Medicines & Healthcare products Regulatory Agency

AGENDA FOR BOARD MEETING HELD IN PUBLIC

10:00 – 12:30 on Tuesday 18 March 2025

Chair: Professor Anthony Harnden

	AGENDA ITEM	**PURPOSE**	**PRESENTER**
10:00	INTRODUCTION		
	1. Purpose of the meeting; Board attendees & absences	Information	Chair
	2. Declarations of Interest	Information	All
	3. Minutes from the last meeting	Approval	Chair
	AGENCY PERFORMANCE		
10:10	4. CEO's report – current activities and priorities	Context	June Raine
10:30	5. Monthly financial and people performance of the MHRA at the end of month 10	Assurance	Rose Braithwaite
	CERSIs		
10:50	6. Centres of Excellence in Regulatory Science and Innovation	Strategic direction	Harriet Teare
	INNOVATION		
11:10	7. Innovative Pathways for Medicines and Medical Devices	Strategic direction	James Pound / Louise Knowles
	YELLOW CARD SCHEME		
11:30	8. Increasing awareness of the Yellow Card Scheme	Strategic direction	Alison Cave
	BRITISH PHARMACOPOEIA		
11:50	9. British Pharmacopoeia strategy	Strategic direction	James Pound / Peter Crowley
	EXTERNAL PERSPECTIVE		
12:15	10. Questions from members of the public on the items on this Board meeting agenda		Chair
12:30	CLOSE OF MEETING		

MHRA Board Declarations of Interest – March 2025

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 Anthony Harnden Chair	Registrant Council Member General Medical Council and Chair of Remuneration Committee (term of appointment finished on 31 December 2024)	Former chair	Yes	No
	University of Oxford Employee and Chair of the Examination board for Masters in Global Health Leadership	Employee and Chair	Yes	Yes
	Co-applicant on a NIHR grant relevant to vaccine safety: Influenza, MenACWY, HPV and COVID-19 vaccines in children: uptake, safety and effectiveness during the COVID-19 pandemic in the UK (01/04/2024 – 31/03/2025)	Co-applicant	Yes	Yes
	Director of Morland House HealthCare Ltd	Director	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
	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

Name and MHRA Role	Name of Other Company or Organisation	Nature of interest	Paid	Current
	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	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
Professor Graham Cooke Non-Executive Director	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

Name and MHRA Role	Name of Other Company or Organisation	Nature of interest	Paid	Current
	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
Dr Paul Goldsmith Non-Executive Director	Cambridge University ARIA NeuroWorks Scientific Advisory Board (SAB)	Scientific Advisory Board member	No	Yes
	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
	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
Mercy Jeyasingham MBE Non-Executive Director	NHS South West London Integrated Care Board	Non-Executive Member	Yes	No
Raj Long Non-Executive Director	Gates Foundation	Ex-Employee – Deputy Director	Yes	No
	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

Name and MHRA Role	Name of Other Company or Organisation	Nature of interest	Paid	Current
	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
	OLS Neurodegenerative Mission	Committee Chair	TBC	Yes
Nicola Rose Interim Executive Director, Science and Research	None	N/A	N/A	N/A
Michael Whitehouse OBE Non-Executive Director	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

Medicines and Healthcare products Regulatory Agency

Minutes of the Board Meeting Held in Public on 19 November 2024

(10:00 – 12:30)

Large Meeting Room, NIBSC, Blanche Lane, South Mimms

Present:

The Board

Professor Graham Cooke	Non-Executive Director & Interim Co-Chair
Dr June Raine DBE	Chief Executive
Rachel Arrundale	Deputy Director, Partnerships
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 Nicola Rose	Interim Executive Director, Science & Research
Dr Laura Squire	MedTech Regulatory Reform Lead (Chief HQA Officer)

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
Dr Jessica Wright	Head of Yellow Card Biobank, MHRA

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.

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

2.1. Apologies were received from Michale Whitehouse, Non-Executive Director.

2.2. The Board reviewed the Declarations of Interest (DOIs) for all MHRA Board members. 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. Updates were provided 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 mpox; virology; antimicrobial resistance; new reference materials for influenza; new International Standards; WHO International Standards; the Coalition for Epidemic Preparedness Innovations; Scientific Advice; Clinical Trials; the Innovative Licensing and Access Pathway (ILAP); Alzheimer's disease; and Agency publications;

(ii) **Healthcare access** – including updates on established medicines performance; innovative medicines licensing; the International Recognition Procedure; highly personalised cancer vaccines; companion diagnostics; the International Medical Device Regulators' Forum; the AI Airlock; digital mental health; and e-cigarettes;

(iii) **Patient Safety** – including updates on the Patient Safety Commissioner Principles; GLP-1 agonists; glucose monitoring systems; Yellow Card Biobank recruitment; devices compliance; Criminal Enforcement Artificial Intelligence; the UK Real-World Evidence Network; CPRD patient and public involvement and engagement; the International Society of Pharmacovigilance; and the International Conference of Drug Regulatory Authorities;

(iv) **Partnerships** – including updates on Point of Care manufacture; Medical Device Post-Market Surveillance; Medical Device Pre-Market legislation; and the International Coalition of Medicines Regulatory Authorities;

(v) **Digital and technology** – including updates on RegulatoryConnect; technology maintenance; a 'Rewiring The State' roundtable; and the Gartner European Technology Symposium;

(vi) **Dynamic organisation** – including updates on Business Plan 2024/25; Patient and Public Community; Windsor Framework engagement; the 'Route to Moderate' programme; Freedom of Information; Healthcare organisations system alignment; and Recruitment and workforce planning; and

(vii) **Financial sustainability** – including an update on the Fees consultation.

4.2 The Board thanked Dr Raine for her report and provided comments relating to the new Government's NHS 10-year plan; diagnostics; improving update in to the NHS of new transformative products; personalised medicine; AI in healthcare and horizon scanning; delivery of a target development programme roadmap for ILAP to contribute to the 10-year plan; utilising the recommendations of the Sudlow report to improve data flow for patient safety; supporting prioritisation in the NHS; gaining a greater understanding of the pipeline of disruptive innovative technologies; the cancer vaccine launchpad; the Agency's strong relationship with the FDA; how the Agency is feeding in to the work of the Regulatory Innovation Office; engineering biology; early collaboration; greater transparency; making improvements in productivity and efficiency; and highly personalised cancer vaccines. The Board agreed that the pathway for personalised medicines should be brought to a future meeting for review. The Board thanked Dr Raine for the report.

Action 131: Provide the Board with a paper describing the pathway for personalised medicines. ***Julian Beach***

5. Item 5: What was the financial and people performance of the MHRA at the end of Q2 of 2024/25?

5.1 The Board considered a report describing the financial and people performance of the MHRA at the end of Q2. The Board noted the report and provided comments relating to identifying savings; the increase in recruitment speed; the loss of trading fund status meaning that the Agency is not able to utilise retained surpluses from past years; making improvements in forecasting to increase accuracy to prevent end of year over- or under-spend; addressing staff absence related to mental health, stress and workload; RegulatoryConnect underspend; and ensuring revenue and capital allocations are correct in the current budgeting process. The Board noted the report.

Action 132: Share the letter from ONS regarding removal of Trading Fund status with the Board. ***Rose Braithwaite***

6. Item 6: What was the Agency's Operational Performance in Q2 of 2024/25?

6.1 The Board reviewed the Agency's operational performance against the Key Performance Indicators in Q2. It was noted that 77% of objectives are on track; two are expected to be late and 11 are showing as at-risk and are being monitored. Five out of eight KPIs were off-track at the end of Q2. However, four KPIs are associated with backlogs which are being managed through the Return to Green (RtG) programme where we continue to see a notable reduction in backlogs. These four KPIs will continue to show off-track until the backlogs have been cleared.

6.2 The Board noted the update and provided comments relating to the progress that has been made in a number of areas; clearance of the established medicines backlog and impacts on other KPIs due to the focus in this area; it was agreed that an update on the trajectory established medicines performance will be brought to a future Board meeting. The Board provided further comments relating to the delay on RegulatoryConnect; it was noted that the RegulatoryConnect programme board are closely reviewing progress.

Action 129: Include insight into the themes of complaints the Agency receives in the next report on performance against the Business Plan.

Rose Braithwaite

PATINET SAFETY

7. Item 7: What has been achieved in 60 years the Yellow Card Scheme, and how are we paving the way for the future?

7.1 The Board considered a paper describing the achievements of the Yellow Card Scheme (YCS) during its 60 years of activity, and considered how the aims and activities continue to strengthen the scheme, and how they continue to adapt to technological and cultural changes are sufficient to ensure the Yellow Card scheme continues to support patient safety. The Board provided comments relating to public awareness of the YCS and considerations on how to improve this, including potentially setting targets in the MHRA Business Plan; improving outreach to diverse populations and communities; utilising the NHS app; utilising AI such as automation in triaging, and natural language models to interrogate free text narratives for information; analytical methodologies for signal detection; development of educational materials; and feedback to reporters on what has happened with their report.

7.2 The Board provided further comments relating to impacts on prescribing practice; improving reporting rates for medical devices including software as a medical device; linkage with the Yellow Card Biobank; implementing stratified targets; working with the voluntary sector and charities to improve patient awareness; making improvements to the Patient Information Leaflet; the work of the MHRA's 6 regional Yellow Card Centres to promote reporting; and utilising existing channels to improve awareness.

7.3 The Board provided further comments relating to addressing issues of data qualtiy and standardisation throughout all data systems in the health system;

international collaboration; tackling health literacy; working with community pharmacists and other healthcare professionals to improve awareness and reporting; how the work of the YCS contributes to the NHS 10-year plan; and reviewing real world data as a source of information for the YCS.

Addition to action 128: Consider setting targets in the Business Plan regarding increasing the awareness of the YCS; provide the Board with a proposal to this effect. Alison Cave

8. Item 8: What are we learning so far from the Yellow Card Biobank pilot studies, including the patient perspective?

8.1 Dr Jessica Wright joined for this discussion. The Board considered a paper describing the learnings from the Yellow Card Biobank (YC Biobank) pilot studies, to inform development of a future operating model. The Board provided comments relating to recruitment of participants; leveraging clinical trials to improve recruitment, and potentially integrating this with clinical trials in future; considerations of how to scale up; data linkages within the health system; careful consideration of what will provide the most value to patients; and increasing the use of genomics in the drug development pathway.

8.2 The Board provided further comments relating to prioritisation such as focusing on high value drugs or common syndromes; the seriousness threshold; established drugs which have higher patient exposure; phenotypes; ensuring high quality of the data that the YC Biobank generates; and when the data gathered will have enough power to enable review. The Board thanked Dr Wright and requested a further update on an analysis of the pilot, how work will be prioritised for maximum public benefit, and a proposal of the future model.

Action 134: Provide the Board with an analysis of the results of the Yellow Card Biobank pilot; including how work will be prioritised for the maximum public benefit, and a proposal for the future YC Biobank model. Alison Cave

ASSURANCE

9. Item 9: What assurance can be provided by the Organisational Development and Remuneration Committee?

9.1 The Board considered an assurance report from the Organisational Development and Remuneration Committee (ODRC). The ODRC met on 7th October 2024 and reviewed the progress on the integration of the Return to Green (RtG) Programme and the Route to Moderate (RtM) Programme; progress of RegulatoryConnect Programme; the wellbeing survey results and actions to improve performance; and the Annual Review of Equality and Diversity performance. The Board noted the update and provided comments relating to corporate risk taking; culture and leadership; assurance mapping; supporting and communicating with staff

to enable change in working practices; and reviewing the results of exit interviews, which will be considered at the next ODRC meeting. The Board noted the report for assurance.

EXTERNAL PERSPECTIVE

10. What questions do members of the public have for the MHRA Board?

10.1 The Board answered a range of questions which had been submitted by members of the public before and during the meeting. These questions concerned the Yellow Card Scheme including following up with reporters; the process of signal detection and the MHRA's role in taking action on a safety issue; lessons learned from demand signalling and use of horizon scanning for future capacity challenges in the NHS; and meetings with industry to understand the pipeline.

ANY OTHER BUSINESS

11.1 The Board noted that Dr Raine was recognised by the International Collaboration for Medicines Regulatory Authorities (ICMRA) for outstanding contributions to the work of ICMRA. Dr Raine noted this reflects the Agency's international role and its excellent work across basic science, regulatory innovation and real world evidence.

11.2 No further items of other business were raised, and the Chair closed the meeting.

MHRA
November 2024

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

18 March 2025

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 backlog of medicines licensing applications by end of March; all applications received from 1 September 2024 will meet statutory timelines.
- Innovative medicines approved in February include nemolizumab (Nemluvio) to treat eczema and prurigo nodularis and gozetotide (Illuccix) for diagnosis of prostate cancer.
- We licensed a new vaccine to protect against Chikungunya disease (Ixchiq) and an mRNA vaccine (mRESVIA) to protect against respiratory syncytial virus (RSV).
- Our public consultation on draft guidance on the regulation of individualised mRNA cancer immunotherapies (cancer vaccines) is attracting wide interest and comment.
- Supporting the government's mental health mission, we published new guidance on the characterisation, qualification and classification of digital mental health technologies.
- We issued a safety reminder for healthcare professionals relating to sodium valproate harms; review by two specialists is required if starting treatment in patients under 55.
- Our review of dependence associated with gabapentinoids, benzodiazepines and Z-drugs, aims to better communicate risks of addiction, withdrawal and tolerance.
- We continue to review the safety of breast implants and will be updating our webpage to reflect the latest data on Breast Implant Associated-Anaplastic Large Cell Lymphoma.
- High-profile media outreach by our enforcement unit continues on the risks associated with buying GLP-1 agonist (weight-loss) medicines without a medical prescription.
- The Research in Europe and Diversity Inclusion project (READI), in which we are a partner, aims to identify and break down barriers to participation in clinical studies.

HEALTHCARE ACCESS

Established medicines Performance

1.1 The backlog of Marketing Authorisation applications for established medicines has continued to be cleared and we are on track to eliminate the backlog by the end of March 2025. Assessment continues on applications submitted after 1 September 2024, and we are on track to meet our commitment to process all of these within statutory timeframes. The focus now is on ensuring sustainable performance and maintaining predictability for all Marketing Authorisation applications.

Innovative medicines

1.2 We approved several new medicines in February 2025, including:

- Nemolozumab (Neluvio) for the treatment of two skin conditions – prurigo nodularis and atopic dermatitis
- Efanesoctocog alfa (Altuvoct) to treat and prevent excessive bleeding in patients with haemophilia A
- Gozetotide (Illuccix), a medical imaging agent approved for diagnosis of prostate cancer

New vaccines

1.3 We also approved two new vaccines in February 2025:

- The chikungunya vaccine (Ixchiq) for adults to protect against the Chikingunya virus
- An mRNA Respiratory Syncytial Virus (RSV) vaccine (mRESVIA) to protect against lower respiratory tract disease caused by RSV.

Blood products made from UK blood donations

1.4 We supported the re-introduction of blood products made from UK blood donations. These are the first products with UK-sourced plasma to be released since 1999. UK plasma had not been used for over 20 years due to concerns about the risk of Variant Creutzfeldt-Jakob Disease, until the Commission on Human Medicines advised that the ban could be lifted following a careful review of all available evidence and the EU also lifted the ban on UK plasma.

mRNA-based cancer immunotherapies

1.5 We have published draft guidance on individualised mRNA cancer immunotherapies (also known as personalised cancer vaccines). This novel technology poses regulatory challenges compared to conventional therapies, and the draft guidance proposes a streamlined regulatory pathway to approval. The consultation on the draft guidance will run until 31 March 2025.

Windsor Framework Implementation

1.6 The remaining key guidance on the Windsor Framework arrangements has now been updated on GOV.UK. The temporary option to apply ‘UK only’ as a sticker, rather than print directly on packaging, ends on 30 June 2025. We are preparing communications to ensure any companies using stickers are ready for this transition. The latest position is that 96% of all Market Authorisations are now fully compliant with the Windsor Framework regulations. We are preparing to reach out to fully non-compliant companies and companies with non-compliant Market Authorisations again and are seeking advice on next steps.

Unlicensed Hormone Replacement Therapy implants

1.7 We have communicated to customers and key stakeholders, such as the British Menopause Society, that stock of an HRT product, Estra 25mg and 50mg, will be released to existing patients. This follows a pause in importing which caused concern among patients who rely on these medicines to manage symptoms arising from the menopause. The importer, SmartWay, has decided not to further import this product to the UK, a position that we support. This is due to serious compliance issues that were raised following inspection of the manufacturing site in the USA, which could impact on the safety of the products.

Government Internal Audit Agency Audit

1.8 The draft audit report was received from GIAA for our licencing area and showed a Moderate rating. The audit showed a Substantial rating for an effective productivity and performance management process in place to mitigate the risk of inaccurate management data. There are ongoing exercises to further improve the process, and the report is currently being finalised.

PATIENT SAFETY

Safety and Surveillance performance

2.1 Approximately 98% of Adverse Drug Reactions (ADRs) were processed within target timeframes, with Industry remaining the single highest source of Adverse Incident Reporting for both medicines and devices. There is an increased number of reports for devices, which is expected to increase further once the new Medical Devices Post-Market Surveillance (PMS) Requirements come into effect in mid-2025. In January, three new safety signals were identified and actions determined and assigned to assessors on the following medicines and devices:

- Risdiplam and alopecia
- Azithromycin and increase in blood alkaline phosphatase (product alignment issue)
- L2-CT1211 Assistive scooters and Reg 28 Prevention of Future Deaths Report

Sodium Valproate

2.2 A Drug Safety Update (DSU) article was published in February, communicating that review by 2 specialists remains in place for patients starting valproate under 55 years of age. However, the Commission on Human Medicines (CHM) advised that it will not be required for men (or males) currently taking valproate given there is sufficient risk minimisation in place for this patient group, but that this position should be kept under review. The DSU includes three infographics which have been developed to provide clarity for healthcare professionals about valproate prescribing. In addition to the DSU we sent an email to key stakeholders, including the Valproate Stakeholder Network, advising them of these changes.

GLP-1 agonists

2.3 We continue to secure significant media engagement, including a broadcast on Good Morning Britain, to raise awareness of the risks associated with buying GLP-1 agonist (weight loss) medicines (semaglutide and terzepatide) online without a prescription. Further media engagement is planned through March on this topic.

Digital Mental Health technologies

2.4 We launched new guidance to safeguard users of digital mental health technologies. We produced wide ranging media and social media activity to support the project, including promoting new guidance, a stakeholder engagement event and a new academic paper. This received extensive pick-up across trade press and many positive endorsements on social media.

Dependency-forming medicines

2.5 We are undertaking a review with the aim of improving information supplied with dependency-forming medicines. The project is being conducted in phases to ensure that the medicines within each phase are given the attention required to ensure a comprehensive review. The current phase of the review is looking at gabapentinoids, benzodiazepines and Z-drugs, and the scope is to evaluate the effectiveness of existing warnings in the product information and labelling of medicines, and where necessary to make improvements to facilitate better communication of the risks of addiction, dependency, withdrawal and tolerance. We will liaise with other relevant healthcare system stakeholders to share the findings of our review so that it can inform future clinical practice and guidelines decisions.

Breast Implants

2.6 We continue to review the safety of breast implants taking into account implant surfaces. Breast Implant Associated-Anaplastic Large Cell Lymphoma (BIA-ALCL) is an uncommon type of cancer that can rarely occur in people who have breast implants. We investigate all reports of BIA-ALCL and confirm cases against specific diagnostic criteria defined by the World Health Organisation. We are conducting a benefit and risk evaluation of breast implants, following an observed rise in reports of BIA-ALCL. The risk of BIA-ALCL increases with the duration of implantation. The MHRA BIA-ALCL webpage is currently being updated to reflect BIA-ALCL reports and overall manufacturer sales figures as of 31 December 2023. Based on the available evidence, our advice remains the same across all breast implants, that there is no evidence to suggest patients should have breast implants removed in the absence of symptoms.

SteriFeed colostrum collector

2.7 In October 2023 we issued a Device Safety Information (DSI) communication regarding a capped syringe colostrum collector, following reports of the syringe inadvertently becoming lodged in babies' throats. The manufacturer proposed to address the issue by marketing a new product as a collection and feeding device in addition to the capped colostrum collector, which was launched in July 2024. However, we considered that this measure would not address the choking risk associated with the original product, constituting foreseeable misuse. The company agreed to a voluntary withdrawal of the capped colostrum collector and has stopped sales as of 1 January 2025.

Innovative Health Initiative on diversity inclusion

2.8 The Innovative Health Initiative (IHI) Research in Europe and Diversity Inclusion (READI) project, in which the MHRA is a project partner, was launched on 16 January 2025. READI aims to identify and break down barriers to participation in clinical studies, co-create tools, resources, and training programs to enable more inclusive study designs, and to develop a cutting-edge digital platform to connect stakeholders and foster collaboration. We are co-leading work to understand and characterise underserved and underrepresented populations through real-world data, including by providing access to data from CPRD.

INNOVATION

Clinical Trials legislation

3.1 The parliamentary debates on the new Clinical Trials legislation occurred on 3 February in the House of Commons and 10 February in the House of Lords. The debates reinforced the importance of creating an agile, innovative and, above all, patient-centred regulatory framework for clinical trials. Once debates have concluded in the Northern Ireland Assembly, a 12-month implementation period will begin to ensure stakeholder and sector readiness. Digital and Technology Group has developed the software code for the IT systems supporting operation of the Clinical Trial systems, which will be ready for the coming into effect of the new legislation in early 2026.

Companion diagnostics with clinical trials

3.2 In February, the MHRA received five new applications for companion diagnostic (CDx) performance evaluation within a clinical trial. We met with a manufacturer to discuss two molecular diagnostic tests designed to detect mutations in different genes known to be commonly associated with various cancers, including colorectal and non-small cell lung cancer. These tests are being used as companion diagnostics for different new cancer treatments across different clinical trials. One CDx was approved to be used in a Phase 1 clinical trial of a new medicinal compound in combination with intensive chemotherapy for treatment of newly diagnosed Acute Myeloid Leukaemia.

Innovative Licensing and Access Pathway

3.3 Following the relaunch of ILAP on 30 January 2025 with the publication of details of the new approach, guidance and details of what is on offer a webinar was held on 5 March 2025 which was attended by over 500 people. The ILAP governance has been established with regular meetings of the ILAP Sponsor Board, the most recent held on 27th February. We are in the process of delivering a new digital ILAP form, which will capture essential data and support document uploads, check incoming documents and provide the functionality to generate a unique reference number for each application and a unique innovation passport number, and to introduce a simple collection mechanism for processing application fees.

Innovation and Compliance Group performance

3.4 The 'resource surge' in the Compliance Team has continued through February and March. Reporting shows a decrease in the number of outstanding cases, and work is ongoing to ensure internal processes are optimised to continue clearing outstanding Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) applications.

Medical devices regulatory reform

3.5 Progress continues on the MedTech regulatory reform, and we are currently drafting the government response to the public consultation that closed in January. The response is expected to be published in May 2025, alongside the response to the 2024 consultation on Common Specification requirements for high-risk In-Vitro Diagnostic (IVD) devices. The Government response to the proposal on assimilated EU law was published in February 2025. The Statutory Instrument (SI) that prevents assimilated EU law from expiring prematurely was laid in early March 2025, and is likely to come into force from late May 2025. The draft 'Pre-Market' Regulations are being refined and will be shared with key stakeholders for expert input prior to publication on the WHO website later this year. Work has begun on the development of the guidance to accompany the Pre-Market legislation.

Good Clinical Practice and Good Laboratory Practice Symposia

3.6 We delivered the Good Clinical Practice (GCP) & Good Laboratory Practice (GLP) Symposia in February 2025, which saw over 800 people attend the GCP Symposium and over 400 people attend the Symposium. The events provided an opportunity for GCP inspectors to engage with industry members on a number of key topics including GCP and GLP requirements, and the impacts of the new clinical trials legislation.

SCIENCE AND RESEARCH

Influenza vaccines

4.1 We made significant contributions to the WHO Consultation on the Composition of Influenza Virus Vaccines for use in the 2025-2026 Northern Hemisphere Influenza Season, held in February. The strains are the same as those recommended for use in vaccines for the Southern Hemisphere for winter 2025. We will make available candidate vaccine viruses (CVV) and serum reagents to support vaccine manufacture and control testing. The committee also recommended two new H5 CVVs to anticipate zoonotic preparedness. We will continue to develop previously recommended zoonotic CVVs and associated reagents to support pandemic vaccine development and preparedness.

DNA Sequencing of bacterial infections

4.2 In collaboration with the Barts Health NHS Trust, we have developed a DNA sequencing approach that can be implemented onsite in hospitals so they can diagnose bacterial infections faster and more accurately. This technology will improve patient recovery and outcomes and reduce the risk of outbreaks caused by antibiotic-resistant bacteria. The new approach was published in *Frontiers in Cellular and Infection Microbiology* in early March 2025.

Bacteriophage development

4.3 We are developing a guidance document on bacteriophage use, designed as a 'yellow pages' of information to direct interested parties to relevant regulatory information. This has had input from a cross-agency group and is expected to be published in March 2025. We are in the development phase of several physical reference materials for the phage 'community', including a genome standard to provide a next generation sequencing and bioinformatics system control standard. We are also in the early discovery phases of developing an integrity standard, to support manufacturing to achieve the right dose of active material, and a feasibility study to design a host cell protein reference method.

Reference materials

4.4 The development of the WHO International Standard (IS) for ranibizumab to facilitate global harmonization of the potency of different products is now reaching completion. Following feedback received from participants, the draft WHO report is being finalised for submission to WHO Expert Committee on Biological Standardization (ECBS) for consideration at its meeting in October 2025. Ranibizumab has been approved as a front-line treatment for age-related macular degeneration and diabetic macular oedema. The manufacturing suite was shut down for the duration of February as part of planned maintenance. Issues identified in the air handling units have resulted in an extension of the shutdown period, and work is ongoing to determine if the facility can operate at risk.

Publications

4.5 Our scientists contributed to the publication of a paper in *Frontiers in Immunology* on complex in vitro respiratory models. The study sought to harmonise aspects of experimental methodology between different laboratories, to assess the comparability of different models of human airway epithelium in the context of respiratory viral infections.

WHO Guideline Drafting Group

4.6 We are part of the WHO guideline drafting group that is responsible for revising the WHO recommendations for the preparation, characterization and establishment of international and other biological reference materials. This guideline underpins our work to develop, produce and distribute biological standards and a draft version will be available shortly for public consultation. We have also contributed into the development of WHO guidance for the replacement of animal tests used for the quality control of biologicals, and a draft document is being prepared.

Health and Safety

4.7 The proposed model for our Health and Safety (H&S) structure is currently under review and will be validated by an external independent expert before proposals are implemented. We have finalised the policy for recording and reviewing H&S incidents and lessons learned and this is being issued to staff from March. We are also progressing the first phase of requirements for becoming a WHO Polio Essential Facility and will provide the Health and Safety Executive with corrective action plans by end of March

Centres of Excellence of Regulatory Science and Innovation

4.8 Seven Centres of Excellence of Regulatory Science and Innovation (CERSI) have now been established to strengthen the evidence base for regulation. The areas of research range from integrating evidence from computational models to diagnostics and genomics. A launch meeting with the key stakeholders will be held on 25th March to ensure alignment of goals and to look ahead to evaluation of impact.

PARTNERSHIPS

Relationship with EU

5.1 Resetting the UK relationship with Europe is a UK Government priority. We have been working on commissions from DHSC and Cabinet Office to input into the UK negotiating position, with initial MHRA priorities focussing on patient safety. Discussions will open in early March on how we can input into the EU pharmaceutical reform proposals.

ACCESS Consortium

5.2 The Access Consortium's Heads of Agencies met on 11 February and endorsed the 2025-2028 strategic plan. This will be communicated publicly on the new ACCESS website and through a letter to industry partners by the end of March. The Consortium's goal is to speed up the pace, and ultimately increase the number of applications assessed, to provide faster access to safe, effective, and high-quality medicines potentially to the collective population of over 150 million.

International Coalition of Medicines Regulatory Authorities

5.3 The International Coalition of Medicines Regulatory Authorities (ICMRA) Executive Committee supported the continuation of the Collaborative Hybrid Inspections Pilot for up to a year with the overall ambition of full reliance. The Pilot looks at improving processes to reduce the number of individual inspections at manufacturing facilities, through coordinated inspection to support approval of post-approval changes. ICMRA will also look to draft a statement of support for initiatives looking at implementing the 3Rs (reduction, replacement and refinement of animal use during regulatory testing).

Visit from Japanese Regulatory Agency

5.4 We hosted the Head of Agency and a high-level delegation of the Japanese regulator, PMDA, on 13 February. The positive and productive meeting discussed areas of mutual interest such as clinical trials, safety, medical device regulations and access to innovative medicines.

DIGITAL AND TECHNOLOGY

RegulatoryConnect

6.1 We remain on target for the go-live for the Product Licencing Release in February 2026. In the immediate period we are progressing plans to scale up teams, following additional funding from the Department of Health and Social Care in December 2024. Work continues to ensure contracts are in place for 1 April for service continuity. Work towards the Inspection and Unlicensed Medicines releases and the Medical Devices release has been under way now for 2 months and is progressing to plan. The next steps will be to determine delivery timelines based on affordability and the business service strategy.

Legacy systems

6.2 The risk score remains unchanged as improvements continue across replacing the agency systems. The strategic backup project is progressing through tender stage, and the end of service life IT equipment replacement is ongoing. The modernisation of Agency backup and telephony systems is also under way and progressing as expected. Work continues to deploy the next tranche of network hardware to replace the Agency's end of life equipment for Network Optimisation, and new management and monitoring tools will conclude roll out in March 2026. Upgrade work on the wider agency performance monitoring tool for Infrastructure and Networks has also begun.

Appian E-Cigarettes

6.3 We continue to support the delivery of changes needed, including coding changes to the existing Appian system to support regulatory adherence in managing disposable e-cigarette product notifications. These changes are expected to be delivered by the end of March 2025, and communications to stakeholders are being closely managed.

AI prototyping workstreams

6.4 Significant progress has been made in the AI prototyping workstreams. A number of prototypes have moved onto the next phase in production, with positive feedback from internal and external stakeholders, as well as other Government organisations. The prototypes cover all areas of the product lifecycle and have significantly reduced processing tasks from hours to minutes.

AI Airlock Project

6.5 We have been working closely with the 4 pilot candidates in the AI Airlock project to ensure completion of testing plans by the end of March. The first simulation workshop was held on 28 February 2025 and focused on addressing hallucinations in AI medical devices and the appropriateness of hallucination evaluation frameworks within the current risk management frameworks of the UK Medical Device Regulations.

Data security training

6.6 Overall combined pass percentages for both Data Protection and Security mandatory training modules is 97.3%. Extra efforts are being made to achieve a 100% completion rate for all of the operating groups. The number of phishing emails reported by staff is higher than the previous months' average, highlighting greater staff awareness due to an ongoing phishing campaign.

FINANCIAL STABILITY

Devices Fees

7.1 The medical devices fees consultation closed on 24 October 2024 and the government response to the consultation was published on 6 March 2025. All proposals, apart from Proposal 2 (the MHRA proposes to amend its Medical Device Registration fee to include the costs for medical device post-market work) will be implemented as planned. This means that for the general uplift of fees, implementation will commence through Q1 2025. For the fees affected by proposal 2, we are exploring alternatives to this fee and will update customers and further stakeholders in due course.

DYNAMIC ORGANISATION

Patient and Public Community

8.1 The second meeting of the Patient and Public Community was held on 12 February 2025. There were over 50 attendees. There were presentations on clinical trials, and we offered feedback on recent patient engagement exercises.

Employee Engagement Strategy

8.2 We are working on our employee engagement strategy following the results of the staff survey carried out in 2024, which revealed our employee engagement index of 59%. The One Agency Leadership Group has identified 7 areas of work including workload and wellbeing. The Employee Engagement Strategy 2025/26 – 2027/28 will aim to support the improvement of employee engagement across all areas by supporting our people to be informed, connected, and inspired within our agency. Performance against the deliverables outlined in the strategy will be reported to relevant committees and the Agency Board, when appropriate.

Procurement Policy

8.3 Leaving the EU has provided the UK with the responsibility and opportunity to overhaul the public procurement regulations. To achieve this ambition the Cabinet Office has undertaken a review of Procurement Regulations 2015 and have now introduced the Procurement Act 2023, which came in to force on 24 February 2025. To ensure we meet the changes to the procurement regime, the commercial team is delivering an iterative implementation approach that will provide training and address accountability while ensuring compliance and value for money.

Events Policy

8.4 We have been reviewing our policies and procedures for attending national and international events, following concerns that the current approach was not delivering controlled decision-making and financial sustainability for the agency. We have agreed that events outside of our strategic priorities will not be attended and specific priority international agreements for the Agency to attend have been confirmed, such as the ACCESS Consortium and the International Medical Device Regulators Forum. Attendance at other national or international events will be determined through a decision-making matrix, and other standard operating procedures and tools, to help ensure staff time and agency resources are protected and managed appropriately.

AGENCY PRIORITIES

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

i. Maintain the Agency's focus on delivering its core business activities with safety as our first priority, meeting targets for all key activities and developing sustainable services

ii. Progressing delivery of the new digital systems to support efficient and risk-proportionate ways of working and piloting use of AI where appropriate

iii. Finalise our science strategy and support delivery of Centres of Excellence of Regulatory Science and innovation

iv. Continue to collaborate with our national partners in healthcare on access pathways for innovative products and with international regulators on recognition, reliance and work-sharing

v. Continue to drive recruitment and invest in strategic workforce planning and staff development to ensure the Agency has the skills and capability to deliver our public health mission.

Dr June Raine, CEO
March 2025

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

16 March 2025

Title	What was the financial and People performance of the MHRA for January 2025?
Board Sponsor	Rose Braithwaite
Purpose of Paper	Assurance

What was the financial and people performance of the MHRA for January 2025?

1. Executive Summary

1.1. The Agency finished January (Period 10) with a year-to-date (YTD) resource net underspend of £4.9m compared to budget, driven by underspends in non-pay operating costs and slightly higher income. The Q3 forecast said the full year underspend would be much smaller at £0.3m, reliant on a significant increase in spend and lower income in the last quarter. Judging by January's results, the underspend is likely to be higher.

1.2. The Capital budget was increased by £4m to £29.5m after further funding from DHSC. At the end of January, capital spend was £20.7m, an underspend to the new budget of £2m. The Q3 forecast is for a full year (FY) spend to increase significantly to £33.6m, a £4.1m overspend. The forecast is unrealistic, and we expect the final outturn to be much closer to budget. Any remaining potential overspend will be delayed into next year when the Capital budget is higher.

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 from past years to offset the current forecast overspends.

2. Financial Performance

Resource Spend (RDEL)

2.1. The Agency's resource (RDEL) forecast changed from a £4.7m overspend at Q2 to a small £0.3m underspend at Q3.

2.2. The actual income and expenditure figures from January showed higher income and lower expenditure than forecast (see Table 1), With a £4.9m YTD underspend against budget there will need to be a significant uptick in expenditure or a reduction in income over the final two months of the financial year to deliver the Q3 forecast. The Agency is at risk of a higher full year underspend.

2.3. The Executive Committee are monitoring this closely. With this risk in mind they have approved additional areas of spend in staff costs and to deliver additional functionality on the Safety Connect system.

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

January 2025	Period		Variance vs	YTD		Variance vs	Full Year		Variance vs
Resource	Actual £M	Budget £M	Budget % / £M	Actual £M	Budget £M	Budget % / £M	Forecast £M	Budget £M	Budget % / £M
Trading Income	8.7	8.8	(1%)	85.0	82.8	3%	101.9	100.5	1%
Service Fee Income	3.8	3.8	1%	37.5	37.5	0%	45.0	45.0	0%
Grant Income	1.0	0.4	135%	3.8	4.6	(18%)	4.2	5.4	(23%)
Total Income Position	**13.5**	**13.0**	**0.5**	**126.2**	**124.9**	**1.3**	**151.0**	**150.9**	**0.1**
Staff Costs	8.9	8.2	(8%)	82.6	81.0	(2%)	99.9	97.6	(2%)
Operating Costs	5.4	5.1	(6%)	52.5	57.3	8%	65.8	68.3	4%
Total Cost Position	**14.3**	**13.4**	**(1.0)**	**135.1**	**138.3**	**3.3**	**165.6**	**165.9**	**0.3**
Operating Net Position	**(0.8)**	**(0.4)**	**(0.4)**	**(8.8)**	**(13.4)**	**4.6**	**(14.6)**	**(14.9)**	**0.4**
Project Grant Income	0.0	0.3	(96%)	2.2	2.7	(19%)	2.8	3.4	(17%)
Staff Costs	0.6	0.7	11%	5.3	6.3	17%	6.3	7.7	17%
Projects Costs	1.1	1.0	(12%)	11.3	11.1	(2%)	16.1	15.3	(5%)
Projects Net Position	**(1.7)**	**(1.4)**	**(0.4)**	**(14.3)**	**(14.7)**	**0.3**	**(19.6)**	**(19.6)**	**(0.0)**
Agency Resource Net Position	**(2.5)**	**(1.8)**	**(0.8)**	**(23.2)**	**(28.1)**	**4.9**	**(34.2)**	**(34.5)**	**0.3**
DHSC RDEL Operational Funding	2.0	2.0	0%	19.7	19.7	0%	23.6	23.6	0%
DHSC RDEL Innovation Funding	0.7	0.3	139%	6.7	6.9	(3%)	8.0	8.0	0%
DHSC RDEL AI Funding	0.1	0.1	0%	0.8	0.8	0%	1.0	1.0	0%
DHSC RDEL IDAP Funding	0.2	0.2	0%	1.6	1.6	0%	1.9	1.9	0%
Total Resource DH Position	**2.9**	**2.5**	**0.4**	**28.8**	**29.0**	**(0.2)**	**34.5**	**34.5**	**0.0**
Total RDEL	**0.3**	**0.7**	**(0.4)**	**5.6**	**0.9**	**4.7**	**0.3**	**0.0**	**0.3**

Income

2.4. Operating Income at the end of January was £126.9m, £1.3m above the YTD budget and £0.8m better than the Q3 forecast. Trading income is the largest element of this at £85m, £2.2m above budget. Service fee income at £37.5m is at budget. Although grant income in January performed above budget, the YTD actual still lags behind budget, but this is offset by lower grant related costs.

2.5. Considering January's income results, it now looks likely that income will finish the year higher than the Q3 forecast. HQA income in particular looks stronger than predicted with a likely £1.5m surplus to forecast. At the same time, the risk of a quiet Q4 flu season for S&R also represents a £0.3m risk to the forecast depending on the strain chosen.

Staff Costs

2.6. Year to date operational staff costs are £82.6m, 2% over budget reflecting the number of new roles and fixed term contract extensions approved since the start of the year. January actual of £8.9m was slightly higher than forecast because of a catch up in the recognition of Agency staff costs. The YTD actual is in line with the Q3 full year forecast.

2.7. Projects staff costs for January were very slightly below budget, contributing to a £1m YTD underspend. This is in line with the FY forecast underspend of £1.4m.

Non-Pay Costs

2.8. Spend on non-pay operating costs in January was £5.4m, although this result is inflated by a £1m overstatement of accommodation costs that are currently being revised. Without accommodation costs, the result would be £4.4m, significantly behind the £6.2m monthly forecast. This is important because the Q3 forecast was reliant on increased non-pay spend in Q4. If that doesn't materialise as planned, the FY underspend will be higher.

2.9. Year to date non-pay operating costs are £52.5m, £5.2m behind budget. The Q3 forecast was for spend to increase to £65.8m based on higher spend on IT costs, contracted-out services and building repairs and maintenance. However, we now expect the FY outturn to be lower.

Project Resource Expenditure

2.10. Projects' YTD RDEL net position in January was £14.3m, a small underspend of £0.3m compared to budget. We expect the CERSI payment to be made in February and a small increase in the spend run rate in Reg Connect and CPRD projects. That means the full year project net position should finish the year at budget.

CAPITAL

2.11. All the capital budget for the Agency must 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 £29.5m after an extra £4m was allocated by DHSC. YTD spend is £20.6m, a £2m underspend compared to the new budget. January saw an increase in capital spend in South Mimms, Reg Connect and CPRD projects.

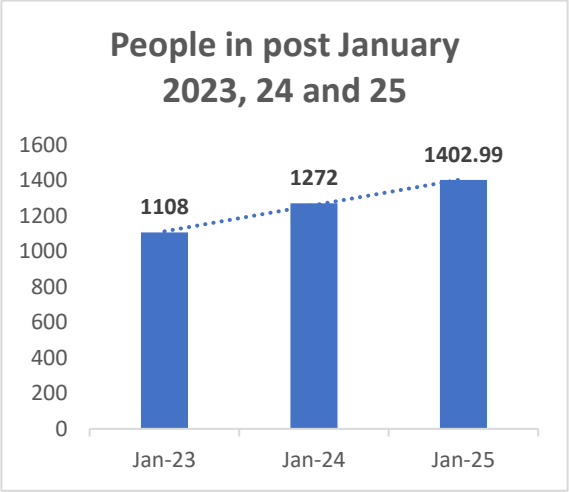
2.12. The FY Capital forecast is for spend to increase significantly to £33.6m by the end of the year which would be a £4.1m overspend. Most of the extra spend is in Reg Connect (£4m over the original budget), and South Mimms (£2.1m over budget). The forecast is unrealistic, and we expect the final outturn to be much lower. We expect new spend projects to meet delays or find more realistic spend profiles. Any remaining potential overspend will be delayed into next year when the Capital budget is higher.

Table 2 – Capital spend to the end of January 2025

January 2025 Capital	Period		Variance vs	YTD		Variance vs		Full Year		Variance vs
	Actual £M	Budget £M	Budget % / £M	Actual £M	Budget £M	Forecast % / £M	Budget % / £M	Forecast £M	Budget £M	Budget % / £M
Projects Costs	2.0	0.9	(121%)	16.1	16.1	1%	0%	21.4	17.6	(22%)
CDEL Operational Costs	1.6	0.9	(86%)	4.5	5.5	(18%)	17%	12.2	7.9	(55%)
Agency Capital Net Position	**(3.6)**	**(1.8)**	**(1.8)**	**(20.7)**	**(21.6)**	**(0.5)**	**0.9**	**(33.6)**	**(25.5)**	**(8.1)**
DHSC Capital Funding	2.3	1.8	29%	22.6	21.6	(11%)	5%	29.5	25.5	16%
Total Capital DH Position	**2.3**	**1.8**	**0.5**	**22.6**	**21.6**	**(2.7)**	**1.0**	**29.5**	**25.5**	**4.0**
Total CDEL	**(1.3)**	**0.0**	**(1.3)**	**2.0**	**0.0**	**(3.2)**	**2.0**	**(4.1)**	**0.0**	**(4.1)**

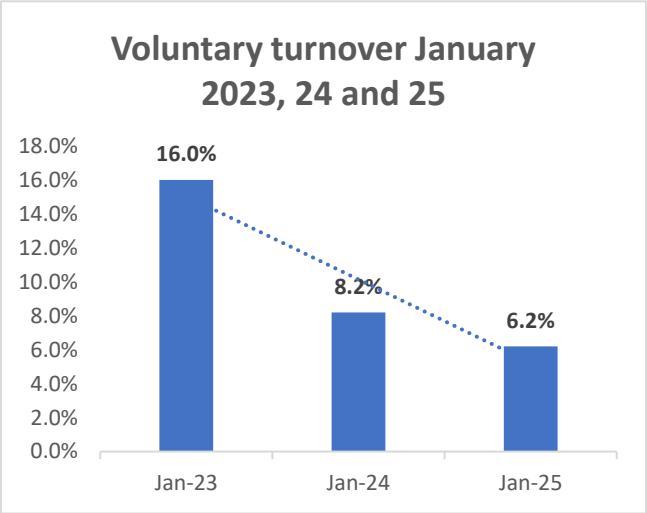
People

2.13. We had 1,402.99 people in post at the end of January 2025 (FTE, permanent, fixed term and PhD students covering established posts), an increase of 15.33 on the end of December. Of this number, 166.95 were fixed term, a decrease of six. Looking at our people data over time, we can see a steady growth in our people in post, an increase of 26.6% compared to January 2023.



Turnover

2.14. The level of turnover remains a challenge. We regard the optimum turnover as between 8-10%, providing ongoing promotion opportunities and new thinking, whilst maintaining operational stability. 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 twenty-seven new starters to the Agency in January versus eight voluntary leavers (14:10 in December).

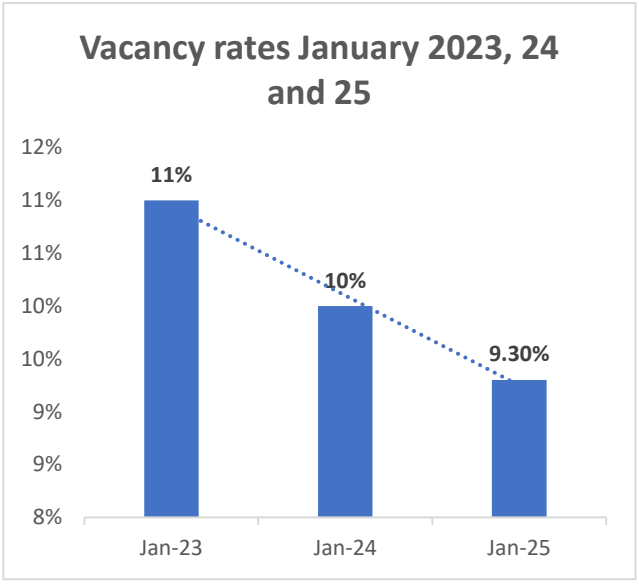


Vacancies

2.15. In respect of our 139 'vacancies' (a decrease on the 143 reported for December due to the creation of new posts), these are split by Group as follows in January:

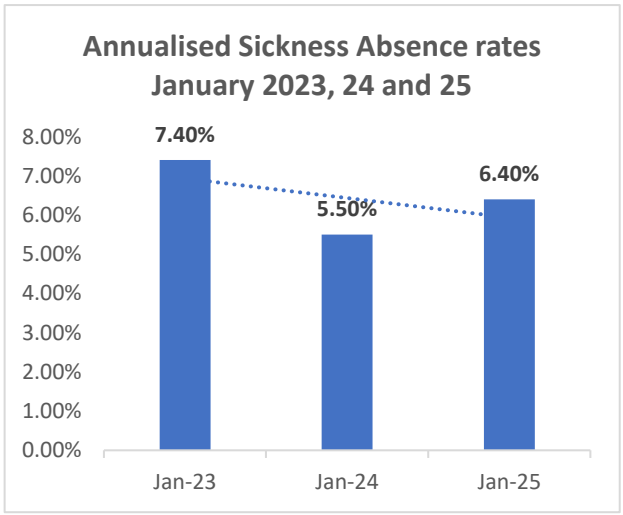
Group	Vacancies count	% vacancies FTE
Corporate	8	6.6%
Digital and Technology	36	28%
Enablement	3	2.5%
Healthcare Quality & Access	47	10.6%
Partnerships	1	3.0%
Safety & Surveillance	27	8.4%
Scientific, Research & Innovation	17	5.2%
Grand Total	**139**	**9.3%**

2.16. Vacancies may be covered by contingent workers or a temporary promotion, with the substantive post filled similarly, hence we do not see the budget impact of 10% voids. Overtime, vacancy rates are declining. We know that gaps in teams contribute to backlogs and general work overload for staff, and this may be reflected in our absence rates.



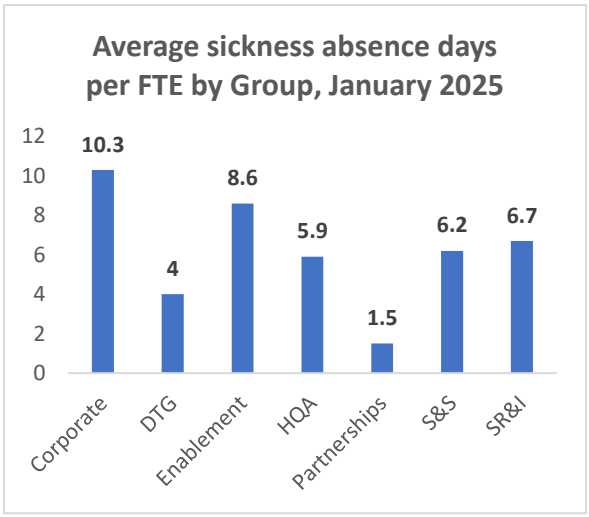
Sickness Absence

2.17. Sickness absence (annualised) is reported as 6.4 days per FTE, a reduction on the 6.9 days reported in December and November. Absence has increased and decreased by marginal amounts across the Groups. Data for the smaller groups can be disproportionately impacted by several cases of long-term sickness absence.



2.18. Current levels of sickness absence are not a concern and not out of kilter with the wider Civil Service at this time of year, but the reasons for absence remain so, with over a third of all absence reportedly due to stress, depression or anxiety.

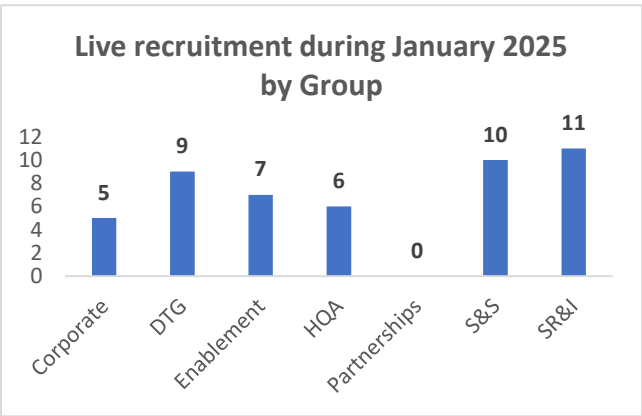
2.19. The highest level of absence remains in the Corporate Group, which is made up of Finance, HR, Commercial and Infrastructure & Laboratory Services functions, followed by Enablement, which is Governance, Strategic Programme Delivery and Communications and Engagement functions.



2.20. We are actively utilising all of our available resources to look to reduce stress in the workplace and will be shortly creating a Less Stress Working Group, to focus on what senior leaders, managers and staff can do to reduce the levels of stress in their work areas, whether this be through improved ways of working or right sizing teams.

Recruitment

2.21. Recruitment activity continues at high pace, in a reactionary manner in the main. Staff in grades AA – SEO have one months' notice, and it can be difficult for hiring managers to respond quickly to begin the recruitment process in that short time, leading to temporary promotion or contingent arrangements. However, roles G7 and above give 3 months' notice, and so hiring managers are much better placed to get quite some way down the recruitment journey before the postholder leaves. During January, there were 46 roles 'live' ie newly advertised, actively interviewing/shortlisted or closed during the month.



2.22. We reported in December that we are working to proactively recruit some posts in cohorts at planned times in the year. However, lack of recruitment resources is impacting on the speed at which we can move to new ways of working and needs to be addressed if this pace is to continue. We will report more detailed recruitment metrics each quarter, for more in-depth analysis and trends that monthly data will not show.

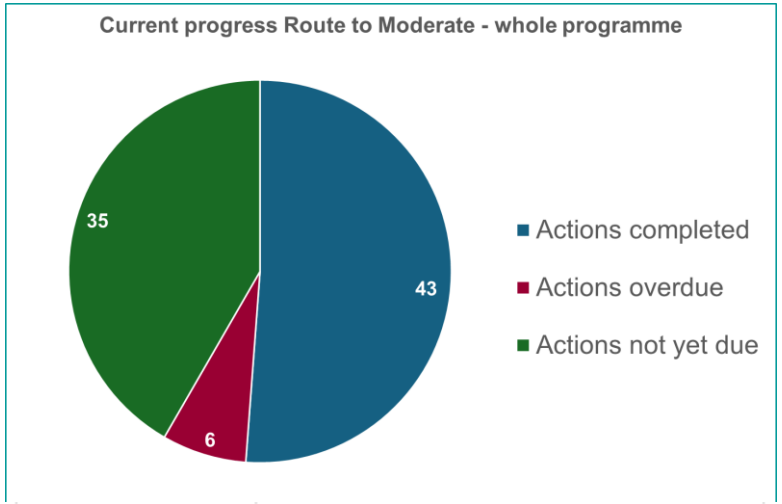
3. Recommendation

3.1. The Board is asked for their views on the January financial performance and projections for year end.
3.2. Does the Board have any comments in particular on the plans to address stress in the workplace?

Rose Braithwaite, CFO

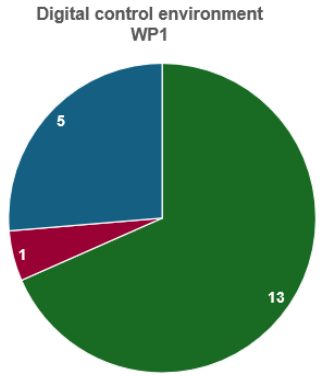
03 March 2025

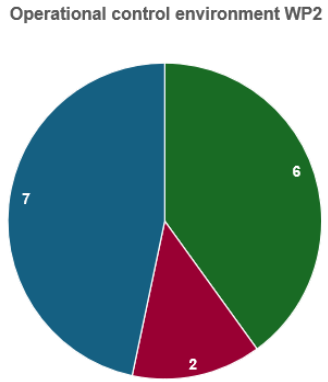
Route to Moderate – Current progress

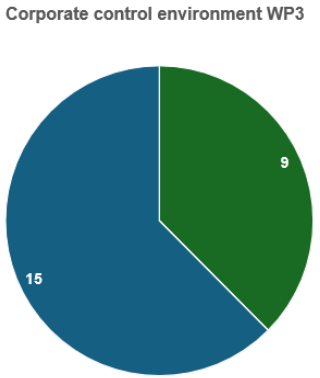


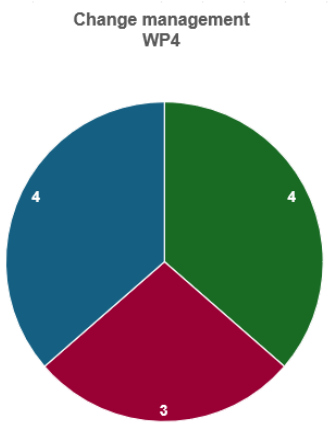
- 43 actions delivered.
- 35 actions due in coming months: (23 due in March, 4 due in April, 5 due in May, 1 due in June, 1 due in July and 1 due in December)
- 6 actions overdue:
  - See table on slide 3 for details.

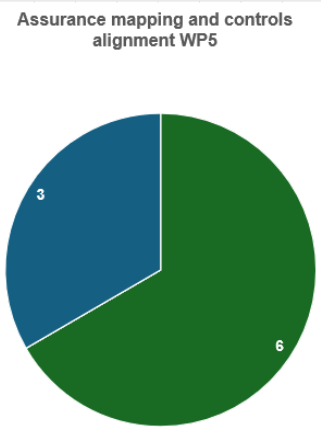
Work Packages	**Percentage progress against expected target.** **Green**: Percentage progress against expected target equal or greater than 0 **Amber**: Percentage progress against expected target between -1 and -25 **Red**: Percentage progress against expected target equal to or less than -25
Work Package 1	-7%
Work Package 2	-25%
Work Package 3	0%
Work Package 4	-43%
Work Package 5	0%
Work Package 6	0%
Whole Programme	-12%

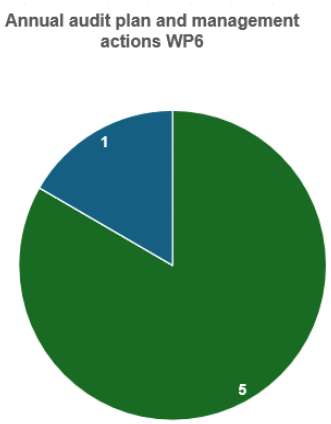










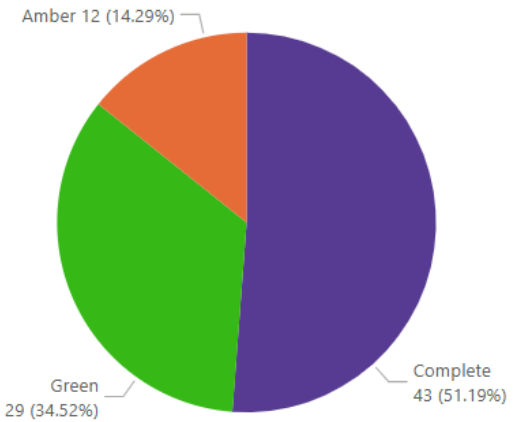


Route to Moderate – Overall Delivery Confidence

Delivery Confidence for Route to Moderate is mostly positive:

- 43 actions have already been completed
- 29 Actions are expected to be delivered within an agreed or extended deadline.
- 12 Amber actions are expected to deliver but later than planned. We are working to identify new delivery dates and how we can support delivery.

Overall Delivery Confidence - RTM All



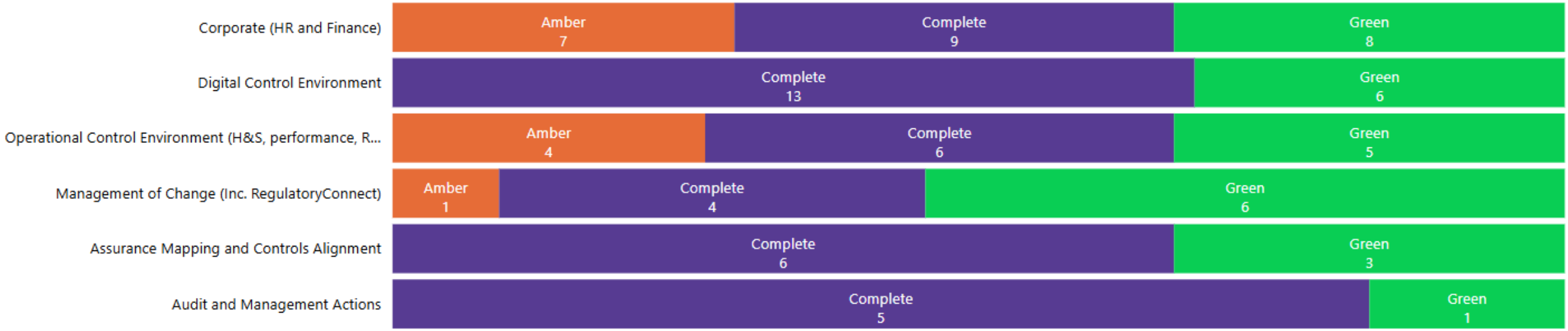
Overall Delivery Confidence RAG definitions:

Red: Significant Risk to Delivery. Will not be delivered under current conditions.

Amber: Some risk to delivery (future deadline) or will be delivered after deadline with no clear delivery date.

Green: On target to deliver fully and on time or with extended clear deadline.

Overall Delivery Confidence by Work Package



Route to Moderate: overdue actions

Work Package		Original due date	Revised due date	Delivery confidence for revised date	Progress
WP1	D1.7 Recruitment of a new senior leader at Grade 6 in the Cyber team to lead at a strategic level	30 Nov 24	31 Mar 25	Green	Ready to start recruitment now
WP2	D2.10: Review of size and shape of H&S against similar sector organisations: - Develop a proposal based on input from organisations - Validate via external expert before delivery to the Agency	28 Feb 25	31 Mar 25	Green	Proposal developed, and taking to exco early March.
WP2	D2.14 : Ensuring end to end performance in the licensing and safety pathways including the independent committee process	28 Feb 25	31 Mar 25	Green	Backlog clearance and redevelopment of services is at an advanced stage.
WP4	D4.6: Delivery of a change checklist	31 Dec 24	31 Mar 25	Green	Delay to change framework launch has affected change toolkit delivery times but these are on track for delivery end of March.
WP4	D4.7: Detailed map of the change process as 2nd deliverable of change toolkit	31 Nov 24	31 Mar 25	Green	
WP4	D4.8: Establishing delivery plan for change toolkit for delivery of 25/26	31 Jan 25	31 Mar 25	Green	

Medicines & Healthcare products Regulatory Agency

Return to Green Reporting Performance Summary

covering period up to 28 February 2025

Monthly data refreshed: Feb 25 (Week 1)
Fortnightly data refreshed: Feb 25 (Week 4)
Weekly data refreshed: Feb 25 (Week 4)
Backlog cleared and within tolerance

Details		Reporting				
Workstream	**Sub-stream**	**Healthy Volume** *on time & (change since last report)* **Actual**	**Backlog** *late & (change since last report)* **Actual**	**Date of compliance for new applications**	**Expected clearance date**	**Ph1 RAG**
Clinical Trials	-	-	-	within timelines	-	G
Medicines Licensing	Established Medicines	467 (▲41)	97 (▼5)	1st September 2024	end Feb 2025	A
	Innovative Medicines	9 (▼4)	3 (▼1)	within timelines	end Mar 2025	G
Variations*	(HQ&A) Type 1b	-	-	within timelines	-	G
	(HQ&A) Type 2	366 (▼10)	110 (▼16)	end December 2024	end Feb 2025	A
	(S&S) Type 1b	-	-	within timelines	-	G
	(S&S) Type 2	315 (▲22)	10^^ (►0)	1st October 2024	end Feb 2025	G
Inspections	**Overall**	286 (▲54)	8 (▼19)	start December 2024	end Mar 2025	G
	GMP	134 (▲19)	6 (▼13)		end Mar 2025	G
	GDP	152 (▲35)	2 (▼6)		end Mar 2025	G
Scientific Advice	**Overall Advice Meetings**	**78 (▲2)**	**85 (▲9)**			A
	Clinical Trials	28 (▼4)	44 (▲3)	August 2025	August 2025	A
	Established Medicines	15 (▲4)	19 (▲4)	August 2025	August 2025	
	Innovative Medicines (NAS and Biols)	35 (▲2)	22 (▲2)	September 2025	September 2025	A

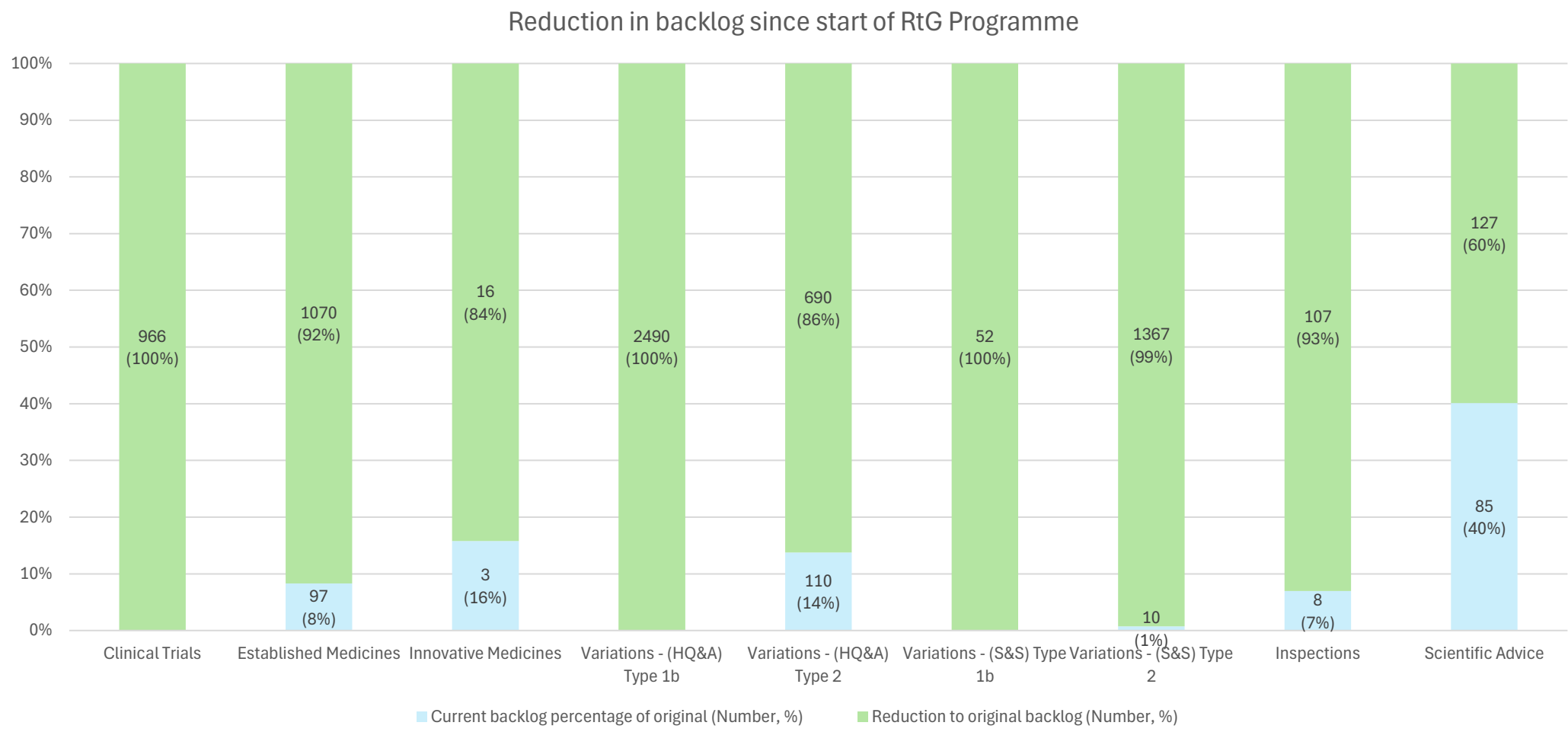
*Variations are either an administrative change, a change to the characteristics of a product that can affect its quality, or a change to the safety, efficacy or pharmacovigilance of the product. Minor changes are either Type 1A or 1B. Type 2 are changes classed as major.
^^ S&S Type II currently has 14 cases excluded due to cases awaiting the MR procedure outcome, a HEAG decision, or waiting for expert advice.

RAG Key: Red – no confidence in plan to clear or growing backlog of items that have failed statutory / internal timelines and/or presently no mitigations in place; Amber – declining backlog with confidence in the plan to clear and return to timelines Green – no backlog, all items are being cleared inside statutory/internal timelines

Updated IM original backlog after ExCo R&P

RtG backlog progress since the start of the program

Figures up to date as of 28 Feb 2025



Current RAG rating for each RtG sustainable strategy by area:

Key	
Effective	Interventions agreed and 'in place' or 'on track' to be implemented
Partial	Interventions partially agreed and / or in place; further work needed
Limited	Limited interventions agreed and / or in place; substantial work needed

Area		RAG Rating						Summary
		People	Process	Mgmt Control	Change Mgmt	Technol-ogy	Quality	
Licensing								**People:** Interim resourcing to clear backlogs, new group structure and ongoing recruitment **Process:** Pending finalised plans for New Licensing Strategy and Risk Appropriateness assessments **Mgmt Control:**Enhanced application monitoring, workload distubution and reporting **Change Mgmt:** Pending finalisation of all sustainability action areas **Technology:** Pending review of sustainable solutions by RegulatoryConnect Programme **Quality:** Pending alignment with Route to Moderate programme
Variations	HQA							**People:** New group structure and ongoing recruitment **Process:** Introduced RAG ratings by complexity and priority and reallocation of admin tasks **Mgmt Control:** Pending introduction of enhanced application monitoring, and alignment between groups **Change Mgmt:** Pending finalisation of all sustainability action areas **Technology:** Pending review of sustainable solutions by RegulatoryConnect Programme **Quality:** Pending alignment with Route to Moderate programme
	S & S							**People:** Funding approved for new EO and G7 procedural role, pending further work on recruitment **Process**: Introduced new ways of working to align with Risk Proportionate assessments **Mgmt Control:** Pending introduction of enhanced application monitoring, and alignment between groups **Change Mgmt:** Pending finalisation of all sustainability action areas **Technology:** Pending review of sustainable solutions by RegulatoryConnect Programme **Quality:** Pending alignment with Route to Moderate programme
Inspections								**People:** Temporary resources onborded **Process:** Process changes identified though pillars & in implementation stage **Mgmt Control:** Pending introduction of enhanced application monitoring, and alignment between groups **Change Mgmt:** Change management plan to be actioned in line with current interventions **Technology:** Limited scope due to RegConnect dependencies, hardware & software solutions to be explored under compliance strategy **Quality:** Pending alignment with Route to Moderate programme
Scientific Advice								**People:** Dependency on additional resources to clear CT and shared resources assigned to statutory clearance **Process:** Immediate interventions identified & approved, currently being implemented **Mgmt Control:** Enhanced application monitoring, workload distubution and reporting **Change Mgmt:** Change management plan confirmed & implementation has started **Technology:** Website changes successfully implemented, limited scope due to RegConnect dependencies **Quality:** Pending alignment with Route to Moderate programme

Programme closure: Assurance of future compliance (1/2)

- Closure of the Return to Green programme is dependent on ExCo acceptance of assurance that operational teams have the required infrastructure and management controls established and embedded to successfully maintain statutory compliance and prevent recurrence of any future backlogs

- Sustainability of compliance has been broken down into six domains and assurance statements developed against each as below:

  - People: The people, skills and structures needed to maintain operational performance in line with Agency targets are in place (or plans are in place to address any gaps)

  - Process: Clearly defined and documented internal processes are in pace and consistently followed with plans for regular review. These support an agreed approach to increasing risk proportionality in processes while maintaining a high standard of compliance and patient safety

Programme closure: Assurance of future compliance (2/2)

- Management controls: Triage, monitoring and performance reporting measures are in place to allow rapid identification of emerging issues with performance, supporting re-prioritization/re-allocation of work when necessary. Three lines of defence model is embedded across the work of the team
- Change management: An agreed Change Management Plan is in place which sets out how staff will be engaged in the identification and implementation of ongoing change, ensuring feedback is taken on board and actioned where appropriate
- Technology: Responsibilities and mechanisms for engaging on the development of RegulatoryConnect and existing and future DTG projects are clear and in place, with sufficient time allocated
- Quality: Quality Management System is in place and monitored appropriately. Peer review or other assurance mechanism is in place for scientific decisions

Post 31st March priorities

Agreed performance data model in place beyond clearance of backlogs (by end of Q1), stratified by forum – Board, ExCo, DPC etc

Continued focus on **redesign of Scientific Advice Model**, bringing RtG work to date together with growth commitments

Ongoing support for workstreams to **fully meet the sustainability assurance statements** (by end of Q2)

Capacity and capability to support workstreams to identify the future changes required to progress **risk proportionate regulation**, supporting process re-design where identified

Consider scope to work with other areas (non-operational) to address calls for increased proportionality

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

18 March 2025

Title	How is delivery of the programme to establish a network of Centres of Excellence for Regulatory Science progressing?
Board Sponsor	Harriet Teare
Purpose of Paper	Strategic Direction

How is delivery of the programme to establish a network of Centres of Excellence for Regulatory Science progressing?

1. Executive Summary

1.1. Seven Centres of Excellence for Regulatory Science and Innovation (CERSI) have been established across a range of themes to gather evidence to inform future regulatory needs.

1.2. The successful CERSI are:

Project Title	Lead PI and Institution	Short description
CERSI for the Digital Transformation of Medicines Development and Manufacturing	University of Strathclyde	Standards for Digital Chemistry, Manufacturing and Control procedures in the pharmaceutical industry.
The UK Regulatory Innovation Network for Advanced Therapies	Cell Therapy Catapult Limited	Regulatory and Clinical Development Acceleration of safe and effective cell and gene therapies by sharing Real World Evidence, Patient-Reported Outcomes, Clinical and PPIE inputs.
RADIANT: Regulatory Science Empowering Innovation in Transformative Digital Health and AI	Brunel University London	An international network of expertise in regulatory science and innovation, empowering transformative digital health and healthcare AI, including creating a Digital Health and AI Observatory to anticipate regulatory challenges and co-design solutions from international regulatory exemplars.
UK CEiRSI - The UK's Centre of Excellence on In-silico Regulatory Science and Innovation - Pilot Phase	The University of Manchester	Developing of tools, standards, and best practices for integrating evidence from computational models into the regulatory processes.
CLEARED (CLinical Evaluation & Assessment for REgulation of Diagnostic tests) Implementation Phase	Psephos Limited	Regulatory science for enabling regulatory approval of innovative In-Vitro-Diagnostics, including tests using AI and computer apps.
Centre of Excellence for Regulatory Science and Innovation in AI & Digital Health Technologies (CERSI-AI)	University of Birmingham	Regulatory science for AI and Digital Health Technologies, centred on AI/software as a medical device.
Centre for Excellence in Regulatory Science and Innovation in Pharmacogenomics	University of Liverpool	Fostering of proportionate regulatory decision making across pharmacogenomic development and implementation pathways in health system partners.

1.3. A launch event will take place on 25th March, to enable the successful CERSI to meet each other, and network with the programme partners (MHRA, the Office for Life Sciences, Innovate UK and the Medical Research Council), advisory committee members (the Department for Science, Innovation and Technology (DSIT), The British Standards Institution), Medicines and Medical Devices Access partners, and trade associations.

1.4. The successful CERSI have each been awarded up to one million pounds, for 12 months. The projects began in January 2025. Part of the focus for their first year will be to generate further funding.

1.5. The Office for Life Sciences (OLS) and MHRA have requested further funding for the CERSI programme as part of their spending review allocation. If successful, this could be used to renew existing Centres, if they demonstrate value, and / or to support new centres in future, particularly in areas that were unsuccessful in this first round.

2. Introduction

2.1. Using funding from the £10m allocated to the MHRA for innovation from the March 2023 budget, the MHRA has contributed £2.5m to fund a programme of CERSI – Centres of Excellence for Regulatory Science and Innovation, which has been match-funded by the OLS contributing £4m to provide a total funding allocation of £6.5m.

2.2. The CERSI funding has been administered by Innovate UK, as a human health focus in a broader call to set up Regulatory Science and Innovation Networks (RSINs). The Medical Research Council (MRC) are supporting distribution of funding.

2.3. The funding has been allocated as a two-stage process, with the initial discovery phase awarding 17 eligible projects £50,000 each to develop their full applications. The development phase started in January 2024, with full applications submitted by 31st August 2024.

2.4. During this time, applicants were encouraged to engage with an allocated sponsor at the MHRA, to discuss future engagement if successful.

2.5. The second phase of funding, the implementation phase, awards up to £1 million to each successful CERSI, for 1 year, depending on the project costs.

2.6. The application process required applicants to set out their plans for the year, including how they would ensure the sustainability of the project, and how they would raise future funding to enable activity beyond the initial year of the project, if relevant.

2.7. A press release was issued on 28th January 2025, by UKRI, to announce the start of the programme.

3. Proposal

3.1. The launch event on 25 March 2025 will provide an opportunity for the CERSI to present their plans for the year, and to update on the work that has already been conducted as part of the discovery phase.

3.2. It will also provide an opportunity for the life sciences industry and health ecosystem partners to meet the centres, to discuss their plans, and to consider potential challenges across the areas of interest.

3.3. The MHRA sponsors will engage with the CERSI throughout their programme, to shape the questions they are addressing, to learn from their findings and evaluate impact. This will inform ongoing work within the agency to anticipate future innovation and changing regulatory needs.

3.4. The future of the programme will rely on sustainable sources of funding. This will be further discussed with project partners and other stakeholders in the next few months.

4. Recommendation

4.1. To reflect on the opportunities the CERSI programme presents, and the actions that must now be taken to ensure its ongoing success and future potential.

4.2. To identify and discuss any notable absences from the areas funded during this first round, to consider other opportunities to support work in these areas.

4.3. To advise on the mechanisms that might be available to ensure the future sustainability of the programme of CERSI.

Harriet Teare
18 March 2025

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

18 March 2025

Title	Innovative Pathways for Medicines and Medical Devices
Board Developer	James Pound
Purpose of Paper	Strategic Direction

Innovative Pathways for Medicines and Medical Devices

1 Executive Summary

1.1 The Innovative Licensing and Access Pathway (ILAP) and the Innovative Devices Access Pathway (IDAP) are flagship initiatives for the UK and MHRA's corporate and business plans. They present a unique opportunity to accelerate patient access for transformational and innovative medicines and devices and forge alignment across the life sciences ecosystem for key healthcare priorities.

1.2 This paper provides an update on progress with the ILAP and the IDAP pilot and potential directions for the future Innovative Pathway and seeks the Board's views on the way forward.

2 Introduction and Background

Innovative Licensing and Access Pathway (ILAP)

2.1 The ILAP was originally launched in January 2021 with the aim of reducing the time to market for innovative medicines by providing a single integrated platform for sustained collaborative working between the MHRA, ILAP partners (Health Technology Appraisal Bodies (the All Wales Therapeutics and Toxicology Centre (AWTTC), the National Institute for Health and Care Excellence (NICE), the Scottish Medicines Consortium (SMC)) and the NHS)) and the medicine developer. Although intended to be involved, NHS bodies were not formally engaged.

2.2 Recommendations in the 2022 ILAP Review and Refresh workshop hosted by MHRA, the Pro-innovation Regulation of Technologies Review (McLean Review), lessons learned from running the ILAP, a Task and Finish Group with HTA bodies and direction from senior leadership across the partners, have highlighted challenges and opportunities for improvement, and the need to formally involve the NHS as a core partner.

2.3 NHS England has now formally joined the ILAP partnership, alongside representatives from NHS bodies in Scotland and Wales. A Collaboration Agreement is in place and new governance arrangements are well established. Health and Social Care Northern Ireland is also participating in the ILAP Partnership.

Innovative Devices Access Pathway (IDAP)

2.1 The IDAP pilot was launched on 19 September 2023 to bring transformative medical technologies (including diagnostics and digital health technologies) to market that address unmet clinical needs within NHS (gov.uk). It is delivered in partnership by the MHRA, the HTA bodies (NICE, Scottish Health Technologies Group and Health Technology Wales), NHS England and the Department of Health and Social Care (DHSC), with the Office for Life Sciences as a supporting partner. The aim of IDAP is to enable and improve patient access to innovative and transformative medical devices by providing an integrated and enhanced regulatory and access support and advice package to developers. Eight products were selected for the pilot and were announced on 14 February 2024. The pilot is scheduled to complete in March 2025.

2.2 The pathway builds on the government's intention to clarify the route to market for innovative medical technology as set out in the Medical Technology Strategy published on 3 February 2023.

3 Innovative Licensing and Access Pathway (ILAP) progress and next steps

Relaunch of the new ILAP

3.1 Following the publication of a statement of intent in November 2024, on 30 January 2025 the refreshed ILAP was formally relaunched, with details of the new approach, guidance and details of what is on offer published on gov.uk. A webinar was held on 5 March 2025 and the new ILAP will open to applications on 31 March. This presents a unique offer for the UK, as the only global example of a pre-market access pathway where developers can engage at an early stage of clinical development with the Regulator (MHRA), the Health Technology Assessment (HTA) bodies (NICE, SMC and AWTTC) and the national health system (NHS).

3.2 A stepwise approach to ILAP is being taken to ensure primarily we can provide a reliable process for ILAP decisions, with ILAP products meeting a strict set of criteria focussing on transformative promise and unmet need. In this initial launch the focus has been on delivering more predictable process and timelines to enable workforce planning and provision of a core, but deliverable, number of services from day 1. The ambition is to build out from this to further strengthen and increase the number of services by building in regular review and delivering continuous improvements/enhancements. All ILAP Partners, including the MHRA, have confirmed their commitment to the successful delivery of ILAP.

Value of ILAP for developers

3.3 The new ILAP will give developers coordinated and collaborative support, to enable a system-wide approach for product development and access to the UK market. The benefits for developers include:

- De-risking of product development pipelines, helping companies succeed by offering earlier insights into regulatory, HTA and NHS access requirements.
- More efficient and joined up progress through the UK medicines development landscape, removing complexity to facilitate access (removing delays, inefficiencies and costs associated with independent interactions) with enhanced ability for parallel evaluation of data by multiple organisations, as well as data sharing.
- More predictable timelines, enabling developers to plan more effectively.
- Early interaction with patients and the NHS to facilitate smoother routes for routine access and system-wide adoption.
- A dedicated point of contact to coordinate all support provided through the ILAP, offering bespoke engagement and support from key ecosystem partners throughout product development.
- Access to pivotal services that support clinical development (including clinical trial delivery), market access, and health system adoption, reducing the end-to-end timeline for product R&D and facilitating rapid safe access to the UK market.

3.4 Plans for the ILAP have been informed by extensive engagement with industry through a series of Trusted Advisor Meetings (held between February 2024 and June 2024) and three industry workshops held in September and October 2024. There has been support for the ILAP's vision with the new approach being acknowledged as a positive move forward, recognising the offer will develop over time. In particular, the inclusion of the NHS as a partner, has been viewed as a significant and unique formal value proposition.

3.5 Industry has highlighted the need to publish key measures to demonstrate effectiveness as the pathway embeds to build confidence. In doing so they have indicated strong willingness to support the development of measurable markers of success and to actively contribute to the plans to evolve the pathway in the future.

Patient and Public Involvement and Engagement (PPIE)

3.6 Public and patient involvement is embedded within the ILAP through a number of routes:

- Applications for an Innovation Passport will be reviewed by public reviewers against the published selection criteria. Their review will be jointly considered with the reviews by the ILAP Partners to inform decisions on which products enter the ILAP.

- Patient groups, including those with lived experience, will be involved in the ILAP Joint Scientific Advice meetings and ILAP Access Forum.

- Access to the NIHR Patient Engagement in Clinical Development Service to help ensure clinical trials are participant-friendly, enabling direct engagement with patients, members of the public, and carers to improve the design and delivery of clinical trials.

3.7 Patient engagement activities have taken place, including two roundtables with patient representatives in autumn 2024 to inform the approach to gather perspectives and ideas on the plans for PPIE within the new ILAP. Feedback highlighted the importance of initiating early PPIE conversations and information sharing between developers including patient representatives, patient groups and those with lived experience to maximize opportunities for meaningful contributions.

3.8 Recognising that ILAP will be taking a stepwise and continuous improvement approach to its activities, we are committed to further enhancing the approach to PPIE as ILAP progresses.

4 Update on Innovative Devices Access Pathway (IDAP)

Progress with delivering IDAP for the eight products

4.1 The IDAP Partners have been working with the eight companies since February 2024. Engagement to provide system navigation advice has now been completed from an MHRA perspective, and each of the pilot tools (such as joint scientific advice) have been tested by at least one company. For the MHRA, the focus has been on supporting companies to build the regulatory evidence base (and seeking to align this with HTA and NHS evidential requirements where possible) and ensure readiness for regulatory certification. The pilot is designed to capture evidence to enable refinements to be developed to optimise future innovative pathways to support medical technologies.

4.2 The IDAP has created a unique opportunity for MHRA to work more closely with manufacturers during the development phases for new medical devices, beyond advice related to the conduct of clinical investigations. The system navigation advice offered via IDAP is one area which has been positively received to gain insights into the regulatory and health system landscape in the UK and to gain understanding of readiness for Health Technology Assessment. This highlights opportunities for MHRA to consider how to strengthen its approach to providing pre-

market support and advice to manufacturers of innovative devices as part of reforms to the MedTech regulatory frameworks.

4.3 Evaluation of the IDAP pilot has started and work is ongoing to evaluate the pathway effectiveness, distil lessons learnt, identify key successes and explore opportunities for the future. The evaluation will conclude with a full report expected in summer 2025.

5 Innovative Access Pathways

5.1 The ILAP and IDAP pilot are key initiatives which provide a mechanism to support the most promising medicines and medical device technologies from early-stage development through to uptake in the NHS and access for patients. Both aim to do this by providing a complementary pathway that gives developers coordinated system-wide support, to streamline product development and access to the UK market.

5.2 As work proceeds over 2025 with the relaunch of the ILAP and completion of the IDAP pilot, we will explore opportunities for further development, including how key lessons might be embedded to support the further development of innovative regulatory pathways for Healthcare Products.

5.3 Scientific progress with the integration of different combinations of therapeutic approaches, such as companion diagnostics and Artificial Intelligence, increasingly blurs the traditional boundaries between medicines and devices. The new ILAP has already expanded its remit to support combination products. In addition to the growing convergence of pharmaceuticals and medical technologies, the increasing use of personalised medicines is also broadening the scope of innovations in health. Going forward, it is our intention to work with our partners to explore opportunities to further streamline access to innovative pathways for all types of Healthcare Products.

6 Recommendation

6.1 The Board is asked to comment on the progress on the IDAP and ILAP.

6.2 The Board are asked to reflect on the future of innovative pathways in light of the changing landscape and opportunities highlighted.

James Pound

3 February 2025

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

18 MARCH 2025

Title	Increasing awareness of the Yellow Card scheme
Board Sponsor	Alison Cave
Purpose of Paper	Strategic direction

Increasing awareness of the Yellow Card scheme

1 Executive Summary

1.1 The Yellow Card scheme, which collects and monitors information on suspected safety concerns involving healthcare products, like a side effect with a medicine or an adverse medical device incident relies on reporting of problems associated with a healthcare product by the public (including patients, parents and carer givers) as well as from healthcare professionals. The scheme also collects suspected safety concerns involving defective (not of an acceptable quality), falsified or fake healthcare products, e-cigarettes and blood products.

1.2 Spontaneous reporting schemes are the bedrock of vigilance for safety monitoring. However, the Yellow Card scheme, as with all other spontaneous reporting systems around the world, is recognised as having an unknown and variable level of under-reporting. Higher reporting rates would facilitate earlier identification of both new safety concerns and changes in incidence, severity or progression of known risks. Spontaneous reporting is never the sole source of data but is used alongside all other available vigilance safety information to support regulatory decision making.

1.3 The Board is asked to consider the activities outlined to increase awareness of the scheme, with the ultimate aim to increase reporting, to ensure the Yellow Card scheme continues to support patient safety.

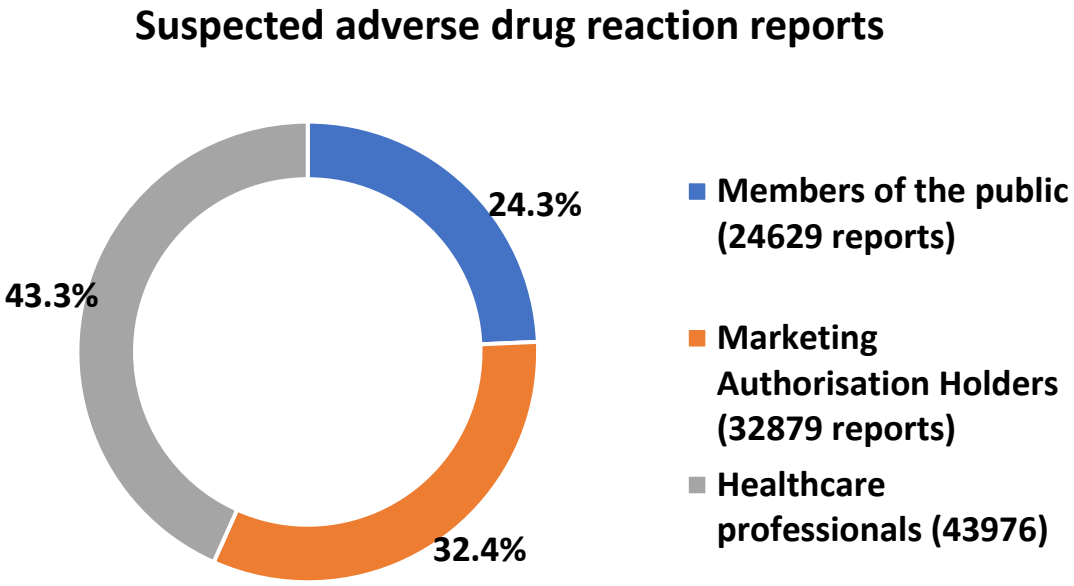
2 Introduction

2.1 Suspected ADRs are collected on all licenced and unlicenced medicines and vaccines, irrespective of the route through which they are accessed, including those medicines traditionally issued on prescription to medicines bought over the counter from a pharmacist, shop or more recently online. The scheme also includes suspected adverse reports to herbal preparations, e-cigarettes and blood products. In 2014, the scheme was extended to collect reports of incidents with medical devices, defective medicines and reports of suspected counterfeit medicinal products. Bringing all healthcare products under the Yellow Card scheme simplified reporting by providing a single front door for people to report issues irrespective of the type of healthcare product. Reports can be made by anyone - patients, carers and healthcare professionals.

2.2 Lack of awareness and issues with the Yellow Card scheme have been highlighted, particularly by patients, through independent reviews and other feedback. Awareness of the scheme has grown in recent years, partly due to publicity during the Covid-19 pandemic and the number of initial reports received in 2024 are the highest ever with over 101,000 suspected adverse drug reactions initial reports and ~34,000 suspected medical device incidents initially reported. However, adverse drug reactions continue to have a significant impact on patient's

lives and an estimated £2.2bn direct in hospital annual cost on the NHS in England[1].

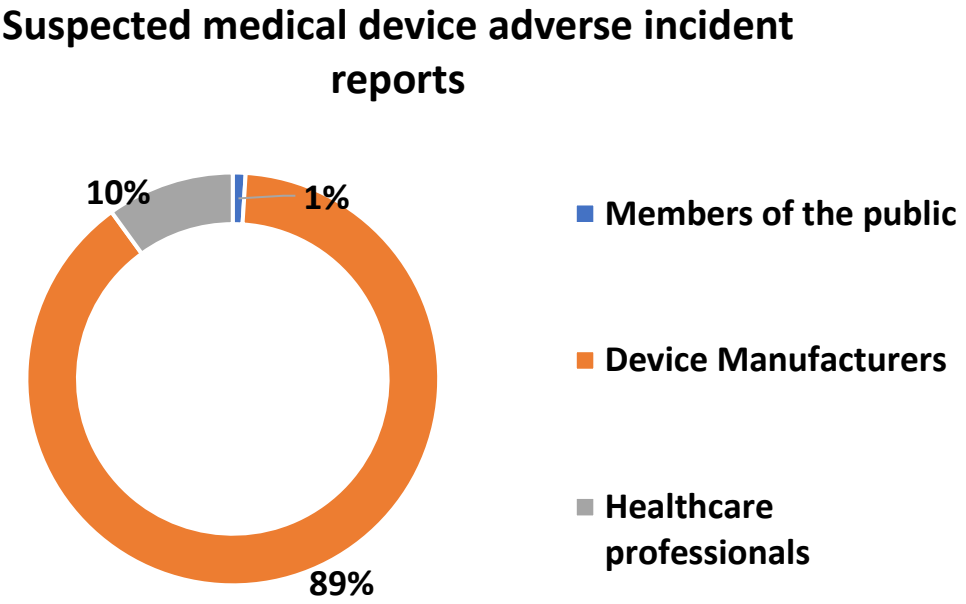
2.3 Below is a 2024 breakdown of the main reporting groups for suspected adverse drug reactions where MHRA received over 101,000 initial reports:



2.4 The above figure reflects a 5% decrease (1,239 initial reports) in patient reporting compared to 2023. However, the last five year trend, shows a 165% increase (14,929 initial reports) since 2020 (pre-pandemic reporting levels). Reports from healthcare professionals increased by 43% (14,233 initial reports) in 2024 and 103% (21,951 initial reports) over the same 5 year period.

2.5 However, there is more to do, particularly in relation to reporting of device adverse incidents, where in 2023 only 1% of the initial device reports were from patients and the number of initial reports from healthcare professionals are also low (with the vast majority of reports being received from device manufacturers). We anticipate reporting to increase significantly because of the new Post Market Surveillance (PMS) obligations of the Medical Device regulations, which clarifies reporting guidelines and imposes stricter reporting timelines. Below is the breakdown of reporting groups for suspected adverse incidents involving medical devices:

[1] Osanlou R, Walker L, Hughes DA, et al. Adverse drug reactions, multimorbidity and polypharmacy: a prospective analysis of 1 month of medical admissions BMJ Open 2022;12:e055551



2.6 The sharp increase in reporting of ADRs in recent years (mainly from patients) is likely due to better awareness of the scheme following significant communications activity during the COVID-19 vaccination campaign. During the pandemic, we worked with our key partners to provide information about the Yellow Card scheme relating to COVID-19 treatments, coupled with MHRA campaign and outreach work that generated extensive media coverage and exposure of the scheme including through advertising online and on social media. In the World Health Organisation's Vigibase (the global database of individual case safety reports (ICSRs), up until the end of 2023, the UK accounted for 5.13% of the total reports, the 4th largest contribution globally. However, the UK was only 10th in terms of submission of ICSRs per million population over a period of five years globally. The Agency wants to ensure it continues to be one of the main contributors to Vigibase which is important for the facilitation and vigilance of global patient safety monitoring.

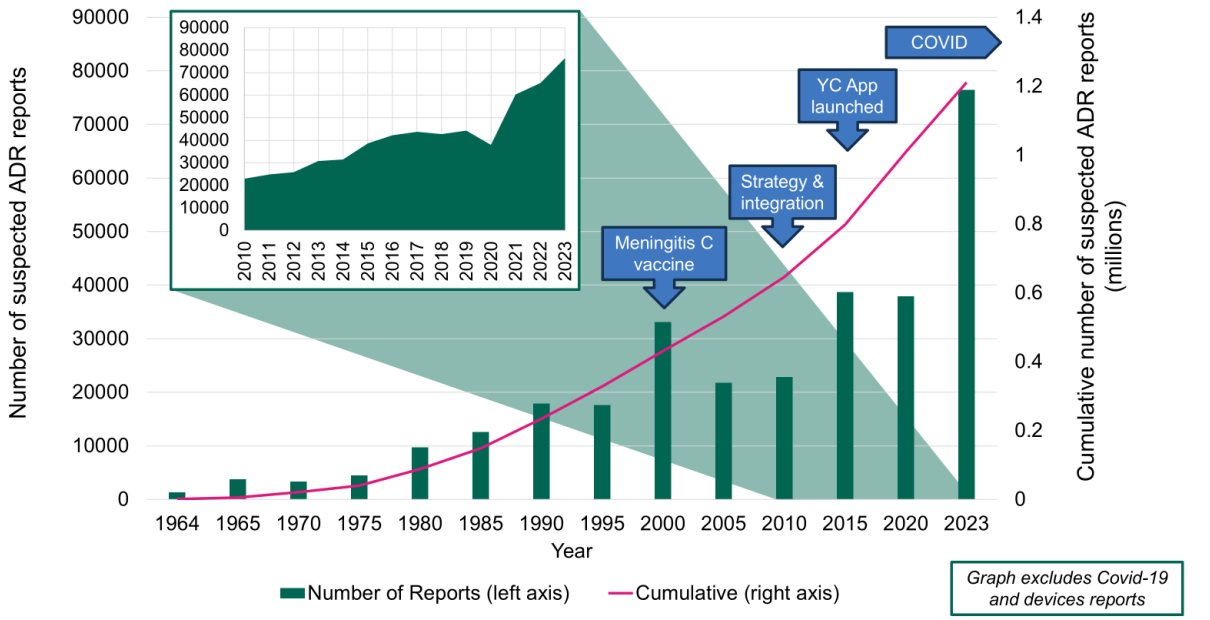
2.7 A paper 'Yellow Card scheme: 60 years of reporting and how it can best continue to support patient safety' was considered by the Board in November 2025 which highlighted the themes of our strategy to strengthen the Yellow Card scheme. This paper outlines proposed activities to increase awareness, strengthen and improve the number and quality of reports.

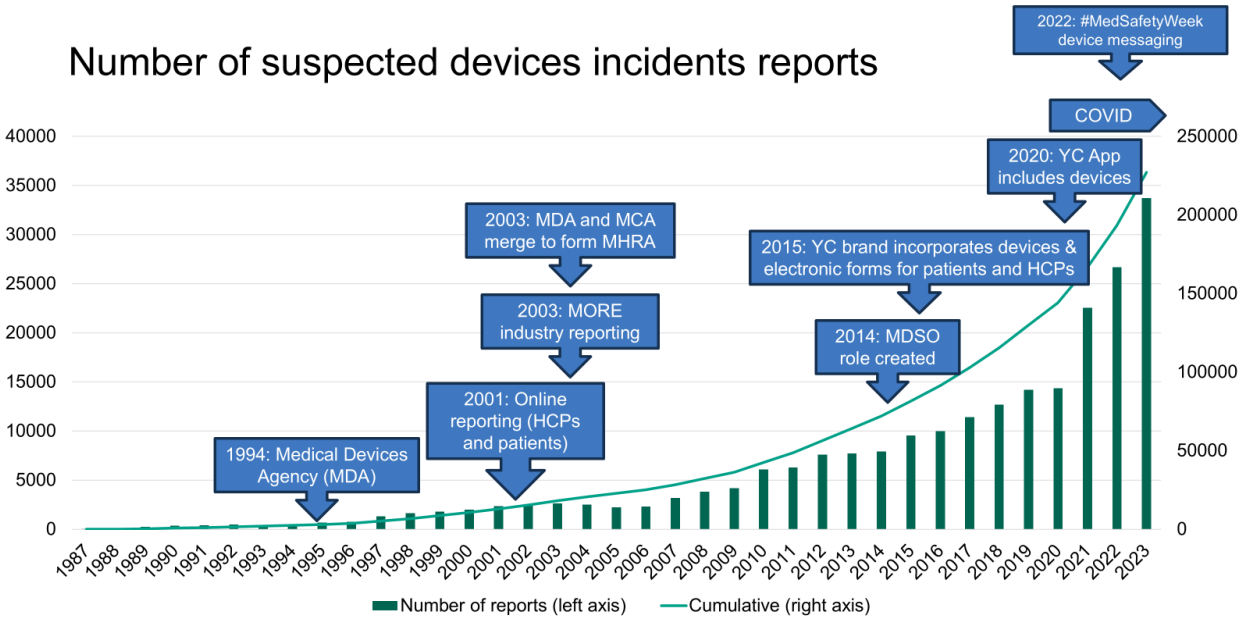
3 How will awareness of the Yellow Card scheme be increased?

3.1 Customer insight has shown low awareness levels of the scheme or its purpose, and recall of, and access to the scheme when it is needed by external users is low. Nevertheless, reporting levels to the Yellow Card scheme have increased steadily over time and have never been higher (see graphs below). Awareness of the

scheme was raised through the COVID-19 pandemic and the Agency must continue to build on this with continued promotion and communication strategies. We intend to explore how partnerships with UKHSA and NHSE and the communication routes they leverage can support our ambition to significantly increase awareness of the scheme.

Yellow Card scheme: Annual and cumulative numbers of suspected ADR reports





3.2 Within current available resources, there is an ongoing programme of work to raise awareness of the Yellow Card across the UK and activities include:

3.2.1 The six Yellow Card Centres (YCC) in Wales, Scotland, Northern Ireland, Northern & Yorkshire, North West, West Midlands have responsibility to raise regional awareness and use of the scheme and

are key partners in our efforts to further increase awareness. They provide local education and outreach to medicines and medical device users and have developed successful initiatives such as the establishment of Yellow Card champions in local trusts to educate and promote reporting. The YCCs prepare annual reports on their activities, including report numbers and the outreach work they undertake and the quarterly meetings are used to collectively consider how to increase reporting and awareness, within the resources available.

3.2.2 For example, since its launch in September 2023, the YCC Northern Ireland (YCC NI) conducted a 300 mile autumn roadshow across their trusts, achieving 387 in-person interactions with healthcare professionals, patients and members of the public. Their community pharmacies and GP Practices were supported by distribution of a poster as well as sessions with 354 healthcare professionals. Twenty-two promotional events were held as well as a push for #MedSafetyWeek campaign. YCC NI has worked to foster a renewed culture of vigilance and proactive reporting, to contribute to improving patient safety across its region with an encouraging upward trend of reporting over Q3 and Q4 showing a 43% increase compared with Q1.

3.2.3 Every year, the Yellow Card Strategic Development Team exhibit at a series of conferences across the UK, specifically with the aim of promoting the Yellow Card scheme amongst healthcare professionals. These events include the Royal College of General Practitioners Annual Conference, the Royal College of Nursing Congress, the Royal College of Pharmacists Annual Conference, the Health Service Journal's Patient Safety Congress and the National Association of Medical Device Educators and Trainers Conference. These are well attended conferences and provide an opportunity to speak directly to healthcare professionals about the Yellow Card scheme, but also to share information about resources available and obtain feedback.

3.2.4 The Medical Devices Safety Officer (MDSO) Network and Medication Safety Officer (MSO) Network were created in 2014 following the publication of a joint MHRA and NHSE Patient Safety Alert that aimed to help healthcare providers increase the quality and frequency of reporting and maximise learning. The Networks act as a forum for discussing potential and recognised safety issues, identifying trends and actions to improve the safe use of healthcare products. The MDSOs and MSOs help to increase reporting and awareness of the Yellow Card scheme within their organisation, share learnings from issues and support actioning of safety messages. The Agency provides operational support to both Networks and has regular contact via monthly webinars and a joint annual MDSO and MSO Conference which is delivered in partnership with NHSE each year.

3.3 The Agency uses the opportunity to promote the Yellow Card scheme as part of the risk and safety information provided to the public and healthcare professionals through MHRA platforms and channels (including press releases, stakeholder

emails and social media). This has included providing content to media medics, to encourage them to highlight the Yellow Card scheme as appropriate.

3.4 In order to significantly increase awareness of the Yellow Card scheme and increase initial report numbers, there needs to be further investment both in terms of funding and operational resources. Areas highlighted in the November 2024 Board paper included improving integration of reporting with other systems; increasing the availability of the Yellow Card scheme when it is required; increasing the number of initial reports in relation to devices, blood products and increasing the number of reports from under-represented populations; further improving the usability of the Yellow Card reporting services; and further improving the transparency of how the Yellow Cards contribute to the broader patient safety work. In addition to increasing patient reporting in general, we need to target under served and under-represented patients where report numbers are very low. The Agency needs to increase its work with patient organisations, voluntary sector and larger charities to encourage them to help raise awareness and leverage community pharmacists and other community settings.

3.5 Targeted campaigns will continue to be used to drive reporting through digital channels such as social media, including paid marketing initiatives for particular campaigns. However, due to the need to carefully manage public spending on communications and marketing activity, we are changing our emphasis from driving awareness to prompt spontaneous recall of potential users, and focussing instead on work to increase the availability of the scheme when potential users need to find it. The Agency needs to make sure that the Yellow Card scheme is at the front of mind if someone needs to report. This involves improving search engine optimisation of content, and increased third party advocacy and linkage to the scheme. Work is underway to further enhance the current suite of stakeholder materials and communication assets available to support engagement and build on knowledge and understanding of the scheme. This includes engagement and distribution planning, covering both no cost/ low cost activities, as well as paid for activities. To significantly extend our reach, external advertising/ paid activities needs to be considered. Previous campaigns have resulted in a spike in reporting and brand awareness, however over time this reduces again. Our aim is to achieve a more consistent increased awareness, through an always-on baseline approach.

3.6 While we will continue our activities to raise awareness of the Yellow Card scheme, further options, subject to budget allocation and the Board's view, would include:

3.6.1 Always on digital marketing (social media and search engine advertising being the most likely formats) to run constantly with a set budget to ensure promotion for those searching for key terms likely to mean they should be directed to the Yellow Card scheme.

3.6.2 Increased partnership marketing through relevant third parties, including use of health influencers and media partnerships.

3.6.3 Piloting regional radio advertising, which has always been very effective with call-to-action reporting activities.

3.6.4 Continued organic media outreach promoting the scheme through milestone activities.

3.7 The MHRA proactively contributes to national and global campaigns, like World Patient Safety Day. MHRA set up and contributes extensively on an annual basis to the global planning and delivery of #MedSafetyWeek held in November with different targeted themes annually building on previous messaging. As pioneers of this global awareness week, our support continues in developing consistent materials for global regulators and their stakeholders enabling them to activate PR, media, and marketing initiatives both on-line and in person. This work is jointly led through the Uppsala Monitoring Centre to boost awareness about the importance of reporting patient safety concerns, especially for patients. This year regulators from 94 countries and 107 organisations took part in #MedSafetyWeek across the globe. The 2024 campaign reached 24.9 million people; with 109K interactions and 4.2K mentions. Preparation for #MedSafetyWeek 2025 has already commenced. Although #MedSafetyWeek focusses on the reporting of suspected side effects, MHRA has always utilised the opportunity to promote the reporting of safety concerns for all healthcare products including medical devices. However, due to substantial differences in product profiles, it is challenging to create a campaign that encompasses all healthcare products. Therefore, there could be benefit in creating a dedicated campaign to target medical devices incident reporting specifically (e.g. Device Safety Week) which would provide more opportunity to highlight unique barriers to reporting and incident types for medical devices.

3.8 A particular focus is to increase access and availability of the scheme at the point a patient or healthcare professional wishes to or needs to report. The changes implemented through the SafetyConnect programme will help enable the integration of Yellow Card into other services such as the NHS App; this integration needs be taken forward to optimise the benefits and improve access for patients and other reporters. The initial phase has been in relation to single sign on through the NHS App, but this first phase work has been challenging in relation to issues such as multi factor identification and has therefore taken longer than anticipated. Ideally, and subject to significant resourcing and prioritisation, more could potentially be done in relation to pre-populating patient information and the ability to better share Yellow Card information. We will work with NHS colleagues to support better links between the NHS app and the Yellow Card website and app, aiming for increased visibility of the Yellow Card and improved reporting of suspected reactions. The Agency is contributing to the NHS 10 Year Health Plan and highlighting the importance of the Yellow Card scheme.

3.9 With regards to the concept of report once and share the data as required through the connection of systems used by healthcare professionals in the UK, the Agency has been working closely with NHSE to determine how to better share data with Learning from Patient Safety Events (LFPSE). The feasibility and requirements for an application programming interface (API) between NHSE and the MHRA data collection platforms to streamline patient safety requirements had been explored. However significant further resource will need to be identified in order to pursue this further with a third party who would have the technical capability and it is not straight forward. Grants and bids for this next stage of work have been

unsuccessful and therefore at this stage the Agency cannot rely on LFPSE for increasing reporting numbers.

3.10 The Agency has been working with one of the GP IT system providers, EMIS, to improve Yellow Card reporting and a prominent Yellow Card branded button to the main screen to make it easier for GPs to report and further work is currently being rolled out to have the system proactively prompt GPs to report. EMIS and MHRA are monitoring report numbers to see the impact on report numbers these changes have made. EMIS has also been supporting the Agency in raising awareness and sharing metrics of the number of times an article on Yellow Card has been accessed – four articles were published reaching 7.5 million patients through their Patient Access and online with an open rate of 55%. The MHRA will continue to support EMIS and other organisations and system providers with improving Yellow Card linkages and automation and an analysis is being conducted to drive this work forward. The MHRA will continue to proactively encourage reporting of adverse effects through better connections between clinical systems and ongoing outreach work and will work with the wider healthcare system to explore potential routes to improve reporting of suspected side effects and adverse incidents.

3.11 There are educational and learning resources available on the Yellow Card website, including some e-learning modules that are accredited for Continuous Professional Development (CPD) for healthcare professionals. Updates have been made to the website in recent months including revised partner resources and new animations with video segments to show how the Agency uses the Yellow Cards received that can be deployed by partners across their channels have also been launched. There are also a number of case studies that show the action MHRA has taken in response to receiving reports. Having these resources available helps others to share the message about the importance of reporting and awareness of the scheme. We recognise the importance and key role our partners play in the promotion of the scheme and are currently adding to the suite of materials to further improve engagement and buy-in. Work will continue with other organisations to have links on their websites to these materials or for them to signpost on our behalf.

3.12 Our recently published Strategy to Improve Safety Communications sets out our 3 year plan to transform the way we communicate about the risks and safety of medicines, medical devices and healthcare products in the UK to support effective implementation of new safety measures, and work to deliver against this is well underway.

3.13 We have worked extensively to feature prominent references to Yellow Card on partner channels across the healthcare system. There are, for instance, links across every single NHS page relating to a medicine or vaccine through to Yellow Card and all patient literature clearly features reference the need to report to the scheme where incidents occur. We will continue to build on partnerships including with patient organisations and the voluntary sector to seek their support with links to the Yellow Card scheme.

3.14 MHRA worked closely across the DHSC and the NHS Business Services Authority (NHSBSA) to ensure that Yellow Card information and reporting suspected side

effects, as well as medical device incidents is now included in prints of the paper prescription form FP10, held by patients and carers for repeat prescriptions. We will liaise with the DHSC procurement and supply teams to see if they are able to help raise awareness of the YC scheme.

3.15 Amongst healthcare professionals and particularly patients, there is more work to be done to raise awareness of the ability to report safety concerns / incidents involving medical devices via the Yellow Card scheme. For example, in the same way that we have standardised Yellow Card messaging within all Patient Information Leaflets (PIL) for medicines, this could be made more prominent and we could explore the possibility of adding equivalent wording within the Instructions For Use (IFU) for medical devices.

3.16 We also have materials which are available on the website and shared with patient groups and charities and other organisations, such as the Royal Colleges and system providers, for them to use in their own communications. These need to be continually reviewed and updated to improve and increase stakeholder engagement and activity.

3.17 We have worked to secure placement of messaging within primary healthcare settings including pharmacy through a print and digital fulfilment campaign, ensuring hard copy materials available for patients and healthcare professionals together with video waiting room content to prompt awareness in a target rich environment.

3.18 The hard copy Yellow Card reports in the back of the printed British National Formulary (BNF) has been a physical reminder of the scheme, but this reinforcement/reminder of the scheme is reduced with the move to the digital BNF. The Agency is working with the BNF to help maintain awareness through its digital channels and they will also be supporting the Yellow Card 60th anniversary in their back cover of the BNF 89 edition.

4 Conclusion and next steps

4.1 The Agency works hard to raise awareness of the Yellow Card scheme and improve accessibility. The MHRA will keep communicating the key message that the Yellow Card remains the bedrock of vigilance but is reliant on people reporting. We will continue to actively encourage reporting of any safety concerns to the Yellow Card scheme to help improve the safe use of medicines and medical devices for everyone and continue to deepen its use and connectivity into the healthcare system for healthcare professionals and patients. Additional funding and resources are required to significantly increase awareness of the Yellow Card scheme as well as cope with increased volumes and workloads.

5 Recommendation

5.1 Is the Board assured that the proposed activities will improve awareness of the Yellow Card scheme to make a difference to patient safety?

5.2 Are there any other approaches that the Board would like to suggest?

Alison Cave
March 2025

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

18 March 2024

Title	What should the strategic direction of the British Pharmacopoeia & Laboratory Services be, and how will it support the wider objectives of the MHRA?
Board Sponsor	James Pound
Purpose of Paper	Strategic Direction

What should the strategic direction of the British Pharmacopoeia & Laboratory Services be, and how will it support the wider objectives of the MHRA?

1. Executive Summary

1.1. A review of the British Pharmacopoeia and Laboratory Services (BP&LS) has been undertaken considering the current environment and previous strategic plans. The resulting strategy (Annex A) is aligned to the Agency Corporate Plan and aims to provide direction for the next 5 years.

1.2. The Board are asked to review and approve the strategic recommendations and direction of the BP&LS strategy considering the objectives of the wider Agency and health family.

2. Introduction and background

2.1. Now in its 160th year, British Pharmacopoeia (BP) standards support public health and patient access by providing a statement of the minimum quality expectations for medicinal products placed on the market. Standards work to reduce the cost of developing analytical procedures and specifications necessary to assure quality of a medicinal product.

2.2. The British Pharmacopeia Commission, an advisory non-departmental public body, has the responsibility under the Human Medicines Regulations 2012 to publish quality standards for medicines in the British Pharmacopoeia. On behalf of the Commission, the BP&LS team manages delivery of an annual publication and its supporting catalogue of Chemical Reference Substances.

2.3. In addition to being the minimum legal standard for medicines on the UK market, the British Pharmacopoeia is used and referenced in over 100 countries where it forms an inherent part of established medicines regulations. Wider use of the BP in overseas markets benefits UK patients by expanding the pool of products meeting UK expectations, thus building resilience in the medicines supply chain, as well as reducing costs to the NHS by supporting a competitive supply market.

2.4. The BP also produce content supportive of HM Government's policy, including the UK Life Sciences Vision and Greener NHS Goals. We collaborate with key stakeholders to generate this content. An example of success is working with the Cell & Gene Therapy Catapult and others in the provision of best practice guidance to efficiently determine the quality of Advanced Therapy Medicinal products (ATMPs), helping to build alignment in this innovative area. Another example is our growing portfolio of published case studies encouraging research laboratories to adopt sustainable working practices.

2.5. The BP generates an income from sale of its publications and chemical reference standards which grows ~5% year to year covering its costs. With pricing having been fixed for 12 years, this growth is indicative of the greater and wider use of the BP, and by extrapolation, a wider volume of medicinal products meeting UK expectations.

2.6. Since 2018 the British Pharmacopoeia has implemented a change programme built on customer insight, developing innovative features for the BP Website as well as influencing scientific content and strategic marketing of its services. Feedback has

been very positive with significant improvements to customer satisfaction in all areas of the BP as well as the importance users place on them (Annex B). Importantly, stakeholders are happy with the rate of change noting "*I'd say it's been evolution not revolution. I don't feel I've been forced to relearn it at any point*".

2.7. A number of other Pharmacopoeia exist globally, but the BP is unique with its integration within a medicines regulator enabling us to efficiently produce standards controlling products in line with UK public health priorities, as well as act in support of wider UK government policy.

2.8. In addition, our laboratory services also provides the Agency regulatory functions with a wide array of analytical testing, directly supporting decision making for marketing authorisations, compliance and enforcement activity.

2.9. Publishing and laboratory services are provided through contracts with two suppliers (TSO and LGC), both of which are subject to comprehensive contract management and performing within their established KPIs.

3. Proposal

3.1. The BP&LS strategy (Annex A) sets out 6 strategic recommendations with the aim of ensuring the BP remains fit for the future. It will ensure we continue to deliver while building data to evidence the value of the work we do as well as measuring the success of future improvements. The following summarises these recommendations which are aligned to the Agency's Corporate Plan priorities.

3.2. Aligned with Maintaining Public Trust, we are currently developing the means to measure the patient impact of publishing BP standards and other content, considering reductions in application assessments as well as improved patient access. We aim to further refine this in FY 2025/26 while using it to prioritise our work. We will then review and align the framework of BP expert groups to support priority work areas. We will also strengthen internal and external partnerships to deliver the best value to patients through standards that support access to established and innovative medical and healthcare products. Currently we are mapping and prioritising our established Memorandums of Understandings (MoUs), in alignment with the Partnerships function, prior to establishing connections with ACCESS consortium countries (Australia, Canada, Singapore and Switzerland). Successes include initiation of a project to create harmonised standards with the United States Pharmacopoeia.

3.3. Under Enabling Healthcare Access, we will continue to develop standards transparently articulating UK regulatory expectations, supporting high quality generic applications through the Agency's Healthcare Quality and Access (HQA) group, to support the NHS and ultimately ensure timely UK patient access. In FY 2026/27 we will develop a greater understanding of what drives the sales growth, and so wider use of BP publications and BP Chemical Reference Substances (BPCRS), implementing metrics to track our growth in key supply markets in future. We will continue to greater align publication and reference substance marketing strategies particularly for developing geographical regions and novel approaches, such that the user base for both types of products evolve with the pharmaceutical industry.

We will further develop our prioritisation data to include Intelligence form Agency, NHS and other DHSC bodies in addition to product usage and criticality, expanding our range of BP monograph and reference substances seeking to differentiate from and complement global pharmacopoeia. The resulting increased transparency of

UK regulatory expectations with respect to quality and will help to accelerate product approvals increasing the attraction of UK market entry for both generic medicines and innovative therapies.

3.4. Under Delivering Scientific and Regulatory Excellence, we will in FY 2025/26 develop meaningful metrics which clearly articulate performance recognising the value of keeping the pharmacopoeia up to date alongside non-monograph activity. This includes a measurement of patient-impact. We will build upon the successes of our non-mandatory guidance on ATMPs looking for opportunities to develop formal standards. We will also look to apply the model of working with partners to develop non-mandatory guidance as a means to disseminate knowledge and build alignment enabling stakeholders in research and development to engage with regulators, supporting other innovative areas including mRNA, Phages and Point of Care manufacturing.

We will conduct a full pricing strategy review, to take account of current costs, peer/competitor pricing, distribution costs and customer feedback. We will also conduct a feasibility and risk/benefit study into a paperless future for the BP alongside new subscription models. We will leverage existing contract management to collaborate on identifying and implementing continuous improvements and determine best commercial model for subsequent tenders to deliver value for money.

Subject to approval, for the budget round of FY 2026/27 we will develop a fully costed and deliverable benefits plan, working with our Financial Business Partner, to secure net surplus reinvestment into the BP & Labs functions and products, in line with Treasury guidelines. We will also make strategic capital investment to expand laboratory capabilities to address, for example, demand for greater sensitivity to impurities, investigative capability for enforcement, and applicability for the growing biopharmaceutical/ personalised medicines market.

Lastly under Delivering Scientific and Regulatory Excellence, and building on our corporate plan and in our role as global thought leader, we will establish a means to measure the environmental impact of new and revised monographs. The BP is an enabler for the wider Life Sciences community and we will progress engagement with the global pharmacopoeia to establish a common set of climate-friendly principles in the derivation and provision of standards.

3.5. Under Becoming an Agency Where People Flourish, we will invest in our team development through evolution of our technical training packages, forging alliances with trusted partners like the Cell & Gene Therapy Catapult and exploring technological solutions for routine tasks. We have already developed a training programme on standards development which has been delivered to all junior staff and are developing an Artificial Intelligence chatbot in collaboration with the Digital & Technology group which has developed an understanding of the BP and can generate logical responses to queries. Further areas for training are being identified as are user cases to expand the scope of the AI chatbot. Historically the BP has been an entry point and springboard for staff to experience and take up roles elsewhere in the Agency and Civil Service, as their critical thinking skills are appreciated elsewhere. With an eye to continue that tradition, we will evolve our team structure to meet the wider strategic aims of BP & Labs, identifying skills, capacity and capability gaps, exposure to development opportunities in the Agency, ensuring an engaged and resilient team.

4. Recommendation

4.1. Work is progressing within the BP&LS team to develop groundwork for implementation of the BP&LS strategy. The Board is asked to consider the following points.

4.1.1. As summarised in section 3, does the board support the outlined strategic direction?

4.1.2. Does this strategy enable and support the Agency's future plans and lifecycle model?

4.1.3. Are there any areas where the BP could increase collaboration with other parts of the Agency to achieve its strategic goals or support successful outcomes of wider agency goals?

4.1.4. Does the strategy support wider HMG priorities?

James Pound
February 2025