collecting, monitoring, researching, assessing and evaluating information from healthcare providers and patients on the adverse effects of medicines, biological products, herbals and traditional medicines.

1.5 Value Added Tax (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 (CPRD)

Following the ending of the joint arrangement in March 2022 and in agreement with NIHR, funding continues to be retained by the 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. The spending plan agreed with NIHR ends in March 2028.

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 the type of income stream and stages completed.

The MHRA has the following income streams:

Licenses, inspections and clinical trials

- 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

- 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

Vigilance, risk management and enforcement

- Service fees: These are invoiced annually 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

Research

- Standards income is recognised when an order has been fulfilled

- Research grants: As research projects progress, income is recognised in line with expenditure incurred 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

Others

- 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

- CPRD income is recognised as earned when the service is provided, any income invoiced and paid in advance is deferred

- Devices income is recognised as earned when the service is provided

- Miscellaneous income: This is non-statutory income and is recognised as earned when the service has been provided

- 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-cigarettes notifications is due on invoicing, which occurs at the start of the process. The proportion of the fees receivable for marketing authorisation applications, and variations 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.

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. All biological reference materials, standards, and reagents are available to buy online and meet the IAS 2 definition of inventories as assets held for sale in the ordinary course of business or in the process of production for such sale.

Inventories are valued at the lower of cost or net realisable value. Each calculation uses a total number of years stock held, which is estimated by calculating the average sales over the last four financial years. This is projected to a maximum of fifteen years, as this is the likely useful lifetime of the products. Net realisable value is estimated by calculating the present value of the net sales income per unit of stock multiplied by the number of years of stock held. Each year the total direct costs plus associated overheads of production are divided by the number of ampoules added to inventory in the year to derive a cost per unit that is used in subsequent calculations. The historical cost of inventory is estimated by multiplying the number of years of stock held and the unit cost for a year of production.

MHRA take a prudent view to adjust the inventory value for flu standards inventory over two years old, as after this date the standard management considers this to be old and few requests will be received for it. A second prudent adjustment is made for stock whose sale in the current year was less than 24 units, as the judgement is that this is unlikely to increase. As a result, stock meeting either of these criteria is not included in the inventory valuation.

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 for in accordance with IFRS 16 Leases.

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.

Right-of-use asset

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

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 (2024/25: 4.72%). 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 (page 177).

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. Where changes in future lease payments result from a change in an index or rate or rent review, right of use assets and lease liabilities are remeasured using an unchanged discount rate.

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. Details are disclosed in Note 2.

1.11 Provisions

A provision is recognised when the MHRA 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 the 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 MHRA 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 when 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.

2024/25	Science and Research £'000	Innovation and Compliance £'000	Healthcare Quality and Access £'000	Safety & Surveillance £'000	Total £'000
Income from external customers	25,013	19,637	58,302	55,548	158,500
Total income	**25,013**	**19,637**	**58,302**	**55,548**	**158,500**
Direct costs	(20,374)	(22,234)	(23,485)	(33,476)	(99,569)
Indirect costs	(29,172)	(19,740)	(25,649)	(27,766)	(102,327)
Total expenditure	**(49,546)**	**(41,974)**	**(49,134)**	**(61,242)**	**(201,896)**
Net operating deficit	**(24,533)**	**(22,337)**	**9,168**	**(5,694)**	**(43,396)**

2023/24	Science and Research £'000	Innovation and Compliance £'000	Healthcare Quality and Access £'000	Safety & Surveillance £'000	Total £'000
Income from external customers	26,408	18,789	50,911	53,728	149,836
Total income	**26,408**	**18,789**	**50,911**	**53,728**	**149,836**
Direct costs	(20,544)	(19,074)	(18,977)	(31,194)	(89,789)
Indirect costs	(30,515)	(16,986)	(22,203)	(27,750)	(97,454)
Total expenditure	**(51,059)**	**(36,060)**	**(41,180)**	**(58,944)**	**(187,243)**
Net operating deficit	**(24,651)**	**(17,271)**	**9,731**	**(5,216)**	**(37,407)**

3. Trading Income

	2024/25 £'000	2023/24 £'000
Licenses and Inspections	50,707	42,656
Vigilance, Risk Management and Enforcement	46,757	45,820
Devices	4,043	3,908
Clinical trials	4,076	3,825
British Pharmacopoeia	6,366	6,050
Tobacco Products Directive	2,326	2,401
Research	24,847	26,684
CPRD	17,868	16,400
Other trading income	1,510	2,092
Total	**158,500**	149,836

4. Staff costs

	2024/25 £'000	2023/24 £'000
Wages and salaries	79,055	69,673
Social security costs	8,581	7,782
Other pension contributions	20,489	17,005
Sub total	108,125	94,460
Less recoveries in respect of outwards secondment	-	(5)
Total	**108,125**	94,455

See staff report on page 120.

5. Operating costs

	2024/25 £'000	2023/24 £'000
Computing, consumables, support and maintenance	30,704	28,847
Depreciation and amortisation	15,518	13,699
Accommodation	8,353	11,190
Medicines testing and Laboratory expenses	12,099	10,818
Travel and subsistence	1,336	1,335
Other operating costs	25,761	26,899
Total	93,771	**92,788**
Other operating costs include:	£'000	£'000
Contracted out services	21,743	14,562
Legal services	1,954	1,488
Printing and stationary	1,397	1,637
Notional non-cash audit fees	174	153

6. Property, Plant and Equipment

2024/25	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 2024	**3,051**	**123,198**	**11,749**	**38,894**	**2,111**	**179,003**
Additions	10,368	-	-	-	-	10,368
Transfers	(8,063)	288	3,282	3,042	1,451	-
Reversal	2	-	-	-	-	2
Revaluation	-	(4,796)	-	166	129	(4,501)
Disposals	-	-	(2,599)	(555)	(21)	(3,175)
At 31 March 2025	**5,358**	**118,690**	**12,432**	**41,547**	**3,670**	**181,697**
Accumulated Depreciation						
At 1 April 2024	**-**	**-**	**6,946**	**24,329**	**147**	**31,422**
Charge for the year	-	4,977	1,657	2,625	197	9,456
Revaluation	-	-	-	79	12	91
Elimination of accumulated depreciation	-	(4,977)	-	-	-	(4,977)
Disposals	-	-	(2,589)	(554)	(21)	(3,164)
At 31 March 2025	**-**	**-**	**6,014**	**26,479**	**335**	**32,828**
Net book value						
At 31 March 2025	**5,358**	**118,690**	**6,418**	**15,068**	**3,335**	**148,869**
Net book value at 31 March 2024	3,051	123,198	4,803	14,565	1,964	147,581
Owned	**5,358**	**118,690**	**6,418**	**15,068**	**3,335**	**148,869**

Land and buildings

A professional valuation of land and buildings was carried out on 31 March 2025 which resulted in a net increase of £180k, which in line with International Accounting Standard 16, has been offset by the elimination of accumulated depreciation of £4,977k against the carrying amount of the asset. The net amount restated to equal the revalued amount.

2023/24	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 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

7. Right of use assets

2024/25	Land and Buildings £'000	Other £'000	Total £'000
Cost or valuation			
At 1 April 2024	**7,843**	**-**	**7,843**
Addition	**-**	88	88
Remeasurement-existing leases	368	-	368
At 31 March 2025	**8,211**	**88**	**8,299**
Depreciation			
At 1 April 2024	**850**	**-**	**850**
Charge for the year	895	12	907
At 31 March 2025	**1,745**	**12**	**1,757**
Carrying value			
At 31 March 2025	6,466	76	6,542
At 31 March 2024	6,993	-	6,993

2023/24	Land and Buildings £'000	Other £'000	Total £'000
Cost or valuation			
At 1 April 2023	13,290	-	13,290
Addition	7,843	-	7,843
Disposals*	(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	-	50
Disposals	(1,520)	-	(1,520)
Amortisation at 31 March 2024	850	-	850
Net book value at 31 March 2024	6,993	-	6,993
Net book value 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 Department of Health and Social Care.**

8. Intangible assets

2024/25	Computer Systems £'000	AUC £'000	Software Licences £'000	Total £'000
Cost or valuation				
At 1 April 2024	**51,316**	**13,685**	**3,399**	**68,400**
Additions	-	21,184	-	21,184
Transfers	6,521	(6,640)	119	-
Disposals	(1,311)	-	(267)	(1,578)
Revaluations	483	-	4	487
At 31 March 2025	**57,009**	**28,229**	**3,255**	**88,493**
Amortisation				
At 1 April 2024	**34,804**	**-**	**3,258**	**38,062**
Charge for the year	5,086	-	69	5,155
Disposals	(1,311)	-	(267)	(1,578)
Revaluations	254	-	2	256
Amortisation at 31 March 2025	**38,833**	**-**	**3,062**	**41,895**
Net book value at 31 March 2025	**18,176**	**28,229**	**193**	**46,598**
Net book value at 31 March 2024	16,512	13,685	141	30,338
Owned	**18,176**	**28,229**	**193**	**46,598**

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

9. Inventories

	31 March 2025 £'000	31 March 2024 £'000
Current		
Biological Standards	**898**	685
Laboratory consumables and other stores	**30**	154
Total current	**928**	839
Non-current		
Biological Standards	**11,336**	10,132
Total	**12,264**	10,971

Inventories are shown net of a provision for flu stock obsolescence of £4,779k (2023/24, £5,270k) and stock with sales less than 24 units per annum of £1,635k (2023/24, £2,409k).

When first recorded in the NIBSC balance sheet at 31 March 2010 an opening inventory position 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 2024/25 was £63k (2023/24, £211k). Inventories consumed during the year amounted to £1,914k (2023/24 £1,311k).

10. Trade and other receivables

	31 March 2025 £'000	31 March 2024 £'000
Amounts falling due within one year		
Trade receivables*	**10,917**	7,849
Other receivables	**3,158**	1,475
Contract assets	**5,777**	6,145
Accrued income	**4,846**	6,340
Prepayments	**6,724**	4,401
Total	**31,422**	26,210

***Trade receivables are shown net of a provision for bad debts of £2,263k (2023/24, £2,171k) and credit notes for all unpaid periodic fees at year end of £1,592k (2023/24, £860k).**

11. Cash and cash equivalents

	31 March 2025 £'000	31 March 2024 £'000
Balance at 1 April	**85,460**	77,822
Net change in year	**(18,584)**	7,638
Balance at 31 March	**66,876**	85,460
Made up of		
Government Banking Service	**66,876**	85,460

12. Trade and other payables

	31 March 2025 £'000	31 March 2024 £'000
Amounts falling due within one year		
Payments received on account	**6,232**	4,137
Taxation and social security	**3,967**	4,030
Contract liabilities	**1,517**	2,220
Other trade payables	**5,876**	3,426
Other payables	**-**	4
Accruals	**16,591**	20,096
Total	**34,183**	33,913

Payments received on account are receipts from customers that are not yet allocated to invoices and contract liabilities are these receipts relating to IR35 income streams, e.g. applications and variations, clinical trials and research grants.

13. Lease liabilities

2024/25	Land and Buildings £'000	Plant and Equipment £'000	Total £'000
Lease liabilities at 1 April 2024	**7,108**	**-**	**7,108**
Interest accrued during the year	**263**	**4**	**267**
Payments	**(1,072)**	**(14)**	**(1,086)**
Disposals	**-**	**-**	**-**
Remeasurement existing leases	**368**	**-**	**368**
Additions	**-**	**88**	**88**
At 31 March 2025	**6,667**	**78**	**6,745**
Current	**1,060**	**33**	**1,093**
Non-current	**5,607**	**45**	**5,652**
At 31 March 2025	**6,667**	**78**	**6,745**
Obligations under leases			
Within one year	**1,060**	**33**	**1,093**
Between two to five years	**5,302**	**52**	**5,354**
Over five years	**1,304**	**-**	**1,304**
Less interest	**(999)**	**(7)**	**(1,006)**
At 31 March 2025	**6,667**	**78**	**6,745**
Cash outflow for leases			
Cash outflow — interest	**263**	**4**	**267**
Cash outflow — capital	**1,072**	**14**	**1,086**
Total cash outflow for leases	**1,335**	**18**	**1,353**

2023/24	Land and Buildings £'000	Plant and Equipment £'000	Total £'000
Lease liabilities at 1 April 2023	8,815	-	8,815
Interest accrued during the year	275	-	275
Payments	(1,010)	-	(1,010)
Disposals	(8,815)	-	(8,815)
Remeasurement existing leases	-	-	-
Additions	7,843	-	7,843
At 31 March 2024	7,108	-	7,108
Current	1,010	-	1,093
Non-current	6,098	-	5,652
At 31 March 2024	7,108	-	6,745
Obligations under leases			
Within one year	1,010	-	1,010
Between two to five years	4,040	-	4,040
Over five years	3,260	-	3,260
Less interest	(1,202)	-	(1,202)
At 31 March 2024	7,108	-	7,108
Cash outflow for leases			
Cash outflow — interest	275	-	275
Cash outflow — capital	1,010	-	1,010
Total cash outflow for leases	1,285	-	1,285

14. Other liabilities

	Current		Non-current	
	31 March 2025 £'000	31 March 2024 £'000	**31 March 2025 £'000**	31 March 2024 £'000
Deferred revenue:				
Other fees	**3,975**	3,931	**40**	40
Contract liabilities	**11,905**	16,528	**4,673**	11,104
Others:				
DHSC Contribution to CPRD	**3,581**	3,620	**2,634**	5,044
Total	**19,461**	24,079	**7,347**	16,188

15. Provisions

	Current		Non-current	
	31 March 2025 £'000	31 March 2024 £'000	**31 March 2025 £'000**	31 March 2024 £'000
Dilapidations	**-**	-	**1,998**	1,998
IR35*	**3,725**	6,333	**-**	-
Total	**3,725**	6,333	**1,998**	**1,998**

***A provision in lieu of unpaid PAYE and NI relating to incorrect application of IR35 regulations. 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 offset. A payment of £2m in relation to the estimated IR35 liability was made to HMRC in 2024/25. Further engagement with HMRC and suppliers will be undertaken in 2025/26.**

Movement in provisions

	Total £'000
At 1 April 2024	**8,331**
Provisions utilised in the year*	**(2,000)**
Unwinding of provision	**(608)**
At 31 March 2025	**5,723**

Expected timing of cash flows:

Within one year	**3,725**
Between two to five years	**-**
Over five years	**1,998**
Total	**5,723**

***Provision utilised in year relates to a payment to HMRC in relation to the estimated IR35 liability**

16. Capital commitments

Contracts entered into not provided for in the accounts	31 March 2025 £'000	31 March 2024 £'000
Property, plant and equipment	**1,672**	2,507
Intangible assets	**6,751**	1,449
Total capital commitments	**8,423**	3,956

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 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.

During 2024/25, 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.

Notes

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