Medicines & Healthcare products Regulatory Agency

Public Pack - 0726 Board Meeting Held in Public

MEETING

7 July 2026 10:00 BST

PUBLISHED

3 July 2026

MHRA Board Attendee List – 7 July 2026

	Name	Role	Board held in public	Board Seminar
Board Members				
1.	Prof Anthony Harnden	Chair	Y	Y
2.	Lawrence Tallon	CEO	Y	Y
3.	Dr Junaid Bajwa	Non-Executive Director	Y	N
4.	Julian Beach	Interim Director, Healthcare Quality & Access	Y	Y
5.	Jason Bonander	Chief Digital & Technology Officer	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.	Prof Jacob George	Chief Scientific & Medical Officer	Y	Y
10.	Dr Paul Goldsmith	Non-Executive Director	Y	Y
11.	Mercy Jeyasingham	Non-Executive Director	Y	Y
12.	Raj Long	Non-Executive Director	Y	Y
13.	Michael Whitehouse	Non-Executive Director	Y	Y
Regular Attendees				
14.	Vicky Dare	Deputy Director - Medicines Regulation & Prescribing, DHSC	Y	Y
15.	Tasneem Blondin	Chief People Officer, MHRA	Y	Y
16.	Rachel Bosworth	Director of Communications & Engagement, MHRA	Y	Y
17.	Sarah Gilbert	Company Secretary, MHRA	Y	Y
Other Attendees				
18.	Rebecca Jennings	Deputy Director, MHRA, Medicines and Pharmacy Team, GLD	Y	N

19.	Dr Ed Middleton	Director of Strategy, MHRA	Y	Y
20.	Andy Morling	Deputy Director, Criminal Enforcement Unit	Y *(item 6 only)*	N
21.	Dr Nicola Rose	Interim Executive Director, Science & Research	N	Y *(item 2 only)*
22.	Marie Donatantonio	Deputy Director Health & Safety and Quality Assurance	N	Y *(item 2 only)*
23.	‘Alani Vailahi	Private Secretary, MHRA	Y	Y

Apologies

1.	Dr Junaid Bajwa	Non-Executive Director, MHRA Board	Board Seminar

Agenda

Location	Date	Time
10SC	7 Jul 2026	10:00 BST

	Item	Purpose	Owner	Page
	INTRODUCTION			-
1	Chair updates			-
1.1	New Board Member: Jason Bonander (Chief Data & Technology Officer)	Information	Jason Bonander	-
1.2	Declarations of Interest	Information	Chair	5
1.3	Minutes and actions (January Board held in public)	Approval	Chair	8
1.4	Board Schedule	Approval	Chair	15
	AGENCY PERFORMANCE			-
2	CEO's report – current activities and priorities	Context	CEO	17
3	MHRA finance, operational & people performance report	Assurance	Rose Braithwaite	25
	ASSURANCE			-
4	Audit and Risk Assurance Committee assurance report	Assurance	Michael Whitehouse	39
5	MHRA Annual Report 2025-26	Approval	Sarah Gilbert	48
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6	Criminal Enforcement Unit	Information	Dr Alison Cave / Andy Morling	51
	EXTERNAL PERSPECTIVE			-
7	Questions from members of the public on the items on this Board meeting agenda		Rachel Bosworth	-
	CLOSE OF MEETING		Chair	-

MHRA Board Declarations of Interest – July 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
	Director of Morland House HealthCare Ltd	Director	No	No (Exp. 03/2026)
	Director Nutriberry Ltd	Director	No	No (Exp. 03/2026)
Lawrence Tallon Chief Executive	Football Health Alliance Cc Interest Company	Director	No	Yes
	PharosAI (publicly funded, not for profit capacity building initiative)	External Advisory Board member	No	Yes
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
	Flagship Pioneering	Senior Partner	Yes	Yes
Julian Beach	None	N/A	N/A	N/A

Name and MHRA Role	Name of Other Company or Organisation	Nature of interest	Paid	Current / Date expired
Interim Executive Director, Healthcare Quality & Access				
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
	30 Technology Ltd	Consultant/Advisor	Yes	Yes
Professor Jacob George Chief Medical and Scientific Officer	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
	Institute of Global Health Innovation (IGHI), Imperial College, London	Visiting Professor	No	Yes
	NHS	Consultant Neurologist	Yes	Yes
	NHS	Clinical Senate Member	No	Yes
	Closed Loop Medicine	Director	No	Yes
	Clinical advisory support to BRPD Therapeutics	Consultant	Yes	Yes

Name and MHRA Role	Name of Other Company or Organisation	Nature of interest	Paid	Current / Date expired
	Limited - migraine potential products			
	Radix Big Tent Foundation	Trustee	No	Yes
Mercy Jeyasingham MBE Non-Executive Director	NHS Blood and Transplant	Panel Member (to appoint two NEDs to their Board)	Yes	Yes (Exp. 04/2026)
	Royal College of Speech and Language Therapists	Executive Coaching	Yes	Yes
Raj Long Non-Executive Director	Bristol-Myers Squibb	Ex-Employee Shareholder	Yes	Yes
	Novartis	Ex-Employee Shareholder	Yes	Yes
	Gates Venture – EC Innovative Medicines Initiative (IMI) Non-Product – IMI European platform for Neurodegenerative Disorders	Advisory	Yes	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
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 MHRA BOARD MEETING HELD IN PUBLIC

14:00 – 16:00 Tuesday 20 January 2026
10SC Round Room

Chair: Professor Anthony Harnden

MHRA Board members present

Professor Anthony Harnden	Chair
Lawrence Tallon	Chief Executive
Dr Paul Goldsmith	Non-Executive Director
Mercy Jeyasingham	Non-Executive Director
Michael Whitehouse	Non-Executive Director
Professor Graham Cooke	Non-Executive Director
Raj Long	Non-Executive Director
Professor Jacob George	Chief Medical and Scientific Officer
Dr Alison Cave	Chief Safety Officer
Julian Beach	Interim Executive Director, Healthcare Quality & Access
Rose Braithwaite	Chief Finance Officer

Regular MHRA Board attendees

Tasneem Blondin	Chief People Officer
Rachel Bosworth	Director of Communications and Engagement
Sarah Gilbert	Company Secretary
Victoria Dare	Deputy Director, Medicines Regulation and Prescribing, DHSC
‘Alani Vailahi	Private Secretary

Other MHRA attendees

Erika Warner	Events Lead
Professor Henrietta Hughes	Patient Safety Commissioner (for item 4)
Stephen Maddocks	Head of Pre-Submission Advice Support (for item 5)

Apologies

Junaid Bajwa	Non-Executive Director

1. Board administration

1.1. The Chair opened the meeting and welcomed Board members, attendees and observers, noting apologies. It was confirmed that, as an advisory body, the Board does not take regulatory decisions on medicines or medical devices, as these are made by executive officials within the organisation. The Chair also reminded attendees that the meeting was being held in public rather than constituted as a public meeting, and that a recording would be published

Declarations of interest

1.2. No new declarations of interest were made and there are no previously declared declarations related to items on the agenda.

Minutes of July MHRA Board meeting held in public

1.3. Minutes of the July MHRA Board meeting, held in public, were approved and all actions from that meeting were confirmed to have been completed and closed.

Board Terms of Reference

1.4. The Board approved the amended Board Terms of Reference, noting that only minor changes had been made to the previous version.

Board Assurance Committees Terms of Reference

1.5. Updated Terms of Reference for the three assurance committees were approved following their annual review: the Audit and Risk Assurance Committee, the Regulation and Safety Committee, and the People and Public Engagement Committee.

Board Schedule

1.6. The Board reviewed future meeting dates and agreed to bring forward the July 2026 Board meeting to 7 July 2026 to support the approval of the annual accounts ahead of the parliamentary recess. The September meeting will be held in Scotland and will move to 21–22 September to facilitate attendance. The Board meeting in March will be held at the Science Campus.

1.7. Work to strengthen joint engagement with the National Institute for Health and Care Excellence (NICE) is continuing. A workshop has been arranged for April for both Non-Executive and Executive members, followed by a joint half-day Board meeting planned for the autumn. Dates for these sessions will be confirmed shortly.

2. CEO Report – current activities and priorities

2.1. An update was provided on recent leadership changes, including the appointment of a new Chief Medical and Scientific Officer and ongoing recruitment for a Chief Digital and Technology Officer. Formal thanks were recorded to those who have covered interim responsibilities.

2.2. The annual people survey showed a significant improvement in staff engagement, which has indicated a positive shift in overall sentiment. Work has commenced to address the themes identified, supported by benchmarking with the results of other arm’s-length bodies.

2.3. Staff recognition initiatives, including the introduction of an agency-wide awards programme, were highlighted as an important contributor to strengthening organisational culture and have been well received by colleagues. Thanks were recorded to the judging panel and to those who submitted nominations, with recognition of the large number of deserving nominees. Congratulations were extended to all staff who were nominated.

2.4. Strong operational performance was reported across core regulatory functions, with statutory targets consistently met. Work continues to enhance the scientific advice service, which is not subject to statutory targets but remains a priority for improvement, and strong progress is being seen. Clinical trials performance targets are consistently met, with an ambition to go beyond the statutory targets through introduction in April of a 14-day turnaround time for initial reviews and a new notification route for low-risk studies to support faster trial start-up times.

2.5. The agency continues to respond effectively to criminal threats involving illicit products and remains focused on staying ahead of emerging risks. Recent engagement activity included a successful public campaign on the safe use of medicines over the festive period. There have been a number of publications in high-profile journals, several successful grant awards, and ongoing collaboration with external research partners.

2.6. Ongoing partnership activity was highlighted across several areas. The annual meeting of the Centres of Excellence for Regulatory Science and Innovation (CERSI) focused on developing a sustainable model for future collaboration.

2.7. An open call for evidence from the national commission on AI is underway, inviting contributions from patients, the public and developers on the regulation of AI in medical devices.

2.8. Work also continues on national data initiatives, including collaboration with Health Data Research Service (HDRS) to curate UK longitudinal data to strengthen safety surveillance.

2.9. The MHRA has assumed the role of Chair of the Access Consortium for the year ahead, providing an opportunity to deepen collaboration with international regulators and strengthen joint approaches to innovation and clinical trial development. Discussions are also progressing on extending collaborative arrangements with international counterparts, with a shared ambition to advance collective work across the five participating agencies.

2.10. The Board welcomed the continued progress being made across the organisation and recognised the positive momentum in its development. The improvement in staff engagement was noted with appreciation, reflecting a broader sense that the agency is moving into a stronger and more confident position.

3. Finance, operational and people performance report

3.1. Income continued to exceed budget during November, with trading income around five per cent above forecast. Year-to-date underspend remains under review, and the forecast indicates this is expected to narrow as the year progresses. Expenditure patterns have been more variable than in previous years, including the impact of the difficult but responsible decision to close a digital technology programme. Work is underway with external advisers and the DHSC as our sponsor

department to determine the appropriate treatment of associated costs, to maximise any reusable elements and to consider future financial planning. Interim external audit work will begin in early February.

3.2. Progress continues in strengthening recruitment processes, with improvements in diversity representation and ongoing investment in leadership development, including the roll-out of 360-degree feedback for senior staff. The graduate scheme remains successful, with positive feedback from participants. A Non-Executive Director noted the number of FTEs appointed via exceptions. People team advised that exceptions are overseen by the Civil Service Commission, who are working with to ensure we remain compliant.

4. Patient Safety Commissioner

4.1. The Board welcomed the Patient Safety Commissioner, Professor Henrietta Hughes who provided an update on her role and priorities. The Patient Safety Commissioner role is now hosted by the MHRA, following recommendations from the Review of patient safety across the health and care landscape by Dr Penny Dash in 2025.

4.2. Priorities for the role in the coming months include strengthening patient involvement, improving the clarity and accessibility of medicines information, and contributing to national discussions on the regulation of AI in medical devices. The Patient Safety Commissioner acts as deputy chair of the National Commission into the Regulation of AI in Healthcare. The Commissioner expressed a desire to deepen her understanding of the MHRA's functions and to identify further opportunities to bring diverse patient perspectives into decision-making, recognising that some voices are less often heard.

4.3. When asked what good looks like for patient safety, the Commissioner described an ambition to ensure that patients and service users are involved from the earliest stages of development through to the use and understanding of their medicines. She emphasised the importance of improving every aspect of medicines safety, fostering collaborative working across the health and care system, and bringing people together to shape better outcomes. Good, she noted, would mean an aligned quality management approach across the system that supports improved patient outcomes, better experiences, and reduced harm.

4.4. Board members welcome the opportunity that hosting the Patient Safety Commissioner provides, noting the value of having an independent voice acting as a constructive critical friend to the organisation. When asked how differing views would be handled, the Commissioner emphasised that independence enables her to seek understanding, identify where long-standing practices may need to evolve, and make recommendations where appropriate. She noted that an external perspective can surface issues that may have become normalised, allowing the organisation to consider alternative approaches and future-focused improvements. The independence of the role is fundamental and is well understood by the MHRA and safeguarded.

5. An overview of the alignment of processes between MHRA and NICE

5.1. An update was provided on the programme of work to align regulatory processes with those of NICE. This collaboration aims to streamline scientific advice, reduce administrative burden for developers, and support faster access to innovative medicines and medical devices. Work began in March 2025 under joint commitments made in the government's regulatory action plan, to align the timing of health technology approvals and reduce the time to patient access for new medicines.

5.2. Progress includes the development of an integrated scientific advice service with a single point of entry, with launch planned in the coming months. Alongside this there is ongoing engagement with health partners across the devolved administrations to enable alignment. Further improvements in development include the introduction of a new advice portal and refinements to communications and technical guidance, with continued focus on ensuring equitable access for patients.

5.3. Board members discussed the scope of ambition, including strengthening capacity within the advice service, ensuring consistent delivery, and improving early engagement with innovators so that regulatory and assessment needs are addressed from the outset. It was noted that closer alignment between regulatory and health technology assessment processes presents opportunities but also challenges, particularly in integrating requirements early in clinical development.

5.4. Ongoing work with industry, including pilots and user research, is helping to identify where joint or sequenced approaches may add value. The importance of continuing to build on international experience, expand the evidence base, and integrate learning from existing initiatives was highlighted.

5.5. Overall, Board members were supportive of the strategic direction and acknowledged the important role this work will play in shaping the organisation's future strategy. The Board highlighted the importance of clear communication of the process to give confidence in our approach.

6. Rare disease therapies

6.1. An update was provided on the development of a new pathway for rare disease therapies. The approach aims to enable earlier and more flexible development of treatments for rare diseases, which often affect small and dispersed patient populations. The approach is centred around risk-proportionate regulation and will include the introduction of a designation step for eligible therapies, and the use of prior knowledge and platform approaches to support progression through development and regulatory assessment. The programme is also exploring an investigational market authorisation model to enable staged entry points, with consideration of a process licence tailored to different diseases or patient groups. This work seeks to facilitate the regulatory pathway while maintaining a clear focus on patient safety and treatment efficacy.

6.2. Work is under way to consider how this approach could link to reimbursement frameworks so that regulatory innovation translates into timely patient access. Close alignment with NICE and the NHS, including the rare diseases action plan, is being pursued to ensure system readiness and clarity for developers and patients. Draft guidance is expected later in the year, followed by public consultation and piloting to test and refine the model.

6.3. Discussion recognised the particular challenges for rare conditions, such as small cohorts, ethical considerations in trial design, and the need for proportionate evidence generation, and highlighted the opportunity to strengthen links with diagnostics (including genomics) to shorten time to diagnosis and better target clinical development. Plans include a clinical monitoring plan and robust post-market safety surveillance capable of operating across international boundaries, supported by collaboration with domestic and international partners. Members noted that clear communication of scope and expectations, integration with related innovation work, and ongoing international collaboration will be important to sustain momentum.

6.4. Developing effective pathways for rare diseases therefore represents a significant shift in regulatory practice. The UK's strengths in cell and gene therapy provide a strong foundation to lead in this area, with the potential to support life-changing and, in some cases, life-saving treatments. While some therapies may be costly, the right regulatory approach can reduce development costs and encourage innovation. Early engagement with international partners and the wider rare disease community has been positive, and there is strong confidence in the direction of travel.

6.5. The Board emphasised the importance of maintaining momentum, leveraging existing procedures, and ensuring that this work is effectively connected with other innovation programmes across the system. The Board expressed their full support for this activity.

7. Board Assurance Committee assurance reports

People and Public Engagement Committee (PPEC)

7.1. The PPEC provided assurance to the Board on its work to enhance the organisation's public-facing information, including improvements to the MHRA website to support greater accessibility and transparency, with a further update expected in May. The contributions of lay members were noted as adding valuable perspective, and the committee has held constructive discussions on how best to improve the accessibility of information to strengthen transparency.

7.2. The committee is working to support development of the people elements of the future strategy, with plans to examine the annual people survey in greater depth to ensure the themes are fully reflected in the new strategic approach.

7.3. A review of progress against the current people strategy indicated strong strides have been made, and highlighted areas where further focus will help shape priorities for the new MHRA 2030 strategy.

Regulation and Safety Committee (R&SC)

7.4. The R&SC provided an update on the committee's work to support the development of the MHRA2030 strategy, with two focus areas. Codifying best practise to enable the measurement of performance and ensuring better understanding of the efficacy and effectiveness of medicinal products and their performance in the real world.

7.5. The R&SC held a workshop on risk proportionality, attended by stakeholders from the wider health ecosystem, helping to develop greater understanding of what risk proportionality means to different stakeholders and inform the application of the principles in future regulatory approaches.

7.6. Thanks were recorded to the PPEC and R&SC committee chairs for their support, challenge and objectivity, and for their leadership in taking forward these important areas of work.

8. Questions from members of the public on agenda items

8.1. Two pre-submitted questions were received, related to the items on the agenda, which were answered in the meeting. Seven other questions were raised which were not related to agenda items and these will receive responses by correspondence.

8.2. A question was raised on the rare therapies paper regarding the perceived role of the British Pharmacopeia within the strategy for the rare disease pathway. It was explained that work is still under development, but evolving guidance is being considered. The British Pharmacopeia provides science-based quality standards that enable innovation, support global harmonisation, and facilitate development. The inclusion of additional general chapters is being explored to ensure that appropriate standards are set for different technology types.

8.3. A question was raised on whether the current UK master file system might be expanded to include regulatory dossiers for rare therapeutics. It was explained that the principles of the system will be used where appropriate, although it may not be as applicable to some aspects of the rare therapies pathway. However, the principles are translatable, and comments on this proposal are welcomed as part of the public consultation.

8.4. A question was raised via the Q&A function relating to the clinical trials item in the CEO report. It sought clarification on the commitment to restore a 14-day timeline for the initial review of Phase 1 clinical trials asking whether this would be place by the end of 2026. The MHRA confirmed that this commitment has been made.

Action: Questions received which have not received a response during the meeting are to receive answers via correspondence.

9. Closing remarks

9.1. The Chair thanked all Board members and attendees for their contributions to a constructive and informative meeting. He also thanked members of the public for their interest in the work of the agency and reaffirmed the MHRA commitment to protecting patients and supporting the health and care system.

Actions arising

Action	Responsible
Questions received which have not received a response during the meeting are to receive answers via correspondence.	Sarah Gilbert (Company Secretary)

MHRA Board Schedule of Business – July 2026 to November 2027

	7 July 2026 10SC	21-22 September 2026 Glasgow, Scotland	15 October 2026 NICE Headquarters	10 November 2026 Science Campus
	Board in Public	**Board**	**Joint Board**	**Board**
Context	CEO report	CEO report	MHRA-NICE Board (Board only)	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		Science Plan Devolved administration engagement update Digital System update on next steps *(TBC)*		
Assurance	ARAC Assurance Report	RSC report PPEC report		ARAC Report
Governance	MHRA Annual Report and Accounts 2025/26			Health & Safety Board training (high level)
	Board Seminar	**Board Seminar**		**Board Seminar**
Strategic Development	Health & Safety annual report Strategy launch update Operation Pegasus Report Security Classification Use Policy	Update on delivery of the 5 Year Strategy Healthcare data usage		Update on delivery of the 5 Year Strategy ESG - Environment, Sustainability, Governance *(TBC)* Science Campus engagement and science presentations
Annex for CEO Report	Health Inequalities	Strategic workforce plan		
Board Development	Board Schedule	Board Schedule		Board Schedule

Proposed Board Schedule 2027	
Tuesday 19 January 2027	Held in public at 10SC
Tuesday 16 March 2027	South Mimms
Tuesday 18 May & Wednesday 19 May 2027	Belfast, Northern Ireland
Tuesday 8 June 2027	Away Day
Tuesday 6 July 2027	Held in public at 10SC
Tuesday 21 September & Wednesday 22 September 2027	Edinburgh, Scotland
Tuesday 16 November 2027	10SC

OFFICIAL SENSITIVE

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

Tuesday 7 July 2026

Title	CEO Board Report
Board Sponsor	Lawrence Tallon
Purpose of Paper	Context

OFFICIAL SENSITIVE

CHIEF EXECUTIVE'S REPORT TO THE BOARD – JULY 2026

Introduction

1. As we reach the end of the first quarter of this financial year, I am pleased to set out my July Board report.

2. Since my last report, we have made meaningful progress in key areas which have served to strengthen the Agency's impact on the public and our national and international reputation, including a new framework for the regulation of Rare Disease Therapies and deeper engagement with Northern Ireland, Scotland and Wales to strengthen UK-wide collaboration.

3. As ever, this has been made possible through great efforts from our dedicated colleagues, supported by our Board's leadership and our many partners and stakeholders.

4. The next quarter of this year will also see a significant programme of activity, including launching the MHRA Strategy to 2030, laying our Annual Report to Parliament for 2025/26 and publishing the report of the National Commission on the Regulation of AI in Healthcare, and the Agency's response.

5. In the past couple of months, we have welcomed new ministers at the Department of Health and Social Care. James Murray MP was appointed Secretary of State for Health and Social Care and Preet Kaur Gill MP as Parliamentary Under-Secretary of State for Health Innovation and Safety, with responsibility for the MHRA. The Chair and I met with Minister Gill in June.

6. Within the Agency, we continue to see colleagues acknowledged for their commitment to public services. I would like to take this opportunity to congratulate Dr Nicola Rose for being recognised in the 2026 King's Birthday Honours. Nicola has been appointed an OBE for services to science and public health. Two other colleagues, one from our Science Campus and one from our Inspectorate, were honoured to attend Royal Garden Parties in May in recognition of their contribution to their public service for the Agency.

7. We recently welcomed Jason Bonander as our new Chief Digital and Technology Officer (CDTO). Jason will bring great expertise and experience from his leadership roles at the US Centres for Disease Control and Prevention (CDC).

8. I would also like to give my huge thanks to Rose Braithwaite, our Chief Financial Officer, who will be moving to the role of Executive Director of Finance and Commercial at the Royal College of Obstetricians and Gynaecologists this month. She has navigated significant challenges in recent years, and her leadership has put the Agency back on a stable financial footing. We wish her all the best for her exciting new role at the Royal College.

Key developments

9. The MHRA has now concluded its scientific dialogue with the trial sponsor on the PATHWAYS clinical trial and a modified protocol has been agreed as meeting the required regulatory standards. We sought the advice of independent experts from the Commission on Human Medicines on participant safety and the adequacy of proposed strengthened safeguards. I would like to thank colleagues across MHRA and our legal advisors for the care and diligence with which they have handled this complex and sensitive clinical trial, ensuring participant safety will be safeguarded.

10. In late May, we launched our public consultation on a new rare disease therapies regulatory framework. A central tenet of this framework is the proposal to develop a new 'Investigational Marketing Authorisation', which would combine clinical trial approval with market authorisation, meaning patients gaining access to innovative treatments more quickly and still safely. The consultation closes on 30 July.

11. The Agency will soon launch the MHRA 2030 Strategy, marking a significant milestone for the organisation in setting out our ambitious goals for the next five years. The strategy development process has involved staff across the Agency and has benefited from input from many partner organisations. I look forward to reporting on strategy implementation to Board in the coming months.

12. The Agency supported the work on supplying treatments for Hantavirus and worked with international partners in our response. Immediate priorities focused on resolving regulatory processes, addressing emerging treatment demands and maintaining safe patient discharge pathways.

AI and med tech

13. The Agency continues to make strides on AI and med tech. We are currently inviting views on proposed changes to medical device regulations, namely new pre-market regulatory requirements for medical devices and in vitro diagnostic devices entering the GB market. The notification provides an opportunity for World Trade Organisation members to comment on the draft pre-market regulatory requirements. The MedTech industry, approved bodies, healthcare providers and patients are also invited to share their views on the impact of the proposed changes via an MHRA survey.

14. We launched a pioneering London AI sandbox, known as London Region I, which will create a monitored space to safely test AI-enabled medical devices. This will support delivery of the NHS 10 Year Health Plan by enabling faster adoption of technologies that improve patient outcomes.

15. Ahead of the formal report of the National Commission on the Regulation of AI in Healthcare in the autumn, we published two reports setting out the findings of the extensive programme of engagement carried out to inform future rules on how AI can be used safely in healthcare. The Research and Engagement report sets out how AI is currently perceived, used and governed across the UK health system and the Call for Evidence findings bring together the

voices of 760 people and institutions. The level of engagement from the public and organisations highlights the importance of this work.

16. The research and engagement activities showed there is broad recognition of the potential for AI to improve outcomes and support healthcare delivery. However, support for its use depends on how AI is used in practice and the level of risk involved. A key finding was that current regulatory approaches are not well matched to systems whose behaviours may vary across contexts. The reports do not set out policy recommendations but will form the evidence base that will inform the Commission's forthcoming recommendations.

17. We also recently announced a new regulatory sandbox funded by the Regulatory Innovation Office to explore how AI tools can be used to predict how medicines behave in the body. Researchers and companies will be able to work within a controlled testing environment to better understand medicines safety and predict potential side effects, and how they could be used to accelerate the development of the next generation of medicines, especially in areas of unmet need.

Partnerships and external affairs

18. June saw considerable, positive parliamentary engagement. Early in the month, our Chief Safety Officer Alison Cave and I had a constructive meeting with members of the Health and Social Care Committee to discuss a range of topics across safety and surveillance, including Diethylstilbestrol (DES), Poly Implant Prothèse (PIP) implants and dopamine agonists. We were pleased to hear that the Committee was supportive of the work of our Criminal Enforcement Unit. The Agency also appeared at the Lords Childhood Vaccination Rates Committee, and the Lords Science and Technology Committee to give evidence on innovation in the NHS.

19. Turning to the international stage, MHRA colleagues, the Chair and I attended the Drug Information Association (DIA) Global conference in Philadelphia in June. The week was a fantastic opportunity to showcase how MHRA is contributing to global conversations on the future of medicines regulation and patient access. Both the Access Consortium and MHRA Town Hall events were well attended and garnered interest from colleagues around the world, which will strengthen existing relationships and present opportunities for new partnerships.

20. At DIA Global, the FDA Deputy Commissioner, Grace Graham, and I announced the MHRA-FDA liaison programme, a notable milestone in the US-UK regulatory relationship, which will improve communication, streamline collaboration and deepen cooperation.

21. We also look forward to the first DIA-MHRA Global Summit, which we are co-hosting as part of London Life Sciences Week in November 2026.

22. I joined the Minister for Health Innovation and Safety, Preet Kaur Gill, and other senior colleagues as part of the UK delegation to the BIO International Convention in San Diego, California, last month. This included taking part in a discussion with the Minister and

BioIndustry Association (BIA) Chief Executive Prof Chris Molloy, on the importance of faster clinical trial set-up, supporting innovative SMEs and strengthening the UK's position as a global destination for life sciences. This was another excellent opportunity to promote the UK's strengths in life sciences and our role as a fast and enabling regulator.

23. I was also honoured to be a guest speaker at the '2026 Global Healthcare Grand Rounds by Cedars-Sinai International' while in the US, where I spoke about how global trends in science, technology and geopolitics are reshaping healthcare regulation.

24. MHRA colleagues joined experts at HLTH Inc. Europe to discuss the challenges of navigating rapidly evolving expectations around AI, data and innovation in healthcare. It was clear that robust post-market surveillance and a whole-system approach to assurance would be critical.

25. Since our last Board meeting, we have continued to move from strength to strength on embedding closer working relations across the Devolved Administrations and with international partners.

26. Our May Board meeting in Cardiff helped to maintain momentum on our shared priorities in health, medtech and surveillance infrastructure. I also visited the Life Sciences Hub in Wales to meet with senior officials to discuss in more detail how we can maximise our liaison work programme in Wales.

27. The Agency recently announced a new programme of liaison days in Wales and an MHRA hub in Northern Ireland which aim to strengthen collaboration through direct engagement with our colleagues. We are currently in the process of finalising arrangements in Scotland.

Clinical trials and licensing

28. Since 1 May, the MHRA has licensed the following new products, as well as seven new/extension indications:

    a. **DAWNZERA:** Indicated for routine prevention of recurrent attacks of hereditary angioedema (HAE) in adults and adolescents aged 12 years and older.
    b. **REZDIFFRA:** Indicated in conjunction with diet and exercise for the treatment of adults with noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH) with moderate to advanced liver fibrosis (consistent with fibrosis stages F2 to F3).
    c. **VYJUVEK:** Indicated for the treatment of wounds in patients with dystrophic epidermolysis bullosa (DEB) with mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene, from birth.
    d. **WAYRILZ:** Indicated for the treatment of immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments

29. We continue to play a key role in the authorisation and monitoring of GLP-1s, with the approval of the first GLP-1 tablet for weight loss in the UK. Whilst this tablet is approved for use in the UK, it is not available currently via the NHS. As with all new treatments, decisions on NHS use will follow established processes, including an evaluation by NICE.

30. The Agency and NICE have launched the next phase of the Real-World Evidence Scientific Dialogue, following a successful pilot in 2025. This provides pre-competitive, "safe-harbour" workshops bringing together developers of medicines and medical devices with regulators and health technology assessment (HTA) bodies to discuss real-world evidence generation, including study design, data sources and analytical approaches.

31. We are also approaching the first anniversary of the Life Sciences Sector Plan and the Office for Life Sciences will shortly publish its 'Year One Update'. MHRA remains central to delivering these ambitions, particularly around reducing unwarranted barriers to market entry. We continue to work with partners and across Government on this important work.

Safety and enforcement

32. The Agency has taken a number of significant actions recently to communicate widely with the public about the safety of medicines and medical devices.

33. In May, we issued a Drug Safety Update (DSU) on Finasteride and Dutasteride regarding psychiatric side effects and sexual dysfunction. The strengthened and additional warnings in the updated product information will provide clearer guidance on these adverse reactions for healthcare professionals and patients, helping to minimise the associated risk. In June, we issued a DSU on ACE-inhibitors to raise awareness of the risk of the uncommon or rare side effect of angioedema and provide advice to healthcare professionals.

34. The Agency issued several Device Safety Information documents to inform healthcare professionals about potential risks associated with specific devices and outline necessary actions to mitigate these risks. This included a DSI intended to reduce the risk of complications associated with the use of Allurion Gastric Balloons.

35. We issued advice on using medicines and medical devices safely during hot weather, including how to store medicines and medical devices, reducing the risk of dehydration when taking certain medicines and reducing the risk of sunburn when using some common medicines. This gained substantial media and social media attention.

36. Users of the Yellow Card scheme can now log in with their NHS account. This will allow more than 41 million NHS account holders to access their Yellow Card reports using credentials they already have for NHS services, making reporting of adverse events a more seamless experience.

37. A CPRD competition recently closed for a free 12-month CPRD licence to stimulate research that addresses key regulatory questions in strategic areas of proactive pharmacovigilance, underserved populations, safety of medical devices, effectiveness and

safety of medicines in real populations, and children and pregnant women. Twenty-six expressions of interest were received and are currently being evaluated.

38. In the largest ever seizure of unlicensed weight loss medicines ever made by the MHRA to date, the Criminal Enforcement Unit arrested two people after raiding a country estate near Northampton. Supported by Northamptonshire Police, the operation resulted in the seizure of around 12,000 doses of unlicensed weight loss medicines. This demonstrates the MHRA's tireless commitment to maintaining public safety and the continued success of the CEU in stopping illicit activity across the country.

Science Campus

39. Our Science Campus continues to demonstrate strong scientific leadership and influence across a range of areas:

Publications and grants:

40. We continue to make material contributions in academia through seven scientific publications in the areas of international standards, method development to support biological medicine development and antimicrobial resistance surveillance in wastewater and the microbiome.

41. Funding has been awarded to develop and validate serological assays to support vaccine R&D for Oropouche virus, an emerging vector-borne virus which causes a sudden, influenza-like illness and can have severe complications including foetal transmission and neurological issues (pandemic preparedness).

Partnerships:

42. We hosted a successful visit by colleagues from the National Institutes for Food and Drug Control (NIFDC), China. The visit highlighted the current and future collaborative work between the two organisations, which are both WHO Collaborating Centres for the Standardization and Evaluation of Biologicals.

43. Control Testing colleagues participated in a meeting of Official Medicines Control Laboratories, attended by delegates from over 40 countries and 60 laboratories. This engagement strengthens assurance of the MHRA control testing strategy through international alignment and exchange of data and expertise.

Public health

44. The Vesicle Vaccines team is working with the UK Health Security Agency (UKHSA) to facilitate understanding on whether the recent Meningitis B outbreak was due to a strain mutation and subsequent emergence.

45. Our Control Testing identified a batch of a coagulation factor medicine that did not meet the usual quality standards and UK potency specifications, an issue not detected by the manufacturer. The batch was not released for the UK, demonstrating the critical role of NIBSC Control Testing in ensuring patient safety.

46. Influenza reagents to support the vaccine production for the northern hemisphere season have been produced and >16,000 units dispatched to date.

Capacity Building and Outreach

47. The Polio team conducted a successful training visit to the Institute of Medical Biology, Chinese Academy of Medical Sciences, Kunming, China, focused on the use of technology to help scientists check the quality and consistency of oral polio vaccines.

People

48. Our workforce size is now tracking at circa 1,600 FTE, with turnover at c.5.7%. Strong progress is being made across workforce metrics and we remain focussed on supporting line managers in creating inclusive environments that support a culture of openness, trust and empowerment.

49. Our people survey leads remain active across the organisation, leading important work locally that makes a difference to our colleagues. I remain impressed with the passion and commitment shown at our all staff calls where the great work of our colleagues across the organisation is showcased, demonstrating a collective commitment in delivering actions that focus on the issues that matter most to our colleagues.

50. Our Public Sector Equality Duty report was published on Gov.uk in May. This report outlines the progress the organisation is making in promoting equality, diversity and inclusion across our operations. It also highlights key achievements and milestones from January 2025 to January 2026, emphasising the importance of embedding equality consideration in decision-making and public engagement. Overall, this report shows a regulator increasingly using science, data and lived experience to improve equity for patients and the public, and an organisation committed to strengthening the leadership capability, culture and systems required to meet its PSED responsibilities with confidence and credibility.

51. We have had a record breaking 99.8% of colleagues complete our annual cyber and security training. This outstanding result demonstrates our collective commitment to cyber security awareness and organisational resilience. This is important work during a time when cyber risks continue to be an issue for many organisations.

Lawrence Tallon
Chief Executive Officer, MHRA
July 2026

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

7th July 2026

Title	MHRA Finance, operational and people performance report – May 2026
Board Sponsor	Rose Braithwaite / Tasneem Blondin
Purpose of Paper	Assurance

Chair's Summary for Pre-Reading (Summary created using AI)

The Board is asked to consider the May 2026 Finance, Operational and People Performance Report and confirm whether it provides adequate assurance on delivery across the Agency. The report shows a positive start to 2026/27, with income and resource spend broadly close to budget. Capital spend remains the main area requiring attention, with early-year underspend and a forecast small surplus indicating a need for projects to implement spending plans at pace.

Operational performance remains strong, with all eight core KPIs achieved in May and Scientific Advice performance sustained at 100% for a third consecutive month. The report also flags risks to future performance from Clinical Trials software issues and recent Power BI outages, which are being monitored through the ExCo performance subcommittee.

The people position is broadly stable, with turnover reduced to 5.4%. Continued focus is needed on recruitment to fill vacancies, workforce planning, ensuring staff complete their conflict-of-interest declarations, and preparation for the updated Equality and Human Rights Commission Code of Practice.

Decisions required of the Board

Board members are asked to confirm that they have adequate assurance on Finance, Operational and People Performance delivery, noting the areas requiring continued oversight.

MHRA finance, operational and people performance report – May 2026

1. Executive summary

1.1 The finance results for the first two months of the 2026/27 financial year are positive with both income and resource spend close to budget. Capital spend during this early period of the financial year is lower than budget increasing the need for projects to fully utilise their budgets by implementing their spending plans as soon as possible.

1.2 We started the 2026/27 performance year strongly, with all eight of the Agency's core KPIs achieved, continuing the positive position with which we finished at the end of the last financial year.

1.3 We had 1,602.8 full time equivalent (FTE) staff in post at the end of May. There were 161 vacancies with the vacancy rate for May at 10%. End of year performance assessment validation meetings have largely taken place.

2. Finance performance

Table 1 - Agency Financial Performance for May 2026

May 2026 Resource DEL	Period Actual £M	Period Budget £M	Variance vs Budget % / £M	YTD Actual £M	YTD Budget £M	Variance vs Budget % / £M	Full Year Budget £M
Trading Income	10.7	9.9	8%	19.8	19.8	0%	123.4
Service Fee Income	4.2	4.2	1%	8.4	8.4	0%	50.4
Devices Service Fee Income	0.2	0.2	9%	0.3	0.4	(18%)	8.8
Grant Income	0.3	0.7	(52%)	1.4	1.3	2%	11.0
NIHR Drawdown	0.1	0.3	(70%)	0.2	0.7	(68%)	4.0
Total Resource Funding	**15.5**	**15.3**	**0.2**	**30.1**	**30.6**	**(0.5)**	**197.7**
Staff Costs	10.8	10.5	(2%)	21.1	20.9	(1%)	135.9
Operating Costs	6.5	6.0	(8%)	12.0	12.4	3%	79.1
Projects - Staff Costs	0.2	0.3	46%	0.4	0.6	43%	4.1
Projects - Operating Costs	0.8	1.0	20%	1.4	1.9	28%	14.9
Grant Costs	0.0	0.0	0%	0.0	0.0	0%	0.0
Total Resource Costs	**18.2**	**17.8**	**(0.4)**	**34.9**	**35.9**	**1.0**	**234.0**
Running Hot	**0.0**	**0.0**	**(0.0)**	**0.0**	**0.0**	**(0.0)**	**(3.3)**
Agency Net Resource Position (Statutory Accounts)	**(2.7)**	**(2.5)**	**(0.1)**	**(4.8)**	**(5.3)**	**0.5**	**(36.3)**
DH Funding	2.8	2.8	0%	5.5	5.5	0%	33.1
Agency Resource Total	**0.1**	**0.3**	**(0.1)**	**0.7**	**0.2**	**0.5**	**0.0**

2.1 The Agency's Year to Date (YTD) operating income was £0.5m behind budget due to a timing difference in the draw down of funding from the National Institute for Health and Care Research (NIHR).

2.2 Trading income met its budget with both Licensing and National Applications income recorded at budget and higher Variations income making up for a shortfall in income from Labels and Leaflets.

2.3 Sales of Scientific Standards were significantly higher than budget due to strong sales during the flu season with sales expected to return to baseline by Quarter 2.

2.4 Service fee income, as in previous years, is recognised to budget until more detailed information is available later in the year.

Staff costs

2.5 Staff costs in May were 2% above budget. The YTD position is slightly (1%) over budget. The budget assumes the vacancy rate will fall gradually during the year as vacancies and new approved roles are filled.

2.6 The publication of the 2026/27 Cabinet Office Pay Guidance in May, which includes a higher percentage increase than budgeted, creates an additional pressure to pay costs, the impact of which will be reviewed as part of the first quarter forecast in July.

Operating costs

2.7 Operating costs are 3% below the YTD budget; historically, non-pay spend tends to be slower in the first quarter but is expected to increase as we move through the financial year.

2.8 Project staff and operating costs are £0.7m below the YTD budget due to slightly lower spend in several key projects including Strategic Data and Intelligence Capability (SDIC), AI Airlock, MARRS and the 'Medicines and devices supply chain resilience' project. This is due to delays in recruitment and reprofiling of some work to quarters 2 and 3.

Capital

May 2026 Capital DEL	Period Actual £M	Period Budget £M	*Variance vs Budget % / £M*	YTD Actual £M	YTD Budget £M	*Variance vs Budget % / £M*	Full Year Budget £M
UK Government Grants	0.8	0.7	9%	1.0	0.5	117%	3.9
DHSC Capital Funding	3.5	1.3	173%	7.1	1.6	347%	42.3
Total Capital Funding	**4.3**	**2.0**	**2.3**	**8.0**	**2.0**	**6.0**	**46.2**
Capital Costs	**1.4**	**1.1**	**0.3**	**2.1**	**1.6**	**0.5**	**43.9**
Agency Net Capital Position	**2.9**	**0.9**	**2.0**	**6.0**	**0.4**	**5.5**	**2.3**

2.9 YTD spend and the forecast small surplus of £2.3m indicate projects will need to implement spend plans as quickly as possible to manage underspend risk. The business case for the MARRS programme is progressing, however, uncertainties over work scope creates a risk of underspend by year-end.

2.10 The Strategic Data & Intelligence Capability (SDIC) project is in the Discovery phase with spend expected to increase in July following the completion of the Discovery phase.

3. Operational performance

3.1 We started the 2026/27 performance year strongly, with **all 8 core KPIs meeting target**, continuing the strong position we finished with at the end of the last financial year.

3.2 **Scientific Advice**: Performance remained at 100% for the third consecutive month, demonstrating sustained improvement. Customer feedback scores are also improving, following earlier complaints linked to long processing times during backlog clearance.

3.3 **Application Volumes**: Continue to rise across national licensing and variations. While positive, this growth places additional pressure on capacity and resourcing to maintain service levels. Mitigations include more assessor roles and enhanced monitoring of the work in progress.

3.4 **Forward look**: Operational performance is closely monitored by an ExCo subcommittee that reports to ExCo on a monthly basis. The subcommittee has flagged two risks to future performance:

- **Clinical Trials software** – system issues may impact the ability to meet June targets, creating a risk to KPI compliance.
- **Power BI outages** – recent issues presented incorrect data and required manual workarounds. This impacted the operational ability to monitor workload effectively. This issue appears to have stabilised for now.

4. People performance

Key highlights

4.1 The current number of vacancies remains at 161 with the vacancy rate for May at 10%. Business areas are being encouraged to prioritise recruitment activity to ensure we can drive quality applications through the process to reduce volume of applications to hiring managers and reduce the overall time to recruit. Workforce planning principles are being developed to support line managers ensure they have the right skills and capability in place across their teams to deliver 2030 strategic objectives.

4.2 End of year performance assessment validation meetings (for all grades, including SCS) have largely taken place. Final validation meetings need to be concluded by 22nd June for SCS. ExCo will then carry out a SCS final validation meeting with results being submitted to Cabinet Office for a cross-government consistency check taking place in early July.

4.3 During each financial year there is a requirement for declarations of conflicts of interest (COI) to be completed by 31st May. This is a mandatory requirement for all staff to complete on a yearly basis or when changes in personal circumstances may warrant a declaration. For 26/27 financial year, as at 23 June 2026, 64%, of staff have completed their COI declaration. The break down by group is as follows:

Group	Yes	No
People Team	67%	33%
Finance, ILS, Corp Executive & Commercial	80%	20%
Communications and Engagement	100%	0%
Strategy, Governance & Partnership	13%	88%
Digital and Technology	71%	29%
HQA	65%	35%
Safety & Surveillance	68%	32%
Science & Research and Innovation*	45%	55%

* We are unable to split Science & Research and Innovation at this time.

People in post

4.4 We had 1602.8 FTE in post at the end of May 2026 (permanent, fixed term and Ph.D. students covering established posts), an increase of 18.4 FTE compared to April 2026.

4.5 The number of apprenticeships across the agency remains steady at 105 which equates to approximately 7% of total workforce.

Turnover, Vacancies and Recruitment

4.6 We welcomed 19 new starters to the Agency in May 2026 compared to 17 in March 2026. We saw 8 leavers in May 2026 (14 in April 2026). Voluntary turnover (for the rolling year) at the end of May 2026 has decreased to 5.4% compared to 5.7% in April 2026. We had 161 vacancies at the end of May 2026 which represents an increase of 1 vacancy from April.

4.7 In order to gain a better understanding of retention issues we have begun to track and will report on the types of leavers across the agency.

Leaver Reason	April 2026	May 2026
End of Fixed Term Contract	1	4
Resignation - Personal Reasons (Non-Work Related)	6	1
Resignation - ODG Transfer	2	0
Dismissal	1	0
Retirement	4	3
Total	**14**	**8**

4.8 All leavers are offered the opportunity to have a face-to-face exit interview and are also sent an electronic questionnaire to complete. Of the 22 leavers 1 had a face-to-face exit interview and 8 completed the online link.

4.9 The vacancy rate at the end of May 2026 was stable at 10.1%.

4.10 34 staff have now started at our Leeds Digital hub. There are an additional 12 campaigns with 4 at offer stage and 8 onboarding.

Sickness Absence

4.11 In May 2026, the average working days lost to sickness absence was 4.7 days per FTE. This is a sustained position from April 2026.

4.12 The highest contributor to days lost continues to be cold, coughs, flu at 1547 working days which equates to 19% of all sickness. Non-work-related mental ill health remains the second highest contributor to days lost at 997 days and 12% of all absence with gastrointestinal problems being the third highest contributor at 909 days and 11% of all sickness days recorded.

4.13 Work-related mental ill health was the fourth highest contributor to sickness absence in the 12 months up to 31st May 2026. It continues to reduce, accounting for 585 days lost and 7.2% of all absence.

Wellbeing and inclusion

4.14 The Public Sector Equality Duty report was published on in May. This report is a yearly statutory requirement which means the agency is fully compliant with the Public Sector Equality duty requirement. The report focusses on key achievements from January 2025 to January 2026. It evidences how the MHRA has complied with the Equality Act 2010 and met its specific requirements across our regulatory work, our engagement with patients and the public, and our role as an employer.

4.15 The Minister for Women and Equalities, has laid the Equality and Human Rights Commission's (EHRC's) draft updated Code of Practice for services, public functions and associations in Parliament. The Code has been updated to reflect the Supreme Court ruling of April 2025, which confirmed that "sex" in the Equality Act 2010 refers to biological sex. The code is likely to become statutory in early August 2026. In order to mitigate risk of legal challenges, MHRA should aim to update all policies and guidance impacted by the code, where relevant, as soon as reasonably possible.

Diversity representation

4.16 Our diversity representation across MHRA remains relatively strong with 3 of the 8 measures below civil service benchmarks (Disability at AA-SEO; LGBT at AA-SEO and LGBT at G7-SCS below the benchmarks).

	Civil Service March 2025	Dec 25	Jan 26	Feb 26	Mar 26	Apr 26	May 26
Headcount	**549,660**	1,599	1,674	1,695	1,693	1,620	**1,630**
Disability	**17.90%**	**9.88%**	**9.8%**	**9.91%**	**9.76%**	**9.8%**	**9.8%**
AA-SEO	13.57%	11.47%	9.75%	9.57%	9.34%	9.5%	9.4%
G7-SCS	10.31%	9.36%	9.86%	10.31%	10.25%	10.1%	10.2%
Ethnic Minority	**18%**	**39.9**	**38.47**	**38.47%**	**38.12**	**39.40%**	**39.3%**
AA-SEO	15.51%	51.24	49.32	48.40%	48.02%	50%	49.5%
G7-SCS	11.35%	33.73	26.9	26.97%	26.71%	27.50%	27.5%
Female	**54.60%**	**61.48**	**61.59**	**62.01%**	**61.94%**	**61.6%**	**61.7%**
AA-SEO	54.64%	63.13	63.72	64.36%	64.18%	62.9%	63%
G7-SCS	50.12%	59.76	59.29	59.29%	59.37%	60.2%	60.2%
LGBT	**7.20%**	**3.56**	**3.58**	**3.54%**	**3.47%**	**3.46%**	**3.44%**
AA-SEO	5.16%	3.18	3.06	3.30%	3.08%	2.92%	2.86%
G7-SCS	5.74%	4.01	4.17	3.82%	3.92%	4.06%	4.10%

5. Recommendation

5.1 The Board is asked to confirm that they have adequate assurance on the Finance, People, and Operational Performance delivery that this report provides.

Rose Braithwaite & Tasneem Blondin

Chief Financial Officer & Chief People Officer

July 2026

Medicines & Healthcare products Regulatory Agency

Agency Performance Report

May 2026

Report version: Monthly

Finance & Corporate Business Planning Function

Contents

Purpose of Report

To provide a clear and concise overview of the Agency's operational performance, including key metrics, trends, and any exceptions.

This pack is used to inform performance oversight, assurance, and decision-making at the Delivery and Performance Committee (DPC), Executive Committee (ExCo), and the Board.

Content

- Core KPIs
- Executive Summary
- Reporting Exceptions – performance deviations and any agreed escalations

Reporting & Review Cycle

KPIs & Operational Metrics

Dashboard Extractions

Core KPIs

Click **here** for dashboard access

Data extract: 15/06/26

Provides a high-level view of performance against core targets and any overall trends in delivery.

KPI	KPI Description	Target	YTD % On Time	Current Month % On Time	Next Month (M+1) % On Time	M+2 % On Time	M+3 % On Time
1	We will assess 95% of all initial Clinical Trial Authorisation (CTA) and Clinical Investigation applications within their category's statutory timeline.	95%	↑ 99%	99%	99%	98%	98%
2	We will certify 95% of vaccine batches within 43 days and 95% of blood product batches within 15 days of submission.	95%	↑ 100%	100%	100%	100%	100%
3	We will determine 95% of medicines licence applications within 210 days via the national route.	95%	↓ 99%	98%	98%	99%	100%
4	We will determine 95% of medicines licence applications within 60 days via recognition Route A and within 110 days via Route B through the International Recognition Procedure (IRP).	95%	↓ 99%	97%	97%	96%	96%
5	We will determine 95% of all national variations within their category's statutory timeline.	95%	↓ 99%	98%	98%	99%	99%
6	We will grant, vary or refuse 95% of manufacturing and distribution authorisations within their category's statutory timeline.	95%	↑ 99%	99%	100%	100%	100%
7	We will process 90% of all UK initial spontaneous Reports of Adverse Incidents related to healthcare products within 24 hours.	90%	↑ 96%	96%	96%	96%	96%
8	(a) We will offer a meeting date for 90% of scientific advice requests within 10 working days of submission.*(b) We will deliver the formal written advice for 90% of requests within 30 working days of the meeting date or, if no meeting is required or requested, within 30 working days of receiving company documentation.	90%	↑ 100%	100%	100%	100%	100%

Overall Experience with MHRA from SAMs (rolling 6 month average)	% of CI/CT Cases Recorded as First in Human (out of all assessed cases)	% of Manufacturing and Distribution Licences Requiring Inspection	% of Medicine Licences via the National Route	Agency Staff Vacancy Rate (latest available)
9.1	**9%**	**10%**	**59%**	**8%**
Prior month **8.8**	Prior Month **17%**	Prior Month **12%**	Prior Month **48%**	Prior Month **8%**

Executive Summary

Click **here** for dashboard access

Data extract: 15/06/26

Supporting metrics providing context behind core KPI performance, including compliance, volumes, and processing times.

Operational Flow with Forecast

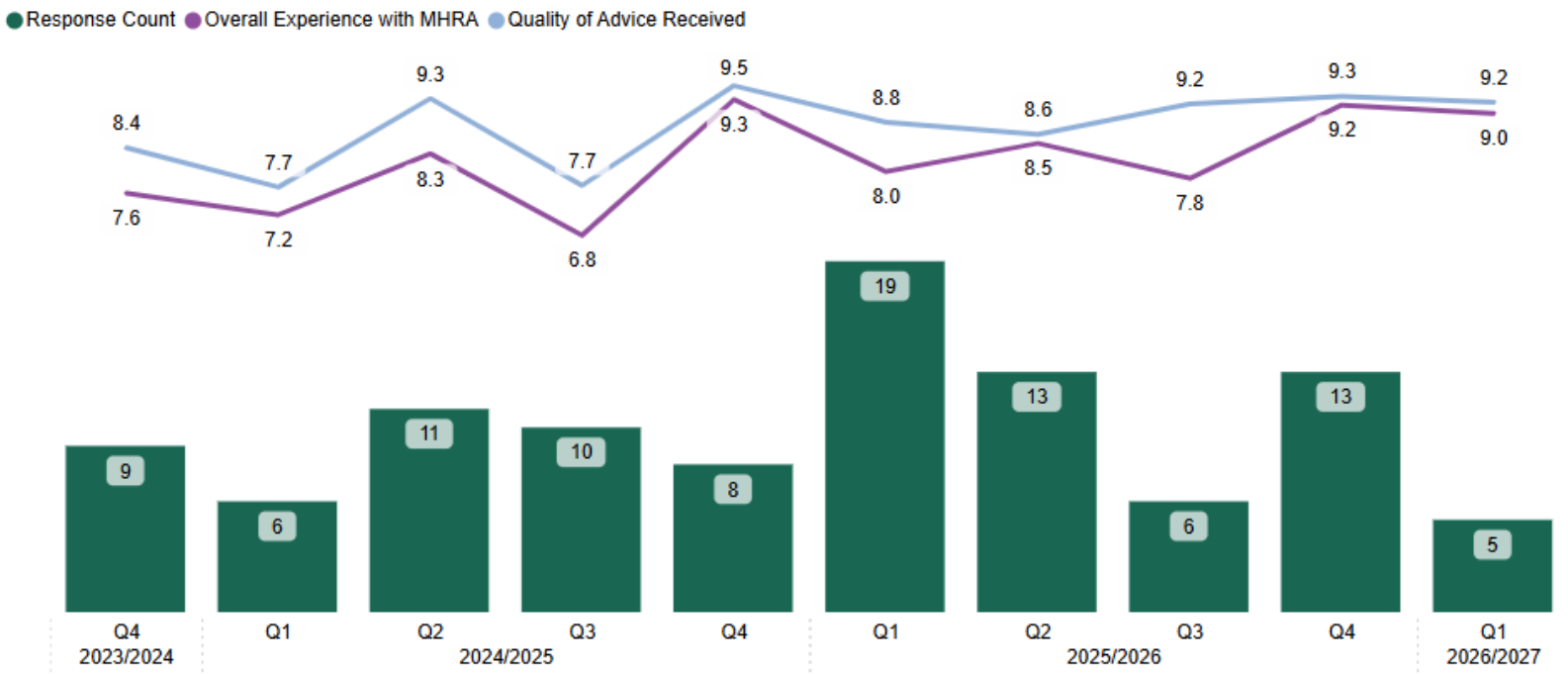
Latest Date	Process	Stage	Type	Volume	Target (days)	Median * (days)	Min* (days)	Max* (days)	KPI Target (%)	Current Month % On Time	Next Month (M+1) % On Time	M+2 % On Time	M+3 % On Time
12/6/26	Adverse Incident	Process Report	Device	3,290	1	1	0	7	90%	95%	95%	95%	94%
12/6/26	Adverse Incident	Process Report	Medicine	9,679	1	1	0	23	90%	97%	97%	97%	96%
29/5/26	Batch Control Testing	Batch Certification	Blood	54	15	5	1	13	95%	100%	100%	100%	100%
29/5/26	Batch Control Testing	Batch Certification	Vaccine	37	43	1	0	22	95%	100%	100%	100%	100%
11/6/26	Clinical Investigation	Assess Amendment	GB	11	21	7	2	31		91%	90%	91%	89%
11/6/26	Clinical Investigation	Assess Application	GB	5	60	58	58	59	95%	100%	100%	100%	100%
11/6/26	Clinical Investigation	Assess Application	GBNI/NI External Expert	1	65	58	65	65	95%	100%	100%	100%	100%
12/6/26	Clinical Trial	Assess Application		61	30	29	0	61	95%	98%	98%	98%	98%
1/6/26	Manufacturing Licences	Grant Authorisation	New Application	0	90	0			95%	100%	100%	100%	100%
1/6/26	Manufacturing Licences	Grant Authorisation	Variation (Inspection)	7	90	33			95%	100%	100%	100%	100%
1/6/26	Manufacturing Licences	Grant Authorisation	Variation (No Inspection)	62	30	12			95%	100%	100%	100%	100%
10/6/26	Medicine Licence Application - IRP	Application Complete	Route A	12	60	57	52	59	95%	100%	100%	100%	100%
10/6/26	Medicine Licence Application - IRP	Application Complete	Route A - Extended	8	110	83	63	111	95%	88%	86%	84%	81%
10/6/26	Medicine Licence Application - IRP	Application Complete	Route B	10	110	94	79	110	95%	100%	100%	100%	100%
10/6/26	Medicine Licence Application - IRP	Application Complete	Route B - Extended	7	210	111	111	196	95%	100%	100%	100%	100%
10/6/26	Medicine Licence Application - National Route	Application Complete	Established Medicines	52	210	196	75	237	95%	98%	98%	99%	100%
10/6/26	Medicine Licence Application - National Route	Application Complete	New Active Substance	1	210	167	167	167	95%	100%	100%	100%	100%
10/6/26	Medicine Licence Variation	Determination Complete	TYPE IB	787	30	15	0	80	95%	99%	99%	99%	100%
10/6/26	Medicine Licence Variation	Determination Complete	TYPE II	179	90	44	0	248	95%	96%	96%	96%	97%
11/6/26	Scientific Advice	Deliver Written Advice		18	30	24	12	29	90%	100%	100%	100%	100%
11/6/26	Scientific Advice	Offer Meeting Date		19	10	6	1	9	90%	100%	100%	100%	100%
1/6/26	Wholesale Dealer Licences	Grant Authorisation	New Application	12	90	44			95%	100%	100%	100%	100%
1/6/26	Wholesale Dealer Licences	Grant Authorisation	Variation (Inspection)	6	90	32			95%	100%	100%	100%	100%
1/6/26	Wholesale Dealer Licences	Grant Authorisation	Variation (No Inspection)	44	30	12			95%	98%	97%	97%	97%

Click **here** for dashboard access

Reporting Exceptions

Data extract: 15/06/26

Areas of performance requiring focus, including SPC alerts and any emerging risks or issues reviewed and escalated by DPC.

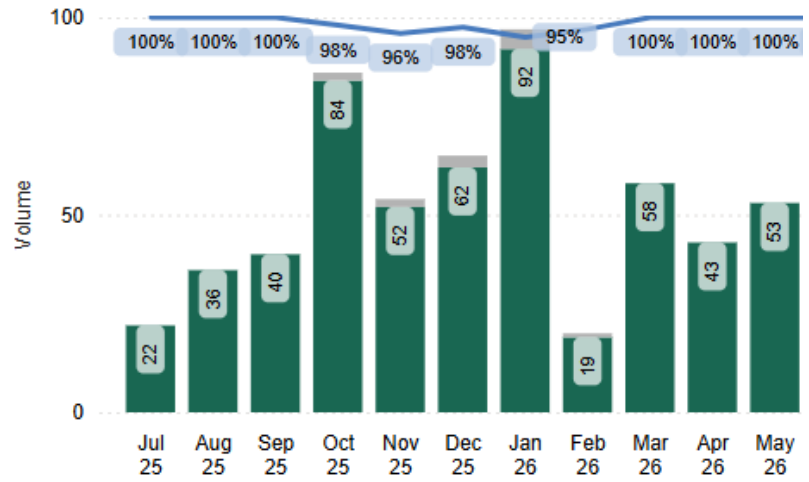
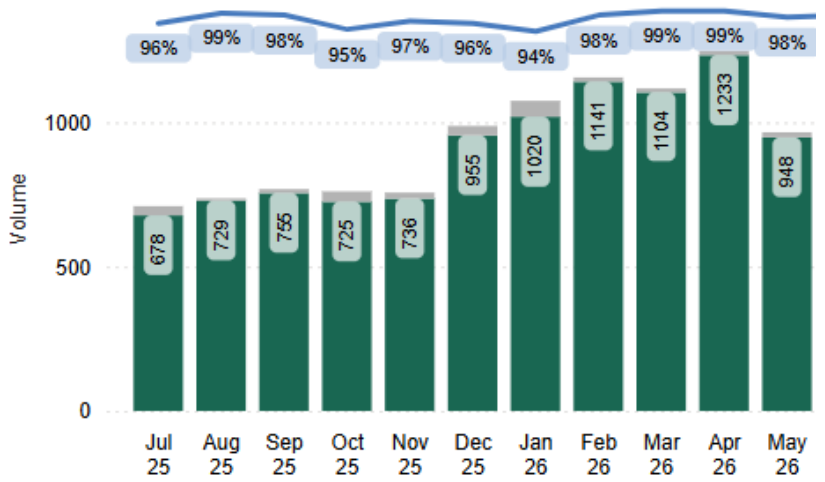
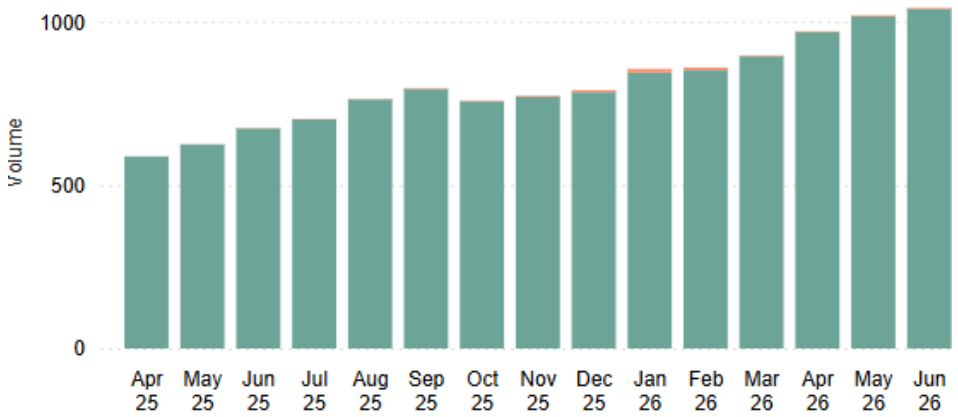
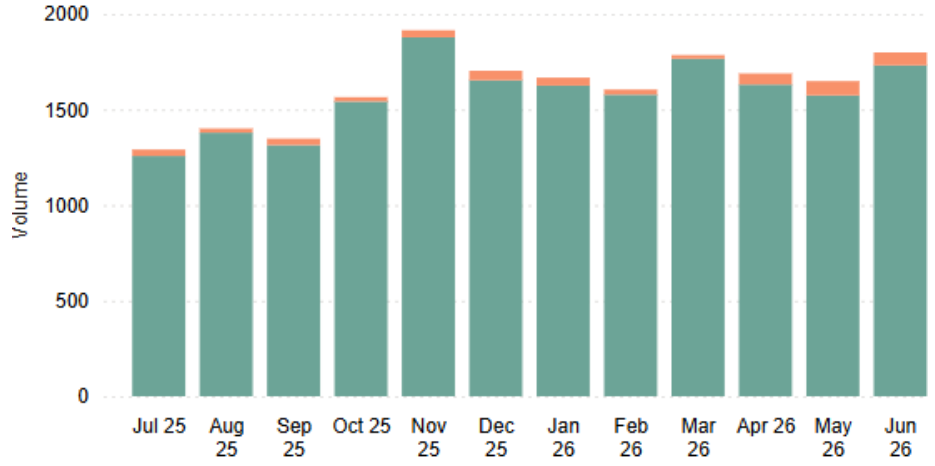
Metric	Performance
Scientific Advice: Improving feedback scores *Feedback Survey Scores:* • *Overall Experience with MHRA* • *Quality of Advice Received*	

Reporting Exceptions

Click **here** for dashboard access

Data extract: 15/06/26

Areas of performance requiring focus, including SPC alerts and any emerging risks or issues reviewed and escalated by DPC.

Metric	Medicines Licensing: National	Variations: National
	Completed - On Time; Completed - Late; % Completed On Time	In Progress - On Time; In Progress - Late
Output		
Work in Progress (WIP)		

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

7th July 2026

Title	**Audit and Risk Assurance Committee (ARAC) Annual Assurance Report to the Board 2025-2026**
Board Sponsor	Michael Whitehouse
Purpose of Paper	Assurance

Chair's Summary for Pre-Reading (Summary created using AI)

The Board is asked to receive the Audit and Risk Assurance Committee (ARAC) Annual Report for 2025–26, which provides an independent assessment of the adequacy and effectiveness of the MHRA's governance, risk management, financial controls and internal control environment. The Committee's overall view, based on the totality of assurance received, is that financial controls are well designed and operating effectively, with continued improvement in governance and risk management arrangements over the past year. This is supported by a second consecutive Moderate assurance opinion from Internal Audit.

The report highlights a strong control environment overall, with the majority of internal audit reviews receiving Moderate or Substantial assurance, and confirms that the National Audit Office intends to issue an unqualified audit opinion on the 2025–26 financial statements. The Committee notes specific areas requiring continued focus, including strengthening contract management controls, maintaining momentum in risk management improvements, and addressing themes arising from whistleblowing and workforce processes.

Looking ahead, ARAC's focus will support delivery of the MHRA 2030 strategy, with particular emphasis on sustaining operational performance, strengthening cyber resilience, improving productivity and transparency, embedding effective risk management, and ensuring that change programmes deliver intended benefits. The Committee will continue to provide oversight and assurance as the Agency implements its strategy and evolves its operating model.

Decisions from the Board

The report is for assurance. Board members are asked to receive the report and note ARAC's assessment of governance, risk management and controls, and its priorities for 2026–27.

Audit and Risk Assurance Committee Annual Report 2025-26

1. Executive Summary

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

1.2. The Board is asked to receive the report and to note in particular the Committee's assessment of the work undertaken in 2025-26 (paragraphs 3, 4 and 5) and the anticipated focus for the coming year.

1.3. This report also records the Committee's review of external audit's work. Following ARAC's most recent meeting on 1 July we are pleased to report to the Board that the National Audit Office (NAO) will be advising the Comptroller and Auditor General that he can issue an unqualified audit opinion for the MHRA's Financial Statements for 2025-26 (paragraphs 4.8)

2. Introduction

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

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

2.3. The Committee's membership changed during 2025-26: Amanda Calvert stepped down as a Non-Executive Director, and we welcomed Raj Long and Mercy Jeyasingham as new members of ARAC in April and December 2025 respectively. Sharon McCarthy continues to support the Committee as independent adviser and has attended meetings since February 2024. We are intending to appoint another independent advisor next year and will report on its progress to the board.

2.4. The Committee met five times in 2025-26. All our meetings were quorate. Only one Conflicts Of Interest (COI) was declared during this year which is appropriately recorded in the Board COI Register.

3. Audit and Risk Assurance Committee's assessment

3.1. The assessment of the Committee based on the totality of the work presented to it, including but not exclusively, internal and external audit work, is that financial controls are well designed and managed. The Committee has seen consecutive annual improvements in the Agency's approach to risk management supported by a robust framework for identifying and managing risks and issues.

3.2. On wider governance and internal control, the Committee is pleased to see that improvements are continuing. The Government Internal Audit Agency awarded the Agency Moderate assurance rating for its overall control environment for the second year (paragraph 4.4), which reflects considerable work by the Agency to improve its service delivery as well as its internal control and resilience.

3.3. In April 2025 the agency's new Chief Executive Officer took up the post and the Committee is pleased to report that under his new leadership the agency has seen significant progress across risk, governance and performance.

4. Information supporting the Committee's opinion

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

- **Internal Audit**

4.1. The MHRA's internal audit service is provided by the Government Internal Audit Agency (GIAA). ARAC can, should the need arise, commission private or specialist firms to perform discrete audits or investigations. There was no requirement to do this during 2025-26. All work was performed by GIAA which drew on its own specialists.

4.2. Until December 2025, the head of Internal Audit for the MHRA was Jo Charlton and Andrew O'Donnell assumed this responsibility after Dec 2025. The Committee has agreed to an annual work programme for internal audit at the beginning of the year. This was finally made up of 11 comprehensive reviews including one advisory audit which is unrated. These are set out below together with the period when they were delivered, and the assurance rating awarded. Annex A explains the ratings.

Audit Title	Timing	Rating
Date Security and Protection Toolkit	Q1	Moderate
Assurance Mapping	Q1	Moderate
Data Assurance and Quality (DAQ)	Q2/Q2	Substantial
Safety Variations	Q2/Q3	Moderate
Contract Management	Q3	Limited
Freedom of Information	Q3	Substantial
Complaints Handling	Q3/Q4	Substantial
Leavers Process	Q4	Moderate
Performance and Productivity	Q4	Advisory Audit
Sustainability of Plans across Technical Areas	Q4	Moderate
Non-Current assets	Q4	Moderate

4.3. The contract management audit identified significant gaps in the Agency's controls for managing contracts. The Committee recognises contract management as critical to securing supplier benefits and delivering value for money. It has received assurance that the audit recommendations are being progressed and will continue to monitor improvements to ensure effective controls are in place and the Agency's contract management capability is strengthened.

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

4.5. The number of internal reports receiving moderate or substantial assurance has remained at nine, which accounts for just over 80% of the plan. Internal Audit recognised commented positively about strengthening and further maturing of internal control and governance during 2025-26.

- **External Audit**

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

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

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

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

- **Non-Regulatory Fraud and Error**

4.10. ARAC has received quarterly reports on fraud and errors which showed that across the year, identified financial losses were predominantly due to operational errors rather than fraud. Staff overpayments totalled c.£25.7k, largely arising from payroll set-up issues, maternity-related payments, and historic promotion errors, while Government Procurement Card (GPC) errors totalled £2.8k, mainly due to user mistakes and supplier billing issues. The majority of these amounts have either been recovered or have recovery plans in place.

4.11. Two dual working fraud cases were identified during the year, including one resulting in dismissal and another under investigation led by a separate Civil Service organisation. In response, controls have been strengthened across payroll, recruitment and GPC processes, alongside the development of targeted awareness activity to mitigate risks such as dual working. Overall, recovery rates are strong, and actions are in place to reduce recurrence and improve preventative control.

- **Raising Concerns and Whistle blowing**

4.12. The number of concerns raised increased significantly in 2025–26, with 47 concerns raised by 35 staff (up from 13 concerns the previous year), highlighting issues primarily in recruitment practices, treatment by senior managers, value for money, and delivery pressures. Four formal whistleblowing investigations were undertaken which were mostly concluded in a timely manner although one experienced major delay due to operational priorities. No consistent systemic themes were identified although recruitment is emerging as a recurring theme.

4.13. The Raising Concerns Policy was updated in October 2025, and awareness activity continued; however, staff awareness of how to raise concerns declined slightly. Priorities for 2026–27 therefore focus on strengthening awareness through targeted engagement, improving the timeliness of investigations, benchmarking activity levels, and enhancing data capture to better identify trends and risks.

- **Regulatory Fraud**

4.14. During the 2025/26 reporting period, no new strategic regulatory fraud risks have been identified across the Agency. Existing risks remain consistent with those previously reported and continue to be monitored through established governance, intelligence, and enforcement mechanisms.

4.15. The Agency's most significant current regulatory fraud risk continues to relate to the diversion of medicines from the legitimate supply chain and the potential for reintroduction into the regulated supply chain. Although no current investigations relate to confirmed reintroduction of diverted legitimate medicines, the risk remains assessed as significant due to the potential impact on patient safety, regulatory integrity, and public confidence.

4.16. One investigation has been undertaken concerning a falsified GLP-1 medicine supplied in counterfeit packaging which entered the regulated supply chain and was dispensed by a pharmacy in the West Midlands. The method by which the product entered the supply chain remains under investigation. The General Pharmaceutical Council (GPhC) is fully engaged in the ongoing regulatory response.

- **Information Governance**

4.17. The Committee received a few internal audit reports on information governance:

i) The Data Security and Protection Toolkit received a Moderate rating. The overall risk across all five objectives were assessed as Low; meaning that MHRA is meeting the baseline profile established by NHSE. The committee recognises that MHRA is continually developing their cyber security control framework although there are areas for improvement such as supply chain, response plan, testing and exercising.

ii) The audit of Data Assurance and Quality (DAQ) provided Substantial assurance over the adequacy and effectiveness of the MHRA's arrangements for Data Assurance and Quality team which is responsible for ensuring that Marketing Authorisation applications are accurately entered and validated on the Agency's regulatory database system, Sentinel.

iii) The audit of Freedom of Information process also provided Substantial assurance over the adequacy and effectiveness of MHRA's arrangements for responding to requests for information under the Freedom of Information (FOI) Act. The review

4.18. Department of Health and Social Care also sponsored an audit of MHRA Data Protection Officer Role during Q4 2025-26. The outcome of this audit provided Limited Assurance however following MHRA challenge, GIAA has acknowledged that a few of the key improvements have already been implemented / are nearing completion.

- **Assurance Mapping and Functional Standard**

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

- identification of corporate risks linked to business objectives
- assessment and management of risks/issues falling outside of the agency's risk appetite
- monitoring of the effectiveness of internal controls
- monitoring of financial controls and exception reporting
- considering of any instances of non-compliance with laws or regulations
- review of independent assurance reports.

4.20. We comment specifically on risk management in paragraphs 4.23-4.27.

4.21. Internal Audit's moderate assessment for the MHRA's assurance mapping exercise including its newly drafted framework highlights the maturity and the effectiveness of the annual assurance mapping exercise which started in the past couple of years in its current style. During 2025-26, ARAC endorsed the 3-year plan of improving this exercise with the aim of optimising the synergy between risk management, assurance, and quality management and positioning assurance as a strategic enabler that drives continuous Improvement and reliability. The Committee will continue to oversee this exercise over the next 12 months drawing on Internal Audit's independent scrutiny.

4.22. ARAC receives the annual report on the compliance of the agency with Government Functional Standard each year. In 2025-26, 71% of functions met the mandatory requirement (10 out of 14) and 78% met the optional requirements (11 out of 14). The committee noted that Continuous Improvement Assessment Framework (CIAF) will be rolled out to relevant functions next year to strengthen monitoring and reduce duplication.

- **Risk Management**

4.23. The Risk Management Framework (RMF) sets out the MHRA's approach to risk management. It defines various risk impacts, outlines roles and responsibilities, explains how risk governance operates, including the agency's risk appetit. The risk approach aligns with the principles and concepts set out in HM Treasury's Orange Book: Management of risk.

4.24. The ExCo and its dedicated management committee (Risk and Assurance Group) meet monthly and support the Executive Team and the Accounting Officer by ensuring the effective management of risks and issues across the Agency to help enable the successful delivery of Agency objectives. RAG is chaired by the Director of Communications and Engagement with members from across the organisation.

4.25. The Committee reviews the risk register at each of its meetings reporting any emerging risks or control weaknesses as appropriate to the Board and ExCo. The Committee also periodically undertakes deep dives into risks and issues. During 2025-26, the committee held detailed discussion on the delivery delay and later the closure of the Regulatory Connect, the risks of delivery failure in science campus due to infrastructure / critical equipment failure and IR35 non-compliance.

4.26. The Committee has seen considerable strengthening of the Agency's risk identification and management over the last three years. Following a review during summer, the number of risks and issues at the corporate level fell following the de-escalation of the stable risks which were assessed to be within the agency's risk appetite.

4.27. Over the coming months the Chief Executive is leading the development of a new 5-year strategy for the MHRA. Once completed, Agency's risk register and appetite should be refreshed to support its implementation.

- **Governance and Management Reporting.**

4.27. The Committee received a range of assurance reports from management throughout the year. These included: losses and write offs, waivers, and declarations of interest and conflicts of interest management. There were no material issues in 2025-26 to bring to the Board's attention.

5. Focus of the Committee in 2025-26.

The next twelve months will be a period to get behind the new strategy and deliver a sustainable performance as the Agency launches MHRA 2030, to set the direction of travel for the next 5 years. To this end, a new dashboard is created providing better and earlier insight into key performance indicators so that any performance dip or control weakness is identified ASAP. The Committee will seek ongoing assurance that the Agency's operating model is delivering consistent standards of performance and assurance will be guided by the following:

1. Improved performance in meeting the Agency's statutory functions is maintained. The Agency has consistently met its statutory deliverables and successfully delivered against the new shortened timelines in 2025–26. Sustained performance in its statutory functions is key to maintaining and strengthening the Agency's positive reputation.

2. Cyber security is sufficiently resilient**.** All organisations face this risk which is escalating in scale. Internal Audit's reports in 2025-26 shows that significant improvements have been made and is still in progress to strengthen agency's digital control environment. The Committee will continue to seek assurance that this is the best it can be.

3. Improvements in productivity and efficiency are delivered and are transparent. As the Agency continues to transform its processes it is having to recruit new people and enhance its skill base. This needs to be combined with greater transparency over the Agency's efficiency and productivity. The Agency is committed to developing productivity measures which strengthen both its ability to deploy staff and financial budgeting.

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

5. Change is well managed and benefit realisation is transparent. The Agency has undergone considerable changes over the last five years, some of which have been implemented more successfully than others. Further change will occur as under the new leadership and aligned with the new strategy operational priorities and therefore responsibilities may change. ARAC supports the greater clarity and accountability this should provide but emphasise the importance of this being supported by the necessary culture change which is also a critical component of sound governance. The Committee will continue to focus on evidence of sustained cultural change.

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

7. Sustained operational performance and risk proportionate regulation are dependent on enhanced digital ways of working and the delivery of Regularity Connect programme replacement is a key enabler. The Agency has recently created Enterprise Portfolio Management Office with the introduction of a new framework that supports objective prioritization of projects and programmes. The Committee will continue to seek assurance on progress in realising intended benefits of the new programme.

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

Michael Whitehouse,
Chair, Audit and Risk Assurance Committee
July 2025

Annex A : GIAA classification systems

Opinion

Substantial	The framework of governance, risk management and control is adequate and effective.
Moderate	Some improvements are required to enhance the adequacy and effectiveness of the framework of governance, risk management and control.
Limited	There are significant weaknesses in the framework of governance, risk management and control such that it could be or could become inadequate and ineffective.
Unsatisfactory	There are fundamental weaknesses in the framework of governance, risk management and control such that it is inadequate and ineffective or is likely to fail.

Medicines & Healthcare products Regulatory Agency

BOARD MEETING

7 July 2026

Title	Annual Report and Accounts 2025-26
Board Sponsor	Rose Braithwaite
Purpose of Paper	Board approval

Chair's Summary for Pre-Reading (Summary created using AI)

The Board is asked to consider and approve the MHRA Annual Report and Accounts 2025–26, which sets out the Agency's performance, governance arrangements and financial results for the year ending 31 March 2026. The report has been prepared in accordance with the relevant reporting requirements and is subject to National Audit Office audit. It reflects a year of strengthened operational performance, with historic backlogs cleared, seven of eight core KPIs met across the year and all eight achieved by March 2026. It also describes the Agency's continued focus on patient safety, regulatory innovation, international collaboration, and improved governance and risk management.

The Annual Report highlights significant delivery during the year, including improved performance across statutory services, the launch of MHRA–NICE aligned pathways, progress on AI regulation through the AI Airlock, strengthened enforcement activity, and the removal of 28.5 million doses of illegally traded medicines from circulation. The Governance Statement sets out the progress made in strengthening the control environment, while also recognising areas requiring continued oversight, including the closure of RegulatoryConnect, contract management, IR35 compliance, cyber security and legacy infrastructure risks. The Head of Internal Audit opinion remains Moderate for the second consecutive year, providing assurance on the overall governance, risk and control framework.

Decisions from the Board

Board members are asked to approve the Annual Report and Accounts 2025–26 for signature by the Accounting Officer and submission to the Comptroller and Auditor General, subject to closure of the financial audit and any final non-material changes.

Annual Report and Accounts 2025-26

1. Executive Summary

1.1. The MHRA Annual Report and Accounts 2025 - 26 have been prepared in accordance with the relevant requirements and are subject to audit by the National Audit Office (NAO). The Executive Committee (ExCo) and the Audit and Risk Assurance Committee (ARA) have both reviewed and approved the report.

1.2. The Board is asked to approve the annual report and accounts 2025-26 and advise the CEO as Accounting Officer to sign the report and accounts prior to submission to the NAO for the Comptroller and Auditor General's certification. It will then be laid in Parliament ahead of summer recess. The report will be tabled at the meeting to share the final designed version.

2. Introduction

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

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

2.3. ExCo and ARAC have approved the report on 1 July and 6 July. ARAC Chair has provided details of this approval in the ARAC assurance report to Board.

3. Proposal

3.1. We are subject to strict controls over what must be included in the report, how it must be presented and where in the document it is positioned. This can sometimes mean that elements of the report can appear repetitive, but we have worked closely with Communications colleagues and taken advice from NAO colleagues on how best to provide and cross-reference material.

3.2. The accounts are also subject to a detailed audit by the National Audit Office, subcontracted to KPMG, who take a close interest in the governance statement and check for a balanced and consistent report throughout.

Performance

3.2 The performance section is the first half of the report. We have worked hard to capture all that has been achieved by the Agency, including but not limited to objectives set out in the Corporate and Business Plan. We have also included the

high-level key performance indicators (KPIs) and a selection of specific KPIs to add context to the reporting. This section outlines the MHRA successes during the year and demonstrates that we have sustained performance improvements and continued to improve on our performance during the year.

Governance

3.3 The Governance Statement, particularly the section on internal controls, outlines the progress we have made this year in strengthening our governance framework and actions taken to address control issues identified during the year. This section also includes the Head of Internal Audit's annual opinion on the Agency, which remains a Moderate rating for the second consecutive year, following last year's increase from Limited.

Finance

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

3. Recommendation

4.1 The Board is asked to approve the draft Annual Report and Accounts 2025-26 and advise the Chief Executive as Accounting Officer to sign and submit them to the Comptroller and Auditor General for his approval, prior to laying them in both Houses and publishing ahead of summer recess.

Sarah Gilbert, Company Secretary
30/06/2026

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

7 July 2026

Title	An update on the strategic work performed by the MHRA's Criminal Enforcement Unit in response to the evolving illegal trade in human medicines.
Board Sponsor	Alison Cave
Purpose of Paper	To update the Board on the strategic direction of the CEU to protect the public from the threat posed by the illegal trade in human medicines.

Does the Board endorse the continued strategic importance of criminal enforcement as a core component of the MHRA's public protection mission.

1. Executive Summary

1.1. The MHRA's Criminal Enforcement Unit (CEU) is one of the Agency's principal public protection capabilities. It provides the specialist law enforcement function that protects patients from the criminal manufacture, importation and supply of illegal medicines and medical devices, safeguarding both public health and confidence in the UK's regulatory system.

1.2. Medicines crime has changed significantly over the past decade. What was once a relatively niche criminal market has evolved into a highly organised, digitally enabled and increasingly international form of serious organised crime. Criminal groups now exploit online marketplaces, social media platforms, encrypted communications and global supply chains to market and distribute illicit medicines directly to UK consumers. The rapid growth in demand for medicines purchased outside traditional healthcare settings, including GLP-1 weight-loss medicines, has accelerated these trends and created new opportunities for criminal exploitation.

1.3. The CEU has adapted to this evolving threat through intelligence-led investigations, digital disruption, prosecution, financial investigation and close collaboration with UK and international law enforcement partners. Its work has become increasingly sophisticated, reflecting the complexity of modern medicines crime and the need to tackle organised criminal networks rather than isolated offenders.

1.4. This paper provides an overview of the changing medicines crime landscape, the strategic role of the CEU in protecting public health, and the value it delivers in supporting the MHRA's statutory mission.

2. Introduction

2.1. The purpose of this paper is to provide the Board with an overview of the MHRA's Criminal Enforcement Unit, the evolving criminal threat relating to medicines and medical devices, and the contribution the Unit makes to protecting patients and maintaining confidence in the UK's regulatory framework.

2.2. The paper also highlights how the nature of criminality continues to evolve and the importance of maintaining a modern, intelligence-led enforcement capability equipped to respond to increasingly sophisticated organised crime.

3. Strategic Context – The Role of the Criminal Enforcement Unit

3.1. In 2017, the healthcare supply chain contributed £12.6bn to the UK economy and 196,000 jobs across the pharmaceutical, medical technology and biotechnology sectors. The sale of falsified and unauthorised medicines represents a significant risk to patient safety and the integrity of the UK pharmaceutical supply chain. One EU study estimated that counterfeit medicine is responsible for €10.2 billion in lost revenue annually for manufacturers and wholesalers within the EU.

3.2. Criminal enforcement is a core component of the MHRA's public protection mission. By identifying, disrupting and prosecuting those who deliberately circumvent medicines legislation for criminal gain, the CEU protects patients from unsafe products while supporting confidence in the UK's regulatory system.

3.3. Effective regulation depends on effective enforcement. Public confidence in the UK's medicines regulatory framework rests on the assurance that those who manufacture, import or supply medicines illegally will be identified and held to account. A credible enforcement capability also acts as a deterrent, reducing the attractiveness of the UK market to organised criminal groups.

3.4. The CEU therefore represents an essential operational capability within the MHRA, complementing the Agency's regulatory functions by addressing deliberate criminality that falls outside routine compliance activity.

The Changing Nature of Medicines Crime

3.5. The medicines market has undergone significant structural change. Demand for medicines purchased online has grown considerably, accelerated by digital healthcare, changing consumer expectations and the emergence of globally recognised products such as GLP-1 weight-loss medicines.

3.6. Criminal organisations have adapted rapidly. Today's medicines crime increasingly involves organised international networks using sophisticated online marketing, social media advertising, encrypted communications, complex logistics and financial crime techniques to reach UK consumers directly.

3.7. At the same time, fake medicines have become more convincing, online sales more accessible and criminal business models more resilient to traditional enforcement activity. This is not likely to be a temporary increase in criminality but a long-term shift in the operating environment.

3.8. The CEU has evolved considerably beyond a traditional regulatory enforcement team and today it delivers a highly specialised capability comprising:

- intelligence development;
- covert and overt investigations;
- online vigilance and digital disruption;

- financial investigation under the Proceeds of Crime Act;
- criminal prosecution;
- national and international operational cooperation;
- strategic disruption of organised criminal networks.

3.9. This integrated approach enables the MHRA to intervene across the full criminal lifecycle - from identifying emerging threats through to conviction and confiscation of criminal assets. The Unit has established strong operational partnerships with police forces, Regional Organised Crime Units, UK Border Force, the National Crime Agency, the Crown Prosecution Service and international regulators.

Public Value and Strategic Benefits

3.10. The CEU delivers value far beyond publicised individual publicised investigations. Its work protects patients from potentially dangerous illicit medicines and supports wider Government priorities in a number of ways. This includes:

- Targeting organised criminal groups involved in the manufacture, importation and supply of illicit medicines, contributing directly to the national response to serious organised crime.
- Supporting broader efforts to tackle online harms and protect consumers from fraudulent and dangerous activity, through enhanced monitoring and disruption of websites, social media accounts and online marketplaces.
- Using restraint, confiscation and asset recovery powers under the Proceeds of Crime Act, helping tackle illicit finance by denying criminals the proceeds of their offending.
- Preserving confidence in the regulated medicines market by protecting legitimate manufacturers, distributors and pharmacies from unfair and unlawful competition.

3.11. The CEU sets its strategic priorities to ensure the public continues to have access to safe and effective medicines, free from the dangers stemming from criminal activity. These priorities provide the framework for both strategic and operational decision-making, guiding proactive enforcement activity while ensuring an effective response to emerging threats and reactive demand.

3.12. Based on the current threat assessment, the CEU's key strategic priorities are to reduce the criminal threat from:

- falsified medicines entering the regulated supply chain;
- the illegal supply of the most harmful UK authorised medicines;
- the illegal supply of the most harmful unauthorised medicines.

3.13. Recent operational performance illustrates this impact. During the twelve months from April 2025 the CEU and its partners:

- seized more than **20 million** doses of illegally traded medicines with an estimated street value approaching **£45 million**;
- denied organised criminals access to more than **£2.1 million** through restraint and confiscation of criminal assets;

- prevented more than **two million** illegal e-marketplace listings from reaching consumers.
- disrupted more than **1,500 websites** and social media accounts;
- removed more than **1,200** illegal online advertisements.

3.14. The CEU also undertakes proactive patient and public outreach to reduce demand for falsified and unauthorised medicines by increasing awareness of the associated risks and encouraging safe purchasing behaviours. This includes promotion of the MHRA's FakeMeds campaign, providing media interviews, and contributing to national and local news coverage to educate the public about the dangers of obtaining medicines from unregulated sources.

3.15. The Unit also works closely with industry partners, professional bodies, healthcare organisations and digital platforms to strengthen reporting mechanisms, improve information sharing, encourage vigilance and support regulatory compliance. These partnerships enhance intelligence development, help disrupt illegal supply routes and reinforce confidence in legitimate medicines supply chains.

3.16. Taken together, these activities contribute directly to the MHRA's public protection mission by preventing harm, disrupting criminality and maintaining trust in the UK's medicines regulatory system.

Increasing Demands on the Enforcement Unit

3.17. The CEU is experiencing a sustained increase in demand, particularly in relation to online offending. Between August 2025 and January 2026, it received more than 1,000 online referrals, representing a 240% increase compared with the same period in the previous year. This growth reflects both a change in illicit online medicines markets and increasing public awareness of the Unit's key role in safeguarding health.

3.18. During the same period, the CEU managed almost 800 non-internet referrals, demonstrating that digital growth is adding to, rather than replacing, existing enforcement pressures.

3.19. These trends reinforce the need for an intelligence-led and digitally enabled operating model. Continued focus on specialist online investigative capabilities, analytical capacity and preventative interventions will be essential if the CEU is to maintain pace with the evolving medicines crime landscape and respond effectively to growing public demand.

Criminal Enforcement Case Studies

Case Study 1 – Operation Subaru: Tackling Organised Medicines Trafficking

Operation Subaru represents the largest criminal investigation ever undertaken by the MHRA's Criminal Enforcement Unit. In April 2025, following a complex intelligence-led investigation, 148 officers from the MHRA, police forces and the National Crime Agency were deployed in coordinated enforcement activity across four counties.

The operation resulted in the execution of 38 search warrants, the arrest of 14 suspects, and 20 individuals interviewed under caution.

The CEU operation led to the seizure of approximately four million doses of falsified and unauthorised medicines, including benzodiazepines, gabapentinoids and tapentadol, which are associated with substantial risks of harm when obtained outside legitimate healthcare channels. The investigation also resulted in cryptocurrency restraint orders exceeding £3.5 million, alongside the seizure of £158,000 in cash, gold bullion and other criminal assets, disrupting the financial networks underpinning the illicit trade.

Operation Subaru demonstrates the CEU's ability to lead complex, intelligence-led, multi-agency investigations that disrupt organised criminal networks, recover the proceeds of crime and protect the integrity of the UK medicines supply chain. It also illustrates the scale of criminality facing the UK medicines regulatory system and the importance of maintaining a strong criminal enforcement capability.

Case Study 2 – Disrupting Illegal Manufacture of Weight Loss Medicines

In May 2026, the Criminal Enforcement Unit dismantled a large-scale illicit manufacturing and distribution facility producing unauthorised weight loss medicines.

Two suspects were arrested following a coordinated operation with Northamptonshire Police, with MHRA enforcement officers seizing approximately 12,000 doses of medicines – including falsified retatrutide and tirzepatide - together with pharmaceutical substances, manufacturing equipment and packaging materials.

This was the MHRA's largest ever seizure of unauthorised weight loss medicines and forms part of an ongoing enforcement campaign targeting organised criminal groups exploiting growing public demand for these products.

By disrupting production at source, the operation prevented potentially harmful medicines from reaching patients and reinforced the MHRA's commitment to protecting public health.

Case Study 3 – Operation Pangea: Protecting the UK Border and Online Marketplace

As part of an international operation, the Criminal Enforcement Unit worked with UK Border Force and global enforcement partners to disrupt the illegal medicines trade across both physical and online supply routes.

In March 2026, during the two-week operation, more than two million doses of illicit medicines, with an estimated value of £4.6 million, were intercepted at the UK border, including large quantities of controlled drugs and prescription-only medicines.

In parallel, the CEU targeted websites, social media accounts and online marketplace listings facilitating illegal medicines sales.

The operation highlighted the CEU's contribution to international enforcement activity, its ability to combat increasingly sophisticated online criminality, and its role in protecting UK patients from unsafe medicines.

The CEU's Online Public Protection Activity

3.20. The global online trade in illicit medicines presents a significant and growing risk to public health. A large number of illegal online pharmacies are believed to operate worldwide at any one time, selling falsified and unauthorised medicines that may contain incorrect, contaminated or no active ingredients. Many of these websites operate outside UK jurisdiction, limiting the ability of law enforcement to remove them.

3.21. The CEU is currently testing a 'Not Recommended' online checking service, enabling the public to determine whether a medicines website has been assessed as unsafe before making a purchase. The service is designed to inform, educate and safeguard consumers, steering them away from fraudulent websites targeting UK patients.

3.22. A complementary online reporting facility will enable the public to report suspicious websites, social media accounts and online marketplace listings. Reports are reviewed by specialist internet investigators within the Criminal Enforcement Unit, generating valuable intelligence, identifying emerging threats and informing enforcement action where appropriate.

Strategic Outlook and Future Capability

3.23. The medicines crime landscape will continue to evolve as organised criminal groups exploit technological developments, changing consumer behaviour and emerging healthcare markets. Increasing digitisation, the use of artificial intelligence, encrypted communications and global e-commerce are likely to increase both the scale and sophistication of future criminality.

3.24. The CEU is therefore continuing to adapt its operating model to address both current and emerging threats. Alongside traditional investigations and prosecutions, the Unit will look to strengthen its overt and covert online capabilities, enhance digital monitoring of websites, social media platforms and online marketplaces, and develop new approaches to identifying and disrupting criminal activity at an earlier stage. Prevention initiatives, including the MHRA's online public protection services, complement enforcement action by reducing consumer exposure to unsafe medicines while generating valuable operational intelligence.

3.25. Looking ahead, the CEU anticipates continued growth in domestic ("home-grown") illicit production and assembly of medicines, alongside trafficking through international postal, courier and freight networks. Advances in manufacturing techniques, ready access to pharmaceutical ingredients and evolving online distribution models are lowering barriers to entry for organised criminal groups and creating new challenges for enforcement agencies.

3.26. Medicines crime is inherently international. Criminal networks routinely operate across multiple jurisdictions, exploiting differences in regulatory frameworks and the limitations of national enforcement powers. The CEU therefore plays a key role in international partnerships and operations, including coordinated activity with overseas regulators, customs authorities and law enforcement agencies. Such collaboration is essential to disrupting transnational supply chains, sharing intelligence and preventing unsafe medicines from reaching UK consumers.

3.27. Maintaining pace with this changing environment requires sustained investment in specialist digital investigation capabilities, advanced analytical and intelligence functions, and the ability to recruit, develop and retain highly skilled personnel. Continued organisational support will enable the CEU to modernise its operating model, strengthen prevention and disruption activity, and maintain a credible enforcement capability that protects patients and preserves confidence in the UK's medicines regulatory system.

4. Conclusion

4.1. The MHRA has established one of the world's leading specialist medicines law enforcement capabilities.

4.2. As medicines crime continues to evolve, the CEU will remain a critical component of the Agency's public protection mission, providing the specialist investigative,

intelligence and enforcement capability required to identify and disrupt increasingly sophisticated organised criminal activity.

4.3. Through its intelligence-led approach, operational partnerships and focus on patient safety, the CEU makes a significant contribution to protecting the public, maintaining confidence in medicines regulation and supporting wider government objectives to tackle serious organised crime.

5. Recommendation

5.1. The Board is invited to:

- note the changing nature of medicines and medical devices crime and the increasing sophistication of organised criminal groups;
- note the strategic role of the Criminal Enforcement Unit in protecting patients, maintaining confidence in the UK's regulatory framework and supporting wider law enforcement partners;
- support the continued evolution of the CEU towards a more digitally enabled, intelligence-led and prevention-focused operating model capable of responding to emerging threats; and
- endorse the continued strategic importance of criminal enforcement as a core component of the MHRA's public protection mission.

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