Medicines & Healthcare products Regulatory Agency

AGENDA FOR BOARD MEETING HELD IN PUBLIC

09:00 am – 11:30 pm on Tuesday 17 September 2024

Chair: Professor Graham Cooke

	AGENDA ITEM	**PURPOSE**	**PRESENTER**
09:00	INTRODUCTION		
	1. What is the purpose of this meeting, who are the Board Directors and are there any absences?	Information	Chair
	2. Are there any new Declarations of Interest?	Information	All
	3. What were the minutes and actions from the last meeting?	Approval	Chair
	AGENCY PERFORMANCE		
09:10	4. What are the most important current activities and priorities from the CEO's point of view?	Context	June Raine
09:25	5. What are the financial and people performance of the MHRA in July 2024?	Assurance	Rose Braithwaite
09:40	6. What was the Agency's Operational Performance in Q1 of 2024/25?	Assurance	Rose Braithwaite
	ACCESS		
10:00	7. How effectively is the system of international recognition enabling access to medicines for UK patients?	Assurance	Julian Beach
	PATIENT ENGAGEMENT		
10:20	8. What were the results of the evaluation of the Patient and Public Involvement Strategy and how will these help put patients at the heart of all Agency activities?	Discussion	Rachel Bosworth
	ASSURANCE		
10:40	9. Is the Board assured that the current Health & Safety measures are effective and how can these be further strengthened?	Assurance	Nicola Rose

11:00	10. What assurance can be provided by the Organisational Development and Remuneration Committee?	Assurance	Amanda Calvert
11:10	11. What assurance can be provided by the Patient Safety & Engagement Committee?	Assurance	Mercy Jeyasingham
	EXTERNAL PERSPECTIVE		
11:20	12. What questions do members of the public have about the items on this Board Meeting Agenda?		Chair
11:30	CLOSE OF MEETING		

MHRA Board Declarations of Interest – September 2024

The MHRA Board is responsible for advising and agreeing the strategic direction of the Agency, endorsing the Agency's recommendations to Ministers on key financial and performance targets, and advising on and monitoring plans to ensure those targets are met.

The Board supports the Chief Executive Officer in the effective 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 that controls are in place to manage risk.

The Board and its Non-Executive Directors have no involvement in any regulatory decisions affecting medicines, medical devices or any other products or services delivered by the Agency. These decisions are the responsibility of the Chief Executive Officer, supported by the Executive Committee.

Name and MHRA Role	Name of Other Company or Organisation	Nature of interest	Paid	Current
Professor Graham Cooke Non-Executive Director & Interim Co-Chair	Imperial College NHS Trust and Chelsea & Westminster NHS Foundation Trust	Honorary NHS Consultant	Yes	Yes
	NERVTAG	DHSC NERVTAG committee member	No	Yes
	NIHR	NIHR Research Professor	Yes	No
	NIHR	Influenza platform trial in the UK	Yes	Yes
	NIHR	Chair DSMB (PROTECT-V trial)	No	Yes
	Pfizer	Pneumonia study with Imperial College Healthcare Partners	Yes	No
	30 Technology Ltd	Consultant/Advisor	Yes	Yes
	DNAnudge Ltd	Consultant/Advisor	No	Yes
	Seventh Sense Biosystems	Consultant/Advisor	Yes	No
	Sanofi CoV	Chair of End Point Review Committee for vaccine trial	Yes	Yes
	WHO	Member of Committee for Selection and Use of Essential Medicines	No	Yes
Dame June Raine Chief Executive	World Health Organisation (WHO) Committee on Safety of Medicinal Products	Member	No	Yes
Dr Junaid Bajwa Non-Executive Director	Microsoft	Ex-employee (Chief Medical Scientist at Microsoft Research), Shareholder	No	No
	Merck Sharp and Dohme	Ex-employee shareholder	No	No
	Ondine biomedical	Non-Executive Director	Yes	Yes
	UCLH	Non-Executive Director	Yes	Yes
	Whittington NHS Trust	Non-Executive Director	Yes	Yes

Name and MHRA Role	Name of Other Company or Organisation	Nature of interest	Paid	Current
	NHS	GP, Physician (Sessional)	Yes	Yes
	Nuffield Health	Governor (NED)	Yes	Yes
	Nahdi Medical Corporation	Non-Executive Director	Yes	Yes
	DIA Global	Board Member	No	Yes
	HDR UK	Trustee	No	Yes
	Flagship Pioneering	Senior Partner	Yes	Yes
Julian Beach Interim Lead, Healthcare Quality & Access	None	N/A	N/A	N/A
Liz Booth Chief People Officer	None	N/A	N/A	N/A
Rose Braithwaite Chief Finance Officer	Mental Health Foundation	Treasurer	No	No
Amanda Calvert Non-Executive Director & Interim Co-Chair	Astrazeneca	Ex-employee shareholder Immediate family member	No	Yes
	Quince Consultancy Ltd	Provides consultancy services including companies in the healthcare sector.	Yes	Yes
	Athenex Pharma	Quince Consultancy providing strategic consultancy on oral oncology chemotherapy platform. ILAP applicant and Marketing Authorisation applicant.	No	No
	Cambridge Judge Business School	Member of Advisory Board	No	Yes
	Duke Street Bio	Advisory / Consultant	Yes	Yes
	Fennix Pharmaceuticals	Founder of start-up company planning to develop oral chemotherapy product into Phase 2 trial. Not yet trading.	No	No
	High Value Manufacturing Catapult	Non-Executive Director	Yes	Yes
Dr Alison Cave Chief Safety Officer	None	N/A	N/A	N/A
Dr Paul Goldsmith Non-Executive Director	Closed Loop Medicine Ltd	Shareholder, director & employee; MA submission	Yes	Yes
	Lanthor Ltd	Book publishing and medico-legal reports	Yes	Yes
	Ieso Digital Health	Shareholder	No	Yes
	Institute of Global Health Innovation (IGHI), Imperial College, London	Visiting Professor	No	Yes
	MDU Ltd	Director	Yes	No
	MDU Investments Ltd	Director	Yes	No
	NHS	Consultant Neurologist	Yes	Yes
	NHS	Clinical Senate Member	No	Yes

Name and MHRA Role	Name of Other Company or Organisation	Nature of interest	Paid	Current
	Radix Big Tent Foundation	Trustee	No	Yes
	Sleepstation	Co-founder of original programme, 2012-2014	No	No
Claire Harrison Chief Digital & Technology Officer	None	N/A	N/A	N/A
Haider Husain Non-Executive Director	Healthinnova Limited	Chief Operating Officer	Yes	Yes
	Milton Keynes University Hospital NHS Foundation Trust	Non-Executive Director	Yes	Yes
	British Standards Institute	Chair – TC304 Healthcare Organisation Management Committee	No	Yes
	Madad UK	Trustee	No	Yes
	World Wars Muslim Memorial Trust	Trustee	No	Yes
	Microsoft Corp	Ex-employee shareholder	No	Yes
	BBC	Family Member	No	Yes
	NHS Buckinghamshire, Oxfordshire and Berkshire West Integrated Care Board	Digital and Data Advisor / Member of the System Productivity Committee	Yes	Yes
Mercy Jeyasingham MBE Non-Executive Director	NHS South West London Integrated Care Board	Non-Executive Member	Yes	Yes
Raj Long Non-Executive Director	Gates Foundation	Employee – Deputy Director	Yes	Yes
	Bristol-Myers Squibb	Ex-Employee Shareholder	Yes	Yes
	RESOLVE (Sustainable solutions to critical social, health, and environmental challenges)	Scientific Advisory	No	Yes
	Novartis	Ex-Employee Shareholder	Yes	Yes
	BioNTech Global Health (non-profit)	Strategic Advisory for only Sub-Saharan Africa Public Health for Equitable Access	Yes	Yes
	Gates Venture – EC Innovative Medicines Initiative (IMI) Non-Product – IMI European platform for Neurodegenerative Disorders	Advisory	Yes	Yes
	WHO – Sustainable COVAX Manufacturing Strategy for Regional Health Security	Advisory Expert	No	Yes
	UK Health Security Agency	Associate Non-Executive Board Member	Yes	Yes
	EU Innovative Health Initiatives (IHI)	Advisory Expert for this EU public-private partnership funding health research and innovation funded by European Commission	Yes	Yes
Nicola Rose	None	N/A	N/A	N/A

Name and MHRA Role	Name of Other Company or Organisation	Nature of interest	Paid	Current
Interim Executive Director, Science and Research				
Laura Squire OBE Chief Healthcare Quality & Access Officer	None	N/A	N/A	N/A
Michael Whitehouse OBE Non-Executive Director & Interim Co-Chair	South East Coast Ambulance Services NHS Foundation Trust	Deputy Chair & Senior Independent Non-Executive Director Chair of Audit Committee Chair of Charities Committee	Yes	Yes
	Cruse Bereavement Charity	Trustee Chair of Finance and Audit Committee	No	No
	Republic of Ireland Audit Office	Member of Audit Committee	No	No
	National Audit Office	Board Member and Chief Operating Officer until 17 April 2017	No	No
Glenn Wells Chief Partnerships Officer	None	N/A	N/A	N/A

Medicines and Healthcare products Regulatory Agency

Minutes of the Board Meeting Held in Public on 09 July 2024

(10:00 – 12:30)

MHRA, 10 South Colonnade, Canary Wharf E14 4PU

Present:

The Board

Professor Graham Cooke	Non-Executive Director & Interim Co-Chair
Dr June Raine DBE	Chief Executive
Dr Junaid Bajwa	Non-Executive Director
Julian Beach	Interim Executive Director, Healthcare Quality & Access
Liz Booth	Chief People Officer
Rose Braithwaite	Chief Finance Officer
Amanda Calvert	Non-Executive Director & Interim Co-Chair
Dr Alison Cave	Chief Safety Officer
Dr Paul Goldsmith	Non-Executive Director
Claire Harrison	Chief Digital & Technology Officer
Haider Husain	Non-Executive Director
Mercy Jeyasingham	Non-Executive Director
Raj Long	Non-Executive Director
Dr Laura Squire	Med Tech Regulatory Reform Lead (Chief Healthcare Quality and Access Officer)
Dr Glenn Wells	Chief Partnerships Officer
Michael Whitehouse OBE	Non-Executive Director & Interim Co-Chair

Others in attendance

Rachel Bosworth	Director of Communications and Engagement, MHRA
Carly McGurry	Director of Governance, MHRA
Natalie Richards	Head of the Executive Office, MHRA
Kathryn Glover	Deputy Director, Medicines Regulation and Prescribing, DHSC
Sarah Gilbert	Head of Governance, Risk and Assurance, MHRA (for item 6)
Dr John Connelly	Deputy Director, Scientific Data & Insight, MHRA (for item 8)

INTRODUCTION

1. **Item 1: What is the purpose of this meeting and who are the Board Directors?**

1.1. Professor Graham Cooke opened the meeting. The Chair set out his expectations and priorities for this Board meeting. This meeting was not live streamed due to the proximity to the General Election, however the meeting was recorded and will be published shortly.

2. Item 2: Are there any Apologies or Declarations of Interest?

2.1. Apologies were received from Dr Nicola Rose, Interim Executive Director, Science & Research.

2.2. The Board reviewed the Declarations of Interest (DOIs) for all MHRA Board members. There were no new items to declare. The Chair reviewed the DOIs and was satisfied that there were no conflicts of interest preventing any Board Member from participating in the full agenda of this meeting.

3. Item 3: What were the minutes and actions from the last meeting?

3.1. The Board reviewed the minutes and actions from the last meeting; no comments were received on the minutes and they were accepted as an accurate record of the last meeting. The Board provided updates on the actions.

AGENCY PERFORMANCE

4. Item 4: What are the most important current activities and priorities from the CEO's point of view?

4.1. Dr June Raine presented the Chief Executive's monthly report, which covered the following:

(i) **Science, Research and Innovation** – including updates on pandemic preparedness; the Centre for Infectious Diseases Reagents; quality assurance of biological medicines; assay development and harmonisation; a multiplex immunoassay study; Crimean-Congo hemorrhagic fever virus vaccine development; health and safety; freeze driers; and visiting students;

(ii) **Healthcare access** – including updates on established medicines; the International Recognition Procedure; personalised medicines; the International Council for Harmonisation; machine learning medical devices; and in-vitro diagnostics;

(iii) **Patient Safety** – including updates on topiramate and harms in pregnancy; topical corticosteroids and withdrawal reactions; SafetyConnect; CPRD ethnicity records uptake; the fastest CPRD validation study; Criminal Enforcement Unit interventions; and the Criminal Enforcement IT system;

(iv) **Partnerships** – including updates on data sharing; international partnerships; general election planning; and the Windsor Framework;

(v) **Digital and technology** – including updates on cyber security; clinical trials; RegulatoryConnect; and haemovigilance;

(vi) **Dynamic organisation** – including updates on Return to Green; the All Staff Meeting; the One Agency Leadership Group; and the Culture Survey.

4.2 The Board thanked Dr Raine for her report and provided comments relating to the CPRD ethnicity records uptake and how this improves quality and outcomes; the importance of an end-to-end system; utilisation of measures such as patient activation measures and measures of deprivation; evidence generation and safety supply; effective collaboration to bring medical products to patients faster; ensuring the Agency has the appropriate resources; personalised medicines; the Agency's Science Strategy; the Agency's contribution towards the UK's dementia mission; a YC biobank pilot to understand how to identify pharmacogenomic markers of risk to apply more targeted risk minimisation; and international recognition. The Board noted the update and thanked Dr Raine for her report.

5. Item 5: What was the financial and people performance of the MHRA for this year up to 31 May 2024?

5.1 The Board considered a report describing the financial and HR performance of the MHRA for this year up to 31 May 2024. The Board noted the report and provided comments relating to mitigating the risk of underspending against the Agency's budget; RegulatoryConnect; analysing vacancy rates, contract workers and exit interview learnings; the use of professional services contracts to address backlogs; working on the Agency's employer brand to attract talent. The Board agreed that ExCo should review learnings from exit interviews, and an update should be provided to the Board.

Action 125: Provide the Board with an update on learnings from exit interviews.
Liz Booth

6. Item 6: How well does the 2023/24 Annual Report and Accounts reflect the performance, governance and financial results of the MHRA over the last year?

6.1 The Board reviewed the annual report and accounts for the Agency, which were prepared in accordance with the relevant requirements and are subject to audit by the National Audit Office (NAO). The ExCo and the Audit and Risk Assurance Committee (ARAC) have both reviewed and approved the reports. The Board noted that a further amendment is required to be made to the accounts The Board approved the annual report; and agreed to delegate authority to the ARAC to approve the accounts once finalised.

Action 126: The Board approved the annual report. The Board delegated authority to ARAC to approve the accounts; once complete this should be submitted to the Auditor & Comptroller General and lain in Parliament.
Carly McGurry

PATIENT SAFETY

7. Item 7: How will the MHRA implement the recommendations of the Infected Blood Inquiry?

7.1 The Board considered a paper describing how the MHRA will implement the recommendations of the Infected Blood Inquiry. The Board noted the proposals and provided comments relating to the complexity of the risk and the importance of simplifying this system for patients; bringing the multiple haemovigilance systems together in to alignment; working with the clinical community to improve communication to address patient concerns over the safety of blood and blood products; understanding if there are other areas of healthcare where there are similar levels of complexity, and taking proactive measures to reduce complexity to reduce risks in these areas.

7.2 The Board provided further comments relating to the Agency's compliance strategy; seeking the perspective of patients when reviewing and redesigning this system; utilising data and technology to support this process; funding MSc course to develop online materials to improve patient safety; working with the Medical Schools Council to integrate this into educational systems; and maintaining a focus on all healthcare workers. The Board agreed that there is further work to do to raise awareness; an action was taken to link up cross-government to reduce complexity in the reporting systems; an in addition MHRA should liaise with the Medical Schools Council to consider how better this can be integrated in to educational systems.

7.3 The Board agreed a further update should be provided once further work has been undertaken to address the recommendations.

Addition to action 121: There should be greater linkage cross-government to reduce complexity in reporting systems. Work with Medical Schools Council to embed reporting in student learning. Provide the Board with a further update.
Alison Cave

DATA STRATEGY

8. Item 8: How can the Data Strategy provide important value for the Agency's services and regulatory science?

8.1. Dr John Connelly joined for this discussion. The Board considered a paper describing how the Data Strategy will provide important value for the Agency's services and regulatory science. The board considered the strategy and provided comments relating to ensuring the Agency has adequate resource and capability to deliver the data strategy; utilising academic partnerships to deliver the strategy and using Centres of Excellence in Regulatory Science and Innovation (CERSIs) as a tool; and ensuring there are clear deliverables, milestones, a programme board and appropriate resource.

8.2. The Board provided further comments relating to linkage of primary and secondary care data; working to move the healthcare system towards a prevention focused service; ensuring there is appropriate patient involvement; delivery of RegulatoryConnect; articulation of major milestones and outcomes in relation to

patient and public health; utilising statutory powers to draw information through the system; and working across government especially with the devolved nations.

Addition to action 70: Draw up fixed milestones and a delivery plan for the data strategy; including delivery of new tools, methodologies, expertise and capacity. An internal programme governance board should be put in place to manage delivery. Ensure the relevant powers are included in the introduction to the data strategy. Provide the Board with a further update in the autumn.

Alison Cave

GOVERNANCE

9. Item 9: What will the Board effectiveness review cover in the upcoming review?

9.1 The Board considered a paper describing the topics the Board effectiveness review will cover. The Board requested that the Board Charter which was previously agreed be shared with Board members. The Board endorsed the topics for review in the Board effectiveness review.

ASSURANCE

10. Item 10: What assurance can be provided by the Organisational Development and Remuneration Committee?

10.1. The Board considered an assurance report from the Organisational Development and Remuneration Committee (ODRC). The ODRC met on 10th May 2024 and reviewed the progress on the Return to Green Programme with focus on the clearance of backlogs; reviewed how quality will be embedded into the ways of working for the delivery of future services; and discussed the scope and priorities for the MHRA Workforce Plan. The Board provided comments related to sustained performance of clinical trials; embedding quality and sustainability through Return to Green; RegulatoryConnect; the importance of a workforce plan to build the Agency's ability to recruit and develop capability; and changing the Agency's culture. The Board noted the report for assurance.

11. Item 11: Audit and Risk Assurance Committee Annual Report

11.1. The Board considered the annual report from the Audit and Risk Assurance Committee (ARAC), to provide the Board assurance on the effectiveness of the MHRA's governance, risk management, financial and internal control arrangements over the last 12 months. The Board considered the report and provided comments relating to improving risk management; development of a route to moderate programme to address the outcomes from the audit programme, noting that improvements have already been made; and cyber security risks. The Board thanked the Chair of ARAC for the valuable insights and clarity offered by the committee.

Action 127: Share the Route to Moderate plan from the audit programme with the Board. ***Carly McGurry***

ANY OTHER BUSINESS

12.1 The Chair gave thanks to Fleur Ruda, Head of the MHRA, Medicines and Pharmacy Legal Team at the Government Legal Department, who is moving to a new role.

12.2 No additional items of other business were raised and the Chair closed the meeting.

MHRA
July 2024

ACTIONS FROM MHRA BOARD MEETING IN PUBLIC – 09 July 2024

The actions highlighted in red are due this month

Action Number	Action	Owner	Date	Status
Carried Forward from previous meetings				
29	16/03/21: Present an Agency Science Strategy to the Board. 15/11/22: Revise the Science Strategy to include clear prioritisation; and greater inclusion of in-house expertise on behavioural science with a complementary expert group. Include vaccines work as a specific area of expertise, alongside biologics and the UK Stem Cell Bank, to create a distinctive offering to make the UK an internationally recognised centre of excellence in this field. A review of scientific committees should also be undertaken. Present a further update to the Board in March 2023. 21/03/2023: Science Strategy to be presented to the Board in July. 11/07/23: Present an update to the Board on progress against each of the themes in the Science Strategy at the end of 2023.	~~Marc Bailey~~ Nicola Rose	~~21/09/21~~ ~~16/11/21~~ ~~17/05/22~~ ~~15/11/22~~ ~~21/03/23~~ ~~11/07/23~~ ~~12/12/23~~ 19/11/24	
70	18/01/22: Develop and present a Data Strategy to the Board. 09/07/24: Draw up fixed milestones and a delivery plan for the data strategy; including delivery of new tools, methodologies, expertise and capacity. An internal programme governance board should be put in place to manage delivery. Ensure the relevant powers are included in the introduction to the data strategy. Provide the Board with a further update in the autumn.	Alison Cave & Claire Harrison	~~17/05/22~~ ~~18/10/22~~ ~~15/11/22~~ ~~18/04/23~~ ~~12/12/23~~ ~~19/03/24~~ ~~09/07/24~~ 19/11/24	
73	15/02/22: Develop a Sustainability Strategy.	Glenn Wells	~~17/01/23~~ ~~16/01/24~~	

			~~19/03/24~~ 19/11/24	
101	11/07/23: Action: Present an update to the Board on the performance and proactive communications and engagement activities related to clinical trials which will maintain trust in the Agency from industry and research customers. 19/09/23: Provide an update to the Board in November 2023 on the progress of the new clinical trial process pilot. Prepare a plan for training and upskilling of staff to increase resilience across the Agency. 21/11/23: Provide the Board with an update on the new proposed Clinical Trials process. Undertake a review of any other backlogs in the Agency. 16/01/24: Present a paper to the Board containing operational detail including a clearly defined budget; how this is resourced (skill and headcount); and demand estimation over the next year and beyond. 19/03/24: Explore developing a model for a clinical trial hub and lead coordinator.	James Pound	~~21/11/23~~ ~~16/01/24~~ 19/11/24	
104	19/09/23: Develop a reputation strategy for the Agency with reputation index measures.	Rachel Bosworth	~~21/11/23~~ ~~19/03/24~~ 17/10/24	
108	21/11/23: Provide the Board with an update on the Trusted Research Environment	Alison Cave	~~19/03/24~~ 17/10/24	
110	21/11/23: Provide a further update on the progress of the Health, Safety & Wellbeing Strategy to the Board.	~~Marc Bailey~~ Nicola Rose	~~21/05/24~~ 17/09/24	On agenda
114	19/03/24: Deliver an operating model for established medicines which will deliver sustained performance.	Julian Beach	~~21/05/24~~ 17/10/24	
117	19/03/24: Provide an update on innovation pathways to future Board meeting.	James Pound	17/10/24	

118	19/03/24: Additional work on Raising Concerns Champions to be carried out with Mercy Jeyasingham.	Liz Booth	21/05/24	Complete
119	19/03/24: Undertake a review of long-term sickness rates.	Liz Booth	21/05/24	Complete
120	19/03/24: Create a feedback survey for Board effectiveness, including external stakeholders.	Liz Booth	09/07/24	Complete. The Board Charter was also shared with the Board.
121	21/05/24: Review the recommendations from the Infected Blood Inquiry and consider how the Agency can take action on these recommendations. 09/07/24: There should be greater linkage cross-government to reduce complexity in reporting systems. Work with Medical Schools Council to embed reporting in student learning. Provide the Board with a further update in January 2025.	Alison Cave	~~18/06/24~~ 21/01/25	
122	21/05/24: Present the Agency's strategic workforce plan to the Board	Liz Booth	18/06/24	
123	21/05/24: Prepare an update for the Board on scientific advice activities around the Agency	Julian Beach	17/09/24	
124	21/05/24: Bring an update to the Board on the MHRA website and options to improve this.	Rachel Bosworth	09/07/24	Completed
New Actions				
125	09/07/24: Provide the Board with an update on learnings from exit interviews.	Liz Booth	19/11/24	
126	09/07/24: The Board approved the annual report. The Board delegated authority to ARAC to approve the accounts; once complete this should be submitted to the Auditor & Comptroller General and lain in Parliament.	Carly McGurry	31/07/24	Complete; the ARA was laid in Parliament on 30 July 2024.
127	09/07/24: Share the Route to Moderate plan from the audit programme with the Board.	Carly McGurry	15/10/24	

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

17 September 2024

Title	**What are the most important current activities and priorities from the CEO's point of view?**
Board Sponsor	June Raine
Purpose of Paper	Context

What are the most important current activities and priorities from the CEO's point of view?

TOP 10' HEADLINES

- We remain on track to eliminate the original backlog of established medicines by the end of September, and to assess all new applications within statutory timelines from September

- We authorised lecanemab (Leqembi), the first treatment for Alzheimer's disease for use in Great Britain that shows some evidence of efficacy in slowing progression of the disease

- We communicated advice that men on sodium valproate for epilepsy or other conditions should use contraception due to a possible increased risk of neurodevelopmental disorders in children

- We published guiding principles for transparency for machine learning-enabled medical devices alongside the US FDA and Health Canada, to support their safe and effective use

- We secured additional funding for poliovirus research to improve prevention and treatment via improved rapid methods for poliovirus detection in clinical and environmental samples

- We have progressed guidance on a new regulatory pathway on personalised cancer vaccines which will be consulted on, and explored whether new legislative provisions are needed

- The British Pharmacopoeia has developed and published new guidance on Advanced Therapy Medicinal Products (ATMP) including T Cell and NK Cell Characterisation Assays

- We laid the Agency's Annual Report and Accounts 2023-2024 in Parliament on 30 July

- Our July culture and pulse survey showed that we need further action to drive the desired cultural change, and this will be discussed at the next One Agency leadership group meeting

- The local action plan to strengthen health and safety compliance at the Science Campus is on track for the HSE deadline of December and a Biosafety Risk Adviser post is being added.

SCIENCE AND RESEARCH

Poliovirus research

1.1 We have contributed to whole-genome sequence analysis of poliovirus isolates to better understand the origins of poliovirus transmission in Gaza, which has ultimately led to the first polio case detected in the region in the last 25 years. The vaccination campaign underway in Gaza is utilising the hyper-attenuated nOPV2 vaccine, which our research and development programme has demonstrated to have superior stability compared to traditional OPV vaccine. Two Bill & Melinda Gates Foundation grants have been extended until 2027, supporting our work developing improved rapid methods for poliovirus detection in clinical and environmental samples and expanding sequencing capacity in multiple World Health Organisation (WHO) polio laboratories globally.

Capacity building in harmonised methodologies

1.2 The polio team and next generation sequencing (NGS) team delivered a training workshop in Hyderabad (India) for two polio vaccine manufacturers on the NGS analysis of polio vaccines for batch release to ensure the supply of high-quality novel oral polio vaccines for global use. Training workshops for Direct Detection and Nanopore Sequencing for WHO African polio laboratories in in Angola and Tanzania was also delivered.

Pandemic preparedness

1.3 The MHRA's partnership with the Coalition for Epidemic Preparedness Innovations (CEPI) continues, with scientists from the Viral Vaccines group attending the face-to-face meeting between the CEPI centralised laboratory network currently including 19 laboratories worldwide. The meeting offered the opportunity to strengthen our collaborations, critical considering the new service order signed for the technology transfer of the MHRA-developed neutralisation assay for Lassa virus to two CEPI partners laboratories in Africa, and the new projects under negotiation.

Crimean-Congo Haemorrhagic Fever Virus

1.4 A scientific report of a collaborative study involving members of Diagnostics team, members of Standards Lifecycle and collaborators at UK Health Security Agency Porton was published, investigating correlations of protection. The work was funded by a grant from Innovate UK awarded to Diagnostics. Crimean Congo Haemorrhagic Fever Virus (CCHFV) causes severe haemorrhagic fever in humans which is fatal in up to 83 % of cases; it is listed as a WHO priority pathogen; there are currently no widely approved vaccines. Characterisation of the serological reactivities within these samples will establish their value as reference materials to support assay harmonisation and accelerate vaccine development.

International Society for Blood Transfusion

1.5 Issues in the cold storage of platelets were discussed at the International Society for Blood Transfusion (ISBT) Working Party for Blood Components. These are of direct relevance to our on-going development of a WHO reference reagent for platelet flow cytometry. Further outreach for this project was delivered through a poster session and identified user concerns about viability dyes and new participants for the International collaborative study. Scientific talks revealed alternative formulation options to better preserve platelets, which we will investigate.

Cell therapy products

1.6 The Cell Therapy team is optimising processes to develop a novel reference reagent for detection of residual Pluripotent Stem Cells (PSCs). As starting materials for cell therapies, PSCs have the potential to profoundly impact many clinical areas, by improving consistency, increasing scale and reducing the cost of manufacturing. However, it is crucial to ensure the absence of residual undifferentiated PSCs from final products, as these constitute a tumorigenicity risk. We are collaborating with the Cell and Gene Therapy Catapult's consortium to enhance the detection of residual PSCs in cell therapy products; with the goal of developing a detection assay with PSC-specific markers and creating a reference reagent that ensures assay sensitivity, maximizing its utility for safe cell therapies.

Cell and gene therapies

1.7 In July and August, the UK Stem Cell Bank (UKSCB) released a further 5 human embryonic stem cells lines for clinical application under HTA2007 regulations. This substantially increases the availability of lines to our customers for advanced therapies, helps to improve our relationship with stakeholders and depositors, and shows that the UKSCB is an important resource for research. As the only public repository in the UK for human Embryonic Stem Cell lines, we are also consolidating much of the clinical/GMP grade material generated by the four major Universities (Sheffield, Kings College London, Manchester and Edinburgh), and as such we will be the major source of clinical grade material for distribution.

Tetanus toxin cell-based assay

1.8 Tetanus vaccines contain tetanus toxoid and are currently tested for the absence and irreversibility of tetanus toxin activity by manufacturers and control laboratories. Testing methods currently depend on guinea pig or mouse assays, and there is a need for an in vitro assay. The University of Sheffield has created a cell-based, one-step luminescence immunosorbent assay with sensitivity and specificity to tetanus toxin. The MHRA has been collaborating with the University of Sheffield over the long term throughout the development and validation of this method. Recently, a joint application to the National Centre for the Replacement, Refinement and Reduction of Animals in Research secured funding for an international collaborative study. This study enables tetanus vaccine producers to use the cell-based assay and provide real-world evidence for its safety testing suitability.

Health and Safety

1.9 After submitting our response to the Health & Safety Executive on time on the issues in their Improvement Notice of March 2024, we are now reviewing the 'model' of Health and Safety in the Science Campus together with an external expert. We are also recruiting to a new BioRisk Adviser post.

HEALTHCARE ACCESS

Established medicines

2.1 Significant progress in reducing the backlog of established medicines Marketing Authorisation applications continued through July and August as planned. By 9 September, the original backlog (applications over 210 days old as of 9 January 2024) has decreased from 1167 to 201. The total backlog, including overdue work, is now 490. A comparison with the start of the year shows that the oldest applications have been reduced, and the overall numbers are significantly lower. The Return to Green Programme has continued making progress by reducing backlogs and implementing changes in business processes.

Lecanemab for dementia

2.2 The MHRA has approved the first treatment for Alzheimer's disease authorised in the UK, Lecanemab (Leqembi), to treat adults in the early stages of Alzheimer's disease who have one or no copies of the apolipoprotein E4 gene. The Commission on Human Medicines (CHM) advised the imposition of a controlled access programme and post-authorisation safety study to promote safe and effective use and to ensure that the safety and efficacy of lecanemab remains under close review when being used within routine clinical practice. On 22nd August the MHRA announced the product licence for lecanemab had been granted alongside the NICE decision which was that the costs to NHS were not justified for the modest benefit.

Covid-19 vaccines

2.3 In July and August we granted 8 line extensions (strain updates) for Comirnaty, a COVID19 mRNA vaccine. This is an adapted form of the already approved vaccine that targets the JN.1 COVID-19 subvariant. The authorisation was granted as part of the International Recognition Procedure (IRP), via the reference regulator, the European Medicines Agency (EMA).

Zolbetuximab for stomach cancer

2.4 In August, the MHRA approved zolbetuximab (Vyloy), a new targeted cancer treatment, given in combination with a standard chemotherapy, for adults with stomach (gastric) or gastro-oesophageal junction cancer. Zolbetuximab is a monoclonal antibody that can recognise and attach itself to certain cancer cells to destroy them. Zolbetuximab is prescribed for patients whose tumours are positive for the "Claudin18.2 (CLDN18.2)", and negative for the "Human epidermal growth factor receptor 2 (HER2)" proteins. It is given

to patients whose gastric or gastro-oesophageal junction cancer cannot be removed by surgery or has spread.

International Recognition Procedure

2.5 Applications via the International Recognition Procedure (IRP) continue to meet statutory timeframes. To address the challenge of unavailability of assessment reports (ARs) for generic applications, we have developed a solution for targeted assessments. A pilot of this solution will be conducted in September and October, with the outcomes and updated guidance scheduled for release in November, and a full implementation target of January 2025. A process and training refresh for the teams involved is planned for this quarter and a second self-audit is planned for the end of the year to review quality and decision making at the triage meetings.

MedTech International Reliance

2.6 By learning from experienced regulators in Australia, Singapore, Brazil, and others, we plan to implement measures to rely on decisions made by comparable regulators when determining product access in the UK. We already permit EU-approved products in the UK market, a practice that will continue in line with EU transition rules until at least 2028, and up to 2030 for certain products. In May 2024, we published draft proposals for long-term international reliance and recognition from more countries. Since then, we have collaborated with volunteer companies using 18 example products across various sectors to refine these proposals, preparing for a detailed public consultation this year, pending government approvals.

Personalised cancer vaccines

2.7 On 19 July we held a regulatory sandbox meeting to better understand the cancer neoantigen selection and manufacturing aspects of an individualised mRNA cancer immunotherapy. Another is planned with industry stakeholders. These insights are informing the draft guidance for developers, to be shared with the Highly Personalised Medicines Expert Working group (EWG) on 10 September for discussion and advice. In parallel, MHRA is in discussion on whether new legislative provisions are needed to licence highly personalised medicines. A first draft, including advice on cancer neoantigen selection and manufacturing, will be completed by end September. Informal feedback will be requested from national healthcare partners and international regulatory partners. In parallel, follow-up meetings with industry will inform the non-clinical, clinical, lifecycle and vigilance aspects, aiming to publish draft guidance by the end of 2024, for consultation.

Clinical trials, investigations and inspections

2.8 Clinical trials and investigations (CIT) continues to meet all statutory timelines for applications and amendments. Additional resources are being deployed from September to eliminate the backlog in Scientific Advice Meetings for clinical trials by the end of December 2024. In terms of inspections, we have seen a significant improvement in meeting statutory timeframes for manufacturing and distribution licences, which have improved from c.25% in December 2023 to c.70% in August 2024. The backlog is reducing with a target of elimination by December 2024.

Clinical Trials data lab

2.9 The Clinical Investigations and Trials (CIT) Operations Team has launched a ‘data lab’ with the introduction and full operationalisation of MicroStrategy. This step allows the team to perform real-time analysis, creating intelligence for CIT and the Agency. Furthermore, the data extraction will support the introduction of Applied Evidence-Based Regulatory Science (AEBRS) research within CIT. AEBRS represents the generation of the evidence to support our regulatory decision-making processes.

Innovative Licencing and Access Pathway

2.10 The Innovative Licensing and Access Pathway (ILAP) programme is making great strides in its enhancement and optimisation. In August, a collaboration agreement was signed among ILAP partners, with the NHS joining the initiative. We are aiming to launch the refreshed ILAP in the coming weeks if the government agrees.

ACCESS Clinical Trials Working Group

2.11 After agreeing to MHRA proposals at the November 2023 ACCESS HoA meeting in Melbourne, CIT's Deputy Director was named chair of the ACCESS Clinical Trials Working Group (CT WG). The Access Consortium CTWG first met in July to explore collaboration and work sharing on assessing complex, innovative trials and scientific advice meetings. Data on CT WG activities will be collected and reviewed in October, setting the stage for effective collaboration on clinical trial assessment and scientific advice from 2025 onwards.

PATIENT SAFETY

Valproate and risk of neurodevelopmental disorders

3.1 Findings from a retrospective observational study, combining analyses of electronic medical records in Norway, Denmark and Sweden, indicated a possible increased risk of neurodevelopmental disorders in children born to men treated with valproate in the 3 months prior to conception. As a precaution, the MHRA has recommended that male patients use effective contraception throughout the valproate treatment period and for 3 months after stopping valproate. This new advice sits alongside the introduction of the prescribing requirements in all patients under 55 years of age (female and male). We will continue to work with the Valproate Stakeholders Network to monitor the impact of the strengthened measures to prevent harms from valproate.

Antidepressant risk minimisation

3.2 The inaugural meeting of the Commission on Human Medicines' antidepressant risk minimisation expert working group (EWG) took place in July. The EWG has been established to consider the effectiveness of the current patient information leaflets for communicating the risks associated with antidepressants and the potential need for other methods to communicate risks. The EWG will consider all newly published data since the previous regulatory review relating to the risk of suicidal behaviours (in 2019) and sexual side effects which may continue when antidepressants are stopped.

Yellow Card reporting

3.3 We have been working closely with Egton Medical Information Systems (EMIS) following the feedback they have received from the Agency, the Commission on Human Medicines (CHM), the Pharmacovigilance Expert Advisory Group (PEAG) and from the Patient Safety Commissioner about improving Yellow Card reporting through EMIS. One of the key issues was the visibility of the mechanism to report a Yellow Card, which we have taken action to rectify. EMIS is also carrying out work to look at a more disruptive Yellow Card flow, for example having trigger points such as 'ending a drug' and having a more powerful Yellow Card call to action, and they are carrying out some more user feedback exercises to support this work.

British Pharmacopoeia

3.4 The British Pharmacopoeia (BP) has developed and published new guidance on Advanced Therapy Medicinal Products (ATMP), T Cell and NK Cell Characterisation Assays. The guidance supports standardisation of ATMP operations, offering a practical and phase-appropriate validation tool to help cell therapy programmes to succeed. The guidance was developed in partnership with experts from the cell and gene therapy community including industry, the NHS and academia. The British Pharmacopoeia was successfully published on time in August 2024, and income continues to exceed budgeted targets.

Regulatory reform

3.5 The MHRA's MedTech roadmap outlined plans to amend the 2002 Medical Device Regulations. With government approval, we will propose a Post Market Surveillance Statutory Instrument to Parliament in October 2024. In 2025, we will introduce a Pre-Market Statutory Instrument aimed at boosting patient safety with stricter measures, including higher classification and subsequent increased scrutiny of some medical devices, as well as tighter regulations on manufacturers' claims. We are in particular considering what preparations need to be in place to manage potentially increased device reporting and the submission of post market surveillance plans. We are focussed on ensuring SafetyConnect device reporting is fully functional for the end of the transition period. The AI Airlock is now seeking proposals for evidence generation which will contribute to the regulation of these innovative digital products.

Enforcement

3.6 Throughout the summer, the CEU has worked to build upon its already strong relationships with financial institutions and payment processing platforms. This has led to the emergence of a number of initiatives whereby conventional and cryptocurrency accounts identified as being used to facilitate medicines crime are disrupted.

PARTNERSHIPS

ACCESS Consortium

4.1 The MHRA has led the development of the ACCESS Consortium website, delivering a one-stop-shop for all-ACCESS related questions. A soft launch of the ACCESS Consortium website was undertaken, In addition, we have engaged with Access partners to develop the consortium's refreshed strategy ready for launch in 2025. This updated strategy will aim to consolidate worksharing and expand on the number of procedures We have supported the MHRA Deputy Director for Clinical trials to relaunch and lead the Access Clinical Trials Working Group.

Point of Care manufacture

4.2 Introduction of the new Point of Care manufacture framework is progressing. We are finalising the legislation and accompanying documents and we are aiming to lay the Statutory Instrument on 17th October. We are playing a leading role in the international discussions on Point of Care manufacture, together with Japan, at the International Coalition of Medicines Regulatory Authorities.

International agreements

4.3 We initiated the process to sign an information-sharing agreement with WHO, with the view to progress and apply to become a WHO listed authority.

Windsor Framework

4.4 Additional guidance was published on UK-wide licencing and Pharmacovigilance on 30 August. Further guidance including on control testing and for wholesalers and manufacturers is being finalised for publication in the coming weeks. This guidance reflects and builds on existing Windsor Framework Guidance for labelling and licencing. We are also intensifying proactive communications on implementation requirements including social media activity and webinars.

Mental Health Mission support

4.5 Partnerships has received grant funding for a position to collaborate with academic leaders in the mental health mission. This multi-year grant aims to enhance understanding between the MHRA and the mental health community.

DIGITAL AND TECHNOLOGY

RegulatoryConnect

5.1 The new RegulatoryConnect system which replaces existing legacy systems, faces delays due to the complexity and cost of requirements. The Programme Board agreed on a new plan: to proceed for 3 months with Product Licensing and related features using a smaller team to stay within budget. This period will determine actual design, build, and test costs rather than relying on questionable estimates. Early signs are promising, with activities mostly on schedule and some ahead of schedule.

Legacy platforms

5.2 Delays to some aspects of the RegulatoryConnect programme mean that some legacy systems cannot yet be decommissioned. The Technology Maintenance programme continues to deliver critical updates to Agency systems, including legacy issues. These were last reviewed on 21st August 2024 with no change to the residual risk score.

Cyber security

5.3 The Cyber Security programme continues to progress critical workstreams to continue to strengthen and mitigate this risk. The residual risk score was reduced in March 2024, from 25 to 16. Whilst progress is being made on the programme, the delays in RegulatoryConnect and the length of some of the workstreams means that no further reduction in residual risk score is yet achievable. The risk was last reviewed on 21 August.

DYNAMIC ORGANISATION

Annual report and accounts

6.1 We successfully laid the designed version of the Agency's Annual Report and Accounts in Parliament on 30 July. The report provides an extensive overview of our performance, achievements, finances, and the events that have had most impact on the agency during the past year.

Assurance rating

6.2 Our independent auditor at the Government Internal Audit Agency provided the Agency with a 'limited' assurance rating at the end of the last financial year, which was published in the Annual Report 2023/24. This suggests weaknesses in our governance, risk and control across the organisation which require holistic and integrated improvements. However, the auditor did recognise that improvements had once again been implemented and embedded in year in different parts of the Agency, particularly in our maturing approach to risk management. Addressing variability across the Agency will be a key step in returning to a moderate assessment, which the Executive have specifically targeted for 24/25.

Spending Review

6.3 The final submission of the formal spending review commission was completed on 2nd September. The commission was for five years' worth of plans. Funding for 2025/26 is expected to be agreed as a single year and further work will take place in the autumn on the remaining 4 years to produce a 4-year Spending Review by the spring.

Culture Survey

6.4 In July, the agency conducted a culture and pulse survey, with 430 colleagues participating and sharing positive feedback. The analysis indicated we are not yet doing enough to drive the desired culture change. Results are available on INsite, and the One Agency Leadership Group is responsible for ensuring local actions address these findings.

Electronic Quality Management System

6.5 The Agency is in the process of configuring and implementing an electronic Quality Management System to manage Auditing, Corrective & Preventative Actions tracking and recording of associated activities.

Business Code of Conduct

6.6 To support our staff to understand the expectations required of them as part of the agency, our new Code of Business Conduct has been published. This is aligned with the Department of Health and Social Care Code, and forms a critical part of our governance framework, demonstrating both Civil Service and our Agency values, and helping to make the MHRA the best place to work.

Freedom of Information requests

6.7 Under our commitment to be a transparent and accessible organisation our new FOI management system is supporting continued timely response to FOI requests, achieving 98.6% compliance in June.

AGENCY PRIORITIES

In summary, the current priorities for the Agency are to:

i. Maintain the Agency's overarching focus on delivering its core business activities, meeting targets for all key services and ensuring risk proportionality via new ways of working

ii. Strengthen our Patent Involvement Strategy, addressing the findings of the independent evaluation and ensuring that patients are informed of the impact of their contribution

iii. Further develop our sustainable business model through revision of our fees based on the results of activity recording, and roll our activity recording to functions who have not yet participated

iv. Continue to invest in our technology systems to improve the tools used by our staff and the services for our customers and patients

v. Continue to collaborate with our national partners in healthcare and with international regulators, in particular on our approaches to new regulatory frameworks.

Dr June Raine, CEO
September 2024

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

17th September 2014

Title	What are the financial and people performance of the MHRA in July 2024?
Board Sponsor	Rose Braithwaite
Purpose of Paper	Assurance

What was the financial and people performance of the MHRA in July 2024?

1. Executive Summary

1.1 The Agency finished July (Period 4) with a small YTD Resource surplus of £1.8m compared to budget, driven by underspends in pay and non-pay costs. The Q1 RDEL full year forecast, however, shows a £2.6m overspend to budget as pay catches up with budget and non-pay spend increases in the second half of the year. Capital spend was only £0.1m behind budget and is forecast to remain spending to budget.

1.2 The Executive Team has considered the Q1 forecast of a full year £2.6m and additional bids of £5.1m, totalling a potential forecast overspend of £7.7m. Savings proposals of £5.3m have been put forward that will reduce the total forecast overspend to £2.5m. These decisions to reallocate budget to key projects such as Return to Green rather than reduce it, were taken in light of the £1.8m underspend year to date. The position will be reviewed further at the midyear point to assess the validity of the full year forecast which, given this underspend, still holds too much optimism bias.

1.3 As an Arm's Length Body (ALB) within the accounting boundary of the Department for Health and Social Care (DHSC), the Agency is not able to utilise any retained surpluses for future years. In contrast to the financial arrangements of the Agency when it was a Trading Fund, our new reporting requirements mean the Agency must manage all expenditure and income within the financial year and does not allow the Agency access to any previous year reserves.

2. Introduction and Background

AGENCY PERFORMANCE – RESOURCE

Income

2.1 The YTD trading income position is now £0.2m above budget after a good performance in July, particularly in Science and Research. Periodic fee income is released at budget and will continue to be assessed as more data emerges in future months. Grant income performed better in July as activity caught up but is still significantly behind budget because of a slow start of the year in Science and Research.

2.2 The full year forecast for income is positive, with performance at budget. Strong HQA trading income in Authorisation Lifecycle will make up for weaker performances in Innovation and Compliance and Science and Research. The forecast for grant income is also at budget because of higher-than-expected activity in Safety and Surveillance making up for

slower take up in Science and Research. However, this drives some of the higher pay and non-pay costs in S&S.

Table 1 - Agency Financial performance to the end of July 2024

Finance Report — July 2024

July 2024	Period		Variance vs	YTD		Variance vs	Full Year		Variance vs
Resource	Actual	Budget	Budget	Actual	Budget	Budget	Forecast	Budget	Budget
	£M	£M	% / £M	£M	£M	% / £M	£M	£M	% / £M
Trading Income	8.7	7.8	11%	33.6	33.4	0%	100.7	100.5	0%
Service Fee Income	3.8	3.8	0%	15.0	15.0	0%	45.0	45.0	0%
Grant Income	0.6	0.5	20%	1.4	2.0	(30%)	5.4	5.4	(1%)
Staff Costs	8.2	8.2	0%	32.1	32.9	3%	102.5	102.8	0%
Operating Costs	5.5	5.7	3%	21.7	22.6	4%	72.8	68.8	(6%)
Operating Net Position	**(0.6)**	**(1.8)**	**1.1**	**(3.7)**	**(5.0)**	**1.3**	**(24.3)**	**(20.7)**	**(3.6)**
Project Grant Income	0.0	0.0	(100%)	0.0	0.2	(100%)	3.7	0.5	632%
Staff Costs	0.2	0.2	19%	0.7	0.8	12%	2.5	2.5	(2%)
Projects Costs	1.2	1.0	(19%)	3.5	4.1	14%	14.0	11.8	(18%)
Projects Net Position	**(1.4)**	**(1.2)**	**(0.2)**	**(4.2)**	**(4.7)**	**0.5**	**(12.8)**	**(13.8)**	**1.0**
Agency Resource Net Position	**(2.0)**	**(3.0)**	**1.0**	**(7.9)**	**(9.7)**	**1.8**	**(37.1)**	**(34.5)**	**(2.6)**

Recommended new bids at Q1	**(5.1)**
Recommended savings at Q1	**5.3**
Resulting net position	**(2.5)**

Staff Costs

2.3 Staff costs in July were £8.2m matching the monthly budget. YTD costs remain 3% below budget. Although a number of roles approved in the 24/25 remain vacant as recruitment takes place, the vacancy rate assumption means the overall underspend is small. The full year forecast is for pay spend to increase towards budget on the basis of recruitment and the inclusion of the 5% pay award which is 0.5% higher than budgeted.

Non-Pay Costs

2.4 Spend on other operating costs in July was £5.5m, £0.2m (3%) lower than the £5.7m monthly budget. The YTD position shows a similar underspend of 4%. Areas of material underspend include contracted out services in HQA, which has dedicated budget for external support to reduce backlogs and accommodation costs in Corporate amongst others.

2.5 The Full year forecast is an overspend of £4m (6%). This includes the £2.5m running hot provision, a £1m overspend in D&T because of extra projects and inflationary increases not included in the budget, an increase in CPRD costs above budget because of inflationary pressure.

Project Resource Expenditure

2.6 July RDEL project costs were slightly above budget because we are now recognising NIHR funded CPRD costs, which had not been included in the budget. These also drive higher than budgeted pay and non-pay costs in the forecast. However, they are matched by income so do not contribute to the overspend. The Projects FY forecast is a £1m underspend that recognises the contribution of project income to fund corporate overheads.

AGENCY PERFORMANCE – CAPITAL

Table 2 – Capital spend to the end of July 2024

July 2024	Period		Variance vs	YTD		Variance vs	Full Year		Variance vs
Capital	Actual	Budget	Budget	Actual	Budget	Budget	Forecast	Budget	Budget
	£M	£M	% / £M	£M	£M	% / £M	£M	£M	% / £M
Projects Costs	2.2	2.3	7%	7.4	7.8	5%	19.4	19.5	1%
CDEL Operational Costs	0.2	0.2	(19%)	0.7	0.4	(71%)	6.0	6.0	0%
Agency Capital Net Position	**(2.4)**	**(2.5)**	**0.1**	**(8.1)**	**(8.1)**	**0.1**	**(25.4)**	**(25.5)**	**0.1**
DHSC Capital Funding	2.5	2.5	0%	8.1	8.1	0%	25.5	25.5	0%
Total Capital DH Position	**2.5**	**2.5**	**0.0**	**8.1**	**8.1**	**0.0**	**25.5**	**25.5**	**0.0**
Total CDEL	**0.1**	**0.0**	**0.1**	**0.1**	**0.0**	**0.1**	**0.1**	**0.0**	**0.1**

2.7 All of the capital budget has to be provided either by DHSC or from other Government Departments via the Commissioner Pays model which allows for the transfer of capital budget between departments. The Agency has a FY Capital budget of £25.5m. Spend at YTD and forecast is to budget.

2.8 The largest Capital project is Regulatory Connect, with a budget of £14.1m. The South Mimms Capital Programme is the second largest capital investment area for the Agency, with a budget of £6m. Both areas are forecasting to spend to budget.

3 People Performance July 2024

3.1 We had 1,347.68 people in post at the end of July 2024 (FTE, permanent, fixed term and Phd students covering established posts). Of this number, 167.32 were fixed term.

3.2 There are two categories of fixed term staff in the civil service – fixed term IN where a fixed term post has been advertised fair and open externally and the candidate appointed on merit, and fixed term OUT, where the role has not been advertised externally but perhaps through a recruitment agency or other ‘exception’ to the Civil Service Recruitment Principles.

Turnover

3.3 Turnover of staff has increased from 6.7% in June to 7% in July. Whilst this rate is comparatively low, it is reflective of the large number of relatively new joiners the Agency has welcomed in the last two years in particular and brings much needed stability to our Groups and Functions.

3.4 Despite a challenging employment market for all sectors, we continue to see an increase in the number of joiners versus leavers, reflected in our turnover. We welcomed 39 new starters to the Agency in April versus 6 voluntary leavers.

Vacancies

3.5 In respect of our 138 'vacancies' (a reduction on the 154 reported for June) these are split by Group as follows:

Group	Vacancies	% vacancies FTE
Corporate	11	10%
D&T	15	14%
Enablement	8	8%
HQ&A	49	12%
Partnerships	2	7%
S&S	24	8%
SR&I	29	10%
Total	138	10%

Sickness Absence

3.6 Sickness absence (annualised) has decreased to 5.9 days per FTE compared to 6.5 reported for June. Typically, we would expect to see fluctuations in absence levels over the winter and spring months, and level off as we move into the summer months. This can relate to a reduction in seasonal coughs/colds/flu and other viruses, but another possible link is that colleagues often take more annual leave in the summer months, allowing them to gain some well-deserved rest and recuperation, enabling them to build resilience and better maintain their wellbeing. Absence related to mental ill health remains a top contributor to absence. We know that mental health related absence is generally underreported and 'masked' by staff as something else, so the 'true' percentage is arguably higher that our records show.

3.7 Wellbeing continues to be a major focus of attention, with it being a key strand of the People Survey corporate action plan. A new wellbeing/non-clinical counselling service for staff to access in addition to our employee assistance programme was launched in May, and a stress survey is now live for staff to access. The survey remains live all year round and the Diversity Team within the People function will use data collected from these surveys - along with other measures - to deliver tailored initiatives to support colleagues, particularly where hot spots are identified. High level, anonymised reports will be released on INsite every quarter to show results from the information collected and provide feedback about what action is being taken in connection with those results.

4 Group Performance

Science and Research

4.1 Science and Research's trading income was significantly above budget because of sales of goods and products and sample testing.

4.2 YTD Trading income, however, is £0.9m behind budget because of the Q1 results, in particular the lower income from grants and sales of goods and products. On a positive note, the July actuals point towards an improved run rate for the rest of the year, matching the forecast.

£'000s	Period			YTD			Full Year		
	Actual	Budget	Variance	Actual	Budget	Variance	Forecast	Budget	Variance
Trading Income	2,429	1,730	699	8,079	9,016	(937)	23,597	25,052	(1,455)
Staff Costs	1,356	1,254	(102)	5,382	5,016	(366)	16,320	15,665	(655)
Non-Staff Costs	306	311	5	1,838	2,166	328	5,877	6,205	328
Operating Position	**767**	**165**	**602**	**859**	**1,834**	**(975)**	**1,400**	**3,183**	**(1,783)**

4.3 Staff costs are slightly over budget because not all grant funded roles were included in the original forecast. Unfortunately, this means an overspend for the rest of the year, but without which we wouldn't be able to recover grant income. Non-Pay costs are slightly below budget because of lower spend in Lab costs, but because they are lumpy, the overall forecast is to budget.

HQA

£'000s	Period			YTD			Full Year		
	Actual	Budget	Variance	Actual	Budget	Variance	Forecast	Budget	Variance
Trading Income	3,626	3,356	270	14,435	13,423	1,012	43,077	40,270	2,806
Staff Costs	1,971	1,987	16	7,550	7,948	398	25,636	24,888	(748)
Non-Staff Costs	160	672	511	1,392	2,687	1,294	4,457	4,477	21
Operating Position	**1,495**	**697**	**797**	**5,493**	**2,789**	**2,704**	**12,984**	**10,904**	**2,079**

4.4 HQA has trading income 7.5% above budget. This is good news for the Agency considering the ambitious budgets set to match the efforts to reduce backlogs. For national applications, actuals are only slightly behind their high targets, with complex applications leading performance. Deferred revenue for these categories has also been falling indicating a reduction in backlogs. Income across Authorisation Lifecyle activity is also above budget and is forecast to finish the year strongly in areas such as labels and leaflets and devices registrations. Variations income remains low across HQA and S&S compared to results last year, suggesting we overestimated the income baseline and underestimated the extra income realised last year from backlogs.

4.5 Staff costs are below budget as expected as a material element of the budget relates to new roles that need to be recruited. The FY forecast of a slight overspend depends on the success of that recruitment.

4.6 Non staff costs are significantly underspent because of slower than budgeted spend for external contractors to help reduce backlogs. The forecast, however, is for spend to match budget by the end of the year. This means an overall forecast of a £2m positive variance on the basis of higher income.

Innovation and Compliance

£'000s	Period			YTD			Full Year		
	Actual	Budget	Variance	Actual	Budget	Variance	Forecast	Budget	Variance
Trading Income	1,415	1,613	(198)	5,410	6,412	(1,002)	18,770	20,799	(2,030)
Staff Costs	1,039	1,221	182	3,986	4,883	897	13,584	15,353	1,769
Non-Staff Costs	532	508	(24)	1,660	2,033	373	6,111	6,010	(101)
Operating Position	**(155)**	**(116)**	**(39)**	**(236)**	**(505)**	**268**	**(926)**	**(565)**	**(361)**

4.7 The overall YTD Operating Position is of a small underspend with a significant trading income under-recovery made up by staff and non-pay underspends. YTD Trading income is 16% behind budget. Most of the negative variance is from Inspections income now £0.69m behind its YTD budget, and on course to a FY forecast of £1.28m deficit. Much of the fall is in GMP income due to resource constraints. The GMP symposium will not be held this year with an additional loss of £0.7m income, however costs relating to the event will reduce by approx. £0.2m.

4.8 YTD Pay and non-Pay costs are significantly behind budget, more than making up for the loss in income. The Pay underspend is driven by vacancies. The Non-Pay underspend is a result of lower T&S costs in the Inspectorate and slower contracted out spend in CIT and the Innovation Accelerator. The FY forecast sees spend on both areas increasing towards budget, meaning a small overspend by year end.

Safety and Surveillance

£'000s	Period			YTD			Full Year		
	Actual	Budget	Variance	Actual	Budget	Variance	Forecast	Budget	Variance
Trading Income	1,707	1,530	177	6,484	6,122	362	19,110	18,365	745
Staff Costs	1,733	1,718	(15)	6,776	6,872	96	21,346	21,341	(5)
Non-Staff Costs	1,271	677	(594)	3,345	2,750	(595)	9,961	8,503	(1,457)
Operating Position	**(1,297)**	**(865)**	**(432)**	**(3,637)**	**(3,500)**	**(137)**	**(12,197)**	**(11,480)**	**(717)**

4.9 July's operating net position is significantly overspent because of an accounting error that recognised annual costs all in one month. Once, corrected, non-pay costs will return to budget, meaning an overall positive variance.

4.10 YTD Income is slightly above budget because of higher-than-expected grant income, which should continue until the rest of the year.

4.11 In terms of costs, there is a small pay underspend which should disappear later in the year as roles are filled. YTD non-pay costs should return to budget once costs are correctly profiled during the year. The full year forecast, however, is for a significant overspend which pushed Safety and Surveillance into an overall net overspend. This is driven by higher-than-expected IT costs and other operational costs.

Digital and Technology

£'000s	Period			YTD			Full Year		
	Actual	Budget	Variance	Actual	Budget	Variance	Forecast	Budget	Variance
Trading Income	66	117	(51)	525	467	58	1,439	1,400	39
Staff Costs	692	680	(12)	2,736	2,719	(17)	8,542	8,453	(89)
Non-Staff Costs	1,746	2,202	456	8,114	7,749	(365)	28,661	27,639	(1,021)
Operating Position	**(2,372)**	**(2,765)**	**393**	**(10,325)**	**(10,001)**	**(324)**	**(35,763)**	**(34,692)**	**(1,071)**

4.12 July's non-pay costs are lower than budget because of a further recovery of VAT costs which arose after the re-assessment of high value 23/24 contracts. The YTD operating position shows a overspend of £0.33m, driven by a non-pay overspend. That position worsens to a FY overspend of £1m. The overspend is due to additional work asked of D&T including Return to Work, National Archives, CEC and governance and clinical trials for which no budget was assigned. A further provision is made to additional software requirements and potential commercial negotiations which might lead to higher costs.

Corporate

£'000s	Period			YTD			Full Year		
	Actual	Budget	Variance	Actual	Budget	Variance	Forecast	Budget	Variance
Trading Income	3,759	3,754	5	15,051	15,016	35	45,068	45,054	13
Staff Costs	571	597	26	2,416	2,387	(29)	7,698	7,529	(169)
Non-Staff Costs	1,221	925	(296)	4,106	3,693	(413)	13,442	11,594	(1,849)
Operating Position	**1,967**	**2,233**	**(265)**	**8,529**	**8,936**	**(407)**	**23,928**	**25,932**	**(2,005)**

4.13 Corporate's forecast deficit is driven by it holding the £2.5m running hot provision agreed at budget. Without that provision it would be in an overall surplus. In terms of income, it receives the periodic fee which is then allocated to the fee-earning divisions. For the moment, the periodic fee is forecast at budget because we don't have enough information for a

full assessment. We will continue to review its performance monthly as any change is material to the agency's accounts.

4.14 In terms of costs, excluding the running-hot provision, corporate is at YTD underspend because of lower than expected spend on the 10SC rent and other costs associated with the South Mimms site such as building repairs and maintenance. In terms of the FY forecast, if we exclude the £2.5m provision, it is a small underspend driven by lower Accommodation costs. However, we have added a provision of £0.75m to cover any in-year costs relating to non-compliance with IR35.

Enablement

£'000s	Period			YTD			Full Year		
	Actual	Budget	Variance	Actual	Budget	Variance	Forecast	Budget	Variance
Trading Income	70	0	70	7	0	7	7	0	7
Staff Costs	658	592	(65)	2,466	2,370	(96)	6,996	7,363	367
Non-Staff Costs	279	358	79	1,197	1,451	254	4,260	4,314	53
Operating Position	**(866)**	**(950)**	**84**	**(3,655)**	**(3,820)**	**165**	**(11,249)**	**(11,677)**	**428**

4.15 The YTD position is a small underspend because of low non-pay costs. The Full year forecast is a higher underspend because of pay costs decreasing in the second half of the year. However, if fixed term posts bids in Communications are approved, we expect that underspend to reduce. Non-staff costs are expected to underspend by year end because of lower spend on committees and seminars.

Partnerships

£'000s	Period			YTD			Full Year		
	Actual	Budget	Variance	Actual	Budget	Variance	Forecast	Budget	Variance
Trading Income	0	0	0	0	0	0	0	0	0
Staff Costs	179	180	0	738	719	(20)	2,215	2,234	18
Non-Staff Costs	1	7	5	10	26	16	73	80	7
Operating Position	**(180)**	**(186)**	**6**	**(749)**	**(745)**	**(3)**	**(2,288)**	**(2,313)**	**25**

4.16 Partnerships has a very small YTD deficit because of a pay overspend. However, by the full year forecast, the position reverts to a small underspend. Partnerships will also distribute £2.5m of Innovation funding on CERSI, which is accounted for in projects.

5 Recommendations

5.1 The Board is asked to consider the assurance it gains from the financial data, in particular the year-to-date underspend of £1.8m suggesting continued optimism bias in the full year forecasts at the end of July.

5.2 The Board is asked to consider the HR data and the assurance that it provides on the resourcing of the Agency, and for advice on the steps being taken to address the concerns about staff wellbeing arising from the staff survey data.

Rose Braithwaite
05.09.2024

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

17 September 2024

Title	What was the Agency's Operational Performance in Q1 of 2024/25?
Board Sponsor	Rose Braithwaite
Purpose of Paper	Assurance

What was the Agency's Operational Performance in Q1 of 2024/25?

1. Executive Summary

1.1. At the end of Q1, our performance against Business Plan objectives is generally satisfactory with 70% on track, but three are expected to be late and several are showing as at risk and are being monitored. We are still meeting four out of eight of our KPI targets and there has been a notable reduction in backlogs.

2. Introduction

2.1. The Q1 2024/25 Performance Report is attached. The report provides a progress update on Business Plan objectives and KPI and metric performance for the Delivery and Performance Committee (DPC), the Executive Committee (ExCo) and the Board to review and make performance related decisions.

2.2. The Board is reviewing the Q1 report in September as it did not meet in August. We have noted some more recent developments below.

2.3. The DPC and ExCo have discussed and approved the performance report. At risk items will be tracked by the DPC and there will be a light touch exercise to create a central summary of "what finished looks like" for each business plan objective.

2.4. We have now published the Business Plan 2024/25 internally. We hope to publish it externally by the time of the Board meeting. There has been a delay given the usual communication restrictions associated with elections. Reporting has been done on the assumption that any changes during the approval process would be minor.

3. How did the MHRA perform in the first quarter of 2024/25?

Part 1: Progress on Business Plan Objectives (slides 6-10)

3.1. Overall, the performance against Business Plan objectives was generally satisfactory at the end of Q1. There are 57 objectives and 40 (70%) are Green and on track, 14 (25%) are Amber and at risk and 3 (5%) are Red and are due miss their original deadlines.

3.2. The 14 items showing as at risk are summarised in the annex. They can be grouped into: those where we wish to confirm that new ministers are content following the election, those impacted by initial challenges in delivering the Return to Green programme (or the conscious decision to temporarily reprioritise the programme over wider Business Plan objectives) and those pending approval for resource bids. We expect mitigations to get items back to Green and the DPC will monitor them.

3.3. There are some objectives that are expected to miss their original deadline. We hope to have revised timescales for the Q2 report.

- **RegulatoryConnect**: delivery by Q3 is not possible due to the size and complexity of requirements and affordability. A new plan was agreed at Programme Board to move ahead for a 3-month period with Product Licensing and associated common features with a reduced programme team to keep within budget. This period will define actual design, build and test time and costs rather than being solely reliant on estimates which have been questionable throughout the programme. Early signs during this period are promising with all activities either on or near plan and in some areas, ahead of plan. Several "show and tells" are planned for stakeholders in the coming period.
- **Medical device framework 2024/25 milestones**: the election itself and the usual need to reconfirm ministerial approval following the election has impacted milestones. We have now presented outline plans to ministers to continue with our key commitments to strengthen our regulations for the benefit of patient safety by laying new Post Market Surveillance regulations in 2024, and further pre-market regulations, to include International Recognition, in 2025. New ministers have given their support to our plan, so we are now working to confirm new timelines, aligning with overall government legislative priorities.
- **Annual recognition scheme**: the launch will be combined with an existing staff event but there is nothing suitable in Q3 so this will fall into Q4.

Part 2: Operational Performance KPIs (see slides 11-28)

3.4. The table overleaf shows the status of our 8 KPIs and their associated Return to Green programme RAG ratings (Red, Amber, Green). We have included the data from the Q1 and July performance reports as there are improvements.

3.5. It is also worth noting that, since July, the Return to Green programme has made progress. The programme was established to restore our performance through reducing backlogs by introducing new sustainable approaches for delivery.

- Backlogs have been reduced in all workstreams and nothing is Red rated as clear reduction plans are in place for all of them.
- We have removed the backlog for HQ&A type 1b variations and safety 1b variations are following closely with only a very small backlog outstanding.
- Clinical trials cleared its backlogs seven months ago and have stayed on track.
- All workstreams remain focused on refining our processes to achieve sustainable service provision and prevent future backlogs.

3.6. In July, we hit 4 out of 8 KPI targets. We continue to see good performance on KPIs for clinical investigations, clinical trials, batch tests, the International Recognition Procedure and safety signals.

3.7. The are 4 KPI are still missing their targets. If the trend of clearing backlogs continues it should enable teams to get their KPIs back on track.

- **Medicines licence applications:** there has been a sustained decline in the backlog but efforts to clear it continue to result in variable but low KPI performance. Over the coming months, the team expect to see more reductions in average turnaround times in response to RtG intervention.
- **National variations:** there has been an improvement in the KPIs for both Type 1b and Type II variations as well as a reduction in the backlog for Type II variations (Type 1b are in the green already).
- **Manufacturing and distribution authorisations:** 72% of manufacturing and distribution authorisations were granted, varied or refused within statutory timeframes, which is comparable to June and 20% points higher than May.
- **Scientific advice meetings:** ***i***nitial development of strategic direction and future operating model for ongoing sustainability of SAM service is being planned with the formation of a taskforce in line with RtG timetables. The team plan to update the KPI to account for efforts that encourage applicants to apply for advice as early as possible. A paper will be sent to ExCo shortly.

Key Performance Indicator	Q1 report		July report	
	Performance	RtG RAG	Performance	RtG RAG
1. We will assess 95% of all initial Clinical Trial Authorisation (CTA) and Clinical Investigation applications within their category's statutory timeline.	100% (►0%) On Target	G	100% (►0%) On Target	G
2. We will certify 95% of vaccine batches within 43 days and 99% of blood product batches within 15 days of submission.	100% (►0%) On Target	G	100% (►0%) On Target	G
3. We will determine 95% of medicines licence applications within 210 days via the national route.	3% (▼4%) Off Target	R	17% (▲13%) Off Target	A
4. We will determine 95% of medicines licence applications within 60 days via recognition Route A and within 110 days via Route B through the International Recognition Procedure.	100% (►0%) On Target	G	100% (►0%) On Target	G
5. We will determine 95% of all national variations within their category's statutory timeline.	60% (▼8%) Off Target	A	75% (▲15%) Off Target	A
6. We will grant, vary or refuse 95% of manufacturing and distribution authorisations within their category's statutory timeline.	68% (▼5%) Off Target	A	72% (▲4%) Off Target	A
7. (Interim KPI) We will process 90% of Fatal Adverse Drug Reaction reports for medicines within 24 hours,100% within 72 hours and we will process 95% of serious ADR reports for medicines within 72 hours and 100% in 120.	100% (▼0%) On Target	G	100% (▼0%) On Target	G
8. We will offer scientific advice to 95% of requests within 70 days of the request being made.	33% (▲27%) Off Target	R	31% (▼3%) Off Target	A

4. Recommendation

4.1. Is the Board content with delivery of the Business Plan and the status of our KPIs?

Rose Braithwaite
30 August 2024

Summary table of at-risk Business Plan objectives at Q1

At risk objective	Status
1. Maintaining public trust through transparency and proactive communication	
1.1.4 Establish new **systems to better engage** with healthcare professionals by end Q4.	At risk. Risk and safety comms strategy still to be published. We require confirmation of budget for 2024/25 to progress this, all initial scoping that can be carried out in house is near completion.
1.2.2 Publish accessible **minutes of all independent advisory** bodies and their supporting expert groups within one month of adoption by those committees, from end Q2.	At risk. There are likely to be delays as the main contribution of scientific minutes are provided by the relevant team (HQA and S&S) then checked by Communications. A new process has been established to introduce immediate efficiencies, and further efforts will be made to implement this in the second or third quarter.
1.2.3 **Publish Freedom of Information** responses within one month of replying to the original response from end Q2.	At risk. Current publication are up to date with additional support supporting to clear the backlog, review is current in place to establish sustainable processes moving forward to ensure no backlog emerges again.
1.3.1 Work with the HRA to develop guidance to **encourage clinical trialists to consider equality, diversity, and inclusion** in their clinical trials and clinical investigations by end Q3. (James Pound)	At risk. ExCo paper drafted setting out Agency wide activity and aligned approaches. Ongoing collaboration with HRA. Interdependency of guidance development with any changes to draft CT SI following consideration by ministers.
1.3.2 Publish a road map towards further strengthening of regulatory approaches to tackling **health inequity** by end Q4.	At risk. Plan to scope and develop cross agency approach to this from September. It is currently competing with a number of priorities, including 'Return to Green' work although the variation backlog is due to be cleared by sept.
1.4.1 Identify the types of **automated solutions** that meet our customer needs most effectively (e.g. webforms, self-service, a CRM system) by end of Q3.	At risk. Discovery and planning to commence in Q2. Dependant on funding and cross agency collaboration. Funding decision is expected in August, after which point we can look to revisiting the RAG rating.
1.4.2 Introduce improvements to our **internal knowledge hub** to improve how we handle enquiries and introduce consistent customer service standards by end Q3.	As above.
1.4.3 Pilot a **single unified gateway** for patient, public and industry enquiries by end Q4.	As above.

2. Enable healthcare access to safe and effective medical products	
2.1.1 Optimise the **performance of our regulatory services** to operate reliable and predictable timelines, including eliminating any service objectives by end Q4.	The Return to Green programme has established clearance plans and dates for each priority area where performance improvements are needed and backlogs exist, this has direct oversight from ExCo. Over the next period dates for returning to compliance timeframes will be agreed and plans for service improvements will be established.
2.1.4 Deliver the **2024/25 milestones for medical devices international recognition** in our roadmap of activity, working in parallel on approaches to maintain the UKCA as an attractive route for innovators.	At risk. Good progress has been made to draft the updated regulations. We will now seek a steer from Ministers on next steps.
2.1.6 Provide **individual timeframes for applicants**, encompassing all pre-submission and licensing activities by Q3.	At risk. This is dependent on 'Return to Green' delivering "Green" by this time and also on the delivery of RegulatoryConnect.
3. Deliver scientific and regulatory excellence through strategic partnerships	
3.2.1 Prepare legislation to deliver a new and risk-proportionate UK **clinical trials regulatory framework**, lay legislation in Q2. And publish updated guidance from October 2024.	At risk. Legislation to reform the UK CT legislation was on track to be laid June 2024 prior to the general election. We now wish to confirm that new ministers are content following the election.
3.2.2 Deliver a regulatory framework for **point-of-care manufacture** of personalised medicines, supporting the introduction of these new therapies, by end Q4.	At risk. Legislation to introduce the new framework was on track to be laid July 2024 prior to the general election. We now wish to confirm that new ministers are content following the election.
4. Become an agency where people flourish alongside a responsive customer service culture	
4.2.3 Focus on **process efficiency and productivity improvements** in the context of agreed workload predictions, prior to decision-making about rightsizing teams (ongoing and likely to last into 25/26).	At risk. Through the 'Return to Green' programme, we have put in place interventions to remove current backlogs, alongside this we are identifying and implementing process changes (which address the root cause of performance issues) so we may deliver sustainable services with significantly improved response times. We have put in place clear monitoring process to track the predicted reduction of backlogs, and these are regularly monitored to ensure that progress maintains pace with our predictions.

Medicines & Healthcare products Regulatory Agency

Agency Performance Report

2024/25 – 1st Quarter

Planning & Performance Team

Finance & Corporate Business Planning Function

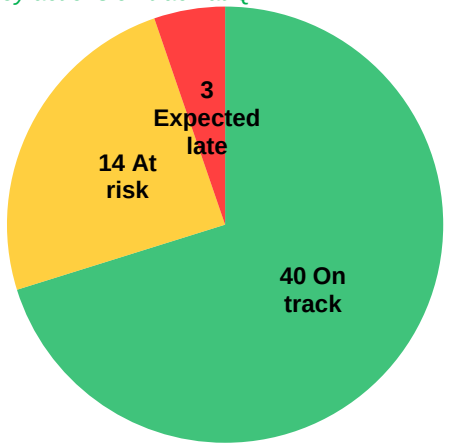
Medicines & Healthcare products Regulatory Agency

Executive Summary

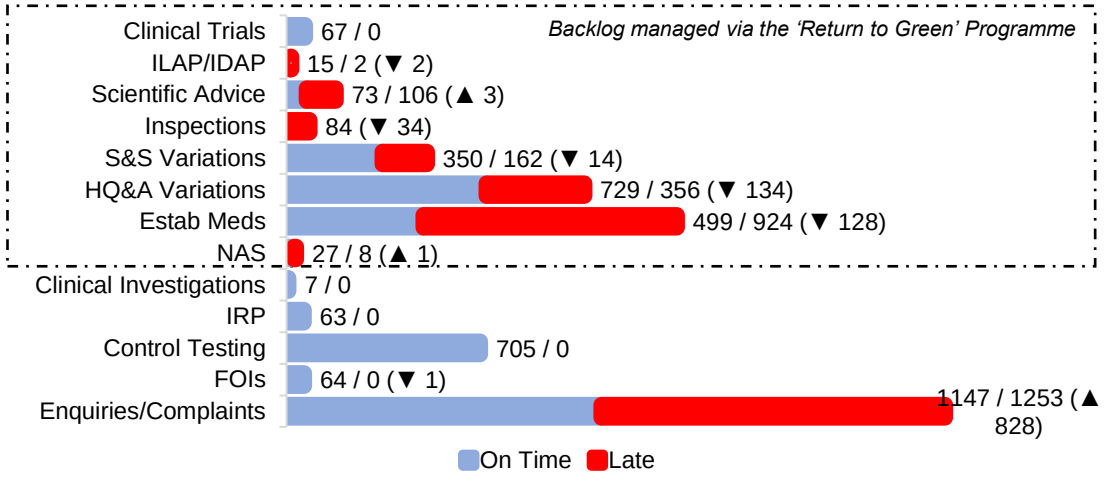
#	Key Performance Indicator (slides 11-28 + overleaf for the RtG update)	Jun 24 Performance	RtG RAG
1	We will assess 95% of all initial Clinical Trial Authorisation (CTA) and Clinical Investigation applications within their category's statutory timeline.	100% (►0%) On Target	G
2	We will certify 95% of vaccine batches within 43 days and 99% of blood product batches within 15 days of submission.	100% (►0%) On Target	G
3	We will determine 95% of medicines license applications within 210 days via the national route.	3% (▼4%) Off Target	R
4	We will determine 95% of medicines license applications within 60 days via recognition Route A and within 110 days via Route B through the International Recognition Procedure.	100% (►0%) On Target	G
5	We will determine 95% of all national variations within their category's statutory timeline.	60% (▼8%) Off Target	A
6	We will grant, vary or refuse 95% of manufacturing and distribution authorisations within their category's statutory timeline.	68% (▼5%) Off Target	A
7	(Interim KPI) We will process 90% of Fatal Adverse Drug Reaction (ADR) reports for medicines within 24 hours,100% within 72 hours and we will process 95% of serious ADR reports for medicines within 72 hours and 100% in 120.	100% (▼0%) On Target	G
8	We will offer scientific advice to 95% of requests within 70 days of the request being made.	33% (▲27%) Off Target	R

Status of Business Plan Objectives (slides 6-10)

40/57 key actions on track at Q1.



Agency Volumes



Summary

Overall, the performance against Business Plan objectives has been satisfactory.

There are 57 objectives and 40 (70%) are Green and on track, 14 (25%) are Amber and at risk and 3 (5%) are Red and due to slip in their final delivery.

The 14 items showing as at risk are summarised on page 4. They can be grouped into those facing risks/delays from: the impact of the election, challenges in delivering "Return to Green" or the need to reprioritise given the focus on RtG and pending approval for resource bids. We expect mitigations to get these items back to Green and DPC will monitor them.

More detail can be seen on slides 6-10.

We hit 4 out of 8 of our KPI targets but there has also been a more notable reduction in backlogs this quarter. If this trend continues it will enable us to get our KPIs back on track by the end of the year.

We continue to see good performance on KPIs for clinical trials, clinical investigations, batch tests, the IRP and ADR reports. The remaining KPI are still missing their targets: medicines licence applications, national variations, manufacturing and distribution authorisations and scientific advice.

More detail can be seen on slides 11-28.

Please turn over for a summary of RtG progress.

N.B – the increase in late enquiries / complaints represents a push to clear a local backlog (which has not got down to around 200/250) rather than a spike in new customer enquiries / complaints.

Overview of Return to Green programme - Latest update as of 11 July 2024

Set up to restore standards of service delivery for our customers across five areas:

- Licensing – including Established Medicines, Innovative Medicines and HQ&A Variations
- S&S Safety Variations
- Inspections
- Scientific advice – inc. scientific advice meetings (SAMs) and the Innovative Licensing Access Pathway (ILAP)
- Clinical Trials with a focus on sustainability of current performance

Focused on eliminating these backlogs through two phases:

(1) ‘Backlog Tactical’ in which interventions are put in place to remove the backlogs; and

(2) ‘Sustainable Strategy’ which is focused on understanding the root cause of why the backlogs arose and developing sustainable services, primarily based on new ways of working

Key highlights

- We are working on both tactical and sustainable interventions in parallel
- In most areas, backlogs are reducing
- No backlogs exist for Clinical Trials or ILAP
- SAMs backlogs exist for Clinical Trials and Established Medicines; none for Innovative Medicines

Return to Green: current status and key interventions

Area	Current status	Key interventions
Established Medicines	• Achieved end June target for “original backlog” • Planning to better expectation of reducing “original backlog” to 200 by end Sept 24 • Working towards clearing “overall backlog” by end Dec 24	• 1 March process changes which include stricter timeframes and greater onus on industry to improve quality of applications, supported by improved guidance, checklists and webinars • Improved resourcing via re-allocation of work, training, mentoring, permanent recruitment campaign and carefully managed professional service contracts • 3-month review of process changes and further RFI analysis with input from Trade Associations planned later this month

Innovative Medicines	• 7 procedures in backlog:
	  ○ small number belies extensive work and comparatively elongated approval timetable
	  ○ currently reviewing these line by line with assessors to confirm expected timelines
		• Focusing on front end of process (i.e. timeline from allocation to start of assessment)
		• Improved resourcing via training, mentoring and recruitment
		• Reviewing / clarifying regulatory requirements
		• Exploring work sharing options with Access collaborators (e.g. Australia/Canada)
		• Review and confirm if/when International Recognition Procedure (IRP) may apply

HQA Variations	• Type IB applications expected to clear by end July 24 • Type II variations – which involve greater complexity when assessing – expected to clear by end Dec 24	• Tighter management controls - focusing on Type IB initially, which has benefited Type II – supported by regular clinic meetings • Allocation of designated resource (i.e. assessors in training) and offering overtime • Considering further re-allocation of work (i.e. reducing admin for assessors) and option to utilise existing professional service partners • Exploring light touch notification route via a review of variation types
Safety Variations (S&S)	• Both Type IB and Type II applications expected to clear by end Sept 24	• Re-allocation of resource alongside formation of new procedural support function • Root Cause Analysis underway to develop a more sustainable model • RFI analysis to explore underlying issues, which aim to address through education / guidance • Backlog cleansing exercise underway.
Inspections	• Aiming to clear by end Dec 24 • Significant progress improving our compliance (% Completed on Time) over the last few months	• Re-allocation of resource to support triage and assessment alongside option to acquire external support • Analysis of inspection model completed for GMP, which has identified process changes that will release additional inspector resource via a risk proportionate approach • Interventions to be implemented as short-term tactical solution and evaluated for longer term benefits
Scientific Advice Meetings (SAMs)	• The Agency continues to deliver a SAM function; reconsidering best way to manage given inter-dependency with other RtG projects	• Tactical intervention to scope required resources to clear backlog by end Dec-24 in progress (e.g. via external resources backfilling so MHRA resources freed up to focus on clearing SAMs) • Initial development of strategic direction and future operating model for ongoing sustainability of SAM service during June / July 2024

Medicines & Healthcare products Regulatory Agency

Return to Green Reporting Performance Summary

Monthly data refreshed: June (Week 5)
Weekly data refreshed: July (Week 2)
Average = 12 months (or max of available data)

Details		Reporting										
Workstream	Sub-stream	Intake		Output		% Completed on Time		Healthy Volume *(on time)*	Backlog *(late)*	Expected clearance date	Expected Statutory timeline Date	Ph1 RAG
		Actual	Avg	Actual	Avg	Actual	Avg	Actual	Actual			
Medicine Licensing	Established Medicines	22(▲11)	43	91(▲6)	69	3% (▼4%)	14%	499 (▲30)	622 (▼6)	end December 2024	1st September 2024	A
	Innovative Medicines	1 (▼1)	2	0 (►0)	0.2	N/A	37%	19 (▼3)	7 (►0)	TBC	TBC	R
Variations	(HQ&A) Type 1b	372	421	461	695	62%	58%	543 (▲39)	9 (▼10)	31st July 2024	Within Timelines	A
	(HQ&A) Type 2	108	106	102	124	48%	55%	378(▲34)	351(▼4)	end December 2024	1st October 2024	A
	(S&S) Type 1b	28 (▼25)	42	50 (▲39)	(45)	70% (▲39%)	54%	62 (▲2)	23(▼15)	27th September 2024	1st October 2024	A
	(S&S) Type 2	89 (▲5)	93	89 (▲11)	97	81% (▲12)	79%	306 (▲28)	67 (►0)	27th September 2024	1st October 2024	A
Inspections	**Overall**	127 (▼97)	135	211 (▲60)	146	68% (▼6%)	57%	144	81 (▼3)	**end December 2024**	**TBC**	A
	GMP	62(▼9)	50	104 (▲32)	88	56	50	58	49	end December 2024		A
	GDP	65 (▼88)	85	107(▲28)	81	80	64	86	32	end December 2024		A
Scientific Advice	**Overall Advice Meetings**	**21 (▼5)**	**24**	**15 (▼1)**	**15**	**33% (▲27%)**	**22%**	**73 (▲16)**	**106 (▲2)**	**May 2025**	N/A (no statutory timelines)	R
	CT	9(▼10)	10	5(►0)	5	0% (►0%)	8%	38 (▼7)	52(▲4)	December 2024		R
	EM (Pop Health)	3 (▼1)	7	3 (▲1)	3	33%(▲33%)	0%	16 (▼7)	31 (▼4)	May 2025		R
	IM (NAS & Biols)	9(▲6)	8	7 (▼2)	6	108	58%	19(▼5)	23(▲3)	Meetings organised for all Applications		A
	ILAP	0 (►0)	1	0 (►0)	0	N/A	N/A	14 (▲14)	0 (►0)	N/A		G
Clinical Trials		71(▲2)	75	58 (▼9)	84	100% (►0%)	68%	67(▲13)	0 (►0)	N/A	Within Timelines	G

Ph1 RAG Key: Red – there is a growing backlog of items that have failed statutory/internal timelines and/or presently no mitigations in place; Amber – new items are now being cleared inside statutory/internal timelines but a backlog still exists, mitigation plan is being implemented Green – no backlog, all items are being cleared inside statutory/internal timelines

Part 1

Progress on Business Plan objectives

Medicines & Healthcare products Regulatory Agency

Progress on Business Plan objectives
1. Maintaining public trust through transparency and proactive communication

Key Action	Objective	Q1	Q2	Q3	Q4	Insight
1.1 **Embed our patient involvement strategy** and begin implementation of our strategy for strengthened safety communications.	1.1.1 Refresh **existing patient networks** to improve our communications to them by end Q3. (Christine McGuire)	G				On track. Some delays because of the pre-election period but should be on track.
	1.1.2 Ensure that **patients who contribute to regulatory and safety reviews receive feedback**, including regarding the impact of their contribution, by end Q4. (Christine McGuire)	G				On track. The project has started and the PPSE team is exploring a digital solution to record and collate feedback from teams across the Agency.
	1.1.3 Embed **greater patient involvement** across regulatory pathways by developing patient involvement in pre-authorisation work by end Q4. (Christine McGuire)	G				On track. Draft guidelines currently being considered by HQ&A.
	1.1.4 Establish new **systems to better engage** with healthcare professionals by end Q4. (Lucy Cooke)	A				At risk. Risk and safety comms strategy still to be published. We require confirmation of budget for 2024/25 to progress this, all initial scoping that can be carried out in house is near completion
	1.1.5 Launch a new design for our **risk and safety communication** products, including a newly designed monthly bulletin, by end Q4. (Lucy Cooke)	G				On track. Risk and safety comms strategy still to be published. Redesign of core materials on track and in discovery phase with testing.
1.2 **Increase accountability and predictability** by improving transparency of key information, including providing a more comprehensive overview of our core services.	1.2.1 Consolidate and **publish key performance** data by end Q4 to provide better transparency and predictability of performance. (Maham Masood)	G				On track. We are recruiting to appoint a new G7 lead for reporting and they will be taking this work forward.
	1.2.2 Publish accessible **minutes of all independent advisory** bodies and their supporting expert groups within one month of adoption by those committees, from end Q2. (Ebru Agca)	A				At risk. There are likely to be delays as the main contribution of scientific minutes are provided by the relevant team (HQA and S&S) then checked by Communications. A new process has been established to introduce immediate efficiencies, and further efforts will be made to implement this in the second or third quarter.
	1.2.3 **Publish Freedom of Information** responses within one month of replying to the original response from end Q2. (Rachel Laszlo)	A				At risk. Current publication are up to date with additional support supporting to clear the backlog, review is current in place to establish sustainable processes moving forward to ensure no backlog emerges again.
	1.2.4 Provide m**ore comprehensive information about how we regulate** and our decision-making processes by end Q3. (Lucy Cooke)	G				On track. Content development to provide more information underway, Agency showreel completed production in Q1 and will be launched in Q2.
1.3 Strengthen regulatory approaches to tackling **health inequity** across the product lifecycle.	1.3.1 Work with the HRA to develop guidance to **encourage clinical trialists to consider equality, diversity, and inclusion** in their clinical trials and clinical investigations by end Q3. (James Pound)	A				At risk. ExCo paper drafted setting out Agency wide activity and aligned approaches. Ongoing collaboration with HRA. Interdependency of guidance development with any changes to draft CT SI following consideration by new government (internal)
	1.3.2 Publish a road map towards further strengthening of regulatory approaches to tackling **health inequity** by end Q4. (Janine Jolly)	A				At risk. Plan to scope and develop cross agency approach to this from September. It is currently competing with a number of priorities, including 'Return to Green' work although the variation backlog is due to be cleared by sept.
1.4 Pilot the introduction of a **single unified Agency gateway** for customers to accelerate enquiry responses and enhance customer satisfaction.	1.4.1 Identify the types of **automated solutions** that meet our customer needs most effectively (e.g. webforms, self-service, a CRM system) by end of Q3. (Rachel Laszlo)	A				At risk. Discovery and planning to commence in Q2. Dependant on funding and cross agency collaboration. Funding decision is expected in August, after which point we can look to revisiting the RAG rating
	1.4.2 Introduce improvements to our **internal knowledge hub** to improve how we handle enquiries and introduce consistent customer service standards by end Q3. (Rachel Laszlo)	A				As above.
	1.4.3 Pilot a **single unified gateway** for patient, public and industry enquiries by end Q4. (Rachel Laszlo)	A				As above.

KEY: Red – late or not possible; Amber – minor slippage; Green – on track; Blue – Complete; Delivery Date – Edged Dark Red

Medicines & Healthcare products Regulatory Agency

Progress on Business Plan objectives
2. Enable healthcare access to safe and effective medical products

Key Action	Objective	Q1	Q2	Q3	Q4	Insight
2.1 **Improve and optimise regulatory services** via development of new risk-proportionate regulatory pathways including international recognition of other stringent regulators' decisions.	2.1.1 Optimise the **performance of our regulatory services** to operate reliable and predictable timelines, including eliminating any service objectives by end Q4. (Mick Foy)	A				The Return to Green programme has established clearance plans and dates for each priority area where performance improvements are needed and backlogs exist, this has direct oversight from ExCo. Over the next period dates for returning to compliance timeframes will be agreed and plans for service improvements will be established.
	2.1.2 **Review our IRP** to ensure the pathway is working as intended and there is ongoing adherence to statutory timelines by Q2. (Julian Beach)	G				On track, audit being conducted in July with process improvements to be implemented by August
	2.1.3 **Balance National Assessment and IRP** so that at least 50% of novel therapies are assessed via a National Assessment route. (Julian Beach)	G				On track. Discussions ongoing on strategy to find the best way to strike a balance between applications coming through via national and recognition.
	2.1.4 Deliver the 2024/25 milestones for medical devices international recognition in our roadmap of activity, working in parallel on approaches to maintain the UKCA as an attractive route for innovators. (Georgia Wain)	A				At risk. Good progress has been made to draft the updated regulations. We will now seek a steer from Ministers on next steps. (internal)
	2.1.5 Develop proposals for a **regulatory pathway for individualised Immunotherapy** with initial consultation by the end of Q3. (Julian Beach)	G				On track. Work progresses at planned
	2.1.6 Provide **individual timeframes for applicants**, encompassing all pre-submission and licensing activities by Q3. (Julian Beach)	A				At risk. This is dependent on 'Return to Green' delivering "Green" by this time and also on the delivery of RegualtoryConnect.
2.2 Deliver **innovative pathways** for access to medicines and medical devices in co-ordination with health technology and health service bodies.	2.2.1 Launch a refreshed **ILAP** to accelerate access to innovative medicines by end Q3. (Louise Knowles)	G				On track. ILAP Sponsor Board meet on 12 July 2024 and agreed plans for launch.
	2.2.2 Finalise the **IDAP** pilot, completing evaluation to determine next steps to be implemented in 25/26 by end Q4. (Anita Lim)	G				On track. Work progresses as planned.
2.3 Launch a **range of new digital tools** that improve delivery of regulatory services for all who use them.	2.3.1 Deliver second release of **RegulatoryConnect**, maximising the use of self service and notification to support optimal performance of licensing procedures for new and established medicines by end Q3. (Mick Foy)	R				This objective will slip. The delivery of RegulatoryConnect in Q3 as originally defined is now not possible. This is due to the size and complexity of the requirements requiring elaboration and through to design, build and test. The team are developing a new plan that will be presented to the Programme Board in July.
	2.3.2 Complete the delivery of **SafetyConnect** to optimise signal detection of all regulated healthcare products by end Q3. (Phil Tregunno)	G				On track. Phase 2 (medicines case management and signal detection) finished in June, with deployment of Microstrategy for business reporting. The next phase will enable use of Microstrategy for reporting on device incident, replacement of haemovigilance solutions and preparation for devices signal detection in the autumn.
	2.3.3 Deliver new **digital services to support Clinical Trials** to make processes more streamlined and efficient by end Q3. (Claire Harrison)	G				On track. Short term tactical improvements to operating systems being taken forward including improvements to the notification scheme and our ability to reporting on performance.
	2.3.4 Deliver the first milestone to secure **Police National Database accreditation** to optimise intelligence sharing with law enforcement and regulatory partners across the UK in support of our mission to protect public health by the end of Q4 (Andy Morling)	G				On track. A project manager is now formally in place and a working group involving the Home Office has been established. The working group met for the first time in June and work is progressing to schedule.
2.4 Improve our **regulatory laboratory capability and services**, especially for new vaccines, cell and gene therapies and immunotherapies.	2.4.1 Improve our **laboratory capability** in the assessment of safety and effectiveness of biologicals, including immunotherapies for conditions such as cancer and inflammatory diseases by end Q4. (Chris Burns)	G				On track. Progress across several areas: i) set up of testing capability for RSV vaccine for new immunisation campaign; ii) development of assay to measure thioredoxin levels in patient sera to determine link to resistance to anti-TNF immunotherapy; iii) development of antigenic profiling to identify epitopes on an anti-TNF monoclonal antibody associated with adverse immune responses in inflammatory bowel disease patients.
	2.4.2 Evaluate **novel reference materials** for establishment as International Standards designed to underpin diagnostic assays, with a particular emphasis on cancer genomics by end Q4. (Chris Burns)	G				On track. International collaborative studies to evaluate the suitability of 6 candidate cancer genomic reference materials have been completed and reports will be submitted to WHO Expert Committee on Biological Standardisation for consideration as WHO Standards at their meeting in October 2024.
	2.4.3 Facilitate an international workshop of **AMR** innovators and stakeholders to identify approaches to accelerate patient access to novel anti-microbial products by end Q4. (Chris Burns)	G				On track. Recruitment of staff into the posts supported by GAMRIF funding is underway. Once in post this new team will plan for the meeting to be held in November 2024.
	2.4.4 Consult on regulatory best practice for **microbiome and phage derived** medicinal products designed as novel anti-microbials by end Q3. (Chris Burns)	G				On track. Draft exploratory guidance documents have been prepared and internal review completed. An appropriate mechanism for publishing these documents for public consultation is currently being established.

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Medicines & Healthcare products Regulatory Agency

Progress on Business Plan objectives
3. Deliver scientific and regulatory excellence through strategic partnerships

Key Action	Objective	Q1	Q2	Q3	Q4	Insight
3.1 Implement our **regulatory science and data strategies**, establishing a network of Centres of Excellence in Regulatory Science and Innovation.	3.1.1 Ensure the Agency uses data optimally to support decision making, publishing our **data strategy** by end Q2 and implement 2024/25 recommendations by end Q4. (John Connelly)	G				On track. Data Strategy will be presented to Board on 9 July.
	3.1.2 Grow the Agency's reputation for scientific excellence by publishing our **science strategy** by end Q3 and implement 2024/25 recommendations by end Q4. (Nicola Rose?)	G				On track. The science strategy is due at Board in October.
	3.1.3 To help ensure our regulatory decisions reflect the best possible science and to create a UK network of **CERSIs** across successful areas by end Q4 (organised through an Innovate UK competition).	G				On track. It has been organised through a 2-phase Innovate UK competition. Candidates are due to send their final submission on 1 September 2024 and successful applicants will be notified at the end of that month.
3.2 Improve and update our **UK regulatory frameworks** in line with evolving science and technology, to streamline our processes and remove unnecessary burdens.	3.2.1 Prepare legislation to deliver a new and risk-proportionate UK **clinical trials regulatory framework**, lay legislation in Q2. And publish updated guidance from October 2024. (Catherine Lenihan)	A				At risk. Legislation to reform the UK CT legislation was on track to be laid June 2024 prior to the general election. We will now seek a steer from Ministers on next steps (internal)
	3.2.2 Deliver a regulatory framework for **point-of-care manufacture** of personalised medicines, supporting the introduction of these new therapies, by end Q4. (Catherine Lenihan)	A				At risk. Legislation to introduce the new framework was on track to be laid July 2024 prior to the general election. We will now seek a steer from Ministers on next steps (internal)
	3.2.3 Progress delivery of an overhauled **regulatory framework for medical devices** in line with the 2024/25 milestones in our roadmap. (Georgia Wain)	R				The election has impacted all milestones and, until the new Government has taken decisions on the way forward, there is no certainty the milestones of the project plan will remain, nor can it be estimated when they will fall. The priorities of new Ministers need to be understood before replanning can take place, which may result in an improvement of the Red status. (internal)
	3.2.4 Supporting access to medicines in Northern Ireland on the same basis as the rest of the UK by implementing the medicines elements of the **Windsor Framework**, by 1 January 2025. (Catherine Lenihan)	G				On track. Work continues updating gov.uk guidance to reflect WF implementation. Working with DHSC, legal drafting to implement WF within HMR is near complete and (internal) due to be laid in Parliament in July.
	3.2.5 Consult on proposals for a regulatory **framework for biotherapeutics and personalised immunotherapies** by end Q4. (Julian Beach)	G				On track.
3.3 Strengthen our **pandemic and escalating infectious disease programme,** contributing to the UK's pandemic preparedness.	3.3.1 To underpin **vaccine development for priority pathogens** and assure the performance of diagnostic tests, develop and distribute novel reference materials in collaboration with our partners including by end Q4. (Marie Donatantonio?)	G				On track. International studies for antibody standards for Marburg virus and SARS-CoV-1 completed in Q1. We aim to establish these standards by end of Q4. A grant agreement has been signed with the UK Vaccine Network (UKVN) to establish the Centre for Infectious Diseases reagents. This initiative, supported by UKVN for the next 4 years, will be built as an expansion of the current research reagent repository at the Science Campus and covers new emerging viral pathogens to increase pandemic and epidemic preparedness.
	3.3.2 Develop, calibrate and distribute critical biological materials through our WHO Essential Regulatory Laboratory for Influenza to support **influenza pandemic readiness** by end Q4. (Marie Donatantonio?)	G				On track. One pandemic relevant antigen has been added to the catalogue in Q1 (H5N8 antigen)
	3.3.3 Conduct regulatory research to establish **immune correlates of protection** for, or markers associated with, 4 escalating diseases that support priority pathogen vaccine development and are calibrated WHO International Standards by end Q4. (Marie Donatantonio?)	G				On track. We are leading a collaboration with scientists at UKHSA and Dstl, Porton Down, where models of escalating diseases are being established. WHO International standards that calibrate serological responses against 4 escalating diseases (Marburg, Nipah, Q Fever and Plague) are being supplied to our partners, who will determine the ability of these standards to protect against infection in Q3 and Q4. Two applications have been submitted in response to the Wellcome Trust/CEPI call on Nipah virus and for filoviruses.
3.4 Strengthen our **strategic partnerships**, in the UK and internationally, to help us deliver our priorities.	3.4.1 Progress **system alignment with our partners across the UK** health family – including HTA and NHS partners across the DAs – enabling technical information to be more routinely shared by end Q4. (Harriet Teare)	G				On track. Information sharing continues, with companies consenting for info to be shared with UK health family partners. Initiative has expanded to include technical information, with several companies consented for specific products of interest.
	3.4.2 Develop operations and a new strategic plan with the **Access Consortium** by end Q4 to maximise international co-operation and make consortium members regulators of choice. (Lisa Fraser)	G				On track. It was discussed at the last Head of Agencies meetings in San Diego in June 2024
	3.4.3 Make a leading contribution to **global regulatory best practice** and harmonisation through the ICMRA, the International Medical Devices Regulators Forum, and the ICH, by end Q4. (Lisa Fraser)	G				On track. We are continuing to engage with each partner to ensure cooperation and harmonisation.

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Medicines & Healthcare products Regulatory Agency

Progress on Business Plan objectives

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

Key Action	Objective	Q1	Q2	Q3	Q4	Insight
4.1 Ensure that we recruit and develop people with the **right skills and capability** to deliver our current and future plans.	4.1.1 Review our external **recruitment and internal promotions** processes to ensure that we develop the workforce needed to deliver current and future business plans by end Q3. (Kerry McEyeson?)	G				On track. Oracle Recruit is currently being implemented alongside a review of our recruitment processes to enhance the experience of all parties. LinkedIN Recruiter also being implemented alongside an employer brand to ensure we can reach the talent needed.
	4.1.2 Implement a new **talent management plan**, ensuring staff understand the support available to enable them to achieve their career goals, by end Q4. (Malgosia Malach)	G				On track. Paper outlining an approach for conducting talent assessments currently with ExCo secretariat for tabling.This is the first step in the new talent management plan.
	4.1.3 Develop **MHRA managers** to support staff development through, setting challenging objectives, giving effective feedback, coaching, mentoring and identifying development opportunities by end Q4. (Malgosia Malach)	G				On track. Civil Service Line Management standards launched in June - will be helpful in landing the supporting interventions to build line management capability across agency.
	4.1.4. Embed our commitment to **diversity and inclusion** in talent acquisition and staff development by end Q4. (Kerry McEyeson?)	G				On track. Employer branding work underway which will incorporate this
4.2 Promote **staff wellbeing** and help staff manage their workloads effectively, including through clarity on targets and with right-sized teams.	4.2.1 Launch an **annual recognition scheme** to celebrate outstanding achievements by end Q3. (Kerry McEyeson)	R				This objective is expected to slip. Due to a desire to keep costs down, the decision was taken to combine the launch with an existing staff event. There is nothing suitable planned for Q3 and so this is now expected to slip into Q4. We propose the delivery date is updated to reflect this for the next quarter.
	4.2.2 Launch a new **wellbeing survey** to better monitor wellbeing concerns and implement new wellbeing tools in response to feedback by end Q2. (Kerry McEyeson?)	G				On track. Survey launched in May 24 and new counsellor appointed also in May to support the current wellbeing support open to staff.
	4.2.3 Focus on **process efficiency and productivity improvements** in the context of agreed workload predictions, prior to decision-making about rightsizing teams (ongoing and likely to last into 25/26). (Hannah Ufland)	A				At risk. Through the 'Return to Green' programme, we have put in place interventions to remove current backlogs, alongside this we are identifying and implementing process changes (which address the root cause of performance issues) so we may deliver sustainable services with significantly improved response times. We have put in place clear monitoring process to track the predicted reduction of backlogs and these are regularly monitored to ensure that progress maintains pace with our predictions.
	4.2.4 Promote **open dialogue about productivity, work processes and priorities** to enable managers to make improvements in work life balance for all colleagues by end Q4. (Sarah Read)	G				On track. Through People Business Partners working with their SMTs
4.3 Deliver a **responsive service culture**, with robust and risk-proportionate decision-making, and achieve an improved internal control environment.	4.3.1 Develop an agency wide view of **culture that combines a high performance and a focus on wellbeing** by end Q2, and pilot use of a culture barometer by Q3. (Malgosia Malach)	G				On track. Culture survey launched in June 2024 to support the culture barometer
	4.3.2 Ensure all our managers are promoting and **supporting risk-proportionate decision-making** in all areas of activity (ongoing and likely to last into 25/26). (Sarah Read)	G				On track. Through People Business Partners working with their SMTs
	4.3.3 Ensure all staff have **meaningful objectives that focus on productivity and wellbeing** by end Q4. (Sarah Read)	G				On track. Regular topic at SMTs via HRBPs
	4.3.4 Deliver an **improved control environment** to safeguard our critical public health outcomes by end Q4. (Sarah Gilbert?)	G				On track. We are establishing a Route to Moderate plan for moving the agency out of Limited assurance (GIAA rating for 3 years in a row). The plan focusses on improving the control environment through assurance mapping, aligned action plans (functional standards, GIAA audit management actions and assurance mapping actions) and delivery of Digital and Change workstreams. R2M is set to deliver improvements to the control environment by Jan 2025 and will be aligned with RtG.
4.4 Review and update our **service and product fees** so the Agency continues to be financially sustainable.	4.4.1 To ensure our costs continue to be covered, launch public consultation on our fees in Q2 and deliver a **fees adjustment** by the first quarter of 2025/26. (Maham Masood)	G				On track. We are getting ready to seek clearance to publish the consultation. There has been a slight delay due to the GE but we have updated our timing plan and it is still possible to deliver on time. [internal]

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Part 2

Operational performance KPIs

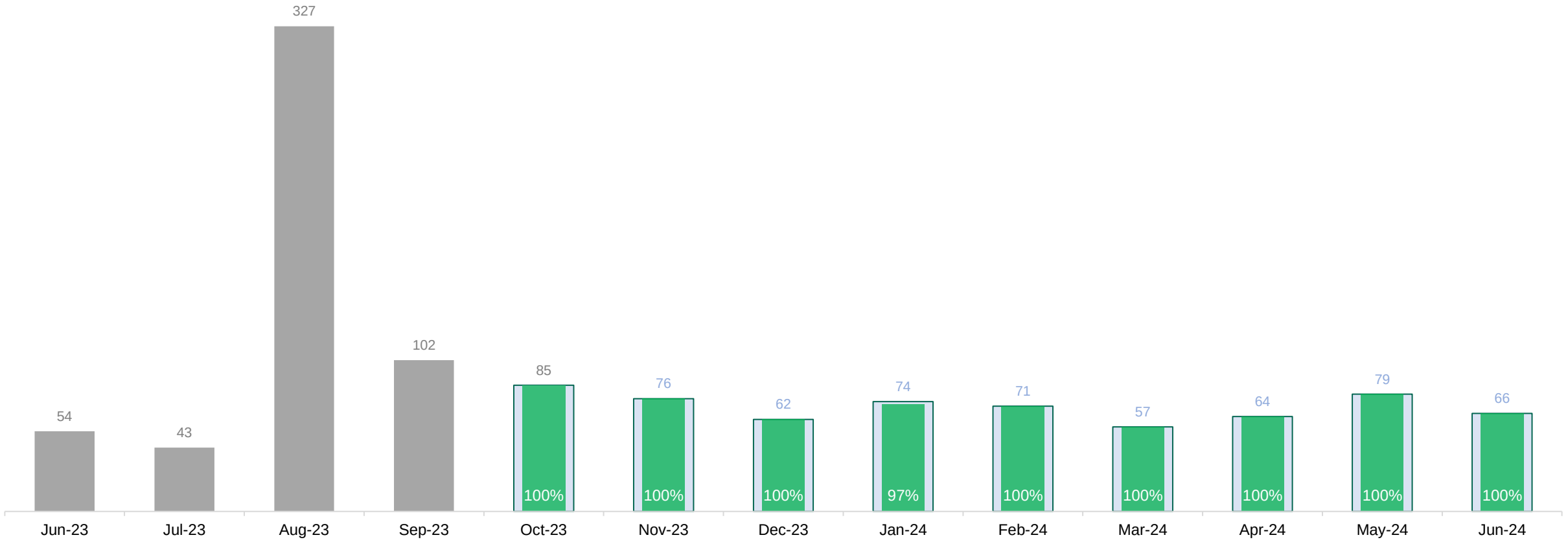
Medicines & Healthcare products Regulatory Agency

Operational Performance KPIs
Clinical Trials and Investigations

KPI 1: We will assess 95% of all initial Clinical Trial Authorisation (CTA) and Clinical Investigation applications within their category's statutory timeline.

Jun 24: 100% (►0%)

On Target



	Jun 23	Jul 23	Aug 23	Sep 23	Oct 23	Nov 23	Dec 23	Jan 24	Feb 24	Mar 24	Apr 24	May 24	Jun 24
Assessed (total)	54	43	327	102	85	76	62	74	71	57	64	79	66
Assessed (on time)					85	76	62	72	71	57	64	79	66

Medicines & Healthcare products Regulatory Agency

Operational Performance KPIs
Clinical Trials

Output

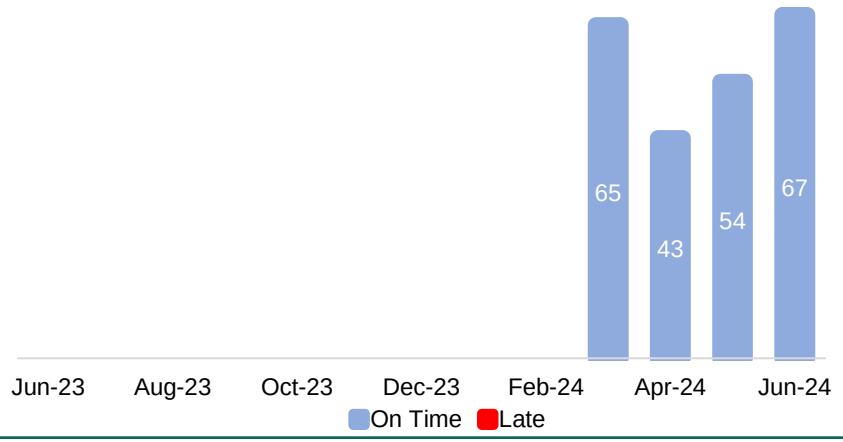
Clinical Trial Authorisation (CTA) applications assessed in and outside of statutory timeframes.

Target: "We will assess 95% of all initial Clinical Trial Authorisation (CTA) applications within their category's statutory timeline".

	Jun 23	Jul 23	Aug 23	Sep 23	Oct 23	Nov 23	Dec 23	Jan 24	Feb 24	Mar 24	Apr 24	May 24	Jun 24
CTA Applications (Assessed on time)	2	0	4	11	76	70	60	69	67	48	57	67	58
CTA Applications (Assessed late)	44	38	316	82	0	0	0	2	0	0	0	0	0
% Completed on Time	4%	0%	1%	12%	100%	100%	100%	97%	100%	100%	100%	100%	100%

Volume

Current volume of CTA applications that are unassessed, split into those that are younger and older than the statutory timeframes.



Turnaround Times

Current time taken to assess a CTA application or amendment.

Description	Target	Jun 24 Actual
Average time of assessment of a Clinical Trial **application**.	**30** days	**28 (▼1) On Target**
Average time of assessment of a Clinical Trial **amendment**.	**35** days	**31 (▲1) On Target**

Insight

Key Performance Indicator
100% of Clinical Trial Authorisation applications were processed within statutory timeframes in June.

Volume
We continue to see a healthy volume of 'on time' Clinical Trial Authorisation applications.

Misc.
Clinical Trial Initial Applications have a 30-calendar day statutory timeframe to issue an outcome from the Application Received Effective Date (Day 0).

The 'output' data from October 2023 onwards, represents the number of Initial clinical trial authorisation (CTA) applications received from 1st September 2023 onwards, assessed in that month.

Volume data represent the number of pending applications received in that month currently under assessment at the time when the data was extracted. The 'live apps' is a constant variable as applications are received and assessed live.

Medicines & Healthcare products Regulatory Agency

Operational Performance KPIs
Clinical Investigations

Output

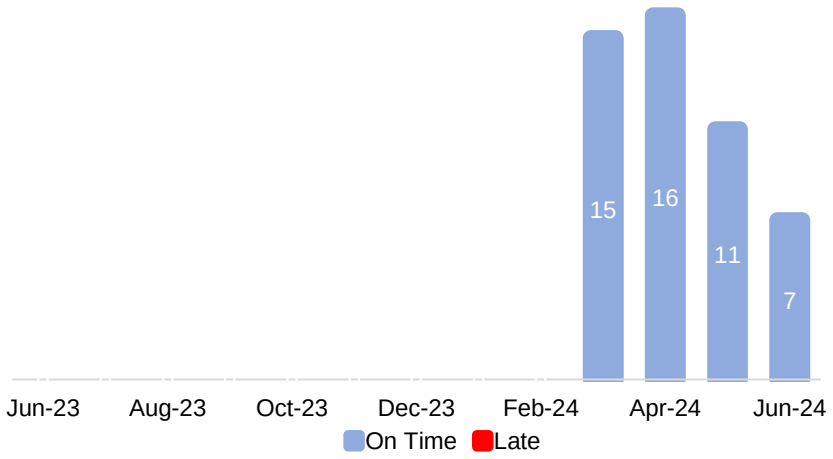
Clinical Investigation applications assessed in and outside of statutory timeframes.

Target: "We will assess 95% of all Clinical Investigation applications within their category's statutory timeline".

	Jun 23	Jul 23	Aug 23	Sep 23	Oct 23	Nov 23	Dec 23	Jan 24	Feb 24	Mar 24	Apr 24	May 24	Jun 24
Clinical Investigations (Assessed on time)	8	5	7	9	9	6	2	3	4	9	7	12	8
Clinical Investigations (Assessed late)	0	0	0	0	0	0	0	0	0	0	0	0	0
% Completed on Time	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%

Volume

Current volume of Clinical Investigation applications that are unassessed, split into those that are younger and older than the statutory timeframes.



Turnaround Times

Current time taken to assess a Clinical Investigation application.

Description	Target	Jun 24 Actual
Average time of assessment of a Clinical Investigation **application**.	**60** days	**50 (▲1) On Target**
Average time of assessment of a Clinical Investigation **amendment**.	**21** days	**10 (▲8) On Target**

Insight

Key Performance Indicator

100% of Clinical Investigation applications were processed within statutory timeframes in June.

Volume

We continue to see a healthy volume of 'on time' investigation applications.

Misc.

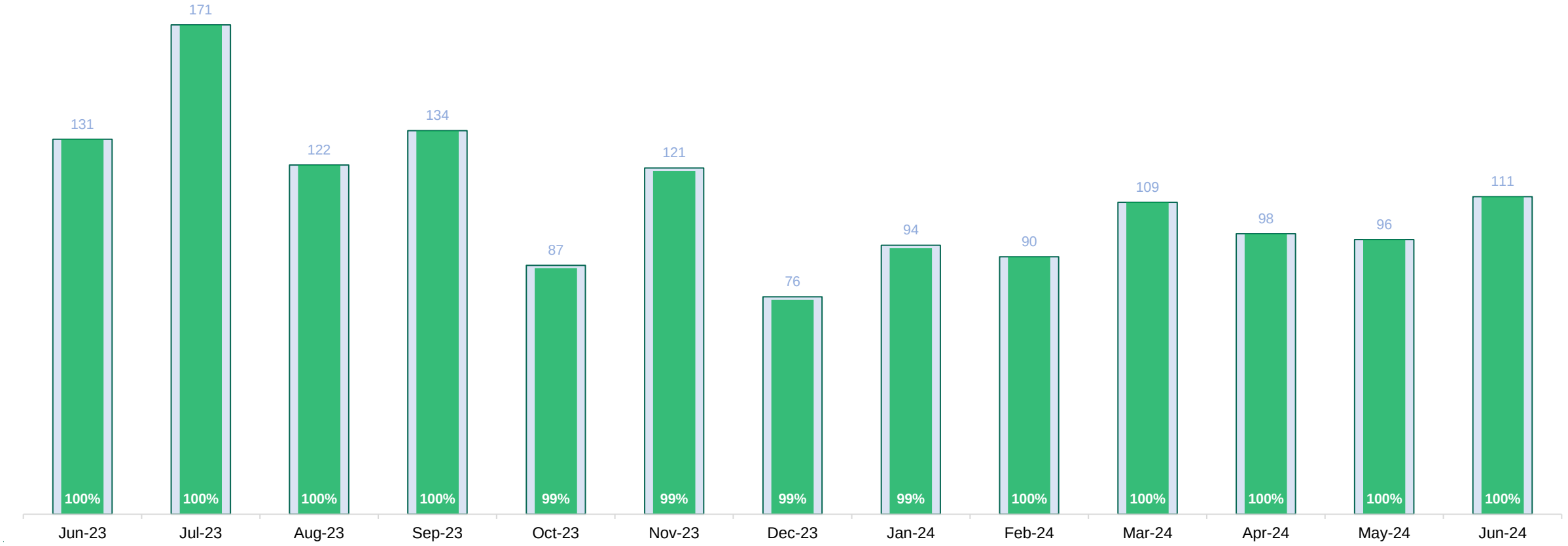
Regulatory timelines are as follows, 60 calendar days for GB studies. For NI studies we have 45 days plus 3 clock stops of 7 days each where we may seek expert advice giving a maximum review period of 66 days. Note, the 'Intake' only refers to applications received and deemed valid as some may be rejected at the point of internal validation. The review period (60 or 45 days) begins the first day after the submission of a valid application.

Operational Performance KPIs
Control Testing

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

Jun 24: 100% (►0%)

On Target



	Jun 23	Jul 23	Aug 23	Sep 23	Oct 23	Nov 23	Dec 23	Jan 24	Feb 24	Mar 24	Apr 24	May 24	Jun 24
Certified (total)	131	171	122	134	87	121	76	94	90	109	98	96	111
Certified (on time)	131	171	122	134	86	120	75	93	90	109	98	96	111

Medicines & Healthcare products Regulatory Agency

Operational Performance KPIs
Control Testing

Output

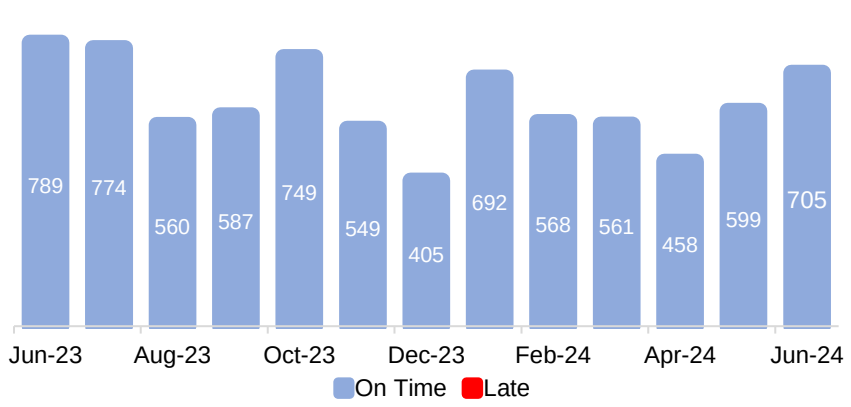
Vaccine and blood product batches certified in and outside of statutory timeframes.

Target: "We will certify 95% of vaccine batches within 43 days and 99% of blood product batches within 15 days of submission".

	Jun 23	Jul 23	Aug 23	Sep 23	Oct 23	Nov 23	Dec 23	Jan 24	Feb 24	Mar 24	Apr 24	May 24	Jun 24
n-COVID Vaccine (on time)	65	108	59	56	32	44	19	28	22	45	28	33	54
n-COVID Vaccine (late)	0	0	0	0	0	0	0	0	0	0	0	0	0
% Completed on Time	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
COVID Vaccine (on time)	1	0	0	22	2	12	2	0	1	0	1	0	0
COVID Vaccine (late)	0	0	0	0	0	0	0	0	0	0	0	0	0
% Completed on Time	100%	N/A	N/A	100%	100%	100%	100%	N/A	100%	N/A	100%	N/A	N/A
Blood Products (on time)	65	63	63	56	52	64	54	65	67	64	69	63	57
Blood Products (late)	0	0	0	0	1	1	1	1	0	0	0	0	0
% Completed on Time	100%	100%	100%	100%	98%	98%	98%	98%	100%	100%	100%	100%	100%

Volume

Number of components submitted for assessment.



Turnaround Times

Current time taken to certify vaccine and blood product batches.

Description	Target	Jun 24 Actual
Average time to certify a **non-COVID vaccine** batch	**43** days	**5 (►0) On Target**
Average time to certify a **COVID vaccine** batch	**43** days	**0 (►0) Target N/A**
Average time to certify a **blood product** batch	**15** days	**6 (►0) On Target**

Insight

Key Performance Indicator

For the fifth consecutive month this year, 100% of batches were certified within our statutory timeframes.

Output

We have seen the expected seasonal increase of influenza vaccine batches for the 2024/25 immunisation campaign.

Volume

We received more sample and document submissions than in previous months with none of them awaiting assessment outside of statutory timeframes.

Turnaround Times

We continue to certify all vaccine and blood product batches well within statutory timeframes

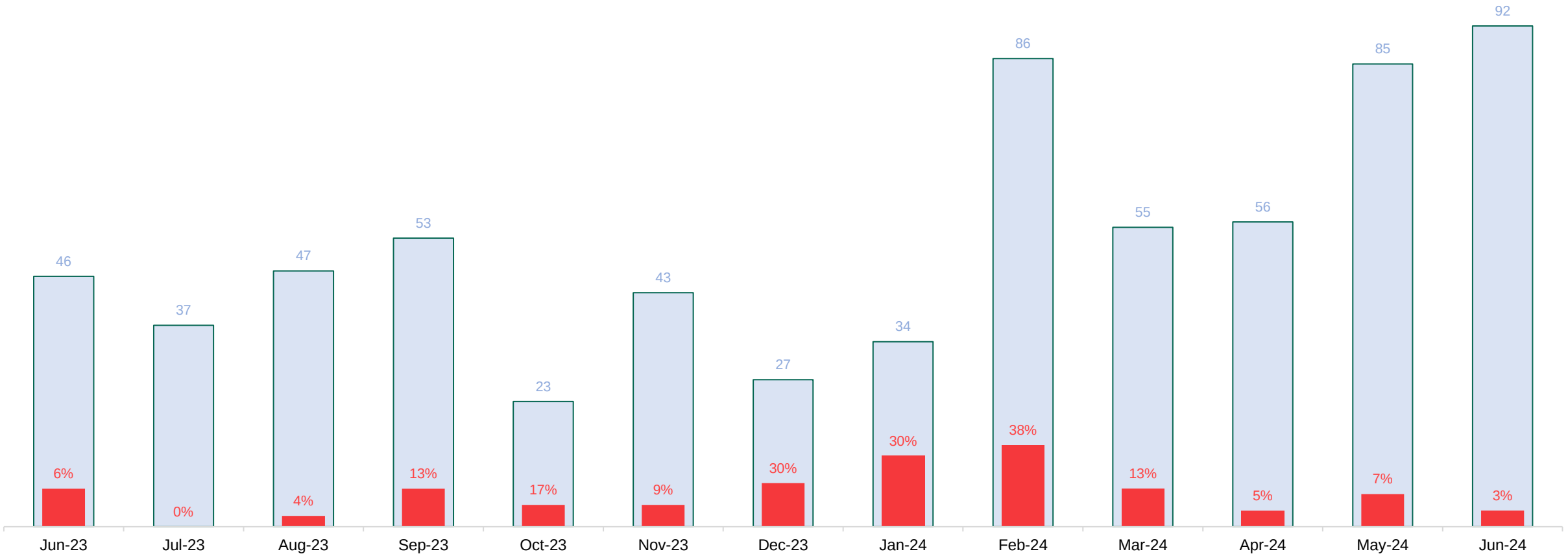
Medicines & Healthcare products Regulatory Agency

Operational Performance KPIs
Medicine Licensing via the National Route

KPI 3: We will determine 95% of medicines license applications within 210 days via the national route.

Jun 24: 3% (▼4%)

Off Target



	Jun 23	Jul 23	Aug 23	Sep 23	Oct 23	Nov 23	Dec 23	Jan 24	Feb 24	Mar 24	Apr 24	May 24	Jun 24
Determined (total)	46	37	47	53	23	43	27	34	86	55	56	85	91
Determined (on time)	7	0	2	7	4	4	8	13	15	7	3	6	3

Medicines & Healthcare products Regulatory Agency

Operational Performance KPIs
Medicine Licensing via the National Route

Output

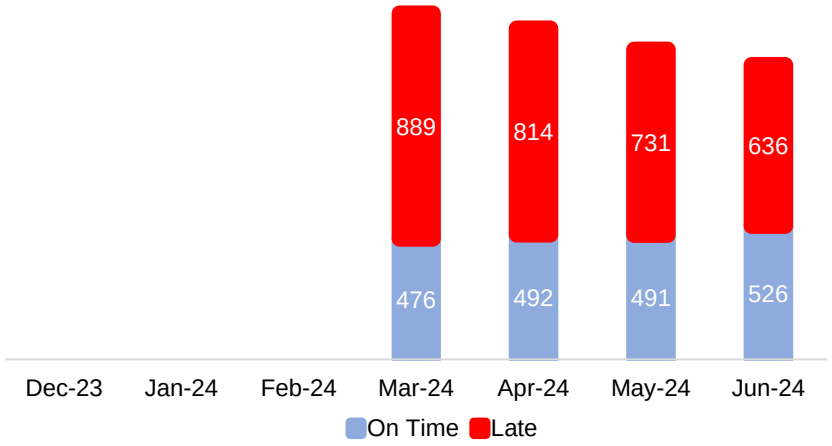
New Active Substances (NAS) and Established Medicines medicine license applications determined via the National route, in and outside of statutory timeframes.

Target: "We will determine 95% of medicines license applications within 210 days via the national route".

	Jun 23	Jul 23	Aug 23	Sep 23	Oct 23	Nov 23	Dec 23	Jan 24	Feb 24	Mar 24	Apr 24	May 24	Jun 24
New Active Substances (Determined on time)	0	0	0	0	1	1	1	0	0	0	0	0	0
New Active Substances (Determined late)	0	0	2	0	2	1	0	0	0	0	0	0	0
% Completed on Time	N/A	N/A	0%	N/A	33%	50%	100%	N/A	N/A	N/A	N/A	N/A	N/A
Established Medicines (Determined on time)	7	0	2	7	3	3	7	13	15	7	3	6	3
Established Medicines (Determined late)	39	37	43	46	17	38	19	21	71	48	53	79	88
% Completed on Time	15%	0%	4%	13%	15%	7%	27%	38%	17%	13%	5%	7%	3%

Volume

Undetermined NAS and Established Medicines medicine license applications via the National route, split into those that are younger and older than the statutory timeframes.



Turnaround Times

Current time taken to determine NAS and Established Medicines license applications via the National route.

Description	Target	Jun 24 Actual
Average time to determine a medicine license application via the National route that **contains a New Active Substance**.	**210** days	**0 (►0) Target N/A**
Average time to determine a medicine license application via the National route that contains an **Established Medicine**.	**210** days	**563 (▲29) Off Target**

Insight

Key Performance Indicator

We continue to see a low scoring of our KPI for medicine license applications as work continues to clear the existing backlog of applications. In order to better illustrate this effort, we have now included an update on progress on clearing the backlog at Annex A.

Volume

There remains a backlog of 636 NAS and Established Medicine applications that are older than our statutory timeframes. This metric shows a sustained decline of backlog.

Turnaround Times

No NAS applications have been completed since Jan 24, so no turnaround times have been provided. This reflects resourcing issues (vacancies and knock-on effects of redeployment). Focus has been put on recruitment, reducing time to allocation and ensuring that timetables for applications received from now on are strictly adhered to, to restore compliance with statutory timelines at the earliest point.

Established medicines remain well over our statutory timeframe of 210 days via the National Route. Over the coming months we expect to see further reductions in average turnaround times, reflecting the positive impact of the introduction of initiatives and process changes. From 1 September, new EM applications will be processed within 210-day statutory timelines, and we will aim to eliminate overall backlogs by end December.

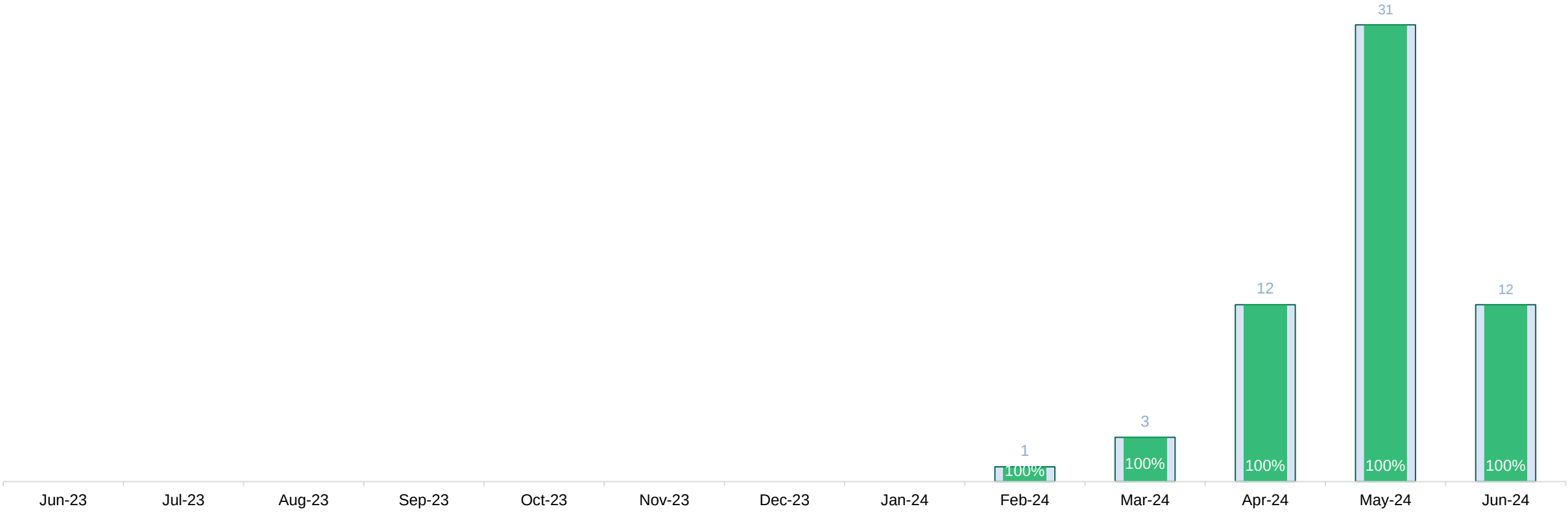
Medicines & Healthcare products Regulatory Agency

Operational Performance KPIs
Medicine Licensing via the International Recognition Procedure

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

Jun 24: 100% (►0%)

On Target



	Jun 23	Jul 23	Aug 23	Sep 23	Oct 23	Nov 23	Dec 23	Jan 24	Feb 24	Mar 24	Apr 24	May 24	Jun 24
Determined (total)	0	0	0	0	0	0	0	0	1	3	12	31	12
Determined (on time)	0	0	0	0	0	0	0	0	1	3	12	31	12

Medicines & Healthcare products Regulatory Agency

Operational Performance KPIs
Medicine Licensing via the International Recognition Procedure

Output

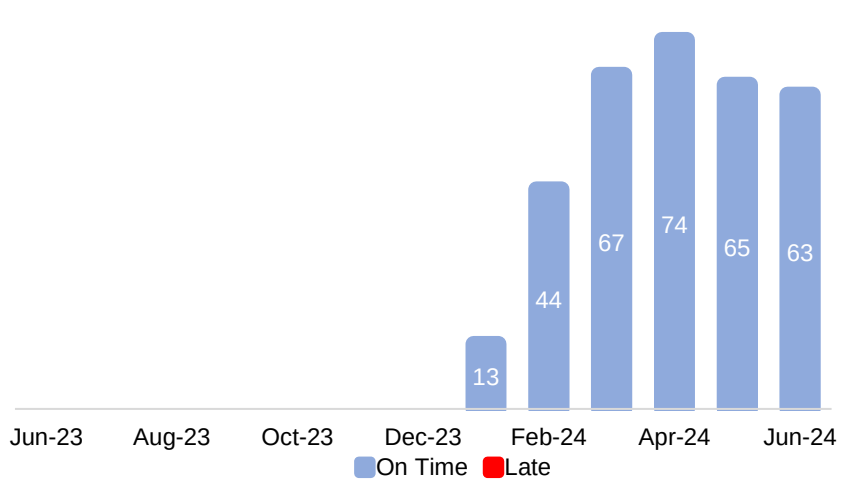
New Active Substances (NAS) and Established Medicines medicine license applications determined via the International Recognition Procedure (IRP) in and outside of statutory timeframes.

Target: "We will determine 95% of medicines license applications within 60 days via recognition Route A and within 110 days via Route B".

	Jun 23	Jul 23	Aug 23	Sep 23	Oct 23	Nov 23	Dec 23	Jan 24	Feb 24	Mar 24	Apr 24	May 24	Jun 24
Via Route A (Determined on time)	0	0	0	0	0	0	0	0	1	3	12	29	11
Via Route A (Determined late)	0	0	0	0	0	0	0	0	0	0	0	0	0
% Completed on Time	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	100%	100%	100%	100%	100%
Via Route B (Determined on time)	0	0	0	0	0	0	0	0	0	0	0	2	1
Via Route B (Determined late)	0	0	0	0	0	0	0	0	0	0	0	0	0
% Completed on Time	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	100%	100%

Volume

Undetermined NAS and Established Medicines medicine license applications via the IRP, split into those that are younger and older than the statutory timeframes.



Turnaround Times

Current time taken to determine NAS and Established Medicines license applications via the IRP.

Description	Target	Jun 24 Actual
Average time to determine a medicine license application via the International Recognition Procedure's **Route A**.	**60** days	**56 (►0) On Target**
Average time to determine a medicine license application via the International Recognition Procedure's **Route B**.	**110** days	**28 (▼45) On Target**

Insight

Key Performance Indicator

100% of medicine licenses via our new International Recognition procedure have been determined on time since the new route opened in January.

Volume

All medicine license applications awaiting determination via the IRP are inside statutory timeframes.

Turnaround Times

The average time to determine a medicine licence via Route A in the IRP is currently at 56 days, this is 4 days below our statutory target of 60 days.

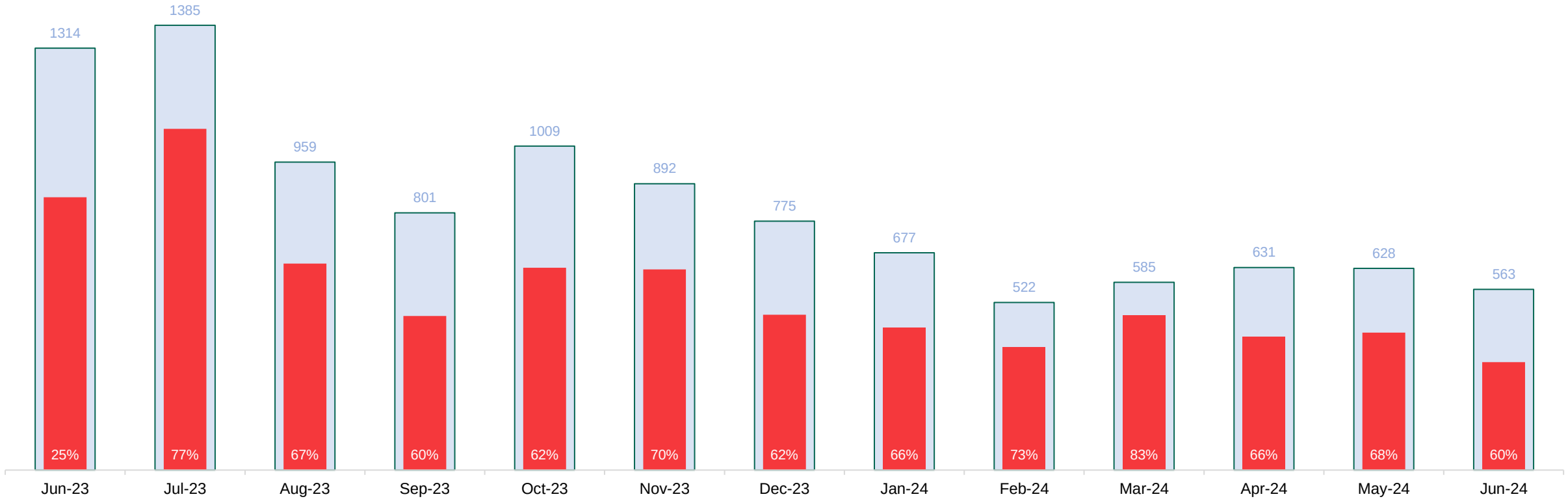
The average time to determine a medicine license via Route B in the IRP is currently at 28 days, this was an increase of 73 days solely because May was the first month we determined a medicine license via Route B.

Operational Performance KPIs
National Variations

KPI 5: We will assess 95% of all national variations within their category's statutory timeline.

Jun 24: 60% (▼8%)

Off Target



	Jun 23	Jul 23	Aug 23	Sep 23	Oct 23	Nov 23	Dec 23	Jan 24	Feb 24	Mar 24	Apr 24	May 24	Jun 24
Assessed (total)	1,314	1,385	959	801	1,009	892	775	677	522	585	631	628	563
Assessed (on time)	850	1,063	643	480	630	625	484	444	382	483	415	428	336

Medicines & Healthcare products Regulatory Agency

Operational Performance KPIs
National Variations

Output

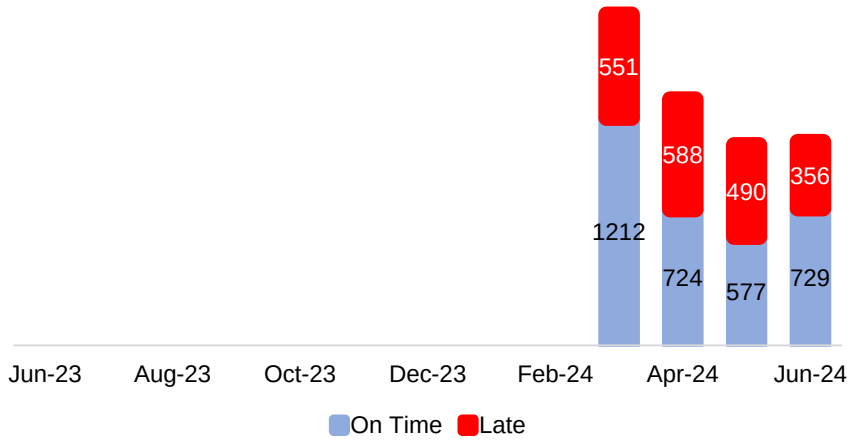
National Variations determined in and outside of statutory timeframes.

Target: "We will determine 95% of all national variations within their category's statutory timeline".

	Jun 23	Jul 23	Aug 23	Sep 23	Oct 23	Nov 23	Dec 23	Jan 24	Feb 24	Mar 24	Apr 24	May 24	Jun 24
Type 1b Variations (Assessed on time)	771	987	584	406	538	552	439	348	314	391	335	370	287
Type 1b Variations (Assessed late)	381	275	289	243	276	185	229	178	96	72	186	142	174
% Completed on Time	67%	78%	67%	63%	66%	75%	66%	66%	77%	84%	64%	72%	62%
Type 2 Variations (Assessed on time)	79	76	59	74	92	73	45	96	68	92	80	58	49
Type 2 Variations (Assessed late)	83	47	27	78	103	82	62	55	44	30	30	58	53
% Completed on Time	49%	62%	69%	49%	47%	47%	42%	64%	61%	75%	73%	50%	48%

Volume

Undertermined National Variations that are younger and older than the statutory timeframes.



Turnaround Times

Current time taken to assess National Variations.

Description	Target	Jun 24 Actual
Average time to determine **Type 1b** National Variations.	**30** days	**45 (▲5) Off Target**
Average time to determine **Type 2** National Variations.	**90** days	**129 (▼5) Off Target**

Insight

Key Performance Indicator

60% of National Variations were assessed on time in June. Performance was negative from May (-8%).

Output

We continue to see national variations being determined late, this is due to the backlog of variations that are currently being tackled via the 'Return to Green' programme, described in more detail in Annex A.

Turnaround Times

On average in June, we processed Type 1b National Variations in 45 days, this was 15 days slower than our statutory timeframe.

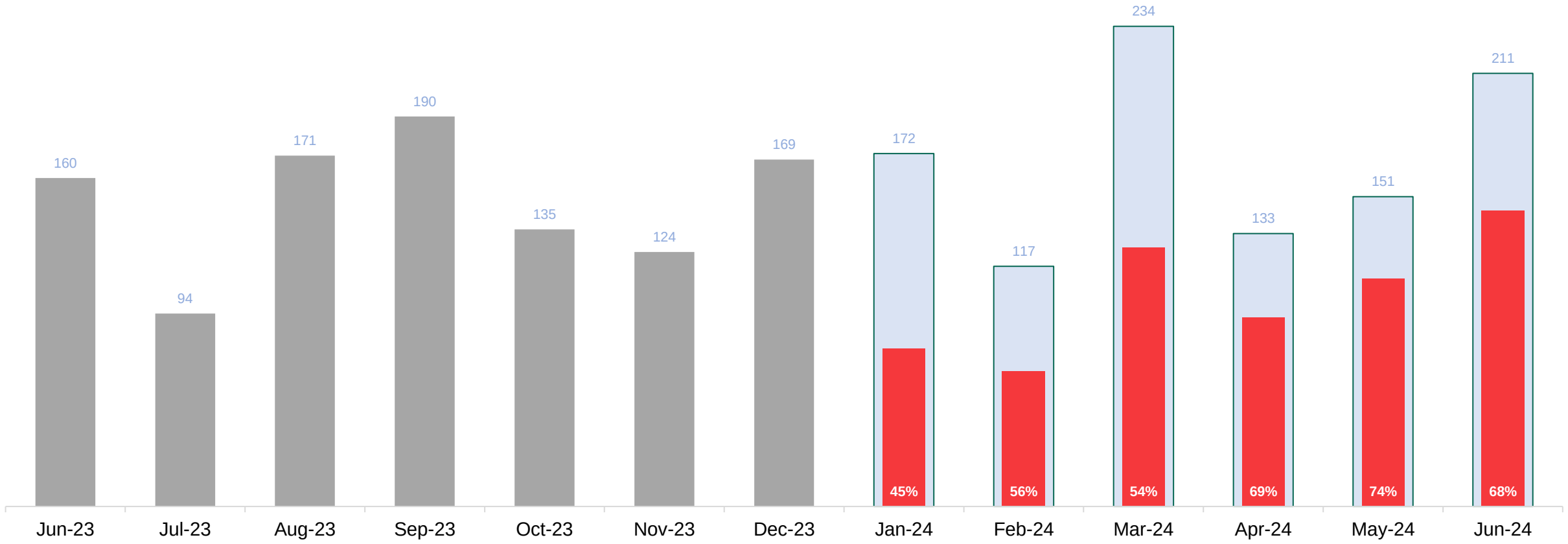
Type 2 National Variation average in June worsened by 39 days and remains outside the statutory timeframe of 90 days.

Operational Performance KPIs
Manufacturing and Distribution Authorisations

KPI 6: We will grant, vary or refuse 95% of manufacturing and distribution authorisations within their category's statutory timeline.

Jun 24: 68% (▼5%)

Off Target



	Jun 23	Jul 23	Aug 23	Sep 23	Oct 23	Nov 23	Dec 23	Jan 24	Feb 24	Mar 24	Apr 24	May 24	Jun 24
Authorisations (total)	160	94	171	190	135	124	169	172	117	234	133	151	211
Authorisations (on time)							51	77	66	126	92	111	144

Medicines & Healthcare products Regulatory Agency

Operational Performance KPIs
Manufacturing and Distribution Authorisations

Output

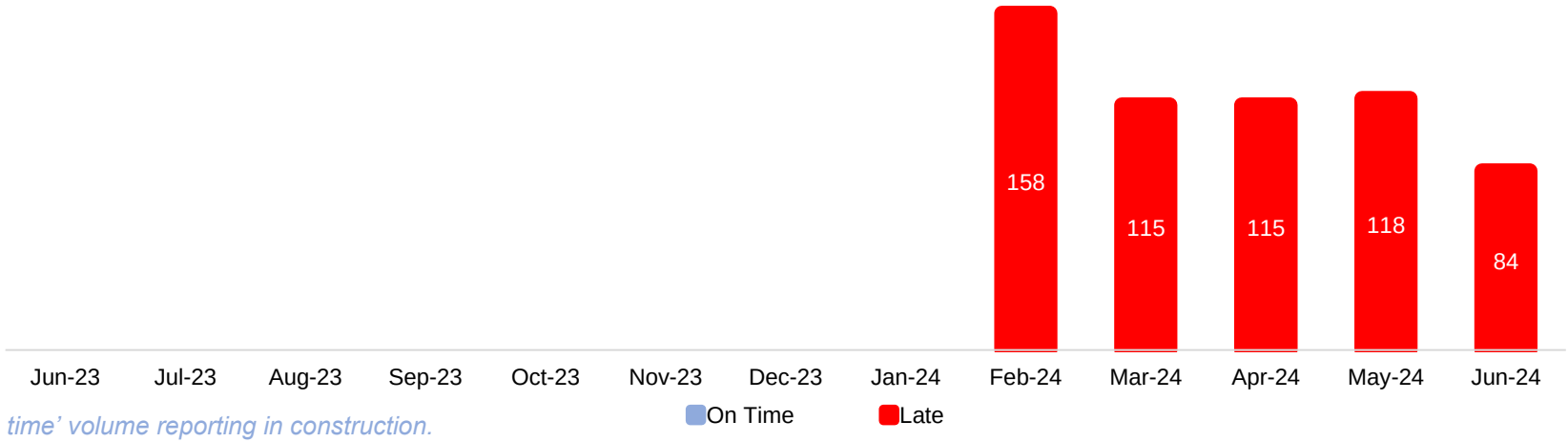
Wholesale Dealer and Manufacturing Licenses granted, varied or refused in and outside of statutory timeframes.

Target: "We will grant, vary or refuse 95% of manufacturing and distribution authorisations within their category's statutory timeline".

	Jun 23	Jul 23	Aug 23	Sep 23	Oct 23	Nov 23	Dec 23	Jan 24	Feb 24	Mar 24	Apr 24	May 24	Jun 24
Via Route A (Determined on time)	160	94	171	190	135	124	29	44	42	54	56	58	86
Via Route A (Determined late)							40	41	25	28	24	21	21
% Completed on Time							42%	52%	63%	66%	70%	73%	80%
Via Route B (Determined on time)							22	33	24	72	36	53	58
Via Route B (Determined late)							78	54	26	80	17	19	46
% Completed on Time							22%	38%	48%	47%	68%	74%	56%

Volume

Sites awaiting triage, assessment or inspection.



'On time' volume reporting in construction.

Insight

Key Performance Indicator

80% of Manufacturing and Distribution Authorisations were granted, varied or refused within our statutory timeframes in June. The proportion of authorisations granted within statutory timelines has doubled since December 2024.

Volume

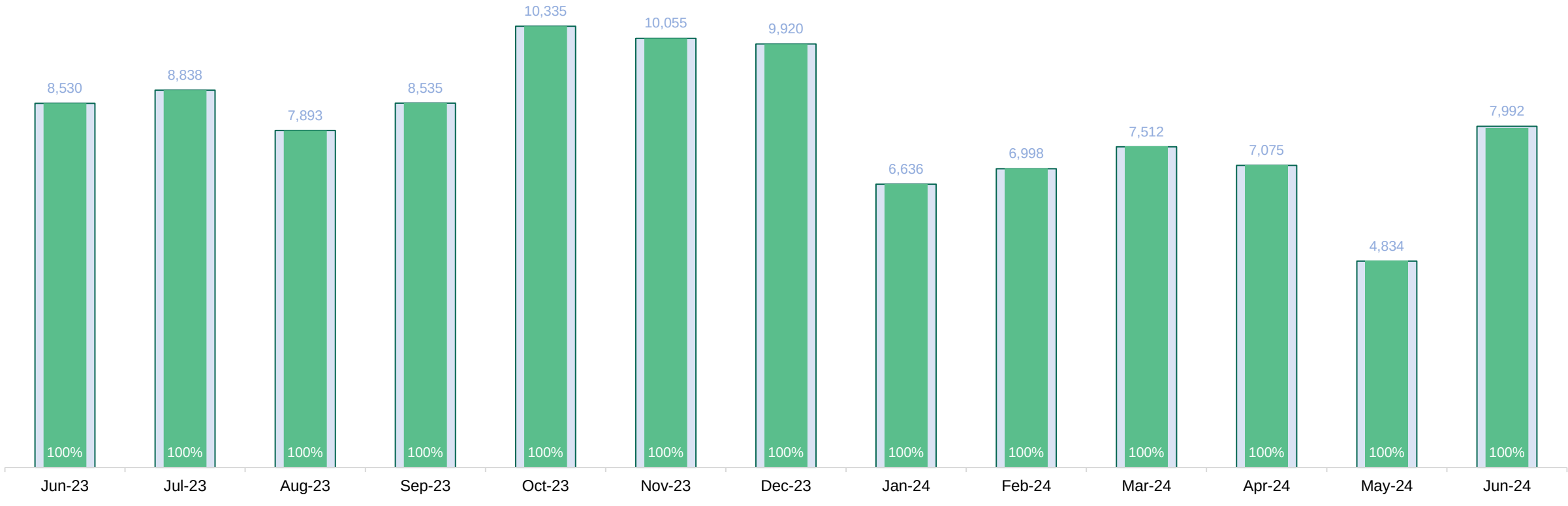
The number outside statutory is 84 at various stages. More detail on progress clearing our backlog of inspections can be found at Annex A.

Operational Performance KPIs
Patient Safety Monitoring

KPI 7: (Interim KPI) We will process 90% of Fatal Adverse Drug Reaction (ADR) reports for medicines within 24 hours,100% within 72 hours and we will process 95% of serious ADR reports for medicines within 72 hours and 100% within 5 days.

Jun 24: 100% (▼0%)

On Target



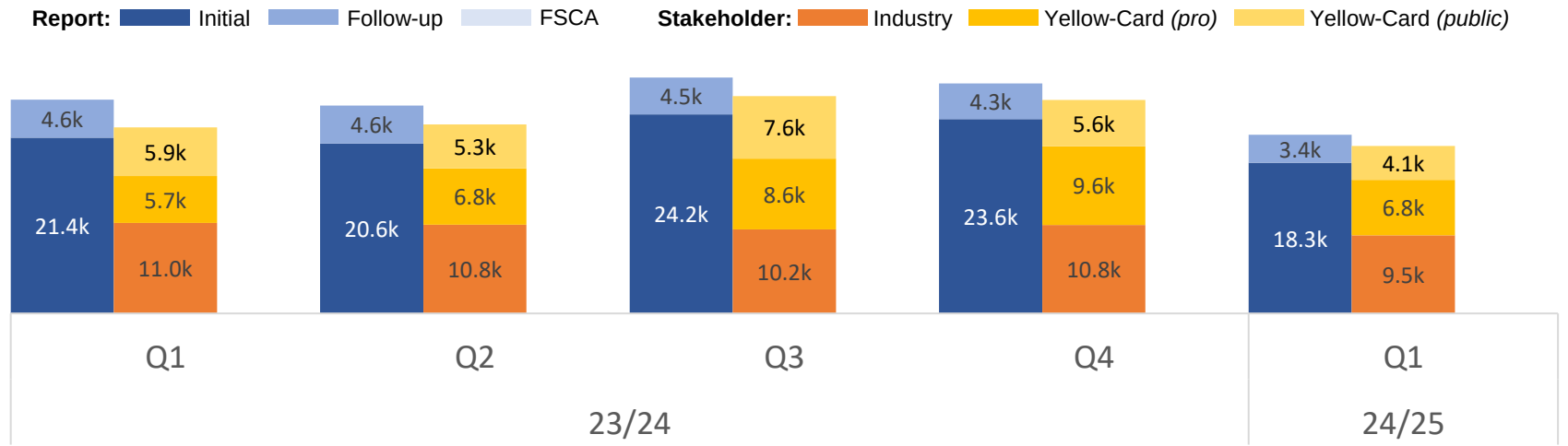
	Jun 23	Jul 23	Aug 23	Sep 23	Oct 23	Nov 23	Dec 23	Jan 24	Feb 24	Mar 24	Apr 24	May 24	Jun 24
Reports Processed (total)	8,530	8,838	7,893	8,535	10,335	10,055	9,920	6,636	6,998	7,512	7,075	4,834	7,992
Reports Processed (on time)	8,530	8,838	7,893	8,535	10,335	10,055	9,920	6,636	6,998	7,512	7,075	4,834	7,955

Medicines & Healthcare products Regulatory Agency

Operational Performance KPIs
Patient Safety Monitoring

Adverse Incident Reports Received - Medicines

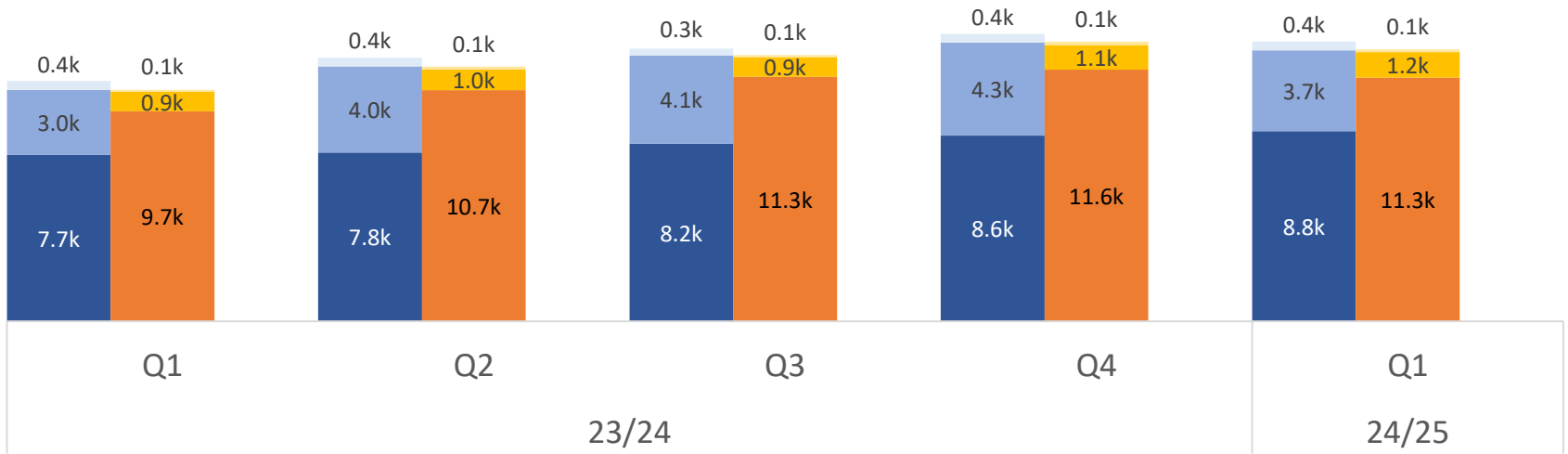
Number of adverse incident reports related to medicines received split by (1) the type of report and (2) the type of healthcare stakeholder who made the report.



CAVEAT: *Medicines data by healthcare reported contains some null returns that have not been categorised.*

Adverse Incident Reports Received - Devices

Number of adverse incident reports related to devices received split by (1) the type of report and (2) the type of healthcare stakeholder who made the report.



Insight

Adverse Drug Reaction Reports

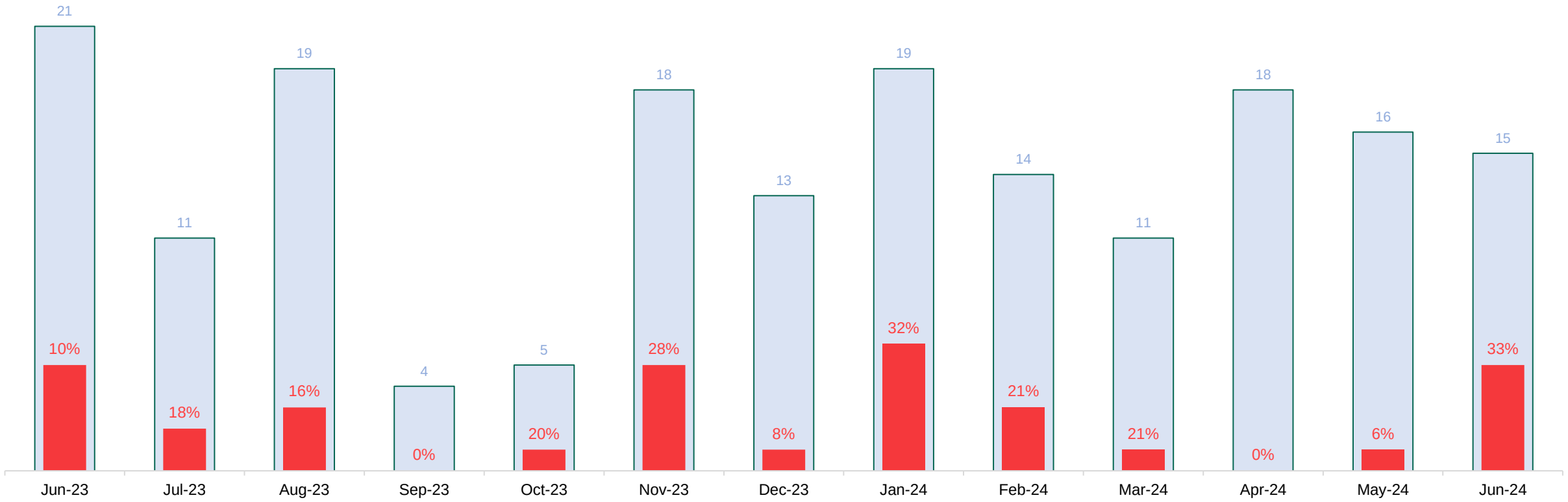
Our interim KPI measures the % of fatal and serious Adverse Drug Reaction reports for medicines. Initial submission for medicines reports should be processed within 11 days as per the KPI. 37 reports missed the 11-day KPI in June. 3 out of the 37 reports for June missed the statutory deadline of 15 days for completion.

Operational Performance KPIs
Scientific Advice

KPI 8: We will offer scientific advice to 95% of requests within 70 days of the request being made.

Jun 24: 33% (▲27%)

Off Target



	Jun 23	Jul 23	Aug 23	Sep 23	Oct 23	Nov 23	Dec 23	Jan 24	Feb 24	Mar 24	Apr 24	May 24	Jun 24
Scientific Advice Offered (total)	21	11	19	4	5	18	13	19	14	11	18	16	15
Scientific Advice Offered (on time)	5	2	3	0	1	5	1	6	3	1	0	1	5

Medicines & Healthcare products Regulatory Agency

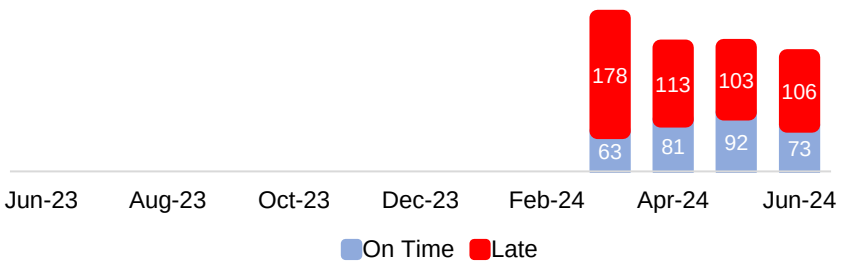
Operational Performance KPIs
Scientific Advice

Output

Target: "We will offer scientific advice to 95% of requests within 70 days of the request being made".

Scientific advice offered on…	Jun 23	Jul 23	Aug 23	Sep 23	Oct 23	Nov 23	Dec 23	Jan 24	Feb 24	Mar 24	Apr 24	May 24	Jun 24
Clinical Trials (on time)	0	0	0	0	0	1	0	2	0	0	0	0	0
Clinical Trials (late)	9	2	7	2	1	3	4	4	6	4	10	5	5
% Completed on Time	0%	0%	0%	0%	0%	25%	0%	33%	0%	0%	0%	0%	0%
NAS (on time)	3	2	2	0	0	1	0	0	0	1	0	0	1
NAS (late)	3	2	3	1	1	2	2	2	2	2	1	6	2
% Completed on Time	50%	50%	40%	0%	0%	33%	0%	0%	0%	33%	0%	0%	33%
Population Health (on time)	1	0	1	0	1	0	0	2	2	0	0	0	1
Population Health (late)	2	3	1	0	1	4	2	5	3	4	5	2	2
% Completed on Time	33%	0%	50%	N/A	50%	0%	0%	29%	40%	0%	0%	0%	33%
Biologicals (on time)	1	0	0	0	0	2	1	2	0	0	0	1	3
Biologicals (late)	2	2	5	1	1	4	4	2	0	0	2	2	1
% Completed on Time	33%	0%	0%	0%	0%	33%	20%	50%	N/A	N/A	0%	33%	75%
PIQ (on time)	0	0	0	0	0	1	0	0	1	0	0	0	0
PIQ (late)	0	0	0	0	0	0	0	0	0	0	0	0	0
% Completed on Time	N/A	N/A	N/A	N/A	N/A	100%	N/A	N/A	100%	N/A	N/A	N/A	N/A

Volume



Turnaround Times

Average time to offer advice on	Target	Jun 24 Actual
Clinical Trial applications	**70** days	**143 (▼35)**
New Active Substances (NAS)		**101 (▼50)**
Population Health		**106 (▼14)**
Biologicals		**85 (▲100)**
Patient Information Quality		**0 (►0)**

Insight

Key Performance Indicator
33% of requests were delivered within the KPI in June.

Volume
Our backlog of outstanding requests for scientific advice has risen by 6 between May and June. This is expected to continue for a while without additional resource as requested.

Quality of Delivery
Direct feedback through a standard form from stakeholders averaged at 8.2/10 for the Quality of the advice received. Feedback is requested with the delivery of every 'Scientific Advice Meeting' letter.

Annex A

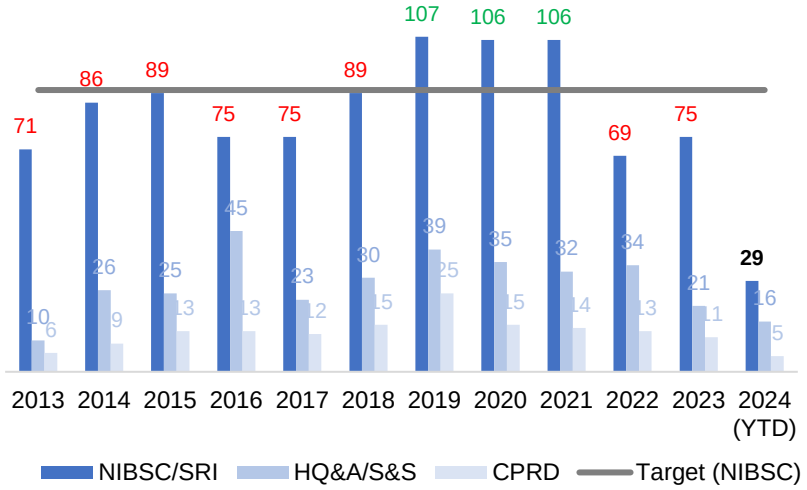
Additional operational metrics

Medicines & Healthcare products Regulatory Agency

Additional Operational Metrics
Research and Development

Agency Publications

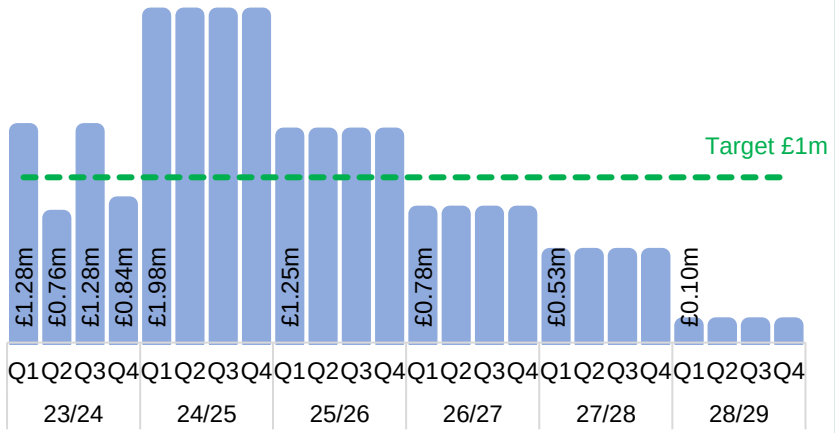
Target: "We will publish 90 scientific publications from NIBSC each year".



Grant Forecast

Grant forecasted income vs minimum target.

Target: "We will forecast a minimum spend of £4m per year".



Insight

Agency Publications

Agency publications are tracked through the calendar year in order to correspond with the year of publication. The number of publications produced is a measure of scientific communication on public and patient health benefits, how the Agency is making available it's lab-based science outputs and supporting product lifecycle aims. So far this financial year, we have had 14 publications in NIBSC/SRI. Our performance target is an annual target and is not tracked in quarter.

Grant Data

Grant usage, which is tracked cumulatively, is behind target. This is due in part to delays in starting spend on grants for staffing (recruiting) or where contract approvals were behind target. One grant will be rebased due to delays in contracts, but the target end date will remain the same. Spend can fluctuate in the year as seen in 23/24.

Grant Usage and Applications

Grant forecast spend vs actual spend demonstrating that we deliver the research we are contracted to through grant agreements and that we are an attractive Agency to whom funding can be awarded. Also, the number of successful, ongoing and unsuccessful grant applications, demonstrating the Agency is an essential provider and partner.

Target: "We will ensure our actual spend is within 10% variance of our forecast".

		Q2 23/24	Q3 23/24	Q4 23/24	Q1 24/25
Grant Usage	Cumulative Forecast Spend	£2.04m	£3.32m	£4.15m	£1.98m
	Cumulative Actual Spend	£2.57m	£3.31m	£4.15m	£1.48m
	% Variance	26.31%	0.05%	0.03%	24.99%
Grant Applications	Successful	5	6	6	5
	Pending/Ongoing	8	11	9	5
	Unsuccessful	2	3	3	4

Medicines & Healthcare products Regulatory Agency

Additional Operational Metrics
Research and Development

Impact of science reported in publications from Science, Research and Innovation (South Mimms)

Topic area	Title	Journal	Scientific Impact
Novel Methods	Alternative Methods for the Detection of Superoxide Anion Generation in Platelets	Journal of Visualised Experiments	This study presents three experimental protocols successfully adopted for the detection of superoxide anions in platelets and the study of the redox-dependent mechanisms regulating hemostasis and thrombosis
Novel methods	Investigation of the Solid-State Interactions in Lyophilized Human G-CSF Using Hydrogen-Deuterium Exchange Mass Spectrometry	Molecular Pharmaceutics	Deuterium uptake in ssHDX-MS has been shown for various proteins, including monoclonal antibodies, to be highly correlated with storage stability, as measured by protein aggregation and chemical degradation. Lyophilisation formulations were compared to inform our production of stable biological standards
Biological Standards	Predicting the Stability of Lyophilized Human Serum Albumin Formulations Containing Sucrose and Trehalose Using Solid-State NMR Spectroscopy: Effect of Storage Temperature on (1)H T(1) Relaxation Times	AAPS Journal	This study informs the formulations required to assure long term stability of certain biological standards.
Bioassays	2023 White Paper on Recent Issues in Bioanalysis: EU IVDR 2017/746 Implementation/Impact, IVD/CDx/CLIA Published in three parts	Bioanalysis	Outcome of a workshop that provided a thorough coverage of all major issues in bioanalysis of biomarkers, immunogenicity, gene therapy, cell therapy and vaccines.
Biological Standards	Defining a metrologically traceable and sustainable calibration hierarchy of international normalized ratio for monitoring of vitamin K antagonist treatment in accordance with International Organization for Standardization (ISO) 17511:2020 standard: communication from the International Federation of Clinical Chemistry and Laboratory Medicine-SSC/ISTH working group on prothrombin time/international normalized ratio standardization	Journal of Thrombosis and Haemostasis	A study concluding that the primary international reference thromboplastin reagent should be used only for calibration of successive batches of the secondary reference thromboplastin reagent.
Cell Therapies	Mechanism of action, potency and efficacy: considerations for cell therapies	Journal of Translational Medicine	One of the most challenging aspects of developing advanced cell therapy products (CTPs) is defining the mechanism of action (MOA), potency and efficacy of the product. This perspective examines these concepts and presents helpful ways to think about them through the lens of metrology.
Stem Cells	Hyaluronan in mesenchymal stromal cell lineage differentiation from human pluripotent stem cells: application in serum free culture	Stem Cell Research & Therapy	The cultivation of human pluripotent stem cells on a planar substrate of hyaluronic acid in serum-free culture media systems shown to be sufficient to yield a distinctive developmental mesenchymal stromal cell lineage with potential to modify the function of haematopoietic lineages in therapeutic applications.
Biological Standards / Pan Prep	Harmonising the measurement of neutralising antibodies against chikungunya virus: a path forward for licensing of new vaccines?	Lancet Microbe	An opinion piece with WHO on the use of the anti-CHIKV WHO IS as being important to resolve the discrepancies observed in the CHIKV animal and sero-epidemiological studies, enable comparison of clinical trial data, and establish a robust correlation of protection against CHIKV
	Recommendations from the AML molecular MRD expert advisory board	Leukemia	The European LeukemiaNet group published findings from an advisory board on the standardisation of molecular AML MRD testing
Biological Standards / Pan Prep	Convalescent human plasma candidate reference materials protect against Crimean-Congo haemorrhagic fever virus (CCHFV) challenge in an A129 mouse model	Virus Research	CCHFV causes severe haemorrhagic fever in humans which is fatal in up to 83 % of cases; it is listed as a WHO priority pathogen; there are currently no widely-approved vaccines. Here, correlates of protection are investigated. characterisation of the serological reactivities within these samples will establish their value as reference materials to support assay harmonisation and accelerate vaccine development.
Novel Methods	Quasi-perfusion studies for intensified lentiviral vector production using a continuous stable producer cell line	Mol Ther Methods	The paper describes a method for scaling up the production of lentiviral vector production, a necessary advancement for effective manufacture.
	Structural basis for inhibition of coagulation factor VIII reveals a shared antigenic hot-spot on the C1 domain	Journal of Thrombosis and Haemostasis	The paper describes an antigenic "hotspot" on the FVIII C1 domain and provide a structural basis for engineering FVIII replacement therapeutics with reduced antigenicity
Novel methods / Biological Standards	Comparison of assays measuring extracellular vesicle-tissue factor in plasma samples: Communication from the ISTH SSC Subcommittee on Vascular Biology	Journal of Thrombosis and Haemostasis	Scientific and clinical interest in extracellular vesicles (EVs) is growing. EVs that expose tissue factor (TF) bind factor VII/VIIa and can trigger coagulation. Highly procoagulant TF-exposing EVs are detectable in the circulation in various diseases, such as sepsis, COVID-19 or cancer. Many in-house and commercially available assays have been developed to measure EV-TF activity and antigen but only a few studies have compared some of these assays. The ISTH SSC Subcommittee on Vascular Biology initiated a multicenter study to compare the sensitivity, specificity and reproducibility of these assays and recommended using a functional assay in the presence of an anti-TF antibody.
Novel Methods	An In Vitro Human Skin Test for Predicting Skin Sensitization and Adverse Immune Reactions to Biologics	Toxics	Biologics, including monoclonal antibodies (mAb), have proved to be effective and successful therapeutic agents, particularly in the treatment of cancer and immune-inflammatory conditions, as well as allergies and infections. However, their use carries an inherent risk of an immune-mediated adverse drug reaction. The study describes the use of a novel pre-clinical human in vitro skin explant test for predicting skin sensitization and adverse immune reactions. The skin explant test was used to investigate the effects of therapeutic antibodies, which are known to cause a limited reaction in a small number of patients or more severe reactions.

Medicines & Healthcare products Regulatory Agency

Additional Operational Metrics
Health and Safety

% of H&S Control of Substances Hazardous to Health (COSHH) and Risk Assessments in date

Target: "We will ensure 80% of COSHH, 100% of high-risk assessments, 90% of medium-risk assessments and 80% of low-risk assessments are in date".

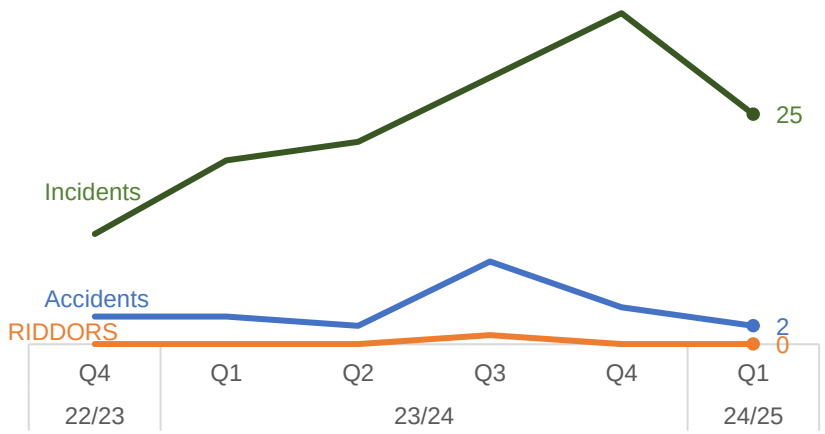
	Q3 22/23	Q4 22/23	Q1 23/24	Q2 23/24	Q3 23/24	Q4 23/24	Q1 24/25
COSHH (% in Date)	78%	72%	N/A	71%	76%	75%	72%
High Risk Assessments (% in Date)	100%	100%	N/A	100%	100%	100%	100%
Medium Risk Assessments (% in Date)	77%	73%	N/A	70%	50%	48%	51%
Low Risk Assessments (% in Date)	65%	68%	N/A	76%	70%	69%	70%

% of documents within review date

Target: "We will ensure 80% of local documents and 70% of cross-agency documents are within their review date.

	Q3 23/24	Q4 23/24	Q1 24/25
Local Office Documents (% in Date)	61%	69%	69%
Cross-Agency Documents (% in Date)	52%	63%	54%

Reporting of Accidents, Incidents and Injuries, Diseases and Dangerous Occurrences Regulations (RIDDORS)



Insight

COSHH and Risk Assessments

Progress in seeing an increase continues to be slow. Targeted chasing and reminders up to now have very much focussed on SRI with the consideration that this was an area with large backlogs. This has paid off and good progress has been seen in SRI figures with higher percentages in date for all categories compared to full Agency. For example, 79% of Low Risk Assessments in date which is just about at target. Next steps are therefore to look at other Groups in the Agency to see where further support may be required and help either tidy up historical assessments that need archiving or provide support where needed. This will however take time and resource from the H&S team to do this at a time of already intense work. Continued Agency messaging to remind staff.

Agency-wide document reviews

No one group/function is meeting the 80% target for cross-Agency policies and procedures yet. Some areas are at 25%.

Local document reviews

Figure remains the same as previous quarter. Continued messaging and support offered by SRI QA team and system superusers.

Accidents and incidents

A reduction in both accidents and incidents this quarter across the Agency, and no RIDDORs reported.

Medicines & Healthcare products Regulatory Agency

Additional Operational Metrics
Standards Lifecycle

Cost recovered from distribution of reference materials

Data is sum of last 12 months, updated quarterly. This smooths seasonal variation but represents a better measure of long-term health.

Target: "We will aim for a rolling +6% growth in costs recovered annually, +1.5% per quarter".

	Q2 23/24	Q3 23/24	Q4 23/24	Q1 24/25
World Health Organisation	£4.36m	£4.89m	£5.43m	£5.63m
Diagnostics	£1.05m	£0.97m	£0.81m	£0.81m
Other	£0.93m	£1.00m	£1.18m	£1.23m
Influenza	£6.56m	£6.91m	£6.99m	£5.75m
Freight	£0.70m	£0.77m	£0.86m	£0.91m
Contract and Revenue Share	£1.80m	£1.44m	£1.66m	£1.91m
Total	**£15.40m**	**£15.98m**	**£16.93m**	**£16.24m**
%Growth	**+6.2%**	**+3.7%**	**+6.0%**	**-4.1%**

Number of distinct users and volume of reference materials supplied

We aim to expand the numbers of users benefitting from our reference materials

Target: "We will aim for a 2% growth in the number of distinct users each quarter.

	Q2 23/24	Q3 23/24	Q4 23/24	Q1 24/25
Units Shipped	30,582	41,557	54,992	32,461
Number of Different Users	**737**	**733**	**837**	**669**
% Growth in Users	**+16%**	**-1%**	**+14%**	**-20%**

Number of different products in our catalogue

Target: "We will aim for a 20 new item in the catalogue each quarter.

	Q2 23/24	Q3 23/24	Q4 23/24	Q1 24/25
Different catalogue items ordered	752	810	838	838
Number of distinct items in our catalogue	**1,366**	**1,393**	**1,424**	**1,375**
New Items in the catalogue	**+50**	**+27**	**+31**	**-49**

Insight

Costs recovered from distribution of reference materials

There is a drop in the rolling average compared to last quarter. This is not the effect of the backlog clearance dropping out of the rolling average, that will occur in Q3 and Q4 and will cause a further decline. It is, mostly, due to the dropping of a single large order of flu reagents in Q1 23/24. This was expected to be one-off order and has been accounted for in budgeting.

Diagnostic rolling average continues to decline. The decline has been for a prolonged period and analysis of distribution patterns is being conducted.

Distribution of influenza materials has also declined as described above.

The remaining categories have grown.

Distinct users and volume of reference materials supplied

The drivers behind the decline (units shipped) in Q1 are mostly due to lower distribution of flu reagents compared with Q1 last year. The numbers of users are a sharp drop compared to Q4. However, Q4 was characterised by a clearance of the backlog which likely resulted in an increase in discrete users as well as elevated volumes. By comparison to Q1 last year the users are up 3.4%.

Number of different products in the catalogue

Eight products were added to the catalogue this month, lower than the 20 expected. No cause for this has been identified and currently this is considered a fluctuation. The total number of available items has reduced as the portfolio is rationalised.

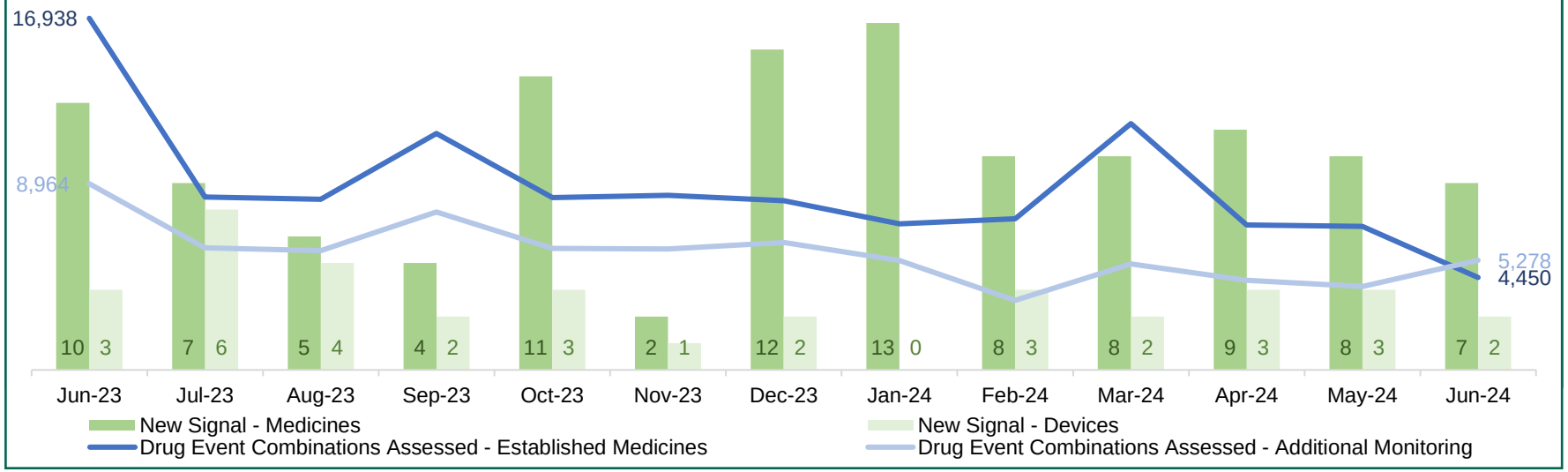
Database updating and cleansing has caused historic figures to change. A full refresh of all data conducted on the costs recovered dashboard has been completed.

Medicines & Healthcare products Regulatory Agency

Additional Operational Metrics
Patient Safety Monitoring

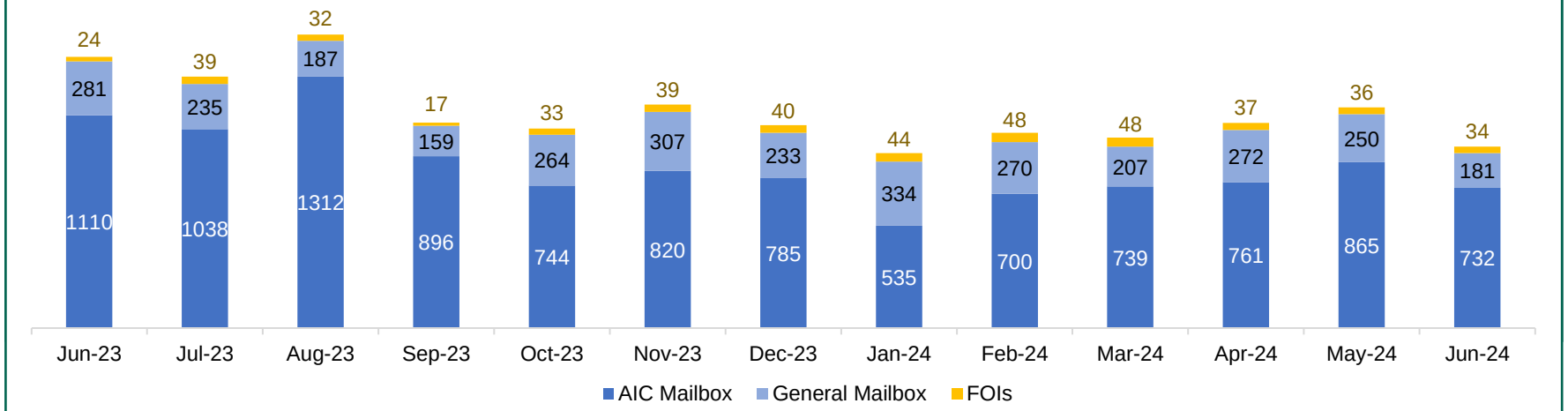
Signal Detection

Number of drug event combinations assessed and of those assessed; how many new signals were identified for further assessment.



Number of Enquiries

Volume of enquiries via our general mailbox, freedom of information requests and via the Adverse Incident Centre (AIC) mailbox



Insight

Reports

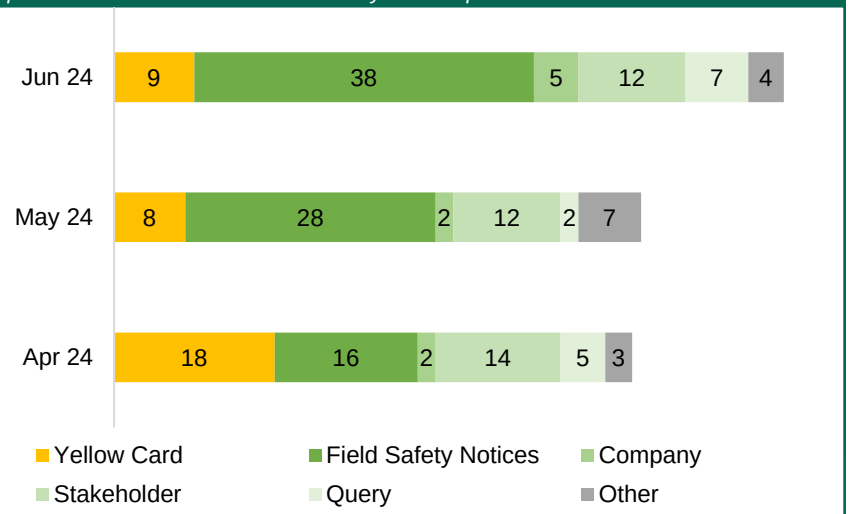
The number of reports for May is still lower than the actual number of reports received for that month due to the systems cut over period. Over 2000 reports are awaiting re-processing via system suppliers and as such will appear in July's statistics. The number of signal alerts for established medicines in June is lower than in previous months due to the switch to new systems and a more refined focused way of flagging safety concerns of interest to assessors for review. Alerts concerning additional monitoring medicines has increased and will likely stay at this level again due to the way in which the logic for highlighting issues for review via CVW has been implemented. The volume of alerts as well as the algorithms that trigger these alerts are being monitored over the next few months.

Medicines & Healthcare products Regulatory Agency

Additional Operational Metrics
Benefit Risk Evaluation

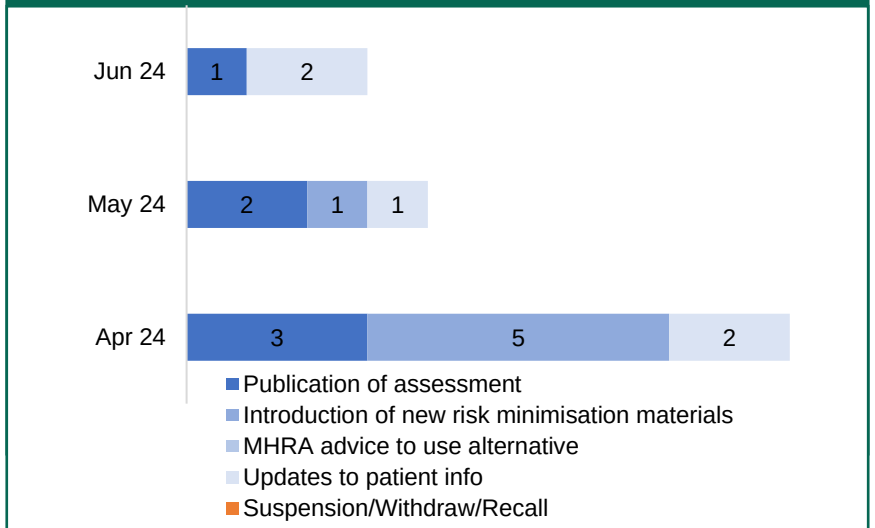
Benefit Risk Evaluation – Issues Investigated

Further assessment of a potential safety issue to determine whether further actions are required to reduce the risk of unnecessary harm to patients from medicines or devices.



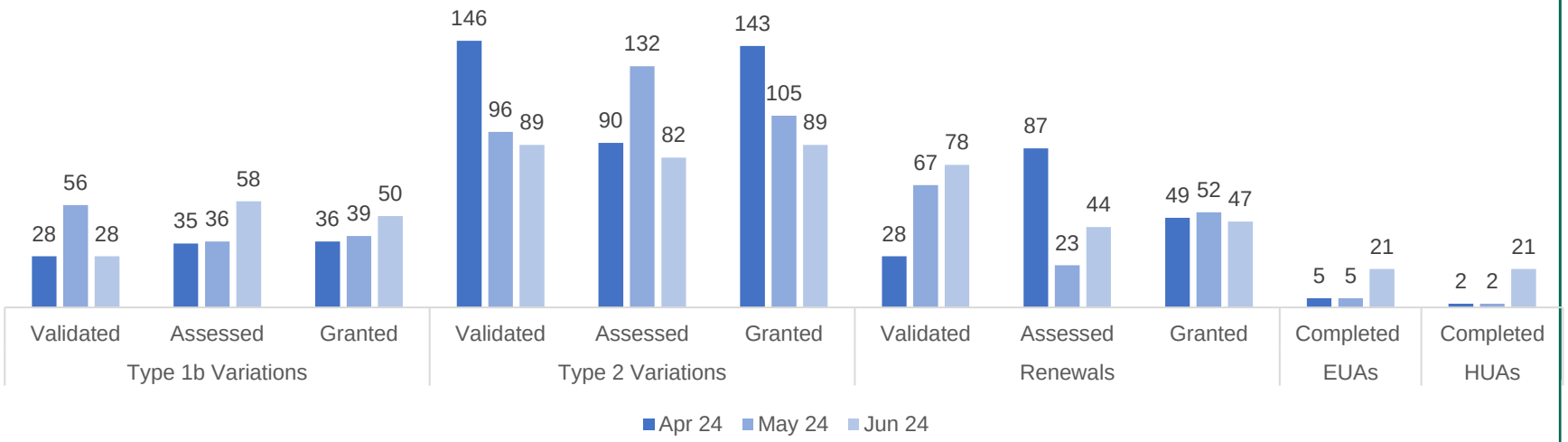
BRE: Actions taken to minimise risk to patients

Actions taken to reduce the risk of unnecessary harm to patients from medicines or devices.



Number of Variations, Renewals and Exceptional/Humanitarian Use Applications (EUAs and HUAs)

Number of applications received, assessed and approved by the MHRA/BRE to update to the product safety or risk management information for medicines.



Insight

Issues Investigated

In June BRE investigated 75 potential safety issues. Investigation/assessment is prompted by information received from a range of sources including signals originating from reports of adverse drug reactions for medicines and adverse incidents for medical devices, safety concerns from Field Safety Notices for medical devices and issues raised with us directly by stakeholders. Assessment of the issue will determine whether further action is required including actions to mitigate risks to patients. Safety issues predominantly came from Field Safety Notices with 38 notices being received.

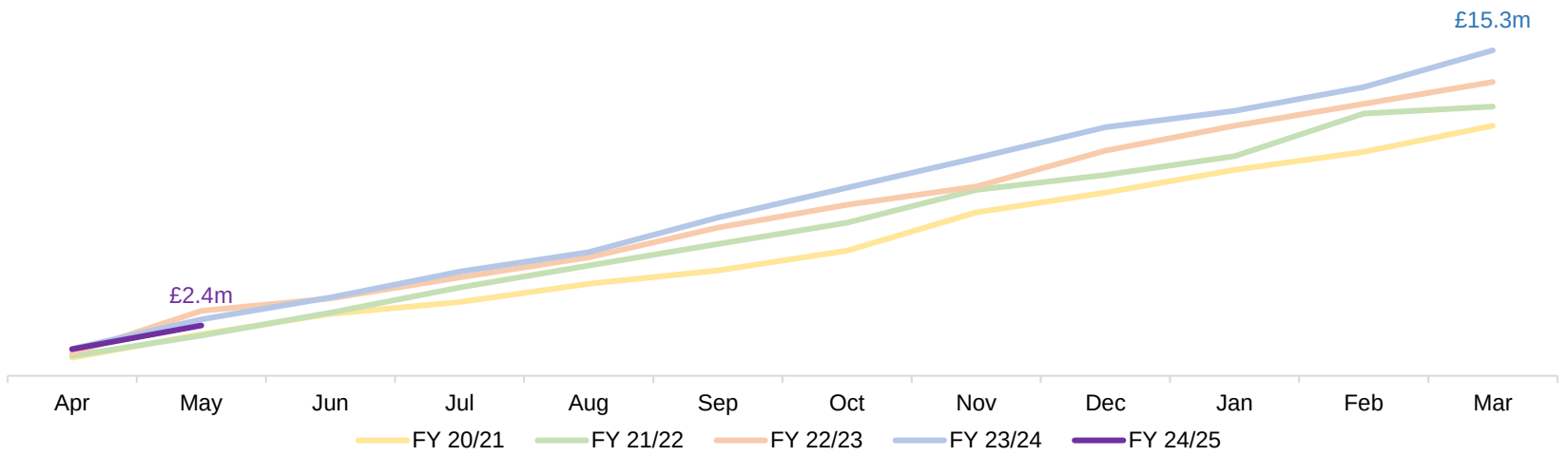
Actions taken to minimise risk to patients

Assessment of the safety issues raised resulted in 3 actions taken to mitigate risk of medicines/medical devices during June. Actions that can be taken in response to safety issues included publication of scientific assessment reports, introduction of new risk minimisation materials, updates to the patient information and in some cases, suspension, withdrawal or recall of the product.

Medicines & Healthcare products Regulatory Agency

Additional Operational Metrics
Clinical Practice Research Datalink

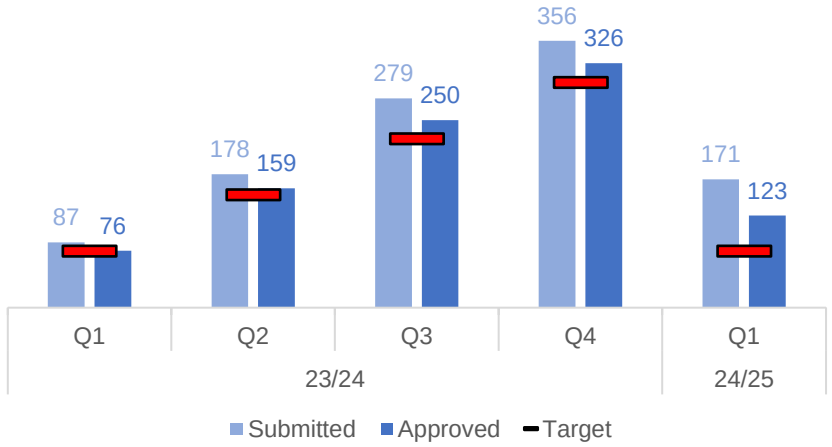
CPRD Cumulative Income



CPRD Protocols Submitted and Approved (Cumulative)

Number of submissions and approvals to use Clinical Practice Research Datalink (CPRD) data for published studies.

Target: "We will approve 75 protocols per quarter".



Turnaround Times

Current time taken to approve applications.

Description	Target	Jun 24 Actual
Average time to approve a **Research Data Governance (RDG)** Application	**28** days	**9 (▲5) On Target**

Insight

Clinical Practice Research Datalink continues to show strong performance.

Cumulative income is tracking slightly down on FY 23/24 and is 4% lower than budget, but June income indicates a stronger performance then April & May. There are some income discrepancies that are being investigated by CPRD and Finance

CPRD Protocols both submitted and approved remained above target for Q1, demonstrating a continued interest in CPRD services

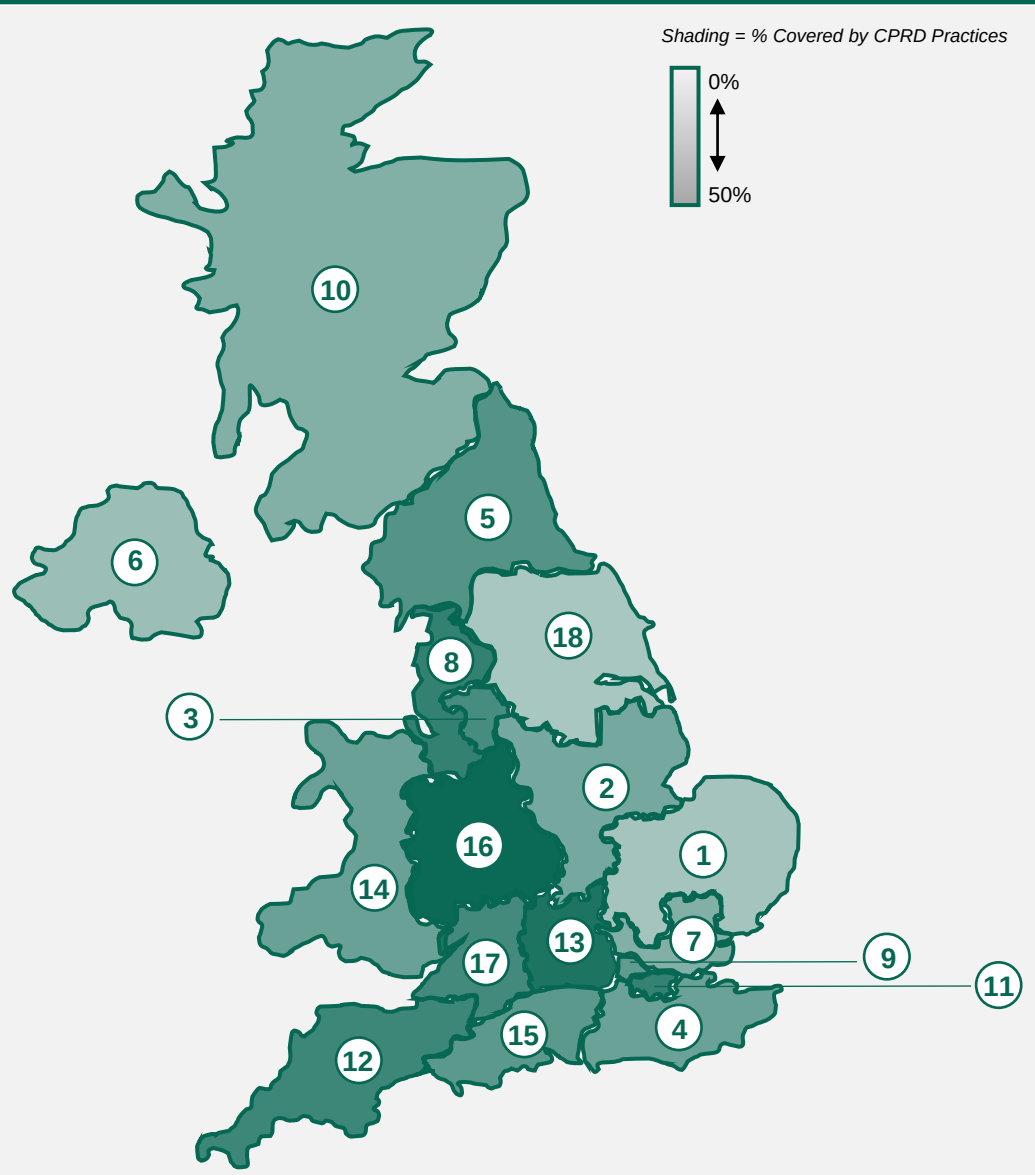
The average time to approve a Research Data Governance (RDG) application in June was 4 days

CPRD geographical coverage for GP practices continues to be above target at over 10% for each region.

Additional Operational Metrics
Clinical Practice Research Datalink

CPRD Geographical Coverage

#	Region	CPRD Practices	Not CPRD	%Coverage
1	East of England	62	316	16.40%
2	East Midlands	136	373	26.72%
3	Greater Manchester	156	275	36.19%
4	Kent, Surrey and Sussex	125	314	28.47%
5	Northeast and North Cumbria	116	232	33.33%
6	Northern Ireland	58	256	18.47%
7	North Thames	166	520	24.20%
8	Northwest Coast	215	314	40.64%
9	Northwest London	107	236	31.20%
10	Scotland	212	680	23.77%
11	South London	147	219	40.16%
12	Southwest Peninsula	91	146	38.40%
13	Thames Valley and South Midlands	113	135	45.56%
14	Wales	110	269	29.02%
15	Wessex	66	140	32.04%
16	West Midlands	369	384	49.00%
17	West of England	86	145	37.23%
18	Yorkshire and Humber	94	513	15.49%
Total		**2,429**	**5,467**	30.76%

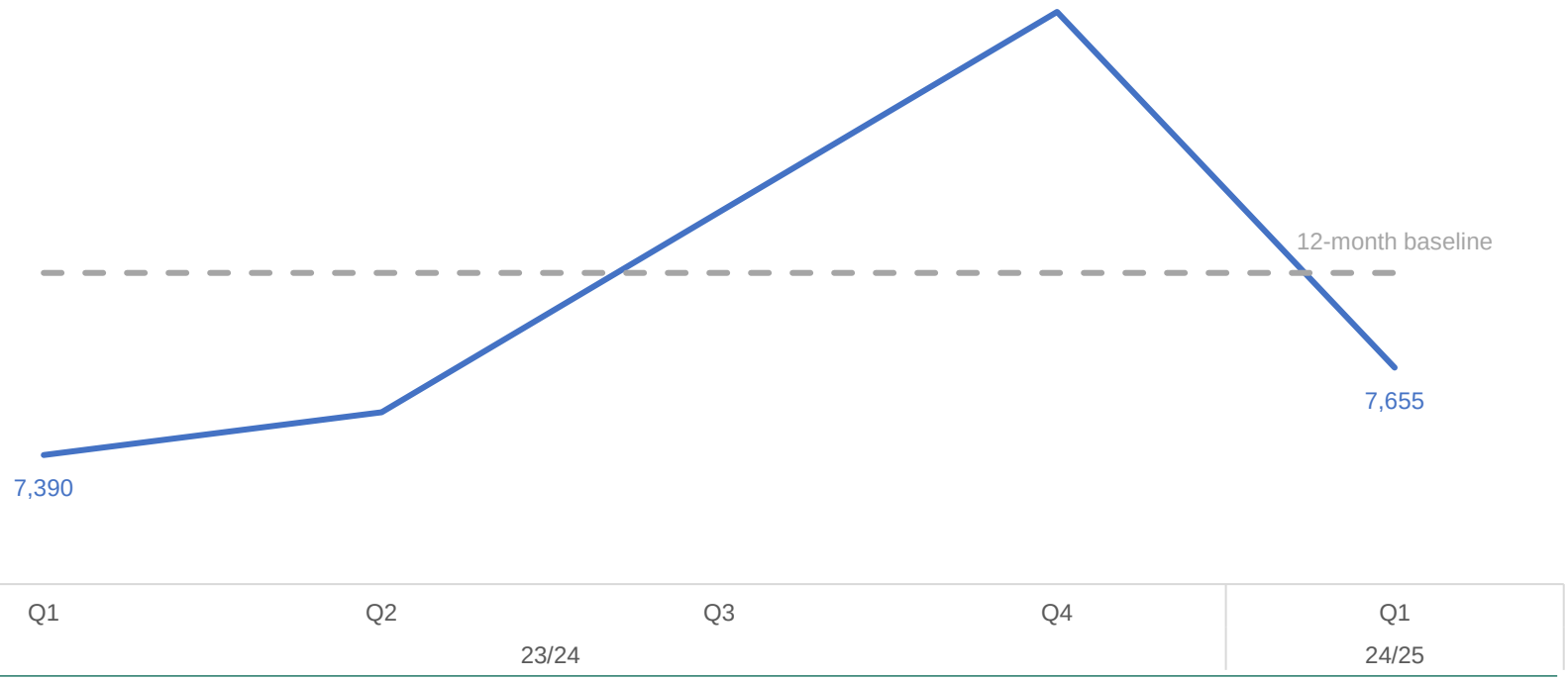


Medicines & Healthcare products Regulatory Agency

Additional Operational Metrics
Criminal Enforcement Unit

Threat Reduction Index

Assessed threat reduction impact of interventions completed by the Criminal Enforcement Unit



	Q2 22/23	Q3 22/23	Q4 22/23	Q1 23/24	Q2 23/24	Q3 23/24	Q4 23/24	Q1 24/25
Minor Interventions	280	250	257	491	206	251	348	226
Moderate Interventions	6	2	6	4	10	8	9	3
Major Interventions	0	0	1	0	3	3	1	3
Weighted TRI Score	1,700	1,350	1,685	2,655	1,830	1,955	2,290	1,580
TRI (Rolling 12 months)				7,390	7,520	8,125	8,730	7,655

Insight

The Threat Reduction Index (TRI) is calculated by weighting all minor, moderate and major interventions made by the criminal enforcement unit (5, 50 and 100 points respectively) into a rolling 12-month score.

This quarter, there is a small deviation in the TRX from its baseline. This is mainly attributable to the natural exclusion of the exceptionally high number of minor TRIs reported in Q1 of 2023/2024 from the rolling index. Since this period, the number of minor TRI's has been at a more consistent level, reflected in the current rolling TRX score. There is an increase in major TRIs in this reporting period, due to the conclusion of criminal trials and sentencing on three significant investigations. The officer abstractions needed to support these has meant a slight reduction in the number of moderate TRIs.

Medicines & Healthcare products Regulatory Agency

Additional Operational Metrics
Innovative Licensing/Devices and Access Pathways (ILAP/IDAP)

Output

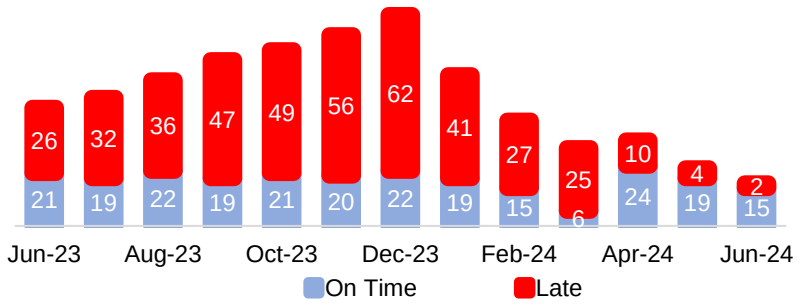
ILAP/IDAP Innovation Passports (IPs) and Target Development Profiles (TDPs) completed in and outside of timeframes.

Target: "We will complete 95% of Innovation Passport and Target Development Profile applications their categories timelines".

	Jun 23	Jul 23	Aug 23	Sep 23	Oct 23	Nov 23	Dec 23	Jan 24	Feb 24	Mar 24	Apr 24	May 24	Jun 24
ILAP IPs (on time)	0	0	0	0	0	0	0	0	0	2	0	6	5
ILAP IPs (late)	0	0	0	0	0	0	0	19	22	11	0	4	0
% Completed on Time	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0%	0%	15%	N/A	60%	100%
ILAP TDPs (on time)	0	0	0	0	0	0	0	0	0	0	0	0	0
ILAP TDPs (late)	0	1	1	0	0	0	0	0	0	0	0	0	0
% Completed on Time	N/A	0%	0%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
IDAP IPs (on time)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	81	N/A	N/A	N/A	N/A	N/A
IDAP IPs (late)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0	N/A	N/A	N/A	N/A	N/A
% Completed on Time	N/A	N/A	N/A	N/A	N/A	N/A	N/A	100%	N/A	N/A	N/A	N/A	N/A
IDAP TDPs (on time)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	1	7	N/A	N/A	N/A
IDAP TDPs (late)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0	0	N/A	N/A	N/A
% Completed on Time	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	100%	100%	N/A	N/A	N/A

Volume

Uncomplete ILAP/IDAP applications that are younger and older than timeframes.



Turnaround Times

Current time taken to complete ILAP/IDAP applications.

Average time to complete an…	Target	Jun 24 Actual
ILAP Innovation Passport	**10** days	**21 (▲2)**
ILAP Target Development Profile		**0 (►0) Target N/A**
IDAP Innovation Passport		**0 (►0) Target N/A**
IDAP Target Development Profile	**3** days	**0 (►0) Target N/A**

Insight

New ILAP Innovation Passport applications continue to be progressed within expected timeframes.

2 late IP outcomes.

Medicines & Healthcare products Regulatory Agency

Additional Operational Metrics
Customer Experience

Output

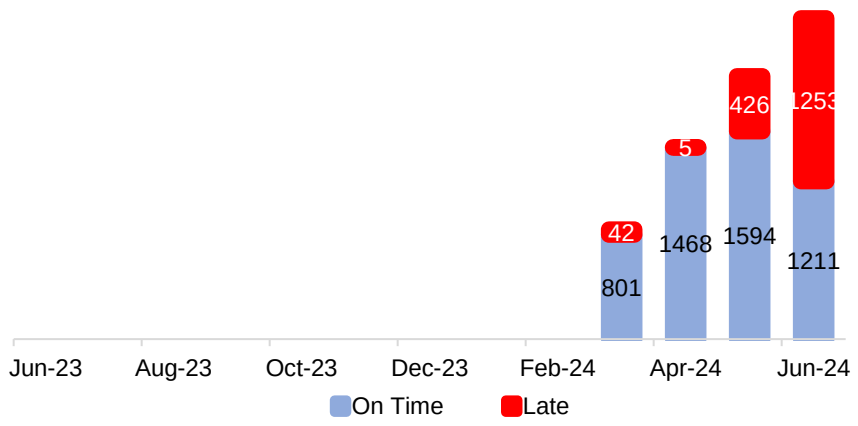
Number of enquiries, complaints and FOIs handled in our Customer Experience Centre (CEC), closed in and outside of timeframes.

Target: "We will close 90% of enquiries in 18 days, complaints in 20 days and FOIs in 20 days of receiving them".

	Jun 23	Jul 23	Aug 23	Sep 23	Oct 23	Nov 23	Dec 23	Jan 24	Feb 24	Mar 24	Apr 24	May 24	Jun 24
CEC Query (closed on time)	3378	2974	3183	3471	3684	4025	2717	3152	3165	3279	3576	3062	3957
CEC Query (closed late)	872	868	681	429	355	322	322	284	282	29	28	264	816
% Completed on Time	79%	77%	82%	89%	91%	93%	89%	92%	92%	99%	99%	92%	83%
Complaint (closed on time)	623	210	488	393	129	145	93	521	469	328	68	54	48
Complaint (closed late)	73	139	56	38	38	28	16	21	27	0	2	23	23
% Completed on Time	90%	60%	90%	91%	77%	84%	85%	96%	95%	100%	97%	70%	68%
FOIs (on time)	29	59	59	57	78	86	100	75	104	107	93	89	75
FOIs (late)	33	41	44	27	32	18	9	3	6	4	3	3	1
% Completed on Time	47%	59%	57%	68%	71%	83%	92%	96%	95%	96%	97%	97%	99%

Volume

Unactioned enquiries, complaints and FOIS that are younger and older than timeframes.



Turnaround Times

Current time taken to process enquires.

Average time to close…	Target	Jun 24 Actual
Enquiries	**18** days	**9 (▼1)**
Complaints	**20** days	**14 (▲1)**

Insight

In June, there was an increase in the number of general enquiries handled across both our mailboxes and phonelines. This reflects a concerted push to clear our backlog rather than a spike in queries.

The average time to close overall slightly increased to 13 days, up from 12 days in May with the average time to close within the CEC at 9 days despite the rising number of enquiries.

Much of the increase has been attributed to increasing our capability and focus on performance across our main Customer service phoneline and targeted training to upskill staff in areas of high demand such as our Regulatory Information Service. Onboarding is expected throughout July to fill remaining vacancies, with ongoing plans in place to cross train staff to increase capability and flexibility amongst the team and reduce the amount of queries issued late.

Overall volume of complaints reduced in June with 20% reduction in status update queries from Industry with Track My Case now deployed since March 2024. We continue to monitor feedback working closely with the RegulatoryConnect project team and HQA colleagues, with Industry continuing to seek updates and timelines related to applications currently held up in backlogs.

A small spike in queries about the postponement of the July public board were received from members of the public, these have been responded to using approved line to take.

FOI compliance reached an all-time high in June at 98.68% , the highest rate the Agency has recorded.

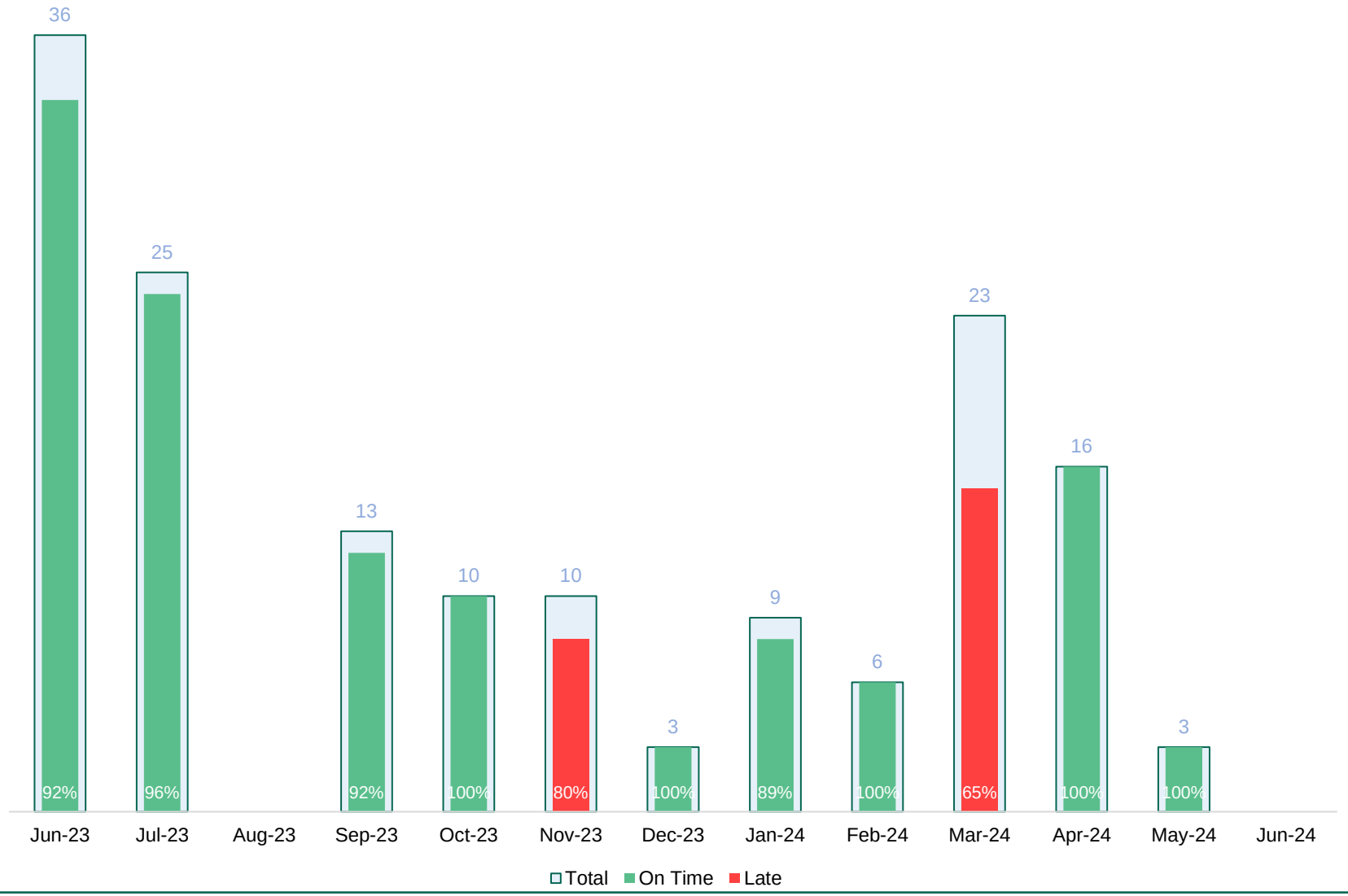
Medicines & Healthcare products Regulatory Agency

Additional Operational Metrics
Parliamentary Questions

Parliamentary Questions Compliance Rate

Number of Parliamentary Questions (PQs) responded to by our parliamentary deadline.

Target: "We will respond to 85% of Parliamentary Questions by the parliamentary deadline of 1-2 days".



Insight

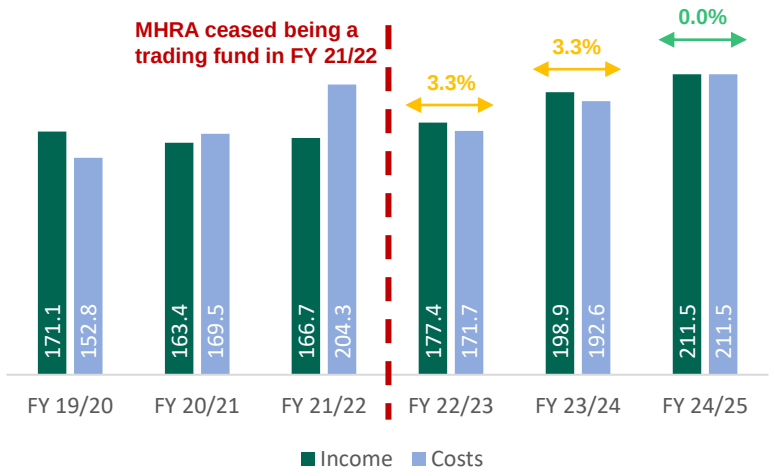
There were no Parliamentary Questions received in June 2024. At the end of May, the Prime Minister called a general election for the 4th July. During the pre-election period, no Parliamentary Questions are tabled.

Medicines & Healthcare products Regulatory Agency

Additional Operational Metrics
Finance/Infrastructure and Laboratory Services

Income v Costs

Target: "We will ensure our full year forecast income equals our costs", Red – any overspend or >5% underspend, Amber – 1-5% underspend, Green – 0-1".

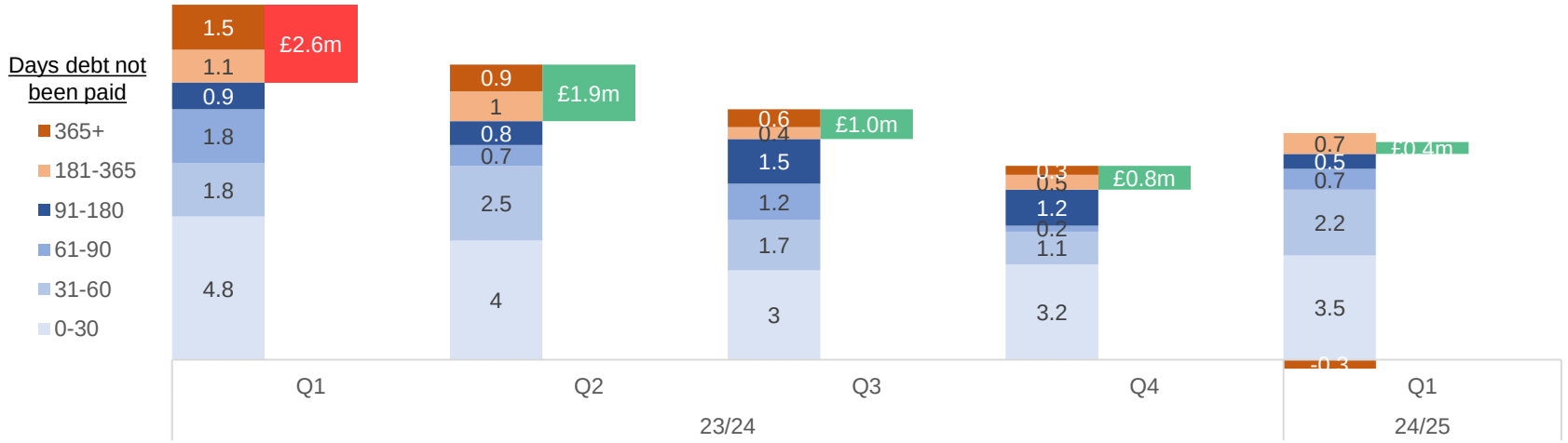


RDEL Full Year (£m)	Budget
Trading Income	100.5
Service Fee Income	45.0
Grant Income	5.9
Staff Costs	103.5
Operating Costs	68.8
Operating Net Position	**(20.9)**
Staff Costs	1.8
Projects Costs	11.8
Projects Net Position	**(13.6)**
Resource Net Position	**(34.5)**
DHSC Operational Funding	**34.5**
Total RDEL	**0.0**

CDEL Full Year (£m)	Budget
Projects Costs	19.5
CDEL Operating Costs	6.0
Capital Net Position	**(25.5)**
DHSC Capital Funding	25.4
Total CDEL	**(0.1)**

Agency Debt Profile

Target: "We will hold no more than £2.3m of debt that is over 181 days (6 months) old in FY 23/24".



Insight

Income v Costs

The first quarterly forecast has not been completed yet and, therefore, the forecast income is not available. However, the budgeted income for 2024/25 is £211.5m which is intended to nett off to zero against Agency costs.

Agency Debt Profile

Agency Aged debt reduced significantly in 2024/25 Q1, including debts over 6 months old which dropped by 7% against KPI. For Q1 2024/25,although on par with Credits & Cash our Billing was high which has pushed up the overall debt.

Contributions to Net Zero

Water leak repairs and operational efficiencies were carried out at the beginning of the year to reduce depletion of natural resources and to reduce spend. Our water consumption in Q4 was 3,037 m3, this was a reduction of 57.4% over the year, far exceeding our annual target of 20%.

Installation of a new roof mounted solar array started in Q2 and final commissioning was completed towards the end of Q3. The combined old and new solar arrays will reduce the Agency electricity bill by about £200k per annum.

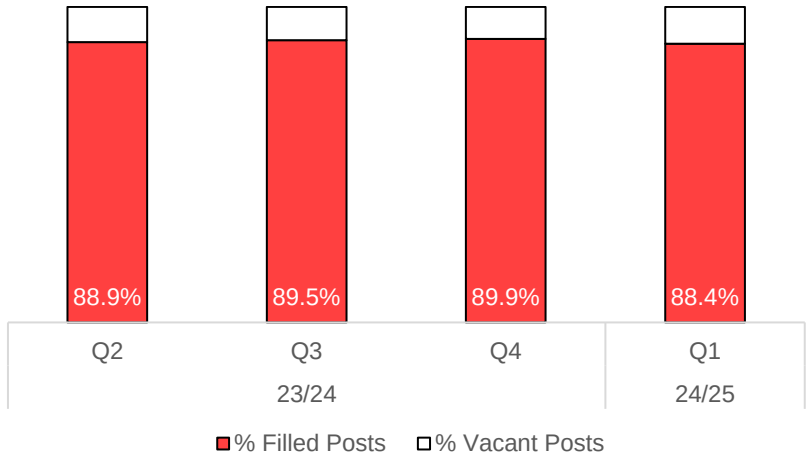
Medicines & Healthcare products Regulatory Agency

Additional Operational Metrics
Human Resources

Staff Vacancy Rate

% of posts filled in the Agency.

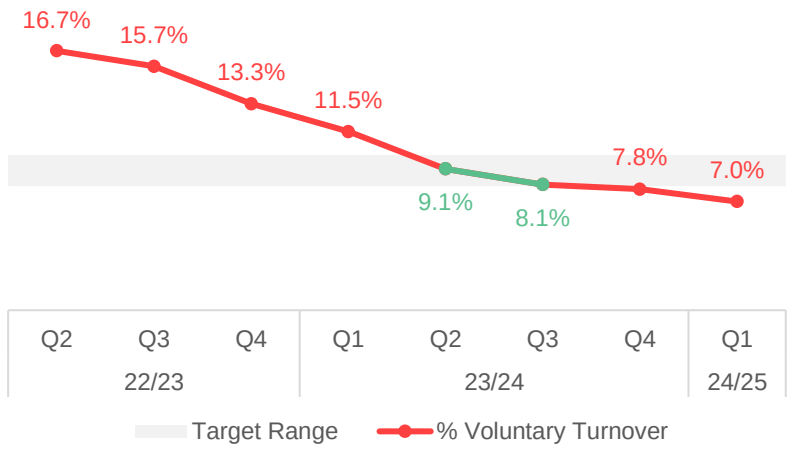
Target: "We will aim for 95% of all posts to be filled".



Staff Voluntary Turnover Rate

% of staff volunteering to leave the Agency.

Target: "We will aim for a staff turnover rate between 8-10%"



Insight

Staff Vacancy Rate

% of available posts filled by staff in the Agency taken a marginal reduction in Q1 and we are still however 6.6% away from our internal target of 95%. We continue to recruit at pace to fill vacancies in what is a national challenging market and are implementing new tools such as LinkedIn recruiter in order to enhance our capacity to source key skills directly.

Staff Voluntary Turnover Rate

% of staff volunteering to leave the Agency has fallen below our 'healthy' range of 8-10% at 6.7%. Whilst turnover is below the CIPD healthy range (10-15%), we have welcomed significant numbers of new staff in the last 2 years which will impact on natural voluntary turnover. We will continue to monitor but this rate is in part reflective of pre-COVID and pre transformation turnover in many of our professions.

Agency Diversity

% of BME staff and staff declared as disabled across the Agency has continued to show positive upward trends across all grades. SEO BME ratios continue to be well above the London benchmark however Grade 7 and above ratios continue to be well below the benchmark. Implementation of the LinkedIn recruiter license will support our aim of increasing the diversity of our workforce, particularly at the more senior levels, through targeted sourcing and advertising to a broader demographic than Civil Service Jobs and specialist media alone, along with an employer branding exercise running in tandem.

Misc

Our overall Engagement Index score shows improvement, in 2023 we scored at 58%, significantly up from 49% in 2022 and 51% in 2021.

Agency Diversity

% of Black and Minority Ethnic (BME) staff and staff declared as disabled employed by the Agency.

Target: "We will aim for our employed staff to match the London 2021 benchmark of ratio of population that is BME (46%) and are declared disabled (16%)".

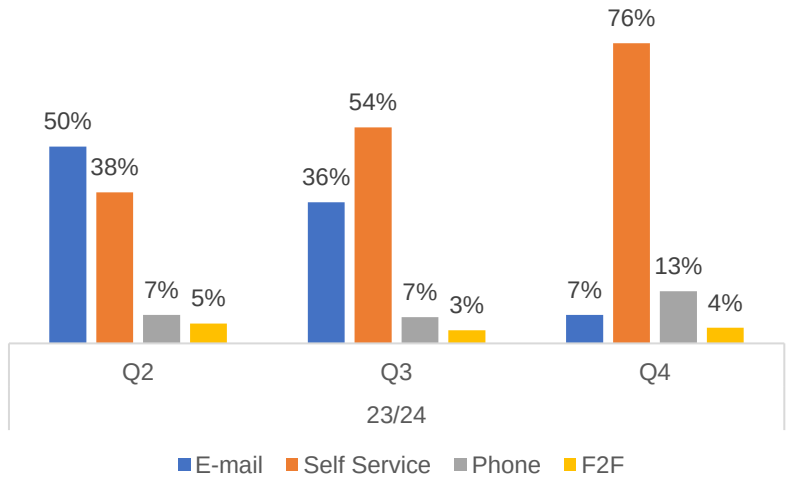
		Q2 23/24	Q3 23/24	Q4 23/24	Q1 24/25
% BME staff employed	SEO and Below	46%	47%	49%	50%
	Grade 6 and 7	25%	25%	25%	26%
	Senior Civil Servants	13%	13%	16%	17%
% of staff employed that are declared as disabled	SEO and Below	8%	8%	11%	11%
	Grade 6 and 7	8%	8%	9%	9%
	Senior Civil Servants	10%	9%	11%	11%

Medicines & Healthcare products Regulatory Agency

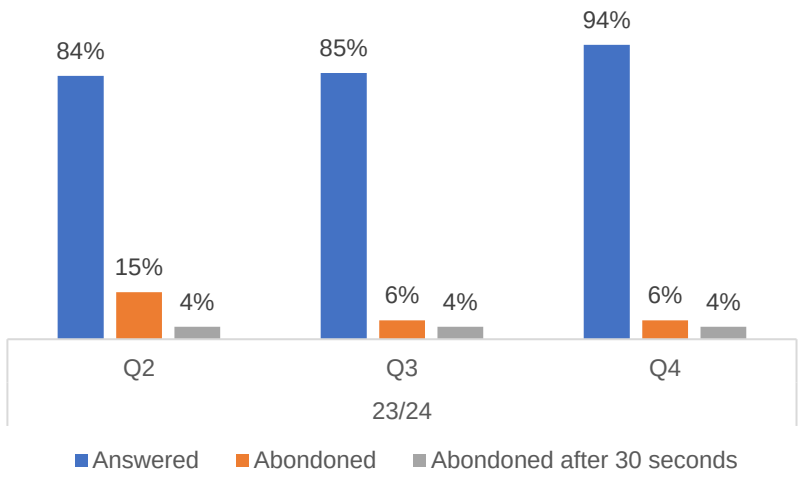
Additional Operational Metrics
Digital and Technology

Service Management – IT Service Desk Volumetrics

Request received, and way they were received, through the Self-Service Portal



Service Management – Call Answering



Insight

Cyber Security

Our MS email filtering tool is showing a consistent rate of proven malicious (phishing) emails that have needed to be blocked. Q1 levels were up on those in Q4 2023-2024 in all categories which continues to show that the Agency is under significant threat and email continues to be the key method for malicious cyber activity.

On the Agency's behalf, NHS England manage and report Microsoft Defender (now M365) alerts which are triggered when a security risk or threat is identified in relation to an Agency end point device (e.g. laptops). The number of these alerts can be a good assessment of the volume of threats the Agency face as well as potentially insecure practice by agency staff and vulnerabilities on agency devices that need to be rectified. These alerts are immediately assessed and managed by the Information Security Team. This new quarter has seen a significant increase from Q4 2023-2024.

In Q1 2024-25 there was a reduction in the number of 'report a message' clicks by staff, from the previous quarter. However, it is significantly higher than the same quarter last year when only 161 messages were reported.

Our new mandatory security and data protection training provided through Bobs Business-Cyberlearn was launched on 23rd May and take up has been positive. At the end of Q1 the number of employees completed trained was 265 (19% headcount) data protection training and 198 (14% headcount) security training.

Security Audits and Reviews

The ITHC programme for 2024-2025 is yet to be determined, and the timing is dependent on a procurement exercise to establish a new security testing services framework contract. A remediation plan for the vulnerabilities discovered in the external/on-site South Mimms test completed Q4 is being reviewed with networks team.

Cyber Security – Malware Threats

Date	High risk emails inspected and blocked	Number containing malware	Number of confirmed phishing emails blocked
Jul 23	274,719	317	10,394
Aug 23	34,413	425	11,290
Sep 23	73,330	776	12,487
Oct 23	132,807	704	10,420
Nov 23	70,136	560	10,539
Dec 23	23,613	195	7,466
Jan 24	159,723	172	5,973
Feb 24	95,676	296	6,074
Mar 24	102,715	453	6,596
Apr 24	103,467	403	12,741
May 24	124,652	693	6,507
Jun 24	160,006	638	5,459

Cyber Security – Staff Awareness to Phishing

Date	'Report a message' button clicks	Trend
Jul 23	51	
Aug 23	41	
Sep 23	53	Worse
Oct 23	60	
Nov 23	81	
Dec 23	152	Better
Jan 24	295	
Feb 24	74	
Mar 24	89	Better
Apr 24	86	
May 24	107	
Jun 24	44	Worse

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

September 2024

Title	How effectively is the system of international recognition enabling access to medicines for UK patients?
Board Sponsor	Julian Beach
Purpose of Paper	Assurance

How effectively is the system of international recognition enabling access to medicines for UK patients?

1. Executive Summary

1.1 This report looks at how effectively we have implemented the International Recognition Procedure into our strategy to enable access to medicines for UK patients. It provides an overview of recent developments as we evolve our processes and scope, to maximise the benefit of leveraging the assessment work carried out by other regulators.

1.2 It is recognised that IRP is one of three routes of access for medicines, including direct National Applications, and Collaborative assessment.

1.3 We have been using evolving information and knowledge from industry through pipeline meetings and information sharing. We plan a webinar on the 26th September 2024, delayed from July due to the General Election, to communicate requirements of the pipeline meeting further. The meetings serve as a platform for engaging industry stakeholders to gain early visibility into upcoming innovations. The information we have gained so far feeds into the discussion in Section 4, where we expand on our broader strategy, detailing how the IRP integrates within this framework, including our forecasting approach and its importance to ensure we have adequate resource.

1.4 Our evaluation of the IRP process shows commonality of personnel and processes which are shared across multiple submission pathways such as the IRP, National Route, EAMS, ACCESS Consortium, Project ORBIS, and Scientific Advice. Therefore, making it essential we prioritise process evolution and capability / capacity growth to sustain delivery across all our workstreams and maintain >95% compliance for IRP, the target for the KPI. To develop this further we are establishing joint pipeline meetings as a collaborative tool with UK health partners, for example NICE to streamline our approach.

1.5 We have completed our first internal self-audit and process improvement of the International Recognition Procedure; findings show that timing of activities can be modified to improve the reliability of meeting the published timelines of 60 or 110 days for Routes A and B respectively. Common issues have been identified, such as insufficient documentation submitted or compliance with UK requirements for labelling, which result in requests for correction on receipt of applications. These are being communicated to industry to prevent recurrence.

2. Introduction

2.1 The International Recognition Procedure (IRP) launched in January 2024. This update informs the Board about the current performance of the procedure. Key findings from the recent audit are presented, along with a summary of revisions to the process used and to external guidance in response to experience to date and the audit's recommendations. These are updated in operating procedures to ensure consistency and adequacy of training.

2.2 This paper will also explore future trends and review forecasting to strategically position the International Recognition Procedure within the broader organisation. The MHRA's focus is on finding an optimal balance between direct national and recognition procedures to ensure a robust strategy that facilitates access and maintains our expertise to evaluate medicines in the UK.

2.3 A comparison of both Route A and B performance is outlined in Table 1, with the number of applications received and granted under IRP. The median processing time for Route A has decreased from 53 days (as presented in April) to 48 days. Ongoing, monitoring and continuous improvement efforts have led to further efficiencies in our processes, enabling us to assess applications within published timelines (60 days for Route A and 110 days for Route B) and consistently maintain 100% compliance. Route B applications have been triaged and are processed with a slightly longer timeframe, however our experience and learning is immature with this route due to smaller numbers received and processed so far and it is too early to see the impact on timelines of those requiring CHM review. There is a clock stop after initial review where necessary if applications need to be returned to the applicant for clarification.

2.4 Table 1 - Summary of applications the MHRA have received between 1 January 2024 and 31st July 2024:

Of the 45 Route B applications received, 1 is referencing Australia's TGA, 1 Health Canada, 8 the US FDA, with the rest referencing EMA, MRDC and EU national regulators. We have granted 2 generic applications referencing the FDA and Health Canada, with a New Active Substance referencing the FDA currently in final stages of assessment. This demonstrates the attractiveness and effectiveness of the process where companies are utilising non-EU RRs across our innovative and generic portfolios.

Type of Application	Number of Applications received and validated	Number of Applications granted	Median days	% approved within published timelines
Route A	115	75	48 days	100%
Route B	45	7	56 days	100%
Type II variation	694	516	19 days	100%
Type IB variation	1343	1305	7 days	99%

2.5 To date three Route A applications have moved to a 110-day timetable due to outstanding major objections at Day 60. Issues found were due to bioequivalence study design, corrections needed to RMP and labelling and need for additional data to support nitrosamine risk assessment. These correction points required additional time; therefore, companies were informed of the change to assessment timetable, and were provided with a clock-stop to respond.

2.6 Key considerations have been identified in Section [5], including navigating the evolving regulatory requirements in reference regulator countries, addressing instances where assessment reports are not issued by reference regulators, and ensuring appropriate resource to meet the expected increase in demand. The time-intensive process of training new staff amid existing workload demands causes concern, however the team is strategically planning resource allocation to support delivery through regular weekly triage and allocation meetings.

2.7 The applications received have been in the most part for established medicines approval with varying conditions treated. These include: leukaemia, kidney disease, pulmonary fibrosis, type 21 diabetes, aortic stenosis and myeloma.

3. Key activities of MHRA

3.1. Audit and process improvement

Key findings from audit

3.1.1. To ensure the robustness of our processes, we have conducted an internal self-audit on applications submitted via Route A and Route B. Applications submitted from 1st January 2024 to 30th June 2024, were captured in the audit. The purpose of the audit was to evaluate the effectiveness, efficiency, and compliance of the procedure in achieving its intended objectives. This initial audit reviewed timeliness of key milestones from the point an application is received through to determination. A second self-audit will be conducted at the end of the year to review quality measures, decisions made on route of submission by eligibility checker and during the triage meetings. This will be done to support the GIAA audit on Licencing which is planned.

3.1.2. While we are achieving 100% of decisions within the published timelines, the audit highlighted opportunities for enhancing our operational efficiencies and streamlining our processes. Three rate-limiting steps have been identified within the MHRA process that could impact the time to determination. These critical steps are the time of validation, the time to allocation, and the point at which, if necessary, questions are asked of applicants. Our revised Standard Operating Procedure will prioritise process changes to allow prompt timelines for these steps to enhance overall efficiency.

3.1.3. Our expectation was that we would not need to ask questions for Route A applications, however results from the audit showed that the documentation supporting 89% of applications was deficient. Common issues found were lack of UK correct requirements for labelling and artwork mock-ups, and absence of

documentation including missing assessment reports for the active substance master files. These learnings are being presented to industry and further webinars and engagement sessions are planned.

3.1.4. 80% of Route B applications have required correction at the validation stage due to applicants submitting dossiers that do not fully meet the requirements outlined in our guidance. We have had a high interest in utilising IRP for both innovative and generic applications, and we continue to update guidance to reflect the queries being asked. For instances where the assessment report is redacted or not available by reference regulator, often the case for generic applications referencing the FDA, we are developing further process updates to be piloted in September and October to allow applicants to bridge gaps in documentation available. Further details on this can be found in Section [5].

Updates to Standard Operating Procedures and training

3.1.5. We continue to triage all applications submitted through the International Recognition Procedure. This has maximised efficiency and enables the MHRA to deliver on IRP within the published non-statutory timelines. Importantly it facilitates oversight of assessment resource which is shared across IRP and other national procedures. Resource allocation is carefully balanced for IRP with other ongoing procedures and priorities, including our innovative medicines and established medicines portfolios submitted via the national route, EAMS, ACCESS consortium, Project ORBIS and scientific advice meetings. This makes it crucial for us to optimise our processes to operate with maximum efficiency.

3.1.6. The process is developed to provide improved process reliability with modified milestones, to ensure meeting the overall decision timelines is achieved. A significant update to the process aims to complete the initial assessment of Route A applications within 35 days from the start of the timetable. To address recurring issues, we plan to incorporate these requirements into the validation process, minimising their impact on assessment timelines. This allows applicants sufficient time to respond and enable decision within the 60day timetable. Where major objections are still outstanding at Day 60, the timetable will switch to a 110-day timetable. We have three Route A applications that switched to a 110-day timetable, for example where there are concerns with the bioequivalence study design and thus needing advice from CHM in relation to equivalence with the UK Reference Medicinal Product.

3.1.7. The developed process will focus on improvements to our operational procedures. We have identified opportunities to upskill other areas of the organisation, including Authorisation Lifecyle, which will reduce the involvement of assessors and streamline our processes. The upskilling will include training our compliance assessors on certain quality aspects. This development of our staff in different roles is essential to allow new ways of working to be delivered. The next iteration of training will be conducted in September and October.

Updates to External guidance

3.1.8. A webinar was held in May to further support the industry with the tools they need for the successful adoption of IRP. In the webinar we presented the new pre-submission checklists for initial and variation applications to help applicants build a high-quality dossier. This will support the issues that we have found during assessment of Route A's which have led to the need for corrections. We issued a further guidance update in July and will be reviewing this again for Q3 24/25. During the webinar, we also provided an overview of updated guidance reflecting queries we have received post launch of the procedure and the new specific IRP pre-submission form that has been developed to assist industry in submitting their queries to support future applications.

3.1.9. 91% of the 573 attendees stated that the webinar met their expectations. 87% stated that they agreed or strongly agreed the webinar increased their knowledge and understanding of IRP and provided invaluable insights to elevate planning and knowledge of their UK regulatory strategy.

3.1.10. The second release of the eligibility checker will go live in early September to introduce Type II Variations for New Indications. This is an area of considerable interest from applicants. The MHRA continue to address individual queries and simultaneously enhance guidance in line with areas identified for further clarification and new scenarios presented in planned applications. We are planning to hold a further webinar to illustrate updates to guidance, answer questions and share feedback on most frequent errors to reduce the number of questions raised.

3.2. Collaboration

Collaboration with UK Healthcare partners

3.2.1. Enhanced collaboration is key to achieving our goal of early access to medicines. While we are focused on refining our processes and improving efficiency with IRP, we are also committed to working closely with our partners to ensure that we evolve together, aligning on our shared objective.

3.2.2. Joint pipeline/ pre-submission meetings are being explored with healthcare partners to enhance the current pharmaceutical horizon scanning platforms, giving us greater and early visibility. This will enable us to proactively prepare for upcoming developments, ensure appropriate resource allocation, and facilitate constructive discussions with industry stakeholders.

3.2.3. A workshop in collaboration with NICE is scheduled for end of September. It will aim to map out organisation processes and understand interactions and impacts of work across the market access pathway for IRP and national licensing activities. A key objective is to develop a comprehensive understanding of the information required by various organisations and to identify areas where we can reduce duplication of efforts during our assessment process. This initiative is aimed at enhancing efficiency and ensuring a more streamlined approach to our operations, thus saving time.

Engagement with Industry

3.2.4. Ongoing pipeline meetings with industry are fostering engagement and enabling us to validate the information obtained from UK Horizon Scanning platforms. The pipeline meetings enhance our understanding of emerging scientific advancements, allowing us to prepare the necessary resources and skills for assessing anticipated applications for both IRP and national procedures. This approach not only aids in shaping their strategy but also allows us to influence our strategic positioning, as discussed in the Section [4].

International Collaboration

3.2.5. The MHRA is to fostering collaboration with UK health partners, reference regulators, and industry stakeholders. Organisations such as the World Health Organization and DEFRA have shown interest in our operation of IRP, and we actively share our learnings as we evolve to help shape the regulatory landscape. We have also received high interest from other regulators, Heath Canada, South African Health Products Regulatory Agency and regulators in the Andean region, who are looking to improve their reliance/ recognition procedures. Our aim is to leverage the opportunities presented by IRP to enhance the regulatory options and drive successful outcomes for patients, regulatory authorities and marketing authorisation applicants.

4. Strategic positioning, forecasting and resource

4.1. Strategic Aim: to ensure patients get early and sustainable access to medicines, ensuring the agency has the capability to deliver national assessments the fastest route to market, whilst utilising the assessment capabilities from other regulators to drive efficiencies enabling more licence approvals.

4.2. Focus of the national activities can centre around disease areas which are to be agreed and could be proposed to be: Cancer, ATMPs, Respiratory, Cardiovascular, Renal.

4.3. While the successful adoption of the International Recognition Procedure is a significant achievement, it is crucial to maintain a balance between direct national and IRP applications, especially as we maintain our position as a leading regulator that is referenced by others. This equilibrium is essential to ensure that our UK patients have the earliest possible access to breakthrough, life-saving medicines and a range of established medicines with continuity of supply. To achieve this, we need to balance and optimise our resources through various regulatory pathways that enable us to deliver medicines authorisations in the most efficient manner possible.

4.4. IRP allows us to achieve this as we leverage the work conducted by other regulators, where companies are unable to apply to us first, enabling us to focus our assessment resources on the direct national route for new innovative or novel therapies and established medicines including first generics.

4.5. We have two groupings of applications which may be submitted, Innovative and Established Medicines.

Innovative Medicines

4.6. It is considered that we should look to support choice of organisations, however we can provide greater influence on the applications in the Innovative category. This is as time to market, is made up of both the original approval and the subsequent reference regulatory approval, which is significant in the overall time to market for typically unmet medical need applications. It is considered that currently we should configure the balance of these to approximately 50% through each of the national and recognition routes. This includes the applications of new indications via the type II variation route.

4.7. A forecast has been conducted using trends from previous years, data collected from companies on their development pipelines, along with information from UK Pharmascan. Based on this analysis, we anticipate a year-on-year increase in the number of applications submitted to the MHRA, with a projected 25% rise in submissions of New Active Substances by 2026.

4.8. To drive this 50:50 split, our pipeline discussions serve as an effective platform to influence our strategic positioning, allowing us to share our goals with industry stakeholders. We have received positive feedback and a strong willingness to collaborate in shaping the regulatory landscape, combined with proactive planning for what's to come.

4.9. The benefits of this approach allow expertise to ensure rigorous review capability for new and emerging technologies are considered by the MHRA. This is balanced with the requirement to utilise a recognition route building on reviews by our reference regulators. To aim for any less national review as a proportion of applications would compromise the long-term capability of the Agency to develop and maintain the expertise necessary to make appropriate assessments of new and novel technologies.

Established Medicines

4.10. In the established medicines space, we are less able to drive the demand for the split between direct national and recognition routes and are more subject to the demand of organisations to launch medicines which generally are aimed at increasing patient supply in a competitive environment.

4.11. Through market intelligence we expect to receive 70% of applications via the national route, with the remaining 30% utilising IRP. Organisations see benefit in having the UK original application for supply in the UK market and beyond.

4.12. We expect to see an increase over and above long-term trends for the use of IRP for a period of approximately 3 -5 years for the supply of those medicines which are marketed in other jurisdictions. This will allow new entrants to the UK market as suppliers, and new formulations to enter the UK market providing that they demonstrate equivalence with the UK Reference product.

4.13. We have received a high interest in the use of IRP for generic applications, specifically referencing the FDA. Some challenges are found with this due to the unavailability of some assessment reports from regulators such as FDA and Health Canada. This can be due to timelines for their issue or application types not having reports issued. We are actively working to address these challenges by evolving our IRP process to meet stakeholder needs, ensuring that we offer a variety of regulatory options to manufacturers seeking to supply medicines to the UK.

4.14. We anticipate that the development of guidance for accepting generic applications without all documents from the reference regulator may lead to a further increase in applications via the IRP route typically through Route B activity. This will increase assessment requirements. Appropriate resourcing post March 2025 is essential to allow this to develop further. We anticipate that our established medicines portfolio will experience a 30% increase in submissions to the MHRA (IRP and national) as these challenges are overcome. Estimates will be part of the rolling forecast of submissions which is planned to be updated twice per year to enable improved budgeting.

Lifecycle Management

4.15. The management of variations through the lifecycle can be changed by the MAA at any point, these can be assessment though national or changed reference regulators from the original application. Therefore the definition and the reliable delivery of assessment of our variation management process will drive this use, and therefore providing a change to ensure UK assessment for UK procedures can be conducted with a benefit for patients and industry.

Overall considerations

4.16. Our primary objective remains to have all routes of application being efficient and attractive. We require a sufficient quantity of applications to be submitted through the direct national route to enable long term sustainability and attractiveness of the UK regulatory process.

4.17. Further activity is ongoing to support this goal, we are reviewing timelines for the national procedure to enhance its attractiveness to the industry. We continue to drive this initiative through active engagement with companies, influencing their submission plans and aligning our processes to better meet industry needs.

4.18. Our aim is to ensure UK patients access medicines as they are developed and soon after large markets such as the US. To enable this, we suggest our core mandate would be to drive applications in the UK ahead of the position we are trending to, ie a second wave country thereby driving the national assessment for target applications to be in the first wave of regulator approvals.

4.19. The MHRA holds a distinctive position as a regulator that both recognises the decisions of other regulatory bodies and serves as a reference regulator in various jurisdictions. Our active participation and engagement in global initiatives such as the International Committee on Harmonisation, the World Health Organization, as a recognised stringent regulatory authority, will further enhance our global presence.

4.20. There is the ask from industry to deliver assessment reports to be utilised globally as the reference regulator. As an example, we have recently been asked to provide assessment reports for treatments for 2024 Covid Vaccine Approval, as we are ahead of other regulators.

4.21. Our commitment to supporting access to medicines extends beyond the UK, as we actively encourage the industry to leverage our assessments through the national route to facilitate access in international markets. We have received significant interest from markets in Asia, the Middle East, and Latin America in utilising our assessment reports to facilitate access to medicines within their regions.

5. Key considerations and next steps

5.1. **Monitor:** We will continue to carefully monitor the process and performance of IRP. It is expected to see an increase in applications submitted to the MHRA, in the generics area where revised guidance will enable more generic applications to be made. We continue to review the required resources to deliver these applications.

5.2. **Development**: Further process development to address areas where there may be gaps in reference regulator information or associated assessment reports for generic applications are being detailed. Targeted assessments of the original information supporting these applications will be conducted to ensure that the UK requirements are met, and that the generic product is interchangeable with other products on the market. Additional checklists will be designed for applicants to facilitate this assessment and reduce the numbers of issues observed preventing validation of applications. We are piloting this with active engagement over Q3, following this we can confirm the effectiveness and efficiency of this approach.

5.3. **Collaboration**: We have established close working relationships especially with the Reference Regulators on Recognition, as the dynamic landscape of regulatory requirements evolving in RR countries poses a significant challenge. Proactive measures are also being put in place to ensure changes in requirements planned in the next years in the EU are appropriately considered and evaluated. It is critical to maintain oversight of changing regulatory standards across the diverse jurisdictions. We have been working with the RRs to achieve this and focus on strengthening this relationship with our partners will continue.

5.4. **Resource**: Resource is currently shared for submissions under IRP, national route, EAMS, ACCESS consortium, Project ORBIS and scientific advice meetings. The current budget for IRP included as part of the Innovation funding from 2023, finishes in March 2025, which will mean making permanent the resources delivering IRP as this is an essential fee generating area, to ensure we continue to deliver.

5.5. **Self-Audit**: A second internal self-audit will be conducted to review the quality and decision making on applications the organisation has received via IRP. Where inconsistencies are found, a root cause analysis will be conducted to mitigate the issue and optimise ways of working. Key metrics of numbers of applications received

and duration of processing will continue to be actively monitored and provided to internal and external stakeholders.

6. Recommendation

6.1 The Board is asked to note the progress made in implementing and evolving the IRP process, communicating with industry through webinars and updates to guidance and that close monitoring is in place to ensure appropriate progress in all areas of the procedure.

6.2 The Board is asked to comment on any further developments which balance attractiveness of IRP with National Processing to ensure we are optimising our regulatory pathways to deliver medicines to the UK patients that need them.

6.3 Confirm the requirement to determine the appropriate national approach and focus areas for resources.

Julian Beach
September 2024

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

Title	What were the results of the evaluation of the Patient and Public Involvement Strategy and how will these help put patients at the heart of all Agency activities?
Board Sponsor	Rachel Bosworth
Purpose of Paper	Assurance / Strategic Direction

What were the results of the evaluation of the Patient and Public Involvement Strategy and how will these help put patients at the heart of all Agency activities?

1. Executive Summary

1.1. The current Patient Involvement Strategy, launched in autumn 2022, ends in late 2025. An assessment and evaluation of progress to date has been carried out and this paper summarises findings, recommends areas for improvement, and outlines a timetable to publication of a refreshed strategy 2026 onwards.

2. Introduction

2.1. The current Patient Involvement Strategy, launched in autumn 2022, ends in late 2025. An assessment of progress to date was conducted between September 2023 and March 2024. The MHRA Patient, Public and Stakeholder Engagement team (PPSE) collated examples of patient involvement from across the Agency and commissioned an independent external contractor to conduct semi-structured interviews with staff, patients and patient groups with knowledge of the Agency, and group discussions with a sample drawn from the wider population. The findings have been discussed by the Executive Committee (ExCo) and the Board's Patient Safety and Engagement Committee (PSEC).

2.2. In implementing the Patient Involvement Strategy, the MHRA is implementing a complex intervention; with multiple interventions across different business areas. An article by Gibson et al (2017)[1] guided thinking about the key questions to pose when looking at the corporate effort.

- Are there multiple ways for public and patients to be involved?
- Who sets the agenda? Whose concerns?
- Does the patient have a strong or weak voice? Are they "heard".

2.3. In summary evidence was collected through:

- Desk research conducted by the MHRA Patient, Public and Stakeholder Engagement team.
- Interviews with members of the public familiar with MHRA work, both those contributing on MHRA patient involvement strategy in general, and those

[1] Gibson A, Welshman, J, Britten N. (2017) Evaluating patient and public involvement in health research: from theoretical model to practical workshop. *Health Expectations*, Volume 20, Issue 5, October 2017, pages 826-835. **https://doi.org/10.1111/hex.12486**

who have engaged on specific lived experience of a condition or treatment. A total of ten semi-structured interviews were conducted.
- Three focus groups were conducted with members of the public with health issues but no previous contact with the MHRA.

2.4. Limitations of the approach
- This is a relatively small-scale study. Findings are based on desk research and a small number of semi-structured interviews.
- The evaluation was coordinated by MHRA staff. It is arguable that this introduces a level of bias to reporting.

2.5. *Feedback to patient contributors*. Feedback was shared with the Patient Group Consultative Forum at a meeting on 3 September.

2.6. *Overall assessment of the evaluation*. While the evaluation does not offer generalisable results, it gives useful insight into how the Patient Involvement Strategy can be refreshed and which patient involvement quality standards need attention.

3. Findings

3.1 An online report will be published on GOV.UK in due course. The following offers a top line summary.

3.2 A good range of examples of patient involvement and engagement were found across the Agency, adapted to business needs (Annex 1 offers examples). The Patient, Public and Stakeholder Engagement team (PPSE) ensured that training and induction is in place for all staff, support and written material is available for staff planning engagement activity. The MHRA is represented at relevant Arms-Length Body discussion groups and other fora.

3.3 Interviews with MHRA staff suggested general support for, and understanding of the drive for increased patient involvement over the last two to three years. However, patient involvement was recognised as hugely resource intensive. Staff voiced a need for continued support in accessing patient populations and in developing interview skills.

3.4 The external researchers' overall impression of the interviews with patients and patient groups suggested a recognition of the journey that the Agency was on. However, although movement was seen as in the right direction, it was early days and there much more to do. Although there was praise for the Agency's PPSE team, there was some criticism more generally of the Agency's approach. For example,

- There was frustration about the opportunities to contribute, and it was not clear to respondents that their contributions were valued or indeed used.
- Some felt that Agency “listening” was poor. Respondents saw “listening” as including “responding” with feedback. Yellow Card was cited as an example of poor listening with no follow up nor outward communication.
- Outward communications were valued by public and patients, and increased focus would be welcome.
- There was little sense that there were opportunities to help set the agenda, nor acknowledgement of patient-defined priorities.
- Support for those members of the public talking to experts needs to be reviewed as the experience can be intimidating.

3.5 Three focus groups were held with members of the public with little knowledge of the MHRA. Among this small sample, there was some knowledge of medicine recalls but in general little knowledge of how to raise a concern. Preferences for reporting concerns included online methods and through healthcare professionals.

4 Next Steps

4.1 A report on the findings from the evaluation will be available on GOV.UK in late 2024.

4.2 For the remaining period of the current Strategy (September 2024 to December 2025), further PPSE staff time will be invested in explaining quality standards in patient involvement to staff across the Agency, encouraging their adoption. In addition, effort will focus on assessing the impact of patient contributions and feeding back to those patients who give of their time. The Patient Group Consultative Forum (PGCF) membership will be refreshed and expanded, with MHRA staff given the opportunity to present their work to the Group and receive feedback.

4.3 A revised strategy (2026-2031) will be launched in late 2025. Priorities for the following five years will be identified through discussions with partner agencies and patient groups. We anticipate that the timetable will be as follows:

- January-July 2025, seek views from partner agencies and public
- July – September, preparation of a new strategy document
- Oct-Nov, sign-off and online publication

5 Financial implications

5.1 Continued work in 2024-2025 on quality standards is already within current budget.

5.2 As priorities for 2026 onwards are identified, more information on costs will be provided.

6 Recommendation

6.1 That the Board note the key findings.

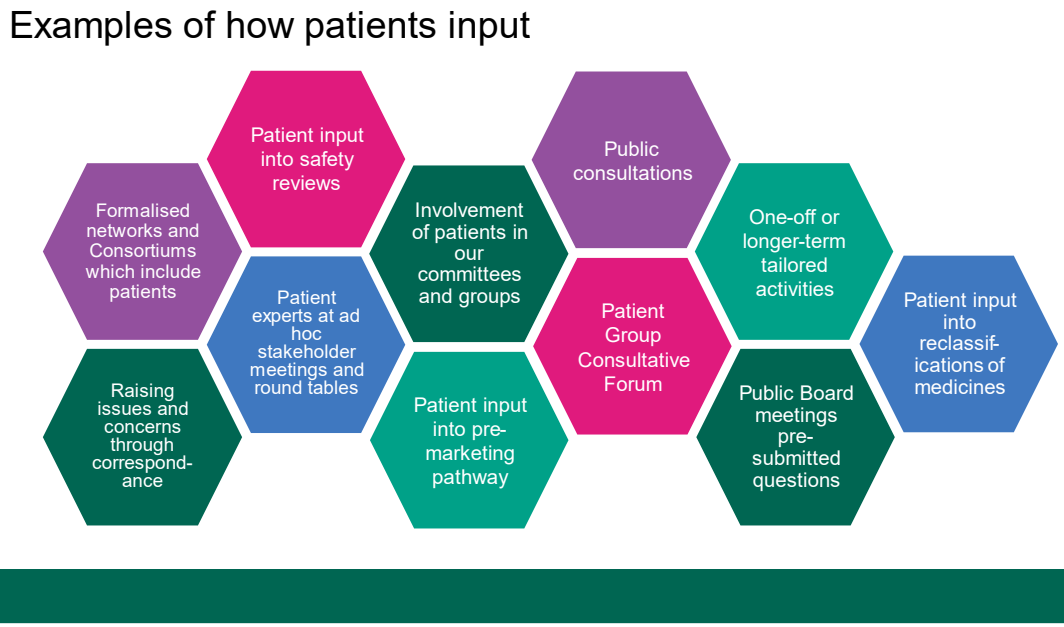
6.2 That the Board comments on the findings.

6.3 That the Board agrees the forward plan for a strategy refresh.

Rachel Bosworth
17 September 2024

ANNEX 1 – Examples of Patient Involvement and Engagement across the MHRA Regulatory Pathway

Figure 1 below summarises ways in which public and patients input into Agency business.



Looking across the regulatory pathway, the following offer more detailed examples.

Getting new medicines and medical devices to market

As part of a pilot engagement event in 2023, members of the public were invited to discuss Software as a Medical Device. This has helped the Agency consider public understanding of software in healthcare, their expectations of how these devices would be used, and their preferences for how such software should be regulated.

As part of the *Cancer Immunotherapy Vaccines Expert Working Group (CIV EWG)*, patient views will be considered in the regulation of these new products. The PPSE team supported the participation of two of the Patient Experts in the April CIV EWG

Patient and public experts took part in the selection of the eight products for the Innovative Device Access Pathway (IDAP).

Improving access to medicines

Healthcare Quality and Access have been working to involve patients in decision-making pre-marketing authorisation for medicines. For example, staff met with sickle cell patients to understand the lived experience of individuals living with this rare disease as part of the process of authorising the world-first gene therapy Casgevy. Patient experts have been recruited to the Cancer Immunotherapy Vaccines Expert Working Group.

Balancing the benefits and risks

In recognition of the findings in the Independent Medicines and Medical Devices Review led by Baroness Cumberlege, the Safety and Surveillance Group has focused much of its patient involvement activity on the work of the Benefit-Risk Evaluation team, ensuring patient views are considered in safety reviews.

- Staff worked with patients on the review of the existing guidelines for healthcare professionals on pulse oximeters and inaccuracies with darker skin pigmentation
- Staff worked with patients on the risk-benefit review of the cystic fibrosis drug Kaftrio. An edited recording of group discussions with patients and parents of children taking Kaftrio was shown to the Neurology Pain and Psychiatry Expert Advisory Group. Members of the charity who ran the discussion, together with patient experts, were present in order to answer any questions after the recording was viewed.
- Two parents of children who have experienced changes in behaviour and mental health challenges following treatment with Montelukast shared their experiences with the Pharmacovigilance Expert Advisory Group.
- The Commission on Human Medicines heard directly from patients, carers and those who support them (e.g., charities, health care professionals) to understand patient views and experiences on the safety of prescribing sodium valproate.
- Patients prescribed fluoroquinolones presented their experiences at the Commission for Human Medicines
- Patients and other stakeholders presented to the Isotretinoin Expert Working Group.

Building a patient focused agency

In-house guidance has been developed to help assessors identify how to include the patient voice in their decisions and the PPSE team has worked directly with staff to deliver involvement activities. For example, patients and patient groups have been involved in safety reviews of valproate, isotretinoin and topiramate.

An external contractor was commissioned to review how the Agency currently recruits and supports Committee members drawn from the wider population (lay members). The aim was to understand how to strengthen these processes, with a view to improving the number and diversity of lay representatives across our committees. Work is ongoing.

As well as advising other Business Groups on engagement activity, the Patient, Public and Stakeholder Engagement Team has:

- Led on initiatives to develop the Agency's patient-focused culture. The team worked with the University of Oxford to produce a series of videos of patient talking about their experiences of medicines and devices. These "*Patient Stories"* are released for internal viewing every other month. In addition, a section on patient involvement is now included in the Agency staff induction.
- Increased efforts on voluntary sector and academic liaison.
- Led on liaison with Arms-Length Bodies on the Shared Commitment to Public Involvement, the NHSE-led People and Communities Committee and its Sub-Committee on Payment.
- Produced tailored guidelines to support staff focus on issues such as safeguarding, data protection and designing consultations. A policy on payment of public and patient contributors is under development.

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

17 September 2024

Title	Is the Board assured that the current Health & Safety measures are effective and how can these be further strengthened?
Board Sponsor	Nicola Rose
Purpose of Paper	Assurance

Is the Board assured that the current Health & Safety measures are effective and how can these be further strengthened?

1. Executive Summary

1.1. Health and Safety management is provided for the entire MHRA through a team in the Science & Research Group. The specific H&S requirements for the MHRA's South Mimms Laboratory Campus are routinely audited by the Health and Safety Executive (HSE) as part of a scheduled Intervention Plan. Some specific activities, for example our work on radiation, are also subject to scrutiny by external bodies such as the Environment Agency and also HSE.

1.2. Review of the wider MHRA governance around health and safety is provided through the MHRA's internal governance committee structure and reporting requirements and is externally reviewed through the Government Internal Audit Agency (GIAA) at intervals. The most recent of these audits took place earlier in 2024 and gave moderate assurance with some recommendations made for improvements to enhance the health and safety maturity model.

1.3. This paper presents measures to strengthen the assurance of regulatory compliance.

2. Introduction

2.1. The work of the MHRA is wide-ranging and hence requires a broad application of health and safety oversight. The Board receives a general health and safety annual report with an overview on all activities, and to provide assurance that health and safety measures are effective.

2.2. Specific areas of interest expressed by the Board this year have been around the monitoring by HSE through its normal intervention plan programme and the MHRA's response to any findings in relation to those interventions.

2.3. Since March, following an Improvement Notice from the HSE, there has been a local action plan comprising existing audit, inspection and monitoring arrangements, and comparing with best practice across the biosafety sector.

2.4. There is closer working between Health and Safety and Quality Assurance to develop a common approach to auditing across the Science Campus, including process-based audits to provide an improved level of assurance. Improvements are being made to inspection templates for users to ensure that safety critical controls are checked and monitored on a regular basis, including spot checks on SOP compliance.

2.5. The work above to address the HSE requirements has also included a full review of safety procedures in containment level 3 (CL3) laboratories to support the longer-term goal of improving our systems. Refreshed training has been rolled out to each CL3 laboratory alongside a renewed process to assure that protocols capture safety-critical tasks in a clear and comprehensive manner.

3. Current position

3.1. A H&S management system requires continuous improvement, with all aspects subject to the process of Plan-Do-Check-Act. A number of actions are under way to further strengthen the systems in place at the MHRA.

- Work is continuing to address the HSE Improvement Notice, with close interaction with HSE to ensure a robust process of audit, inspection and monitoring is put in place.

  The Health and Safety team is to be strengthened by the addition of a Bio risk Adviser post that is under recruitment.

- An independent expert has been engaged to advise on the options for a new 'model' of Health and Safety given the new scientific challenges and opportunities for the Agency, hybrid working etc in the context of how similar organisations with a variety of models of service delivery manage their Health and Safety responsibilities.

3.2. A H&S sub-group of the MHRA Executive Committee is now in place under revised governance arrangements and is responsible for assuring progress against actions arising from audits, clarifying and reviewing end to end governance forums relating to H&S, and for considering and advising on the appropriate future model of H&S delivery for the Agency.

3.3. Training is being enhanced in several areas to support the requirements set out for improved auditing and monitoring processes, and to consider improvements in risk assessment techniques. We are looking at some external training provision to support these areas, and to further enhance our existing internal training programme.

3.4. Capital investment for the MHRA needs to ensure that health and safety requirements are being closely monitored. We regularly review the prioritisation of capital projects to ensure continued investment in current and future needs for infrastructure and equipment, with safety as a critical category in the prioritisation process.

4. Recommendation

4.1. Is the MHRA Board assured that the activities described here underpin the strengthening of our H&S measures?

4.2. Does the Board wish to suggest any modifications to the current plan or further actions to strengthen how the Agency fulfils its Health and Safety responsibilities?

Nicola Rose
17 September 24

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

17 September 2024

Title	**What assurance can be provided following the meeting of ODRC 12th August 2024**
Board Sponsor	Amanda Calvert
Purpose of Paper	Assurance

What assurance can be provided from the meeting of ODRC?

1. Introduction

The Organisation Development and Remuneration Committee (ODRC) met on 12th August 2024

- To review the progress on the Return to Green Programme with focus on the clearance of backlogs.
- To review progress against delivery of Phase 2 of Regulatory Connect Programme.
- To discuss the proposals for improving recruitment processes for the agency.
- Review proposals for executive remuneration.

2. Review of progress of the Return to Green (RtG) programme and timelines for elimination of backlogs

The committee reviewed the progress that has been made following the re-establishment of the programme in Q1 2024.

- Root Cause Analysis – There has been excellent progress to undertake a root cause analysis and to produce a roadmap of interventions for scientific advice and safety amendments with the remainder of projects due to be produced by end August.
- Root causes and proposed interventions have been collated across key categories of
    - Communication
    - Culture
    - Process
    - Regulations and Policy
    - Resources
    - Technology
- This analysis and proposed interventions provide an excellent framework for all leaders and teams within the Agency to use in order to improve both operational performance and the delivery of projects. Many of the proposed interventions are simple and practical steps that can be taken by leaders and team members immediately.
- The committee noted that this was one of the best analyses they had seen which outlined both root causes of issues and offered practical actions for improvement.
- The committee welcomed the closer integration of the RtG programme and the Route to Moderate programme. Together these two programmes can codify improved ways of working to implement and sustain improvements in working processes into “business as usual” operations policies and procedures.

3. Progress with elimination of backlogs

- **Progress –** The committee were pleased to see that there were agreed trajectories for eliminating all the different types of backlogs. Progress was reviewed and the highlights are summarised below

    - Established Medicines (EM) – From 1st September all newly received applications should be assessed within statutory guidelines. Regular meetings continue with trade associations and further industry webinars are planned for September.

Additional resources including a new cohort of pharmaceutical assessors continue to strengthen the expertise within the team

- Clinical Trials – No backlog. All applications are being cleared within statutory timelines. Work on laying new regulations has resumed following the election pause.

- Innovative Medicines – The backlog has been reduced from 7 to 3. Biosimilars will now be assessed with their own team.

- Variations – The types of variations have been categorised and assigned to relevant teams. The backlog for the simpler Type 1B variations was cleared as planned on 31 July. The more complex Type 2 variations backlog is on track to be cleared by end December 2024. Type 1B and type 2 safety variations are on track to be cleared by end of September 2024.

- Inspections – Root cause analysis work has been completed and process improvements have been identified. These will be developed into an improvement plan to deliver inspections in line with statutory requirements and to clear the backlogs by end December 24.

- Scientific Advice – There has been increased priority on improving performance in this area. Improvements in the processes and guidance for offering and delivering scientific advice to applicants as well as the types of advice offered are being reviewed.

4. Regulatory Connect

Release 1 delivered in March 2024 continues to support the improvements in performance across the Agency.

The committee were informed that Release 2 which was designed to deliver improvements in internal case management of product licencing, clinical trials and inspections would not deliver at end November 2024 or within its original budget.

Measures have been taken to control spending. This included pausing work on the clinical trials, inspections and medical devices modules. Work will continue on product licencing module for 3 months after a full review of the programme has been completed and a revised business case and implementation plan is agreed.

The programme governance board members are working together to reframe the programme and to exert leverage over delivery partners to ensure that there is focus on delivery of this important programme.

5. Recruitment

Recruitment of staff with appropriate skills has been a high priority for the Agency and the committee wanted to be assured that lessons had been learned following some of the challenges that had been experienced during the transformation programme.

The level of recruitment activity was reviewed. The recruitment team remains small although has been strengthened recently with new permanent members joining. Whilst Agency turnover levels have now reduced to a healthy 8% from a peak of 17% in

December 2022, the levels of recruitment remain at least double the historical levels (pre-2020) and this puts pressure on this small team.

Improvements have been made in several areas including securing funding to develop the MHRA brand, securing a LinkedIn recruiter licence and the procurement of the Oracle Recruit platform which is currently being configured and implemented to improve the candidate experience.

Successful graduate and apprenticeship schemes have been launched with 8 graduates starting in 2023 and over 40 apprentices welcomed to the Agency.

Plans are in place to develop medium- and long-term plans for recruitment including a bigger focus on candidate experience and on-boarding and less reliance on contingent workers and fixed term contracts.

6. Executive Remuneration

A review was undertaken by the committee and the CEO.

7. Concluding Remarks

- The Return to Green programme has undertaken a comprehensive root cause analysis into the causes of poor performance in the delivery of statutory services and has suggested actions that need to be taken to improve and sustain performance. The committee strongly supports the implementation of these proposals which include:
    - Improve communications to industry and stakeholders and continue to build performance management metrics and reporting
    - Better sharing of data across the agency to improve cross functional working
    - Improvements in the regulatory assessment decision-making processes to ensure closer collaboration between groups, collective assessment of relative risks and benefits and clear escalation routes where agreement cannot be reached.
    - Faster implementation of the governance framework discussed in the May ODRC to clarify roles and responsibilities to encourage collaboration and faster decision-making.
- The backlogs that have been identified in licencing applications are on track to be cleared by end December 2024 and new processes are being embedded to sustain this performance.
- Improvements have been identified to improve delivery of scientific advice and inspections. These need to be progressed to avoid backlogs developing.
- Regulatory Connect is not going to deliver Phase 2 improvements that included new technology to support product licencing, clinical trials and inspections process improvements within the original timescale (November 2024) and budget.
- A complete review of the programme including looking at the governance and performance of the IT partners. A revised business case and implementation plan is being developed.
- Work is progressing to deliver the product licencing module and progress will be reviewed after 3 months.
- Progress is being made to tailor recruitment processes to be more closely aligned with needs of the Agency and to improve the experience for candidates. The agency offers

opportunities to people with a wide range of skills ranging from digital specialists through to scientists, medical professionals and policy experts.

- The graduate and apprentice programmes have been particularly successful both for the agency and for the candidates.

Amanda Calvert
Chair of the Organisational Development and Remuneration Committee
August 2024

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

17 September 2024

Title	What assurance can be provided by the Patient Safety and Engagement Committee (PSEC)?
Board Sponsor	Mercy Jeyasingham
Purpose of Paper	Assurance

What assurance can be provided by the Patient Safety and Engagement Committee (PSEC)?

1. Executive Summary

1.1 PSEC discussed patent safety and engagement on four substantive items which were: Antidepressant Patient Information Leaflets safety advice review – how can we manage expectations while conducting stakeholder engagement on a focused issue?; Review of women's health regulatory inequities for medicines and medical devices – recommendations and implementation; Topiramate safety review – how will we know if regulatory action was effective in protecting patient safety?; Clozapine review - how should we conduct a comprehensive stakeholder engagement to ensure a balance of representative views are obtained?

1.2 On antidepressants PILs safety advice the Committee discussed the proposed stakeholder engagement and emphasised the need to make sure that the benefits and risks of treatment are sensitively handled during stakeholder engagement and with any future developments in patient information. Surveying organisations such as the Samaritans, Young Mind and others were suggested as a way of potentially segmenting the survey recipients, so the views of a diverse group of users on the wording of product information for patients could be considered.

1.3 The review of women's health regulatory inequities was well received, and the Committee endorsed the recommendations and roadmap on delivery.

1.4 The concerns on the growing use of topiramate during pregnancies and further evidence linking developmental issues with topiramate led to a further review informed by patients views. The Committee noted the proposed approach for monitoring the effectiveness of the new safety measures, which included plans for further engagement with stakeholders. After some scrutiny the Committee was satisfied with the quality and breadth of stakeholder engagement.

1.5 Supporting the safe use of Clozapine is of particular concern and the Committee agreed that broader stakeholder engagement is required. It will be important to proactively communicate with all stakeholders to ensure that they are kept up to date as the work on safe use of clozapine progresses in order to maintain public trust. The Committee noted the successful engagement with patient charities and professional organizations, which will be crucial in gathering feedback and ensuring the measures resonate with stakeholders.

2. Introduction

2.1 The Patient Safety and Engagement Committee met on the 5th September 2024 and introduced the new PSEC lay member. The PSEC agreed the actions arising from the meeting of 9 May 2024.

3. MHRA Antidepressant Patient Information Leaflets safety advice review – how can we manage expectations while conducting stakeholder engagement on a focused issue?

3.1 Antidepressants are a large group of medicines used to treat depression as well as a range of other conditions including pain, generalised anxiety disorder, post-traumatic stress disorder, eating disorders, obsessive compulsive disorder and phobias. There are 30 different active ingredients within the antidepressants on the UK market which are held by 105 marketing authorisation holders. Following various detailed assessments of the data within the UK and Europe over the years, the product information for some antidepressants currently contains warnings about the risk of suicidal behaviours and sexual dysfunction which may continue after stopping treatment. These issues remain under close monitoring using routine pharmacovigilance processes. However feedback from patients and families is that current information in the Patient Information Leaflet on the risks of suicidal behaviours and sexual dysfunction which may continue after stopping needs to be improved and is likely to be overlooked and ignored by patients who have a diagnosed mental illness. The aim of the current review is to explore how to improve the Patient Information Leaflet wording on these important safety issues.

3.2 The Committee deliberated on the options for stakeholder engagement including a survey and the challenges of conveying these matters to patients, considering their diversity, the variety of active ingredients, and their mental health conditions. The Committee felt it was important that the risks are not amplified as not taking medication could cause patient harm. The Committee suggested that a focussed approach with organisations such as the Samaritans, Young Mind and others as well as focus groups to develop communication approaches to consider the needs of different groups of patients may be a better approach.

4. Patient and Public engagement with MHRA Review of women's health regulatory inequities for medicines and medical devices – recommendations and implementation

4.1 A review was conducted by MHRA of the current national and international regulatory landscape in women's health for medicines and medical devices. Historically 'women's health' has tended to focus on their fertility, reproductive capabilities and illnesses associated with women's reproductive organs and life course events such as menstruation and menopause. While these areas are important, comparatively little attention has been paid to the health needs of women outside these spheres and in particular how the performance and safety of medicines and medical devices may vary in women. Recommendations from the review and a roadmap on implementing those recommendations were discussed at PSEC. The review identified themes covering all stages of the life cycle of products from clinical trials to post marketing surveillance.

4.2 PSEC discussed the regulatory focus of the agency, drugs in pregnancy, clinical trials, the organisations we can work with and influence, the work of the FDA, and the diversity of women especially socio-economic and ethnic differences. It was supportive of the proposals for patient and public engagement review and recommendations.

5. Topiramate safety review – how will we know if regulatory action was effective in protecting patient safety

5.1 Topiramate is approved in the UK for the treatment of epilepsy in adults and children and also for the prevention of migraine headaches in adults. It has been known for some time that topiramate may harm a baby if it is taken during pregnancy – it is linked to an increased risk of birth defects and an increased risk of the baby being born smaller and weighing less than expected. New data has become available from observational studies suggesting a potential increased risk of autism spectrum disorder, attention deficit hyperactivity disorder and effects on learning development in children born to mothers who took topiramate during pregnancy. Following a recent review of the safety of use of topiramate during pregnancy, new contraindications to use of topiramate have been introduced and a Pregnancy Prevention Programme is being implemented. These measures aim to support safe the effective use of topiramate, protect public health by minimising the risk of exposure of children to topiramate in the womb, and to reinforce awareness of the risks and improve adherence to risk minimisation measures.

5.2 The patient perspective was informed by a small number of listening sessions held with patients living with epilepsy and also patients living with migraine. Data was also considered from the Medicines and Pregnancy Registry (MPR) and CPRD suggesting increasing use in female patients of childbearing age and a high number of topiramate exposed pregnancies. The Committee noted the proposed approach for monitoring the effectiveness of the new safety measures, which included plans for further engagement with stakeholders.

5.3 After some scrutiny the Committee was satisfied with the quality and breadth of stakeholder engagement. The team flagged the need to consider engagement strategies tailored to those with learning difficulties going forward. The team clarified that post-marketing studies are not yet underway, some of which will be conducted by the Marketing Authorisation Holders in due course. The Committee highlighted an opportunity to engage and influence at the protocol design phase to enhance data collection.

6. Clozapine safe use review - how should we conduct a comprehensive stakeholder engagement to ensure a balance of representative views are obtained?

6.1 Clozapine is prescribed when other medicines have failed for schizophrenia as well as severe disturbances in thoughts and behaviour of people with Parkinson’s Disease. It provides an effective treatment for patients with no other treatment options. Clozapine is associated with a range of potentially life-threatening side effects and interactions with other medicines that must be effectively monitored and managed to minimise the risk. Stakeholders including members of the media, coroners, clinicians, academics and family members of patients taking clozapine or patients who died whilst taking clozapine, have contacted the MHRA raising some separate, overlapping and contradicting concerns.

6.2 Safe use of clozapine is of particular public concern and broader stakeholder engagement is required. It will be important to proactively communicate with all stakeholders to ensure that they are kept up to date as the work on clozapine progresses in order to maintain public trust. PSEC noted key stakeholders have been advised that this is likely to be an in depth review, particularly with respect to consideration of the haematological monitoring requirements due to the extensive data involved.

6.3 The Committee noted that successful engagement with patient charities and professional organizations, will be crucial in gathering feedback and ensuring the measures resonate with stakeholders. The Committee was satisfied with the quality and breadth of the proposed stakeholder engagement. The team flagged the need to consider engagement strategies tailored to those with learning difficulties going forward.

7. PSEC Forward Plan

7.1 The forward plan for the committee was discussed to schedule topics in a timely way and to determine what questions the committee would like addressed. Further discussions with Chief Officers and senior staff are planned to ensure a broad range of topics that cover the whole of the agencies work.

8. Conclusions

8.1 The Patient Safety and Engagement Committee discussed the need to consider surveys before they were conducted or reviews early in their implementation. This would ensure that advice and scrutiny from the committee on MHRA plans for Patient and Public engagement are given in a timely manner.

Mercy Jeyasingham
Chair, Patient Safety and Engagement Committee
Non-Executive Director MHRA
September 2024