Medicines & Healthcare products Regulatory Agency

20 Jan 26 Board Meeting held in Public

MEETING

16 January 2026 14:00 GMT

PUBLISHED
16 January 2026

Agenda

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1	Welcome and introductions		Chair	14:00	3
1.1	Declarations of interest	Information	Chair	14:02	5
1.2	Minutes (July Board held in public)	Approval	Chair	14:04	9
1.3	Updated Board Terms of Reference	Approval	Chair	14:06	14
1.4	Updated Terms of Reference – Board Assurance Committees	Approval	Chair	14:08	27
1.5	Board schedule	Approval	Chair	14:10	48
2	CEO report – current activities and priorities	Context	CEO	14:15	50
3	Finance and people performance report	Assurance	Rose Braithwaite	14:40	59
4	Patient Safety Commissioner	Information	Henrietta Hughes	14:55	67
5	An overview of the alignment of processes between MHRA and NICE	Information	Julian Beach	15:10	71
6	Rare disease therapies	Information	Julian Beach	15:25	76
7	Board Assurance Committee assurance reports	Assurance			-
7.1	People & Public Engagement Committee (PPEC) assurance report	Assurance	Mercy Jeyasingham	15:40	82
7.2	Regulation & Safety Committee assurance report	Assurance	Paul Goldsmith	15:45	85
8	Questions from members of the public on the items on this Board meeting agenda		Chair	15:50	-
9	CLOSE MEETING				-

MHRA Board Attendee List – 20 January 2026

	Name	Role	Board Seminar	Board held in public
Board				
1.	Prof Anthony Harnden	Chair	Y	Y
2.	Lawrence Tallon	CEO	Y	Y
3.	Dr Junaid Bajwa	Non-Executive Director	N	N
4.	Prof Jacob George	Chief Medical & Scientific Officer	Y	Y
5.	Julian Beach	Interim Director, Healthcare Quality & Access	Y	Y
6.	Rose Braithwaite	Chief Finance Officer	Y	Y
7.	Dr Alison Cave	Chief Safety Officer	Y	Y
8.	Prof Graham Cooke	Non-Executive Director	Y	Y
9.	Dr Paul Goldsmith	Non-Executive Director	Y	Y
10.	Mercy Jeyasingham	Non-Executive Director	Y	Y
11.	Raj Long	Non-Executive Director	Y	Y
12.	Michael Whitehouse	Non-Executive Director	Y	Y
Regular attendees				
13.	Victoria Dare	Deputy Director - Medicines Regulation & Prescribing, DHSC	Y	Y
14.	Tasneem Blondin	Chief People Officer, MHRA	Y	Y
15.	Rachel Bosworth	Director of Communications & Engagement, MHRA	Y	Y
16.	Sarah Gilbert	Company Secretary, MHRA	Y	Y

Other attendees				
17.	[redacted]	Private Secretary	Y	Y
18.	Ed Middleton	Director of Strategy, MHRA	Y	N
19.	James Pound	Interim Executive Director, Innovation & Compliance, MHRA	Y	N
20.	Rachel Arrundale	Interim Director of Partnerships, MHRA	Y	N
21.	Matthew Honeyman	Deputy Director, Strategy MHRA	Y	N
22.	Rebecca Jennings	Deputy Director, MHRA, Medicines and Pharmacy Team, GLD	N	Y
23.	[redacted]	Principle Policy Specialist	Y (item 2)	N

Apologies:

1.	Dr Junaid Bajwa	Non-Executive Director	Apologies

MHRA Board Declarations of Interest – January 2026

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	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
	Director Nutriberry Ltd	Director	No	Yes
Lawrence Tallon Chief Executive	None	N/A	N/A	N/A
Dr Junaid Bajwa Non-Executive Director	Ondine biomedical	Non-Executive Director	Yes	Yes
	UCLH and Whittington NHS Trust	Non-Executive Director	Yes	Yes
	Vir Health Ltd	Non-Executive Director	Yes	Yes
	NHS	GP, Physician (Sessional)	Yes	Yes
	Nahdi Medical Corporation	Non-Executive Director	Yes	Yes
	DIA Global	Board Member	No	Yes
	HDR UK	Trustee	No	Yes

Name and MHRA Role	Name of Other Company or Organisation	Nature of interest	Paid	Current / Date expired
	Flagship Pioneering	Senior Partner	Yes	Yes
Julian Beach Interim Executive Director, Healthcare Quality & Access	None	N/A	N/A	N/A
Rose Braithwaite Chief Finance Officer	Lloyd's Register Foundation	Independent member of the Audit, Risk and Investment Committee	No	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	No (Exp. 06/2025)
	30 Technology Ltd	Consultant/Advisor	Yes	Yes
	DNAnudge Ltd	Consultant/Advisor	No	Yes
Professor Jacob George Chief Medical and Scientific Officer	Novartis	Consultancy	Yes	Yes
	AstraZeneca	Advisory Board, Consultancy and Congress travel	Yes	Yes
	PHOSP-COVID (NIHR Funded)	Steering Committee	No	Yes
	British Hypertension Society	Guidelines Committee	No	Yes
	Consensus Action on Salt and Health (CASH)	Expert Member	No	Yes
	NIHR	Chair, Capital Investment Committee	No	Yes
	Clinical Research Malaysia, Ministry of Health	Scientific Advisory Panel Member, for Phase 1 trials	Yes	Yes
Dr Paul Goldsmith Non-Executive Director	Cambridge University ARIA NeuroWorks Scientific Advisory Board (SAB)	Scientific Advisory Board member	No	Yes
	Foundation for Evolution and Mental Health	Trustee	No	Yes
	Lanthor Ltd	Book publishing and medico-legal reports	Yes	Yes
	Ieso Digital Health	Shareholder	No	Yes

Name and MHRA Role	Name of Other Company or Organisation	Nature of interest	Paid	Current / Date expired
	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
Mercy Jeyasingham MBE Non-Executive Director	None	N/A	N/A	N/A
Raj Long Non-Executive Director	Bristol-Myers Squibb	Ex-Employee Shareholder	Yes	Yes
	RESOLVE (Sustainable solutions to critical social, health, and environmental challenges)	Scientific Advisory	No	Yes
	Novartis	Ex-Employee Shareholder	Yes	Yes
	BioNTech Global Health (non-profit)	Strategic Advisory for only Sub-Saharan Africa Public Health for Equitable Access	Yes	Yes
	Gates Venture – EC Innovative Medicines Initiative (IMI) Non-Product – IMI European platform for Neurodegenerative Disorders	Advisory	Yes	Yes
	WHO – Sustainable COVAX Manufacturing Strategy for Regional Health Security	Advisory Expert	No	Yes
	UK Health Security Agency	Associate Non-Executive Board Member	Yes	Yes
	EU Innovative Health Initiatives (IHI)	Advisory Expert for this EU public-private partnership funding health research and innovation funded by European Commission	Yes	Yes
	System Partners Engagement Forum, an advisory group to the Neurodegeneration Initiative	System Partners Engagement Forum Chair	No	Yes

Name and MHRA Role	Name of Other Company or Organisation	Nature of interest	Paid	Current / Date expired
Michael Whitehouse OBE Non-Executive Director	South East Coast Ambulance Services NHS Foundation Trust	Chair	Yes	Yes
	Jersey Audit Office	Chair	Yes	Yes

Medicines & Healthcare products Regulatory Agency

MINUTES OF BOARD MEETING HELD IN PUBLIC

10:00 – 12:30 on Tuesday 8 July 2025

Round Room, 10 South Colonnade, Canary Wharf, London

Chair: Professor Anthony Harnden

Present:

The Board

Professor Anthony Harnden	Chair
Lawrence Tallon	Chief Executive
Julian Beach	Interim Executive Director, Healthcare Quality & Access
Rose Braithwaite	Chief Finance Officer
Dr Alison Cave	Chief Safety Officer
Amanda Calvert	Non-Executive Director & Interim Co-Chair
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

Carly McGurry	Director of Governance
Rachel Bosworth	Director of Communications and Engagement
Tasneem Blondin	Chief People Officer
Dr Harriet Teare	Interim Director of Partnerships
James Pound	Interim Executive Director Innovation and Compliance
Kathryn Glover	Deputy Director, Medicines Regulation and Prescribing, DHSC
[redacted]	Head of Yellow Card Biobank *(item 8 only)*
[redacted]	Private Secretary

Apologies

Junaid Bajwa	Non-Executive Director
Ed Middleton	Strategy Director
[redacted]	Head of Executive Office
[redacted]	Private Secretary

INTRODUCTION
The Chair opened the meeting held in public and welcomed those joining online. The Chair went around the room for the Board to introduce themselves and noted apologies.

1. Declarations of interest

1.1. The Chair opened the item and noted the importance of the policy which is currently being revised.
1.2. The Chair asked if there were any new interests to declare to which Paul Goldsmith noted that he is a Board member for a mental health charity. Nothing further to declare.
1.3. The Board noted that a revised conflicts of interest policy will be tabled for discussion at the September Board meeting.

Action: The secretariat to contact Paul Goldsmith to update conflict of interest register.

[redacted]

Action: The updated Conflict of Interest policy to be tabled for discussion at the September Board meeting.

Carly McGurry

2. Minutes and actions

2.1. The Board approved the minutes.

Action: The secretariat to contact comms to publish the March meeting held in public minutes.

Carly McGurry / Rachel Bosworth

3. Terms of Reference

3.1. The Chair noted the Terms of Reference (TOR) has been updated. The Board received an outline of key changes to the TOR, including Board Assurance Committees.
3.2. The PPEC Chair noted an amendment to the PPEC in the TOR.
3.3. The Board approved the TOR.

Action: The secretariat to amend the TOR with reference to the PPEC.

Carly McGurry

AGENCY PERFORMANCE

4. CEOs Report – current activities and priorities

4.1. The Chair noted the publication of the 10 Year Health Plan and the key focus areas in which the agency is referenced.
4.2. The Board received a summary of the paper as follows:
4.2.1. The Agency had sustained and consolidated its performance improvements against statutory targets. The next area of focus would be the non-statutory targets for scientific advice.
4.2.2. There had been notable government publications, including the 10 Year Health Plan, the Life Sciences Delivery Plan and the Penny Dash Review into Patient Safety. The MHRA will have a significant role to play across those publications and policies in relation to clinical trials, an aligned authorisation

pathway with NICE, pioneering the regulation of AI in healthcare and hosting the Patient Safety Commissioner in the new safety architecture.

4.3. The Board also received a number of others updates on key activities across groups:

4.3.1. Operation Subaru, which had been led successfully by the Criminal Enforcement Unit, had arrested a number of people involved with trafficking medicines illegally.

4.3.2. There had been a significant media campaign about safe use of GLP1 medicines, and in particular avoiding them during pregnancy.

4.3.3. An experienced Programme Director had been recruited to take stock of RegulatoryConnect and to make recommendations.

4.3.4. The agency had issued a request for applicants for the second phase of its unique AI Airlock Programme.

4.3.5. The new Chief People Officer will lead on the establishment of the Agency's new digital hub location in Leeds.

4.3.6. The agency is continuing to stay connected with devolved administrations and working with key agencies such as NICE, HRA, EMA and the Access Network.

4.3.7. The Board received an update on joint reviews with NICE and the work to date that will involve changes in processes across both organisations, which is going well.

4.4. The Board discussed the agency hosting the Patient Safety Commissioner. Members noted that we have a strong safety system in place which we will continue to strengthen and look forward to working with the commissioner on longer-term goals.

Action: To amend the paper to the correct name of the team from HSE team to the H&S team.

[redacted]

5. Monthly MHRA finance and people performance report

5.1. The Board received updates on income generation and spending, which is due to the timing of some activities, but the agency is in a good position and current financial situation (balanced against other moving parts) will help de-risk awarding other capital that the agency will receive this year. The agency is doing well with FTE recruitment budget and low staff turnover.

5.2. The Board discussed other financial issues in relation to maintenance at South Mimms and pay forecasting and profiling. The Board also discussed agency performance that will generate income. The CEO noted that he would shortly write to NEDs about work underway to improve our monitoring and reporting of agency wide performance.

Action: CEO to write to NEDs about agency performance monitoring and reporting
Lawrence Tallon

ANNUAL REPORT

6. ARAC Annual Report to the Board

6.1. The Chair explained the overall purpose of the Audit and Risk Assurance Committee (ARAC).

6.2. The ARAC Chair noted that there is a requirement to provide an annual report to the Board in tandem with the MHRA Annual Report and financial statements, to provide support to the process for approving and laying the report in Parliament.

6.3. The Board received an update on the agency's improved annual audit opinion. The Chair outlined three areas of focus for ARAC over the coming year: firstly, ensuring that the excellent work in the Route to Moderate and Return to Green programmes

are embedded across the agency; secondly that improvements in risk management are maintained, particularly in identifying and mitigating risk effectively as the new strategy is developed; and thirdly continued scrutiny of RegulatoryConnect. The Board agreed that the agency must not be complacent and must embed the strengthened governance, risk and control.

Action: To highlight as part of internal comms the Raising Awareness Champion (para 3.14 refers)

Rachel Bosworth / Mercy Jeyasingham

Action: The agency has a Specific Animal Pathogens License which covers work at South Mimms (para 3.19 refers)

Dr Nicola Rose

7. MHRA Annual Report & Accounts

7.1. The Chair noted that the annual report and accounts are required to be laid in Parliament before the recess.

7.2. The Board thanked everyone involved in putting together the Annual Report and Accounts and advised that the CEO should sign the report as a full and fair account of the Agency's activities in 2024/25.

Action: The CEO should approve and sign the MHRA Annual Report and Accounts for submission to the Comptroller and Auditor-General.

Lawrence Tallon / Carly McGurry / Rose Braithwaite

YELLOW CARD BIOBANK

8. Yellow Card Biobank pilot & feedback on recruitment

8.1. The Board received an update on the programme and its aim to generate data to support investigation of the role of genetics in adverse drug reactions (ADRs). The pilot was launched two years ago and focused on adverse reactions relating to: 1) allopurinol and severe skin reactions; 2) DOACs and severe bleeding; and has now been extended to GLP1s and acute pancreatitis. The Board received an update on key themes relating to recruitment:

8.1.1. Patient Yellow Card reporters typically have a high sign-up rate to the study, leading to a future focus on topics with high patient reporting rates

8.1.2. Disappointingly low patient sign-up rate from contacting HCP Yellow Card reporters, however, new pathways are being implemented to improve response and reaching out to patients

8.1.3. The importance of recruitment via Clinical Practice Research Datalink (CPRD), accounting for 2/3 of participants recruited

8.1.4. The key challenge of ensuring the project is diverse and includes people from across the Devolved Nations

8.2. The Board discussed diversity and encouraged the team to be creative and consider other platforms and avenues for recruitment. There was discussion on possible examples outside the UK that can be replicated. On GLP1s, the Board noted that this work is more centred on discovery, and that on diversity, some other datasets could be explored pertaining to representation, inclusivity, and choosing topics where the drugs are used at scale in particular populations, such as some diabetes medications.

8.3. The Board noted the paper and referred further discussion on this topic to the Regulation and Safety Committee.

Action: The Board noted the paper and lessons learned as well as providing suggestions to increase recruitment success. Further matters on recruitment will be referred to the RSC before returning to the Board.

Dr Alison Cave / Paul Goldsmith

ASSURANCE

9. People & Public Engagement Committee (PPEC) Assurance Report

9.1. The Chair noted key priorities for the committee in relation to improved public engagement and staff survey scores.

9.2. The PPEC Chair provided an update – the PPEC will review the TOR again before submitting to the full Board for approval. Another key priority for the committee is the refresh of the Patient and Public Involvement Strategy.

10. Regulation & Safety Committee (RSC) Assurance Report

10.1. The RSC Chair provided an overview for the Board. The RSC Chair noted that the committee is working through the beginnings of a framework to help flesh out key pieces of work the Committee will focus on.

EXTERNAL PERSPECTIVE

11. Questions from members of the public on the items on this Board meeting agenda

11.1. The Chair opened the item noting that there were three pre-submitted questions on issues not on the agenda today. Each will receive a written response by the end of the week.

11.2. There was a question from the audience during the meeting: *To what extent can the Regulation and Safety Committee's work on "ways to improve the reputation of the UK as a market for medicine and device development" be informed by product developers who may be considering the UK as a market?* The Chair invited Julian Beach to answer the question, who noted that the agency has pipeline meetings and are working proactively to identify which products will come through in the next couple of years, as well as developing robust frameworks to ensure the UK is attractive while continuing to prioritise safety. The RSC Chair noted that the committee has the right mix of membership to discuss and challenge on this issue and noted broader issues around the competitive advantage to attract more investment through data from NHS.

CLOSE OF MEETING

The Chair closed the meeting and acknowledged three departing Board members: Haider Hussain, Mandy Calvert and Claire Harrison. The Chair also noted the final meeting for an attending Executive Member, Harriet Teare.

Medicines & Healthcare products
Regulatory Agency

Agency Board

Terms of Reference

Document Control[1]

Document Description:

Document Title	Agency Board Terms of Reference
Issuance/ Revision	5.0
Date Adopted	20 January 2026
Owner	MHRA Board
Author	Carly McGurry, [redacted]
Security Level	N/A

Approvals

Name	Role	Date
MHRA Board	Approve	

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.
14/08/2025	4.2	[redacted]	Amendment to PPEC as per Board action from the 8 July meeting. The Board approved the TOR following this amendment and in effect from 9 July 2025.
11/12/2025	5.0	[redacted]	Amendment to membership and frequency (sections 4.2, 5.3 and 9.1) following completion of refresh of the Board in September 2025. Approved at January 2026 Board meeting.

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.

[1] Document control to be annexed on ToR

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 (MHRA or Board 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;

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[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 MHRA Chair and the Chief Executive Officer. The MHRA 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. The current membership is 6 Non-Executive Directors and 6 Executives, plus the non-executive Chair.

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 following 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:

- Chief Executive Officer
- Chief Finance Officer
- Chief Medical and Scientific Officer
- Chief Technology and Digital Officer
- Chief Safety Officer
- Interim Executive Director, Healthcare Quality & Access

5.4. Committee meetings will also be regularly attended by other members of the Executive as the agenda demands. Other members of Agency staff shall be invited at the discretion of the Board when matters relating to their areas of responsibility are being discussed. The Board may ask any or all of those who normally attend but who are not members to withdraw to facilitate open and frank discussion of particular matters.

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 Board Chair should determine an appropriate course of action, ranging from exclusion for a particular item of business to cessation of membership. Where the Board 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 Public 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 Board 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. Of these meetings one meeting per year will be held in Scotland and one in either Wales or Northern Ireland, alternating annually. There will be two meetings held in public each year.

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 Board 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 Chief People Officer, Director of Communications and Engagement, 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 Company Secretary 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 Board 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 Committee 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

Audit and Risk Assurance Committee

Terms of Reference

Document Control[1]

Document Description:

Document Title	Audit Risk and Assurance Committee Terms of Reference
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Date	20 January 2026
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Author	Carly McGurry, [redacted]
Security Level	N/A

Approvals:

Name	Role	Date
ARAC Chair	Recommend	11 December 2025
MHRA Board	Approve	

Document Change History:

Date	Issuance/ Revision	Author	Description of Changes
06.01.2020	1.0	Carly McGurry	First initial draft
05.01.2023	2.0	Carly McGurry	Moving to Agency ToR template
08.02.2023	2.1	Carly McGurry	Further revisions to ensure alignment with other board assurance committees
21.02.2023	2.2	[redacted]	Reducing duplication in the responsibility section 3.
11.12.2025	3.0	[redacted]	Minor updates to membership following refresh of the Board Assurance Committees. ToR agreed by ARAC Chair 11 December 2025 and to ensure the Terms of refence aligns with the other Board Assurance Committees

Distribution

To all Board members and added to Insite for use by all staff.

[1] Document control to be annexed on ToR

1. Introduction

1.1. These Terms of Reference set out the principles that should underpin the roles and responsibilities of the Audit and Risk Assurance Committee, as a committee of the MHRA Board. These Terms of Reference should be consistent with the roles and responsibilities set out in the MHRA Board Terms of Reference, which are themselves consistent with wider applicable guidance and requirements.

2. Purpose of the Audit and Risk Assurance Committee

2.1. The purpose of the Audit and Risk Assurance Committee (ARAC) is to support the MHRA Board and the Chief Executive as Accounting Officer in their responsibilities for management of risk, control and governance, including the review and approval of the MHRA's Annual Report ahead of the formal board approval and the integrity of financial statements.

2.2. The Accounting Officer provides assurances to the Board about the audit and risk performance of the MHRA and it is the role of the ARAC to review the integrity and reliability of those assurances.

3. Responsibility

3.1. The Committee operates in an independent advisory capacity, providing advice to the Board and Accounting Officer on:

- The integrity and reliability of assurances provided by the MHRA relating to the effectiveness of processes for identification, assessment and management of risk, the operation of internal controls and governance, the governance statement and achievement of value for money.
- The accounting policies, the accounts, and the annual report of the organisation, including the process for review of the accounts prior to submission for audit, levels of error identified, and management's letter of representation to the external auditors.
- The planned activity and results of both internal and external audit.
- Adequacy of management response to issues identified by audit activity, including external audit's management letter.
- Anti-fraud policies, whistle-blowing processes, management of conflicts of interest and arrangements for special investigations.
- Its own effectiveness, which the Committee will review periodically and report the results of that review to the Board.

3.2. To fulfil these responsibilities, for each meeting ARAC will be provided with:

- A report summarising any significant changes to the organisation's strategic risks and a copy of the Corporate Risk Register.
- A progress report from the Head of Internal Audit summarising work performed

against plan, key issues emerging, management responses and any resourcing issues affecting the delivery of the objectives of internal audit

- A progress report (written or verbal) from the External Audit representative summarising work done and emerging findings.
- A Finance Report
- Reports on Whistleblowing cases and fraud errors and concerns.

3.3. As and when appropriate the Committee will also be provided with:

- Proposals for the terms of reference of internal audit/the internal audit charter
- The internal audit strategy and delivery of Annual Plan.
- The Head of Internal Audit's Annual Opinion and Report.
- Quality Assurance reports on the internal audit function.
- The draft accounts of the organisation.
- The draft Governance Statement.
- A report on any changes to accounting policies.
- External Audit's management letter.
- A report on co-operation between internal and external audit.
- The organisation's Risk Management strategy.
- Management assurance reports focused on specific risks and issues e.g., health and safety detailing the challenges/ mitigations and controls of our live risks and issues

3.4 The ARAC is an advisory body and holds no decision-making power, nor does it exercise any line management or executive functions. It may suggest and agree actions with the Executive and may make recommendations to the Board, who retain decision-making responsibility in respect of the functions set out in its Terms of Reference. This does not prevent the ARAC from fulfilling its responsibilities to report to the Board and offer its view on the assurance provided as detailed in paragraph 13.

4. Composition

4.1 Membership of the ARAC, appointed by the Board, will consist of three non-executive members of the Board, one of whom will be appointed as Committee Chair. The Committee Chair shall be nominated by the Board Chair and agreed by the Board. The Board Chair shall not be a member of the Committee.

4.2 Members should together possess the appropriate range of skills in risk, governance and internal control, including recent and relevant financial experience. Non- executive members will use their experience and skills to provide constructive, effective and objective challenge to accounting officer.

4.3 All new members will be provided with induction training and the MHRA will provide for any additional development which is deemed necessary for the member to fulfil their role on the Committee. The Chair of the Audit and Risk Assurance Committee will hold an annual review with each member and any training or development needs will be taken

forward with the agreement of the Board Chair and Accounting Officer.

5. Membership

5.1. Committee meetings will normally also be attended by the Chief Executive Officer as Accounting Officer, the Chief Finance Officer, Director of Strategy, Head of Internal Audit, and a representative of External Audit. The Head of Internal Audit and the representative of External Audit will have free and confidential access to the Chair of the Audit and Risk Assurance Committee.

5.2. The Committee may ask any or all of those who normally attend but who are not members to withdraw to facilitate open and frank discussion of particular matters.

5.3. Where unavoidable, deputies for executive members should be agreed in advance with the Committee Chair. Once admitted, deputies have the same rights and responsibilities within ARAC as non-deputies.

5.4. The Chair of the Board may, by agreement of the Committee Chair, attend meetings as an observer where their presence is considered beneficial. Such attendance should be exceptional and not routine, and the Board Chair will not participate in decision-making or influence the Committee's independent assurance role.

6. Conflicts

6.1. Members should pro-actively declare any actual or potential conflicts of interest arising either from business on the agenda or from changes in their personal circumstances. The Committee Chair should determine an appropriate course of action, from exclusion for a particular item of business to cessation of membership. Where the Committee Chair has, or may have, a conflict of interest, the other members present should determine the appropriate course of action.

7. Quorum

7.1. A quorum for meetings will consist of a minimum of two of the three non-executive members. Where the ARAC Chair is unable to attend a meeting, the Committee should elect a deputy from the remaining members.

7.2. If a meeting is not quorate it may still proceed, with agreement from a majority of Committee members (including those not in attendance). In such circumstances, any proposed recommendations to the Board will be non-binding and will require subsequent ratification from a quorate meeting or with absent members by correspondence. If any members are not content to ratify through correspondence or on the basis of the minutes, this may trigger a further discussion in the next following meeting or in extraordinary circumstances, a short, extraordinary meeting may be held.

7.3. A decision put to a vote at a quorate Committee meeting will be determined by a simple majority of voting members and deputies present. In the case of an equal vote, the Chair of the Committee at that meeting will cast a second, deciding vote.

8. Sub Committees

8.1. The Committee may, subject to the approval of the Board, establish sub-committees to carry out specific aspects of Committee business, on its behalf.

9. Frequency of Meetings

9.1. The Committee will meet quarterly and at least four times a year. Additional meetings may be called at the discretion of the Committee Chair.

9.2. The Board or the Chief Executive may ask the Committee to convene further meetings to discuss particular issues on which they want the Committee's advice.

9.3. The Committee will hold closed meetings at least annually with Internal Audit and the National Audit Office.

10. Attendance

10.1. Non-Executives should attend at least two of the four quarterly meetings.

10.2. Other individuals may be invited to attend for all or part of any meeting for a specific agenda item.

11. Secretariat

11.1. The ARAC will be supported by a Committee Secretary from within the MHRA's Governance Office. The Secretary will be responsible for:

- Preparing the agenda in consultation with the Committee Chair
- Developing and maintaining a twelve-month schedule for the ARAC which aligns with the Board schedule and ARAC's responsibilities, avoiding duplication and enabling timely consideration of key matters
- Commissioning Committee papers with clear deadlines, sufficient notice and working with staff to continually improve the quality of papers
- Circulating Committee papers to members and invitees a minimum of five working days before each meeting
- Producing and circulating draft minutes of the Committee meetings to members, within ten working days after each meeting
- Maintaining an action log

12. Delegated Authority

12.1. The Board authorises ARAC to investigate or have investigated any activity in line with its responsibilities, as set out in these Terms of Reference. In doing so, the Committee can rightfully inspect any documents, ensuring that data, confidentiality and security are maintained, and all relevant policies adhered to. The ARAC has authority to require any member of the organisation to report on the management of risk or the control environment within their areas of responsibility, in general terms or in respect of specific matters, either by:

- Attending an ARAC meeting; or
- Providing a written report(s) to the ARAC for the purpose of providing information to assist the committee in fulfilling its role.

13. Reporting to the Board

13.1. Following each Committee meeting, and at the next appropriate meeting of the Board, ARAC will formally report to the Board on the assurance it can provide on the matters set out in paragraph 3.1. This written assurance report will be agreed by the non-executive members of ARAC. The Committee Chair will use the assurance report to draw to the attention of the Board any issues that require disclosure to the full Board, or that, in the view of ARAC, require executive action.

14. Review of these Terms of Reference

14.1. The Committee will review its Terms of Reference at least annually. Amendments will be subject to review and approval by the MHRA Board.

Medicines & Healthcare products
Regulatory Agency

Regulation and Safety Committee

Terms of Reference

Document Control[1]

Document Description:

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Author	Carly McGurry, [redacted]
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Name	Role	Date
R&SC Chair	Recommend	6 January 2026
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Document Change History:

Date	Issuance/ Revision	Author	Description of Changes
07.04.2025	0.1	Carly McGurry	First draft for consideration by R&SC Chair and Board Chair
16.04.2025	0.2	[redacted]	Minor changes following consideration by CEO, R&SC Chair and Board Chair.
16.04.2025	0.3	Paul Goldsmith	Minor comments and changes following Chair review.
16.12.2025	0.4	[redacted]	Minor changes to ensure alignment of the Board Assurance Committee Terms of Reference.

Distribution

To all Board members and added to Insite for use by all staff.

[1] Document control to be annexed on ToR are agreed

1. Introduction

1.1 These Terms of Reference (ToR) set out the principles that should underpin the roles and responsibilities of the Regulation and Safety Committee (R&CS), as a committee of the MHRA Board. These Terms of Reference should be consistent with the roles and responsibilities set out in the MHRA Board Terms of Reference, which are themselves consistent with wider applicable guidance and requirements.

2. Purpose

2.1. The purpose of the Regulation and Safety Committee is to:

- Provide strategic oversight of the MHRA's regulatory approach, ensuring it is proportionate, risk-based and protects patient safety throughout the lifecycle of all products.
- Ensure the regulator is able to optimise the availability and safety of medicines and devices for UK patients, in line with wider government policy to support UK life sciences companies, including through international alignment
- Enhance real-world monitoring of medicines and devices to improve risk-based approaches to regulatory decision-making and enable faster responses to emerging safety issues.
- Promote whole health ecosystem collaboration to ensure the safe and optimal use of drugs and devices, in turn enabling the regulator to make more proportionate, risk-based assessments.

3. Responsibility

3.1. The Committee is responsible for advising the Board on the regulator's approach to and delivery of regulation and safety, as it relates to the following areas.

Patient engagement:

- Ensure meaningful patient and clinician input into regulatory decision-making processes.
- Promote transparency and clarity in regulatory processes, so the public and industry understand how decisions are made.

Safety:

- advising the Board on approaches to patient safety in the Agency's procedures for its assessments of clinical trials, medicines, medical devices and blood products and the continued surveillance of their use
- assuring the Board that patient safety is and remains the priority in such activities and a culture of continuous, iterative improvement is embedded and supported

Regulatory alignment & modernisation:

- Evaluate and advise on proportionate, risk-based regulatory approaches rather than rigid rules-based frameworks.

- Support life sciences growth by ensuring regulation is predictable, innovation-friendly, and globally competitive.
- Identify opportunities for alignment with major life sciences / commercial markets to facilitate innovation and patient access while maintaining UK-specific flexibility.

Post-market surveillance and data-driven regulation:

- Progress the integration of real-world evidence, ensuring regulatory decisions are informed by continuous safety monitoring.
- Advocate for strengthened data-sharing mechanisms across the NHS and industry to improve post-market surveillance and regulatory responsiveness.
- Ensure a faster, risk-proportionate response to emerging and established safety issues based on real-time data.

Whole health ecosystem working:

- Promote collaborative working across regulators, NHS, industry, and patient groups to optimise drug and device use.
- Advocate for regulatory decisions that account for real-world clinical practice rather than isolated theoretical risks and incorporate insights from frontline practice

3.2. The R&SC will review its Terms of Reference on an annual basis, or more frequently if there are changes, to ensure they remain accurate. The R&SC will also periodically review its own effectiveness and report the results to the Board.

3.3. To meet these responsibilities the Committee will:

- Scrutinise the processes, systems and structures within the Agency regarding the delivery of our core regulation and safety functions, including how we involve patients appropriately in delivering those functions
- Provide assurance to the Board that the Agency has appropriate procedures in place for preventing, detecting and addressing any safety or quality issues with medicines, medical devices or blood products, in the interests of patient safety.
- Provide guidance and input into the development of strategies, including maximising the methods used by the Agency to deliver our core functions.
- Provide challenge to the Executive on aspects of the regulatory systems that could be modified to improve patient safety.
- Operate in an action-oriented style, ensuring clear recommendations and timelines rather than prolonged consultation cycles

3.4. To fulfil these responsibilities, the non-executive members will use their experience and skills to provide constructive, effective and objective challenge to Executive members and provide an independent perspective on the matters listed in 2.1. Executive members will provide expertise and in-depth knowledge of the Agency's operations, opportunities and risks to enable the committee to discharge its responsibilities.

3.5. Following each Committee meeting, and at the next appropriate meeting of the Board, the Committee will formally report to the Board on the assurance it can provide on the regulatory and safety activities of the Agency.

3.6. The committee holds no decision-making authority, nor does it exercise any line management or executive functions. It may suggest and agree actions with Executive members and may make recommendations to the Board, who retain decision-making responsibility in line with their schedule of reserved matters. This does not prevent the committee from fulfilling its responsibilities to report to the Board and offer its view on the assurance provided.

3.7. The Committee will operate in accordance with the unitary status of the Agency Board by taking a collaborative approach, utilising constructive challenge, to fulfil the purpose and responsibilities set out above.

4. Composition

4.1. Membership of the R&SC will comprise up to four non-executive members appointed by the Chair of the Agency Board. One of the non-executive members will be appointed as chair and any of the non-executives can deputise in the appointed chair's absence. Three Executive members, including the Chief Executive Officer will be appointed to the committee by the Chief Executive Officer.

5. Membership

5.1. Committee meetings will also be regularly attended by other members of the Executive as the agenda demands. Where unavoidable, deputies for executive members should be agreed in advance with the Chair. Once admitted, deputies will have the same rights and responsibilities with R&SC as non-deputies.

5.2. Other members of Agency staff shall be invited at the discretion of the Committee when matters relating to their areas of responsibility are being discussed.

5.3. The Committee may ask any or all of those who normally attend but who are not members to withdraw to facilitate open and frank discussion of particular matters.

5.4. The Chair of the Board may, by agreement of the Committee Chair, attend meetings as an observer where their presence is considered beneficial by the Committee Chair. Such attendance should be exceptional and not routine, and the Board Chair will not participate in decision-making or influence the Committee's independent assurance role.

6. Conflicts

6.1. Members should pro-actively declare any actual or potential conflicts of interest arising either from business on the agenda or from changes in their personal circumstances. The Chair should determine an appropriate course of action, from exclusion for a particular item of business to cessation of membership. Where the Chair has, or may have, a conflict of interest, the other members present should determine the appropriate course of action.

7. Quorum

7.1. The quorum of the committee will be five members, including at least two Non-Executive members, and at least two Executive members.

7.2. If a meeting is not quorate it may still proceed, with agreement from a majority of Committee members (including those not in attendance). In such circumstances, any decisions made will be non-binding and will require subsequent ratification, however decisions may be ratified by correspondence. If any members are not content to ratify through correspondence or on the basis of the minutes, this may trigger a further discussion in the next following meeting or in extraordinary circumstances, a short extraordinary meeting may be held.

7.3. A decision put to a vote at a quorate Committee meeting will be determined by a simple majority of voting members and deputies present. In the case of an equal vote, the Chair of the Committee at that meeting will cast a second, deciding vote.

8. Sub Committees

8.1 The Committee may, subject to the approval of the Board, establish sub-committees to carry out specific aspects of Committee business, on its behalf.

9. Frequency of Meetings

9.1. The Committee will meet quarterly and otherwise, with the flexibility to discuss matters arising via correspondence or extraordinary meetings as the Chair of the Committee deems necessary.

10. Secretariat

10.1 The Committee Secretariat will be responsible for:

- Preparing the agenda in consultation with the Chair;

- Commissioning Committee papers;
- Circulating Committee papers to members and invitees, normally five working days before each meeting;
- Documenting the outcome of all votes taken in the Committee meeting minutes;
- Producing and circulating draft minutes of the Committee meetings to members, normally ten working days after each meeting, for approval at the following meeting;
- Maintaining an action log.

11. Delegated Authority

11.1. The Board authorises the R&SC to investigate or have investigated any activity in line with its responsibilities, as set out in these Terms of Reference. In doing so, the Committee can rightfully inspect any documents, ensuring that data, confidentiality and security are maintained, and all relevant policies adhered to. It may seek relevant information from any employee, other committee, sub-committee or Group set up by the Board to assist it in the delivery of its functions.

12. Reporting to the Board

12.1 Following each Committee meeting, and at the next appropriate meeting of the Board, R&SC will formally report to the Board on the assurance it can provide on the matters set out in paragraph 3.1. The Chair will use the assurance report to draw to the attention of the Board any issues that require disclosure to the full Board, or that, in the view of R&SC require executive action.

13. Review of Terms of Reference

13.1. The Committee will review its Terms of Reference at least annually and suggest amendments as necessary. Amendments to the Terms of Reference will be subject to review and approval by the Board.

Medicines & Healthcare products
Regulatory Agency

People and Public Engagement Committee

Terms of Reference

Document Control[1]

Document Description:

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Approvals

Name	Role	Date
PPEC Chair	Recommend	13 November 2025
MHRA Board	Approve	

Document Change History

Date	Issuance/ Revision	Author	Description of Changes
06.02.2025	0.0	Mercy Jeyasingham	First initial draft
27.03.2025	0.2	Carly McGurry	First formal draft for consideration by CEO, PPEC Chair and Board Chair.
06.08.2025	0.3	Rachel Bosworth	Minor comments regarding transparency following first PPEC meeting.
10/11/2025	0.4	[redacted] Rachel Bosworth, Tasneem Blondin	Minor updates following first two PPEC meetings.
14/11/2025	0.5	[redacted]	TOR agreed with one minor amendment following PPEC meeting of 13/11/2025.
16/12/2025	0.6	[redacted]	Minor changes to ensure alignment with other Board Assurance Committee Terms of Reference.

Distribution

To all Board members and added to Insite for use by all staff.

[1] Document control to be annexed on ToR are agreed

1. Introduction

1.1 These Terms of Reference set out the principles that should underpin the roles and responsibilities of the People and Public Engagement Committee (PPEC), as a committee of the MHRA Board. These Terms of Reference should be consistent with the roles and responsibilities set out in the MHRA Board Terms of Reference, which are themselves consistent with wider applicable guidance and requirements.

2. Purpose

2.1. 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 MHRA **engagement with the public** in order to bolster and maintain public confidence in the outcomes the Agency delivers.

3. Responsibility

3.1. In relation to the **People** focus of the committee, it is the responsibility of the Committee to:

i. Provide assurance to the Board that the Agency has the appropriate approach, process and supporting culture in place to effectively manage workforce capabilities.

ii. Examine, scrutinise and challenge the effectiveness of workforce management to provide advice and assurance to the Board that the Agency will meet its strategic objectives.

iii. Scrutinise the processes, systems and structures in place within the Agency to attract, retain and develop staff capabilities and retain talent of all types in a challenging environment.

iv. Challenge and support the Executive appropriately on the development and implementation of an effective People Strategy which ensures the Agency meets its strategic objective of being a great place to work, as reflected in survey results and other measures.

v. Provide a formal and transparent process for determining Executive remuneration

vi. Review its own effectiveness periodically and report the results of that review to the Board.

3.2. In relation to the **Public Engagement** focus of the committee, it is the responsibility of the Committee to:

i. Scrutinise the systems in place to ensure information is shared effectively with the public on the operations of the Agency as a public body.

ii. Ensure that public expectations are taken into account by the Agency in its strategy development and delivery.

3.3. To meet these responsibilities the Committee will:

MHRA PEOPLE

- Scrutinise the processes, systems and structures within the Agency to focus on how we best support, grow and develop our workforce
- Review the Risk Register regarding staff and report concerns to the Board
- Regularly review workforce data, including Equality, Diversity and Inclusion data
- Regularly review and provide constructive challenge on the progress of the People Strategy and associated People Priorities
- Provide guidance on the development of targeted people initiatives required to support the operational performance of the Agency

PUBLIC ENGAGEMENT

- How we most effectively and appropriately engage with the wider public and ensure transparency in our operation.
- Review the Risk Register regarding public engagement and report concerns to the Board
- Provide guidance and input into the development of strategies, including maximising the methods used by the Agency to engage with the public.
- Provide challenge to the Executive on aspects of the regulatory systems that could be modified to improve public engagement.
- Regularly review impact metrics, including Equality, Diversity and Inclusion data.
- Operate in an action-oriented style, ensuring clear recommendations and timelines rather than prolonged consultation cycles

3.4. To fulfil these responsibilities, the non-executive members will use their experience and skills to provide constructive, effective and objective challenge to Executive members and provide an independent perspective on the matters listed in 3.1 and 3.2. Executive members will provide expertise and in-depth knowledge of the Agency's operations, opportunities and risks to enable the committee to discharge its responsibilities.

3.5. Meetings will be structured to ensure the two distinct areas of focus are considered separately, with dedicated agenda items and discussions aimed at improving staff experience and survey outcomes (People) and enhancing transparency and public accountability (Public Engagement), as per the matters listed in 3.1 and 3.2.

3.6. Following each Committee meeting, and at the next appropriate meeting of the Board, the Committee will formally report to the Board on the assurance it can provide on the people and public engagement activities of the Agency.

3.7. The committee holds no decision-making authority, nor does it exercise any line management or executive functions. It may suggest and agree actions with Executive members and may make recommendations to the Board, who retain decision-making responsibility in line with their schedule of reserved matters. This does not prevent the

committee from fulfilling its responsibilities to report to the Board and offer its view on the assurance provided.

3.8. The Committee will operate in accordance with the unitary status of the Agency Board by taking a collaborative approach, utilising constructive challenge, to fulfil the purpose and responsibilities set out above.

4. Composition

4.1. Membership of the PPEC will comprise four non-executive members appointed by the Chair of the Agency Board. One of the non-executive members will be appointed as chair and any of the non-executives can deputise in the appointed chair's absence. Three Executive members, including the Chief Executive Officer will be appointed to the committee by the Chief Executive Officer.

4.2. PPEC will also appoint two lay members to a non-voting position on the committee, to supplement its range of skills and experience and embed a robust lay perspective in discussions.

5. Membership

5.1. Committee meetings will also be regularly attended by other members of the Executive as the agenda demands. Where unavoidable, deputies for executive members should be agreed in advance with the Committee Chair. Once admitted, deputies will have the same rights and responsibilities with PPEC as non-deputies.

5.2. Other members of Agency staff shall be invited at the discretion of the Committee when matters relating to their areas of responsibility are being discussed.

5.3. The Committee may ask any or all of those who normally attend but who are not members to withdraw to facilitate open and frank discussion of particular matters.

5.4. The Chair of the Board may, by agreement of the Committee Chair, attend meetings as an observer where their presence is considered beneficial by the Committee Chair. Such attendance should be exceptional and not routine, and the Board Chair will not participate in decision-making or influence the Committee's independent assurance role.

6. Conflicts

6.1. Members should pro-actively declare any actual or potential conflicts of interest arising either from business on the agenda or from changes in their personal circumstances. The Chair should determine an appropriate course of action, from exclusion for a particular item of business to cessation of membership. Where the Chair has, or may have, a conflict of interest, the other members present should determine the appropriate course of action.

7. Quorum

7.1. The quorum of the committee will be five members, including at least two Non-Executive members, at least two Executive members and at least one lay member.

7.2. If a meeting is not quorate it may still proceed, with agreement from a majority of Committee members (including those not in attendance). In such circumstances, any decisions made will be non-binding and will require subsequent ratification, however decisions may be ratified by correspondence. If any members are not content to ratify through correspondence or on the basis of the minutes, this may trigger a further discussion in the next following meeting or in extraordinary circumstances, a short extraordinary meeting may be held.

7.3. A decision put to a vote at a quorate Committee meeting will be determined by a simple majority of voting members and deputies present. In the case of an equal vote, the Chair of the Committee at that meeting will cast a second, deciding vote.

7.4. All decisions made by the Committee are related to Committee matters and do not refer to Agency decisions, as stipulated in 3.3.

8. Sub Committees

8.1 The Committee may, subject to the approval of the Board, establish sub-committees to carry out specific aspects of Committee business, on its behalf.

9. Frequency of Meetings

9.1. The Committee will meet quarterly and otherwise, with the flexibility to discuss matters arising via correspondence or extraordinary meetings as the Chair of the Committee deems necessary. The frequency of meetings will take into account the timing of the Agency's talent management and remuneration processes.

10. Secretariat

10.1. The Committee Secretariat will be responsible for:

- Preparing the agenda in consultation with the Committee Chair;
- Commissioning Committee papers;
- Circulating Committee papers to members and invitees, normally five working days before each meeting;
- Documenting the outcome of all votes taken in the Committee meeting minutes;
- Producing and circulating draft minutes of the Committee meetings to members, normally ten working days after each meeting, for approval at the following meeting;
- Maintaining an action log.

11. Delegated Authority

11.1. The Board authorises the PPEC to investigate or have investigated any activity in line with its responsibilities, as set out in these Terms of Reference. In doing so, the

Committee can rightfully inspect any documents, ensuring that data, confidentiality and security are maintained, and all relevant policies adhered to. It may seek relevant information from any employee, other committee, sub-committee or Group set up by the Board to assist it in the delivery of its functions.

12. Reporting to the Board

12.1. Following each Committee meeting, and at the next appropriate meeting of the Board, PPEC will formally report to the Board on the assurance it can provide on the matters set out in paragraphs 3.1 and 3.2. The Committee Chair will use the assurance report to draw to the attention of the Board any issues that require disclosure to the full Board, or that, in the view of PPEC require executive action.

13. Review of Terms of Reference

13.1. The Committee will review its Terms of Reference at least annually. Amendments to the Terms of Reference will be subject to review and approval by the Board.

MHRA Board Schedule of Business – January 2026 to November 2026

	20 January 2026 10SC	10 Feb 26 10SC	18 March 2026 Science Campus	18-19 May 2026 Wales (DA)
	Board in Public	**Extraordinary Board**	**Board**	**Board**
Context	CEO report	Strategy Development Day. Including: **Core operational excellence**: Presentation of new performance dashboard. **Specialisation:** CERSIs update.	CEO report	CEO report
Finance & Performance	Financial and People Performance Report Month 8		Q3 Business Plan performance (including Q3 operational performance in new dashboard)	Q4 Business Plan (including Q4 operational performance)
Strategic Direction	Patient Safety Commissioner MHRA / NICE parallel process Rare Diseases		RegulatoryConnect update on closure and next steps Exercise Pegasus Report HQA decisions processes overview (TBC)	Joint items with Wales. Wales specific items. TBC
Assurance	Regulation and Safety Committee Assurance Report. Patient and Public Engagement Committee Assurance Report.		Audit and Risk Assurance Committee Assurance Report. People and Public Engagement Committee Assurance Report.	Audit and Risk Assurance Committee Assurance Report.
Governance	Approval of updated Board and Board Assurance Committee Terms of Reference.		Agency Risks	
	Board Seminar (closed)		**Board Seminar**	**Board Seminar**
Strategic Development	Confidential updates MHRA2030 Strategy development session		MHRA2030 Strategy update and next steps	MHRA2030 Strategy update
Annex for CEO Report				
Board Development	Board Schedule		Board Schedule	Board Schedule

	10 June 2026 London	7 July 2026 10SC	14-15 September 2026 Scotland, Glasgow [Under Review]	10 November 2026 South Mimms [Under Review]
	Board Away Day	**Board in Public**	**Board**	**Board**
Context	Board development	CEO report	CEO report	CEO report
Finance & Performance		Financial and People Performance Report Month 2	Q1 Business Plan (including Q1 operational performance)	Q2 Business Plan (including Q2 operational performance)
Strategic Direction		Yellow Card Biobank	Science Plan	TBC
Assurance		Audit Risk and Assurance Committee Assurance Report MHRA Assurance Report	Regulation and Safety Committee Assurance Report. People and Public Engagement Committee assurance report.	Audit Risk and Assurance Committee Assurance Report.
Governance		Annual Report and Accounts approval		Health & Safety Report
		Board Seminar	**Board Seminar**	**Board Seminar**
Strategic Development		Update on MHRA2030 Strategy Health Inequalities	Update on MHRA2030 Strategy Strategic workforce plan	Update on MHRA2030 Strategy
Annex for CEO Report				
Board Development		Board Schedule	Board Schedule	Board Schedule

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

20 January 2026

Title	CEO's report – current activities and priorities
Board Sponsor	Lawrence Tallon
Purpose of Paper	Context

MHRA CHIEF EXECUTIVE'S REPORT TO THE BOARD – JANUARY 2026

Introduction

1. I am pleased to present to the Board my first report of 2026, which gives an overview of the Agency's recent and forthcoming activities. As usual, this report presents an overview rather than an exhaustive list of our work.

2. We begin the new year with a sense of optimism as our core performance, internal morale and external reputation have strong foundations and are all on improving trajectories. We stand on a stable platform and can be increasingly ambitious in our emerging five-year strategy for our pivotal role in UK health services and life sciences.

3. The US-UK pharmaceutical deal that was announced at the start of December is highly significant and positive for the context in which we operate. The deal means there will be no tariff barriers between our two countries for pharmaceuticals; HM government has committed to raising the NICE Quality Adjusted Life Years (QALY) threshold by 25%; there will be a substantial increase in investment in innovative medicines in the UK in the years ahead; and the rebate that pharmaceutical companies pay on branded medicines will be reduced from 22.9% to 14.5%.

4. Taken together, these measures will improve access for UK patients to innovative medicines and make the commercial environment in this country more supportive for research, manufacturing and supply of new medicines.

5. Less positively for the context in which we operate, the British Medical Association is continuing its industrial dispute with the government over resident doctors' pay and conditions. These strikes, together with a cold winter and high rates of influenza and other respiratory viruses, has meant the NHS is under a great deal of operational pressure.

People and leadership

6. Before Christmas we received the results from our 2025 Civil Service People Survey, which we presented at a special all staff meeting on 15 December. This is an important annual exercise across all civil service departments and arm's length bodies which enables us to understand the experiences and perspectives of our people and to compare them with our own past results and our current peer group. It is the most reliable and in-depth data we have on the experience of working at the MHRA, so I have included an extended section in this report.

7. Overall, our 2025 People Survey shows significant improvements, both in comparison to our results from last year and previous years, and in terms of our relative position in the civil service peer group. We can be pleased with the direction of travel, but we are far from complacent because the survey results also show there is a lot more to do before we can be confident that all of our people consider the MHRA to be a great place to work all of the time.

8. The headlines of the 2025 People Survey are as follows:

   - We had the highest response rate on record for the Agency at 81%, an improvement of 19 percentage points on last year – with many thanks to the 1,195 colleagues who completed the survey. This high response rate means we can be confident in the results as a basis for action.
   - The key composite measure for benchmarking purposes is the Employee Engagement Index, which is up 6 percentage points on last year. Of the large organisations (1,000 people and above), we were jointly the most improved on this measure in the civil service, equal with the Land Registry. In recent years, MHRA has been towards the lower end of the peer group, within the 9th or 10th decile. This year we have moved into the top half.
   - The number of our people agreeing with the statement, 'I feel positive about the future of my organisation' is up 12 percentage points on last year and is 9 percentage points above the civil service benchmark.
   - 'Senior leaders have a clear vision for the future of my organisation' is up 10 percentage points on last year.
   - The proportion of colleagues wanting to stay with the organisation for at least three years is up 7 percentage points on last year.
   - Satisfaction with pay and benefits is up 6 percentage points on last year, but the overall score remains relatively low.
   - Leadership and management of change is up 10 percentage points on last year.
   - Belief that senior managers will take action on the results of the survey is up 6 percentage points on last year.
   - There were various other minor fluctuations up and down, but very few measures have deteriorated in any statistically significant way since last year.

9. Overall, these are positive results about the direction of travel for the agency. I am very grateful to all colleagues who completed the survey and who have contributed to this improved working environment over the last year.

10. However, there are also some important notes of caution. Whilst the Engagement Index has improved appreciably to 65% (from comparatively low scores of 59% last year and 58% the year before), that lifts MHRA up only to around the middle of the civil service peer group. We should be aiming for the upper reaches in subsequent years. Whilst the scores overall have moved positively, there remain some pockets of concern, either with specific issues or within teams, which gives us plenty more to work on before we can be truly satisfied that the MHRA is consistently a great place to work. This will be our relentless focus in the year ahead.

11. On 9 December we celebrated our end of year awards in a special all-staff ceremony presided over by our Chairman. Many congratulations to the four prize winners, all of whom who were nominated by their colleagues, for awards for Collaboration, Innovator, Patient and Public Champion, and Unsung Hero.

12. In leadership news, we are delighted to welcome Professor Jacob George who took up his role as our first Chief Medical and Scientific Officer on 5 January. Plans are progressing well for the recruitment of our new Chief Digital Technologies Officer with interviews taking place in early February. Rachel Arrundale has decided to leave her role as interim Director of Partnerships at the end of March and I would like to thank her for the substantial contribution she has made to the agency over the last six years.

Performance and licensing

13. We continue to deliver compliance against our statutory performance targets for licensing and clinical trials. The remaining (non-statutory) target on scientific advice is close to returning to compliance and we are investing in more assessor posts to ensure this important service can be delivered consistently and in a timely fashion in future.

14. By the end of the first quarter of 2026, I expect us to be reporting a wider data set in our new performance dashboard. The dashboard is being developed with input from external stakeholders, as well as substantial internal engagement across the Agency. I am grateful to Non-Executive Directors for their input to this dashboard which will provide a richer and fuller overview of our performance and activity than the current, more limited set of measures.

15. We have granted marketing authorisations for a number of new products and indications in recent months, including some products that are first in market in the UK. In addition to fifteen new indications we licensed the following new products, and the first agency in the world to approve Exdensur:

    - **Siiltibcy:** Diagnostic aid for detection of Mycobacterium tuberculosis infection (including disease) in adults and children aged 28 days or older.
    - **Alhemo**: Indicated for routine prophylaxis of bleeding in patients with haemophilia A (with FVIII inhibitors) or haemophilia B (with FIX inhibitors), aged 12 years or older.
    - **Lagevrio**: Indicated for treatment of mild to moderate COVID-19 in adults with a positive SARS-CoV-2 test and at least one risk factor for severe illness.
    - **Comirnaty:** Indicated for active immunisation to prevent COVID-19 in individuals 12 years and older.
    - **Tivdak:** Monotherapy indicated for treatment of adult patients with recurrent or metastatic cervical cancer with disease progression after systemic therapy.

- **Itovebi**: In combination with palbociclib and fulvestrant, indicated for treatment of adult patients with PIK3CA-mutated, ER-positive, HER2-negative, locally advanced or metastatic breast cancer after recurrence on or within 12 months of adjuvant endocrine treatment.
- **Ezmekly:** Monotherapy indicated for treatment of symptomatic, inoperable plexiform neurofibromas (PN) in paediatric and adult patients with neurofibromatosis type 1 (NF1), aged 2 years and above.
- **Exdensur:** Indicated as add-on maintenance treatment of asthma in adults/adolescents (12+ years) with type 2 inflammation and as add-on therapy for severe chronic rhinosinusitis with nasal polyps (CRSwNP) in adults.

Public safety and communications

16. The Agency has used the themes of the festive season to promote safe use of medicines and medical devices, and has delivered extensive national and regional media and social media coverage throughout December and early January on a range of topics including festive foods and their interactions with medicines, emollient creams and weight loss medicines. Our Deputy Director of Criminal Enforcement appeared before Christmas on the Today Programme and on BBC Breakfast News in the New Year, highlighting the dangers of unregulated medicines.

17. Amongst our greatest priorities in the year ahead will be high profile public communications on the safe use of weight loss medicines and enforcement activities against criminals and unregulated suppliers. I anticipate that we will need to expand of our Criminal Enforcement Unit (CEU) in recognition of this growing threat and the broadening span of the CEU's operations.

18. Like many of our peer medicines regulators in other countries, we have been reinforcing evidence-based communications around the safety of vaccines. Despite vaccines being amongst the most effective public health interventions, this country, like many others, has seen a gradual reduction in childhood vaccination rates, very sadly with a small number of fatal effects emerging in un-vaccinated people with measles and whooping cough. The Agency has been using its trusted voice to communicate the safety of the new MMRV vaccine in collaboration with the UK Health Security Agency.

Clinical trials and innovation

19. In early December, the Association of British Pharmaceutical Industry (ABPI) published a report on UK clinical trials, which presented a mixed picture. On the one hand, the number of clinical trials initiated in the UK had increased by 35.7% on the previous year, but on the other hand, the number of patients recruited into industry trials fell for the fourth year in a row.

20. It is crucial for optimal patient care and for life sciences investment that the UK sustainably improves its performance on commercial clinical trials. The Government has set out its intention to reduce the average time for clinical

trials set-up from around 250 days to 150 days by March 2026. It is clear that the main challenge to achieving this target is no longer the regulatory approval element of the clinical trial lifecycle, but the mobilisation and patient recruitment at participating NHS sites.

21. Nevertheless, there is more that the MHRA can do, working closely with the Health Research Authority, to contribute to improved set-up times on clinical trials. We have a range of reforms underway, including a more streamlined approvals process for low risk clinical trials, more accessible scientific advice and greater use of AI to process some elements of trial applications (though with ultimate human sign-off). Professor Bola Owolabi of the CQC and former National Director of Health Equalities recently wrote a thought-provoking guest article for our strategy series about the importance of participant diversity in clinical trials.

22. The Agency recently approved a widely publicised clinical trial application from King's College London, known as the Pathways Trial, on the use of hormone therapy to supress the onset of puberty in young people experiencing gender incongruence. This trial is a direct response to the report on the issue of gender incongruence in young people from Dr Hilary Cass in 2024, which recommended that any such hormone therapies in this country should be conducted only in the context of an authorised clinical trial that is part of a wider programme of research evaluating outcomes of psychosocial interventions and hormones. We recognise that the issue of gender incongruence in young people is highly sensitive and there is high public interest in the trial.

23. In order to strike the right balance between maintaining safety and enabling appropriate access to effective new medicines and novel therapies, we must always put patients at the heart of our approach to innovation. Before Christmas we held successful patient engagement events, hosted by our Interim Executive Director of Healthcare Quality, both for the Rare Diseases Consortium which we are leading and on potential new approaches to Patient Information Leaflets.

24. On 7 January our Senior Leaders Forum heard from a remarkable guest speaker, [redacted], who became an international campaigner on individualised therapies for patients with very rare diseases after the tragic death from Batten Disease of her daughter [redacted]. I also commend to the Board one of our latest guest blogs from [redacted] who tells the uplifting story of his son [redacted]'s successful gene therapy for Spinal Muscular Atrophy. As we develop our strategy for the years ahead, we will continue to put patients and their advocates at the heart of our work.

Science and research

25. Recent months have seen a number of successes for our scientists in terms of grants and publications including:

    - an article in *Nature Antimicrobials and Resistance* on how medicines interact with gut bacteria;

- the MHRA's collaboration with Imperial College London on a major study published in *Nature Microbiology* on the spread patterns of vaccine-derived poliovirus type 2, offering valuable insights for efforts to eradicate polio;
- a successful award from the Department of Science, Innovation and Technology (DSIT) Engineering Biology Sandbox Fund. This multi-agency look at the regulations around phage products across One Health has a focus on engineered and synthetic phages.

A further 3 Gates Foundation-funded awards to support reference material and assay development pertinent to vaccine development (*Klebsiella pneumonia*, Group B streptococcus, gonorrhoeal disease). We have also put in place independent control testing to support the introduction of the varicella vaccine to the UK immunisation programme from January 2026.

26. Whilst the intellectual capability of our scientists is in good health, the physical fabric of our Science Campus, in places, is less so. To secure the continuing productivity of this vital site, with its world class capabilities in biological standard-setting, we will need to continue to invest in its physical and digital infrastructure for the strategic period ahead and that will be supported by the Spending Review settlement.

27. In December we held a successful annual meeting of the network of CERSIs (Centres of Excellence for Regulatory Science and Innovation). There are both successes and lessons to be learned from their first year in operation. Prof George will now take an overall lead for the Agency on the network of CERSIs from this year onwards, whilst sponsor teams will retain their links with closely related CERSIs. In the years ahead, we will make greater use of their potential to help us deliver the Agency's strategy and to stretch our intellectual capability in emerging and complex areas, such as the regulation of AI, *in silico* modelling and more.

Health technologies

28. The National Commission on the Regulation of AI in Healthcare is now well into its stride, with multiple expert meetings of the main Commission and its working groups having taken place in late 2025. The Commission has launched a major 'Call for Evidence' to hear from as many interested parties as possible. There will be a series of open, deliberative events held in the first quarter of 2026 to ensure widespread participation. The expertise and energy going into this National Commission positions it well to lead the global standard setting on the regulation of AI in healthcare for years to come. We are immensely grateful to the many experts leading and contributing to this vital work.

29. We are now mobilising our ARISE programme, funded by the Regulatory Pioneer Fund, to develop AI tools within our own regulatory workflows. This will build on and expand recent our efforts to speed up regulatory processes with AI augmenting human expertise.

30. We have also received a £2m grant from Wellcome to build our capacity for the regulation of digital mental health technologies. This is a fast-growing field that offers a great deal of promise for supporting public mental health, but in which there is also a need for a robust framework of regulation, especially for direct-to-consumer products.

31. The closure of the RegulatoryConnect programme, including capturing the value of the development work to date, is progressing according to plan. James Pound will continue as Senior Responsible Officer (SRO) to oversee the close down of that programme to its conclusion.

32. We have also commenced early planning for a new programme that will better meet the needs of the Agency in future. A business case will be prepared in the first half of this year and the SRO for this new programme will be Julian Beach to ensure the needs of the end users are front and centre of its design and implementation. The new Chief Digital Technologies Officer, when appointed, will also have a vital role to play as our internal expert leader in this area.

33. Our programme of med tech regulatory reforms continues apace. We have issued guidance on Health Institution Exemptions, which enables clinically led innovation in medical devices and technologies within a clear regulatory framework across the NHS and related bodies. We have announced a pilot in the first quarter of 2026 to waive fees for small enterprises undertaking clinical investigations to promote start-up growth and innovation.

Partnerships

34. There have been important leadership developments at two of our most significant national partner organisations. Baroness Nicola Blackwood has been appointed Chair of the new Health Data Research Service (HDRS). A Chief Executive for HDRS is expected to be announced imminently. Professor Jonathan Benger has been appointed as the new Chief Executive at NICE, having previously been the organisation's Chief Medical Officer.

35. Following our successful Board meeting in Belfast in November, we have issued a statement on how we will enhance collaboration with health services and life sciences in Northern Ireland. This will include the expansion and promotion of the Yellow Card system, resolving the regulatory issues that have been affecting clinical trials and increasing the Agency's ,presence in Northern Ireland for greater dialogue and more effective and timely bilateral communications.

36. This month, we have taken over from Swiss Medic the chairing and coordination of the Access Consortium for the year ahead. This is a coalition of like-minded regulatory authorities who work together to promote greater regulatory collaboration and alignment of regulatory requirements. There is a shared commitment amongst the five heads of agencies from the national regulatory authorities of Australia, Canada, Singapore, Switzerland and the MHRA to make this a year in which Access really grows in its scope and ambition.

37. In addition, we have announced even closer collaboration with the Health Sciences Authority of Singapore on clinical trials, AI and regulatory alignment as part of a new regulatory innovation corridor between our two countries. I envisage a growing and strengthening network of reciprocal partnerships of this kind within the international dimension of our forthcoming strategy.

Lawrence Tallon
Chief Executive Officer, MHRA
January 2026

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

20th January 2026

Title	Finance and people performance report
Board Sponsor	Rose Braithwaite
Purpose of Paper	Assurance

Finance and people performance report

1. Executive Summary

1.1. The full year forecast prepared at the end of September (Q2) is for a small resource underspend of £0.6m. This is achieved by higher-than-expected income and lower than budgeted non-pay operating costs.

1.2. At the end of November, the Agency has a £8.4m year to date (YTD) resource underspend. During the month we had an overspend against budget of £4.2m in our non-pay operating costs. We expect this spend to continue to increase in the coming months.

1.3. However, the Q2 resource forecast is at risk due to the impact of closing the Regulatory Connect programme. Expenditure incurred post-announcement is expected to be impaired and therefore recorded as resource spend rather than capital, which will place significant pressure on the Agency's resource budget. Latest forecasts indicate a potential £2.8m overspend against this year's Regulatory Connect resource budget.

1.4. The capital forecast at the end of Q2 showed an underspend of £2.3m. However, it is expected that the closure of the Regulatory Connect will lead to a higher capital underspend that will be reflected in the Q3 forecast at the end of this month.

1.5. Staff turnover, calculated on an annual rolling rate as at the end of November 2025 was 5%. There were 131 listed 'vacancies' as at the end of November 2025. Recruitment activity continues with 31 live recruitment campaigns.

2. Introduction

AGENCY FINANCIAL PERFORMANCE

2.1. The Agency started 2025/26 with a budget that overprogrammed (ran hot) by £2.3m. As set out in Table 1, at the end of Q2 we were forecasting for this to reduce to a small underspend of £0.6m. This is attributable to trading income being higher than budget and Business-As-Usual (BAU) non-pay costs being lower than budget.

Income

2.2 The Agency's YTD resource income is £0.8m higher than budget, driven by £3.6m of additional trading income. The full year forecast is for overall income to be £1.8m higher than budget.

2.3 In particular there has been a high demand for Licensing activity with national applications and variations exceeding expected volumes.

Staff costs

2.4 Staff costs are on track and are forecast to be slightly over budget by the end of the financial year. The forecast spend increases in the coming months on the expectation of further recruitment into existing vacancies. Staff costs are closely tracked by Finance as they constitute approximately 60% of the Agency costs.

Table 1 – Agency Financial Performance for November 2025

November 2025	Period		Variance vs	YTD		Variance vs	Full Year		Variance vs
Resource	Actual	Budget	Budget	Actual	Budget	Budget	Forecast	Budget	Budget
	£M	£M	% / £M	£M	£M	% / £M	£M	£M	% / £M
Trading Income	8.6	8.7	(1%)	74.7	71.1	5%	112.4	109.1	3%
Service Fee Income	4.1	4.3	(4%)	32.7	34.1	(4%)	49.0	51.1	(4%)
Devices Service Fee Income	0.0	0.0	0%	0.0	0.0	0%	0.0	0.0	0%
Grant Income	0.5	0.6	(25%)	3.7	4.0	(7%)	6.3	6.5	(4%)
NIHR Drawdown	0.2	0.3	(41%)	1.7	2.7	(37%)	3.5	4.1	(13%)
DHSC - Baseline Funding	2.0	2.0	0%	15.7	15.7	0%	23.6	23.6	0%
DHSC - Additional Funding	0.9	0.9	0%	7.4	7.4	0%	12.6	11.2	13%
Total Resource Funding	**16.2**	**16.8**	**(0.6)**	**135.9**	**135.1**	**0.8**	**207.4**	**205.6**	**1.8**
Staff Costs	10.1	10.1	0%	76.8	76.8	0%	117.8	117.6	0%
Operating Costs	7.4	5.7	(27%)	41.1	48.4	15%	69.9	71.2	2%
Projects - Staff Costs	0.4	0.3	(30%)	2.9	2.7	(8%)	4.6	3.8	(21%)
Projects - Operating Costs	0.4	0.6	26%	2.5	4.3	42%	6.6	6.7	1%
Grant Costs	0.0	0.0	0%	0.0	0.0	0%	0.0	0.0	0%
Total Resource Costs	**18.3**	**16.7**	**(1.6)**	**123.4**	**132.2**	**8.8**	**198.9**	**199.4**	**0.5**
Running Hot / Risk Appetite	**0.0**	**(0.2)**	**(0.2)**	**(1.8)**	**(1.5)**	**0.3**	**(1.8)**	**(2.3)**	**(0.5)**
Projects – Regulatory Connect	**2.6**	**0.7**	**(1.9)**	**7.4**	**5.9**	**(1.5)**	**9.7**	**8.5**	**(1.2)**
Agency Net Resource Position	**(4.6)**	**0.4**	**(4.2)**	**6.9**	**(1.5)**	**8.4**	**0.6**	**(0.0)**	**0.6**

Non-Pay Operating Costs

2.5 The YTD underspend of £7.3m in non-pay operating costs drives the overall YTD result of a £8.4m resource surplus to budget. The FY forecast moves closer to budget based on a significant increase in non-pay spend in the remaining of the year. This pattern of spend has started in November with a 27% overspend against the month's budget.

2.6 Table 3 shows the material variances to budget of non-pay spend in November, YTD and the FY forecast. Most of the YTD underspend sits in IT costs in Digital & Technology (D&T) and CPRD.

2.7 With regards to CPRD, this is due to lower activity and lower inflation than assumed, and more VAT recoverable costs than anticipated. The underspend within CPRD is forecast to continue in the remaining period of the financial year.

2.8 D&T are currently underspending across their IT costs and Contracted-out services but, as the November D&T non-pay overspend shows, we expect the rate of spend to increase in future months. Spend will increase mainly on the cyber programme as well as on infrastructure and platform maintenance.

2.9 Accommodation costs are behind budget because of lower building repairs and maintenance costs in South Mimms and variable costs in 10SC. We expect activity to increase for both and table 2 shows that this has started in November.

Table 2 – Non-pay operating costs

	November			YTD			Full Year		
	Actual	Budget	Variance	Actual	Budget	Variance	Forecast	Budget	Variance
Contracted Out Services	1,681	759	(922)	6,432	7,007	575	11,230	9,786	(1,444)
IT Costs	2,461	1,955	(506)	15,873	20,000	4,127	27,135	28,757	1,622
Accommodation	896	884	(12)	5,359	7,070	1,712	9,573	10,607	1,034
Laboratory Costs	1,208	1,129	(79)	7,251	8,302	1,051	11,791	12,818	1,027
Other Costs	1,105	951	(154)	6,197	6,049	(148)	10,177	9,216	(961)
Total	**7,351**	**5,678**	**(1,673)**	**41,112**	**48,428**	**7,316**	**69,906**	**71,184**	**1,278**

Capital

2.10 The Agency's capital budget 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.

2.11 Table 3 shows a small £1.4m underspend due to a November underspend in Regulatory Connect. The FY capital forecast at Q2 was for a £2.3m underspend by the end of the year. Stopping the Regulatory Connect programme, however, will mean a significantly higher underspend which will be confirmed at the Q3 forecast later this month.

Table 3 – Capital Spend for November 2025

November 2025	Period		*Variance vs*	YTD		*Variance vs*	Full Year		*Variance vs*
Capital	Actual	Budget	*Budget*	Actual	Budget	*Budget*	Forecast	Budget	*Budget*
	£M	£M	*% / £M*	£M	£M	*% / £M*	£M	£M	*% / £M*
DHSC Capital Funding	**3.3**	**3.3**	**0%**	**23.2**	**23.2**	**0%**	**50.0**	**47.0**	**6%**
Capital Costs	**1.9**	**3.3**	**43%**	**21.8**	**23.2**	**6%**	**47.7**	**47.0**	**(1%)**
Agency Net Capital Position	**1.4**	**0.0**	**1.4**	**1.4**	**0.0**	**1.4**	**2.3**	**0.0**	**2.3**

AGENCY PEOPLE PERFORMANCE

People in post

3.1 We had 1,537.5 people in post at the end of November 2025 (FTE, permanent, fixed term and Ph.D. students covering established posts), an increase of 15.4 FTE from October. Of this number, 133.4 were fixed term, a decrease of 1.17 FTE. Of those fixed term, 111.6 are fixed term IN (where a role has been advertised fair and open and an appointment made on merit, in accordance with the civil service recruitment principles) and 21.8 are fixed term OUT, where the role has been filled via a recruitment agency, or utilising some other exception to the recruitment principles. The fixed term OUT category has declined (by 2.97 FTE) compared to October.

3.2 There were 9 new temporary promotions in October (an increase on the 7 reported in October) and 16 contingent workers filling vacant roles (included in the fixed term out quota). The majority of temporary promotions will be to fill gaps created by maternity / parental leave or long-term sickness, or to back fill other temporary promotions.

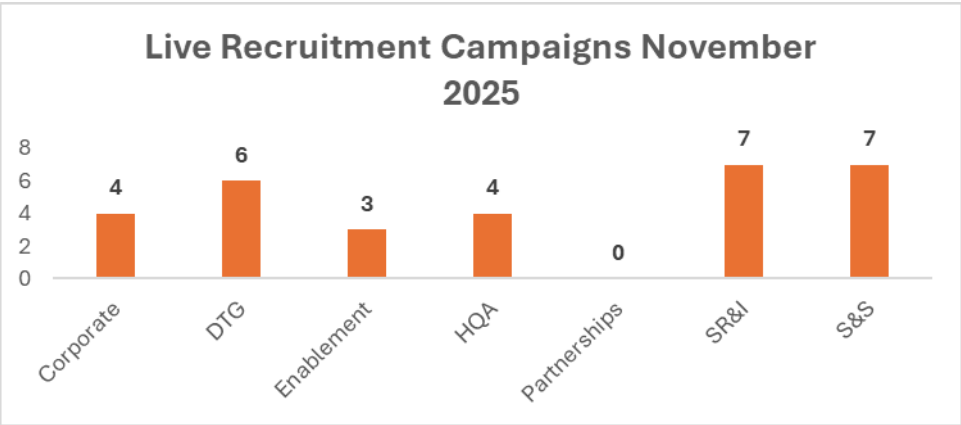
Attract and Retain the Right People – turnover, vacancies and recruitment

3.3 We welcomed 26 new starters to the Agency in November and saw 7 voluntary leavers (31:7 in October).

3.4 Voluntary turnover (for the rolling year) at the end of November was 5%, the same as reported in October.

3.5 We had 131 ‘vacancies’ at the end of November a minor decrease on the 133 vacancies reported in October. The creation of numerous new posts that are being advertised or about to be, will impact this number. Most will be covered either by contingent supply or temporary promotion pending recruitment. The vacancy rate at the end of November was 8.4%, a reduction on the 8.7% reported in October. Proportionally DTG and Partnerships have the highest level of vacancies (15.7% and 15.3% respectively)

3.6 Recruitment activity continues at high pace as Groups work through their priority posts to fill. In November, there were 31 campaigns live:



3.7 Time to hire data for October and November:

Measure	November	October
Time to hire (advert close to formal offer)	27.15 working days	32.05 working days
Formal offer to start date requested	9.29 working days*	11.94 working days**

* likely due to 50% being internal. 16.8 working days for external candidates only
** likely due to 54% being internal. 20.82 working days for external candidates only

Employee Wellbeing - Sickness Absence

3.8 Sickness absence (annualised) has remained at 6.2 days per FTE. The highest absence levels continue to be in Corporate Group (11.2 days per FTE, a reduction on 12.7 days reported in October), followed by Enablement, which has increased to 7.8 days. The lowest absence levels continue to be within Partnerships which report 4.5 days per FTE, albeit an increase on the 2.3 days reported last month. Data for the smaller groups can be disproportionately impacted by cases of long-term sickness absence.

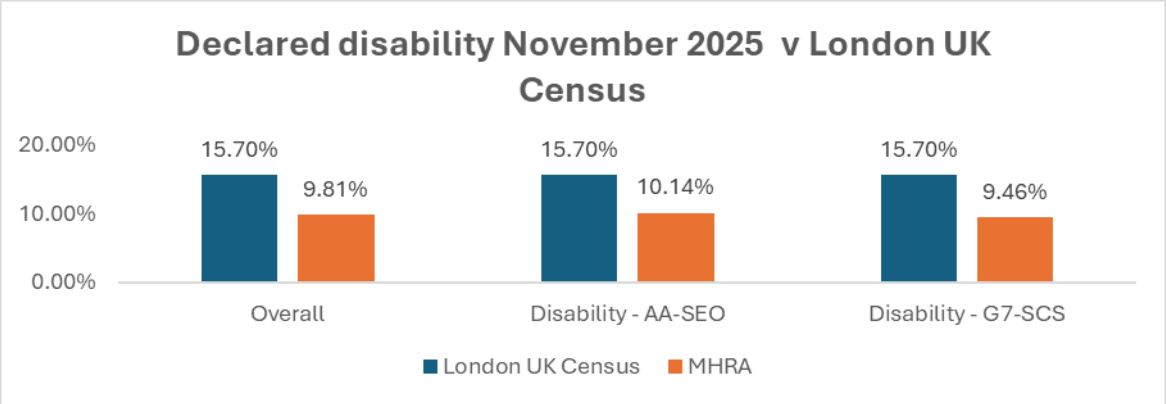
Staff Engagement - People Survey 2025

3.9 Results of the 2025 survey are released to everyone in early December, when the embargo is lifted by Cabinet Office. A People Survey Community has been created with representatives from every Group/Function to ensure that the results are fully understood by all areas of the MHRA, and that the findings enable action plans at a local level, with regular communications about progress on those plans.

3.10 Once the embargo is lifted, a summary is published to aid prompt and local discussion. A timeline for sharing the results after that includes from 11 December onwards People Survey Community meetings begin, localised action planning starts, local calls to discuss results take place and an all staff call scheduled to share results and the response plan. Board will consider a report setting out the results at the January meeting, and key themes will be agreed by 1st February with local and agency wide action plans confirmed and agreed.

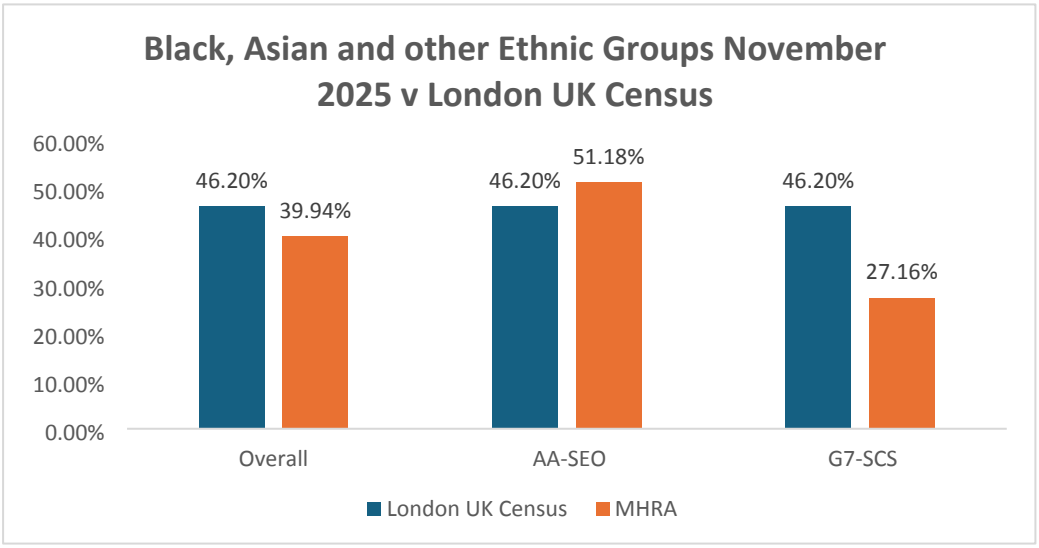
Diversity and Inclusion

3.11 We continue to strive to be a diverse and inclusive employer, seeking our workforce to reflect the London UK Census 2021 targets. Our declaration rates compared to the census were as follows:

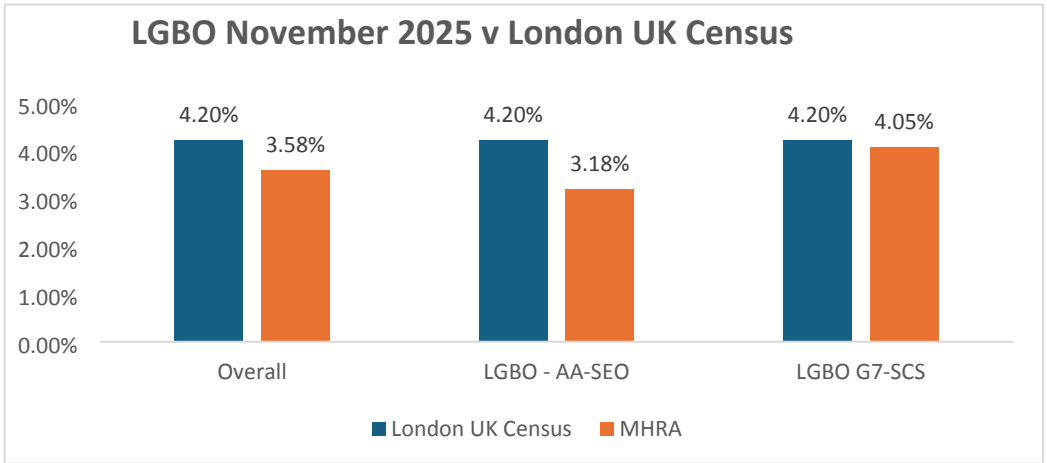


3.12 Our declaration rates by staff are lower than the % of people in the London UK Census who have declared a disability, at 9.81% (10.14% for the AA-SEO grades).

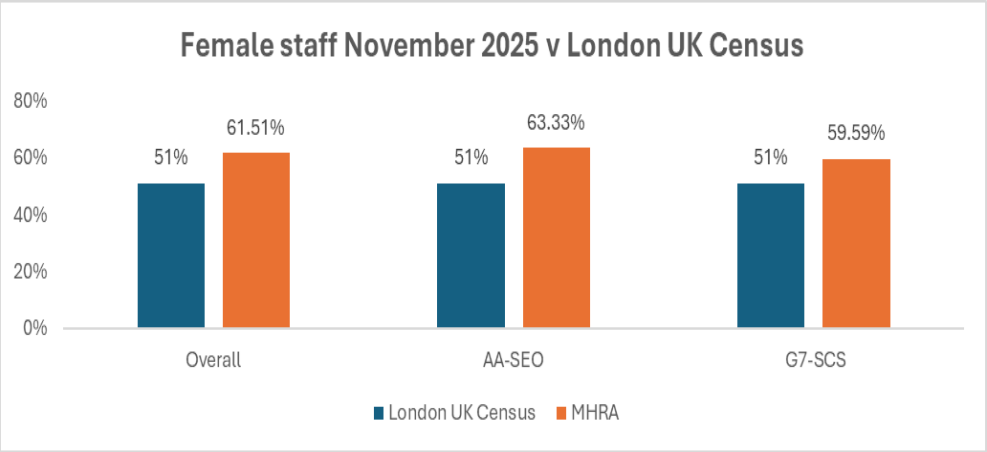
3.13 In respect of Black Asian and other ethnic groups, the AA-SEO grades exceed the reported census population, at 51.18%, but this is significantly under the census population at the G7+ grades at 27.16% meaning there is still work to do in respect of recruitment and retention of Black, Asian and other ethnic groups at the more senior levels.



3.14 In respect of LGBO declarations, these are lower than the London UK Census declarations at 3.58%, but higher at the G7 – SCS grades.



3.15 More than 61% of the MHRA workforce is female, with proportions at all grades exceeding the London UK census population. With all data comparisons, it's recognised that our workforce is not fully London based, but this was the target audience established in the 2023 People Strategy.



Talent and capability

3.16 In support of the continued professional development across the agency an additional Talent Partner has been onboarded and will focus on the current and future management and leadership development offering across the line manager and SCS groups.

3.17 The pending changes to the CS learning framework continues to be worked through and an alternative training procurement process is in place to ensure the continuation of an 'off the shelf' training provision remains in place.

4 Recommendation

4.1 The Board is asked to consider the assurance it gains from the financial data, in particular the strong YTD surplus in trading income and the year-to-date resource underspend of £8.4m. The impact of the Regulatory Connect closure costs on the resource and capital forecast positions are being quantified for the Q3 forecast and will result in additional pressure to the resource forecast and an increase in the capital forecast underspend.

4.2 The Board is asked to consider the People data and the assurance that it provides on the resourcing of the Agency.

Rose Braithwaite
January 2026

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

20 January 2026

Title	The Patient Safety Commissioner's strategic priorities to strengthen patient voice and safety in medicines and medical devices
Board Sponsor	Rachel Bosworth
Purpose of Paper	Strategic Direction

The Patient Safety Commissioner's strategic priorities to strengthen patient voice and safety in medicines and medical devices

1. Executive Summary

1.1 The Patient Safety Commissioner (PSC) is an independent statutory role established under the Medicines and Medical Devices Act 2021 to advocate for patient safety and amplify patient voice in relation to medicines and medical devices. The PSC's work aligns with MHRA's vision of safeguarding public health through regulatory excellence.

1.2 The PSC has been appointed for a second term, starting in September 2025.

1.3 The Board is asked to consider how MHRA can best support the PSC's strategic priorities, including embedding the Patient Safety Principles across the health system and promoting the patient voice in relation to the safety of medicines and medical devices.

2. Introduction

2.1. The PSC role was created following the Cumberlege Review recommendations to address systemic safety issues and ensure patient voices are heard. The Commissioner operates independently of government and MHRA but works closely with these and other stakeholders to influence policy and practice. The PSC has duties to promote patient safety as well as the views of patients and public with regard to medicines and medical devices.

2.2. Substantial improvements to the use of high-risk medications including the most potent teratogens has been achieved in the past 3 years through collaborative working between patient groups, MHRA, PSC and system leaders. This collaborative approach can be enhanced and continued to achieve similar gains in other areas, working in partnership with patients to get the best outcomes.

2.3. Recent developments include the transition of PSC hosting from DHSC to MHRA as recommended by the Dash Review and included in the government's 10-Year Health Plan. With regard to medicines and medical devices this will reinforce the opportunities for improving patient safety, the value of listening to patients and putting patients first by increased collaboration between MHRA and PSC.

3. Proposal

3.1. Embed the Patient Safety Principles into the work of the MHRA. The Patient Safety Principles include creating a culture of safety where patients are at the heart of everything. Where we treat people equitably and identify and act on inequalities. We identify and mitigate risks, are transparent and accountable and use information and data to drive improved care and outcomes. This will help with the MHRA strategic priority of maintaining public trust through transparency.

3.2. Improve information to patients in relation to medicines – this includes the work on electronic patient information led by MHRA and improved licensing and packaging for patients with visual impairment - both recommendations to MHRA in The Safety Gap report published in March 2025. This will help with the MHRA strategic priority of maintaining public trust through proactive communications.

3.3. Improve post market surveillance and oversight of medicines and medical devices, including the use of the Yellow Card system. Promote yellow card reporting of medical devices to patients, the public and healthcare professionals. This will help with the MHRA strategic priority of healthcare access to safe and effective medical products.

3.4. Work collaboratively in regard to the National Commission into the Regulation of AI in Healthcare. This will help with the MHRA strategic priority of healthcare access to safe and effective medical products.

Benefits: Strengthened patient voice in regulatory decisions; improved safety culture and transparency; better patient outcomes and reduced harm; enhanced public trust in MHRA and healthcare system.

4. Recommendation

4.1. The Board is asked to:

- Promote the independence of the PSC role within the hosting arrangements
- Endorse MHRA's active partnership with the PSC on strategic projects.
- Support joint initiatives promoting patient voice, transparency and proactive communication to the public, including in the National Commission into the Regulation of AI in Healthcare and accessibility improvements for vulnerable groups.

4.2. These actions will position MHRA as a leader in patient-centred regulation and deliver tangible improvements in safety outcomes.

Author: Henrietta Hughes / Patient Safety Commissioner.
Board Sponsor: Rachel Bosworth

Date: 8 January 2026

Annex: Recent PSC Initiatives

- Patient Safety Principles: Patient Safety Principles - Patient Safety Commissioner
- The Safety Gap: The Safety Gap Report - Patient Safety Commissioner
- PSC Strategy: Strategy - Patient Safety Commissioner
- PSC Recommendations: Recommendations - Patient Safety Commissioner
- The Hughes Report: The Hughes Report - Patient Safety Commissioner
- PSC Impact Paper: PSC Impact - Patient Safety Commissioner
- PSC Annual Reports: Our Reports - Patient Safety Commissioner
- Martha's Rule: https://www.england.nhs.uk/patient-safety/marthas-rule/

Medicines & Healthcare products Regulatory Agency

BOARD MEETING - HELD IN PUBLIC

20th Jan 2026

Title	An overview of the alignment of processes between MHRA and NICE
Board Sponsor	Julian Beach
Purpose of Paper	Assurance

An overview of the alignment of processes between MHRA and NICE

1. Executive Summary

1.1. This paper provides an update on the joint working actions with NICE as part of the Life Sciences Sector Plan, the UK Governments Regulatory Action Plan and the NHS 10-year health plan for England.

1.2. MHRA, working in partnership with NICE, launched the outline of an aligned pathway for same time decision making, and a supportive Integrated Scientific Advice service at a webinar on the 1st October and are now working to a full launch by 1st April 2026.

1.3. The board are asked to note the progress being made on the joint actions with NICE including the next steps as we build toward delivery.

2. Introduction

2.1. The UK Governments Regulatory Action Plan, published in March 2025 introduced elements of joint working between the MHRA and NICE. Annex 1 contains the full commitments as published.

2.2. These commitments were later refined in the 10-year health plan & Life Sciences Sector Plan following feedback from industry and cross government stakeholders. These refinements and specific action points are:

2.2.1. The 10 Year Health Plan states that "…by April 2026 MHRA and NICE will launch a new joint process, supported by information sharing and joint scientific advice, that will boost the speed of decisions and cut administrative burdens for the system and industry."

2.3. Together with NICE, the Agency ran a webinar on the 1st October which signalled our intentions and processes 6-months early and encouraging early adopters for both the pathway and the advice service. This webinar received over 3000 registrations from across 46 different countries, which was our first signal of the positive interest in these initiatives.

2.4. Communication of full launch will go ahead before the end of the financial year, with another webinar to support the launch provisionally scheduled for late March 2026.

2.5. The Agency board are asked to consider the progress of actions toward meeting our public commitments, as well as the proposals for next steps below.

3. Update

Delivering the aligned pathway and integrated advice commitments

3.1. Following the launch of the outlining of the projects in October, the team have set down the parameters of the aligned pathway and focussing on building a strong value proposition to ensure uptake of the pathway long term, with the communications teams liaising across organisations.

3.2. While we are clear that there should be no influence in the decision-making processes between our experts, we acknowledge the opportunity that an integrated scientific advice service gives us in doing all we can in aligning expectations for core data packages up front.

3.3. We will be delivering a follow up webinar on our joint commitments toward the end of March 2026 to detail the steps we have made since the 1st October 2025 and the full pathway proposition. This will also be the full launch of the services.

3.4. While we expect to launch fully in March 2026, we have received 3 expressions of interest for the integrated scientific advice to date and expect to be running these projects as early adopters prior to full launch. NICE have also already been aligning publication dates to expected regulatory timelines and expect to have a small number of same time publications prior to full launch.

Engagement across the Devolved Governments and beyond

3.5. While the key commitments are shared across MHRA and NICE, we are aware that NICE are the Health Technology Assessment body for England. While the Northern Ireland executive accept all NICE recommendations, and Wales adopting the majority, we are aware that the Scottish equivalent organisation (Scottish Medicines Consortium) have different methods and different outcomes for medicines appraisals than NICE.

3.6. It is key that we, as the regulator across the UK, work with the devolved governments to ensure that patients across the 4 nations benefit from these initiatives. We have been in contact with Scottish, Welsh and Northern Ireland Government officials explaining what processes are changing and how all can benefit.

3.7. We will continue to work with the Medicines and Medical Devices Access steering committee to ensure that the benefits from operational information sharing remain available for all 4 nations, while looking to enhance this process to ensure that horizon scanners right across the UK Health and Care system can plan to ensure rapid access and take up of new medicines.

3.8. Since the webinar on 1st October, we have had in person discussions with a number of public sector delegations from across the globe who have been extremely interested in the progress and indicating they would like to learn from us on how to deliver an aligned timing on regulatory and HTA decisions.

3.9. Having other major markets wanting to deliver this aligned approach is key to driving a change in the behaviours of the pharmaceutical industry to ensure that there is more engagement across regulatory and HTA teams at an earlier stage of development.

3.10. This engagement across other nations will drive earlier patient access to new, safe and effective medicines even earlier, hopefully reducing administration burden and eventually lower the cost of development of medicines and ensuring rapid global rollout for patients.

Operational improvements to ensure delivery

3.11. Internally, we have undertaken a programme of work to ensure that we are prepared to deliver high quality, reliable and scientifically excellent initiatives for our stakeholders.

3.12. Work continues to refine our operational information sharing to ensure that organisations across the UK health and care system receive accurate and timely information about expected regulatory timelines. We are also investigating digital options to ensure long term success.

3.13. Building relationships between our experts is key to delivering these initiatives. We have conducted workshops with our expert medics, statisticians and clinical pharmacologists from across organisations to further build relationships and explore how to maximise the opportunities this work gives us, for the benefit of clarity for medicines developers.

3.14. The Agency's digital and technology function have worked across organisations and with industry to develop a brand new, efficient online form for applying for the integrated scientific advice service and associated guidance. The team are in the final stages of design and are on track to launch early in 2026.

Building on the improved relationships across the UK Health and Care system

3.15. The public interest around our work with NICE and the deliverables under the 10-Year Health plan and Life Sciences Sector Plan has driven engagement between the Agency and the rest of the UK Health and Care System. For example, a group across DHSC, NHS England, NICE, MHRA and OLS, which will continue through 2026/27.

3.16. While we acknowledge that working with our UK Health and care system partners is key to moving forward. It is key that we are also engaging with the upcoming 5-year strategy so that the MHRA are also taking into account where the MHRA may also play their role within the global regulation of medicines.

4. Recommendation

4.1. The board are asked to note the steps taken toward delivering on our commitments with NICE as well as the next steps as we move to full launch in Q4 FY25/26.

Julian Beach
20/01/2026

Annex 1 – Key commitments for MHRA and NICE from UK Governments Regulatory Action Plan.

MHRA and NICE	Improve alignment between MHRA decision and NICE guidance publication - The MHRA and NICE will tackle information sharing and collaboration between technical experts to remove delays to patient access to medicines. This pilot will see the MHRA and NICE exploring the development of a joint process to provide a new offer to industry: concurrent marketing authorisation (from the MHRA) and technology appraisal (from NICE), enabled by enhanced data sharing and collaboration between technical teams, saving time and delivering further efficiencies intended to benefit industry and patients.
MHRA and NICE	Integrated pre-market scientific advice - Working in partnership, the MHRA and NICE will launch a fully ‘Integrated Scientific Advice’ service, accessed through a single point of entry. The new service will further establish the UK as a primary destination for clinical trials and investigations while ensuring translation of investigative medicines and medical devices to licensed products and quicker access to the healthcare system.

Medicines & Healthcare products Regulatory Agency

BOARD MEETING - HELD IN PUBLIC

20th Jan 2026

Title	Overview of the current status and progress of the pathway development for Rare Disease Therapies
Board Sponsor	Julian Beach
Purpose of Paper	Strategic Direction

Overview of the current status and progress of the pathway development for Rare Disease Therapies

1. Executive Summary

1.1. This paper proposes a flexible end to end UK regulatory pathway for rare disease therapies that:

- introduces a Designation step to triage candidates based on severity of disease, unmet need, prognosis, rarity and quantifiable barriers to standard development.
- operationalises the proportionate use of prior knowledge, platform definition.
- pilots an Investigational Marketing Authorisation (IMA) with staged entry, linked managed access and structured post-market evidence generation.
- describes work ongoing between MHRA, NICE/NHSE to further align and develop strategies in line with the Rare Therapies Action Plan.

The proposals consolidate deliberations from the three in-person Rare Diseases Workshops, two patient representative workshops and the working group meetings from a broad consortium with considerable patient engagement and support, led by MHRA autumn–winter 2025.

1.2. We recommend Board endorsement of the framework and timetable:

(i) complete outline guidance for review in February 2026 and for endorsement at Commission for Human Medicines (CHM) / Highly Personalised Expert Working Group in Q4 2025/2026.

(ii) consult publicly by Q2 2026.

(iii) run live case study pilots through 2026 with progressive guidance iterations.

(iv) Develop detailed guidance in each discipline area as needed through 2026

2. Introduction

2.1. Rare disease therapies often face small, scattered populations, heterogeneity, and limited natural history, making conventional trials - and standard marketing authorisation routes and requirements - inefficient or unfeasible. Industry feedback emphasises that regulatory processes do not enable development of products in the most efficient and effective manner including with off label or unlicensed use.

2.2. MHRA has signalled intent through the Business Plan for 2025/6, and the Rare Disease Therapies Position Paper from October 2025 to articulate a flexible development, licensing and manufacturing model, integrated early scientific advice, and recognition of prior knowledge and platforms to reduce burden without compromising patient safety. The provision of the Investigational Authorisation will be essential in enabling a process rather than a product to be authorised.

2.3. Considered Options:

A) Maintain status quo with options of Research under Clinical trial Authorisation (CTA), Marketing Authorisation (MA) (full, Early Access to Medicines Scheme (EAMS), and unlicensed): this option retains fragmentation and potential delays; has limited suitability for personalised therapies in terms of ongoing personalisation and doesn't alter significant development, manufacturing and inspection challenges with the current framework.

B) Conditional MA: enables controlled use but lacks investigational flexibility and currently platform reuse based on prior knowledge built on supportive investigations or products, in place of direct efficacy and safety evidence. Not appropriate where confirmatory clinical trials are not feasible. Same issues for personalised therapies above.

C) IMA model (recommended): single, flexible authorisation spanning investigation with reimbursement potential with lifecycle breaks, with planned scientific opinion potential giving product development oversight and clearer pathways to patient access.

3. Proposal

3.1. Conventional regulatory pathways assume large trials and validated endpoints, which are often unfeasible for rare diseases. While authorisations have been granted for rare diseases under exceptional circumstances, the length of time and costs incurred remain largely prohibitive

3.2. The proposed Rare Therapies Pathway is delivered through distinct process steps, which may include:

- Initial pathway entry and eligibility confirmation
- Early regulatory engagement
- Enabling process licencing of products which will be individualised in some manner
- Evidence-informed development checkpoints
- Assessment and decision-making activities
- Post-authorisation regulatory support

3.3. Not all steps would be mandatory for all products. Progression through the pathway would be dependent on evidence readiness and regulatory need. The level and timing of interaction would reflect the evidence requirements for each pathway stage and how best to achieve them.

3.4. Early stages may require comparatively limited data to support regulatory discussion, while later stages should be more developed enabling a clearer strategic regulatory direction and interaction. Applicants would be responsible for ensuring submissions meet the evidence expectations for the relevant step.

3.5. The IMA pathway is designed for therapies for traditionally described rare conditions with a prevalence of < 5 in 10,000 in the UK, where there are quantifiable barriers in conducting a 'standard' clinical development programme or 'standard' regulatory approval. The expectation is that the most significant benefit will be where patient numbers are significantly lower than the orphan limit.

3.6. The aim of a unified UK licensing category combining CTA and MA elements to support rare/innovative therapies is to accelerate and expand the licensure of medicines for the treatment of rare diseases.

3.7. In principle, the Rare Therapies Pathway proposes a technology-agnostic framework grounded in proportionality, patient-centred benefit–risk, and lifecycle oversight. It complements existing MHRA routes by integrating elements of CTA, Conditional MA, MA under exceptional circumstances, and EAMS principles within a single IMA construct that enables investigational, controlled therapeutic use, and progression to full authorisation as evidence matures, with the potential for reimbursement. The process retains ability to inspect or take regulatory, or inspection action through established routes.

3.7.1. The IMA model provides an organising licensing framework for rare therapies, with designation and early interaction to align evidence expectations.

3.7.2. Adopt staged scientific opinions across the lifecycle (designation, discovery, development, reimbursement, and post-authorisation review) to provide earlier regulatory certainty and reduce downstream rework.

3.7.3. The ability to licence a process with appropriate definition and control.

3.7.4. Formalise the application and provide clarity of the regulatory requirements of prior knowledge and platform approaches via Platform Definition and change process, aligned to ICH Q8–Q12, enabling comparability-based reuse across products.

3.7.5. Operationalise flexible, risk-appropriate evidence generation (adaptive designs, external controls, surrogate endpoints) with mandatory Real World Evidence generation plans and scalable, proportionate Good Clinical and Manufacturing Process oversight.

3.7.6. Establish post-authorisation surveillance and clinical monitoring tailored to rarity and personalisation, including pre-specified review points which could be time (e.g., 6–12 months then annually), or patient-number based. platform-wide signal management. This is expected to be specifically defined at point of regulatory interaction and can be technology, and product-based dependant on the criteria of prior knowledge and platform use.

3.8. The work ongoing is collaborative with patient voice built at the centre, and with system partners including NHS, DHSC, NICE closely involved and engagement with Devolved Administrations being informed of progress. The intent is to support driving cross-system alignment for rare therapies to link regulatory decisions with other critical points to enable access.

4. Impact of the guidance

4.1. The regulatory changes proposed by the rare pathway represent a material shift in the development paradigm, with the primary impact being a reduction in

development timelines through earlier regulatory engagement, flexible evidence requirements, and iterative or modular approvals across the product lifecycle. By enabling proportionate, risk-based decision-making and greater use of prior knowledge and real-world data, the MHRA framework has the potential to shorten the time from discovery to patient access, particularly for therapies targeting severity, patient prognosis and including high unmet need.

4.2. A secondary but significant effect is on development cost, as streamlined trials, smaller datasets, and earlier go/no-go decisions may reduce late-stage attrition and capital intensity, hence reducing cost of development. For start-up and early-stage companies, this can materially improve business models with earlier value inflection points.

4.3. A shift from traditional development pathways to the proposed rare disease pathway is expected to deliver a meaningful compression of timelines across the development lifecycle, with the greatest gains occurring in early clinical development and regulatory decision-making. Under conventional routes, rare disease programmes typically require 10–15 years from discovery to marketing authorisation, driven by sequential phase progression, long term evidence generation, and late regulatory interaction.

4.4. Under the new approach proposed by the MHRA, early scientific advice, pre-designation engagement, and modular or iterative approvals could reduce this to approximately 6–10 years, with some high unmet-need therapies potentially reaching initial patient access earlier.

4.5. Overall, the new pathway shifts time investment from a longer pre-authorisation period to where earlier access is enabled and further investigation is addressed post-authorisation through structured controlled evidence generation, with in-depth ongoing scrutiny.

5. Implementation Overview (Time, People, Financial)

5.1. The guidance is currently being developed with a broad stakeholder mix which is driving the development timetable. The components are as follows:

- Complete outline guidance by Q4 2025/2026 for endorsement at Commission for Human Medicines (CHM) / Highly Personalised Expert Working Group;
- Initiate consultation publicly in Q2 2026; and finalise guidance for 2027
- Run live case study pilots through 2026 with progressive guidance iterations.

5.2. People: Continue with the internal cross-functional core team (Science and Research, Healthcare, Quality and Access, Innovation and Compliance, Safety and Surveillance, Communications and Engagement, Partnerships) and the external patient, industry, system, and academic partners including Health Research Authority, with clear governance; to drive the delivery of the appropriate level of detailed policy.

5.3. Financial: It will be necessary to develop incremental fees aligned with each pathway step (entry, interactions, assessments, post-authorisation activities) as a

single end-to-end charge does not fit the proposed model. The detail of this will be completed as the guidance is finalised and workload becomes clearer. Forecasting of demand and resource requirements will be developed during 2026, leading to a rollout as guidance and legislative processes allow.

5.4. Legal Risk: Government Legal Department (GLD) have been kept abreast of this activity. Elements of proposals will require update of Human Medicines Regulations 2012. Consultation with GLD is planned and any legislative changes will be subject to Parliamentary approval.

6. Recommendation

6.1. The Board is asked to endorse the strategic direction of the Rare Diseases Pathway, the immediate next steps towards developing, and defining the IMA framework, guidance development and planned consultation.

6.2. Support the rollout of the principle of phases 1) implement, what can be implemented as without regulatory change 2) plan those changes requiring regulatory change and have a later implementation.

6.3. Fees, and resource modelling to ensure an efficient and effective rollout of this will be required during 2026.

Author : [redacted]
29 Dec 2025

Board Sponsor: Julian Beach
29 Dec 2025

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

20 January 2026

Title	Patient and Public Engagement Committee (PPEC) assurance to the Board
Board Sponsor	Mercy Jeyasingham
Purpose of Paper	Assurance

Patient and Public Engagement Committee (PPEC) assurance to the Board

1. Executive Summary

1.1. The Patient and Public Engagement Committee has met once, since the last update to the Board on 11 November 2025 (13 November 2025).

1.2. The Committee agreed the Terms of Reference, which has been amended following the refresh of the committees. This will be formally adopted by the Board at this meeting. The committee also considered initial thinking related to the People strategy, data usage and enhancements to the MHRA website.

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

People Strategy

2.1. The Committee received an update on early thinking for the 2026–2030 People elements of the MHRA2030 Strategy, noting progress made since 2023 in reducing vacancies and turnover and improving diversity. Members were asked for assurance on the proposed next steps and the approach to winding down the current strategy, including coordinated communications with the Engagement team. The discussion focused on ensuring the new strategy reflects staff survey feedback, and includes the emerging themes of building capability, strengthening leadership, and fostering a culture of openness, trust and empowerment. The Committee highlighted the need to understand the differing subcultures across the organisation, promote psychological safety, equip line managers effectively, and improve core processes such as recruitment and onboarding. It also reflected on the agency's evolving identity and the potential role of graduate schemes in supporting organisational development. The Committee will review the People Survey results at the February 2026 meeting.

Improving our Gov.uk website

2..3. The Committee received an update on the ongoing improvements to the MHRA's website, following the 2024 decision to remain on the GOV.UK domain and focus on enhancing clarity, accessibility and user experience. Recent work has included audits of the most-visited pages, creation of clearer content hubs, updated industry guidance and improved signposting to public resources, alongside a major navigation redesign planned for completion in April 2026. The Committee was assured on the current approach and discussed future public-facing priorities.

2.4. Lay members highlighted the need for clearer, more accessible language on patient-focused topics, and the team outlined their use of multiple feedback channels, including patient groups and plain-English specialists. The Committee also discussed opportunities to use AI tools to support content simplification and noted the growing importance of optimising content for AI-driven search behaviours.

Suggestions included exploring MHRA validation markers in search results to strengthen public trust. The Communications team confirmed that, while GOV.UK remains central, a broader communications and reputation plan to align with the Agency's new 5 year strategy will return to PPEC in 2026.

3. Conclusion

3.1. The Committee discussed early development of the People strand of the MHRA2030 strategy, emphasising the need to strengthen culture, leadership capability and staff experience, and agreed to review People Survey insights at a future meeting. The Committee also reviewed improvements to the MHRA presence on GOV.UK, supporting the focus on clearer, more accessible content and the evolving digital strategy, including adapting to AI-driven search behaviours. Overall, the Committee was supportive of the direction of all work areas and encouraged continued engagement and refinement.

Mercy Jeyasingham
Chair Patient and People Engagement Committee
Non-Executive Director MHRA
January 2026

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

20 January 2026

Title	Regulation and Safety Committee (RSC) assurance to the Board
Board Sponsor	Paul Goldsmith
Purpose of Paper	Assurance

Regulation and Safety Committee (RSC) assurance to the Board

1. Executive Summary

1.1. The Regulation and Safety Committee has met twice, since the last update to the Board on 11 November 2025 (20 November and 6 January).

1.2. The Committee considered a range of strategic issues relating to the Agency's regulatory role, external positioning, and future direction and strategy, and conducted a workshop, with external guests, to consider the concept of a risk proportionate regulatory framework.

1.3. The Committee discussed opportunities arising from the cross-government Exercise Pegasus to strengthen MHRA's profile and increase awareness of the work taking place at the Science Campus.

2. Meeting in November 2025

1.1. The committee met on 11 November and discussed the following topics:

Platform Technologies

1.2. The Committee discussed developments in rare disease and platform technology regulation, informed by recent engagement at the Rare Disease Consortium. Challenges around reimbursement were recognised and the Committee noted the emerging potential of value-based payment models and agreed that platform technologies represent a significant opportunity for the MHRA to demonstrate global thought leadership, provided that any associated regulatory flexibilities are underpinned by clear guardrails.

AI Commission

1.3. The Committee received an update on the work of the AI Commission. Discussions focused on product assurance, developer accountability and deployment-specific oversight. Two forms of oversight were noted, post market surveillance and local post deployment monitoring to ensure models perform as intended.

1.4. Members highlighted challenges associated with agentic AI, liability, and the aggregation of bias, and noted emerging areas such as AI-designed molecules. The Committee emphasised the importance of ensuring that accountability extends beyond the technology itself and includes the developers and deployers. Sensitivity versus specificity was discussed as well as opportunities for data collection.

Medical Devices Strategy

2..4. The Committee also considered the emerging Medical Devices Strategy, which will support innovation, and help to position the UK as a first-in-market jurisdiction. The committee stressed the need for robust safety monitoring and appropriate internal expertise. Regulation and Safety Committee will continue to monitor the Medical Devices Strategy development alongside the wider MHRA2030 strategy.

Subconscious reactions to terminology in relation to the developing strategy

2.5. The Committee discussed the importance of considering terminology in the developing strategy. It noted that phrases such as “risk-proportionate regulation” could be open to misinterpretation, and highlighted the importance of clear, accessible language that emphasises patient benefit. The Committee noted forthcoming Board sessions to refine the strategy, alongside engagement with Communications and Engagements colleagues and the People and Public Engagement Committee.

3. Workshop in January 2026

3.1. A workshop was held by the Regulation and Safety Committee on 6 January 2026, bringing together internal MHRA subject matter experts as well as a variety of external expert guests to further develop the concept and detail of a risk proportionate regulatory framework for the MHRA. The aim of the framework is to enable consistency of risk benefit decision making and increase transparency. In turn it is hoped that this will enable patients and their health care providers to make decisions that are right for them, in their individual circumstances.

3.2. The objectives of the workshop were to:

- Share the importance of and the opportunities that this work will bring to the agency.
- Understand the work that is already taking place within the Agency and how these decisions are currently made.
- Discuss what an MHRA framework should include
- Discuss how each dimension of risk impacts decision making
- Advise how we consider devices and diagnostics in this work

3.3. The workshop was successful, with next steps being to articulate this in a written plan, supported by academic risk experts, to be brought to the main board later this year.

4. Conclusion

4.1. The Regulation and Safety Committee continues to provide robust oversight and strategic input on matters critical to the Agency’s regulatory role and future direction. Recent discussions have reinforced the importance of positioning MHRA as a global leader in innovation, underpinned by clear governance and patient-focused principles. The Committee’s work on platform technologies, AI assurance, and the emerging Medical Devices Strategy reflects a commitment to enabling innovation while safeguarding public health.

4.2 The successful January workshop marks a significant step toward developing a risk-proportionate regulatory framework that will enhance transparency and consistency in decision-making. The Committee will maintain close engagement on these priorities and report further progress to the Board later this year.

4.3 The next meeting of the RSC will be on 19 February 2026.

Paul Goldsmith
Chair Regulation and Safety Committee
Non-Executive Director MHRA
7 January 2026