Medicines & Healthcare products Regulatory Agency

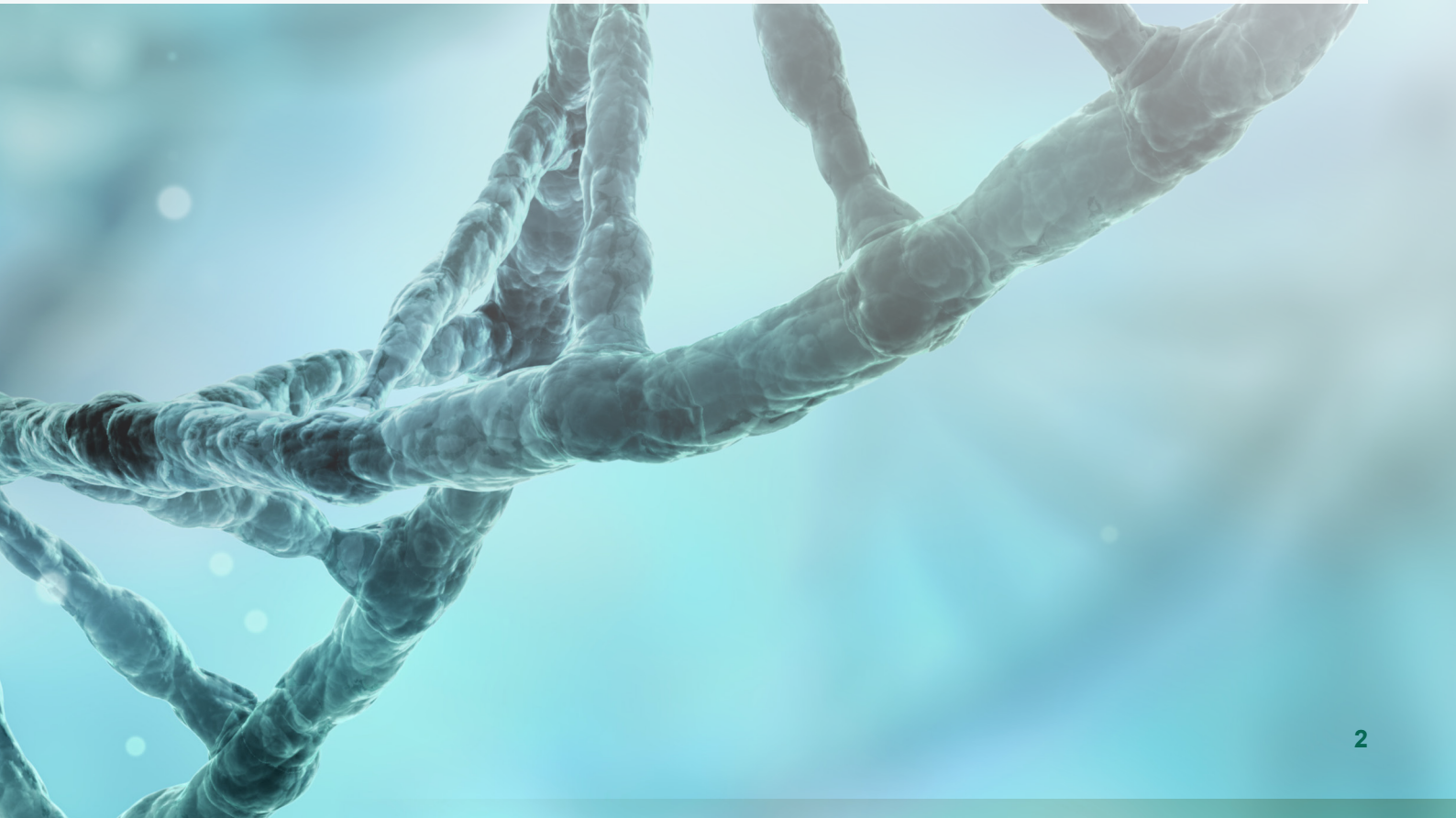
Business Plan

2025-2026

Keeping patients safe and enabling access to high quality and effective medical products through innovation across the UK

25 June 2025

Contents



Foreword

A new chapter for the MHRA

This Business Plan marks the start of a new chapter for the MHRA. We play a vital role in protecting and improving public health. We are an engine for UK growth and innovation. The MHRA is an indispensable part of the UK health system and plays a major role globally, working with international partners.

This is the final year of our three year Corporate Plan 2023–26. The last two years have been challenging as we addressed delays in some of our statutory services. We have now restored our performance and are delivering statutory services to the expected timelines. We have cleared backlogs in medicines licensing, with all applications received on time since 1 September 2024, and our clinical trials performance has consistently been within targets since September 2023. This has been achieved with improvements in our systems and a massive effort from all our staff, whose scientific and regulatory expertise plays such a vital role in patient safety and supporting innovation. Our talented colleagues have demonstrated strong commitment to keeping people safe and to facilitating access to innovative medicines, products and treatments.

We also want to pay tribute to Dame June Raine, who stood down at the end of March – her strong leadership of the MHRA through challenging times has placed us well for the future.

Our new Business Plan sets out priorities for 2025–26 - protecting public safety and maintaining public trust; delivering efficient, predictable services through regulatory excellence; being an agile organisation that drives innovation; being a great place to work and providing excellent customer service.

The MHRA is in a good financial position, with major investments this year in transforming our service through our regulatory programmes and investing in facilities at our Science Campus. These investments contribute to enabling us to fulfil our crucial role in the Government's life sciences growth agenda and the 10 Year Health Plan.

We are also looking to the future, to develop a new ambitious strategy for the next three years. This will set out to build on our major contribution towards patient and public safety, our support for the NHS and UK innovation, and underscore the leadership we provide internationally.

We play an important independent role in supporting public health, scientific research and development, whilst supporting the Government's growth initiatives related to innovation, data and technology.

Ultimately, we keep the UK public and patients safe, play a key role in delivering the Government's economic ambition and share the ambition to build an NHS fit for the future. There are many opportunities ahead and – we are determined to seize them.

Anthony Harnden
Chair

Lawrence Tallon
Chief Executive

Introduction

Welcome to the Medicines and Healthcare products Regulatory Agency (MHRA) business plan for 2025–26.

We are the UK regulator of medicines, medical devices and blood components for transfusion. 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 (DHSC), we serve ministers and Parliament. Our work directly impacts patients throughout the UK.

This plan sets out our commitments that support the delivery of DHSC and wider government priorities, including the missions to ensure safe and fast regulatory approval, help build an NHS fit for the future, and to drive innovation and growth in the UK's life sciences sector.

We are dedicated to implementing an agile and risk-proportionate regulatory environment that enables growth and meets the ambitions set by the Prime Minister's Initiatives for Growth, and delivering our actions in the Chancellor of the Exchequer's Regulation Action Plan. From 23 July 2025, new regulations will allow the safe development of highly personalised and critical medicines to be manufactured and supplied for patients in hospitals or in their homes, at the point of care. This will make it easier to manufacture innovative medicines in the UK and will increase the attractiveness of the UK as a destination to market new life-saving medicines. We will also deliver on our commitments to work with NICE to offer a joint submission process and a joint pre-market scientific advice service.

Patient safety and public trust will always remain our highest ongoing priority, guiding every aspect of our work throughout the lifecycle of the products we regulate. This year, we will further improve access to timely, accurate information, when patients and healthcare professionals need it most. We will continue to address health inequalities and champion patients to be at the centre of the regulatory process and provide more opportunities for them to participate in decisions that impact them.

Last year, we made significant strides in delivering efficient performance and going forward, we will embed the changes needed to maintain consistent performance and deliver our core services efficiently within predictable timeframes.

We are modernising our systems to support this, ensuring we continue to work in the most efficient and transparent way. In 2025–26, we will deliver the next phase of our RegulatoryConnect system, which enables improved customer experience and usability, faster, more efficient approvals while maintaining safety, and improved information sharing and cooperation between UK healthcare system partners.

Our unique combination of regulatory science and real-world data, underpinned by our new data strategy and new scientific priorities, will mean we remain ready to embrace advancements in data, artificial intelligence, and personalised therapies. Strengthening our collaboration with partners will be vital for us to bring these transformational opportunities through to the UK public.

To ensure the MHRA is ready for its place in a rapidly changing regulatory world and is capable of delivering sustainable and excellent performance, we will support and invest in our people and continue developing our expert workforce.

Delivery of our Business Plan 2025–26 means we will actively demonstrate our role in supporting growth, attracting more companies to choose the UK market for first access and bringing products for the benefit of UK patients as quickly as possible, without compromising our strict safety standards.

What do we do

Science, Research, and Innovation Support

- Encouraging innovation in medicines and medical devices through expert advice services.
- Providing guidance to developers to help bring safe and effective products to market.
- Overseeing clinical trials and investigations to ensure new treatments are properly tested before public use.
- Conducting scientific research to stay ahead of advancements and improve regulatory processes.
- Developing reference materials to ensure the consistent quality of biological medicines.
- Developing and maintaining biological standards to ensure the safety and effectiveness of biological medicines, including vaccines, blood products, and cell therapies.
- Testing batches of biological medicines, blood products and vaccines to confirm they are safe and effective.

Authorisation and Validation

- Approving new medicines and vaccines, ensuring they meet strict safety, quality, and effectiveness standards.
- Regulating medical devices, overseeing everything from pacemakers to software and artificial intelligence as a medical device, to ensure they're safe and effective.
- Overseeing UK Approved Bodies that certify medical devices for market approval.
- Conducting inspections to ensure medicines and certain high-risk medical devices are manufactured, stored, and distributed safely.
- Granting emergency approvals, fast-tracking treatments in urgent situations like pandemics while maintaining rigorous safety standards.
- Updating regulations, adapting rules to keep pace with scientific advancements and evolving public health needs.
- Setting and enforcing advertising regulations for medicines in the UK.

Surveillance and Safety Monitoring

- Continuously tracking safety and running the Yellow Card scheme, which allows anyone to report a concern about medicines, vaccines, medical devices, blood products or e-cigarettes.
- In-depth assessments and responding swiftly to safety concerns by issuing warnings, updating product information, or removing unsafe products from the market.
- Protecting the safe supply chain by preventing counterfeit and illegal products through enforcement activities.
- Inspecting and making safety recommendations to blood establishments and hospital blood banks.
- Operating the Clinical Practice Research Datalink to support medical research and inform public health decisions.
- Deriving data insights from real world data including the conduct of bespoke studies.

The corporate teams in the MHRA provide essential support services that enable the agency to fulfill its regulatory mission effectively. They manage key functions such as accountability to the DHSC, finance, commercial, human resources, IT, partnerships, communications, patient involvement, and strategic planning, ensuring that all operations run smoothly and efficiently.

Our priorities for 2025–26

1 Protect patient safety and maintain public trust

1. Establish an enhanced role for the MHRA as a champion for patients to build confidence and trust.
2. Refresh our Patient Involvement Strategy 2021-25 and deliver this year's actions to ensure ongoing meaningful patient input into key decisions.
3. Complete the delivery of SafetyConnect to improve our ability to proactively protect patient safety.
4. Continuously improve how we communicate about safety and the accessibility of our patient information, and develop a strategy for more effective monitoring of the impact of risk minimisation activities.
5. Initiate a programme of work to address health inequalities across the areas we regulate.

2 Efficient, predictable services through regulatory excellence

1. Ensure efficient, predictable delivery of new medicines and efficient product life cycle maintenance based on risk-proportionate approaches.
2. Improve alignment between MHRA regulatory decisions and NICE guidance publication to minimise delays to patient access of medicines.
3. Modernise the regulatory framework for medicines and medical devices, including diagnostics and AI.
4. Drive innovation in global regulation through the development of reference materials and novel tests to support the introduction of diagnostics, new biologicals and the safety testing of products.
5. Deliver next phase of risk proportionate compliance strategy incorporating medical device.

3 An agile organisation that drives innovation

1. Launch a new integrated pre-market scientific advice service with NICE.
2. Develop a streamlined innovation pathway for transformative medicines and MedTech.
3. Develop a new framework to improve the regulation of therapies for rare diseases and personalised immunotherapies.
4. Enable innovation through implementing next phase of AI Airlock and develop our CERSI programme, including the use of in-silico approaches in clinical trials.
5. Deliver this year's goals in our MHRA Data Strategy and define and implement new scientific priorities.

4 A great place to work where careers flourish together with a responsive customer service

1. Attract and retain people with the right skills and potential through a strategic workforce plan.
2. Develop exceptional people and people leaders.
3. Value diversity and promote wellbeing and inclusion.
4. Deliver our RegulatoryConnect milestones for the year to enable better customer service and faster, risk-proportionate and more efficient approvals.
5. Finalise and begin delivering a new Customer Strategy with a roadmap of actions to improve our customer service.

Objectives for 2025–26

This section shows more detailed objectives under each of our four priorities:

1. Protect patient safety and maintain public trust

1.1 Establish an enhanced role for the MHRA as a champion for patients to build confidence and trust.

Patient safety will continue to guide every aspect of our work across the lifecycle of the products we regulate. Recognising that the patients and the public are important stakeholders in our work, in the year ahead we will focus our patient engagement activity in the pre-authorisation space. We will also strengthen the accessibility and transparency of information, ensuring patients, healthcare professionals, and the wider public can easily find and understand the latest safety information when they need it most.

1.2 Refresh our Patient Involvement Strategy 2021–25 and deliver this year's actions to ensure ongoing meaningful patient input into key decisions.

To ensure we continue to engage and involve the public and patients in our work, by end Q3, we will refresh our Patient Involvement Strategy based on our experiences and feedback received since its launch. In line with our commitment to embed patient involvement in all parts of the regulatory pathway, we will complete our pilot of patient involvement in pre-marketing authorisation by end Q4.

1.3 Complete the delivery of SafetyConnect to improve our ability to proactively protect patient safety.

We will deliver the final phase of SafetyConnect to modernise our safety reporting systems by end Q3. Our SafetyConnect Programme helps make safety monitoring faster, more efficient, and more data driven. Amongst other improvements, the final phase will enhance our safety signal detection of medical devices and deliver a common platform for medicines and medical devices.

Protect patient safety through robust safety surveillance systems

Protecting patients is at the heart of what we do. We run a robust safety surveillance system to continuously monitor medicines, medical devices, and blood components. Our SafetyConnect Programme allows us to detect safety signals earlier and take a more proactive approach, allowing faster action, such as product recalls, safety warnings, or updated usage guidelines. To inform the actions we take, we closely with our partners across the healthcare system, as well as with healthcare professionals and patients. Our Criminal Enforcement Unit helps protect patients from poor quality, fake and dangerous medical products by disrupting the illegal trade and bringing to justice those responsible. Overall, we provide patients with strong protection and ensure the UK healthcare system remains trustworthy, responsive, and focused on safety.

Objectives for 2025–26

1.4 Continuously improve how we communicate about safety and the accessibility of our patient information, and develop a strategy for more effective monitoring of the impact of risk minimisation activities.

We will refresh our existing patient safety communication products to make them more user-friendly by end Q2. We will also launch a consultation to get feedback from patients and the public on wider ideas to improve safety communications by end Q3.

We will develop a new strategy to deliver consistent processes to enable monitoring of the impact of risk minimisation activities by end Q4.

We will improve the accessibility of our healthcare advice for patients: we will work with healthcare system partners to better integrate our messaging with theirs, increasing our reach and accessibility by end Q4.

We will work with patients, healthcare professionals and our partners to scope the existing available sources of healthcare information, seek ideas for improving them, and finalise an action plan aimed at delivering better patient access to healthcare information by end Q4. This will also contribute to meeting the recommendations of the Patient Safety Commissioner's Safety Gap report.

1.5 Initiate a programme of work to address health inequalities across the areas we regulate.

By end Q3, we will finalise an action plan for tackling health inequalities between men and women and develop an action plan for tackling wider health inequalities, including increasing diversity in clinical research, encouraging product innovation in underserved populations and incorporating equality impact assessments into regulatory decision making.

We will improve diversity in UK clinical studies to help ensure that medical products are effective and safe for everyone and to build trust. We will launch a pilot with the Health Research Authority on developing diversity and inclusion action plans for UK clinical trials; We will also begin work with our Innovative Health Initiative (IHI) partners to identify unserved and underrepresented patients in clinical studies across Europe.

Objectives for 2025–26

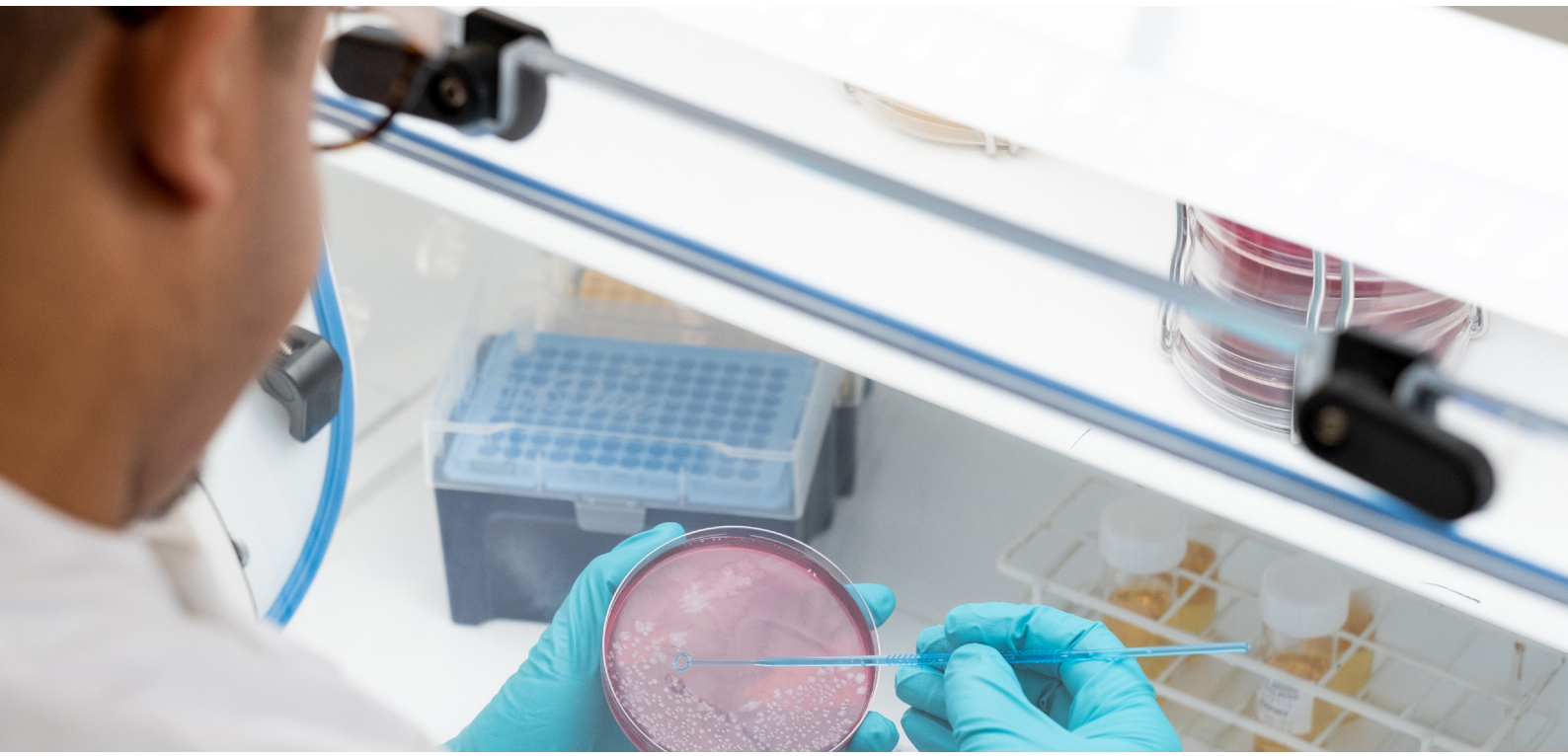
2. Efficient, predictable services through regulatory excellence

2.1 Ensure efficient, predictable delivery of new medicines and efficient product life cycle maintenance based on risk proportionate approaches.

We are committed to providing excellent services, maintaining predictable and reliable performance, and ultimately keeping patients and the public safe. Last year, we cleared our backlogs, and we will consolidate on that by embedding improvements to ensure this performance is sustainable. We will continue to publish data on our performance to be transparent and provide applicants with information on expected timescales.

2.2 Improve alignment between MHRA regulatory decisions and NICE guidance publication to minimise delays to patient access of medicines.

As part of our commitment to the Life Sciences Sector Plan and the 10-Year Health Plan, we will work with NICE to develop a new offer for industry: concurrent marketing authorisation from us and technology appraisal from NICE, enabled by enhanced data sharing and collaboration between our respective teams. This will save time, deliver further efficiencies, and increase the attractiveness of the UK as a place to launch novel therapies. A pilot of this new initiative will be launched by end Q4.



Objectives for 2025–26

2.3 Modernise the regulatory framework for medicines and medical devices, including diagnostics and AI.

We will work up proposals for modernising the UK's medicines regulatory regime to ensure it continues to deliver what patients and the wider sector expect and helps attract the life sciences industry to the UK. Priority areas will be identified, and policy development will begin by end Q4.

We will deliver the actions in our Medical Devices Regulatory reform roadmap, including:

- Publish the results of our consultations on In Vitro Diagnostics, International Reliance, Coronavirus test device approvals and Common Specs by mid Q1.
- Publish a statement of policy intent for early access and innovation by end Q1.
- Publish our In Vitro Diagnostics Roadmap by end Q2.
- Amend pre-market rules to improve safety and access for medical devices by end Q4.
- Deliver the second phase of our AI Airlock project by end Q4.

Objectives for 2025–26

2.4 Drive innovation in global regulation through the development of reference materials and novel tests to support the introduction of diagnostics, new biologicals and the safety testing of products.

We play a key role in the development, production and distribution of biological reference materials. They are used as benchmarks that help ensure accuracy, consistency and reliability of biological measurements which is essential for ensuring the quality, safety and efficacy of biological medicines and diagnostics. By Q4 we will provide 4 new and 8 replacement World Health Organization (WHO) standards to support development, evaluation and control of biological products and diagnostic assays across different areas including: therapeutic monoclonal antibodies, infectious disease serology, blood products and vaccines.

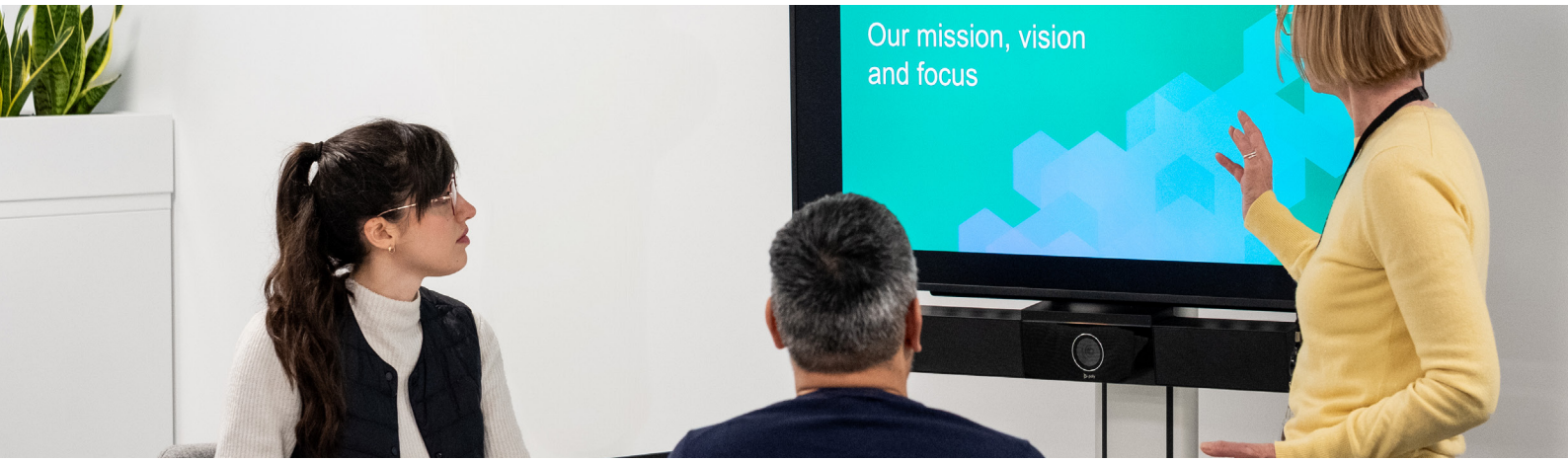
2.5 Deliver next phase of risk proportionate compliance strategy incorporating medical devices.

We will ensure compliance across the medical products lifecycle is risk-proportionate to promote patient safety and enable innovation. We will publish an integrated compliance strategy for medicines and medical devices by end Q3, and implement the first phase of its delivery plan by end Q4.

Embracing risk-proportionate regulation

Risk-proportionate regulation means adjusting regulatory requirements based on the level of risk. Rather than applying a one-size-fits-all approach for everything, we aim to focus our resources on high-risk areas while ensuring that lower-risk areas face fewer burdens. Our goal is to strike a balance between protecting patients, maintaining the integrity of the market and avoiding unnecessary regulatory costs or barriers to innovation – thus helping to promote growth. We are always looking for new ways to bring safe and effective medicinal products to patients in the UK. Most changes can be taken forward within existing legal frameworks, but where legislative change is needed, we consult with stakeholders and work through the Parliamentary process to ensure this happens.

Objectives for 2025–26



3. An agile organisation that drives innovation

3.1 Launch a new integrated pre-market scientific advice service with NICE.

As part of our commitment to the Life Sciences Sector Plan and the 10-Year Health Plan, by end Q1, we aim to pilot a new joint advice service with NICE that offers both shared and individual expertise. This will provide industry with the information, insights and applied knowledge to confidently and reliably create singular, shared end-point requirements for both regulatory decisions and Health Technology Assessment advice. This service will provide advice on medicines and will provide a single integrated report.

3.2 Develop a streamlined innovation pathway for transformative medicines and MedTech.

We will work with UK HTA and NHS bodies to explore how to develop a streamlined UK 'Innovation Gateway'. This will bring together, and modernise, current innovation pathways to provide rapid and continuous support and assessment of the most transformative medicines and devices.

- Launch of the new Innovative Licensing and Access Pathway (ILAP) and completion of the Innovative Devices Access Pathway (IDAP) pilot by end Q1.
- Work with health system partners to develop a new streamlined innovation gateway drawing on insights and lessons from the ILAP and IDAP pilot over Q2 to Q4, with a view to launching a pilot in Q1 2026/27.

3.3 Develop a new framework to improve the regulation of therapies for rare diseases and personalised immunotherapies.

We will launch a consultation to seek views on improving the regulatory framework for personalised immunotherapies, such as treatments for cancer, by end Q1 and update our guidance by end Q3. We will develop a framework to seek feedback on how to improve the regulation of therapies for rare disease by end Q4. We aim to promote access for underserved patient groups with rare conditions. We will include in this the development of how we will implement the concepts of platform approaches, which allow multiple products that use a common technology or process to be assessed more efficiently to streamline approvals.

Objectives for 2025–26

3.4 Enable innovation through implementing the next phase of AI Airlock and develop our CERSI programme.

The MHRA AI Airlock was launched in 2024 and is a controlled and safe environment for testing AI as a Medical Device (AIaMD) products. The project combines our expertise and partners including the UK Approved Bodies, the NHS and other regulators. The aim of the work is to accelerate the development of solutions to novel regulatory challenges for AIaMD. This year, we will work with a new cohort of candidates to address further regulatory challenges by end Q4.

Seven Centres of Excellence for Regulatory Science and Innovation (CERSIs) have been established, in partnership with Innovate UK, the Office for Life Sciences and the Medical Research Council. These projects are collaborative networks led by academic institutions, independent innovators or regulatory leaders. They will develop an evidence-base across key topics for the agency to help accelerate the delivery of pioneering treatments, ensuring patients benefit from cutting-edge innovations. One area of note this year is that we will be supporting the development of in-silico (computer modelling) approaches to testing treatments to reduce the time and costs involved in bringing new products to market. We will convene stakeholders to identity opportunities and ways of addressing regulatory challenges and of using in-silico evidence to support regulatory decision-making by end Q4.

Effective partnership working

Our ability to work well in partnership is crucial for the delivery of our objectives. We work closely with partners across the UK and international health systems to enhance our effectiveness, keep pace with developments, support patient access to innovative products and protect public health. This is important for helping to promote UK life sciences. We work with stakeholders to create a regulatory environment that encourages innovation while ensuring safety. It is also important for protecting public health, for example collaborating with the NHS and public health agencies to respond to safety concerns, or working with patient groups to ensure patient needs are considered.

Objectives for 2025–26

3.5 Deliver this year's actions in our new MHRA Data Strategy 2024-27 and define and implement new scientific priorities.

We will modernise and enhance the use of data in our operations for the benefit of patients and to ensure we are more efficient. This will include the increased use of AI and advanced data-analysis in signal detection, and especially in the context of medical devices. We will define and implement new scientific priorities for the agency by Q2 to maximise the value of our science capability.

A pilot "Scientific Dialogue Programme for Real World Evidence" was launched in February 2024. It aims to enable innovators to bring products faster to market and make them safer. The pilot will complete in July 2025 and if the evaluation is positive, a permanent programme will be started.

We have launched new Centres of Excellence in Regulatory Science. They will foster collaboration with academia and make tangible progress in developing our data science. By the end of Q4, we will publish guidance on the use of real-world data external control arm. This will support clinical trial sponsors planning a trial that includes a real-world data external control arm to use the trial to support a regulatory decision.

Objectives for 2025–26

4. A great place to work where careers flourish together with a responsive customer service

4.1 Attract and retain people with the right skills and potential through a strategic workforce plan.

We will implement year one of our three year strategic workforce plan including introducing contractual flexibility for new colleagues in Q1, planned recruitment strategies incorporating direct sourcing by end Q3, the initial planning for a new pay system and the identification of new workplaces by Q4.

4.2 Develop exceptional people and people leaders.

We will launch the “MHRA Academy” and deliver its first-year objective of a comprehensive core learning and continuing professional development offering for our regulatory professionals in Q2, and we will provide bespoke eLearning for staff by launching a new learning management system by end Q3. We will continue to embed the Civil Service line management and leadership standards into our development programmes, further utilise coaching and mentoring across the agency, and continue to promote the accredited pathway for Senior Civil Servants as is currently being rolled out by the Cabinet Office.

4.3 Value diversity and promote wellbeing and inclusion.

We will review our workforce and consult with our staff by end Q2 and begin implementing measures by Q4 that promote a senior workforce that better reflects the diversity of the UK.

In collaboration with our Trade Unions, we will introduce wellbeing initiatives to help managers support their teams more effectively, with a particular focus on neurodiversity, and our senior leaders will lead an initiative to improve our People Survey staff engagement scores by Q3

Fostering an inclusive workplace where people flourish

We strive to create a patient focused workforce where people and excellent performance are valued equally. The wellbeing of our people and their satisfaction with the MHRA as an employer is key to delivering agile innovative regulation in a culture where opportunities for learning will consistently improve performance. We value diversity of thought and a change mindset that supports growth. We strive to build the trust of our people through living our values and setting challenging, achievable objectives that relate to our common purpose of keeping UK patients safe.

Objectives for 2025–26

4.4 Deliver our RegulatoryConnect milestones for the year to enable better customer service and faster, risk-proportionate and more efficient approvals.

RegulatoryConnect is a strategic change programme across MHRA's regulation of medical products including a new IT system that will modernise our existing regulatory IT systems and make our regulatory services more streamlined. It improves the service we provide to customers by giving them the ability to track their applications and view live authorisation details. It also helps make the agency more efficient by capturing more data to inform risk-proportionate regulatory decisions, providing timely and accurate reporting, and automating routine or administrative tasks.

The project is a multi-year programme and this year we will deliver the next major release of improvements. By end Q4, we will enable improved customer experience and usability resulting in faster, more efficient approvals, improved information sharing and cooperation between UK healthcare system partners.

4.5 Finalise and begin delivering a new Customer Strategy with a roadmap of actions to improve our customer service.

Our new three-year Customer Strategy will set out a roadmap of service enhancements that are designed to ensure improved, more timely and consistent handling of enquiries from our customers. This year we will finalise the strategy and begin delivering the first year's actions. This will include streamlining and improving the ways customers can contact us, making our processes more efficient, ensuring consistent standards, and improving performance metrics to encourage better customer service.

Our key performance indicators

Our key performance indicators for 2025/26 and their targets are shown below.

Last year, we made significant progress in delivering efficient performance. We have now restored our performance and are delivering statutory services to the expected timelines. We also now publish performance data each month to ensure greater accountability for our services and improve the customer confidence in our reliable, predictable performance.

We are committed to maintaining our performance within predictable and statutory timeframes and providing excellent services for our customers. In addition, we will aim to continuously drive down median times in all the areas below.

1. **We will complete 95% of all initial Clinical Trial Authorisations and Clinical Investigation applications within their category's statutory timeframe (30 days and 60 days, respectively).**

2. **We will certify 95% of vaccine batches within 43 days and 99% of blood product batches within 15 days of submission.**

3. **We will determine 95% of medicines licence applications within 210 days via the national route.**

4. **We will determine 95% of medicines licence applications through the International Recognition Procedure within 60 days via recognition Route A and within 110 days via Route B.**

5. **We will determine 95% of all variations within their category's statutory timeline (Type 1b: 30 days and Type 2: 90 days or 120 days).**

6. **We will grant, vary or refuse 95% of applications for manufacturing and distribution authorisations within their category's statutory timeline (90 days and 30 days, respectively).**

7. **We will process 90% of all UK initial spontaneous reports of adverse incidents related to healthcare products within 24 hours.**

8. **We will offer a meeting date for 95% of Scientific Advice requests within 10 days of submission and we will deliver the formal written advice for 95% of requests within 30 days of the meeting date or, if no meeting is required or requested, within 30 days of receiving company documentation.**

Budget 2024–25

As an executive agency of the DHSC, our budget is a mix of government funding and revenue from fees and grants. We set our fees to recover the full cost of delivering the respective service. This is standard practice as outlined in HMT guidance “Managing Public Money”. To ensure we continue to recover our costs, we aim to update our fees every two years. The year 25/26 will see a increase two-fold in our funding: we are increasing our fees plus we have received additional funding from DHSC as part of the Spending Review.

Our ambition is to remain financially sustainable and recover the costs for our day-to-day operational responsibilities through this Corporate Plan period. However, we are not able to use income for capital investment and continue to rely on DHSC. DHSC has provided a large uplift in investment for 25/26 to invest in our South Mimms scientific campus plus our IT programme, Regulatory Connect.

The table below shows our budget for this year’s Business Plan:

	£m
Operational Income	169.1
DHSC resource DEL Funding	34.8
Total Funding	**203.9**
Staff	116.7
Operating	67.7
Projects	19.4
Total Costs	**203.8**
Surplus/Deficit	0
DHSC Capital Funding	**47**

Corporate governance

We are governed by an agency board that is responsible for advising on our strategic direction and ensuring that objectives in the Business Plan are met. More details, including the board's membership, can be found here.

The board supports the Chief Executive in the delivery of services and overall performance by providing leadership, advising on strategy and the delivery of policies, maintaining high standards of governance, scrutinising performance and ensuring controls are in place to manage risk.

Our Chief Executive, as the Accounting Officer, is responsible to ministers, the Permanent Secretary of the DHSC and Parliament directly for the use of public funds and for the day-to-day management of the agency.

As a public body, we take our responsibilities to ensure optimal governance seriously. Last year we delivered a substantial Executive owned programme to strengthen our control environment. With a relentless focus on driving improvement, we have significantly strengthened our assurance mapping of the agency, mapping controls across our activities and services, conducting a detailed analysis of the control environment and increasing our compliance with the Government Functional Standards.

Throughout the year, we will continue to strengthen our control environment with a commitment to ensuring our agency is well run, with controls to ensure we meet our objectives consistently. This is a responsibility for all staff.

In support of this commitment, we will:

- Manage risks at all levels, in line with our risk management framework, to enable delivery in our challenging and complex operational environment.
- Work closely with Government's Internal Audit Agency to facilitate the delivery of the audit programme and act swiftly on audit recommendations to address any identified opportunities for improvement.
- Enhance our assurance maps to ensure proportionate effective controls and deliver activities to increase our compliance with the Government Functional Standards.
- Enhance our Quality Management System by providing challenge to our current systems, addressing areas for improvement and continuing to develop our approach to quality in support of sustainable services.
- Be vigilant to health and safety risks and ensure we follow guidance to maintain our own wellbeing and promote the wellbeing of our colleagues.
- Ensure value for money in our use of public funds, including via our fees, and apply the Public Sector Equality Duty to ensure we consider the impact of changes on patients, the public and our staff protected by the Equality Duty.

These commitments and controls support our collective responsibility for ensuring the agency delivers effectively.

Contact us

If you are a patient, member of the public, healthcare professional, or work in the sectors we regulate and would like more information on our work, please contact us.

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