Medicines & Healthcare products Regulatory Agency

MHRA Business Plan

2023-24

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

Published September 2023

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Introduction

We are the Medicines and Healthcare products Regulatory Agency (MHRA), the UK's regulator of medicines, medical devices and blood components for transfusion in the UK.

We are an Executive Agency of the Department of Health and Social Care (DHSC) and details on our relationship with DHSC can be found in our Framework Agreement.

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. We are an integral part of the UK health ecosystem, working closely with the devolved health systems and the research and development community.

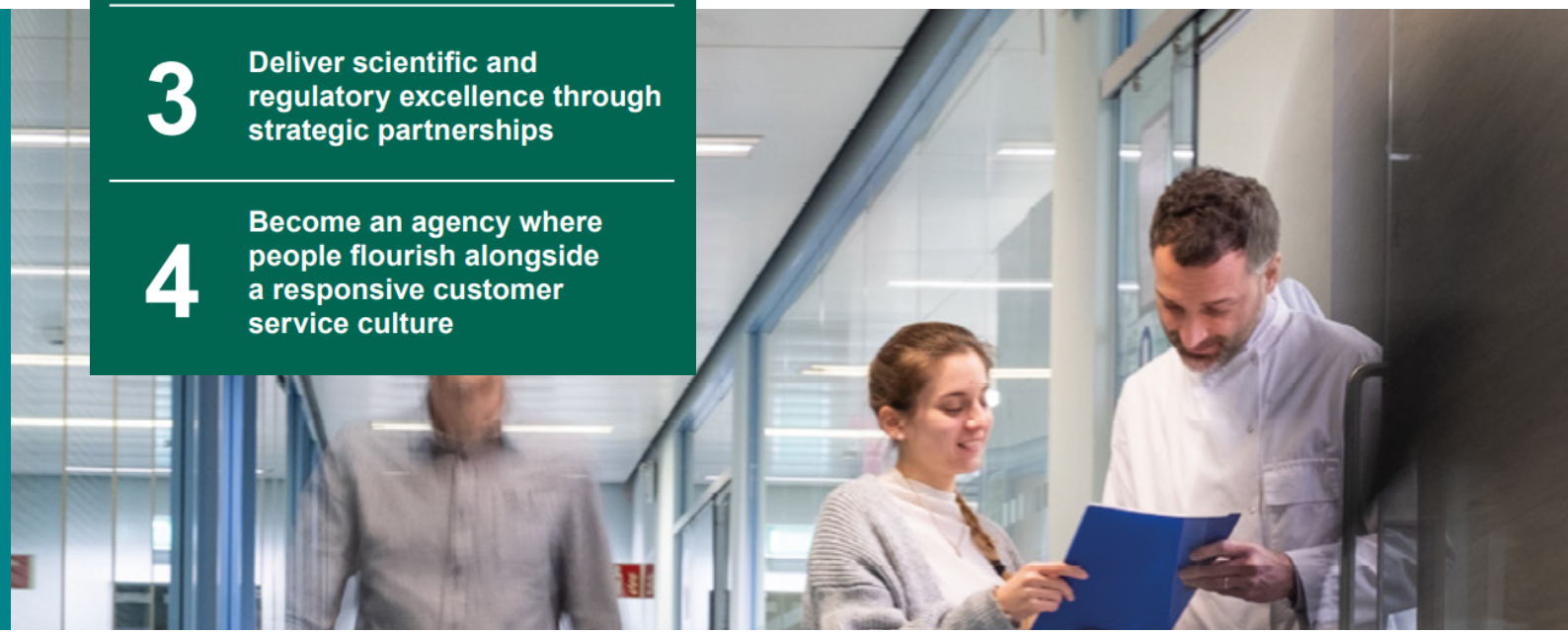
Our Corporate Plan 2023-26 sets out our strategic priorities for the next three years, which are to:

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**

The Corporate Plan also lists key actions for each of these strategic priorities and over each of the three years of the Plan.

This document, our Business Plan for 2023-24, provides detail on our objectives for the first year of the Corporate Plan. Over this year, we will also work to ensure that we are ready to deliver our second year's key actions on time. More details will be provided in our next annual Business Plan.

Over this year and into the next there will be a number of important developments including optimisation of our service delivery times in priority areas, improved patient access to innovative products by formalising new recognition pathways for UK and the introduction of new guidance and legislation on critical areas such as clinical trials, Medtech and UK Point of Care Manufacture to build on our opportunities as an independent regulator in particular to strengthen patient safety.



1. Maintain public trust through transparency and proactive communication

Our 3 key actions and their underpinning objectives for this year are:

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.

- Ensure patient involvement activities remain ethical, meaningful and impactful by embedding new tailored guidelines for priority agency functions by end Q3.
- Develop a new risk communication strategy to ensure more coordinated, proactive risk and safety communications to patients, the public and healthcare professionals, by end Q4.
- Design a new approach to recruit and train additional lay committee members (non-clinical, academic or scientific) to ensure our independent advisory bodies benefit from greater lay perspectives and challenge by end Q4.

Successfully achieving this key goal:

Greater patient involvement results in medical products that better meet the needs of patients, more effective patient safety actions and ultimately improving public trust in our decisions and public.

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

- Establish a consistent, inclusive and systematic approach to ongoing patient involvement in our benefit and risk evaluation assessments by end Q3.
- Complete a review of regulatory opportunities to address health inequalities by end Q4.
- Identify two safety topics affecting underserved groups by end Q3 and engage with patients so they can raise concerns and to inform our approach by end Q4.
- Broaden our communications channels to reach under-represented and under-served populations, ensuring the contribution of more diverse voices by end Q4.

Successfully achieving this key goal:

The information we use to inform our decisions will be more representative of the UK's diverse population, helping to address health inequalities by making our patient safety actions more targeted.

1. Maintain public trust through transparency and proactive communication (continued)

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.

- Make Yellow Card incident report data available in the new COVID-19 interactive format for medicines by end Q2 and devices by end Q3.
- Pilot publication of safety signals assessed by our Pharmacovigilance Expert Advisory Group on our Yellow Card website and the publication of accessible lay summaries of our benefit and risk evaluation assessments by end Q4.
- By end Q4, establish the governance of the Yellow Card biobank and successfully demonstrate procedures in action for participant recruitment, sample collection and sample storage.
- By end Q4, regularly publish a public statement following approval of all new chemical entities within one week and provide a summary to provide the evidence for the regulatory approval within one month.

Successfully achieving this key goal:

We will maintain and build the trust and confidence that patients, the public and the wider health and social care system have in our decisions.

2. Enable healthcare access to new, safe and effective medical products

Our 3 key actions and their underpinning objectives for this year are:

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.

- Identify service improvements across all priority areas with robust plans for implementation and effective change management to be in place by end Q4.
- Eliminate current service backlogs by end of Q4 keeping stakeholders up-to-date.
- Deliver phase one of our innovation-enabling and risk-proportionate medicines compliance strategy including the development of a pilot project for an outcome-based model by end Q4.
- Fully embed our new SafetyConnect vigilance system and realise patient and operational benefits by end Q4.

Successfully achieving this key goal:

Developers, manufacturers and distributors of medicines and medical devices will continue to rely on us to provide robust decisions in predictable timeframes.

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.

- Establish the UK healthcare systems' priorities for medicines and medical devices in terms of patient need and proactive supply chain management and to inform our priorities by end Q3.
- Establish the Innovative Licensing and Access Pathway (ILAP) and the Innovative Devices Access pathway (IDAP) by delivering a partnership governance that delivers ILAP activities and the IDAP pilot project by end of Q4.
- Work with the Health Research Authority to implement the 60-day review period of clinical trial applications in line with the recommendation of the O'Shaughnessy Review by end of Q4.
- By end Q3, work with stakeholders to lay the foundation for electronic Patient Information (ePI) by 2026 to ensure more accessible information for patients.

Successfully achieving this key goal:

Closer alignment across the UK healthcare systems' will enable the successful delivery of our wider objectives and enhance the attractiveness of the UK as an enabling environment in which to develop and launch new medicines and healthcare products.

2. Enable healthcare access to new, safe and effective medical products (continued)

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.

- Launch the first release of our new regulatory management system by end Q4.

Successfully achieving this key goal:

New streamlined and automated processes will support new risk-proportionate regulatory approaches and enable competitive delivery timescales for the UK determination of every type of application, in comparison with other international regulators.

3. Deliver scientific and regulatory excellence through strategic partnerships

Our 3 key actions and their underpinning objectives for this year are:

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.

- Launch our MHRA Science Strategy, including engagement with key stakeholders, and delivery of key themes by Q4.
- Publish a Data Quality Strategy for our Clinical Practice Research Datalink services, including proposals for revised and extended data quality checks and refresh our data quality webpage by end Q3.
- Establish processes to identify future areas of innovation, working with national and international partners to align priorities with patient need by end Q4.

Successfully achieving this key goal:

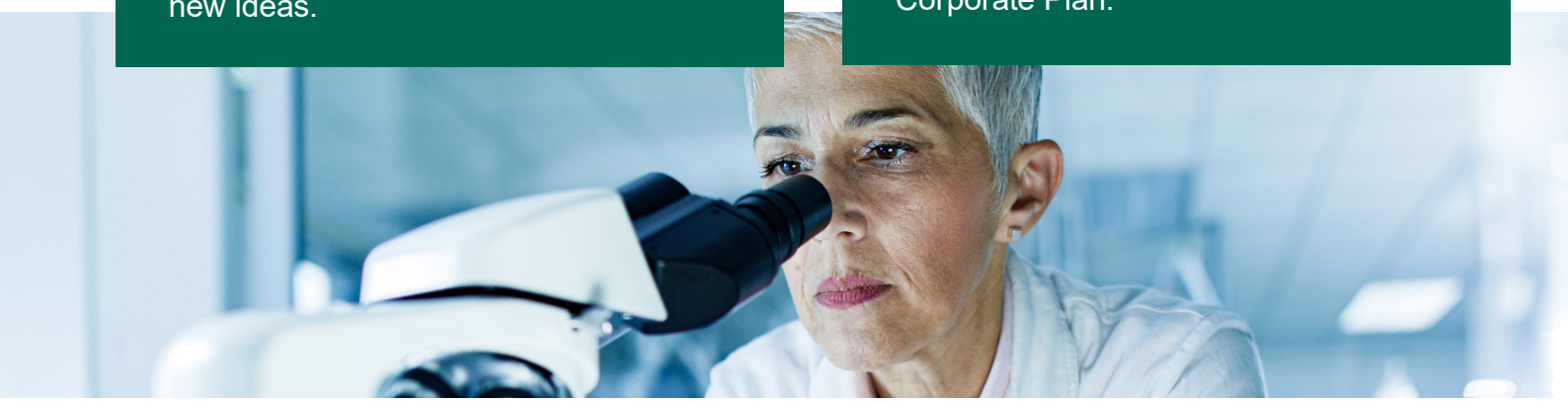
A new MHRA Science Strategy which aims to maintain and grow our reputation for scientific excellence by both maintaining the science that is unique to the agency and by partnering with leading scientific experts and nurturing new ideas.

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

- Run a trial from Q2 to end Q4 aimed at improving our distribution approach, increasing the volumes of standards we provide globally and raising awareness of our offer.
- Develop a new strategy for the British Pharmacopoeia and associated laboratory services by end Q4 including income investment plans to improve services.
- Link the Innovation Accelerator activities with academia and other stakeholders by Q4 to provide support for the CERSI recommendation in the McLean Report.
- Implement a new risk-proportionate approach for the independent control testing of biological medicines to expand our ability to perform laboratory assessments by end Q4.

Successfully achieving this key goal:

Our efforts on standards, control testing and underpinning research will be more clearly contributing to the wider goals set out the science strategy and our Corporate Plan.



3. Deliver scientific and regulatory excellence through strategic partnerships (continued)

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.

- Deliver a new framework for UK Point of Care Manufacture, lay legislation before Parliament and publish guidance by end Q4.
- Establish active bilaterals and wider collaborations nationally and internationally with work programmes in place on healthcare product innovation areas of interest by end Q4.

Successfully achieving this key goal:

Point of Care Manufacture reform will improve the availability of novel products for patients, often in situations where there may currently be no or few treatment options. International cooperation will drive progress in promising areas of regulatory science.

The second year of our Corporate Plan 2023-26 will have a focus on the introduction of new guidance and legislation and wider work to build our status as an independent regulator in a global environment and to ensure the UK remains a great environment to develop novel and innovative medical products. There are also some milestones for this year:

- Implement the Windsor Framework for a commencement date of 1 January 2025: issue essential guidance by end Q3, place legislation before Parliament in 2024 and issue further guidance and communications as needed up to the commencement date.
- Prepare legislation by Q4 to deliver reform of the UK clinical trials regulatory framework.
- Drive forward reform of medical devices regulation to ensure that medical devices are subject to future requirements for quality, safety and performance, whilst allowing increasing numbers of patients to benefit from innovative products placed onto the UK market. This included laying regulations for transition provisions by end Q2 to maintain the supply of medical devices in GB and for future regulations to strengthened Post Market Surveillance by end Q4 to strengthen requirements for medical devices on the market and increase patient safety, and clarifying plans, including consulting if needed, for international recognition of devices approved in other jurisdictions by end Q3.
- Launch a new international recognition route by 1 January 2024 for medicines utilising pre-existing approvals from Australia, Canada, the European Union, Japan, Switzerland, Singapore and the United States. This new framework will support patients in the UK with expedited access to safe and effective medicines that have been approved by trusted regulatory partners.

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

Our 3 key actions and their underpinning objectives for this year are:

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.

- Introduce an MHRA-wide workforce plan by end Q3 to ensure our workforce needs are known and can be acted on.
- Refresh our Culture Action Plan by end Q2 and deliver its actions by end Q4 to support our strategic priorities and the delivery of our redesigned services.
- Deliver a plan for core learning and development for 2023/24 that identifies and strengthens capabilities in priority areas by end Q4.
- Update our Leadership Development Plan by end Q2 and deliver new actions to strengthen leadership capability across the agency by end Q4.

Successfully achieving this key goal:

Greater visibility of capability and workforce needs will be evident, and we will be better placed to address them. Our staff will invest time in learning and development opportunities, leading to improved performance. A continued focus on developing our leaders will ensure we are well-positioned to tackle future challenges.

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

- The first graduate scheme cohort to commence our new 3-year programme and complete the on-boarding of 8 new graduates by end Q2.
- Increase the number of apprenticeships towards the target of 40 by end Q4.
- Update our talent management approach, aligning it to workforce planning and ensuring a clear link with business planning by end Q4.

Successfully achieving this key goal:

There will be more rapid access to a broader pool of high-calibre candidates for MHRA roles. Clear career pathways will enable the development of specialists and increase retention, as colleagues will feel incentivised and recognise the agency as a great place to work.

4. Become an agency where people flourish alongside responsive customer service (continued)

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.

- Staff activity recording to commence in fee earning areas by end Q3 to ensure we have a greater understanding of our costs to serve.
- Produce new improved financial management reporting using DataRails by end Q2 to ensure better data and more informed decision-making.
- Develop new pricing for services and products by Q4 to improve cost recovery across the Agency and consult on and deliver the next uplift in our fees by 1 April 2025.

Successfully achieving this key goal:

Our fees and charges will be underpinned by a more validated and accurate cost modelling; improved financial management reporting will ensure decisions are backed by better evidence; overall, the Agency will be better placed to deliver value for money and maintain its financial sustainability.

Metrics for our core business

This section shows our priorities targets for our statutory and non-statutory functions. Following the restructure of our organisation, we have developed new reporting metrics, aligned to our priorities and services. These will be further matured as we complete the refinement of our services and performance improvement. We will report against these in our Annual Report and Accounts, which is laid in Parliament.

PM1 – Clinical trials and investigations

Metric ID	Measure	Target
PM1a	Percentage of clinical trial applications assessed within 30 days of submission	98%
PM1b	Percentage of Clinical investigations decision letters (objection/no objections) issued within 60 calendar days of submission	100%

PM1a – Target for assessment of clinical trial applications was not met due to resourcing challenges. We have committed to meeting our timelines for clinical trial approvals by 1 September 2023. We have increased capacity by recruiting and training new staff, we are clearing backlogs and improving communications to help provide companies with more certainty on the timelines.

Our performance metrics for clinical trials are published monthly on the gov.uk website.

PM2 – Licensing of medicinal products

Metric ID	Measure	Target
PM2a	Percentage of medicines assessed via national route which contain a new active substance within 210-days (excluding time awaiting applicant responses)	97%
PM2b	Percentage of medicines assessed via recognition within published recognition pathway timeline (excluding time awaiting applicant responses)	80%
PM2c	Percentage of established products assessed via national route within 210-days (excluding time awaiting applicant responses)	50% (Target increasing for 2023/24)
PM2d	Percentage of products approved via recognition of another regulator's decision:	
	New Active Substance (NAS) Reliance	Establishing baseline
	Established products Reliance	Establishing baseline

Metrics for our core business (continued)

PM2e	Percentage of Type 1B and Type II variations assessed within the following timelines (excluding time awaiting applicant responses):	
	Variations assessments – Type IB changes include simple “tell and do” changes such as changing location of manufacture, with Type 2 changes being complex changes with changes of formulation such as new or replacement excipients	
	I. 30 days (Type 1B)	50% (Target increasing for 2023/24)
	II. 30 days (Type II expedited timetable)	50% (Target increasing for 2023/24)
	III. 90 days (standard or complex Type II timetable)	50% (Target increasing for 2023/24)
	IV. 120 days (extended complex Type II timetable)	50% (Target increasing for 2023/24)
PM2f	Number of Parallel Imports determined: Parallel Imports – Where there is a product available in an EEA country which is needed in the UK, provided the product has no therapeutic difference from a licenced product in the UK, subject to certain other conditions we can allow it to be imported	
	I. Parallel Imports – Number of initial applications determined	Establishing baseline
	II. Parallel Imports – Number of variation applications determined	Establishing baseline
PM2g	Unlicensed Medicines: We review and verify medical items imported for supply to patients under prescriber oversight, where no UK licence exists. MHRA role is to determine if there are any issues where we would object to importation, e.g., issues with controls in place for distribution to a patient or concerns about adequate controls in the supply chain	
	Unlicensed Medicines – Total number of notifications determined	Establishing baseline

We are working hard to improve our performance timelines for licensing of medicines. Recruitment to vacant roles, changes in practices and service redevelopment, along with industry awareness have been critical themes in ensuring our performance improves.

PM2a – We are undertaking assessor recruitment and training to support improvement against this metric and bring performance back into target for 2023/24.

PM2b – We are developing new business processes for this regulatory route to support improvement of our performance against this metric during 2023/24.

Metrics for our core business (continued)

PM2c – To improve our performance timelines for assessment of established products we have undertaken the Established Medicines Task and Finish Group to work collaboratively with industry. We have committed to meeting our timelines for established medicines by 1 January 2024. Phased targets have been set to take account of current challenges and provide a realistic estimation of expected performance, with a target of 80% for 2023/24 and 90% for 2024/25.

PM2e – Although our internal target is met, we aim to improve our performance timelines for assessment of variations. We have committed to improving our timelines for Type 1B variations by 1 July 2023. Phased targets have been set to take account of current challenges and provide a realistic estimation of expected performance, with a target of 90% for 2023/24 and 97% for 2024/25.

Our performance metrics for established medicines are published monthly on the gov.uk website.

PM3 Innovative Licensing Access Pathway (ILAP)

<table>
<tr><th>Metric ID</th><th>Measure</th><th>Target</th></tr>
<tr><td rowspan="2">PM3</td><td colspan="2">Innovative Licensing Access Pathway performance:
Medicines on the ILAP pathway, which fulfil the criteria, are awarded an Innovation Passport designation initially. They can then progress to a Target Development Profile, if they are intending to progress to market, which sets out a regulatory roadmap for delivery to patients</td></tr>
<tr><td>I. Total number of applications for Innovation Passports (IPs)
II. Number of Innovation Passports awarded
III. Number of Innovation Passports not awarded
IV. Total number of Target Development Profile (TDP) applications
V. Number of Target Development Profiles awarded /TDP roadmaps issued</td><td>Establishing baseline</td></tr>
</table>

PM4 – Medical device regulation

Metric ID	Measure	Target
PM4a	Number of approved bodies designated	Establishing baseline
PM4b	Initial review of applications for designation completed within 2 weeks	100%
PM4c	Required surveillance and witnessed audits of designated Approved Bodies have completed as required by UK Medical Devices Regulations 2002 (UKMDR 2002)	100%

PM4b – Target for the initial review of applications for designation has not been met due to resourcing challenges due to vacancies in the team during the year. Vacancies have now been filled and the performance is improving.

PM5 – Inspectorate inspections

Metric ID	Measure	Target
PM5	Number of routine inspections completed for:	
	I. Good Manufacturing Practice (GMP) II. Good Distribution Practice (GDP) III. Good Clinical Practice (GCP) and Good Manufacturing (GMP) Quality Consultations (GCP/GMPQC) IV. Good Laboratory Practice (GLP) V. Good Clinical Practice GCP, including Bioequivalence (GCP/BE) VI. Good Pharmacovigilance Practice (GPvP)	Establishing baseline

Metrics for our core business (continued)

PM6 – Post marketing surveillance activity

Metric ID	Measure	Target
PM6a	Total number of safety signals identified for further assessment.	Establishing baseline
	Adverse Drug Reaction (ADR) reports processed within the following timescales: I. Fatal ADR II. Serious ADR III. 85% of potential signals evaluated within 5 working days	90% in 24 hrs, 100% in 72hrs 95% in 72 hrs, 100% in 5 days 85%
PM6c	Defective medicinal product recalls: NatPSA / Class 1 recalls – The defect presents a risk of death or disability. Class 2,3,4 recalls – The defect may cause non-life-threatening harm, is unlikely to cause harm, has a minor defect not likely to impair the product. Company led recalls – the license holder has identified all affected customers	
	I. Total number of defective medicinal product recalls II. National Patient Safety Alerts (NatPSA) / Class 1 recalls III. Class 2, 3, 4 recalls or company led recalls	Establishing baseline

PM7 Criminal Enforcement Unit (CEU)

Metric ID	Measure	Target
PM7	Interventions conducted by the CEU that are assessed to have disrupted or degraded an identified criminal threat: The grading of the intervention as minor, moderate or major is determined by assessing the immediate impact on threat and its likely duration	
	I. Total number of CEU interventions II. Major interventions III. Moderate interventions IV. Minor interventions	Establishing baseline

Metrics for our core business (continued)

PM8 – Batch release / control testing

Metric ID	Measure	Target
PM8	Percentage of independent batch assessments completed within target times for:	
	I. Vaccine batches – Certified within 43 working days II. Blood products – Certified within 15 working days	95% 99%

PM9 – Science Research & Innovation (SR&I) standards

Metric ID	Measure	Target
PM9a	Numbers of products sold from the following product groups: I. Reference Standards and reagents (including British working standards) II. WHO International Standards, Reference reagents and Reference Panels III. CE-marked diagnostic reference materials IV. Influenza reagents	Establishing baseline
PM9b	Numbers added to portfolio: I. Reference Standards and reagents (including British working standards) II. WHO International Standards, Reference reagents and Reference Panels III. CE-marked diagnostic reference materials IV. Influenza reagents	Establishing baseline

PM10 – British Pharmacopoeia (BP)

Metric ID	Measure	Target
PM10a	Number of new British Pharmacopoeia (BP) standards developed and added to the 2023 BP publication: The British Pharmacopoeia protects public health by providing chemical standards for the quality checking of UK pharmaceutical substances and medicinal products as well as monographs which detail the way a product should be tested and analysed to ensure it is the correct formulation and activity	
	I. Documentary standards (monographs) II. Physical standards (British Pharmacopoeia Chemical Reference Standards – BPCRS)	Establishing baseline
PM10b	Sales of British Pharmacopeia standards	5% increase

PM11 – Clinical Practice Research Datalink (CPRD)

Metric ID	Measure	Target
PM11a	Percentage of applications to CPRD for access to data for research studies receiving first moderated review feedback within 30 working days of a valid application	90%

PM11a – In June 2021 we launched a new research data governance process to manage CPRD data in response to an independent review. The new process relies on volunteer external reviewers undertaking approximately 70% of the application reviews. While the target has not been met the average feedback time is under 15 working days. Going forwards, while CPRD cannot enforce feedback times for external reviewers, we will work towards streamlining our internal processes and guidance to provide additional support to external reviewers.

PM12 – Research and development

Metric ID	Measure	Target
PM12a	Number of scientific research publications	Establishing baseline
PM12b	External grant and research contract funding	Establishing baseline

PM13 – Working towards NetZero

Metric ID	Measure	Target
PM13a	Increased solar panel savings in electricity costs on the South Mimms Site	50% increase in savings due to use of solar panels
PM13b	Savings in water wastage on the South Mimms Site through a programme of works to reduce water loss	20% reduction in water usage on South Mimms Site
PM13c	Heat Decarbonisation Plan production and application for Public Sector Decarbonisation Scheme funding to support our ambition of NetZero by 2030	Funding application submitted by December 2023

Financial forecast

Our ambition is to become financially self-sufficient from the 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 DHSC 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.

The table below shows our financial forecast for this year's Business Plan:

MHRA	2023/24 Financial Plan £m
Trading income	138.9
Staff costs Operating costs Project costs	94.9 60.4 3.8
Total comprehensive expenditure	20.2
DHSC resource funding	20.6
DHSC capital funding	25.5

Corporate governance

We are governed by a unitary Agency Board that is responsible for advising on the strategic direction of the MHRA, ensuring that objectives in the Business Plan are met.

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

Our Chief Executive, as the MHRA 's 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. We are committed to meeting the Government's Functional Standards at a minimum. Ensuring our Agency is well run, with appropriate controls to ensure we can meet our objectives consistently is the responsibility of all staff.

In addition to the objectives above, over 2023/24, our staff will be:

- Fulfilling their commitments to remain vigilant to any health and safety risks that may impact them or others and report these proactively. Staff are responsible for ensuring they follow existing guidance and best practice procedures to maintain their own wellbeing and promote the positive wellbeing of their colleagues.
- Working closely with Government's Internal Audit Agency to facilitate any audit engagements and deliver actions agreed in response to audit recommendations to address any weaknesses in our operations and or control environment.
- Supporting our Quality Management System through working with colleagues to provide challenge and review of our current systems, addressing areas for improvement and developing our approach to quality in support of our service redevelopment.
- Constantly managing operational risks at all levels in the organisation, in line with our risk management framework, to best enable delivery against our objectives in our challenging, complex and uncertain delivery environment.

This is in addition to the duty on all staff to ensure value for money in our use of public funds, including where such funds are created through our fees for services.

We aim to apply the Public Sector Equality Duty requirement to new or changing policies, projects and services impacting patients, the public and our staff.

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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