Medicines & Healthcare products Regulatory Agency

AGENDA FOR BOARD MEETING HELD IN PUBLIC v4

10:00 – 12:30 on Tuesday 8 July 2025

Chair: Professor Anthony Harnden

	AGENDA ITEM	PURPOSE	PRESENTER
10:00	INTRODUCTION		
	1. Declarations of Interest	Information	Chair
	2. Minutes and actions	Approval	All
	3. Updated Board Terms of Reference	Approval	Carly McGurry
	AGENCY PERFORMANCE		
10:10	4. CEO's report – current activities and priorities	Context	Lawrence Tallon
10:40	5. Monthly MHRA finance and people performance report	Assurance	Rose Braithwaite
	ANNUAL REPORT		
10:50	6. ARAC Annual Report to the Board	Assurance	Michael Whitehouse
11:10	7. MHRA Annual Report & Accounts	Approval	Carly McGurry & Rose Braithwaite
	YELLOW CARD BIOBANK		
11:30	8. Yellow Card Biobank pilot & feedback on recruitment	Strategic Direction	Alison Cave
	ASSURANCE		
11:45	9. People & Public Engagement Committee (PPEC) Assurance Report	Assurance	Mercy Jeyasingham
12:00	10. Regulation & Safety Committee (RSC) Assurance Report	Assurance	Paul Goldsmith
	EXTERNAL PERSPECTIVE		
12:15	11. 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 – July 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 / Date expired
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 (Exp. 31/12/ 2024)
	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	No (Exp. 31/03/ 2025)
	Director of Morland House HealthCare Ltd	Director	No	Yes
Lawrence Tallon Chief Executive	None	N/A	N/A	N/A
Dr Junaid Bajwa Non-Executive Director	Microsoft	Ex-employee (Chief Medical Scientist at Microsoft Research), Shareholder	No	No (Exp. Sept 2024)
	Merck Sharp and Dohme	Ex-employee shareholder	No	Yes
	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
	Nahdi Medical Corporation	Non-Executive Director	Yes	Yes

Name and MHRA Role	Name of Other Company or Organisation	Nature of interest	Paid	Current / Date expired
	Nuffield Health	Governor (NED)	Yes	No (Exp. 30/07/ 2024)
	DIA Global	Board Member	No	Yes
	HDR UK	Trustee	No	Yes
	Flagship Pioneering	Senior Partner	Yes	Yes
Julian Beach Interim Lead, Healthcare Quality & Access	None	N/A	N/A	N/A
Tasneem Blondin Chief People Officer	None	N/A	N/A	N/A
Rose Braithwaite Chief Finance Officer	None	N/A	N/A	N/A
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
	Cambridge Judge Business School	Member of Advisory Board and Chair of Remuneration Committee	No	Yes
	Duke Street Bio	Advisory / Consultant	Yes	Yes
	High Value Manufacturing Catapult	Non-Executive Director & Chair of Audit Committee	Yes	Yes
Dr Alison Cave Chief Safety Officer	Drug Industry Association	Council of Regulators	No	Yes
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 Senior Investigator	Yes	Yes
	NIHR	Influenza platform trial in the UK	Yes	Yes
	NIHR	Chair DSMB (PROTECT-V trial)	No	Yes
	30 Technology Ltd	Consultant/Advisor	Yes	Yes
	DNAnudge Ltd	Consultant/Advisor	No	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
	Foundation for Evolution and Mental Health	Trustee	No	Yes

Name and MHRA Role	Name of Other Company or Organisation	Nature of interest	Paid	Current / Date expired
	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
	NHS	Consultant Neurologist	Yes	Yes
	NHS	Clinical Senate Member	No	Yes
	Radix Big Tent Foundation	Trustee	No	Yes
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
	Hertfordshire Partnership University NHS Foundation Trust	Non-Executive Director	Yes	Yes
Mercy Jeyasingham MBE Non-Executive Director	NHS South West London Integrated Care Board	Non-Executive Member	Yes	No (Exp. 31/12/ 2024)
Raj Long Non-Executive Director	Gates Foundation	Ex-Employee – Deputy Director	Yes	No (Exp. 06/07/ 2024)
	Bristol-Myers Squibb	Ex-Employee Shareholder	Yes	Yes
	RESOLVE (Sustainable solutions to critical social, health, and environmental challenges)	Scientific Advisory	No	Yes
	Novartis	Ex-Employee Shareholder	Yes	Yes
	BioNTech Global Health (non-profit)	Strategic Advisory for only Sub-Saharan Africa Public Health for Equitable Access	Yes	Yes
	Gates Venture – EC Innovative Medicines Initiative (IMI) Non-Product – IMI European platform for Neurodegenerative Disorders	Advisory	Yes	Yes
	WHO – Sustainable COVAX Manufacturing Strategy for Regional Health Security	Advisory Expert	No	Yes
	UK Health Security Agency	Associate Non-Executive Board Member	Yes	Yes

Name and MHRA Role	Name of Other Company or Organisation	Nature of interest	Paid	Current / Date expired
	EU Innovative Health Initiatives (IHI)	Advisory Expert for this EU public-private partnership funding health research and innovation funded by European Commission	Yes	Yes
	System Partners Engagement Forum, an advisory group to the Neurodegeneration Initiative	System Partners Engagement Forum Chair	No	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	Chair	Yes	Yes
	Jersey Audit Office	Chair	Yes	Yes

Medicines and Healthcare products Regulatory Agency

Minutes of the Board Meeting Held in Public on 18 March 2025

(10:00 – 12:30)

Round Room, MHRA, 10 South Colonnade, Canary Wharf E14 4PU

Present:

The Board

Professor Anthony Harnden	Chair
Dr June Raine DBE	Chief Executive
Rachel Arrundale	Interim 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 (remotely via Zoom for item 8)
Professor Graham Cooke	Non-Executive Director & Interim Co-Chair
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
Michael Whitehouse	Non-Executive Director

Others in attendance

Rebecca Jennings	Deputy Director, MHRA, Medicines and Pharmacy Team, DHSC Legal Advisers, Government Legal Department
Rachel Bosworth	Director of Communications and Engagement, MHRA
Natalie Richards	Head of the Executive Office, MHRA
Kathryn Glover	Deputy Director, Medicines Regulation and Prescribing, DHSC
James Pound	Interim Executive Director, Innovation and Compliance, MHRA
Dr Harriet Teare	Interim Director, Partnerships, MHRA (for item 6)
Dr Louise Knowles	Deputy Director, Innovation Accelerator and Regulatory Science, MHRA (for item 7)
Dr Stephanie Millican	Deputy Director, Benefit Risk Evaluation II, MHRA (for item 8)

Peter Crowley	Head of BP & Labs, MHRA (for item 9)
Suzanne Fuller	Head of Devices Compliance & Audit, MHRA (item 9)

INTRODUCTION

1. Purpose of the meeting

1.1. Professor Anthony Harnden opened the meeting, which was the first MHRA Board meeting held in public since he was appointed as MHRA Chair in January 2025. The Chair set out his expectations and priorities for this Board meeting.

2. Apologies and Declarations of Interest

2.1. Apologies were received from Carly McGurry, Director of Governance.

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. Minutes and actions from the last meeting

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

AGENCY PERFORMANCE

4. 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) **Healthcare access** – including updates on established medicines performance; innovative medicines; new vaccines; blood products made from UK blood donations; mRNA based cancer immunotherapies; the Windsor Framework implementation; unlicensed hormone replacement therapy implants; and an audit by the Government Internal Audit Agency;

(ii) **Patient safety** – including updates on Safety and Surveillance performance; sodium valproate; GLP-1 agonists; digital mental health technologies; dependency-forming medicines; breast implants; SteriFeed colostrum collector; and an Innovative Health Initiative project on diversity inclusion;

(iii) **Innovation** – including updates on Clinical Trials legislation; companion diagnostics with clinical trials; the Innovative Licensing and Access Pathway (ILAP); Innovation and Compliance Group performance; medical devices regulatory reform; and the recent Good Clinical Practice and Good Laboratory Practice Symposia;

(iv) **Science and research** – including updates on influenza vaccines; DNA sequencing of bacterial infections; bacteriophage development; reference materials; publications; the WHO guideline drafting group; Health and Safety; and Centres of Excellence of Regulatory Science and Innovation (CERSIs);

(v) **Partnerships** – including updates on our relationship with the EU; the Access Consortium; the International Coalition of Medicines Regulatory Authorities (ICMRA); and the recent visit from the Japanese Regulatory Agency;

(vi) **Digital and technology** – including updates on RegulatoryConnect; legacy systems; Appian e-cigarettes; AI prototyping workstreams; the AI airlock project; and data security training;

(vii) **Financial sustainability** – including an update on devices fees; and

(viii) **Dynamic organisation –** including updates on the Patient and Public Community; the employee engagement strategy; the Agency's procurement policy; and the Agency's events policy.

4.2. The Board thanked Dr Raine for her report and provided comments relating to the improvements in performance and backlog clearance, noting that all new medicines applications are being processed within statutory timeframes; sustaining this level of performance by development of new processes, training new staff, and close monitoring of KPIs; applying learnings from recent improvements to health and safety processes; development of AI use cases to demonstrate significant time savings in processes from days to hours, and collaborating with other regulators on AI improvements to processes.

4.3. The Board provided further comments relating to sustainability; the Agency's objectives for the MHRA's relationship with the EU and Access Consortium, and the impacts to patient safety and access to medical products, noting that aligning workstreams with international regulators opens a greater market share to industry, and how shared protocols across different jurisdictions enable rapid clinical trials which is a vital tool in a pandemic situation; and facilitating agile risk proportionate regulation in the UK.

4.4. The Board provided additional comments relating to mRNA cancer vaccines and other personalised medicines guidelines; the Agency's review with the aim of improving information supplied with dependency-forming medicines and ensuring there is appropriate insight into the clinical situations which cause

over- or under-use of these products; how best to engage with patients and the public, including through the use of the Patient and Public Community; and the Agency's risk and safety communications strategy. The Board gave sincere thanks to all members of staff who worked to eliminate the backlogs.

Action: Provide the Board with a report on the feedback on the personalised medicines and platform technologies guidelines, to understand the regulatory challenges posed by these new technologies. ***Julian Beach***

Action: The review into information provided with dependency forming medicines should be reviewed by the new Regulation & Safety Committee. ***Alison Cave / Paul Goldsmith***

5. Monthly financial and people performance of the MHRA at the end of month 10

5.1 The Board considered a report describing the financial and people performance of the MHRA at the end of month 10, also including an update on the Route to Moderate and Return to Green programmes. The Board noted the report and provided comments relating to ensuring it is understood that the responsibility for the Route to Moderate programme is collectively shared across the whole of the executive; the volatility in the Agency's spend profile; ensuring reliable financial and business management, in particular strong forecasting to manage optimism bias; the Agency's vacancy rates and development of the Agency's strategic workforce plan to tackle this; addressing stress in the workforce in particular in relation to workload; developing strong leadership; the IR35 tax issue; and staff turnover.

CERSIs

6. Centres of Excellence in Regulatory Science and Innovation

6.1 The Board considered a paper describing the progression of the delivery of the programme to establish a network of Centres of Excellence for Regulatory Science (CERSIs). Dr Harriet Teare joined for the discussion. The Board noted the update and provided comments relating to the good progress which has been made in this exciting programme, and offered their congratulations; understanding the mid- to long-term plans for this work; identifying future sources of funding; understanding what the outputs of each of the CERSI will be; utilising the CERSI to deliver the MHRA's Science Strategy; utilising the CERSI to raise awareness of the MHRA's work as a route to bring new talent in to the Agency; engagement with the wider scientific community to increase the Agency's profile; ensuring a focus on regulatory science; and ensuring a CERSI for real world data is established in future.

6.2 The Board provided further comments relating to long term sustainability by potentially adopting a commercial model; the importance of data sharing; learning from the FDA's CERSI programme which has been running for longer; system alignment with NICE and other devolved administration health technology assessment

organisations; and improving regulation of new innovative products. The Board thanked Dr Teare for the report.

INNOVATION

7. Innovative Pathways for Medicines and Medical Devices

7.1 The Board considered a paper describing the progress with the pilots of the Innovative Licensing and Access Pathway (ILAP) and the Innovative Devices Access Pathway (IDAP), which 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. Dr Louise Knowles joined for the discussion. The Board noted the report and provided comments relating to the anticipated scale of these pathways, and understanding what can be embedded as business-as-usual and what should be taken forward via a bespoke pathway; demonstration of the value that these pathways add; working closely with other partners in the pathway to improve alignment; and seeking industry feedback on their experiences from the pilot.

7.2 The Board provided further comments relating to development of a sustainable innovation gateway, with clear KPIs around the process to monitor delivery; engagement with other regulators including those who regulate fields such as drone technologies for supply chain solutions; ensuring focus on the benefit to patients; bringing payers and commissioners in early; and enabling continuous improvement to the process. The Board noted the progress and noted there is still more work to be done.

YELLOW CARD SCHEME

8. Increasing awareness of the Yellow Card Scheme

8.1 The Board considered a paper describing the activities that have been ongoing to increase awareness of the Yellow Card Scheme (YCS), with the ultimate aim to increase reporting, to ensure the Yellow Card scheme continues to support patient safety. Dr Alison Cave and Dr Stephanie Millican joined for this item. The Board noted the paper and provided comments relating to engaging with the NHS app; understanding what factors drive reporting to the YCS and what prevents reporting; reporting through healthcare software systems and ensuring the process is ‘one click’; stratification of reporters to identify groups of healthcare professionals with lower reporting rates, to target for communication and education; and further development of the marketing strategy for the YCS.

8.2 The Board provided further comments relating to working with healthcare system providers to better facilitate reporting through their systems; identifying tool to facilitate reporting; utilising the Yellow Card Centres to improve reporting rates; improving the feedback loop to those who have made reports; the bridge between awareness of the YCS and improving reporting rates; how to quantify and minimise risk once a signal has been detected; development of an Application Programming Interface (API) which

software providers can call upon; social media marketing; working with Google to improve the YCS during internet searching; engaging with pharmacists specifically; considering an update to the branding; utilising the opportunity provided by legislative changes; involving other regulators such as the Care Quality Commission in this initiative; health literacy; considering other methods of safety surveillance in tandem with the YCS; and how the Sudlow Report will drive forward use of health data to improve patient safety.

BRITISH PHARMACOPOEIA

9. British Pharmacopoeia strategy

9.1 The Board considered the British Pharmacopoeia (BP) strategy, which has been prepared in alignment with the Agency Corporate Plan and aims to provide direction for the next 5 years. Peter Crowley and Suzanne Fuller joined for the discussion. The Board considered the strategy and provided comments relating to personalised medicines, and how standards can help support introduction and uptake of point of care personalised medicines; timeliness of BP guidance production, to ensure first off patent generics and new biosimilar monographs are available prior to the moment that the patent expires, to enable manufacturers to develop a generic product ahead of time, and development of KPIs to track this measure; supporting the upstream activities of the lifecycle model; keeping up with change and ensuring the BP evolves to address new technologies and environments; linkage with science and research; and the importance of sustainability and social responsibility. The Board endorsed this important strategy.

EXTERNAL PERSPECTIVE

10. Questions from members of the public 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 network of Medicines Safety Officers and Medical Devices Safety Officers and their work with the Yellow Card Scheme; automating Yellow Card reporting; supporting underserved communities to report to the Yellow Card Scheme, particularly reporting in other languages; accessing the Yellow Card reporting system with live data in real time; the benefit of reporting to patients; and IDAP.

ANY OTHER BUSINESS

11.1 Professor Harnden gave his and the Board's sincere thanks to Dr June Raine as she steps down as CEO at the end of March 2025, following an exceptional career in public service. Dr Raine took the opportunity to give her thanks and noted it has been a privilege to lead the MHRA through exciting and challenging times; noting that patient safety is paramount to the work of the Agency. Dr Raine gave thanks to the Board for their support in delivery of the MHRA's mission.

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

MHRA
March 2025

Medicines & Healthcare products
Regulatory Agency

Agency Board

Terms of Reference

Document Control

Document Description:

Document Title	Agency Board Terms of Reference
Issuance/ Revision	4.1 NOT APPROVED
Date Adopted	
Owner	Agency Board
Author	Carly McGurry
Security Level	N/A

Document Change History

Date	Issuance/ Revision	Author	Description of Changes
09-2020	1.0	N/A	First draft
09-2020	1.1	N/A	Updates
09-2020	1.2	N/A	Updates
02-10-2020	1.3	N/A	First review by ExCo at 6 October meeting
21.09.2021	1.4	Stephen Lightfoot	Substantial update to Board ToR to reflect appointment of new members and new ways of working
18.12.2022	2	Carly McGurry	Transfer of Board ToR to Agency template
07.01.2023	2.1	Carly McGurry	Formatting improvements
01.03.2023	2.2	Carly McGurry	Change of delegated authority to reserved matters to more accurately reflect arrangements between Board and ExCo
27.03.2023	2.3	Carly McGurry	Updated following Board feedback to clarify distinct roles of Board and ExCo in relation to partnership agreements and future accommodation/location strategy
18.05.2023	2.4	Stephen Lightfoot	Added clarification that Executive Remuneration is delegated to ODRC

12/06/2023	2.5	Carly McGurry	Amendment to clarify quoracy requirements
29/06/2023	2.6	Carly McGurry	Clarification of public questions relating to the Board agenda only and publication of minutes of meetings held in public. Chair content that these minimal changes do not require further approval from the Board.
18/06/2024	3.0	Carly McGurry	Clarifying arrangements for delegation of authority by the CEO via ExCo, deleting reference to Delivery Plans and including a commitment to periodic independent review of Board effectiveness.
12/05/2025	4.0	Carly McGurry	Amending number of times the Board will meet under new chair and changing reference to sub-committees which have now taken new form.
24/06/2025	4.1	Carly McGurry	Further amendments following discussion at Board on 20 May, to clarify approach to public meetings and framework for sub-committees.

Distribution

To all ExCo members and advisors, to chairs of all management committees and added to Insite for use by all staff. Published on the Agency website.

Contents

1. Introduction

1.1 These Terms of Reference set out the principles that should underpin the roles and responsibilities of members of the Agency Board, which should be consistent with the Government Code for Public Appointments[1], Code of Conduct for Board Members of Public Bodies[2], and Managing Public Money[3]. Details of the relationship between the Department of Health and Social Care (DHSC) and the Medicines and Healthcare products Regulatory Agency ('the Agency') are defined in the Framework Agreement[4].

2. Purpose of the Board

2.1. The role of the Board is to support the Chief Executive in their responsibility for the successful operation of the Agency. MHRA has a unitary Board with an equal number of Executive and Non-Executive Directors, plus a Non-Executive Chair, supported by three Board Assurance Committees.

2.2. The 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 as set out in corporate and delivery plans, and advising on and monitoring plans to ensure those targets are met. The Board operates independently in supporting the Chief Executive, as the Accounting Officer, in the effective delivery of services and overall performance of the Agency 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.

2.3. The Board has no involvement in any regulatory decisions affecting medicines, medical devices or any other products or services delivered by the Agency. These are the responsibility of the Chief Executive Officer, delegated as appropriate to Agency civil servants via the oversight and accountability of the Executive Committee.

2.4. Final decisions (and the responsibility and accountability for those) rest with the Chief Executive Officer as the Accounting Officer of the Agency.

3. Responsibility

3.1. The responsibilities and matters reserved for the Board are set out in full in the Schedule of Reserved Matters annexed to these Terms of Reference.

3.2. The Board provides strategic leadership to the organisation and, in support of that:

- Sets the overall strategic direction of the Agency, within the context of Ministerial direction;

[1] https://www.gov.uk/government/publications/governance-code-for-public-appointments
[2] https://www.gov.uk/government/publications/code-of-conduct-for-board-members-of-public-bodies/code-of-conduct-for-board-members-of-public-bodies-june-2019
[3] https://www.gov.uk/government/publications/managing-public-money
[4] https://www.gov.uk/government/publications/dh-and-mhra-framework-agreement

- Approves the Agency's Corporate Plan, Business Plan and supporting strategies designed to enable achievement of the Agency's strategic objectives, and monitors performance against them;
- Holds the Executive to account for the performance and proper running of the organisation, including operating in accordance with legal and government requirements and those set out in the Agency's Framework Agreement with DHSC;
- Ensures that effective arrangements are in place to provide assurance, effective risk management, governance and internal control;
- Promotes effective dialogue between the Agency, its stakeholders, the DHSC and patients;
- Encourages and engenders robust and expansive patient engagement throughout the organisation;
- Agrees which decisions it will make and which will be taken by the Executive as per the Schedule of Reserved Matters;
- Ensures high standards of corporate governance and personal conduct;
- Monitors the performance of the Agency against core financial and operational objectives;
- Provides effective financial stewardship;
- Advises on executive remuneration through delegation to the People and Public Engagement Committee and
- Monitors and reviews its own effectiveness on at least an annual basis, with periodic independent review.

3.3. The Board does not exercise any line management or executive functions. It does not have any involvement in any regulatory decisions affecting medicines, medical devices, or blood components for transfusion or any other services delivered by the Agency. These are the responsibility of the Chief Executive Officer, supported by the Executive Committee and their staff.

3.4. The DHSC is responsible for assessing the performance of the Chair and the Chief Executive Officer. The Chair is responsible for assessing the performance of Non-Executive Directors and the Chief Executive Officer is responsible for assessing the performance of the Executive Directors.

4. Composition

4.1. The Board is led by a Non-Executive Chair, who is appointed by the Secretary of State for Health and Social Care. The Chair in turn is supported by a unitary Board comprising of not more than 16 individuals.

4.2. Board membership should be formed of up to eight Non-Executive Directors (NEDs), appointed through open competition by the Secretary of State for Health and Social Care, and an equal number of Executive Directors, excluding the Chair. The Chief Executive Officer will appoint the Executive members of the Board from the Executive Committee of the Agency.

4.3. The Chair will nominate a Non-Executive Director to be appointed as Deputy Chair of the Board with agreement from the remainder of the Board. The Deputy Chair should be able to deputise for the Chair so that Board business can continue if the Chair is not available for any reason.

4.4. The Chair will also nominate a Non-Executive Director to be appointed as Senior Independent Director of the Board with agreement from the remainder of the Board. The Senior Independent Director will be a sounding board for the Chair and will also be responsible for gathering feedback on the performance of the Chair on an annual basis, without the Chair present, to provide input into the Chair's annual appraisal with the senior DHSC sponsor. They would also be expected to meet with Board members and act as an intermediary if required.

5. Membership

5.1. The Non-Executive Directors of the Board do not represent any specific customer, sectoral or stakeholder interests. Ministers will take into account the balance of skills when NEDs are appointed so that the Agency Board has the requisite skills and experience profile to deliver the Corporate Plan and associated strategy. The primary function of the NEDs will be to provide constructive challenge, strategic guidance, offer specialist advice and hold the executive to account.

5.2. The NEDs will have Terms of Appointment clearly setting out what is required of them, how their performance will be appraised and the duration of their appointment. The Secretary of State for Health and Social Care may terminate an appointment for any reason before the expiry of the fixed period by giving three months' notice in writing. Additionally, a NED may resign by giving three months' notice in writing to the Secretary of State for Health and Social Care.

5.3. The Agency's Executive Directors will be members of the Board and hold full voting rights on the Board. They will be appointed as Senior Civil Servants in their executive roles through the processes and conditions determined by the Civil Service Commission.

6. Conflicts

6.1. All members of the Board are subject to the Agency's Conflicts of Interest policy and the Cabinet Office's Code of Conduct for Board Members of Public Bodies. Members should pro-actively declare any potential conflicts of interest arising either from business on the agenda or from changes in their personal circumstances.

6.2. When a declaration of a potential conflict of interest is made, the Chair should determine an appropriate course of action, ranging from exclusion for a particular item of business to cessation of membership. Where the Chair has a conflict of interest, the other members led by the Senior Independent Director should determine the appropriate course of action.

7. Quorum

7.1. A quorum for meetings will consist of at least eight members, four of whom should be Non-Executive Directors and four of whom should be Executive Directors, plus the Non-Executive Chair or Deputy Chair.

7.2. If a member of the Board has been disqualified from participating in discussion on any matter by reason of a conflict of interest, they will no longer count towards the quorum.

7.3. If no quorum is available, then the Board cannot commit itself to any decision made.

8. Board Assurance Committees

8.1. The Board may set up committees and delegate authority to them, as the Board sees fit. The composition, terms of reference and reporting requirements of such committees shall be approved by the Board. The Board assurance committees currently constituted are:

- Audit and Risk Assurance Committee
- People and Patient Engagement Committee
- Regulation and Safety Committee

8.2 The Chairs of each sub-committee will meet on a regular basis to discuss the activities of their committees, address any potential overlaps or multiple interests and to ensure quality advice to the full Board.

8.3 While the Board may make use of committees to assist its consideration of relevant matters, such committees are advisory in nature and responsibility for decisions remains with the Board. The Board retains responsibility for and endorses advice to the Chief Executive in all of these areas. The Chair should ensure that sufficient time is allowed at Board meetings for committees to report on the nature and content of discussion at sub-committee meetings, on recommendations made, and to agree on actions to be taken in response.

9. Frequency of Meetings

9.1. The Board will meet a minimum of six times per year but may meet more often if required.

10. Format of Meetings

10.1. When Board Meetings are held in public, members of the public will have the opportunity to observe the Board conducting its business via an online broadcast. However, the Board Meetings will not be public meetings and members of the public will not be involved in making decisions at Board Meetings. The Chair will provide an opportunity for members of the public to ask questions directly of the Board on items on the agenda at each meeting if time allows.

10.2. Where a formal decision is required on a confidential item, a Board Meeting in Committee will be held.

10.3. The Board may also meet in a Board Seminar format where there is a more informal opportunity to meet external guests, provide input into the development of new strategies and take time for the Board's own development.

11. Attendance

11.1. The MHRA Director of Governance and Director of Communications, DHSC Senior Departmental Sponsor and representatives from the Devolved Administrations shall have a standing invitation to attend Board Meetings held in public and Board Meetings in Committee.

12. Secretariat

12.1. The Board is supported by a Board Secretary and Director of Governance from the Agency's Governance Office who should ensure that the Board has the policies, processes, information, time and resources that it needs in order to function effectively and efficiently.

12.2. The Board Secretariat will be responsible for the following, and is supported by timely and proactive input from all Board members:

- Preparing the agenda in consultation with the Chair;
- Developing and maintaining an effective eighteen-month schedule for the Board which enables timely co-ordination between assurance committees and the Board so that all standing business is captured and planned in advance;
- Commissioning Board papers and working with Agency staff to continually improve the quality of papers;
- Circulating Board papers to members and invitees a minimum of five working days before each meeting;
- Producing and circulating draft minutes of the Board meetings to members in advance of the next meeting; and
- Maintaining an action log.

13. Delegated Authority

13.1. The Board must operate within the limits of its authority as described in the Framework Agreement and in line with the associated Cabinet Office guidance on executive agencies. The Board may delegate some of its responsibilities to sub-committees to ensure sufficient scrutiny and engagement with the Executive. The Board's Schedule of Reserved Matters is available in Annex A.

14. Board Reporting

14.1. Recordings of Board Meetings Held in Public will be published on GOV.UK, together with the associated Board papers.

14.2. Minutes of the Board meetings will be provided to the Board, the Executive Committee and minutes of public meetings will be made available on the Agency's web page on GOV.UK.

15. Review of these Terms of Reference

15.1. These terms of reference will be agreed by the Board and reviewed at least annually at the beginning of each financial year.

ANNEX A: SCHEME OF DELEGATION

Certain matters are reserved for the Agency Board. The key aspects are summarised as follows:

Function / Duty / Responsibility of the Board	Responsibility of the Executive
Governance & Strategy	
Determining the overall strategic direction of the Agency. Consideration and approval of the Agency's Corporate Plan.	Preparation of the Agency's Corporate Plan for consideration and approval by the Board, ensuring early consultation with the Board.
Consideration and approval of the principle of formal strategic partnerships with other organisations.	Recommendations to the Board for formal strategic partnerships with other organisations and approval of detailed agreements.
Strategic principles governing operational policy relating to the exercise of the Agency's functions, powers and discretions.	Exercise of all the Agency's legal and administrative powers and discretions in furtherance of statutory functions, subject to escalating any high risk/high impact issues in line with the stated risk management approach.
Consideration of the annual Business Plan and associated budget(s).	Preparation of corporate plans and annual budgets in line with the Agency's strategic plan, ensuring early consultation with the Board.
Approval of changes to ToRs for standing committees of the Board and Board Sub-Committees.	To have regard to the annual review of ToRs for the Board and bring to the attention of the Board any changes for adoption / approval.
Approval of the Agency's risk appetite, risk management strategy and risk framework, and consideration of reports of the Audit and Risk Assurance Committee, in conjunction with the Accounting Officer.	The CEO as Accounting Officer will maintain the system of internal control and assurance framework within the Agency and provide the Board and Audit and Risk Assurance Committee with assurance on its ongoing effectiveness. Advise the Board and Audit and Risk Assurance Committee as to material changes thereto. Escalation of issues for consideration by the Board in accordance with the Agency's risk management strategy.
Assurance of appropriate overarching scheme of reservation and delegation within the Agency and its effective use	To advise the Board of arrangements for effective reservation and delegation, within the execution of the CEO's wider responsibilities (as delegated in this document) and evaluation of how those arrangements are working in practice

Approval of Annual Report and Accounts, in conjunction with and support of the Accounting Officer, and following a recommendation from ARAC.	Drawing up the annual report for adoption. Drawing up annual accounts including the annual governance statement for Audit and Risk Assurance Committee consideration and Board approval. The CEO will sign the Agency's Annual Report and Accounts as the Agency's Accounting Officer.
Delegate approval of the Agency's counter fraud and security management arrangements to the Audit & Risk Assurance Committee so that the Committee Chair can update the Board on significant issues in their regular Committee assurance report to the Board.	Preparation of such documents and policies to facilitate such approval with due regard to the Agency's stated risk appetite within this domain.
Delegate approval of the internal audit assurance programme to the Audit & Risk Assurance Committee so that the Committee Chair can update the Board on significant issues arising from the work of the appointed auditors in the regular Committee assurance report to the Board.	Reporting to the Audit and Risk Assurance Committee and the Board matters of significance arising from the work of internal and external auditors.
Consideration and approval of aspects of the corporate governance framework, including principles of good governance, corporate values statements, and such other aspects which may arise from time to time.	All matters of organisation below the level of CEO. Delegation of authority to other Agency staff and preparation and maintenance of a comprehensive scheme of delegation for the organisation.
Consideration and approval of appointments to Board assurance committees, following the recommendation of the Chair.	
Financial / People / Operational	
Approval of the Agency's Standing Financial Instructions and financial scheme of delegation.	Preparation of the Standing Financial Instructions in consultation with the Resources Committee and Executive Committee.
Matters which may have a serious impact on the reputation of the Agency or have a political or public sensitivity.	Exercise of all the Agency's legal and administrative powers and discretions in furtherance of statutory functions, subject to escalating any high risk/high impact issues in line with the stated risk management approach.
Significant variations to the approved annual business plan and financial budget, where the variation would have a fundamental impact on the delivery of the	Mitigations and actions to correct variations to the approved annual business plan and financial budget so that assurance can be

Agency's strategy and its statutory responsibilities.	provided to the Board on the delivery of the agreed plans.
Confirmation of the regular performance reports and information required to provide appropriate scrutiny and assurance of the Agency's overall performance. The Board may ask the Executive Committee or one of the Board Assurance Committees to review any specific areas of concern in more detail so that recommendations for improvement can then be made back to the Board.	Informing the Board of progress in achieving performance objectives and advising of any significant variance from the approved operating plans and budget. Informing the Board of any significant issues in the operation of the Agency.
Approval of significant changes to the organisation, location, and People Strategy of the Agency.	Preparation of the People Strategy and associated policies in consultation with the People and Culture Committee and through the Executive Committee. Preparation of accommodation and location strategies and approval of contractual agreements.
The People and Patient Engagement Committee will make recommendations to the Chief Executive on the performance assessment and discretionary rewards for the Executive Directors.	All appointments and all other HR/people issues throughout the Agency.
Legal / Regulatory	
Approval of significant changes in the Agency's regulatory approach or strategy so that appropriate representations can be made to Ministers and the DHSC.	Exercise of all the Agency's legal and administrative powers and discretions in furtherance of statutory functions, subject to escalating any high risk/high impact issues in line with the stated risk management approach.

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

8th July 2025

Title	MHRA Chief Executive's Report to the Board – July 2025
Board Sponsor	Lawrence Tallon
Purpose of Paper	Context

MHRA CHIEF EXECUTIVE'S REPORT TO THE BOARD – JULY 2025

Introduction

1. In this report I summarise the main areas of activity and progress for the MHRA over the last two months. It is an overview and is not intended to be exhaustive.

2. This has been a period in which the significant performance improvements of last year have been maintained and consolidated. That has allowed the Agency to be more forward-thinking about our future strategy and outward-looking to our many important partners who will help us shape and then deliver our strategy. As we have attained a more stable footing in the here-and-now, we have been able to raise our sights and aspirations for the indispensable and expert role we can play in the future for UK healthcare and life sciences.

Strategy

3. On 11th June, the Chancellor of the Exchequer announced the Government's Spending Review (SR) for the next three years. There were notable commitments to invest in the NHS and in UK life sciences as an engine of economic growth. The SR is to be followed by two significant documents for our sectors: the NHS Ten Year Plan and the Life Sciences Sector Delivery Plan. Having contributed to the drafting, I anticipate both documents will make important references to the MHRA as a key part of the health and science eco-system. This is likely to include our role in supporting the UK to regain its market share of clinical trials, and our thought-leadership in the emergent understanding of regulating AI as a medical device.

4. Following ministerial approval, on 25th June we published our annual business plan for 2025/26, which is the last year of the current SR period. Our task in the year ahead is to co-develop our strategy, with our people and partners, for the next three-year SR period. That requires deep evidence generation and both internal and external engagement, with a view to publishing our new strategy before the 2026/27 financial year. The Board will have multiple opportunities to shape and approve this strategy in the year ahead.

5. The strategy development process commenced with an All-Staff meeting, a Senior Leaders Forum, an Executive Committee deep dive and an away day of the full Board. I am grateful to Dr Lottie McIntyre and Alice Black for their excellent work to begin the strategy development process. We will be bolstered significantly in our strategy capability with the arrival of Dr Ed Middleton (see people section below).

6. Whilst I do not intend to pre-empt the strategy development process ahead, I have taken some early opportunities to set out my emergent thinking on our future strategic direction, in line with the early statements of our Chair, Professor Anthony Harnden. I gave a keynote speech at the UK edition of the Prix Galien, at the invitation of the Chair of the Commission on Human Medicines (CHM), Professor Sir Munir Pirmohamed, in which I set out an optimistic view of how the MHRA can make a major contribution to improving UK health services and life sciences.

Safety

7. The MHRA has been highly active and used its full scope of powers in recent months to protect the safety of patients and the public. At the end of April, our Criminal Enforcement Unit successfully executed Operation Subaru. This was a major operation to combat illicit trafficking of medicines into the UK. Twelve suspects were arrested across the West Midlands and North West and millions of illegal medicines were confiscated in shutting down this dangerous criminal gang that was exploiting consumers and putting them at risk of severe harm. Andy Morling, our Head of the Criminal Enforcement Unit, his whole team and their partners across law enforcement, deserve enormous praise for this large-scale, complex and highly successful operation.

8. On 5 June, our Chief Safety Officer, Dr Alison Cave, led a major national communications intervention around safety risks from GLP-1 receptor agonists. This focused on the need for women to avoid taking that group of medicines during pregnancy and the potential impact of one GLP-1 receptor agonists on the effectiveness of oral contraception. Alison was featured widely across national broadcast, print and social media and demonstrated authoritative and expert advice on the effects of this group of medicines.

9. New post-market surveillance requirements for medical devices came into force on the 16th June. These measures put greater onus on manufacturers and suppliers of medical devices to monitor device performance and report any potential safety risks to the MHRA. This will strengthen protections for patients and the public through faster identification of, and responses to, incidents and emerging risks.

10. From 18 June, the Commission on Human Medicines (CHM) temporarily restricted use of the IXCHIQ Chikungunya vaccine in people aged 65 years and above, following very rare fatal reactions reported in other countries. No fatalities have been reported in the UK, but this temporary restriction has been taken as a precautionary measure while the MHRA conducts a safety review.

11. I have held collaborative dialogues with the National Patient Safety Commissioner, Henrietta Huges, and we will continue to meet regularly. I wrote to the Commissioner to state our support for those findings that are relevant to the MHRA in her recent report, *The Safety Gap*, which addresses patient information for people with sensory impairment.

12. We hosted a productive visit from the Health and Safety Executive at the Science Campus in South Mimms on 23 June, during which they expressed substantial assurance in the progress made at the campus over the past year. I want to extend my thanks to Nicola Rose, Marie Donatantonio and the whole HSE team for their strong progress and continued efforts.

Performance

13. We remain compliant with all of our statutory performance targets for May 2025. The Chair and I met with Minister of State, Karin Smyth MP, to review the MHRA's performance for the last quarter, and received strong endorsement of the Agency's recent work.

14. The MHRA's licensing division has been busy in the last two months and approved a number of new medicines, including:

    - Polyhexanide (Akantior) to treat acanthamoeba keratitis (through international reliance)
    - PCV21 (Capvaxive), a vaccine to protect against pneumococcal infections such as pneumonia and meningitis (through international reliance)
    - rADAMTS13 (ADZYNMA), the first UK treatment for congenital thrombotic thrombocytopenic purpura
    - teprotumumab (Tepezza) as the first UK treatment for adults with moderate to severe Thyroid Eye Disease
    - Vimkunya vaccine approved to prevent disease caused by the chikungunya virus in people 12 years of age and older (through international reliance)
    - The world's first approval of a low carbon pressurised metered dose inhaler Trixeo Aerosphere

15. In addition to maintaining and consolidating our performance on licensing and clinical trials, our focus now turns increasingly to addressing performance targets for scientific advice. Whilst this activity is not part of our statutory requirements, it is a crucial part of the added value the MHRA can offer to developers, by de-risking development, supporting the design of robust clinical trials, reducing developmental timelines for developers, and improving the quality of submissions.

16. The Regulatory Connect programme is intended to support our core processes and performance in future. I am concerned about the delays incurred up to now. With the SRO, James Pound, I have appointed an experienced Programme Director to take stock of this important programme and to make recommendations to the Board and me.

Innovation

17. An important part of this more forward- and outward-looking phase for the MHRA is to increase our contribution to innovation in UK health services and life sciences. We have several innovative initiatives underway, which together will increasingly coalesce into an innovation strand within our forthcoming strategy.

18. We have become the first pioneer country – soon to be followed by our Access consortium partner, Singapore, – in HealthAI's global framework of leading countries that will work together to set best practice for the regulation of responsible AI in healthcare. On 24th June, Lord Vallance, Dr Ricardo Baptista, CEO of

HealthAI, and I launched this innovative agreement with a signing ceremony in Westminster.

19. We have also launched our request for proposals for the second cohort of our AI Airlock, where we work collaboratively with AI companies to understand the implications for regulation of AI as a medical device in a safe 'sandbox' environment.

20. In addition to the regulation of AI as a medical device, we will be looking increasingly to develop AI within our regulatory workflows – something that the US Food and Drug Administration (FDA) have already commenced.

21. The MHRA has also issued guidance on Phage therapies, a form of virus-based treatment that will be increasingly important in our era of Anti-Microbial Resistance. This shows international thought-leadership from the MHRA in an emerging area of biological therapies, which has been widely welcomed.

People

22. Following the decision of the Board at our meeting in May, we have made public our plans to open a new MHRA office in Leeds. This was officially announced by the Secretary of State, Rt Hon Wes Streeting MP, underscoring the importance of this commitment to the Government's 'Places for Growth' initiative to locate more civil service jobs outside London, and to drive regional economic growth in Leeds and Yorkshire as an established hub of health tech innovation.

23. We have reiterated our commitment to our current sites at 10SC in Canary Wharf and to the Science Campus in South Mimms. This new Leeds office will offer additional geographical choice and improve our recruitment reach, especially for the many tech professionals and graduates in the Leeds area.

24. I have now had the chance to get to know many more of our people across the MHRA. There is no doubt in my mind that we are fortunate to have a workforce that is both incredibly expert in regulatory science, and many other disciplines, and also one that is deeply motivated by our public service mission. These fundamental traits give me great confidence for what we can achieve together.

25. However, based on my close reading of the staff survey results, and feedback from many colleagues across the organisation, I also feel there is a pressing need to move the organisational culture and practices to focus more on openness, trust and empowerment. I have written to all colleagues on this theme and these words of 'openness', 'trust' and 'empowerment', will be important recurring features of my leadership of the MHRA.

26. We have some significant senior leadership changes that have taken place recently or are due soon:

- Liz Booth has departed, and we have been joined by Tasneem Blondin as our new Chief People Officer.
- Ed Middleton has joined as interim Director of Strategy.
- Harriet Teare, co-Director of Partnerships, has announced she will take up a new leadership role with Oxford Health Partners.
- Claire Harrison has announced she will be leaving to take up an exciting role at the Department of Business and Trade.
- Over the summer/autumn we will recruit two new Board level roles: a Chief Medical and Scientific Officer; and a Chief Officer for Digital Technologies.

Partnerships

27. The Chair and I have continued an extensive programme of engagements with our many partners, too many to list in full.

28. We are making particularly strong progress on our work with the National Institute for Health and Care Excellence (NICE) on joint scientific advice and the Government's commitment as part of the growth agenda for joint reviews of the MHRA's Marketing Authorisation and NICE's Health Technology Assessment. We will soon announce the timing and guidance for those joint reviews, which will meet the Government's target. I am especially pleased with how closely and collaboratively our two organisations are working together and I know that sentiment is shared by my colleague, the CEO of NICE, Dr Sam Roberts.

29. For National Blood Week we collaborated with NHS Blood and Transplant, NHS North Middlesex University Hospitals and Tottenham Hotspur Football Club on a week's campaign to drive up blood donation and awareness. This successful campaign recruited a large number of new donors and raised awareness of those with universal donor blood type and among ethnic minority groups in whom donation rates are particularly important.

30. Following the successful MHRA Board meeting in Edinburgh in May, a number of conversations have taken place to follow up on the actions agreed. In particular, we will be looking to build on Scotland's rich health data environment to help improve our safety and surveillance systems. We also anticipate similarly productive meetings ahead in Northern Ireland and in Wales, as part of our firm commitment to be a truly national regulator across the four nations of the UK.

31. In the last few weeks, my colleagues and I have engaged widely with international peers and partners, as we become more outward-looking in our worldview. Julian Beach, Alison Cave, myself and a number of other colleagues, represented the MHRA at the major Drug Information Association conference in Washington DC in June.

32. Amongst a packed calendar of engagements, we held a well-received 'Town Hall' meeting in which we presented the Agency's work and priorities. Alison and I also held a collegiate and productive bilateral with Dr Marty Mackary, the new

Commissioner of the FDA, and his team. I had the opportunity to meet at length with my peer Heads of Agency of our Access consortium partners in Singapore, Canada and Australia (our Swiss colleague was not able to attend).

33. On the same trip, I held an MHRA roundtable under the auspices of the Department of Business and Trade at the BIO conference in Boston. Additionally, I have been building collegiate relationships with European peers at the European Medicines Agency's 30th Anniversary Scientific Conference in Amsterdam.

34. Now that I have begun to gain a perspective on how the MHRA is viewed by international partners, I am struck by the deep regard in which the Agency is held for its history, expertise and spirit of collaboration. Long may this continue.

Lawrence Tallon
Chief Executive Officer, MHRA
July 2025

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN COMMITTEE

8 July 2025

Title	**What was the financial and HR performance of the MHRA for May 2025?**
Board Sponsor	Rose Braithwaite
Purpose of Paper	Assurance

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What was the financial and HR performance of the MHRA for May 2025?

1. Executive Summary

1.1. The May 2025 Resource result was a £0.3m underspend to budget, which contributes to a Year-to-Date Resource underspend of £1.3m. The May result is mostly driven by a £1.2 non-pay operational costs underspend which offsets a £0.3m trading income deficit and a £0.4m pay overspend. The non-pay underspend is most likely a time variance, which would leave an income deficit and pay overspend to resolve.

1.2. Although we have a YTD underspend, the Agency's budget is still overprogrammed by £2m in the running hot provision. We estimate a further £2.3m has arisen in further pressures. An income deficit, currently £1.2m under budget, would make the task of moving towards breaking even more difficult.

1.3. The CDEL position as at the end of May 2025 is close to budget at £5.8m versus the planned £6.2m, with a small underspend in Reg Connect which will move to budget later in the year.

2. Agency performance – Resource spend

Income

2.1. The Agency's Operating income for May 2025 finished at £13.1m, a slight improvement on the £12.8m April result, but £0.3m below the planned period budget. This contributes to a £1.2m YTD income deficit which is mostly down to trading income being £1m below budget.

2.2. National Applications are £398k (10%) behind the YTD budget despite a stronger performance in May. The deficit is driven by significantly lower Standard applications income as the projected increase in volume hasn't materialised yet. In contrast, Major and Complex National Applications continue to perform strongly reflecting business prioritisation.

2.3. Inspections income is £294k (28%) behind its YTD target. The local team have given assurance that work is on track, and we should see a significant increase in June once all remaining Q1 invoicing is done.

2.4. The Q1 forecast in early July will help us understand whether the temporary income deficit will recover towards budget later in the year. As a point of comparison, the income deficit to budget in May 24 was £0.5m but then performed over budget in later months. However, that was with the additional

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backlog work being undertaken. Even with a recovery to budget, however, we will need to work on how we close the running hot provision.

Table 1 – Agency Financial Performance for May 2025

May 2025	Period		*Variance vs*	YTD		*Variance vs*	Full Year
Resource	**Actual**	**Budget**	*Budget*	**Actual**	**Budget**	*Budget*	**Budget**
	£M	**£M**	*% / £M*	**£M**	**£M**	*% / £M*	**£M**
Trading Income	8.3	8.7	(4%)	16.4	17.4	(6%)	109.1
Service Fee Income	4.3	4.3	0%	8.5	8.5	0%	51.1
Grant Income	0.5	0.4	9%	0.8	0.9	(14%)	6.5
Total Income Position	**13.1**	**13.4**	**(0.3)**	**25.6**	**26.8**	**(1.2)**	**166.8**
Staff Costs	9.4	9.0	(5%)	18.3	17.9	(2%)	117.6
Operating Costs	4.2	5.4	22%	8.5	11.2	24%	68.9
Total Cost Position	**13.7**	**14.4**	**0.7**	**26.8**	**29.1**	**2.3**	**186.6**
Operating Net Position	**(0.6)**	**(1.0)**	**0.4**	**(1.1)**	**(2.3)**	**1.2**	**(19.8)**
Project Grant Income	0.2	0.3	(32%)	0.4	0.7	(37%)	4.1
Staff Costs	0.4	0.3	(15%)	0.7	0.6	(12%)	3.8
Projects Costs	1.1	1.2	7%	1.8	2.3	20%	15.2
Projects Net Position	**(1.2)**	**(1.1)**	**(0.1)**	**(2.1)**	**(2.3)**	**0.1**	**(15.0)**
Agency Resource Net Position	**(1.8)**	**(2.1)**	**0.3**	**(3.3)**	**(4.6)**	**1.3**	**(34.8)**
DHSC RDEL Operational Funding	2.0	2.0	0%	3.9	3.9	0%	23.6
DHSC RDEL Innovation Funding	0.7	0.7	0%	1.3	1.3	(2%)	9.6
DHSC RDEL AI Funding	0.1	0.1	0%	0.2	0.2	0%	1.0
DHSC RDEL IDAP Funding	0.0	0.1	(50%)	0.1	0.2	(50%)	0.6
Total Resource DH Position	**2.8**	**2.8**	**(0.0)**	**5.5**	**5.6**	**(0.1)**	**34.8**
Total RDEL	**1.0**	**0.7**	**0.3**	**2.2**	**1.0**	**1.2**	**(0.0)**
Running Hot Provision							**(2.0)**
Further unbudgeted spend pressures identified							**(2.3)**
Overall total							**(4.3)**

Staff Costs

2.5. Pay costs in May were £0.4m over budget because the actual vacancy rate is lower than the 15% assumed in the budget. The budget for Q1 doesn't include

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the new roles approved because of a recruitment lag assumption. The monthly pay budget will increase in future months as the vacancy rate assumption reduces to 12% and the budget for the new roles approved is included from July onwards. The YTD variance is also £0.4m.

Non-Pay Operating Costs

2.6. The YTD non-pay underspend of £2.6m drives the overall resource underspend. Most of the underspend is a time variance and costs should move towards budget once projects and activities move out of their planning phase.

2.7. IT costs remain low versus budget as priorities are still being agreed, with Cyber and Operational improvement spend to start in June and August respectively. Budget profiling will be updated to reflect spend plans once confirmed. D&T are already forecasting an overspend.

2.8. Similarly, Accommodation costs reflect low building repairs and maintenance spend in South Mimms and office space alterations spend in 10SC. Both are planned to increase later in the year.

2.9. Looking towards the full year budget, the Agency will need to manage the remaining £2m running hot provision and the £2.3m of new emerging pressures through higher income or reducing our costs.

3. Agency performance – Capital spend

3.1. 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.

Table 2 – Capital Spend for May 2025

May 2025 Capital	YTD Actual £M	YTD Budget £M	*Variance vs Budget % / £M*	Full Year Budget £M
Projects Costs	4.7	5.1	8%	35.9
CDEL Operational Costs	1.1	1.0	(8%)	11.1
Agency Capital Net Position	**(5.8)**	**(6.2)**	**0.3**	**(47.0)**
DHSC Capital Funding	6.2	6.2	0%	47.0
Total Capital DH Position	**6.2**	**6.2**	**0.0**	**47.0**
Total CDEL	**0.3**	**0.0**	**0.3**	**0.0**

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3.2. Capital spend is £0.3m behind budget because of a small underspend in Reg Connect. Spend is expected to catch up with budget in the coming months. South Mimms capital spend is ahead of prior year trends as some projects were paused in March and restarted in April to ensure that we didn't overspend on capital last year.

3.3. The figures do not yet include the additional £2.2m this year that has been allocated to us from the government decarbonisation fund. We have been awarded a total of £10.9m over the next three years. This will allow us to replace gas boilers with electric ones to provide steam to the autoclaves and freeze dryers and humidification to the laboratories along with work on the hot water and heating systems on site.

4. Agency People data – March

People in Post

4.1. We had 1,470.32 people in post at the end of May 2025 (FTE, permanent, fixed term and Phd students covering established posts), an increase of 26.52 FTE. Of this number, 160.9 were fixed term, an increase of 4.7 FTE.

4.2. Whilst the Agency grows and recruits at pace, we are looking to reduce the number of fixed term roles which creates a lack of stability where there are many posts limited by their fixed term tenure.

Turnover

4.3. Voluntary turnover of staff has decreased further still in May to 5.3% (5.7% in April). However, as we increase our posts this will of course have an impact on this number but turnover below our optimum of 8-10% remains a challenge. We continue to see an increase in the number of joiners versus leavers, reflected in our turnover. We welcomed 28 new starters to the Agency in May versus 4 voluntary leavers (27:7 in April).

Vacancies

4.4. 17 of our 99 vacant posts are filled by contingent workers, a decrease of 1 on April. Over time, vacancy rates are declining as hiring managers progress their priority recruitment. In respect of our 'vacancies' (a decrease on the 117 reported for April because of peak levels of recruitment).

4.5. The Digital and Technology Group have the highest level of vacancies and are currently prioritising the new Leeds office in terms of recruitment, where we are utilising specialist recruitment partners that we have worked with successfully on many previous campaigns in recent years, so we are sure to see a reduction in vacancies in the coming months.

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Sickness Absence

4.6. Sickness absence (annualised) is reported as 6.4 days per FTE, a marginal increase on the 6.2 days reported in April. Absence has increased in all Groups except Enablement and SR&I. The lowest absence levels continue to be within Partnerships which reports 2 days per FTE and the highest in Corporate at 8.7, albeit significantly lower than report in previous months. Data for the smaller groups can be disproportionately impacted by cases of long-term sickness absence.

4.7. Current levels of sickness absence are not a concern and not out of kilter with the wider Civil Service, but the reasons for absence remain a concern, with 33% of all absence reportedly due to stress, depression or anxiety, albeit this is again consistent with the Civil Service.

Recruitment

4.8. Recruitment activity continues at high pace as Groups work through their priority posts to fill. During May there were 55 roles ‘live’ ie newly advertised, actively interviewing/shortlisting onboarding or closed during the quarter, 20 more than in April. We expect the high volumes to continue given the recent approval of c160 new permanent or fixed term roles which Groups and Functions have prioritised so that recruitment can be delivered in a planned and coordinated way. S&S, SR&I and Corporate have the most recruitment activity during May. Additional interim resources for the Recruitment Team have been brought in in order to manage the significant volumes that continue.

4.9. The announcement in May of a new Leeds office sees the beginning of an agreement to work with two of our contracted external recruitment partners to run a campaign to fill digital roles in the city. DTG colleagues are currently prioritising which roles these are, and the campaign will be launched as soon as possible.

Rose Braithwaite
27 June 2025

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

8th July 2025

Title	Audit and Risk Assurance Committee (ARAC) Annual Report 2024-25
Board Sponsor	Michael Whitehouse
Purpose of Paper	Assurance

Audit and Risk Assurance Committee Annual Report to the Board 2024-25

1. Executive Summary

1.1. This report provides the Board with an annual review of the Committee's work to provide assurance on the effectiveness of the MHRA's governance, risk management, financial and internal control arrangements over the last 12 months.

1.2. The Board is asked to receive the report and to note the Committee's assessment of the work undertaken in 2024-25 (section 3) and the anticipated focus for the coming year (section 5).

1.3. This report also records the Committee's review of external audit's work. Following ARAC's most recent meeting on 1 July we are pleased to report to the Board that the National Audit Office (NAO) will be advising the Comptroller and Auditor General that he can issue an unqualified audit opinion for the MHRA's Financial Statements for 2024-25.

2. Introduction

2.1. The Committee's primary role is to provide the Board with an independent and objective view of the adequacy and effectiveness of the MHRA's governance arrangements, systems of internal controls, financial control, and the management of risk.

2.2. To discharge this function the Audit and Risk Assurance Committee (ARAC) prepares an annual report for the Board and the Accounting Officer. In addition, throughout the year after each Committee meeting the Board receives a short report summarising its discussion and highlighting any assurance issues to bring to the Board's attention.

2.3. The Committee's membership remained unchanged in 2024-25. In April 2025 we were pleased to welcome Raj Long as a member of ARAC. Sharon McCarthy continues to support the Committee as an independent adviser and has attended meetings since February 2024. No members declared any conflicts of interests for any agenda item during the year.

2.4. The Committee met five times in 2024-25 and all our meetings were quorate. We were pleased to have input from the Chair of the Agency's Patient Safety and Engagement Committee at meetings when we were considering risk or issues where both Committees had a remit. This approach is intended to strengthen governance through a focus on cross cutting themes and good practice. We welcome the opportunity to continue this joint working with the new Regulation and Safety Committee.

2.5. The Committee held one training and development meeting in December 2024. This focused on Assurance Frameworks and the types of evidence which the Audit Committee needs to be confident that assurance governance is effective. The meeting was facilitated by Internal Audit drawing on their recent cross government report on assurance frameworks.

2.6. Audit and Risk assurance Committee's assessment. The assessment of the Committee based on the totality of the work presented to it, including, but not exclusively, internal

and external audit work, is that financial controls are well designed and managed. The Committee has seen consecutive annual improvements in the Agency's approach to risk management as confirmed by Internal Audit's independent review. A robust framework for identifying and managing risk is now in place and operating effectively. A further positive development is work undertaken to define and classify risk appetite.On wider governance and internal control, the Committee is pleased to report significant improvement. For the preceding three years the Government Internal Audit Agency awarded the Agency a Limited assurance rating for its overall control environment. For 2024-25 Internal Audit has increased its assurance rating to Moderate. This improvement reflects considerable work by the Agency through its comprehensive "Route to Moderate" programme. This is a significant achievement. Going forward it is important that the improvements achieved are fully embedded across the Agency so that they are resilient and sustainable.

2.8. In 2024-25 a new Chair of the MHRA was appointed and the Chief Executive retired in March 2025 with her successor taking up post from the beginning of April. The Committee is pleased to report that the transfer of responsibilities was handled well with no dilution in the Agency's control environment or Accounting Officer responsibilities.

3. Information supporting the Committee's opinion

3.1. Summarised below are the key sources of assurance that the Committee has relied upon in formulating its opinion:

- **Internal Audit**

3.2. The MHRA's internal audit service is provided by the Government Internal Audit Agency (GIAA). ARAC can, should the need arise, commission private or specialist firms to perform discrete audits or investigations. There was no requirement to do this during 2024-25. All work was performed by GIAA which drew on its own specialists.

3.3. Until December 2024 the Head of Internal Audit for the MHRA was Stephen Wright. In January 2025 Jo Charlton assumed this responsibility. The Committee agreed an annual work programme for internal audit at the beginning of the year. This was finally made up of 10 substantial reviews. These are set out in the following table, together with the period when they were delivered, and the assurance rating awarded. An explanation of the ratings is provided in Annex A.

Audit Title	Timing	Rating
Data and Security Protection Toolkit (DSPT) 2024 submission	Q1	Moderate
Budgeting and Financial Management	Q2	Moderate
Fees / Cost Modelling	Q2	Moderate
Safety – Signals Management (Devices and Medicines)	Q3	Substantial
Core Functions - Licensing	Q3	Moderate
Information Sharing	Q4	Moderate
Notification and Recording of CPRD Research Data Quality Issues	Q4	Moderate
Insider Threat	Q4	Limited
PPM – Regulatory Connect - Release 2 Service Readiness	Q4	Moderate
Board / Subcommittee Effectiveness	Q4	Moderate

3.4. These audits informed the head of Internal Audit's annual opinion which the Committee reviewed in draft in May, receiving the final version at its July meeting. An opinion of Moderate assurance was issued for the year ending 31 March 2025.

3.5. The number of internal reports receiving moderate or substantial assurance has increased from eight in 2023-24 to nine in 2024-25 which is good progress. Internal Audit recognised this and commented positively that there is evidence of embedding and further maturing of centrally orchestrated governance and that oversight processes are on a positive trajectory and are strengthening controls.

3.6. Internal Audit highlighted three wider systemic areas which the Agency should continue to seek to improve. These are capability and the provision of appropriate training so that the MHRA has sufficient skills and is resilient; having clear and comprehensive organisational policies and procedures; and ongoing cyber resilience.

3.7. MHRA is subject to external audit by the National Audit Office (NAO) which currently subcontracts the audit to KPMG. The responsibility for recommending the audit opinion to the Comptroller and Auditor General (C&AG) is retained by the NAO. The opinion covers whether the accounts are a true and fair view of the financial affairs of the MHRA and whether its funds have been applied for the purposes intended by Parliament (regularity opinion).

- **External Audit**

3.8. In support of the external audit process the Committee reviewed the Agency's accounting policies, the draft financial statements and draft annual report and on behalf of the Board provided the necessary assurances required by external audit.

3.9. The Committee is pleased to report that the NAO will be recommending that the C&AG gives a clear unqualified opinion on the MHRA's financial statements.

3.10. The NAO's Engagement Director and Engagement Manager attend each Audit Committee meeting together with KPMG. As external auditor of all Department of Health Arm's Length Bodies (ALBs) the NAO and KPMG provide the Committee with useful comparative insights from across the sector and more widely from across central government.

- **Fraud, bribery and corruption**

3.11. All health ALBs are required to comply with the Government's Functional Standard GovS 013: Counter Fraud. MHRA's counter fraud, bribery and corruption strategy, policy and response plan is aligned to the Functional Standard. Fraud prevention both internal to the Agency and externally in the unregulated medicines supply chain are standing items on ARAC's agenda.

3.12. For fraud prevention as part of the Agency's day to day business a new Code of Business Conduct was issued in June 2024 supporting staff to know the requirements of them as civil servants. This high lights how to raise concerns over potential fraud or other irregularity. The annual fraud awareness week was held in November 2024. Thirteen concerns were raised with, or identified by, nominated fraud officers in 2024-25. None of these proved to be fraudulent activity but have helped to improve management practices. An updated Fraud Prevention Strategy for 2025-30 is now in place.

3.13. In respect of the Agency's work to prevent and detect fraud in the medicines and medical devices supply chain the Committee remain assured that this activity is well focused and resourced. A most notable recent example was detection and arrest in the West Midlands and the Northwest of England arising from a large-scale criminal conspiracy to traffic medicines.

- **Whistleblowing**

3.14. There was one whistleblowing case in 2024-25 but no wrongdoing was identified, and the case was concluded in August 2024.The Board Raising Concerns Champion was kept informed of progress and the outcome.

- **Information Governance**

3.15. The Committee received one specific Internal Audit Report on information governance. This was Internal Audit 's review of the Agency's compliance with the Data Security and Protection Toolkit which received a Moderate assessment. The Committee were also kept informed about the extent of the Agency's alignment with the National Cyber Security Centre's Cyber Assessment Framework. The MHRA recognises that it has more to do to strengthen its cyber security and in particular resolve digital legacy risks. The Committee will continue to seek evidence to provide assurance that cyber controls are reliable. Internal Audit's 2025-26 programme includes further work on the Agency's compliance with data security good practice.

- **Assurance Framework**

3.16. The Committee has oversight of the operation of the MHRA's internal control and assurance arrangements. These arrangements include the:

- identification of corporate risks linked to business objectives
- assessment and management of high and medium level risks
- monitoring of the effectiveness of internal controls
- monitoring of financial controls and exception reporting
- considering of any instances of non-compliance with laws or regulations
- review of independent assurance reports.

3.17. We comment specifically on risk management in paragraphs 3.20 – 3.24.

3.18. Internal Audit's moderate assessment for the MHRA's overall control environment is a major improvement. Supporting this is the detailed assurance mapping which is now in place. It is important that the Executive receives regular information to provide assurance that the internal control environment remains resilient and to enable it to identify sufficiently early any emerging gaps which need to be addressed. The Committee will continue to seek assurance on compliance with controls set out in assurance maps over the next 12 months drawing on Internal Audit's independent scrutiny

3.19. Issues raised by the Health and Safety Executive (HSE), mainly relating to the Science Campus at South Mimms, have largely been resolved with progress independently validated by HSE. The Board has been kept informed of progress. The main outstanding issue is the need to renew the MHRA 's Specified Animal Pathogens License for which alternative provision has had to be put in place.

- **Risk Management**

3.20. The Risk Management Framework (RMF), which was refreshed in 2024.25 sets out the MHRA's approach to risk management. It defines risk, outlines roles and responsibilities, explains how risk governance operates generally. Risk appetite is now defined. The risk approach aligns with the principles and concepts set out in HM Treasury's Orange Book: Management of risk.

3.21. The ExCo management committee - Risk and Assurance Group meets monthly and supports the Executive Team and the Accounting Officer by ensuring the effective management of risks, issues and opportunities across the Agency to help enable the successful delivery of Agency objectives. The Group is chaired by the Director of Governance. Membership is from across the organisation. The MHRA's risk management was reviewed by Internal Audit in the last quarter of 2023-24 and received a Substantial assurance assessment indicating that management and control are adequate and effective.

3.22. The Committee reviews the risk register at each of its meetings reporting any emerging control issues as appropriate to the Board and ExCo. The Committee also periodically undertakes deep dives into specific risks and their mitigations, for example: Regulatory Connect, Health and Safety and Cyber Security.

3.23. The Committee has seen considerable strengthening of the Agency's risk identification and management over the last two years. We have however commented that until recently there has been little movement in the level at which risks are assessed. We note that a number of risks have now been reduced reflecting the improvement in the Agency's operational performance. We consider that the time is now right to review the strategic risks which the Agency faces particularly in its ability to deliver greater added value to public health, innovation and economic growth.

3.24. Over the coming months the Chief Executive is leading the development of a new strategy for the MHRA. Once completed Agency's risk register should be refreshed to reflect the new strategy. The risk register should also make a clear distinction between strategic and operational risks to help strengthen accountability to the Board.

- **Governance and Management Reporting**

3.25. The Committee received a range of assurance reports from management throughout the year. These included: losses and write offs, waivers, management of complaints and declarations of interest and conflicts of interest management. There were no material issues in 2024-25 to bring to the Board's attention.

4. Effectiveness of the Audit and Risk Committee

4.1. Internal Audit carried out an independent review of the Board and its subcommittees including the Audit Committee in the last quarter of 2024-25. Internal Audit awarded a Moderate assessment. For 2025-26 we will revert to surveying ARAC members and its key stakeholders on the effectiveness of the Committee and how it should continue to develop.

5. Focus of the Committee in 2025-26

5.1. The next twelve months will be a period of change and focused ambition as the Agency develops a new strategy and continues to embed new ways of working which maintain patient safety, support wider access to medical products and help promote growth. To help to support this the Committee's focus and assurance will be guided to ensure the following:

1. **Improvements achieved by route to moderate are embedded.** The Committee will seek assurance through the Agency's new assurance framework that its controls and governance remain both resilient and agile as the MHRA continues to adapt and transform.

2. **Improved performance in meeting the Agency's statutory functions is maintained.** Return to Green has been effective in largely eliminating the backlog and the Agency is now beginning to meet its statutory timelines consistently. Management information is being enhanced to provide better early indicators of where performance may be at risk or where further system redesign is needed. The Committee will seek ongoing assurance that the Agency's operating model is delivering consistent standards of performance.

3. **Ensuring RegulatoryConnect delivers its intended benefits.** Sustained operational performance and risk proportionate regulation are dependent on enhanced digital ways of working. RegulatoryConnect should be a key enabler of

this. The Agency has recently strengthened the management and governance of this programme. The Committee will continue to seek assurance on progress in realising RegulatoryConnect's intended benefits. In the early Autumn the Committee has asked for a walk through of process improvements and the timeline for those planned.

4. **Cyber security is sufficiently resilient.** All organisations face this risk which is escalating in scale. Internal Audit's reports in 2024-25 have identified that while there are improvements, the Agency continues to have more to do to strengthen its digital control environment. The Committee will expect to see more empirical evidence to demonstrate progress and to provide assurance that, as best it can, the Agency has in place resilient cyber security.

5. **Improvements in productivity and efficiency are delivered and are transparent.** As the Agency continues to transform its processes it is having to recruit new people and enhance its skill base. This needs to be combined with greater transparency over the Agency's efficiency and productivity. The Agency is committed to developing productivity measures which strengthen both its ability to deploy staff and financial budgeting. Internal Audit will be reviewing progress and as part of its 2025-26 programme.

6. **Risks are identified and mitigated effectively.** The MHRA has made good progress in strengthening its risk management including defining the Agency's risk appetite. This is also a key enabler of the cultural change particularly in realising opportunities to support innovation which has good potential to benefit patients. The Committee will continue to support the Agency in realising the significant benefits of its enhanced risk management approach as it develops and starts to implement its new strategy.

7. **Change is well managed, and benefit realisation is transparent.** The Agency has undergone considerable change over the last five years, some of which has been implemented more successfully than others. Further change will occur as, under the new leadership, responsibilities are refined and enhanced. ARAC supports the greater clarity and accountability this should provide but emphasises the importance of this being supported by the necessary culture change which is also a critical component of sound governance. The Committee will continue to focus on evidence of sustained cultural change.

8. **The Agency demonstrates evidence-based benefits realisation.** The opportunities for the Agency as an agile regulator are considerable both in helping improve public health, but also in supporting growth in the life sciences industry. Stakeholders' confidence in the Agency will inevitably be influenced by how well it can demonstrate its contribution and the added value it delivers. This emphasises the importance of a transparent and evidence-based benefits realisation framework. The Committee will give particular focus to evidence demonstrating this.

6. Recommendations

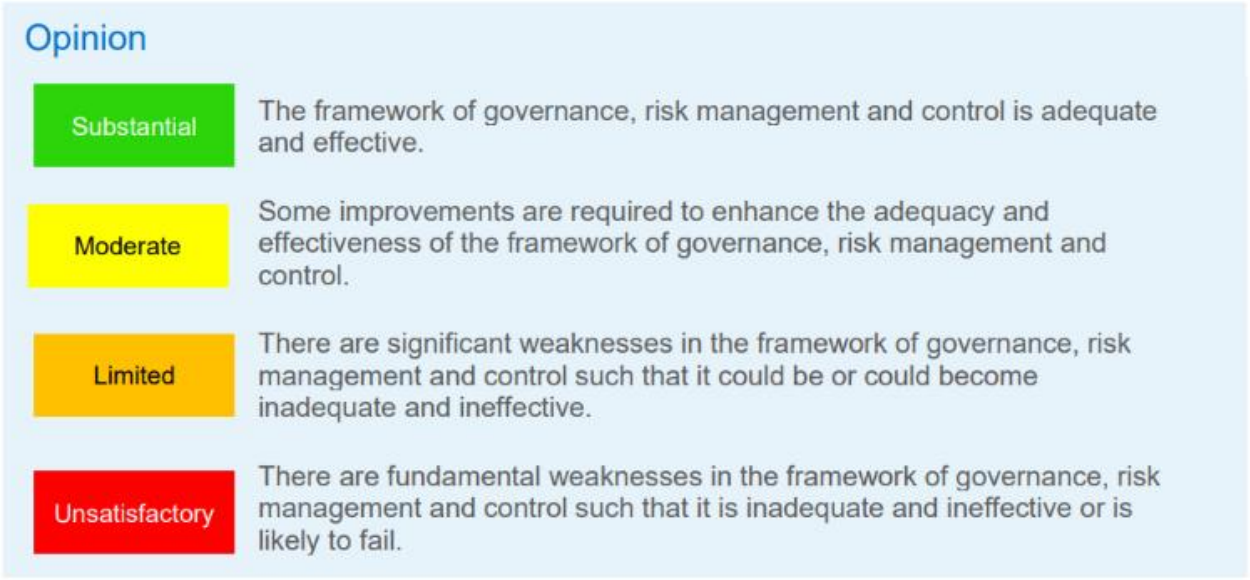
6.1. The Audit Risk and Assurance Committee recommends that the Board receive assurance from the work of the Committee over 2024-25 on the adequacy and effectiveness of the MHRA governance, risk management, financial and internal control arrangements over the last 12 months.

6.2. The Committee wishes to express its thanks for the support it has received from the Governance team over the last year. We also appreciate the work and insights of Internal Audit, the NAO and KPMG which have all been invaluable. Finally, we thank the MHRA executive and their colleagues for the positive way in which they have responded to our scrutiny.

Michael Whitehouse,

Chair, Audit and Risk Assurance Committee
July 2025

Annex A : GIAA classification systems



Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN COMMITTEE

8 July 2025

Title	**How well does the 2024/25 Annual Report and Accounts reflect the performance, governance and financial results of the MHRA over the last year?**
Board Sponsor	Carly McGurry and Rose Braithwaite
Purpose of Paper	Approval

How well does the 2024/25 Annual Report and Accounts reflect the performance, governance and financial results of the MHRA over the last year?

1. Executive Summary

1.1 The MHRA Annual Report and Accounts 2024/25 have been prepared in accordance with the relevant requirements and are subject to audit by the National Audit Office (NAO). The Executive Committee (ExCo) and the Audit and Risk Assurance Committee (ARA) have both reviewed and approved the report.

1.2 The financial audit has almost been completed with currently two outstanding items to be cleared by the auditors and two minor management recommendations.

1.3 The Board is asked to approve the Annual Report and Accounts 2024/25 and advise the CEO as Accounting Officer to sign the report and accounts, prior to submission to the NAO for the Comptroller and Auditor General's certification. It will then be laid in Parliament ahead of summer recess.

2. Introduction

2.1 Every year, MHRA, in keeping with other government bodies, must lay an annual report and audited accounts in Parliament, in order to set out our performance throughout the year and account for our use of public funds (including those arising from charges to service users). This is a legal obligation on all Government organisations. The MHRA numbers are also consolidated into the DHSC accounts as part of their accounts preparation.

2.2 Over recent years, we have embarked on a programme of improvement to our annual report and accounts, to ensure that the report fulfils our obligation in a way that is transparent and user friendly, whether to member of parliament or a member of the public, and that it gives the fullest account of all that the Agency has achieved over the last twelve months. Compilation of the document together is a significant undertaking, begun in January, and reliant upon all areas of the Agency to contribute the required content.

2.3 ExCo and ARAC have approved the report on 1 July. ARAC Chair has provided details of this approval in the ARAC assurance report to Board.

3. Proposal

3.1 We are subject to strict controls over what must be included in the report, how it must be presented and where in the document it is positioned. This can sometimes mean that elements of the report can appear repetitive, but we have worked closely with Communications colleagues and taken advice from NAO colleagues on how best to provide and cross-reference material. The accounts are also subject to a detailed audit by the National Audit Office, who take a close interest in the governance statement and check for a balanced and consistent report throughout.

Performance

3.2 The performance section is the first half of the report (pages 7 to 71). We have worked hard to capture all that has been achieved by the Agency, including but not limited to objectives set out in the Corporate and Business Plan. We have also included the high-level key performance indicators (KPIs) (page 51) and a selection of specific KPIs to add context to the reporting (pages 52 to 54).

Governance

3.3 The Governance Statement (pages 89–102), particularly the section on internal controls (page 97), outlines the progress we have made this year in strengthening our governance framework and addressing key performance challenges. This section also includes the Head of Internal Audit's annual opinion on the Agency (page 99), which has improved to a Moderate rating following three consecutive years at Limited. This uplift reflects the substantial efforts undertaken throughout the year to enhance our control environment and drive meaningful performance improvements.

Finance

3.4 The Remuneration and Staff Report (page 103) and the Financial Statements (page 129) are subject to small changes while the financial audit is ongoing, but we are not expecting these to be substantial. We are not expecting any material changes to the narrative of the report from this version.

3.5 At this point in the audit there are two outstanding items that still need to be finalised before the auditors can sign off on the accounts.

- Following engagement with HMRC, Ministry of Justice and Tax Centre of Excellence, the assumptions relating to the IR35 provision were updated. This reduced the provision by removing the fine element and introducing a clawback for tax relating to tax already paid by the contractors through their limited companies. KPMG and NAO need to gain assurance over the appropriateness of the updated provision.

- In March 2025, MHRA made a payment of £2m towards the IR35 liability. This has been raised with DHSC who have provided an assessment that this does not meet the definition of an irregular payment and therefore does not require HMT sign off. KPMG and NAO are still awaiting confirmation from their technical team regarding this assessment.

3.6 Good progress has been made on the testing of income and expenditure with no issues identified so far. At present the auditors have only provided us with two minor recommendations for how we can improve our processes both of which relate to timing issues with the accounts preparation and audit timelines.

Approval of the Annual Report and Accounts

3.7 Due to tight timelines required for agreeing and finalising the content of the annual report and the comprehensive approval process, The Board is receiving a version of the report which is in PDF and is not yet designed to review ahead of the meeting. The design company (Health Unlimited) is currently creating a designed version of this report for approval, which includes the same content as this PDF version. We will share the designed version as soon as we receive it ahead of the meeting.

3.8 If there are any changes from this version these will be collated and submitted to the designers as one final submission in time for creation of the print copy of the report for laying in Parliament. The Board, ARAC and ExCo will be alerted to any material changes to the final version.

4. Recommendation

4.1 The Board is asked to approve the draft Annual Report and Accounts 2024/25 and advise the Chief Executive as Accounting Officer to sign and submit them to the Comptroller and Auditor General for his approval, prior to laying them in both Houses and publishing ahead of summer recess.

Medicines & Healthcare products Regulatory Agency

BOARD MEETING IN COMMITTEE

08 July 2025

Title	Yellow Card Biobank Progress Update & Recruitment Summary
Board Sponsor	Dr Alison Cave
Purpose of Paper	Discussion

Yellow Card Biobank Pilot Progress and Recruitment Summary

1. Executive Summary

1.1. As part of the pilot phase, the Yellow Card Biobank pilot launched two study topics: allopurinol and severe skin reactions, and DOACs and severe bleeding. The pilot has been extended until 31st March 2026 with the launch of a third topic of GLP-1 RAs and acute pancreatitis.

1.2. The pilot to date has established governance processes, demonstrated successful operational feasibility and undertaken significant stakeholder engagement activities. Key results from recruitment show high engagement from patient Yellow Card reporters while Yellow Card healthcare professional (HCP) reporter recruitment has underperformed.

1.3. This paper summarises recruitment to the Biobank, lessons learned, and actions that are being implemented. The board is asked for suggestions on further methods to improve recruitment rates and to indicate whether they are assured that the recruitment lessons are being effectively identified and acted upon.

2. Introduction

2.1. In June 2023, the MHRA, in partnership with Genomics England, launched the Yellow Card Biobank pilot to generate data to support investigation of the role of genetics in adverse drug reactions (ADRs). Key objectives of the pilot are to demonstrate operational feasibility of a Yellow Card Biobank and use the learnings from the pilot to inform development of a future operating model.

2.2. Two serious drug side effects were launched for the pilot based on their significant impact on public health, patient quality of life and/or ability to help address a current unmet clinical need in the UK. These two topics were allopurinol and severe skin reactions, and Direct Oral Anticoagulants (DOACs) and severe bleeding.

2.3. In the pilot the MHRA are responsible for the recruitment, consent, sample collection, and data collection of participants. Genomics England are responsible for sample storage, genomics sequencing, and managing data access via the National Genomic Research Library (NGRL). Analysis of the data in the NGRL will be undertaken in partnership with external research collaborators on the specific topics.

2.4. As part of a pilot extension to test amendments to the operational aspects of the Biobank, a third topic has been introduced in June 2025; Glucagon-like peptide-1 receptor agonists (GLP-1 RAs) and acute pancreatitis.

3. Recruitment

3.1. The Yellow Card Biobank is recruiting patients through multiple pathways including:

- Yellow Cards reported by patients, and Healthcare professionals (HCPs),
- Clinical Practice Research Datalink (CPRD) GP records,
- Healthcare Professional contact directly

3.2. Participants sign up via online remote e-consent or postal consent, and the Biobank team coordinate remote blood sampling using a nursing provider. Samples are stored and sequenced by Genomics England, with the resulting data hosted on the Genomics England Research Environment.

3.3. The recruitment target for the first two topics was 150 participants (17 allopurinol and 133 DOAC participants). To date 95 patients (9 for allopurinol and 86 for DOACs) are enrolled in the Yellow Card Biobank from a total of 624 patients invited. Annex 1 provides a breakdown of the recruitment pathways and number of participants recruited.

3.4. CPRD has been the most successful pathway, accounting for two thirds of recruitment with a 20% practice sign-up rate, in-line with other CPRD supported studies.

3.5. The recruitment pathway with the highest sign-up rate is via patient Yellow Card reports with a rate of 58% of those invited to participate in the studies. However, only 38 patient Yellow Card reporters were invited to participate likely due to the study topics selected and the few Yellow Card reports received for these. Reflecting on the high patient reporter sign-up rate, a key contributing factor in selection for the 3rd pilot topic of GLP-1 RAs is its high-profile with preliminary analysis showing 35% patient vs 65% HCP Yellow Card reports. The switch to at home saliva sampling is also aimed at increasing patient recruitment rates to the Biobank while being more cost effective.

3.6. Recruitment through HCP Yellow Card reporters has been disappointingly low; only three patients have been recruited from the 416 HCP reporters contacted. The low response rates from HCP Yellow Card reporters can be attributed mainly to two factors: firstly, challenges in recruiting from older historic cases and not being able to get in touch with the HCP or the HCP not remembering/being able to find the details of their original patient, and secondly due to resource limitations/time burden on HCPs.

3.7. Directly working with NHS sites has been more effective with eight patients recruited thus far however this has a high resource burden on the Yellow Card Biobank team in setting up these recruitment pathways and working through governance requirements at NHS sites.

3.8. Active recruitment for these two study topics has now closed however any further participants that get in touch from previous communication activities will still be accepted. Please see Annex 1 for a full breakdown of the recruitment statistics.

3.9. Recruitment for the third study topic commences in June 2025 with the aim of benefitting from key lessons learnt from the first two study topics.

4. Key Lessons learned

4.1. Lessons learned are being collated throughout the pilot and reflected upon as part of routine governance at project operational meetings, with the Patient Advisory Board and by the Steering Committee. One of the core principles of the Biobank pilot is to ensure patient and public involvement in all our activities. This has included review of our processes and documentation throughout the pilot. The Patient Advisory Group

has been invaluable in providing feedback which has been directly adopted as the project evolves. Changes have been made to methodology and stakeholder communication activities in an agile manner as part of the current two topics as well as more significant changes rolled out for the third pilot topic. There are also recommendations from these lessons learnt that are informing development of the scaling up of a long-term Yellow Card Biobank post pilot.

4.2. Topic selection for study is critically important, rare conditions, such as severe skin reactions from allopurinol, are infrequently reported to the Yellow Card scheme which therefore made recruitment difficult. Selecting well defined phenotypes for which reporting rates are high will ensure good engagement with healthcare professionals and patients and increase recruitment rates. This has been reflected in topic selection for the extension of the Biobank pilot with GLP-1 RAs which is currently a high-profile topic and will identify different recruitment opportunities and challenges.

4.3. To address low engagement from Yellow Card HCP reporters a more proactive approach to soliciting key information from HCP Yellow Card reports has been implemented. This includes making use of functionality for conditional questions applied on the Yellow Card website to request specific information on the study topics at the point of first contact and thereby reduce the need for follow-up.

4.4. For consideration for the longer-term model the majority will be only prospective cases invited to participate in Yellow Card Biobank due to resource burden of contacting large numbers of historic cases and resulting low response rate.

4.5. Recruitment via CPRD has been the most effective recruitment method for the first phase of the pilot. However, it has been a relatively high cost for the project. Payment is made per practice for screening and practices that identify a low number of cases are less likely to participate, resulting in a high screen failure rate. Use of CPRD in the long-term Yellow Card Biobank model will be an optional add-on service for recruitment and will have costs passed on to those accessing the service to ensure financial viability of a scaled up long term Yellow Card Biobank.

4.6. The process for set up of recruitment pathways from healthcare professionals at large hospital sites directly has been streamlined and clearer ethical guidance provided; reducing time to site activation. To further reduce HCP burden, a new phase 2 process is seeking ethics approval to allow sites to provide patient contact details to the Biobank team, with the patients' permission. These actions aim to maximise the available recruitment period.

4.7. The patient demographics for the two study topics to date are shown in Annex 1 tables 1-2. The Biobank has encountered difficulties in recruiting participants from diverse ethnic backgrounds and the four nations. In the pilot extension, the Biobank team is expanding outreach to more diverse groups and network champions, including underrepresented regions. The Biobank team is collaborating with the MHRA engagement team to widen outreach and share knowledge on patient/public groups.

Study materials have also been updated with simplified language, larger fonts, and Braille for better accessibility.

5. Conclusion

5.1. The Yellow Card Biobank has gained substantial insights during the pilot phase; establishing robust governance and business processes and demonstrating operational feasibility. Although recruitment has not reached the anticipated level, the volume remains sufficient for analysis as well as providing valuable lessons learnt for improving recruitment processes, topic selection and informing the business case development for long-term operation of a Yellow Card Biobank.

6. Questions for the board

6.1. The Board are asked for further suggestions on ways to increase recruitment success of the Yellow Card Biobank particularly in underrepresented populations.

6.2. The Board is asked to indicate whether they are assured that the recruitment lessons are being effectively identified and acted upon.

Dr Alison Cave
24 June 2025

Annex 1: Key Yellow Card Recruitment Statistics

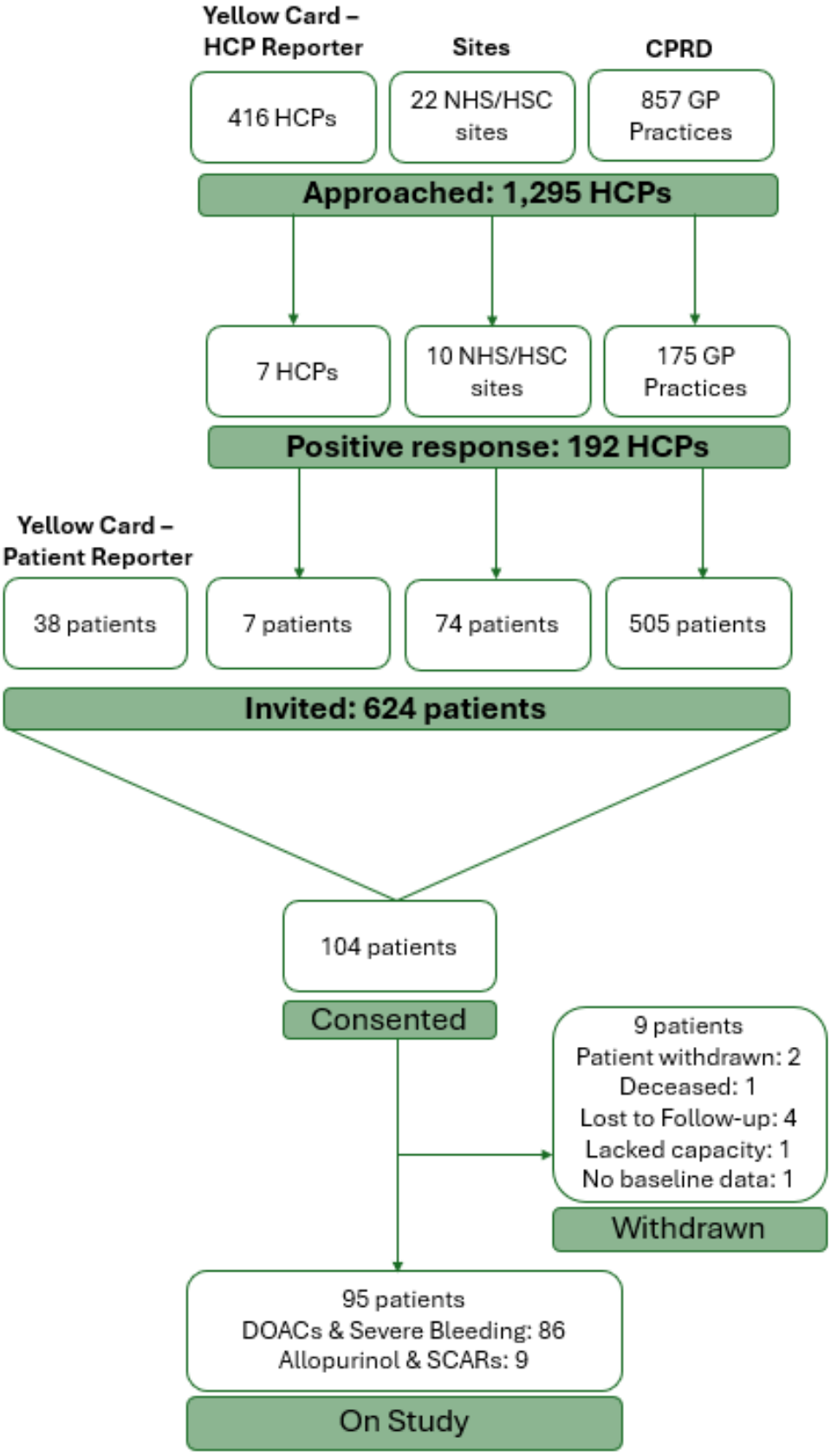


Table 1 Participant Sex - Distribution of Actively Participating Patients

Sex	Total number of active Participants	% of active Participants
Female	32	34
Male	63	66
Total	**95**	**100**

Table 2 Age Range Distribution of Actively Participating Patients

Age range	Total number of active Participants	% of active Participants
<20	0	0
20-29	0	0
30-39	0	0
40-49	<5	<5
50-59	<5	<5
60-69	11	12
70-79	38	40
80-89	35	37
90-99	6	6
>99	0	0.0
Total	**95**	**100**

Table 3 Recruitment Route and Method Used by Actively Participating Patients

Recruitment method/route	Active	% of participants on study
eConsent	**65**	**68**
CPRD	39	41
HCP	7	7
Yellow Card	19	20
Postal	**30**	**32**
CPRD	23	24
HCP	2	2
Yellow Card	5	5
GRAND TOTAL	**95**	**100**

Table 4 Location of Actively Participating Patients

Country	Number of active participants	% of active participants
ENGLAND	89	94
SCOTLAND	<5	<5
NORTHERN IRELAND	<5	<5
WALES	<5	<5
Total	**95**	**100**

Table 5. Response and consent rates: Yellow Card Reporters

Recruitment method	Research Topic	Total number of HCPs approached	Total number of HCPs responded	HCP response rate	Total number of patients invited	Total number of patients consented	Consent Rate *(of those invited)*
Yellow Card – Patient Reporter	**DOACs & Severe Bleeding**				35	21	60%
	Allopurinol & SCARs				3	1	33%
Yellow Card – Healthcare Professional Reporter	**DOACs & Severe Bleeding (Retrospective)**	303	27	8.9%	2	0	0%
	DOACs & Severe Bleeding (Pro-active)	60	4	6.7%	1	0	0%
	Allopurinol & SCARs (Retrospective)	51	12	23.5%	3	2	67%
	Allopurinol & SCARs (Pro-active)	2	1	50.0%	1	1	100%

Table 6. Response and consent rates: Clinical Practice Research Datalink (CPRD)

Recruitment method	Research Topic	Total number of GP practices approached	Total number of GP practices signed up	GP practice sign-up rate	Total number of patients invited	Total number of patients consented	Consent Rate *(of those invited)*
CPRD	**DOACs & Severe Bleeding**	840	171	20.4%	503	61	12%
	Allopurinol & SCARs	17	4	23.5%	2	1	50%

Table 7 Response and consent rates: NHS sites

Recruitment method	**Research Topic**	**Total number of sites approached**	**Total number of sites with approval**	**Total number of sites who invited patients**	**Total number of patients invited**	**Total number of patients consented**	**Consent Rate *(of those invited)***
NHS Sites	**DOACs & Severe Bleeding**	14	10	7	66	4	6.1%
	Allopurinol & SCARs	8	7	3	8	4	50.0%

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

8th July 2025

Title	What Assurance can be provided by the People and Public Engagement Committee (PPEC)?
Board Sponsor	Mercy Jeyasingham
Purpose of Paper	Assurance

What Assurance can be provided by the People and Public Engagement Committee (PPEC)?

1. Executive Summary

1.1. The People and Public Engagement Committee met for the first time on 1 May. It discussed Terms of Reference; the Refresh of the Patient and Public Involvement Strategy; and the CPRD Data Reclassification Project. Some amendments were recommended for the Terms of Reference. The Patient and Public Involvement Strategy was approved; however, an evaluation plan was recommended. The need to involve patients, the public and GPs for the CPRD Data Reclassification Project was agreed, with the need to liaise with the communications teams to learn from other projects involved in patient and public involvement before commissioning the work.

2. Introduction

2.1. The People and Public Engagement Committee met for the first time on 1 May 2025. There were three items for discussion. The first was the terms of reference for the new committee; the second was a discussion on the refresh of the Patient and Public Involvement Strategy; and the third was a discussion on the CPRD Data Reclassification Project.

3. Terms of Reference of the People and Public Engagement Committee

3.1. The draft terms of reference for the committee were discussed. It was agreed that the purpose of the People and Public Engagement Committee is to provide independent and objective strategic advice, assurance and recommendations to the MHRA Board and the Chief Executive on their responsibilities relating to:

i. The development of its people and culture strategies and implementation to support delivery of those strategic objectives.

ii. The development and implementation of strategies which seek to maximise Agency engagement with the public in order to bolster and maintain public confidence in the outcomes the Agency delivers.

3.2. The committee, on reviewing its responsibilities, agreed that key outcomes of its work were to assure itself that the people survey scores improve, and that public engagement should focus on transparency and improving public trust. As a new committee it was acknowledged that some amendments may be made on membership and that specific ways of working would develop. The balance between people and public engagement, as two different areas, needed to be maintained. The Committee recommended that a balance between people and public engagement should be reflected in the responsibilities section. Further wording on this would return to the committee. Specific patient involvement work would be covered in the Regulation and Safety Committee.

4. Refresh of the Patient and Public Involvement Strategy

4.1 The MHRA published its first Patient Involvement Strategy in 2021, informed by the Independent Medicines and Medical Devices Safety Review and a public consultation. During implementation of the Patient Involvement Strategy, the Agency has learnt that activities, current and new, should demonstrate that they are: Meaningful – a commitment to genuinely listening and considering different stakeholder views; Appropriate – safeguarding measures (public and staff) are in place and public are provided adequate support and training to contribute; and Proportionate – methods are tailored to context, goals and information needs, and resources.

4.2 The Committee discussed the proposal to refresh the strategy. It commented on the need for meaningful and early involvement; the difference between engagement and involvement and the role of patients and the public to support the Agency's work in risk-benefit analysis and innovation. The Committee discussed the need for evaluation of methods and outcomes and agreed to review proposed metrics and evaluation methods. Outside of the scope of the Patient Involvement Strategy, health literacy and the key role of patient-facing health professionals were also discussed.

5. CPRD Data Reclassification Project

5.1. The Clinical Practice Research Datalink (CPRD) is the MHRA's real world data research service. CPRD works with GPs across the UK gathering pseudonymised real world data and is a vital part of research that aims to safeguard patients and improve lives. CPRD data has been used for over 35 years to monitor the safety of medical products, understand the risk factors of disease and inform public health policy and clinical guidelines. CPRD obtains permission from the NHS Health Research Authority (HRA) research ethics committee and the Confidentiality Advisory Group (CAG) to facilitate this work in a way that is ethical and maintains patient confidentiality.

5.2. Every year CPRD organises patient and public involvement and engagement (PPIE) activities to seek ongoing public support for the collection and use of patient data for public health purposes, as well as consult on CPRD's strategic direction. Patient feedback from a study-specific PPIE workshop last year suggested that CPRD should consider reviewing some of its data flows for linkage purposes so that the data needed for linkage comes in directly to a firewalled section of CPRD rather than to NHS England. However, it is important to gain wider patient, public and GP support before proceeding with this aim. It is proposed that appropriate and well-executed Patient and Public Involvement and Engagement will be key to ensuring public support and a 'social licence' for these links.

5.3. The Committee acknowledged the benefits of reducing data fragmentation, particularly in cases where patient records are lost due to changes in GP practices. It discussed the wider health data landscape and working with other key stakeholders. Engagement with healthcare professionals and key stakeholders would be essential to building confidence in data security. It approved the need for effective communication and stakeholder engagement to ensure public trust and transparency. Sustainability of the project and the resources needed to undertake effective engagement were also explored.

5.4. The Committee agreed to the proposals but suggested further discussions internally and externally to gain maximum support.

6. Recommendations

6.1. The Committee made recommendations on the balance between people and public engagement within the terms of reference for PPEC. Re-wording of responsibilities would return to the Committee when it next meets in August 2025.

6.2. The Committee made suggestions on the refresh to the Patient and Public Involvement Strategy. An evaluation plan with metrics would be brought back to PPEC in due course.

6.3. The Committee recommended that the final patient and public involvement plan for CPRD was discussed with the communications team who had experience in commissioning this type of work.

Mercy Jeyasingham
Chair
People and Public Engagement Committee
July 2025

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN COMMITTEE

8th July 2025

Title	What assurance can be provided by the Regulation and Safety Committee (RSC)?
Board Sponsor	Paul Goldsmith
Purpose of Paper	Assurance

What assurance can be provided by the Regulation and Safety Committee (RSC)?

1. Executive Summary

1.1. The Regulation and Safety Committee was established in early 2025, along with the People and Public Engagement Committee. These committees replace the former Board Assurance Committee, The Organisational Development and Risk Committee (ODRC) and the Patient Safety and Engagement Committee (PSEC) which have now been disestablished.

1.2. The Regulation and Safety Committee was established to focus on ways of improving our core functions, including how we can take a more patient centred approach, including how we can improve post-market surveillance.

1.3. At the first meeting, the Committee agreed the terms of reference and discussed a range of potential priority areas, including the development of a more integrated and sophisticated risk assessment framework, spanning trials, regulatory assessment and post-market surveillance, as well as other ways to improve the reputation of the UK as a market for medicine and device development.

2. Introduction

2.1. The Regulation and Safety Committee met on 29th May 2025.

3. The committee discussed each of the following items at the meeting

3.1. **Development of a risk framework to support risk-proportionate decision-making.**

The Committee discussed risk-proportionality, and the challenges for both patients and clinicians in interpreting benefit–risk information at the individual patient level. It was noted that different individuals and groups perceive risk differently, and there is a need for a framework that recognises this complexity while enabling structured, evidence-based decision-making. It was agreed that a conceptual risk framework be developed, to allow for structured and evidence-based decision-making that factors in patient perspectives as well. This would help balance the Agency's priorities of safety and innovation, to increase access to health products whilst managing safety risks appropriately and both empowering patients and supporting clinicians to make informed decisions. The Committee agreed to begin the process of developing a conceptual risk framework, alongside working on proof-of-concepts with specific examples. The Committee will engage with the Strategic Programme Delivery (SPD) team in the agency who have already begun work on a risk-proportionate model.

3.2. **Post-Market Surveillance: approaches to collecting safety data.**

The Committee discussed post-market surveillance and that some companies have registry-based reporting, where patient data is collected and fed back to the MHRA in

a report, although this is not real-time data. It was noted that pharmacovigilance often informs further clinical trials, leading to label narrowing or widening. Next-generation surveillance could involve near real-time data flows, including in the context of conditionally licensed products such as software and AI-based medical devices (although noting that all licenses are in one sense conditional, as they may be revoked). The Committee discussed constraints and strategies relating to this. If the MHRA wanted to collect more data from particular products, an option would be to impose a post-authorisation safety or efficacy study on them.

3.3. **Any other business**

The Committee agreed the Terms of Reference and agreed the next meeting would be a virtual check-in in July, followed by a full meeting in September 2025.

4. Conclusion

4.1. The Committee discussed several options to improve regulatory decision making and better empower patients and clinicians, supporting risk-proportionate decisions and making the UK a more attractive country for clinical trials, development and manufacturing.

Paul Goldsmith
Chair Regulation and Safety Committee
Non-Executive Director MHRA
June 2025