Medicines & Healthcare products Regulatory Agency

MHRA Impact Report

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

2024–2025

Introduction

About the MHRA

We are the Medicines and Healthcare products Regulatory Agency (MHRA).

We are the UK regulator of medicines, medical devices, and blood components for transfusion. We are responsible for making sure these products meet set standards for safety, quality, and efficacy.

We improve and protect the health of millions of people every day by making sure healthcare products in the UK meet the highest standards and are safe to use.

As an executive agency of the Department of Health and Social Care, we support innovation across the product lifecycle — from early-stage research and clinical trials to market access and post-market surveillance. Our work enables timely access to life-changing treatments while safeguarding patient safety and driving growth in the UK's £100 billion life sciences sector.

A year of progress and purpose

This year has been marked by significant achievements in our mission to protect and improve public health.

Our work has a profound impact on people. Whether it's enabling people to have the next generation of medicines and technologies or protecting patients from harm, our success is measured not just in frameworks and timelines, but in lives improved.

This year, we have further demonstrated our indispensable role as part of the UK health system on a national and international scale through our work with partners across the globe.

As we reflect on our achievements in 2024–25, our focus turns to the future. We are creating a regulatory environment that is agile, reliable, and science-led. We are helping to attract global investment and deliver real-world impact for the health system. And most importantly, we are putting patients at the heart of all our activities.

Professor Anthony Harnden,
Chair, MHRA

Lawrence Tallon,
Chief Executive, MHRA

2024–25: The year in numbers

This year, the MHRA delivered impact at scale — from frontline safety to global standards.

Over 2,000 marketing authorisation licences issued — including 54 new medicines	**Over 5,000** clinical trial applications assessed	**Over 370** clinical investigation applications for medical technologies assessed
Over 101,000 adverse drug reaction reports assessed	**100%** of fatal adverse drug reaction reports processed within 72 hours	**Around 56,000** medical device incidents assessed
Over 911,000 non-compliant medical devices seized	**Over 1,300** vaccine and blood product batches tested	**Over 3,400** plasma pools safety tested for the absence of blood-borne viruses
99% of Freedom of Information (FOI) requests were answered on time	**Over 60,300** enquiries handled from the public and our customers	**Over 450** pages of evidence submitted to the UK COVID-19 Inquiry
Over 1.5 million unregulated listings online blocked by partnering with eBay	**Over £2.6 million** in criminal profits denied	**£37.5 million** worth of medicines seized that could have been sold illegally

Restoring performance, enabling access

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

This year, we issued over 2,000 marketing authorisation licences — including for 54 new medicines that offer real hope to patients.

Throughout the year, we concentrated on restoring our performance and bringing our statutory services back within statutory timescales.

All marketing authorisation applications have been processed on time since 1 September 2024. By March 2025, we cleared all backlogs, and statutory performance targets are now being met.

1 Alzheimer's disease

- Lecanemab for early-stage disease
- Donanemab for early-stage disease
- Flortaucipir for diagnosis

2 Cancer

- Capivasertib for advanced breast cancer
- Tarlatamab for small cell lung cancer
- Lazertinib for non-small cell lung cancer

3 Rare diseases

- Givinostat for Duchenne Muscular Dystrophy
- Leniolisib phosphate for the rare immune disease APDS
- Elafibranor for primary biliary cholangitis
- Eplontersen for the rare nerve disease ATTRv

4 Cardiovascular

- Semaglutide to reduce the risk of cardiovascular events

Protecting patients through vigilance and action

Our robust safety surveillance system continuously monitored medicines, medical devices, and blood components, and we acted promptly on concerns to protect public health.

Safety monitoring

We assessed over 101,000 reports of side effects with medicines and around 56,000 incidents with medical devices, taking action where necessary to manage newly identified risks. We prioritise the safety of patients and the public — 100% of adverse drug reaction reports were processed within the required timeframes throughout the year.

We took action to protect patients by providing new advice for patients or healthcare professionals on 13 detailed benefit-risk assessments

Criminal enforcement

Our Criminal Enforcement Unit removed 16 million illegal doses from circulation and denied £2.6 million in criminal profits. We seized £37.5 million (estimated street value) of medicines that could have been illegally sold, partnering with eBay to block over 1.5 million unregulated listings.

We use the full range of powers and tools available to us to protect the public from the harm caused by those illegally trading in powerful medicines, including prompt investigations.

This year, two pharmacists were sentenced for illegally supplying over 55 million doses of controlled drugs like diazepam.

Supporting innovation across the product lifecycle

This year, we continued our pivotal role in enabling innovation in life sciences — from early-stage research and pre-clinical development to clinical trials, market access, and post-market surveillance.

Launched the AI Airlock pilot

a world-first regulatory sandbox for AI as a medical device, comprised of four cutting-edge projects focused on advancing the role of AI while meeting critical safety standards

Refreshed the Innovative Licensing and Access Pathway (ILAP)

for medicines, streamlining access to transformative products

Completed our Innovative Devices Access Pathway (IDAP) pilot

supporting eight breakthrough technologies with tailored tools and joint expert advice from across the healthcare system

Published 46 new British Pharmacopoeia standards

to support pre-clinical development and manufacturing

Began enhancing our Scientific Advice Service

to guide innovators through regulatory complexity

Global science, local impact

We delivered public health impact through scientifically driven and world-leading regulatory expertise.

Our year in numbers

60+
new biological standards and reference materials developed

127,700+
units of biological standards, reference materials, and reagents provided

£7m+
research grants utilised in the year, supporting our regulatory science research programme

50+
scientific publications published in peer-reviewed journals

This year, we have also supported the reintroduction of UK plasma for production of medical blood products for the NHS.

We launched new and replacement International Standards — approved and endorsed by the WHO Expert Committee on Biological Standardisation.

Examples of our international scientific impact:

Developing international reference material for lung cancer mutations

Launching the first WHO International Standard for HIV-1 p24 antigen

Introducing batch release testing for RSV vaccines

Leading international efforts to strengthen readiness for future pandemics, with significant progress being made on Lassa virus and Marburg virus

Accelerating access to innovation

We are creating a dynamic, world-leading environment for clinical trials and clinical investigations that delivers real innovation and better health outcomes for patients.

We assessed over **5,000 clinical trial applications** and over **370 clinical investigation applications**, keeping within our target timelines throughout.

We maintained strong performance on combined clinical trial assessments, operating within statutory timelines for the full year, with an average **39.5-day turnaround for combined reviews** — well within the 60-day target.

New clinical trial regulations for the UK were signed into law, representing the most significant update in two decades. Soon to be implemented in April 2026, they will ensure patients and their safety are the focus of all clinical trials. These changes will also 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.

We also launched our **Applied Evidence-Based Regulatory Science (AEBRS) programme** — an ambitious initiative that delivered the first comprehensive analysis of the UK trial landscape. This work confirmed the UK's position as a global leader in clinical research and identified key opportunities to enhance patient access to innovative treatments.

AEBRS study key findings:

1 in 8
trials test treatments in humans for the first time

Cancer trials make up nearly
one-third
of all studies

Heart disease,
the world's biggest killer, only makes up
5% of trials

Cutting-edge treatments with the potential to transform care, such as gene and cell therapies, only make up
3.4% of trials

Embedding patient voices in our work

The public and patients are always at the centre of everything we do.

We actively involve patients in shaping our regulatory decisions and priorities, ensuring their voices are heard in the development, evaluation, and safe use of medicines and medical devices. This focus helps us build trust, make better decisions, and uphold our mission to protect and improve public health.

We launched a new Patient and Public Community to embed public voices in our work. The community has **115 members** — **56 organisations** and **59 individuals** who are either patients, patient advocates, or carers. The Community gives us the opportunity to inform the public about the range of work the MHRA undertakes. More tailored engagement activities provide us with opportunities to listen to the voices of the public and patients.

We prioritise clear, accessible communication to ensure patients and the public are well-informed and confident in the safety and effectiveness of the medicines and medical devices they use.

Key achievements

2 Patient and Public Community meetings held

since its launch in October 2024

Patient Involvement Strategy progress assessment published

to inform a refresh of the strategy from 2026 onwards

New guidance developed

on patient and public involvement for a more transparent and responsive approach

Enhanced engagement

with healthcare professionals through new systems and designed communications

7 public consultations held

on a variety of topics

Risk benefit data published

that informed positive regulatory assessments and approvals of 28 new medicines

21 safety updates and 91 safety alerts issued

on medicines and medical devices in plain language, ensuring as many people as possible understand the benefits and risks

A trusted, accountable regulator

As a public body, we take our responsibilities to ensure optimal governance seriously.

Clearer, faster, more responsive

- We answered 99% of FOI requests on time and reduced complaints from over 5,000 in 2023/24 to 467 during 2024/25
- We handled a total of 60,385 enquiries and a new customer strategy is helping us serve the public more effectively
- We also supported the UK COVID-19 Inquiry with over 450 pages of evidence

Stronger systems and safeguards

We improved cyber resilience, modernised our digital infrastructure, and strengthened health and safety governance across the agency. 97% of our staff also completed cyber and information security training.

Investing in our people

We launched a new cohort of our graduate scheme and supported 63 apprenticeships across the UK.

Built to last

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, and conducted a detailed analysis of the control environment across the three lines of defence.

We're now fully compliant with six Government Functional Standards — and on track for full compliance with others in 2026.

Science with a smaller footprint

We're embedding sustainability into our work — from how we power our labs to how we manage waste and water.

We are optimising our estate and operations to help safeguard a healthy environment for current and future generations, in line with the ambitions of the Department of Health and Social Care.

Clinical change commitments

- Achieve a **carbon net zero** building estate by 2030, eliminating direct emissions from gas and refrigerants.
- **Minimise indirect emissions** by embedding sustainability into procurement and project planning
- Prioritise **waste prevention**, improve reuse and recycling, and reduce incineration and landfill
- Promote **sustainable food choices** through catering contracts that support health and the environment

Progress made to date includes:

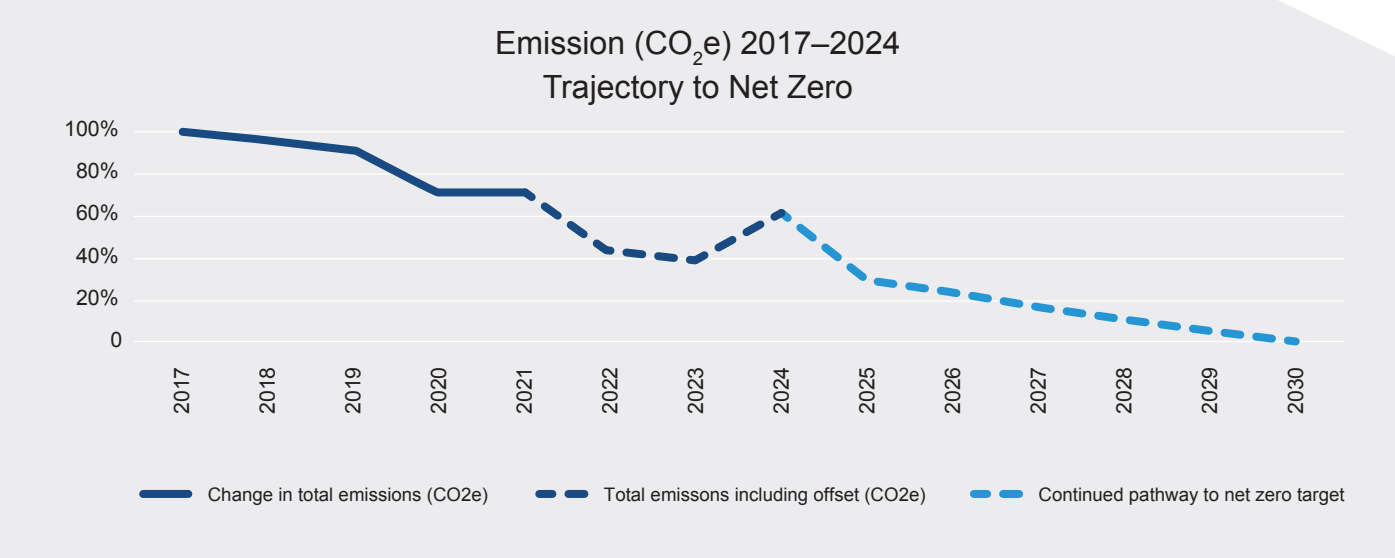
Generated 13%
of the total electricity requirement for the Science Campus from solar panels

Over £200,000 saved
on electricity supply costs

~170 tonnes CO_2e reduction
in annual carbon footprint from solar-generated electricity

41% reduction
in water consumption at the Science Campus from 2023/24

~35% reduction
in carbon emissions since 2017



To our staff, partners, and stakeholders — thank you.

Together, we're delivering science, safety, and innovation for public health.

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