Medicines & Healthcare products Regulatory Agency

MHRA Corporate Plan 2023-26

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

Contents

Introduction

The Medicines and Healthcare products Regulatory Agency (MHRA) has a unique capability in the regulation of medicines, medical devices and blood components for transfusion in the UK, related to our expertise and our assets of ground-breaking science, innovative regulation and real-world data.

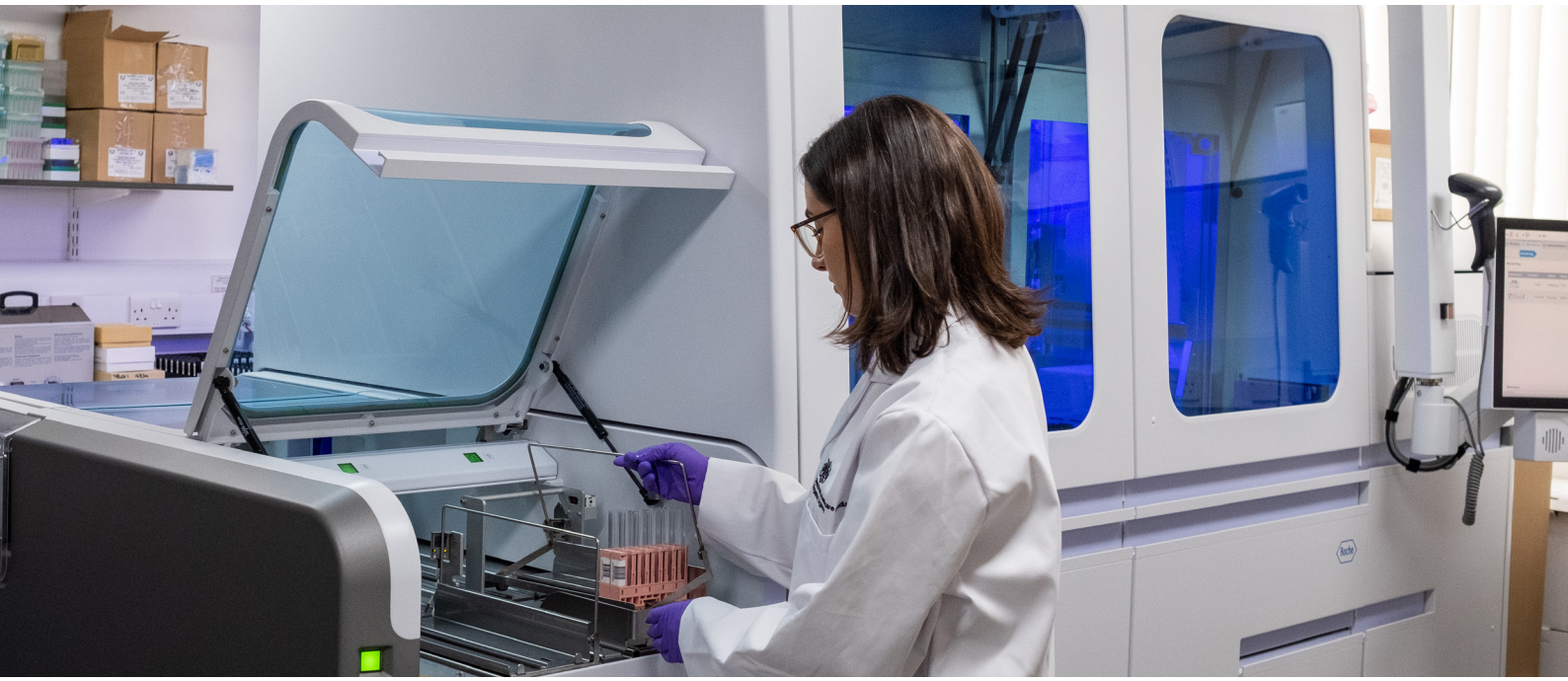
As such, we have a vital role to play in fulfilling the UK Life Sciences Vision, balancing our responsibilities to maintain product safety and champion innovation. Our world-leading response to the COVID-19 pandemic demonstrated what an agile, flexible regulator can accomplish. We will now embed these new ways of working to deliver organisational transformation that both puts patients first and supports research and development.

The transition from being a member of the European regulatory network to becoming a standalone sovereign regulator has presented opportunities for legislative reform to adapt to the needs of new technologies and strengthen patient safety.

It has also brought home the importance of working in partnership with other regulators both nationally and internationally.

Our transformed regulatory processes aim to provide an attractive environment for the life sciences industry. There is an even greater need for the MHRA like other public sector bodies to maximise productivity and deliver value for money, through efficient and risk-proportionate regulation. To maximise scientific and regulatory synergies, we have reduced in size and brought previously separate operating units together. Retaining and motivating our people is a high priority.

Our 2023-26 Corporate Plan responds to all these economic, scientific and people challenges, allowing us to continue playing a central role in securing, high-quality and safe medical products for patients in collaboration with our partners within UK and international health systems. As new medical technologies are developed globally, we will continue to adapt our ways of working to remain relevant. Our critical priority to protect and improve public health is, and will remain, the golden thread through all our work.



Strategic priorities for the next three years

Our core purpose is to use 'scientific expertise, support for innovation and the risk-proportionate regulation of medical products, to protect and improve public health across the UK.'

This definition has been refined to reflect the breadth of the scientific and regulatory activities within the organisation, operating as one agency across all stages of the medical product life cycle including facilitating scientific research and innovation, enabling patient access, and strengthening surveillance.

Our explicit commitment to 'risk-proportionate regulation' also represents a significant intent to increase regulatory oversight on high-risk medical products, applications and indications, especially in relation to new technologies, with a parallel reduction in regulatory oversight on products where there is clear evidence of a lower risk to patients. We will also continue to address health inequalities where regulation can actively contribute and promote greater sustainability.

Following an extensive process of internal and external engagement, our ambitions have been prioritised and are focused on the following four strategic priorities over the next three years:

1 **Maintain public trust through transparency and proactive communication**

2 **Enable healthcare access to safe and effective medical products**

3 **Deliver scientific and regulatory excellence through strategic partnerships**

4 **Become an agency where people flourish alongside a responsive customer service culture**

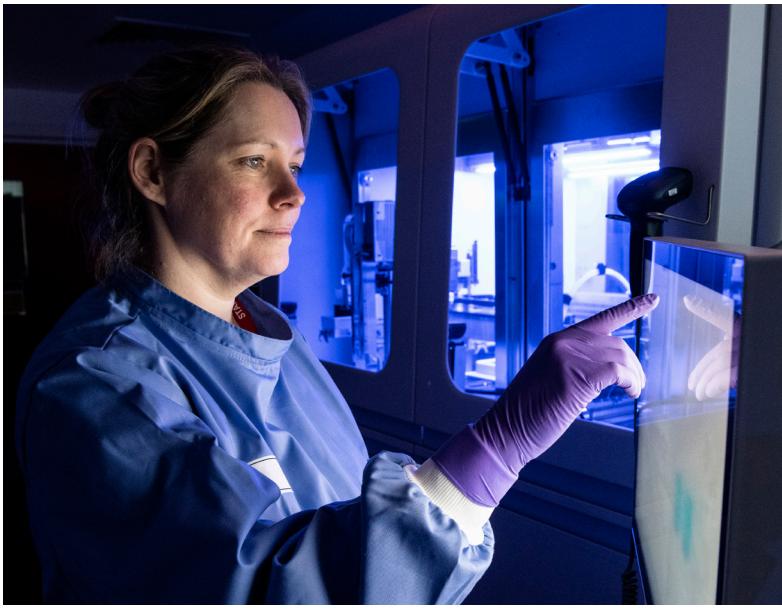
1. Maintaining public trust through transparency and proactive communication

Patients and the public rely on us to ensure that all medical products used in the UK meet the necessary standards of safety, effectiveness, and quality. We retain our independence in making data-driven regulatory decisions consulting our independent expert committees to ensure that the balance of risk and benefit is positive for all medical products being used in the UK.

No medical product is completely free of risk and we will always take our responsibility seriously, rigorously and transparently when balancing the population risks and benefits of each medical product. We have access to an ever-increasing range of data sources and real-world evidence to fulfil our regulatory functions. This requires optimal use of digital technology and analytical tools to assess the impact of specific products on individual patients.

The MHRA must publish conclusions on regulatory approvals and safety actions transparently to the public to fulfil our statutory responsibilities to maintain trust. During the COVID-19 pandemic, we provided a new level of openness and transparency about how our decisions were reached by publishing safety reports on the new vaccines and therapeutics. As the clinical experience and safety data expanded on these products, or when the recommended use of these new products changed, we communicated rapidly and transparently with healthcare professionals and the public.

The MHRA aims to involve patients at every step of the regulatory process to ensure that the balance of risk and benefit is considered from all perspectives.



This will require developers to demonstrate that they have consulted patients in the development of new products and the design of clinical trials and investigations. It also requires us to systematically involve patients and lay representatives in advisory committees while making regulatory decisions and to respond quickly when people report problems.

We will become more proactive in our safety approaches by inviting patients who have reported side effects or safety concerns about specific medical products through the Yellow Card scheme to give a sample of their DNA for analysis. Through the establishment of the Yellow Card biobank we aim to identify genetic factors in patients who have suffered side effects, enabling more targeted approaches to minimise harm and by informing future drug development approaches.

The MHRA will continue to work with partners to ensure the continued effective operation of the self-regulatory system of advertising control and help ensure it continues to adapt to new media and industry practices and maintain confidence and trust of the public.

To maintain public trust, the key actions we will take over the next three years are:

Year 1: 2023/24 (to be completed by 31 March 2024)

1.1 **Embed patient involvement across our regulatory pathways** that is meaningful, proportionate and impactful, to help ensure medical products reach patients without delay, accompanied by efficacy and safety information that better meets the needs of all patients.

1.2 **Enable diverse patient voices** to provide evidence on safety concerns on specific types of medicines and medical devices.

1.3 **Increase transparency of safety signals and the basis of our benefit-risk decisions** by regularly publishing the safety signals on medical products and a public statement following approval of all new chemical entities within one week, plus a summary of the evidence for the regulatory approval within one month.

Year 2: 2024/25 (to be completed by 31 March 2025)

1.4 **Pilot public hearings on major safety issues** to bring the experience of patients and stakeholders into consideration openly and transparently.

1.5 **Pilot the introduction of a single unified gateway to the MHRA** through a new Customer Experience Centre knowledge hub, using automation and easy to access guidance to speed up access to information and enquiry response times.

1.6 **Complete a Yellow Card biobank pilot** focused on two important drug safety issues over two years and develop a business model to roll out across all medicines and vaccines to better minimise risks for all patients by understanding the role of genetics in adverse reactions.

Year 3: 2025/26 (to be completed by 31 March 2026)

1.7 **Patient input into decision-making on scientific assessments** to ensure patient input of experience before product authorisation; and into at least half of our substantial risk-benefit reviews after authorisation.

1.8 **Launch the Customer Experience Centre knowledge hub** as a single point of contact to the MHRA, offering communication that is efficient and customer-focused, with a new target response time for routine public enquiries of 10 working days.

1.9 **Pilot public awareness activities to increase patient understanding of their benefit-risk decisions** through new approaches to increase the clarity, comprehensiveness and transparency of our communications.

2. Enable healthcare access to safe and effective medical products

Developers, manufacturers and distributors of medicines and medical devices rely on us to provide robust decisions in predictable timeframes for high-quality applications in clinical trials and investigations, marketing authorisations, control testing and variations to existing approvals. Medical devices developers require clarity on requirements and standards, and consistency of application across conformity assessment bodies.

In a highly competitive global market, applicants seeking approval to market products need a reliable and responsive regulator so they can plan with confidence and ensure that UK patients can benefit from their new medical products at the earliest opportunity.

The introduction of new legislation and guidance for clinical trials, medical devices, and point of care manufacturing is critically important to attracting innovative products, whilst also providing the stable and predictable regulatory environment that companies require. By working with partners across UK health ecosystem, we will create faster risk-proportionate, and predictable regulatory pathways. These will support innovation and create a compelling reason for companies to introduce new medical products that support health priorities, deliver for diverse patient groups and address health inequalities in the UK.

This approach will be achieved by building on our existing capabilities and creating state-of-the-art specialist expertise in highly innovative areas of medical product development, where risk-proportionate regulation often needs to be established in parallel with the development of innovative products.

Our priority regulatory pathways to support innovation and the introduction of new medical products will be described in our Science Strategy and align with the following areas:

- Vaccines and immunotherapies
- Biotherapeutics, cell and gene therapies
- Diagnostics and genomics
- Data science
- Artificial intelligence (AI) and software as a medical device

This will be further strengthened by working in collaboration with partners across UK health ecosystems to design and deliver joined-up services for developers. This has already started with the development of the AI and Digital Regulation Service; the Integrated Research Application System; and the Innovative Licencing and Access Pathway. We will continue working with our stakeholders to improve these initiatives over the next three years, enhancing the attractiveness of the UK as an enabling environment in which to develop and launch new medical products.

We will streamline and automate our existing national regulatory processes through significant investment in a new regulatory management system incorporating new functionalities such as self-service. This system will support the new risk-proportionate regulatory approaches and enable the MHRA to consistently achieve competitive timescales for the UK determination of every type of application in comparison with other international regulators.

The key actions we will take over the next three years to enable predictable healthcare access to safe and effective medical products are:

Year 1: 2023/24 (to be completed by 31 March 2024)

2.1 **Deliver predictable and reliable operational performance,** having defined our priority improvements for our core services to ensure swift and robust decisions on medical products, safety signals and compliance.

2.2 **Develop and embed system cooperation with UK partner organisations,** including the NHS, to ensure the gap continues to be narrowed between regulatory and health technology approval with a clear path to patient deployment.

2.3 **Launch the improved regulatory management system** to make our services more streamlined, as the first phase of the replacement of legacy IT systems, enabling all new product licences, variations, inspections, and process licences to be efficiently handled, maximising the use of self-service for low-risk decisions.

Year 2: 2024/25 (to be completed by 31 March 2025)

2.4 **Optimise service delivery times in priority areas, including scientific advice**, to strengthen our support for innovation and improve our ranking for quality and turnaround times against comparable regulators. We will do this by using insight and improved processes to target our resources where we add most value.

2.5 **Introduce new guidance and legislation, building our status as an independent regulator in a global environment,** to ensure the UK remains a great environment to develop novel and innovative medical products.

2.6 **Improve patient access by formalising new recognition pathways for UK approval** that complement our national routes to market and that provide a legal base to allow for expedited access for some medicines and medical devices where these have already been approved by trusted regulators.

Year 3: 2025/26 (to be completed by 31 March 2026)

2.7 **Transform the regulation of generic medicines,** building on defined criteria to meet evolving goals where regulator involvement adds most value, for example for sustainable medicines including green chemistry and reduction of plastics.

2.8 **Embed lifecycle risk proportionate approaches** enabling a greater proportion of self-declared or 'do and tell' processing, where defined safety and efficacy criteria are met and there is explicit allocation of responsibility.

2.9 **Implement a revised regulatory framework for compliance,** which is outcome-based and supports the implementation of our wider regulatory reforms such as the clinical trials framework and new provisions for point of care manufacture.

3. Deliver scientific and regulatory excellence through strategic partnerships

We are an integral part of the UK health ecosystem, working closely with the devolved health systems and the research and development community. We will build on our existing relationships to enable timely, safe access to medicines and medical devices. In the UK, this means greater integration, better communication, and more collaboration with partners. This will enable us to respond to national priorities, and to work in an agile way with UK healthcare organisations.

Internationally, we will work closely with other regulators to develop pioneering regulatory practice. This collaborative regulatory environment will help us become established as a national and international partner of choice. International regulators and laboratories rely on us to contribute constructively to the development and alignment of medical product regulations and biological standards around the world. We are an active member of international regulatory groups such as the International Council for Harmonisation, the International Coalition of Medicines Regulatory Authorities and the International Medical Device Regulators Forum (IMDRF).

We are also a member of the Access Consortium. As well as the UK, this includes the medical product regulators of Australia, Canada, Singapore and Switzerland. The consortium is committed to maximising collaboration by aligning regulatory and policy approaches, reducing duplication, and identifying opportunities for work-sharing. By working together, the consortium creates a more attractive market opportunity for global companies than any of the countries on their own. As a standalone sovereign regulator, we are free to forge other bilateral partnerships of mutual interest such as: the U.S. Food and Drug Administration's (FDA) Project Orbis, and with the regulatory authorities of Australia, Brazil, Canada, Singapore and Switzerland.

As regulators globally recognise the place of reliance and recognition in bringing new products speedily and safely to patients, we will continue to build and develop working arrangements with other leading regulators. Our international and national partnerships have numerous benefits as the opportunities for work-sharing and the mutual recognition of regulatory decisions creates a more attractive market opportunity for companies and earlier access to new medical products for UK patients. These partnerships also provide an opportunity for efficiency savings, productivity improvements and less reliance on funding from the Department of Health and Social Care.

Our laboratories perform a vital function as the UK National Control Laboratory and a World Health Organization (WHO) Collaborating Centre for Biological Standards. These are one of only four global WHO Essential Regulatory Laboratories for influenza producing reference materials for influenza vaccines throughout the world. This activity is combined with world-leading research into diseases such as polio through the WHO Collaborating Centre, and partnerships with international philanthropic bodies such as the Bill and Melinda Gates Foundation and Coalition for Epidemic Preparedness Innovations (CEPI), providing strong partnerships around the world and nationally to help protect public health.

We host the UK Stem Cell Bank which supports scientific research and the clinical development of stem cell therapies in the UK and internationally. When combined with world-leading research into cell-based therapies, diagnostics and therapeutics and partnerships with international organisations, we will continue to seek sources of external funding to be at the forefront of protecting public health in the UK and internationally.

We will develop our expertise in data science and its applications to position ourselves as a leading regulator for current advancements such as: artificial intelligence and software as medical devices; the growth of genomics in supporting therapeutic use; the rise of digital therapeutics; the development of *in vitro* diagnostics; and the use of synthetic data, social and behavioural sciences to support treatments for individuals and populations.

All these unique scientific capabilities truly differentiate us from other international regulators, which is why working together as one agency across all specialist disciplines is vitally important. Our overarching ambition is to define and take a lead in the future development of regulatory science.

The key actions we will take over the next three years to deliver regulatory and scientific excellence through strategic partnerships are:

Year 1: 2023/24 (to be completed by 31 March 2024)

3.1 **Introduce the MHRA Science Strategy,** establish and build on partnerships in key priority areas with national and international partners with measurable benefits that support prompt, and robust regulatory decision-making.

3.2 **Re-prioritise standards, control testing and underpinning research** to ensure support for priority areas of our Science Strategy and Corporate Plan.

3.3 **Legislate on Point of Care Manufacture** and drive international regulatory progress in key scientific areas commensurate with scientific and technological advances such as mRNA technology, artificial intelligence and *in silico* data generation.

Year 2: 2024/25 (to be completed by 31 March 2025)

3.4 **Enhance our access to scientific evidence to inform our decision-making** by building on existing and forming new partnerships to establish a network of Centres of Excellence in Regulatory Science, made up of academic and key scientific and research bodies nationally and internationally.

3.5 **Contribute to the UK's pandemic preparedness** via a strategy building on the achievements and skills demonstrated during the COVID-19 pandemic.

3.6 **Deliver a sustainability strategy for medical products** in conjunction with international regulators, which contributes to addressing the climate change emergency.

Year 3: 2025/26 (to be completed by 31 March 2026)

3.7 **Establish a support offer for regulatory system development** in low and middle income countries in collaboration with global public health initiatives and organisations such as the Bill and Melinda Gates Foundation.

3.8 **Complete prioritisation of the biological and chemical standards portfolio** to ensure greater public health impact and support for diagnostics and life sciences innovation, building on work delivered in earlier years.

3.9 **Deliver UK innovation focussed legislation to strengthen our ability to support innovation** and to simplify the UK healthcare products regulatory regime via established recognition mechanisms.

4. Become an agency where people flourish alongside a responsive customer service culture

Our staff expect the agency to provide stimulating and fulfilling work, along with the pride from being part of an organisation which provides a vital public service. Since the EU Exit, we have enhanced our talented and skilled workforce with additional expertise bringing a wide range of new skills and experience to build capability and capacity.

We will continue to invest in the development of staff at every level of the organisation to ensure we have the right capability to deliver our public health role and to help staff develop rewarding careers. We will use our graduate scheme and apprenticeship programme to increase our talent pool. The MHRA will continue to promote shared learning opportunities across the health family, including secondments and loans. We are building a workplace where continuous training and development are supported and expected.

This approach will ensure people flourish, and that customer needs are routinely met or exceeded. We greatly value the expert healthcare professionals and volunteer patient representatives who contribute to our advisory committee and other activities, and will build on the current progress we have made in these important partners. The same approach will be adopted in our corporate functions, where we will be responsive to external enquiries and the level of internal customer satisfaction.

We will ensure that we have performance measures that incorporate external customer responsiveness and outcomes, and that we have the processes to monitor and deliver them. In terms of patient safety, we will measure our timeliness in detecting safety signals in a global context and the time taken to issue alerts from the identification of the initial safety signal. For access to new medical products, the number of high-quality regulatory decisions made within the maximum guaranteed or statutory timescale will be a key measure.

The key actions we will take over the next three years to ensure our people flourish and to support a responsive customer service culture, are:

Year 1: 2023/24 (to be completed by 31 March 2024)

4.1 **Deliver a range of core and specialist learning opportunities** and implement and review the agency leadership development plan, to ensure we have the right capabilities across the organisation.

4.2 **Attract and develop talent** by strengthening existing or creating new recruitment channels such as a graduate scheme and increasing apprenticeships.

4.3 **Develop a new financial plan** to ensure we continue to deliver value for money, invest in people, maintain our financial sustainability and recover the costs of all our services, with updates to our fees to be in force by 1 April 2025.

Year 2: 2024/25 (to be completed by 31 March 2025)

4.4 **Invest in our culture** by delivering our new Culture Action Plan and embedding our refreshed values and behaviours in all our activities.

4.5 **Embed workforce and succession planning** along with an inclusive talent management programme to ensure everyone has career development routes and opportunities to flourish in their role.

4.6 **Increase accountability for our services** by improving the transparency of key performance data we publish, to provide a comprehensive overview of the efficiency and effectiveness of the agency's core activities.

Year 3: 2025/26 (to be completed by 31 March 2026)

4.7 **Improve overall customer service** through refreshed or new service standards and processes in place to monitor delivery with systematic collection of feedback.

4.8 **Achieve the Equality and Diversity Framework** Gold Standard, ensuring an inclusive workplace where staff can thrive.

4.9 **Ensure the MHRA is a great place to work** by becoming an employer of choice as the ultimate outcome of this strategic priority, making sure the culture, leadership style and employee engagement initiatives are desirable to potential candidates and current employees.

Financial sustainability

Now that we have transitioned from a Trading Fund, the agency will closely manage its financial income and expenditure within each financial year.

Our ambition is to become financially self-sufficient from the Department of Health and Social Care (DHSC) for all our day-to-day operational responsibilities through this Corporate Plan period.

However, the agency is not able to use income for capital investment, so will continue to rely on the Department to provide our capital budget.

Additional resource and capital funding from the Department of Health and Social Care will be required to implement new UK Government priorities and to build the digital technology and data analytics capabilities that are required to implement this Corporate Plan.

Realisation of this strategic opportunity

This Corporate Plan sets out our strategic priorities, which are to maintain public trust; enable predictable healthcare access to safe, and effective medical products; ensure scientific and regulatory excellence through strategic partnerships; and to create an agency where people flourish alongside a responsive customer service.

The Plan is intended to provide a high-level roadmap for the next three years and more detailed Annual Business Plans will be published with the key actions for each financial year. Our Executive Committee is accountable for the delivery of this Corporate Plan and each Annual Business Plan.

The Executive Committee reports its progress and mitigation of risks quarterly to the MHRA Board held in public. The conclusions from the Board meeting will then inform the assurance provided to the Department of Health and Social Care through our Quarterly Accountability Meetings.

We are at a pivotal moment in our evolution, and we have a unique opportunity to further our mission to protect and improve public health through our scientific expertise and the risk-proportionate and agile regulation of medical products. We will continue to balance keeping patients safe and enabling the development of innovative new medical products in the UK.

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.

Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf,
London E14 4PU, United Kingdom
Email: **info@mhra.gov.uk**
Telephone: **020 3080 6000**
(weekdays 9am to 5pm)
Website: **mhra.gov.uk**

Published: July 2023