



Medicines & Healthcare products  
Regulatory Agency

# MHRA Results and Forecast 2025/26 | 2026/27

**Protecting  
patients.**

**Driving  
innovation.**

**Delivering for  
the country.**

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## Dr Zubir Ahmed MP

Parliamentary Under-Secretary of State for Health Innovation and Safety

*This past year has shown what a modern regulator looks like: patients first, pace where it matters and standards that never slip. The MHRA has made tangible progress on this government's ambitions for the NHS, public health and the Life Sciences Sector Plan.*

*The direction of travel is clear. With the MHRA operating as a high-performance regulator, the UK is positioned as a global destination for life sciences that is open to innovation, serious about safety and credible on the world stage.*



## Lord Vallance

Minister for Science, Innovation, Research and Nuclear

*A strong life sciences sector depends on a regulator that is trusted by patients, by clinicians and by innovators. The MHRA is demonstrating that trustworthiness through its commitment to delivering for the NHS, public health and economic growth.*

*The MHRA's progress and future direction strengthens the UK's proposition as a global destination for research and development.*

## Key achievements



We are  
**hitting all  
our targets**

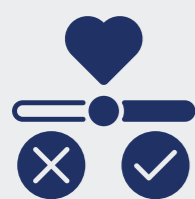


We are in  
**financial  
surplus**

We are  
**leading in  
key areas of  
regulatory  
science**



We have built  
**closer national  
and international  
partnerships**



**Staff  
morale**  
has risen



**External  
sentiment**  
has improved

## Introduction from our CEO and Chair



**Lawrence Tallon**  
Chief Executive

*I want to thank all of my colleagues at the MHRA for the terrific results we have delivered this year. Equally, we are immensely grateful to our many partners across UK health and life sciences, and internationally, without whom we could not have delivered the breadth of progress outlined in this highlights report.*

*After a few challenging years, the MHRA is back to where it needs to be: delivering consistently high-quality, timely regulation that patients, the NHS and industry expect of us. We are championing innovative approaches and supporting developers and the NHS to bring safe, effective medicines and technologies to patients more quickly.*

*2025/26 was a good year for our organisation, but we are determined to go further, faster in the year ahead. We now stand at a pivotal moment, not only for UK regulation but for global health.*

*Healthcare is changing fast: the rate of scientific breakthroughs is accelerating, AI is reshaping what is possible and the expectations on regulators have never been higher. And with that comes enormous opportunity as well as responsibility.*

*This report sets out what we have delivered in the last year, as well as our ambitions for the year ahead: to work in partnership on our mission to improve health and prosperity for the people of the UK.*



**Professor Anthony Harnden**  
Chair

*Over the past year, the MHRA has demonstrated what regulatory excellence looks like in practice. This progress is the result of the skill, professionalism and commitment of MHRA staff across science, regulation, digital, policy and services.*

*Working across the UK health system, with researchers, industry and international counterparts, I have seen first-hand how collaboration strengthens regulation and accelerates access to safe innovation.*

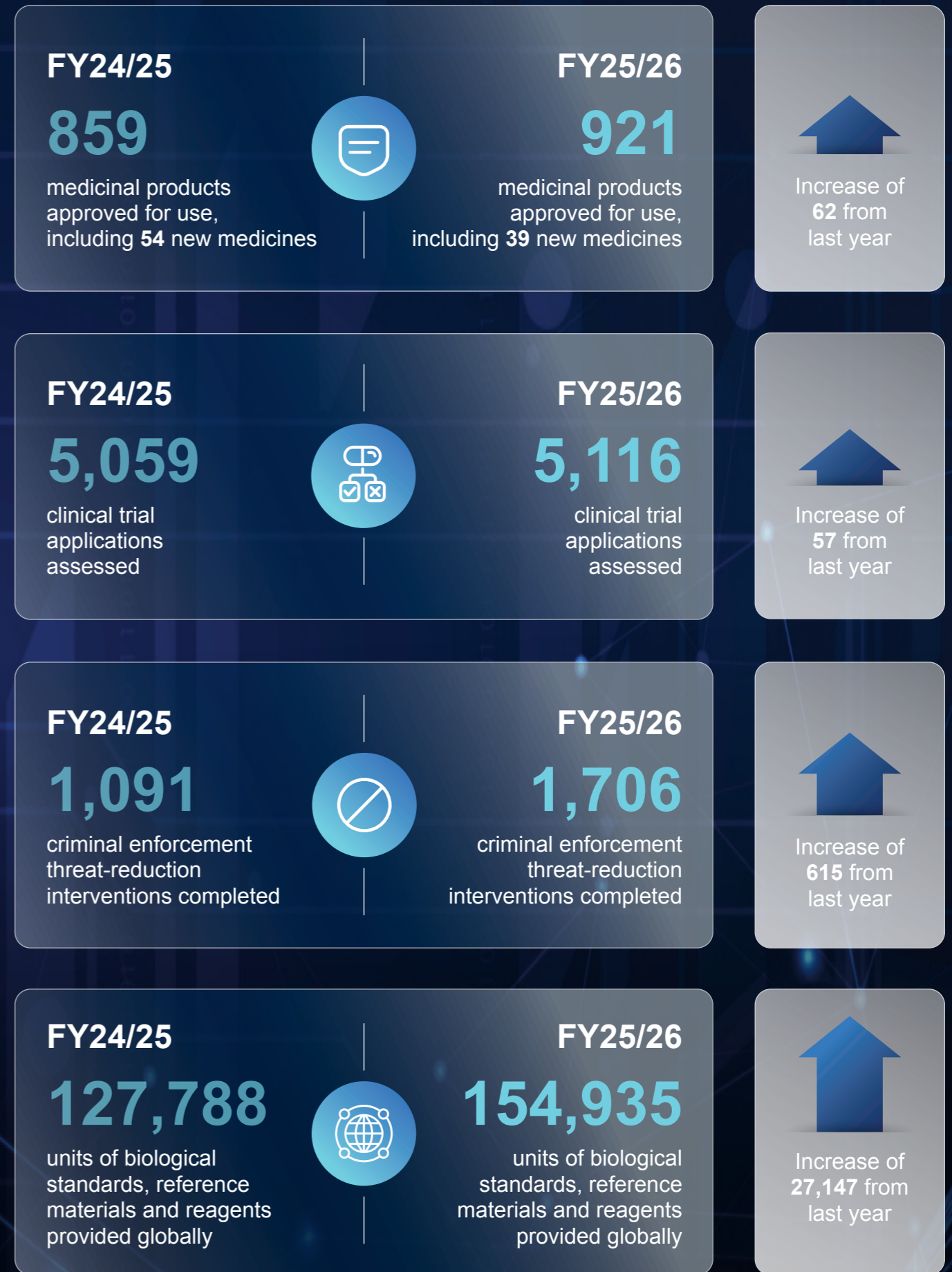
*Globally, the MHRA's contribution to regulatory science is well respected. Our leadership and trusted standards support health systems worldwide.*

*As we look ahead, the MHRA enters the next chapter confident and ambitious that we are a regulator the public can trust and the world can rely on.*

# Confidence in performance

The Medicines and Healthcare products Regulatory Agency (MHRA) delivered against every statutory commitment

Key performance indicators (KPI) targets met by March 2026



## Protecting the public



### Study linking genetics to side effects

We expanded the Yellow Card Biobank to study how genetics affects the risk of acute pancreatitis linked to glucagon-like peptide-1 (GLP-1) medicines.



### Enforcement: stopping harm at source

We removed nearly 28 million unauthorised doses of medicines from circulation and shut down the UK's first known illegal factory producing unlicensed weight-loss injections. We also removed over 176,000 non-compliant medical devices from the market, delivering tangible protection for patients across the UK.



### Tackling vaccine hesitancy head on

Against a backdrop of measles outbreaks and renewed challenges from vaccine hesitancy, we produced accessible safety campaigns to address mis- and disinformation.



### New safety rules for medical devices

We introduced new post-market surveillance regulations for medical devices and diagnostics, strengthening safety oversight once products are in use and supporting the introduction of innovative technologies.



### Strengthening the patient voice in regulation

The hosting of England's Patient Safety Commissioner was transferred successfully to the MHRA.



### SafetyConnect

We completed our multi-year restructuring of the Yellow Card system, creating a world-leading modern digital vigilance architecture.

## Accelerating innovation



Over **£7 million** awarded in regulatory research grants for the next 5 years, in addition to more than **£2 million** awarded in innovation funding this year for new approaches to AI, in silico data and side-effect prediction.



Welcomed products into the refreshed **Innovative Licensing and Access Pathway**, offering enhanced, end-to-end support for transformative medicines.



Launched the **Aligned Pathway and Integrated Scientific Advice service** between the MHRA and NICE, accelerating medicines access by 3–6 months.



The MHRA **continued to support breakthrough medical devices** through the Innovative Devices Access Pathway (IDAP).



**17% year-on-year increase** in clinical investigations in 2025, driven by strong growth in AI-enabled medical devices and neurotechnology, with future UK neurotech growth supported by partnership with Newcastle University and the Advanced Research and Invention Agency (ARIA).



Our AI Airlock moved into the next phase to enable deeper exploration of safety, performance and monitoring challenges.



Strengthened the UK's regulatory-science capability through the Centres of Excellence for Regulatory Science and Innovation (CERSIs).



**5% increase in clinical trial initial applications** received in 2025, with particularly strong growth in early-phase, first-in-human and first-in-UK studies (**12% increase**).

### Dr Richard Torbett MBE, Chief Executive, Association of the British Pharmaceutical Industry (ABPI)

*Over the past year, the MHRA has continued to make important progress in strengthening the UK's regulatory environment for medicines and vaccines... This progress is helping to boost the UK's position as an attractive environment for life sciences research and earlier patient access.*

### Steve Bates OBE, Executive Chair of the Office for Life Sciences

*In the last year, we have seen the UK's regulatory environment generate real excitement among international stakeholders. The MHRA has been central to this, driving innovation through more agile, responsive pathways.*

## Globally connected

- Designated as a World Health Organization (WHO) Listed Authority (WLA).
- Reconfirmed as a WHO Collaborating Centre for the Standardisation and Evaluation of Biologicals.
- Swifter access to products already assessed by trusted regulators in the US, Canada and Australia.
- Collaboration with India's regulator to strengthen supply chains, inspections and regulatory oversight.
- Ran a consultation to propose indefinite recognition of CE-marked medical devices and diagnostics in the UK to guarantee patient access and reduce business friction.
- Founding 'pioneer' country in the HealthAI Global Regulatory Network to shape international standards for AI in healthcare.
- Launched the Regulatory Innovation Corridor, enabling companies to engage with both UK and Singapore regulators simultaneously on innovative products.
- Chair of the Access Consortium — working with Australia, Canada, Singapore and Switzerland to promote greater regulatory collaboration and alignment.
- The British Pharmacopoeia reached over 100 countries through best practice initiatives, including webinars delivered to participants from 76 countries.



### Adjunct Professor (Dr) Raymond Chua, CEO, Singapore's Health Services Authority

*Our longstanding partnership with the MHRA has strengthened through the launch of our Regulatory Innovation Corridor and refreshed memorandum of understanding... Together, we are accelerating innovation in Singapore and the UK to deliver transformative technologies to benefit patients, while upholding the highest standards of safety, trust and excellence.*

## Expertise and morale

### An engaged and expert workforce able to meet the challenges of the future

Staff engagement index rose by 6 percentage points to 65%, meaning the MHRA is one of the top 5 most improved groups in the UK Civil Service for workforce engagement.

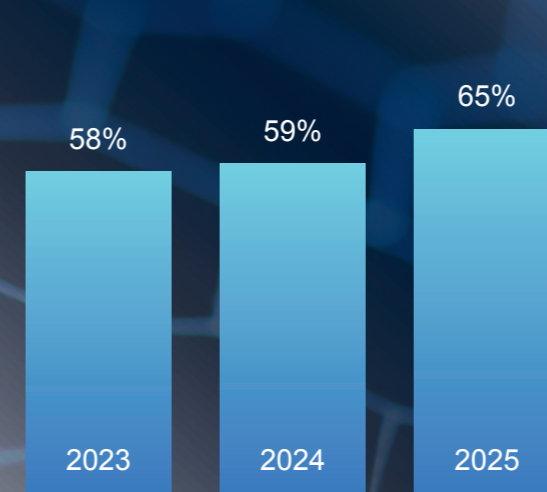
Highest ever staff survey participation rate, with 81% of all staff taking part.

### Investing in people to deliver sustainable performance

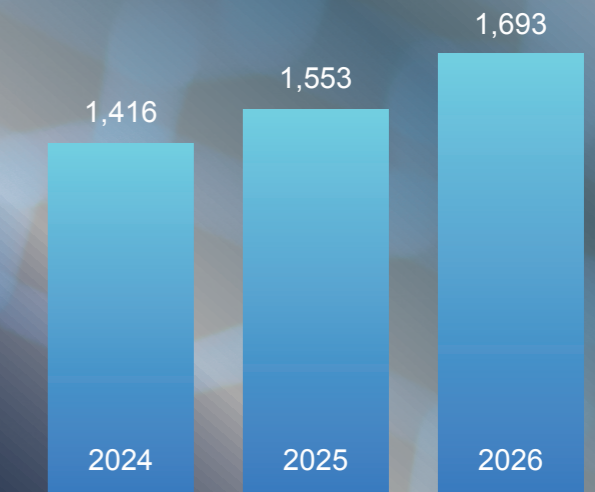
Strengthened capacity by recruiting more assessment staff and investing in training and development for new colleagues.

Grown to meet the demand for our services, with further growth planned in the year ahead.

MHRA staff engagement index



MHRA total headcount



Launched a new digital hub office in Leeds, with its deep concentration of tech talent, to strengthen our work with regional partners and boost growth.

Established the MHRA Academy to deliver high-quality learning in medicines, biological medicines and medical devices regulation.

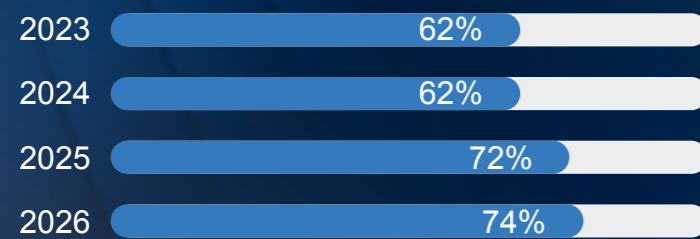
Strengthened collaboration with the devolved governments in Scotland, Wales and Northern Ireland through deeper strategic engagement and a more visible UK-wide presence for the MHRA Board.

Expanded apprenticeships across the MHRA, with over 100 colleagues learning on the job in regulatory, scientific and digital roles.

# Improving sentiment

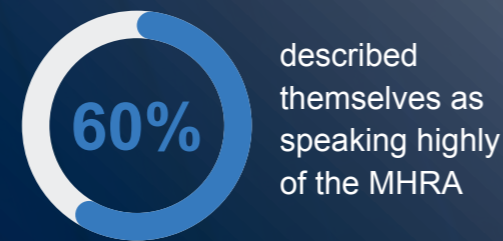
Independent reputation research shows a sustained and positive shift in how the MHRA is viewed by industry, partners and system stakeholders, with the strongest gains achieved over the last 12–18 months.

## An increase in favourable views towards the MHRA



Favourable

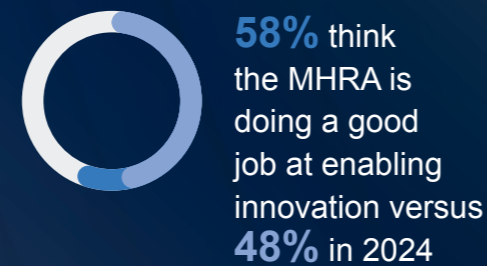
## Advocates



## Regulation



## Enabling innovation



## Customer satisfaction for our services



### Jane Wall, Managing Director, BioIndustry Association (BIA)

The MHRA's strong performance over the past year reflects a regulator that is listening and evolving. The forward-looking initiatives showcased in this report — including the development of a new rare disease pathway — highlight the value of collaborative working to accelerate innovation and deliver better outcomes for patients across the UK.

# Strategic outlook

Lord O'Shaughnessy, former health minister, senior partner at Newmarket Strategy and author of the landmark report into the UK commercial clinical trials landscape

The progress made since I published my review in 2023 has been remarkable. The MHRA is now delivering consistently good approval times while introducing further reforms that are adding speed and flexibility to the process. The MHRA is once again taking a global lead, which is helping to attract more clinical trials to the UK.



## Clear strategic direction

Our new 5-year strategy will set a clear direction later this year for how regulation will evolve to support patient safety, NHS priorities and UK life sciences growth.



## A clearer, more patient-centred regulatory mission

We will set out a renewed focus on supporting patient health and confidence through strong science and clear decision-making.



## A stronger global role and closer collaboration with international partners

We will be an influential, outward-facing regulator, working with global counterparts to speed up access to high-quality medical products.



## Strengthening public trust and confidence

We will be a transparent, evidence-based regulator that people can trust amid rising misinformation.



## Enhanced safety surveillance

We will modernise how we monitor safety, using better data and technology to identify issues earlier and act faster.

### Peter Ellingworth, CEO, Association of British HealthTech Industries (ABHI)

The MHRA's outward-looking and collaborative approach is welcome, particularly its engagement with global partners to drive regulatory harmonisation. Greater alignment across markets will help reduce complexity and reinforce the UK's position as a competitive destination for HealthTech innovation and investment.

# Science and technology

## Clinical trial reform

With new Clinical Trials Regulations from April 2026, we will make it easier and faster to run safe, high-quality trials in the UK through streamlined approvals, risk-proportionate regulation and stronger alignment with international standards.

We will offer a guaranteed first assessment of phase 1 trials within 14 days; there will be a new notifiable route for low-risk trials to avoid waiting for regulatory approvals; and we will allow greater use of new data sources in trial applications, such as real-world data, in silico and international peer data.

## Future-ready regulation for AI in healthcare

We will translate the recommendations of the National Commission into the Regulation of AI in Healthcare into a reformed regulatory framework that enables safe, trusted and fast adoption of AI in healthcare.

## Rare disease framework

Supporting the government's Rare Disease Action Plan for England, we will develop a more flexible regulatory framework to speed up the testing, manufacture and approval of rare disease therapies in the UK, with international leadership and recognition.

## Cancer vaccines

We will support the UK's ambition to lead on cancer vaccines by enabling well-designed trials and proportionate regulation to accelerate patient access to new personalised therapies.

## Medtech regulatory reform

We will deliver major reforms to UK medtech regulation, with clearer routes to market, greater international recognition and a more predictable regulatory environment for innovators and the NHS.

## New Approach Methodologies (NAMs)

We will accelerate the shift away from animal testing by strengthening guidance, capability and regulatory confidence in NAMs across medicines development.

## Supportive environment for reclassification

We will enable safe, evidence-based medicines reclassification that improves patient access, supports pharmacist-led care and reduces unnecessary NHS appointments and costs.

## Future-proofing compliance

Further strengthening our risk-based and proportionate inspection and compliance approach, we will be more data-driven and better equipped to oversee emerging technologies, while maintaining high standards of patient safety and compliance.

## Michelle Riddalls OBE, CEO at PAGB, the Consumer Healthcare Association

*Reclassification is a key opportunity to expand access to medicines, support self-care and reduce pressure on NHS services. The MHRA has a real opportunity to accelerate this shift and... further drive international collaboration and innovation.*

## Matt Westmore, CEO, Health Research Authority (HRA)

*One of the UK's core strengths in health and care research is our joined-up regulatory system. Through close partnership between MHRA, HRA and others, we have streamlined and simplified the approvals pathway... helping patients access potentially life-changing research sooner.*

## Julia Vitarello, Founder and CEO, Mila's Miracle Foundation

*For families like mine facing rare genetic diseases, progress is measured by how many sick and dying children can access today's incredible technologies in time. The MHRA is truly leading the way through action, paving the world's first pathway toward process-based approvals to meet the new, very promising era of individualised medicines. If successful, the UK will prove a new bridge connecting patients in desperate need with the science that can save lives.*



# Global partnerships

**Stronger partnerships. Wider global reach.  
Pathways for innovation and collaboration.**



**Dr Ricardo Baptista Leite, CEO, HealthAI — The Global Agency for Responsible AI in Health**  
*As the first pioneer country in the HealthAI Global Regulatory Network, the UK has helped turn responsible AI in health from a promise into a concrete global ambition. By coupling bold reform with a clear commitment to safety and equity, the MHRA is charting a path that can inspire innovators, regulators and investors worldwide to build AI-powered health systems that truly serve people.*

**Professor Jonathan Benger CBE, Chief Executive, National Institute for Health and Care Excellence (NICE)**  
*Continuing improvements to joint working between NICE and the MHRA are creating a more integrated and frictionless pathway from regulation to patient access. By aligning our expertise earlier and more closely, we can support innovation, reduce duplication and provide clearer, faster routes for effective new medicines and technologies to reach patients sooner.*

## Smarter tools for safety

We will continue to strengthen the UK's protection against unsafe, illegal or poor-quality medicines and devices.

### Enforcement capacity

Building on a strong year of activity, we will expand our enforcement capability, work with new partners to identify threats earlier and use smarter digital tools to keep pace with evolving national and global risks.

### Health Data Research Service (HDRS) collaboration

Working with the new HDRS, we will make better use of health and care data to strengthen real-world monitoring of products, giving patients greater confidence in the latest innovations.

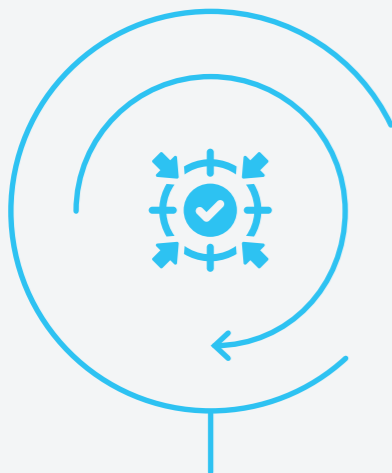
### Smarter, tech-enabled surveillance

We will improve how safety concerns are reported, including closer integration with the NHS App. Using better data, AI and global information sharing, we will spot emerging risks sooner.

### Stronger protection against illicit online sellers

We will strengthen action against fake and unsafe online medicines, alongside providing clearer public guidance on avoiding harmful products.

HDRS will create a single, secure gateway for researchers, and our collaboration will help us:



Identify safety issues earlier



Understand risks faster



Support life-changing research and treatments while protecting patient data and trust

## Good financial health



We enter 2026/27 in a strong financial position, ending the year with a healthy surplus that reflects renewed stability and disciplined delivery across our statutory functions.

This gives us the confidence to invest in regulatory reform, digital modernisation and scientific capability to support innovation, protect patients and contribute to the UK's life sciences ambitions.

This year we are increasing transparency by publishing a richer set of performance data, including quality measures such as customer-reported experience.

We will expand the use of AI in regulatory assessments to strengthen regulatory science and speed up patient access to safe, innovative products.

Alongside this, we are developing an AI-enabled tool using MHRA de-identified data to help sponsors design trials right first time, working closely with industry and academia.

We will also continue to grow our presence across all 4 UK nations, supporting innovation clusters and strengthening partnerships across the health and research system.

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

This MHRA Results and Forecast report sets out our major achievements and highlights for 2025/26 and key projections for 2026/2027.

Full performance and financial details will continue to be reported through the MHRA's Annual Report and Accounts, to be presented to Parliament in summer 2026.

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