Medicines & Healthcare products Regulatory Agency

AGENDA FOR BOARD MEETING HELD IN PUBLIC

10:00 am – 12:30 pm on Tuesday 19 March 2024

Chair: Professor Graham Cooke

	AGENDA ITEM	**PURPOSE**	**PRESENTER**
10:00	INTRODUCTION		
	1. What is the purpose of this meeting, who are the Board Directors and are there any absences?	Information	Chair
	2. Are there any new Declarations of Interest?	Information	All
	3. What were the minutes and actions from the last meeting?	Approval	Chair
	AGENCY PERFORMANCE		
10:15	4. What are the most important current activities and priorities from the CEO's point of view?	Context	June Raine
10:30	5. What was the financial and people performance of the MHRA for this year up to 31 January 2024?	Assurance	Rose Braithwaite
10:45	6. How effectively is the MHRA addressing performance on established medicines, and how will a sustainable established medicines function be established?	Assurance	Julian Beach
11:00	7. How effectively is the MHRA maintaining its performance on clinical trials and how are plans for the new regulatory system progressing?	Assurance	Marc Bailey
	PATIENT SAFETY		
11:15	8. How is the Yellow Card Biobank pilot progressing, to help the Agency move towards our goal of personalised medicines?	Strategic Direction	Alison Cave
	SCIENCE, RESEARCH & INNOVATION		
11:30	9. How well are the Agency's innovation pathways facilitating access to new innovative products and how are these pathways being optimised?	Strategic Direction	Marc Bailey

	ASSURANCE		
11:45	10. What assurance can be provided by the Patient Safety and Engagement Committee?	Assurance	Mercy Jeyasingham
12:00	11. What were the results of the 2023 People Survey and what actions are being taken to address these?	Assurance	Liz Booth
	EXTERNAL PERSPECTIVE		
12:15	12. What questions do members of the public have about the items on this Board Meeting Agenda?	Assurance	Chair
12:30	CLOSE OF MEETING		

Item 2

MHRA Board Declarations of Interest – March 2024

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

The Board supports the Chief Executive Officer in the effective delivery of services and overall performance by providing leadership, developing strategy, advising on the delivery of policies, maintaining high standards of corporate governance, scrutinising performance and ensuring that controls are in place to manage risk.

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

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

Item 2

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

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

Item 2

Name and MHRA Role	Name of Other Company or Organisation	Nature of interest	Paid	Current
	EU Innovative Health Initiatives (IHI)	Advisory Expert for this EU public-private partnership funding health research and innovation funded by European Commission	Yes	Yes
Laura Squire OBE Chief Healthcare Quality & Access Officer	None	N/A	N/A	N/A
Michael Whitehouse OBE Non-Executive Director & Interim Co-Chair	South East Coast Ambulance Services NHS Foundation Trust	Deputy Chair & Senior Independent Non-Executive Director Chair of Audit Committee Chair of Charities Committee	Yes	Yes
	Cruse Bereavement Charity	Trustee Chair of Finance and Audit Committee	No	No
	Republic of Ireland Audit Office	Member of Audit Committee	No	No
	National Audit Office	Board Member and Chief Operating Officer until 17 April 2017	No	No
Glenn Wells Chief Partnerships Officer	None	N/A	N/A	N/A

Medicines and Healthcare products Regulatory Agency

Minutes of the Board Meeting Held in Public on 16 January 2024

(10:0am – 12:00pm)

MHRA, 10 South Colonnade, Canary Wharf E14 4PU

Present:

The Board

Professor Graham Cooke	Non-Executive Director & Interim Co-Chair
Dr June Raine DBE	Chief Executive (remotely via Zoom)
Dr Marc Bailey	Chief Science, Research & Innovation Officer
Dr Junaid Bajwa	Non-Executive Director
Julian Beach	Interim Executive Director, Healthcare Quality & Access
Liz Booth	Chief People Officer
Rose Braithwaite	Chief Finance Officer
Amanda Calvert	Non-Executive Director & Interim Co-Chair
Dr Paul Goldsmith	Non-Executive Director
Claire Harrison	Chief Digital & Technology Officer
Mercy Jeyasingham	Non-Executive Director
Raj Long	Non-Executive Director
Dr Glenn Wells	Chief Partnerships Officer
Michael Whitehouse OBE	Non-Executive Director

Others in attendance

Rachel Bosworth	Director of Communications and Engagement, MHRA
Carly McGurry	Director of Governance, MHRA
Natalie Richards	Head of the Executive Office, MHRA
James Pound	Deputy Director, Standards & Compliance, MHRA (for item 6) (for item 6)
Kathryn Glover	Deputy Director, Medicines Regulation and Prescribing, DHSC

INTRODUCTION

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

1.1 Professor Graham Cooke opened the meeting. The Chair set out his expectations and priorities for this Board meeting held in public which was being live streamed to the registered audience and recorded. The Chair welcomed everyone to the meeting, including a broad range of observers including patients and members of the public,

representatives of patient groups, healthcare professionals, government officials, industry, media and MHRA staff.

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

2.1 Apologies were received from Alison Cave, Chief Safety Officer; Haider Husain, Non-Executive Director; Alison Strath, Chief Pharmaceutical Officer for Scotland; Greig Chalmers, Head of Chief Medical Officer's Policy Division in the Scottish Government; and Cathy Harrison, Chief Pharmaceutical Officer for Northern Ireland.

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

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

3.1 The Board reviewed the minutes and actions from the last meeting and updates were provided.

AGENCY PERFORMANCE

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

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

(i) Science, Research and Innovation – including latest updates on Clinical Trials; the Innovative Devices Access Pathway (IDAP); Patient and Public Involvement for lab-based researchers' workshops; patient engagement on Group B streptococcus; the nOPV2 polio vaccine; zika virus; pandemic preparedness; biosimilars; cell and gene therapies; and grant funding successes;

(ii) Healthcare Access – including updates on performance on established medicines; a new product for advanced melanoma; the launch of the new International Recognition Pathway; the Windsor framework; the British Pharmacopoeia; the MedTech roadmap; and designation of two new Approved Bodies for medical devices;

(iii) Patient safety – including updates on valproate; aripiprazole and impulse control disorders; the work of the Criminal Enforcement Unit; vitamin B12 and cobalt allergy; long COVID; and carbomer eye gels;

(iv) Digital & Technology – including updates RegulatoryConnect; SafetyConnect; international recognition enhancements; and Freedom of Information (FOI) case management;

(v) Partnerships – including updates on the Access Consortium Promise Pathway; Centres of Excellence in Regulatory Science and Innovation (CERSIs); and information sharing;

(vi) Dynamic Organisation – including updates on a leadership event for staff; the Civil Service Staff Survey results; the TOPRA innovation award; and CPRD and global AI cardio-health challenge.

4.2 The Board thanked Dr Raine for her report and provided comments relating to the Windsor framework and disapplication of the Falsified Medicines Directive – the Board agreed the enforcement strategy should be reviewed in the light of the Windsor Framework and the FMD; Approved Body capacity in the UK; improving confidence and transparency of leadership decision making; the Agency's priorities regarding the CERSIs; and real world data. The Board noted the report.

Addition to action 106: 16/01/24: The enforcement strategy should be reviewed in light of the Windsor Framework and the Falsified Medicines Directive.
Alison Cave

Item 5: What was the financial and people performance of the MHRA for this year up to 30 November 2023?

5.1 The Board considered a report describing the financial and HR performance of the MHRA for this year up to 30 November 2023. The Board noted that the financial performance at the end of November shows a Year to Date (YTD) Resource underspend of £10.7m compared to budget and a Capital underspend of £4.9m compared to budget. The latest forecast shows that by the end of the year we are expecting a Resource surplus of £7.9m, a reduction of £1.5m compared to the last finance report, whereas the Capital position is much closer to budget with a forecast underspend of only £0.5m. The forecast underspend has reduced due to the inclusion of most the extra spend bids approved by ExCo, however lower staff costs and higher income means that the forecast surplus has not reduced as much as anticipated. Hence, there is still financial headroom for additional Resource spending as well as the agreed return of unused funding to DHSC.

5.2 The Board noted the report and provided comments relating to the increased spend bids; ensuring the budget and financial reporting is linked to the Agency's statutory functions; revising the performance measures; ensuring a baseline is established to measure performance against; staff performance measures; working with the DHSC accounting department; a request for further details on the decrease in CPRD income; and understanding the pipeline of work to inform workforce planning.

Action 111: The budget and financial reporting should be linked to the Agency's statutory functions in the Performance Report. Provide the Board with further details on the decrease in CPRD income. ***Rose Braithwaite***

Item 6: How effectively is the MHRA maintaining its performance on clinical trials and how are plans for the new regulatory system progressing?

6.1 The Board considered a paper describing how the Agency is maintaining performance on clinical trials, and the plans for a new regulatory system. The Board reviewed the new operating model for regulation of clinical trials including the regulatory strategy, capacity/capability considerations, legislative, cost/fee, communications and digital infrastructure elements. The Board noted that these proposals also address how the Agency will meet the objectives of the UK Government Life Sciences Vision, the outcomes of the Lord O'Shaughnessy review and act as an enabler to UK life sciences.

6.2 The Board considered the report and provided comments relating to the lifecycle approach and integration with the remainder of the regulatory pathway and ILAP; ensuring continuous performance and understanding the pipeline; skills capability building; understanding the key risks to delivery; continuous improvement; workforce capacity and capability; addressing the recommendations in the O'Shaughnessy review; patient recruitment; providing upstream scientific advice; internal redeployment; and ensuring research charities and organisations are included in stakeholder engagement; it was noted that work is ongoing to ensure the stakeholder group is representative.

6.3 The Board provided further comments relating to creation of guidance on the new legislation; ensuring there are no unintended outcomes from resource deployment; connecting with the international recognition procedure; taking a longitudinal approach to this redesign; continual monitoring of the assessment throughput to mitigate the risk of any future backlogs building; interlinkages; and the notification scheme. The Board expressed their thanks for this comprehensive update and requested a further paper at an upcoming Board meeting with more operational detail, including a clearly defined budget; how this will be resourced; and a demand estimation.

Addition to action 101: Clinical Trials: Present a paper to the Board containing operational detail including a clearly defined budget; how this is resourced (skill and headcount); and demand estimation over the next year and beyond.

Marc Bailey

HEALTHCARE ACCESS

Item 7: How is the system of international recognition enabling access to medicines for UK patients?

7.1 The Board considered a paper describing how the new system of international recognition is enabling access to medicines for UK patients. The International Recognition Procedure (IRP) Framework provides an approach which allows the MHRA to take into account the decision-making of trusted regulatory partners thereby creating another pathway for streamlined access to medicines for the benefit of UK patients. The Board considered the key activities of MHRA, the challenges identified so far, and next steps.

7.2 The Board provided comments relating to understanding industry pipelines to forecast levels of work; provision of webinars, guidance and other educational materials; ensuring ongoing active dialogue with industry to obtain their feedback; sharing data between regulators; and pharmacogenomics. The Board thanked Mr Beach for the paper and requested a further update on progress with implementation of the IRP shortly.

Action 112: Provide the Board with an update on the progress with the implementation of the International Recognition Procedure.

Julian Beach

ASSURANCE

Item 8: What assurance can be provided by the Patient Safety and Engagement Committee?

8.1 The Board considered an assurance report from the Patient Safety and Engagement Committee (PSEC). The PSEC met on 7th November 2023 and discussed the Patient Involvement Strategy; CPRD's Research data governance process; and future topics for the committee. The Board considered the report and provided comments relating to risk communications; the Board noted the report for assurance.

Item 9: What assurance can be provided by the Audit and Risk Assurance Committee?

9.1 The Board considered an assurance report from the Audit and Risk Assurance Committee (ARAC). The ARAC met on 1 December 2023 and reviewed progress in addressing issues identified by the Health and Safety Executive (HSE); the Agency's financial position; five reports from Internal Audit; and undertook an assessment of the completeness of the Agency's risk register together with a number of reports supporting the MHRA's governance. The Board provided comments relating to the HSE inspection of the South Mimms site and implementing the recommendations for improvements, noting the importance that this must be resolved quickly; an audit on cyber security; and RegulatoryConnect. The Board noted the report for assurance.

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

10.1 The Board considered an assurance report from the Organisational Development and Remuneration Committee (ODRC). The ODRC met on 18th December 2023 and reviewed the progress made in delivery of the Agency's improved service processes; what progress has been made in delivery of RegulatoryConnect; and reviewed feedback from the Agency Leadership Event held on 30th November 2023. The Board provided comments relating to resource; process and technology infrastructure improvements; ensuring there is adequate programme and change management in place; addressing backlogs; and establishing baselines. The Board noted that a review will be undertaken of performance in all areas of the Agency's statutory functions to identify if there are any backlogs; and an action plan will be presented to the Board. The Board noted the report for assurance.

Action 113: Undertake a review of performance in all areas of the Agency's statutory functions to identify if there are any backlogs; and present the Board with an action plan to address this. ***Glenn Wells***

EXTERNAL PERSPECTIVE

Item 11: What questions do members of the public have for the MHRA Board?

11.1 The Board answered a range of questions which had been submitted by members of the public before and during the meeting. These questions concerned the IRP; polio vaccine; and health and safety.

ANY OTHER BUSINESS

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

ACTIONS FROM MHRA BOARD MEETING IN PUBLIC – 16 January 2024

The actions highlighted in red are due this month

Action Number	Action	Owner	Date	Status
Carried Forward from previous meetings				
29	16/03/21: Present an Agency Science Strategy to the Board. 15/11/22: Revise the Science Strategy to include clear prioritisation; and greater inclusion of in-house expertise on behavioural science with a complementary expert group. Include vaccines work as a specific area of expertise, alongside biologics and the UK Stem Cell Bank, to create a distinctive offering to make the UK an internationally recognised centre of excellence in this field. A review of scientific committees should also be undertaken. Present a further update to the Board in March 2023. 21/03/2023: Science Strategy to be presented to the Board in July. 11/07/23: Present an update to the Board on progress against each of the themes in the Science Strategy at the end of 2023.	Marc Bailey	~~21/09/21~~ ~~16/11/21~~ ~~17/05/22~~ ~~15/11/22~~ ~~21/03/23~~ ~~11/07/23~~ ~~12/12/23~~ 21/05/24	
70	18/01/22: Develop and present a Data Strategy to the Board.	Alison Cave & Claire Harrison	~~17/05/22~~ ~~18/10/22~~ ~~15/11/22~~ ~~18/04/23~~ ~~12/12/23~~ ~~19/03/24~~ 18/06/24	
73	15/02/22: Develop a Sustainability Strategy.	Glenn Wells	~~17/01/23~~ ~~16/01/24~~ ~~19/03/24~~ 09/07/24	
101	11/07/23: Action: Present an update to the Board on the performance and proactive communications and engagement activities related to clinical trials which will maintain	Marc Bailey	~~21/11/23~~ ~~16/01/24~~ 16/04/24	

	trust in the Agency from industry and research customers. 19/09/23: Provide an update to the Board in November 2023 on the progress of the new clinical trial process pilot. Prepare a plan for training and upskilling of staff to increase resilience across the Agency. 21/11/23: Provide the Board with an update on the new proposed Clinical Trials process. Undertake a review of any other backlogs in the Agency. 16/01/24: Present a paper to the Board containing operational detail including a clearly defined budget; how this is resourced (skill and headcount); and demand estimation over the next year and beyond.			
104	19/09/23: Develop a reputation strategy for the Agency with reputation index measures.	Rachel Bosworth	~~21/11/23~~ ~~19/03/24~~ 21/05/24	
105	21/11/23: Provide the Board with an update on how information sharing is managed across the healthcare system and how this aids international recognition processes.	Glenn Wells & Julian Beach	16/04/24	
106	21/11/23: Provide the Board with an update on the work of the Criminal Enforcement Unit. 16/01/24: The enforcement strategy should be reviewed in light of the Windsor Framework and the Falsified Medicines Directive.	Alison Cave	21/05/24	
107	21/11/23: PSEC to review the electronic Patient Information Leaflet	Mercy Jeyasingham / Alison Cave	19/03/24	
108	21/11/23: Provide the Board with an update on the Trusted Research Environment	Alison Cave	~~19/03/24~~ 09/07/24	
109	21/11/23: Provide an update on the People Survey results to the Board	Liz Booth	19/03/24	On agenda
110	21/11/23: Provide a further update on the progress of the Health, Safety & Wellbeing Strategy to the Board.	Marc Bailey	21/05/24	

New Actions				
111	16/01/24: The budget and financial reporting should be linked to the Agency's statutory functions in the Performance Report. Provide the Board with further details on the decrease in CPRD income.	Rose Braithwaite	16/04/24	
112	16/01/24: Provide the Board with an update on the progress with the implementation of the International Recognition Procedure.	Julian Beach	16/04/24	
113	16/01/24 Undertake a review of performance in all areas of the Agency's statutory functions to identify if there are any backlogs; and present the Board with an action plan to address this.	Glenn Wells	19/03/24	Completed

Medicines & Healthcare products Regulatory Agency

BOARD MEETING IN PUBLIC

19th March 2024

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

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

'TOP 10' HEADLINES

- The Agency's licensing performance for established medicines remains a top priority, process redesign is under way, and assessment resources are being increased
- Key performance indicators for clinical trials applications continue to be met and we have collaborated with the GREAT campaign to showcase the UK environment for developers
- We received 81 applications for the pilot of the Innovative Devices Access Pathway and selected 8 including a test for Alzheimer's disease and software as a medical device
- We have authorised the first product, a denosumab injection formulation, via the International Recognition route following 9 initial marketing authorisation applications
- The polio outbreak first detected in London wastewater samples in 2022 was declared over by the WHO in January - the work of our Polio Laboratory was central to this finding
- Funding has been achieved for a project which will improve the ability to detect bacterial gene sequence mutations that confer resistance to selected antimicrobials
- We produced and cascaded a letter from all four Chief Medical Officers regarding the harms of valproate - this will bolster the awareness of strengthened regulatory measures
- We coordinated communications to announce expansion of the Yellow Card Biobank pilot studies to include genetic indicators linked to adverse reactions with stroke medicines
- We are improving our cyber resilience, deploying new technologies, processes and capabilities addressing recommendations from the National Cyber Security Centre
- We hosted a visit by the US FDA to discuss pivotal topics shaping regulation globally: supply chain resilience, evidence generation and artificial intelligence medical devices.

SCIENCE, RESEARCH, AND INNOVATION

Clinical trials

1.1 The Agency continues to meet the Key Performance Indicators for clinical trials approvals. Average timescales for clinical trial assessments in February 2024 were within statutory timeframes, 29 days for initial applications and 27 days for amendments. We are now driving forward our work to deliver our reform of the clinical trials regulations in 2024, following on from the publication of the Government response to consultation on legislative proposals for clinical trials in 2023. This is alongside the important ambitions for clinical research set out in the Life Sciences Vision and the focus brought to commercial clinical trials by the Lord O'Shaughnessy review.

GREAT Clinical Trials Campaign

1.2 As part of MHRA's collaboration with Department of Business and Trade on the “GREAT clinical trials” campaign, a series of three podcasts were published by New Scientist in February 2024. The podcast guests including James O'Shaughnessy and the MHRA Deputy Director of Clinical Investigations and Trials alongside a colleague from industry talked about the UK as an attractive destination for clinical trials and significant recent improvements made by the MHRA to contribute to that. The James O'Shaughnessy podcast was shared on MHRA's LinkedIn page to positive response including 13 reposts, a high level of engagement. Two other podcasts including the one from our Deputy Director of Clinical Investigations and Trials along with videos and articles will be released throughout March 2024.

Innovative Devices Access Pathway pilot

1.3 The Innovative Devices Access Pathway (IDAP) pilot is an initiative to bring transformative medical technologies to market to address unmet clinical needs. The IDAP is delivered in partnership with DHSC, the Office of Life Sciences, NICE, Health Technology Wales, Scottish Health Technologies Group and NHS England. The pilot received 81 applications and IDAP partners and patient and public representatives participated in the selection panel that determined which innovative and transformative medical devices will enter the pilot pathway according to the published criteria. On 14 February 2024 the Government announced the eight new medical devices selected for the pilot including a test for Alzheimer’s disease and software as a medical device. These eight pilot products will receive support from IDAP partners at key stages of their product development. The insights gained during the pilot will be crucial in shaping the future direction of IDAP. The aim of the pilot is to test the main elements of the pathway and to provide learning and feedback that helps to build the future IDAP.

Quality Assurance audits in Science, Research and Innovation

1.4 The SRI Quality Assurance team has managed two external audits. The UK Accreditation Service (UKAS) had audited SRI against the ISO17025 standard in October 2023 covering the competence of testing and calibration laboratories. This standard covers the medicines control testing activities carried out in SRI at the South Mimms site. UKAS confirmed that all improvement actions from the latest audit had been closed and that our accreditation to ISO17025 was maintained. This external endorsement indicates the robustness of the quality system managed by the Health and Safety and Quality Assurance team supporting this standard, and the dedicated work by the staff in the Control Testing Function and those functions supporting these activities. The second Special Audit was carried out by Underwriters Laboratories (UL) for our ISO 13485:2016 certification that covers provision of medical devices i.e. our diagnostic standards. There will be a further effectiveness review by UL in November 2024 to ensure changes relating to previous non-compliances have been fully embedded. This achievement reflects the hard work by the SRI QA team, and scientific and standards production staff.

Cell and Gene therapy

1.5 The European Directorate for the Quality of Medicines and Healthcare (EQDM) is a leading organisation ensuring quality standards for medicines and their use through development of written guidance and standards to be applied worldwide. The gene therapy products working group is a panel of global experts, which meets three times a year to write and edit guidance for the manufacture of gene therapy medicinal products. The Head of Gene therapy in the R&D Biotherapeutics and Advanced Therapies team attended a two-day meeting of the working group and played a key role in developing collaborative and harmonised guidance

with a global outreach - 'Gene therapy medicinal products for human use', ahead of publication by the end of 2024.

Innovation Hubs for Gene Therapies

1.6 Established in 2021 the Innovation Hubs for Gene Therapies aim to accelerate academic development of novel gene therapies across the UK, by offering access to GMP facilities and in-house expertise. The coordinating committee meets four times a year and is responsible for ensuring key aims are delivered by the hubs, develop strategic direction and engage with the wider gene therapy manufacturing community. The Head of Gene Therapy in the R&D Biotherapeutics and Advanced Therapies team is a committee member and ensures the hubs are updated on developments within gene therapy via written and physical standardisation.

Regulatory Sciences for Advanced Gene and Therapies training

1.7 The Head of Gene Therapy in the R&D Biotherapeutics and Advanced Therapies team gave an external presentation at the Regulatory Sciences for Advanced Gene & Cell Therapies, UCL, 'The current landscape of gene therapy products and standardisation.' Training course. This two-day training course delivers up to date information surrounding the regulatory challenges for cell and gene therapy medicinal products. Course content was delivered by experts from UCL, the MHRA and the Cell and Gene Therapy Catapult.

Neurodegeneration cross-Agency work

1.8 Members of the R&D and HQA Diagnostics teams (also members of the Agency's Dementia Mission Working Group) visited UCL to meet Professor Henrik Zetterberg, head of the Biomarker Factory which is part of the UK Dementia Research Institute (headed by Professor Siddharthan Chandran). This has started an important dialogue on the role of the MHRA Science Campus in biological standards and assays for biomarkers of neurodegenerative disease, as well as signposting the group to the MHRA for regulatory advice.

Anti-microbial resistance grant funding

1.9 The R&D Diagnostics Team has been successful is securing new grant funding from Innovate UK through the Knowledge Assets Grant Funding Winter 2023 call. The application entitled, "Improved detection and surveillance of Antimicrobial Resistance (AMR) genes by Next Generation Sequencing (NGS) through biological standardisation" will support an additional post in the AMR team in Diagnostics for 18 months starting in May 2024. The project aims to improve the comparability of NGS-based analysis of clinical samples for the detection of mutations in bacterial gene sequences that confer resistance to selected antimicrobials.

High throughput sequencing analytics

1.10 The head of R&D Bioinformatics is an Expert member of the EDQM High-throughput Sequencing expert working group. The group has successfully completed a Pharmacopoeia document, which is ready for publication. (HTS chapter 2.6.41 which now includes a reference to ICH Q5A guideline for considerations on the replacement of in vivo and in vitro tests for extraneous agents by HTS).

Vesicular vaccines

1.11 On 29 February 2024 the R&D team head attended the UKHSA Vaccine Preventable Invasive Bacterial Infections Forum whose role is to advise the UKHSA Vaccine Programme Board on all scientific and policy matters pertaining to meningococcal, haemophilus and pneumococcal infection using scientific evidence. The UKHSA meningitis reference unit and UK paediatricians and epidemiologists attended. Epidemiology data and other pertinent issues were presented and experts provided an independent perspective. At this meeting

guidelines for public health actions following meningococcal disease outbreaks were revised with input from the SRI expert on vaccine safety data and potential support that the MHRA could provide with issues with reference materials for point-of-care diagnostics.

Polio

1.12 The circulating vaccine derived polio Type 2 (cVDPV2) outbreak first detected in London wastewater samples in 2022, was declared over by the WHO in January 2024, meaning that the UK is no longer considered a polio-infected country. The work of the MHRA Polio Laboratory was central and instrumental for this finding.

Rotavirus

1.13 Scientists in the R&D Viral Vaccines group completed testing and generated a report on behalf of the WHO for a prequalified rotavirus vaccine.

Influenza

1.14 The MHRA Influenza WHO Essential Regulatory Laboratory (ERL) played a key role in the WHO influenza vaccine composition consultation in February. The WHO expert committee recommendation was that 'the influenza vaccine for the next northern hemisphere (NH) winter should remain unchanged from the vaccine for the southern hemisphere 2024 influenza season; however, relative to the current NH winter vaccine, one of the three or four components of the vaccine will be updated.' The ERL contributed data on human serology from panels of pre- and post-vaccine volunteer samples tested against currently circulating viruses. Our ERL role also includes provision of candidate vaccine viruses which manufacturers use to produce inactivated vaccines, and of reagents for vaccine potency testing. Timely supply of these reagents to manufacturers and national control laboratories worldwide is crucial to ensure vaccines are available this autumn. The MHRA-hosted Influenza Hub, a central information repository, was praised at the WHO meeting for its usefulness to the influenza vaccine community.

Standards sales

1.15 Income from standards sales for 2023-24 now exceeds the total income for 2022-23. There was an email backlog which has now been cleared with all emails being actioned within the three-day target. The backlog of sales emails more than three days old was 1140 at beginning of June 2023, reaching as high as 1500 in Mid-October 2023. An action plan was developed and implemented, including significant process improvements and a move to paperless order processing, together with a programme of cross training amongst Sales team staff allowing greater resource flexibility. We are now back to a steady state of around 200 emails (work on hand), with as of 1 March 2024, none more than three days old.

HEALTHCARE ACCESS

New Medicines

2.1 We have approved a number of important new medicines:

- Etrasimod (Velsipity) to treat people with moderately to severely active ulcerative colitis
- Piflufolastat (^{18}F) (Pylclari) as a diagnostic tool for people with suspected or known prostate cancer
- Rozanolixizumab (Rystiggo) to treat adults with generalised myasthenia gravis, an autoimmune disease that causes muscle weakness
- Rubidium (Rb82) Generator (RUBY-FILL) as a diagnostic tool for imaging of the heart, to aid in the diagnosis or assessment of suspected coronary heart disease

- Ganaxolone (Ztalmy) as the first anti-seizure medication in the UK to treat cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD)
- Quizartinib (Vanflyta) to be used alongside chemotherapy as first line treatment for adults who have acute myeloid leukaemia (AML).

Life Sciences - Spring budget

2.2 As part of the Chancellor's Spring Budget, £45million was allocated to fund medical research to develop new medicines for diseases like cancer, dementia and epilepsy. The MHRA will be playing its role in ensuring that products undergoing assessment are safe and effective. The input from our agile Biologics team and our proactive inspectors will be key to unleashing the potential of the new £650m vaccines hub in Speke, not only for UK, but world-wide.

Population health

2.3 New processes from 1 March 2024 are reducing the backlog of applications for established medicines, using risk-based criteria. A targeted checklist assessment report has been adopted for non-complex applications. Targeted multi-disciplinary assessment reports are being undertaken for applications of medium complexity. Complex applications will be routed for expert advice as appropriate. The backlog is now at 978 from the original backlog of 1167 on 9 January 2024. Performance for variations has improved in January and targets have been met. This is notable given the increased output in other assessment areas and reflects the dedication of the assessors. A number of applications have been determined within statutory timelines for expedited products based on public health need.

Patient and public involvement in licensing pathways

2.4 The MHRA met with Forgotten Lives UK to discuss licensing pathways. We heard a powerful testimony about the ongoing impact of COVID-19 on the lives of immunocompromised patients and their families, and the need for more effective prevention. We emphasised our commitment to putting the patient at the centre of what we do and providing opportunities for patient involvement in the pre-authorisation space.

International recognition applications

2.5 Nine initial marketing authorisation applications have been received via this new route by end of February 2024. On 29 February 2024, the MHRA authorised the first product via this route in 30 days, a new prefilled syringe formulation of denosumab (Xgeva). This is a treatment used in adults to prevent serious bone-related complications caused by bone metastasis and to treat giant cell tumour of bone in adults and adolescents. The new formulation can be self-administered, providing a more convenient option for patients.

Electronic patient information

2.6 On 5 February 2024 we attended a productive all-day workshop with the electronic patient information task force, industry representatives, patient groups, pharmacists and GPs. This also included a presentation from the Patient Safety Commissioner Dr Henrietta Hughes on her thoughts on the needs of patients. This was a lively review, which considered the concept of 'how not to leave anyone behind' as we explore moving to digital first patient information with the removal of patient information leaflets from packages.

Advertising and promotion of medicines

2.7 The MHRA has completed its review of the ABPI (Association of the British Pharmaceutical Industry) and PMCPA (Prescription Medicines Code of Practice Authority) consultation on changes to the Code of Practice for the Pharmaceutical Industry, which encompasses the advertising and promotion of medicines in the UK. A number of comments have been submitted with the aim of maintaining the effectiveness of the self-regulatory system.

Medical Devices International Recognition

2.8 A workshop for medical devices International Recognition was held on 26 January 2024 that informed the future recognition of approved devices from comparable regulator countries.

Medical Devices Approved Bodies

2.9 Two new Approved Bodies were designated in January 2024, increasing capacity for supply chain in the UK (now a total of nine Approved Bodies). LNE-GMED UK has been designated as a UK Approved Body to assess and certify general medical devices in accordance with Part II of the UK Medical Devices Regulations 2002. Scarlet NB UK has been designated with a focus on assessing and certifying software and AI as a medical device.

Medical Devices Regulations

2.10 The Medical Devices (In Vitro Diagnostic Devices etc.) (Amendment) Regulations 2023 was agreed by Parliament and comes into effect on 21 March 2024. It gives the MHRA additional powers to enforce the EU IVD Regulations in Northern Ireland to protect patients and public.

British Pharmacopoeia

2.11 The British Pharmacopoeia (BP) has launched an environmental sustainability information pack on the BP website to provide an overview of key resources and case studies on how to improve the environmental impact of laboratories and quality control testing. This supports wider Agency and UK government objectives on sustainability.

Single Inspection Programme

2.12 Along with TGA and Health Canada, we have launched a pilot Single Inspection Program, a global approach to GMP inspections of third country manufacturers. This pilot aims to establish a coordinated global approach to GMP inspections of foreign manufacturing sites of common interest. Using our collective inspection resources, each authority has agreed to cover the scope of the other where possible, reducing the need for multiple inspections of the same site. This builds on the success of our existing collaborative GMP arrangements and will allow for more efficient inspection reliance processes, reduced regulatory burden on industry and enhanced collaboration in our regulatory oversight of global supply chains.

Tripartite Symposium

2.13 In February 2024 we delivered the tripartite symposium on GCP and GPvP with colleagues from US Food and Drug Administration (FDA) (host country) and Health Canada. The topics covered included compliance and technical aspects of Good Clinical Practice (GCP), Bioequivalence (BE) and Good Pharmacovigilance Practice (GPvP). Presentations were given both in person and via recordings submitted prior to the event with inspectors also taking part in panel sessions on all three days of the event. This was the third combined event for GCP and BE since 2018 and is now a regular highlight of the event calendar providing a unique opportunity for stakeholders to engage directly with the three agencies. There were over 200 in-person attendees on each day along with over 13,000 virtual participants from across the world. The symposia form a part of pillar two of the compliance strategy to deliver upstream interventions to prevent non-compliance by educating stakeholders as well as pillar five on international collaboration through a parallel programme of bilateral meetings held with other regulators.

E-Cigarettes

2.14 The e-cigarettes team met with HMRC and Defra on proposed changes associated with the banning of disposable vapes and the introduction of a tax levy on Tobacco containing products. Both changes will affect the way the MHRA undertakes work in this area, and its wider functions.

Mental health

2.15 The Guardian/Observer published an article on Declaration for Mental Health Treatment, which featured an interview with the lead for the project for the MHRA.

PATIENT SAFETY

Valproate safety measures

3.1 Following extensive work with the four Chief Medical Officers' offices, we produced and cascaded a letter from all four Chief Medical Officers regarding the harms of valproate. This will greatly bolster the awareness of the strengthened regulatory measures for valproate.

Codeine linctus

3.2 We coordinated the announcement of the reclassification of codeine linctus cough medicines from pharmacy availability to prescription-only through a Drug Safety Update bulletin, Public Assessment Report, Consultation Outcome report, and Press Release. This announcement was widely publicised across national news and received strong support from pharmacists.

Yellow Card Biobank

3.3 We coordinated a comprehensive communications package to announce the expansion of the Yellow Card Biobank pilot programme to include investigation of genetic indicators linked to adverse reactions associated with direct-acting oral anticoagulants used for prevention of stroke securing press coverage, activating social media and stakeholder engagement activity and preparing for a further training event for healthcare professionals in March 2024.

Spinal rods

3.4 The MAGnetic Expansion Control X (MAGEC X) system is an orthopaedic spinal rod for use in skeletally immature patients less than 10 years of age. It helps correct spinal deformities as the child grows, minimising the need for repeated invasive surgeries to correct the spinal curve. Following an extensive assessment by the MHRA, as of 23 February 2024, the UK suspension of the MAGnetic Expansion Control (MAGEC) System (modified MAGEC X system only) has been lifted. The MHRA is satisfied that the manufacturer, NuVasive Specialized Orthopedics (NSO), has put in place sufficient measures to provide reassurance about the safety of this device.

PARTNERSHIPS

Return to Green initiative

4.1 The cross-Agency Return to Green (RtG) programme has been established to eliminate backlogs in frontline service activities and to put in place interventions that will not only remove the backlogs but will also lead to sustainable services. The programme is being managed as a portfolio to ensure that any lessons learned from one focus area can quickly be transposed to others. It is building on the lessons learnt in the clinical trial initiative. The most advanced of the focus areas are Established Medicines and Safety Variations as these are subject to dedicated projects and these commenced before the wider RtG programme was created. To complement these two workstreams, the RtG programme has

established a small team who are engaging across the portfolio. The Executive team has recently indicated that the focus of the work of the programme team should be to identify interventions, rapidly check these against the medicines and medical devices legislation and implement them as soon as is practical according to agreed timelines.

International – FDA visit

4.2 On Monday 19 February 2024, representatives from the US FDA and the MHRA convened to discuss pivotal topics shaping the regulatory landscape on a global scale. The meeting, characterised by collaborative exchange and mutual commitment to advancing public health, addressed several critical areas of focus including clinical trials regulation, evidence generation, combatting misinformation, collaboration in medical device regulation and promoting global supply chain resilience. The FDA and the MHRA reaffirmed their commitment to ongoing collaboration and information exchange, recognising the imperative of adapting regulatory frameworks to meet the evolving needs of patients, healthcare providers, and industry stakeholders.

DIGITAL AND TECHNOLOGY

RegulatoryConnect

5.1 The RegulatoryConnect Programme Business Case was approved by Minister and is now with Treasury for final approval. All release 1 deliverables are on track for go-live by end March 2024. Key deliverables include the self-service portal enabling customers to track their applications and see granted data and documents, and a new eCTD tool improving our efficiency in the management of electronic documents. Communications are starting to increase in frequency, and a recent webinar for industry stakeholders was well attended with 615 industry representatives. Feedback received was very positive. Release 2 continues to aim for November 2024 delivery and has a plan to recover delays. Data Migration is the other key area of focus with the business requirements due in April. Work relating to post Release 2 functionality continues at pace.

Safety Connect

5.2 User Acceptance Testing (UAT) for Phase 2 Medicines is on track for completion at the end of February 2024. Work on the signal scores with the MHRA epidemiology team is progressing. Development work on Phase 3 Haemovigilance is in progress. Our supplier continues to progress with development of the Vigilance Hub platform and report schema. Further tasks are currently being planned into the data migration work to support additional identified business needs. These tasks facilitate business continuity as do a substantial number of incident reports which are "inflight". Data migration into the Vigilance Hub is also required so that reporting organisations can have access to reports submitted on Lotus Notes.

Freedom of Information case management system

5.3 Project delivery on the FOI case management system is progressing, and the team is working with the selected supplier to meet the financial year end commitment for go-live by the end of March 2024. System configuration work is currently in progress and both system testing and user training are planned. The work to deliver the project into live service management is also on track.

Intelligence and Investigation case management replacement

5.4 Project delivery is currently on track for a planned "go-live" by the end March 2024. System configuration work has been completed and preparations are in progress to commence system testing. Data migration work is also progressing to plan. The service management

team is working with the project team to accept the service into live operations, a big step forward for the MHRA's enforcement function.

Freeze dryer upgrades

5.5 Phase 1 upgrade work for the freeze dryers took place at South Mimms between 17 - 25 January and is now complete pending confirmation of business sign-off. Phase 2 related work is close to completion with the approval of tender documentation needed to progress with the next iteration of planned upgrades. This includes updating the Supervisory Control and Data Acquisition, Programmable Logic Controller and Human Machine Interface on the C150 and CS15 Freeze Dryers. It is expected that the OJEU tender will be published in March. The project team is engaging with SR&I over the coming weeks to understand Digital and Technology (D&T) ongoing support requirements.

Clinical trials

5.6 Discovery work has wrapped up on the new clinical trials system and the team is focusing on delivery of short-term improvements and delivering an initial Notifications Scheme by mid-April 2024. In terms of reporting the aim is to support he business to build capability for self-serve reports. The next project phase will look at opportunities to use AI and for applicants to track their protocols and monitor case progression. Future work will take place with business leads to draw out the detail needed to define the requirements needed to support a new technology solution to deliver the new operating model.

Customer Experience Centre

5.7 Discovery work has completed and been shared with business leads. Focus for the alpha phase is to conduct discovery and analysis to understand the volume and level of correspondence being managed across the agency outside of the Customer Experience Centre, in order to understand the totality of the correspondence and issues agency wide. D&T can then create a service vision for how to improve current ways of working and develop a roadmap of how to meet the 'corporate plan commitment of a single unified gateway'.

Cyber Resilience

5.8 All workstreams relating to cyber resilience are on track to meet deliverables and target dates for procurement and deployment of new technologies, processes and capabilities. All of these help to address audit recommendations and National Cyber Security Centre (NCSC) frameworks alignment. The NCSC has noted the progress made in a short space of time and achievements such as the MHRA becoming the top scorer in some areas amongst comparable organisations.

DYNAMIC ORGANISATION

Line Manager's Conference

6.1 On 29 February 2024 we delivered the first Line Managers' Conference since before the pandemic. The event brought together over 250 line managers from across the agency in a one-day conference with the purpose of creating cohesion and shared sense of purpose across the line manager cohort. The main topics were the 'Return to Green' cross-Agency initiative, communications with teams, and supporting staff wellbeing.

AGENCY PRIORITIES

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

I. Take forward the ‘Return to Green’ initiative with pace, eliminating backlogs and meeting targets for all key services, so that innovative product reach patients safely and without unnecessary delay

II. Introduce new ways of working across all Agency services which will be supported by the RegulatoryConnect system

III. Operationalise the new international recognition framework which allows the Agency to streamline approvals for medicines, and progress plans for international recognition for medical devices

IV. Complete the review our regulatory science strategy so that the evidence base to support robust regulatory decisions is optimised

V. Improve transparency in relation to healthcare product safety by making more information available on vigilance activities, and continue to facilitate patent involvement in safety reviews

VI. Implement our People Survey corporate action plan, focussing on the three main areas of leadership, productivity and wellbeing, and create an environment where our staff’s careers can flourish.

Dr June Raine, CEO
March 2024

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

19th March 2024

Title	What was the Finance and HR performance of the MHRA for the nine months of the financial year up to 31 January 2024?
Board Sponsor	Rose Braithwaite
Purpose of Paper	Assurance

What was the finance and HR performance of the MHRA for the nine months of the financial year up to 31 January 2024?

1. Executive Summary

1.1 Financial performance at the end of January shows a Year to Date (YTD) Resource underspend of £11.6m compared to budget and a Capital underspend of £3.3m compared to budget. Our latest forecast shows that by the end of the year we are expecting a Resource surplus of £6.6m, a reduction of £1.3m compared to the last finance report. The Capital position is forecast at a full year underspend of £1.2m, however we are confident that other opportunities will bring spend much closer to budget.

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

1.3 The forecast underspend has reduced due to the inclusion of most the extra spending bids approved by the Executive Committee (ExCo), a reduction in Trading income because of the re-payment of 2022/23 interest income to HM Treasury and the re-profiling of £1m of the Innovation funding from this financial year into 2024/25.

2. Financial Performance

AGENCY PERFORMANCE – RESOURCE (RDEL)

2.1 The Resource position of the Agency is a large YTD underspend of £11.6m compared to budget. Without DHSC funding, the Agency's Resource net position would be a £6.2m deficit compared to a budgeted deficit of £17.5m. We forecast a full year result of £6.6m RDEL surplus (a reduction of £1.3m from last month) with DHSC funding (see Table 1).

Income

2.2 The Agency receives most of its funding from trading income realised in the performance of its Regulatory obligations, supplemented by direct funding from its sponsor department, the Department for Health and Social Care (DHSC).

2.3 Trading income in January was £11m, which was £1.1m below budget. This was because of the recognition of the return of £1.5m interest income received in 2022/23 in error. Other falls in income against budget include CPRD and the

Periodic Fee. Otherwise, HQA continued to generate higher than budgeted income as changes to processes and efforts to reduce the backlog start to take effect.

2.4 Trading income Year-to-Date (YTD) remains strong at £119.4m, 2% above the YTD budget. The full year forecast is for income to continue at the current rate to finish at £143.2m, 2% over budget.

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

January 2024 Resource	Period Actual £M	Period Budget £M	*Variance vs Budget* *% / £M*	YTD Actual £M	YTD Budget £M	*Variance vs Budget* *% / £M*	Full Year Forecast £M	Full Year Budget £M	*Variance vs Budget* *% / £M*
Trading Income	11.0	12.1	(9%)	119.4	116.9	2%	141.6	140.7	1%
Staff Costs	7.9	8.1	2%	75.7	78.9	4%	91.8	94.9	3%
Operating Costs	5.1	5.1	0%	45.7	49.0	7%	59.4	59.4	0%
Operating Net Position	**(2.1)**	**(1.2)**	**(0.9)**	**(2.0)**	**(11.0)**	**9.0**	**(9.6)**	**(13.6)**	**4.1**
CPRD Revenue Funding	0.0	0.0	0%	0.5	0.5	0%	0.6	0.6	0%
Staff Costs	0.2	0.1	(207%)	0.7	1.1	31%	1.3	1.2	(11%)
Change Costs	0.4	0.7	40%	4.0	6.0	33%	7.5	7.5	0%
Projects Net Position	**(0.6)**	**(0.7)**	**0.2**	**(4.3)**	**(6.5)**	**2.3**	**(8.2)**	**(8.0)**	**(0.1)**
Agency Resource Net Position	**(2.6)**	**(1.9)**	**(0.7)**	**(6.2)**	**(17.5)**	**11.3**	**(17.7)**	**(21.7)**	**3.9**
DH RDEL Operational Funding	1.8	1.7	6%	17.4	17.2	1%	24.3	20.6	18%
DH RDEL Project Funding	0.0	0.0	0%	0.0	0.0	0%	0.0	0.0	0%
Total RDEL	**(0.8)**	**(0.2)**	**(0.6)**	**11.2**	**(0.4)**	**11.6**	**6.6**	**(1.1)**	**7.6**

Staff Costs

2.5 Staff costs in January were £0.2m (2%), below budget, similar to the results of the last few months. Looking forwards, we forecast pay costs to remain at this level turning the YTD 4% underspend to a Full Year 3% underspend. However, the pay forecast has reduced recently as recruitment into the Innovation roles have been slower than planned.

Non-Pay Costs

2.6 Spend on other operating costs in January matched the £5.1m budget. The forecast is for a significant increase in the last two months of the year to completely eliminate the YTD 7% underspend. Most of the forecast expenditure is due in Enablement and Corporate on Contracted Out Services, Accommodation and IT spend, and due to the Q2 extra spending bids. However, the current rate of spend suggests we may not meet our forecast which will result in a higher surplus at year end.

Resource Project Expenditure

2.7 At the end of January, resource change costs were £2.3m behind the YTD budget (see Table 2). Most of the underspend relates to Safety and Surveillance projects, such as Intellicase, which were approved late, and hence started spending late. Budgets were also set in view of scopes that have now changed or reduced. Intellicase for instance is due to be delivered on time in March significantly under budget.

2.8 The FY forecast position, however, is of a significant increase in spend in the last two months of the year towards a small overspend to the £8.6m budget. This is driven by a large increase in forecast RDEL spend in RegulatoryConnect. RegulatoryConnect have spent £1m YTD and are forecasting an additional £1.8m of spend over the next 2 months.

Table 2 – Resource Project Spend

£'000s	RDEL Period			RDEL Year to Date			RDEL Full Year		
	Actual	Budget	Variance	Actual	Budget	Variance	Forecast	Budget	Variance
Platforms									
Regulatory Management System (RMS) Core (R1.0)	15	82	67	1,008	782	(226)	2,848	935	(1,913)
Technology Maintenance Uplift	258	244	(15)	1,000	724	(276)	1,000	1,000	0
	274	**326**	**52**	**2,008**	**1,506**	**(502)**	**3,848**	**1,935**	**(1,913)**
Safety & Surveillance									
SafteyConnect (formerly CIVS)	200	42	(159)	944	114	(830)	665	114	(551)
COVID-19 Inquiry project	113	51	(62)	448	1,088	641	662	1,517	855
Yellow Card Biobank project	137	117	(20)	338	1,256	918	603	1,500	897
IntelliCase Replacement	(317)	208	525	(159)	2,083	2,242	1,171	2,500	1,329
	133	**418**	**285**	**1,571**	**4,542**	**2,971**	**3,100**	**5,631**	**2,531**
CPRD									
CPRD Trusted Research Environment (CPRD TRE)	58	45	(13)	536	494	(42)	648	584	(64)
IRSP Scalability	15	0	(15)	99	0	(99)	114	0	(114)
CPRD Website Enhancement	0	0	0	(18)	0	18	0	0	0
CPRD Online Learning Platform	0	0	0	0	0	0	0	0	0
CPRD Customer Portal	0	0	0	0	0	0	0	0	0
	73	**45**	**(28)**	**617**	**494**	**(123)**	**762**	**584**	**(178)**
Healthcare Quality and Access									
Innovative Devices Access Pathway (IDAP)	130	0	(130)	407	0	(407)	719	0	(719)
	130	**0**	**(130)**	**407**	**0**	**(407)**	**719**	**0**	**(719)**
Scientific Research & Innovation									
South Mimms Capital Programme 23/24	0	0	0	0	0	0	0	0	0
	0	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Enablement									
Redundancy Costs 23/24	5	0	(5)	159	484	325	365	484	119
	5	**0**	**(5)**	**159**	**484**	**325**	**365**	**484**	**119**
Closed projects still incurring costs									
Applications Outsourcing Contract Transition	0	0	0	24	0	(24)	18	0	(18)
Chart of Accounts	0	0	0	(50)	0	50	(50)	0	50
	0	**0**	**0**	**(26)**	**0**	**26**	**(32)**	**0**	**32**
Grand Total	**614**	**789**	**174**	**4,737**	**7,026**	**2,289**	**8,763**	**8,634**	**(129)**

AGENCY PERFORMANCE – CAPITAL

2.9 All of the capital budget has to be provided either by DHSC or from other Government Departments via the Commissioner Pays model which allows for the transfer of capital budget between departments.

2.10 The Agency has a FY Capital budget this financial year of £25.5m, of which £13.9m is set aside for RegulatoryConnect. The YTD position of Regulatory Connect is a £2.3m underspend (see table 3). But we expect spend in February and March to drive the FY position close to budget.

2.11 Other projects with significant capital funding are the South Mimms Capital Programme (£6m), SafetyConnect (£1.1m) and CPRD projects (£2.8m). South Mimms is forecasting to spend all its budget. The other projects are forecasting small underspends by year end. These underspends are being used to fund other capital projects, such as equipment in the BP Labs.

Table 3 - Agency Capital spend

£'000s	CDEL Period			CDEL Year to Date			CDEL Full Year		
	Actual	Budget	Variance	Actual	Budget	Variance	Forecast	Budget	Variance
Platforms									
Regulatory Management System (RMS) Core (R1.0)	1,304	461	(843)	10,658	12,991	2,333	13,743	13,924	182
Technology Maintenance Uplift	61	0	(61)	402	1,162	760	1,229	1,660	431
	1,365	**461**	**(904)**	**11,060**	**14,153**	**3,093**	**14,971**	**15,584**	**613**
Safety & Surveillance									
SafteyConnect (formerly CIVS)	(77)	119	196	135	1,096	961	811	1,096	285
COVID-19 Inquiry project	0	0	0	0	0	0	0	0	0
Yellow Card Biobank project	0	0	0	0	0	0	0	0	0
IntelliCase Replacement	557	0	(557)	557	0	(557)	0	0	0
	480	**119**	**(361)**	**692**	**1,096**	**404**	**811**	**1,096**	**285**
CPRD									
CPRD Trusted Research Environment (CPRD TRE)	102	83	(19)	819	1,198	379	1,002	1,256	254
IRSP Scalability	62	71	8	644	839	194	795	980	185
CPRD Website Enhancement	26	26	0	156	104	(52)	138	156	18
CPRD Online Learning Platform	20	20	0	100	80	(20)	120	120	0
CPRD Customer Portal	50	50	0	200	200	0	300	300	0
	260	**250**	**(11)**	**1,919**	**2,421**	**501**	**2,355**	**2,812**	**457**
Healthcare Quality and Access									
Innovative Devices Access Pathway (IDAP)	0	0	0	0	0	0	154	0	(154)
	0	**0**	**0**	**0**	**0**	**0**	**154**	**0**	**(154)**
Scientific Research & Innovation									
South Mimms Capital Programme 23/24	397	632	234	2,663	1,964	(699)	6,000	6,000	0
	397	**632**	**234**	**2,663**	**1,964**	**(699)**	**6,000**	**6,000**	**0**
Enablement									
Redundancy Costs 23/24	0	0	0	0	0	0	0	0	0
	0	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Closed projects still incurring costs									
Applications Outsourcing Contract Transition	0	0	0	0	0	0	0	0	0
Chart of Accounts	0	0	0	0	0	0	0	0	0
	0	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Grand Total	**2,503**	**1,461**	**(1,042)**	**16,334**	**19,634**	**3,300**	**24,291**	**25,492**	**1,201**

3. People Performance

3.1 We had 1,272 people in post at the end of January 2024 (FTE, permanent, fixed term and PhD students covering established posts).

3.2 There has been a further reduction in our turnover of staff to 8.2% bringing turnover under the levels considered 'healthy' by the CIPD (10-15%) but reflective of Agency turnover pre pandemic and pre transformation. Although this turnover rate is below the 'healthy' range, given the turbulence of turnover through the pandemic and during/post transformation, this would be considered a healthy rate for the Agency at this time, giving much needed stability to Groups/functions and teams.

3.3 Despite a challenging employment market for all sectors, we continue to see an increase in the number of joiners versus leavers, reflected in our steadily decreasing turnover. We welcomed 33 new starters to the Agency in January versus 11 voluntary leavers.

3.4 At the end of January, there were 62 recruitment campaigns live at various stages of the process – advertised, shortlisting or interviewing in that month. Chief Officers

and hiring managers prioritise their recruitment based on their business needs. Recruitment remains high and whilst there is some additional resource in the HR team to help manage this, it is a tricky balance to manage the reactive pipeline and pressure to get adverts out and new staff in. It is worthy of note that the volumes of applications to some of our roles have been exceptionally high in January, with nearly 300 applications for example for 4 EO roles in HR alone. This gives both a flavour of the market, and the impact on hiring managers.

3.5 Recruitment as we know is a resource intensive activity, and it also remains a challenge for Groups to manage shortlisting and interviewing. HR are actively looking at improving the process for all so that the candidate and hiring manager experience is optimal and looking to implement a new recruitment module into Fusion (Oracle Recruit) in the coming months to support this. Management information on this important functional area is also being devised to ensure that Groups are informed and assured.

3.6 In respect of our 129 'vacancies' these are split by Group as follows:

Group	Vacancies	% vacancies FTE
Corporate	12	11.4%
D&T	14	12.9%
Enablement	8	8.1%
HQ&A	27	7.2%
Partnerships	4	15.1%
S&S	34	11.6%
SR&I	30	10.8%
Total	**129**	**10%**

3.7 Sickness absence (annualised) is 5.5 days per FTE. Whilst this is a decrease from 6.1 days as reported for December, it is an increase from the data reported for October of 4.7 days. Typically, we would see fluctuations in absence levels at this time of year with colds/flu/covid and other respiratory illnesses when compared to other times of the year. The Table below shows the data by group.

Group	Average days by FTE
Corporate	10.2
D&T	3.7
Enablement	3.5
HQ&A	5.3
Partnerships	3.7
S&S	4.3
SR&I	6.7
Total	**5.5**

3.8 It is worth noting that the higher level of absence in the Corporate Group is potentially reflective of the varied nature of work activities in this particular Group

compared to others, including in the Infrastructure and Laboratory Services which has many site-based craft roles, HR, Finance and Commercial functions.

3.9 The long and short term split by Group is not given as it could inadvertently identify colleagues, particularly in the smaller Groups or where absence is attributable to one person. Particularly in the smaller Groups and in Functions, the long-term absence of one person can skew the absence rates significantly. We continue to support staff who experience ill health through a range of interventions, including Occupational Health, our Employee Assistance Programme and our internal Wellbeing Ambassadors.

3.10 Absence attributed to mental health/stress or depression continues to be the highest reported reason for absence, at 34% of all absence. We know that mental health related absence is typically under reported or disguised as something else, so this figure is likely higher in reality. As part of our response to this and included in the People Survey corporate action plan, we are seeking additional resource for staff to have confidential conversations about their wellbeing with a specialist advisor/counsellor.

4. Group Performance

4.1 Chief Officers of the three fee-earning operational groups have been set budget for income and expenditure.

4.2 The tables presented below include only those operational budgets over which Chief Officers have control. They don't include DHSC funding and allocated income from the Periodic Fee which the Agency receives to fund non-income generating activity.

Scientific, Research and Innovation

£'000s	Period			YTD			Full Year		
	Actual	Budget	Variance	Actual	Budget	Variance	Forecast	Budget	Variance
Trading Income	2,747	2,790	(43)	24,106	23,278	827	28,316	28,134	182
Staff Costs	1,710	1,563	(147)	16,223	15,136	(1,087)	19,389	18,200	(1,189)
Non-Staff Costs	255	558	303	5,064	4,963	(102)	5,590	5,871	281
Operating Position	**781**	**668**	**113**	**2,819**	**3,180**	**(361)**	**3,336**	**4,062**	**(726)**

4.3 SR&I's operating position at the end of January shows a slight negative variance to the YTD budget, driven by an overspend on Pay costs.

4.4 Although January's trading income of £2.75m was slightly below budget, YTD and FY Income forecast are above budget. This is driven by higher Sales of Goods and Products, because of efforts to clear Standards sales backlogs. Two areas of weaker than budgeted income are Clinical Trials and Grants, where we are now forecasting a significant deficit against the RSRU grant.

4.5 In terms of staff costs, we forecast the YTD overspend to continue to the end of the financial year. This is because of extra roles recruited under the Chancellor's Innovation funding and roles recruited to support Grant work, were not included in the original budget. These are now included in the draft 2024/25 budget to match grant income.

Healthcare Quality and Access

£'000s	Period			YTD			Full Year		
	Actual	Budget	Variance	Actual	Budget	Variance	Forecast	Budget	Variance
Trading Income	4,935	3,469	1,466	40,347	35,620	4,727	48,130	42,784	5,346
Staff Costs	2,412	2,330	(82)	22,377	22,552	175	27,308	27,118	(190)
Non-Staff Costs	338	472	134	4,185	4,675	490	5,132	5,585	453
Operating Position	**2,185**	**667**	**1,518**	**13,785**	**8,392**	**5,393**	**15,690**	**10,081**	**5,609**

4.6 HQA is in a very strong financial position. YTD income is £4.7m over budget. This is because of higher than budgeted income in Innovative Medicines, Authorisation Lifecycle and Population Health. Income figures are due to efforts to reduce the backlogs so more income is being recognised. Next year's income budget is significantly higher on the basis of realising deferred revenue as backlogs are eliminated.

4.7 The only areas that are behind budget are GCP and GDP Inspections because of capacity constraints in those teams. Expense income is also below budget, but this is balanced out by lower T&S expenditure.

4.8 In term of staff costs, spend in January was slightly above budget, but continues to underspend YTD. The profiles of spend will increase slightly because of new roles approved.

4.9 Non-Pay spend is below budget mainly because of lower T&S costs in the Inspections teams.

Safety and Surveillance

£'000s	Period			YTD			Full Year		
	Actual	Budget	Variance	Actual	Budget	Variance	Forecast	Budget	Variance
Trading Income	1,166	1,908	(741)	17,393	18,913	(1,520)	20,954	22,842	(1,889)
Staff Costs	1,646	1,992	346	16,693	19,279	2,586	20,013	23,183	3,169
Non-Staff Costs	1,022	734	(287)	6,684	7,344	660	8,059	8,881	821
Operating Position	**(1,502)**	**(819)**	**(683)**	**(5,983)**	**(7,710)**	**1,727**	**(7,119)**	**(9,221)**	**2,102**

4.10 Safety and Surveillance (S&S) is partly funded through income generated within the group, which is in the Trading Income line above, and by income from the Periodic fee which is not included as it is not direct income in the group's control. Hence, we expect S&S not to cover all of its costs from Trading Income with a Full Year £9.2m budgeted Operating Deficit.

4.11 The overall YTD financial position is £1.73m underspent against budget, because of low pay actuals. This is due to a budgeting error rather than the S&S vacancy position.

4.12 Income at the end of January was £1.5m behind budget and is forecast to end the year £1.9m behind. This is mostly because of lower than budgeted CPRD income. CPRD is performing better than last year in cash terms, but it expects to be £1.6m behind a very ambitious income budget at the end of this financial year. CPRD Platform provider income has not materialised because of legal delays. CPRD Observational income is also down because of a delay in a number of contracts, but CPRD Data is above budget as some clients are choosing to pay for one-off data requests instead of a full licence.

4.13 In terms of non-pay costs, the YTD position is a £0.66m underspend, which is forecast to increase to £0.82m by the end of the year. This is mostly due to lower IT spend on CPRD because of lower workload which is reflected in their lower income forecast.

Corporate Groups

4.14 We have a number of non-fee earning groups which directly support our three fee-earning areas. These include Partnerships, Digital & Technology, Corporate and Enablement Groups.

		Period			YTD			Full Year		
Corporate Overhead groups	**Jan-24**	**Actual**	**Budget**	**Variance**	**Actual**	**Budget**	**Variance**	**Forecast**	**Budget**	**Variance**
Enablement	Trading Income	6	0	6	53	0	53	53	0	53
	Spend	902	990	89	8,710	9,813	1,103	11,641	11,778	137
	Operating Position	**(896)**	**(990)**	**95**	**(8,657)**	**(9,813)**	**1,156**	**(11,589)**	**(11,778)**	**190**
Partnerships	Trading Income	0	0	0	0	0	0	0	0	0
	Spend	219	224	4	1,678	2,170	491	2,136	2,609	473
	Operating Position	**(219)**	**(224)**	**4**	**(1,678)**	**(2,170)**	**491**	**(2,136)**	**(2,609)**	**473**
Corporate	Trading Income	2,020	3,818	(1,799)	36,044	38,185	(2,141)	42,534	45,822	(3,288)
	Spend	2,074	1,633	(441)	16,921	16,307	(615)	21,500	19,658	(1,842)
	Operating Position	**(54)**	**2,186**	**(2,240)**	**19,122**	**21,878**	**(2,756)**	**21,034**	**26,164**	**(5,130)**
D&T	Trading Income	113	92	21	1,499	920	578	1,620	1,104	515
	Spend	2,469	2,766	296	22,862	25,680	2,819	30,394	31,418	1,025
	Operating Position	**(2,356)**	**(2,674)**	**317**	**(21,363)**	**(24,760)**	**3,397**	**(28,774)**	**(30,314)**	**1,540**

4.15 The YTD position in Enablement is a significant underspend in both pay and non-pay costs. In the FY forecast, the underspend reduces significantly because of an increase in spend in Contracted Out Services on the back of bids approved recently. We will keep track of spend against these bids in the last two months of the year.

4.16 The underspend in Partnerships is driven by low pay costs. The main movement in the FY forecast since the last report is the shift of £0.25m of CERSI spend to next year.

4.17 Trading income in January within the Corporate Group was low because of the 2022/23 Interest income correction. The Periodic Fee monthly income was also slightly down because of a downwards adjustment to YTD income in line with the FY forecast. In terms of costs, Corporate is also overspending on Contracted Out Services and Accommodation as spend is brought forward in light of the overall underspend.

4.18 Digital and Technology is significantly underspending on BAU IT costs at YTD. However, YTD project costs is higher than budget. The FY forecast is a significant increase in Contracted Out Services and project costs as work on projects and other bids are sped up towards completion before the end of the financial year.

5. Recommendation

4.19 The Board is asked to note the resource surplus shown in the forecast and consider what lessons learnt the Agency should carry forward into next year's financial planning?

4.20 The Board is asked to note the level of sickness absence in the Agency and whether enough is being done to support staff with absences caused by mental health issues.

Rose Braithwaite
7 March 2024

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

19th March 2024

Title	How effectively is the MHRA addressing performance on established medicines, and how will a sustainable established medicines function be established?
Board Sponsor	Julian Beach
Purpose of Paper	Assurance

How effectively is the MHRA addressing performance on established medicines, and how will a sustainable established medicines function be established?

1. Executive Summary

1.1 This paper provides an update on progress made in delivering the current plan to eliminate the Established Medicines backlog and achieve sustainable operations to agreed targets within statutory timelines.

1.2 Following the update to Board in February 2024, further significant progress has been made in established medicines in terms of performance, people and process. The focus includes maintaining the progress on variations performance, and the launch of the International Recognition Framework.

1.3 During February 2024, there has been process development, guidance writing, industry engagement and launch of a new process to streamline the approval process for applications for established medicines.

1.4 During the month, performance continued to demonstrate improvement in the numbers of applications completed at each stage of the national assessment process. Applications processed have risen to 344 from the work queue with 234 applications from the backlog and 110 in date applications to ensure public health priorities are met since the beginning of January 2024.

1.5 The plan to eliminate the backlog continues to focus on three main interventions: new ways of working, additional resources, and where possible conversion of national applications to recognition. Resources are being sourced to ensure provision of both short-term and long-term capability is developed and utilised. Focus for short-term resources is to ensure previously MHRA trained personnel are employed via contingent labour or professional service contracts.

1.6 It is clear that while progress has been made further acceleration is required. The aim is to eliminate the entire backlog by September 2024.

2. Current status

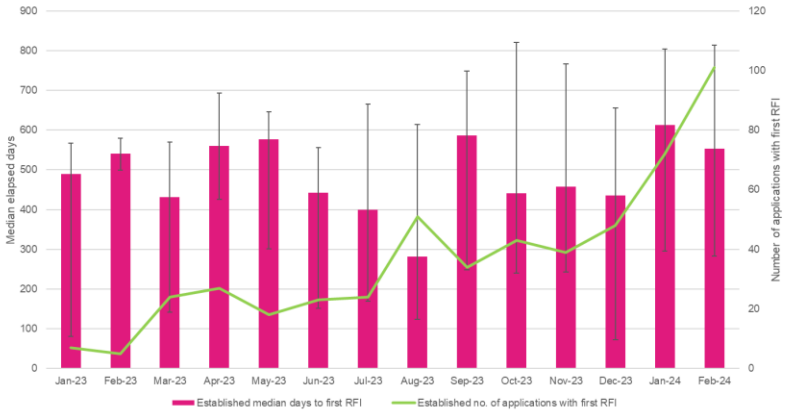
2.1. The size of the current backlog is provided in the table below. Improvements have continued to be demonstrated, and the applications in backlog have been reduced.

Work type	Median time in days	Numbers granted	% in target
Type IB variations – national, reliance	18	983	70%
Type II variations – national, reliance, Project Orbis	82	337	71%
Established medicines national MAA	640	86	12%
Established medicines reliance MAA	195	36	14%

Work on hand	
Overdue individual Product Licences (past the 210 days) as at 5 January 2024	1167
Overdue individual Product Licences (past the 210 days) as of 5 March 2024	933

2.2. One figure is critical to track output, the number of applications determined. For January, as shown on graphs below, a significant increase was observed in initial assessments performed, whilst also progressing processing of RFI responses. Licences granted have also progressed.

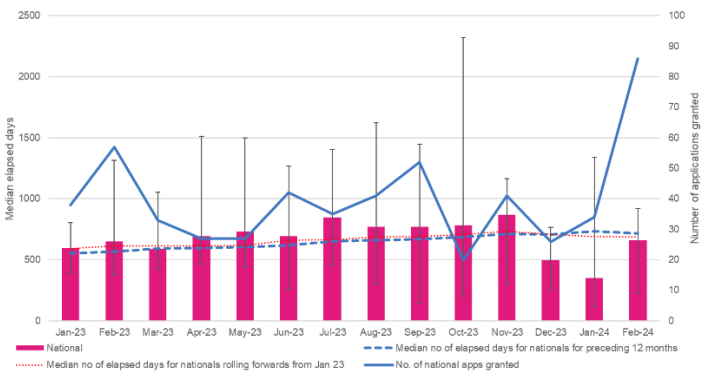
Initial national established licences - median time to first RFI (total elapsed days from received) & number of applications with first RFI for Jan 2023 – Feb 2024



Key features

- This graph shows the median number of elapsed days from application received to first RFI.
- This includes applications which are being worked through from the queue, which is not truly able to be trended.

Established medicines national initial licences granted - median time to determination (total elapsed days since validation) & number of applications for Jan 2023 – Feb 2024, median elapsed days for preceding 12 months, and median elapsed days rolling forwards from Jan 23



Key features

- This graph shows lines for the median elapsed days for national granted applications for the preceding 12 months at each time point as well as the accumulative median at each time point from January 2023 onwards. The number of applications granted for each month is also shown.
- This includes applications which are being worked through from the queue, which is not truly able to be trended and median times are showing an extension.

3. Backlog clearance plan update

3.1. It can be seen that the clearance rate has significantly improved, with the trajectory showing that the weekly numbers received are now routinely below the numbers processed allowing for the clearance of those in the backlog.

3.2. Critical aspects of the clearance performance during 2024 are below:

- 344 licence applications completed and removed from the work queue
- Guidance published on target 28 February 2024
- Industry webinar delivered on the 7 March 2024.

4. External Engagement

4.1. Significant external engagement continues to be conducted during 2024, with the following events taking place. The focus of these has been to share performance information and also to engage discussion on the new process being implemented on the 1 March 2024.

Meetings specifically focused on process changes	When
Workshop with TAs	31st Jan
EMIG Meeting	19th February
BIA meeting	21st February
Task & Finish Group - Focused Meeting	28th Feb
Industry Meeting	28th Feb
BGMA meeting	4th March
Webinar	7th March
Trade Association Meeting	11th March

4.2. Future meetings and engagements are planned to inform key stakeholders of progress to clear the backlog.

Ongoing / future meetings	When
DHSC/BGMA/MHRA meeting	Bi-weekly
Task & Finish Group (ABPI, BIA, BGMA, EMIG, PAGB)	Monthly

5. Future Plan for Established Medicines backlog

5.1. The focus is now on delivering to the developed trajectory and implementation of the new process. It is clear that further acceleration is required. Development of further avenues need to be now completed to increase the throughput. These need to continue to the optimisation in the assessment process and the available resources, All actions need to be focused on the complex application types which require assessments, as all 490 low-complex applications from January 2024 will be completed by the end of March 2024.

5.2. **Process of assessment -** Further optimisation of the assessment process is being developed to achieve further targeting of assessment to the critical aspects of complex applications. The 140 high complexity assessments typically take a minimum of two weeks to complete from a quality perspective, with clinical and non-clinical assessment as needed. This is due to the involved nature of the development, production, and evaluation of the product. These procedures involve for example applications which will be used as the Reference basis for all other products of these types of products, or the use of novel or alternative synthesis for the production of the Active Pharmaceutical Ingredient.

5.3. **Resources available for assessment -** Acceleration of the provision of additional resources to the clearance of the backlog. This needs to be with both internal and external supply of labour. The routes of supply of this resource requires specific additional focus from the HQA group to evolve the capability and capacity of people employed to clear the backlog. This will involve going back through the improvements already implemented. Actions are to go through the different skill types in the scientific disciplines available to the Agency including Pharmacists, Chemists, Biologists who may be employed in the assessment process from various sources.

6. Culture

6.1. The culture is starting to evolve in the assessment organisation. There is acceptance of clearance rates, and licences are being determined through more risk proportionate approaches. Positive engagement with clear understanding of the progress is being made through daily and weekly updates with the revised processes has started to deliver morale building delivery. Actions are in progress to evolve the positive acceptance and draw individuals to encourage the development of the delivery culture. This is through staff rotation, active support, encouragement, and direct supervision. This has been through engaging with the “natural” opinion leaders of the teams in addition to the Managers.

6.2. Given the previous changes and staff turnover, this has taken a significant time to move forward, but now with the positive traction of KPIs over the last six months, is starting to develop a momentum of its own. This cultural change cannot be underestimated, and the effect it will have on licence delivery and the acceptance of further new ways of working.

7. Future sustainability

7.1. The further acceleration of application determination is immediately needed, and optimisation of skill base utilisation, focus on developing the long-term model for sustainability, will be evolved over the next two months, when process and resource requirements are clear.

7.2. Current throughput of applications can be confirmed with the revised processes, to deliver the following Established Medicines performance, from the group of quality assessors over the first two months of 2024.

National Licence First Assessments	171
Reliance Assessments	71
Type 1 B variations	860
Type 2 variations	220

7.3. These data are being used to determine the appropriate group size to ensure that the organisation is rightsized for the future.

8. Recommendation

The Board is asked to:

8.1. Advise on the progress of current and planned activities to eliminate the backlog of applications for established medicines.

8.2. Advise whether the approach to the requirements of future sustainability of the established medicines function is acceptable.

8.3. Provide suggestions for any other options which could be developed and assessed to further accelerate clearance.

Julian Beach
March 2024

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

19th March 2024

Title	How effectively is the MHRA maintaining its performance on clinical trials and how are plans for the new regulatory system progressing?
Board Sponsor	Marc Bailey
Purpose of Paper	Assurance

How effectively is the MHRA maintaining its performance on clinical trials and how are plans for the new regulatory system progressing?

1. Executive Summary

1.1 This paper summarises current performance for clinical trials and provides an update on the development and implementation of the new operating model for regulation of clinical trials. It includes the regulatory strategy, capacity/capability considerations, legislative, cost/fee considerations, communications and digital infrastructure elements.

1.2 The operating model, previously presented at the January 2024 Board meeting, builds on the Government response to consultation on legislative proposals for clinical trials and the lessons learned during the last 9 months as we have eliminated the clinical trials applications backlog and returned to acceptable operational performance.

1.3 All clinical trials applications (initials and amendments) received since 1st September 2023 up to January 2024 have been assessed within statutory timeframes, except for 4 applications in January 2024 which exceeded 30/35 days by up to a maximum of 6 days as a result of administrative errors, and there is no backlog of clinical trial applications.

2. Background

2.1 Clinical Trials regulation under the Medicines for Human Use (Clinical Trials) Regulations 2004 is one of 14 functions of the Medicines and Healthcare products Regulatory Agency (MHRA) as set out in the Framework Agreement between the MHRA and DHSC. It is delivered by the Science, Research and Innovation group (SRI) as a key component of the 'lifecycle' model of our "One Agency" strategy. It integrates medical research on medicines' efficacy with enabling innovation, supporting access to new medicines and patient safety.

2.2 The clinical trials team receives an average of 17 initial applications and 108 amendments for approved clinical trial applications each week. Statutory timeframes for the assessment of clinical trials are 30 calendar days (initial application) and 35 calendar days (substantial amendments).

2.3 The sustainability of the assessment performance of the clinical trial function has a major impact on the national and international clinical trial ecosystem; therefore, a new strategy and operating model are required to ensure ongoing performance.

3. Update on performance

3.1 All applications received from 1 September 2023 to January 2024 for initials and amendments have been assessed within statutory timeframes, except for 4 applications in January 2024 which exceeded 30/35 days by up to maximum of 6 days as a result of administrative errors, and robust reporting processes are in place to monitor performance. The most recent data for clinical trial assessment performance are summarised in Table 1 and Figure 1 below.

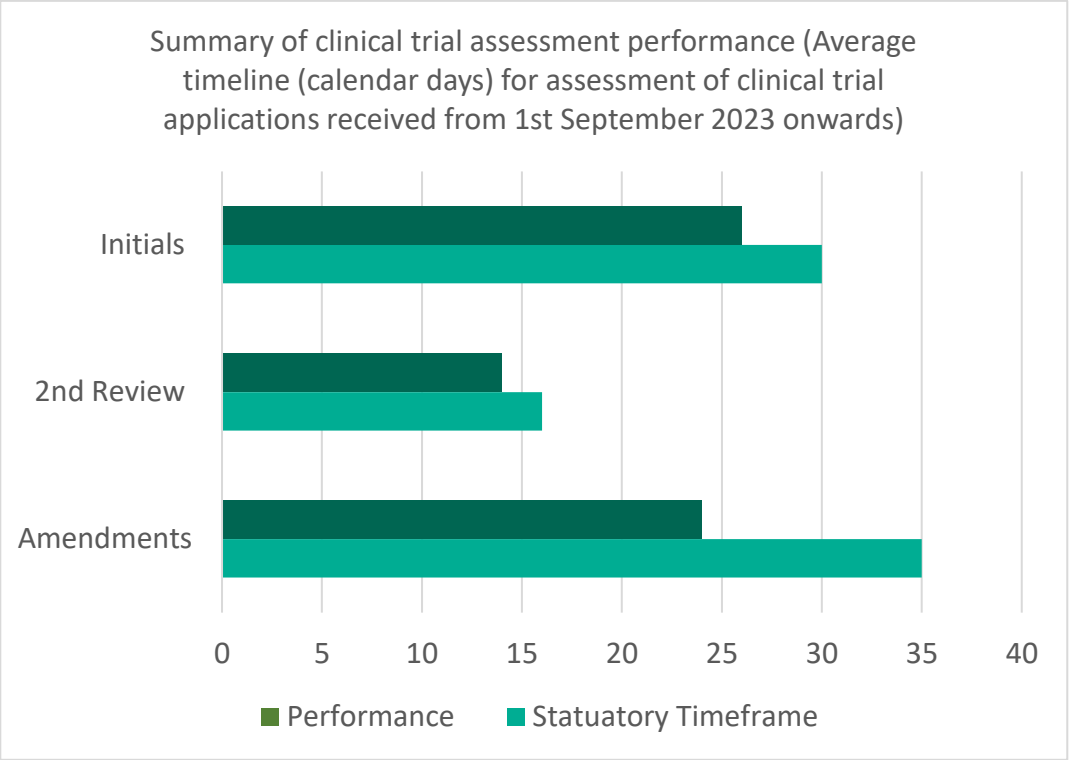
3.2 For the 4 applications (2 initials, 2 amendments) that did exceed statutory timeframes in January 2024, the maximum additional time to process was no more than 6 days. The root cause of these administrative errors has been identified and staff training implemented to prevent a reoccurrence.

3.3 The number of initial CTA applications received in January 2024 decreased compared with December 2023 (from 78 to 70 applications), and the number of substantial amendments received decreased (from 585 to 413 amendments).

Table 1 Summary of applications assessed in January 2024 for both initials and amendments and % compliance to statutory timeframes (30 and 35 days respectively).

Submission type	Assessed	Statutory timelines
Initials	72	97.2%
Amendments	476	99.6%

Figure 2 Summary of clinical trial assessment performance (Average timeline (calendar days) for assessment of clinical trial applications received from 1st September 2023 onwards.



4. Performance management

4.1 Interim measures put in place to resolve the backlog will be withdrawn at the end of March 2024. This includes an end to all residual redeployment of staff from other parts of the MHRA and the use of eternal support. Process changes developed during the elimination of the backlog have been retained and further developed and additional staff have been recruited into the assessor and operational support teams in the Clinical Investigations and Trials function. To mitigate any risk from these changes, the assessment of new applications will be prioritised over other activity within the CIT team, where necessary. Additional contingencies will be implemented if appropriate.

5. Vision for clinical trials

5.1 The Agency's vision for clinical trials and investigations is one that:

- Ensures patients and their safety are at the focus of all clinical trials assessments
- Ensures risk-proportionate regulatory oversight as trials progress through the phases
- Aligns with key partners within the UK healthcare system and internationally making the UK the best location to conduct clinical trials
- World leading in facilitating the use of innovative trial design and technology, including for our own processes
- brings the benefits of clinical trials to everyone, taking in to account the impact of health inequalities.

6. Update on new clinical trials operating model

6.1 The Board endorsed the proposed operating model presented at the January 2024 meeting of the Agency Board The following sections provide an update on the progress of the constituent elements of the operating model**.**

Expansion of the use of notification for clinical trial initial and amendment applications

6.2 The design intent of the new operating model is to maximise the safe use of notifications of clinical trials (both initials and amendments) and enable the Agency to focus our multidisciplinary assessment resources on higher risk and more complex trials, which will predominantly be in earlier phases including First in Human (FIH), as well as on upstream innovation enabling scientific advice. This expanded use of notifications will build on the lessons learned from the scheme launched in October 2023.

6.3 Workshops have been held with stakeholders to further develop (i) expanded criteria for trials eligible for notification at the initial application and (ii) the re-classification of substantial amendments to those that either require risk-proportionate assessment or those that can in future be submitted as a notification.

6.4 The notification of amendments is intended to be independent of the route applied to the review of the initial application. For example, an initial clinical trial authorisation for a trial granted under notification may still require review of substantial amendments based on the changes proposed. Similarly, a trial approved outside of notification may be able to submit substantial amendments as notifications.

6.5 The finalised criteria for notification of clinical trial initial applications and amendments will be presented to the April meeting of the Commission for Human Medicines for their consideration and advice.

6.6 The new clinical trial regulations have been designed to enable the use of notifications, and detailed guidance and support will be developed to underpin the legislation and ensure clarity and ease of use for applicants.

Clinical trial 'lifecycle' package

6.7 As set out at the January board meeting, we intend to further enhance our support across all phases of clinical trials. We will develop the clinical trial life cycle package (CTLP) that will be designed to provide enhanced support across the life cycle of clinical trials from phases 1 to 3 and 4. Under this new approach the sponsor would submit the complete application adopting the combined phase approach, including their plan for phase 1 (e.g. FIH), 2, 3 and 4 to be conducted in the UK as their main centre. This new approach will complement the Innovative Licensing Access Pathway and will be suitably integrated.

6.8 The sponsor would then receive a full scientific advice meeting (SAM) during Phase 1 (e.g., FIH), scientific advice as required in Phase 2 and abbreviated scientific in Phase 3. The primary submission, including all phases, may require amendments following the results of each phase, and this would require the submission of an amendment for each phase. The sponsor would be able to discuss their envisaged amendments during their development plan, and the MHRA assessment team would provide their input before submission.

6.9 This concept has been presented to stakeholders in various fora and has received a positive reception. A workshop is to be held with a sub-group of our stakeholder group in Q1 2024/25 to further validate these proposals including likely volumes/demand for CTLPs.

Capacity and Capability to deliver the new operating model

6.10 At the January 2024 meeting of the Board further detail on the capacity and capability requirements for the new operating model were requested.

6.11 A full assessment has been undertaken of the capacity requirements across assessment and support functions that will be required to deliver the new operating model. This has been informed by modelling of scenarios for the impact of expanded notification approvals (subject to change) and accurate productivity data for assessment. The increased assessment, compliance and support function capacity required have informed budget proposals for FY 24/25 and onwards for CIT and once confirmed recruitment campaigns will be initiated at pace.

6.12 Based on the regulatory model defined in the January 2024 board paper, the capacity needs for assessment by clinical, non-clinical, quality (pharmaceutical)

and scientific assessment can be summarised as detailed in the table below. This also includes a capacity buffer to accommodate increasing demand and to ensure team resilience. The estimates are based the assumptions of on average 17 initials and 108 amendments per week. The productivity is based-on performance achieved since mid-2023 and reflects the average and that some assessments are more complex, and that non-clinical and pharmaceutical assessment is only undertaken for a proportion of total assessments (65% and 80% respectively). The model also includes a capacity of between 2-6 scientific advice/lifecycle package meetings per week.

Role	Number of posts
Clinical Assessor	10
Pharmaceutical Assessor	8
Non-clinical Assessor	5
Scientific Assessor	1
Statistical Assessor	1

A number of these additional posts are already being recruited using the HM Treasury innovation funding.

6.13 The capacity (FTE) needs for CIT operations can be summarised as set out in the table below This reflects increased support from CIT operations for notifications processing, supporting scientific advice planning and triage of non-notification applications, as well as increased resilience in the team.

Role	Number of posts
Business application management and support	8
Safety management	3
Low risk assessors and regulatory advisors	4

6.14 Currently resources to support upstream scientific advice for clinical trials requires input from the GCP compliance team and therefore reduces inspection capacity. Therefore, to enable the proposed refocussing of resources towards upstream scientific advice for complex and innovative trials we propose increasing embedded GCP and GMP expert support, which would also be available to support ILAP and broader regulatory decision making. This is required at senior level to maximise the insight and knowledge that can be used to inform

compliance-by-design at an early stage and is aligned with the Agency's compliance strategy. This additional support can be summarised as:

Role	Number of posts
Regulatory Compliance Assessor GCP/GMP	2

6.15 The following areas have been identified as priorities for skills and capability development.

- Therapeutic areas and technologies identified in the Life Sciences Vision and Agency Science Strategy
- Equality, diversity, inclusion (EDI)
- Use of data
- Drugs in pregnancy and lactation
- In silico trials
- Synthetic control arms (SCAs)
- Digital twins for clinical trials

Progress with new clinical trials legislation

6.16 The drafting of the new clinical trials legislation is progressing well in collaboration with the Health Research Authority. We expect the drafting to be finalised in Q1 FY 24/25, and parliamentary processes to lay the legislation will begin shortly after. We continue to engage the clinical trial community in key discussions relating to the new legislation. A well-attended workshop was held on 29 January 2024 to further develop detail of the notification scheme. We continue to receive support from stakeholders for our policy approaches and we expect to update stakeholders on the progress of the legislation by the end of March.

Plans for stakeholder engagement and development of guidance

6.17 The implementation of the new legislation will be phased with some elements brought in immediately after the legislation passes whilst other parts will come into force within 12 months. The full implementation timeline is currently being developed with consideration of the time needed for industry readiness.

6.18 We are committed to co-creating appropriate guidance with stakeholders to fully support the implementation of the new regulations. We will utilise the engagement of key stakeholders from recent workshops and bring in further technical or operational expertise where required.

Fees and cost model

6.19 The current Clinical Trials fees are not appropriately priced for the future operating model. As per guidelines of HM Treasury's Managing Public Money handbook, the fees we charge must be fully cost recovering. Therefore, the proposed, new future fees will be based on cost modelling volumes forecast, staff required and recording activity data for initials, assessments, scientific advice, and notifications.

6.20 The Fees and Charges review, and the activity recording exercise led by Finance function has been running over January to March 2024 will allow us to price our fees required to deliver the new operating model for Clinical Trials and ensure we are fully recovering our costs. We already have the staff costs and volumes to feed into the activity recording exercise. We will be able to indicate the new fees and percentage increase in our fees for the new operating model by early April 2024.

6.21 We are working closely with Finance colleagues to develop and scrutinise our cost model and future fees alongside consideration of impact of competition on fees level in accordance with HM Treasury's Managing Public Money handbook. The new fees will go live as part of the agency wide fee uplift in April 2025.

Digital Infrastructure

6.22 D&T are exploring both short term improvements to existing technology and processes for Clinical Trials as well as medium-long term substantial improvements to our processes and technology. This will be undertaken in collaboration with HRA, with whom we jointly deliver combined regulatory and ethics approval. It should be noted though that HRA delivery is on a longer timeline.

6.23 Short term improvements update:

Notification Change Request: Tactical enhancements to Appian (the case management system for clinical trials) to improve workflow, in advance of the wider operating model improvements. Currently scheduled for delivery in April 2024

DSURs (development safety update reports): Consolidation of DSURs for non-combined review trials into Appian to allow for up-front collection of fees relating to DSURs. This will remove the need for processing DSURs via Sentinel and support the Sentinel archiving and decommissioning activities planned by March-25. Delivery is being explored via a couple of options in order to deliver as quickly as possible and in the most cost-effective way.

6.24 Medium term improvements update:

Further improvements are being explored with agreement and support from business colleagues and service owners, these include:

- **Notification Scheme Eligibility Checker** - Allows applicants to interactively determine suitability for the scheme, rather than interpreting criteria; reduces reliance on two-way communication and manual intervention for determining suitability, in favour of a self-serve model.
- **Track My Case functionality** - Allows applicants to proactively monitor case progression through the assessment lifecycle, thereby reducing enquiries; also presents opportunities for visible calls to action.
- **Scientific Advice Meeting (SAM)** : Exploring a tool to automate a portion of the SAM booking and scheduling process; solution for open dialogue between those offering scientific advice, and those receiving it; potentially expandable to a communication system integrated with Track My Case, during the assessment phases; potential integration in the future with Eligibility Checker, where scientific advice is provided as part of the new model for the Clinical Trial Lifecycle.
- **Reporting**: Ensuring we leverage the new connection directly to the Appian database to provide management information and valuable data-led insights.
- **AI and Machine Learning**: Exploring how AI can remove some of the manual burden of existing and future processes.

All of the above are being explored as part of the 'Alpha phase' of D&T delivery, due to complete mid-April. This will also provide access to mock ups / prototypes to explore concepts and feasibility of delivery. The focus of this work is to aim to bring in improvements that are future proofed and will support the direction of travel for delivery of the new operating model. In addition to the above the D&T team are also mapping out the blueprint for delivery of the new operating model and driving out the detail needed to support the design and development of a new IT system. Timelines for delivery of a new platform and service will be factored into the wider plans - both internally and externally (i.e. alignment with the HRA modernisation plans) - to ensure deliverability.

Communications and engagement strategy

6.25 We have undertaken a comprehensive communications and engagement programme for clinical trials, to explain action taken to remove backlogs and delays through proactively communicating our work to address these issues, as well as promoting the wider work of the agency. This effort in the context of clinical trials encompasses various strategic activities:

6.26 International marketing campaigns: We have launched targeted international marketing campaigns to showcase the MHRA's expertise and reliability in overseeing clinical trials. Through PR and digital marketing channels, the agency highlights its commitment to ensuring safety and efficacy standards, thereby fostering trust among stakeholders worldwide. This includes a partnership with the UK Government's flagship GREAT campaign which seeks to encourage international investment in the UK in the field of clinical research. Outputs to date include a series of podcasts with influential representatives of the sector including Lord O'Shaughnessy; high engagement through targeted social media marketing

across LinkedIn; coverage in international media including the global Financial Times and overall increased interest in the UK clinical trials service offering being reported through qualitative assessment routes established to evaluate the campaign.

6.27 Stakeholder engagement and provision of information for stakeholder use: The MHRA maintains a proactive approach to engagement with stakeholders, including trade associations, life sciences companies, research institutions, and government.

6.28 Publication of performance data: The MHRA has prioritised the publication of monthly performance data, providing insights into its regulatory activities, decision-making processes, and outcomes. By promoting transparency, the agency aims to build trust and confidence in its regulatory oversight and provide applicants with predictable timescales for the conclusion of clinical trial assessments.

6.29 Improving customer engagement: We have maintained and improved the measures implemented in our initial response to clear backlogs to improve customer contact and provide proactive status updates as applicants move through the clinical trial process. By keeping stakeholders informed and engaged, the agency demonstrates its commitment to responsiveness and accountability; and can reassure applicants with trials under regulatory review of our timescales continuing to be under statutory limits. We are within our SLA timescales and are responding to customers inquiries within a timely fashion, providing access to further advice or signposting to guidance where necessary.

6.30 Overall, these efforts reflect the MHRA's dedication to enhancing the UK’s reputation in the field of clinical trials, both in the UK and internationally. As we move forward, the focus of our work will be enabling delivery of regulatory reform through effective communications and stakeholder engagement; specifically, by championing the development of high-quality guidance that is accessible across the MHRA and wider stakeholder channels to support applicants with implementation and use of new tools; and continuing to deliver more of what has worked to build the UK’s reputation in this space.

7. Recommendation

The Board is asked to consider the information provided and advise:

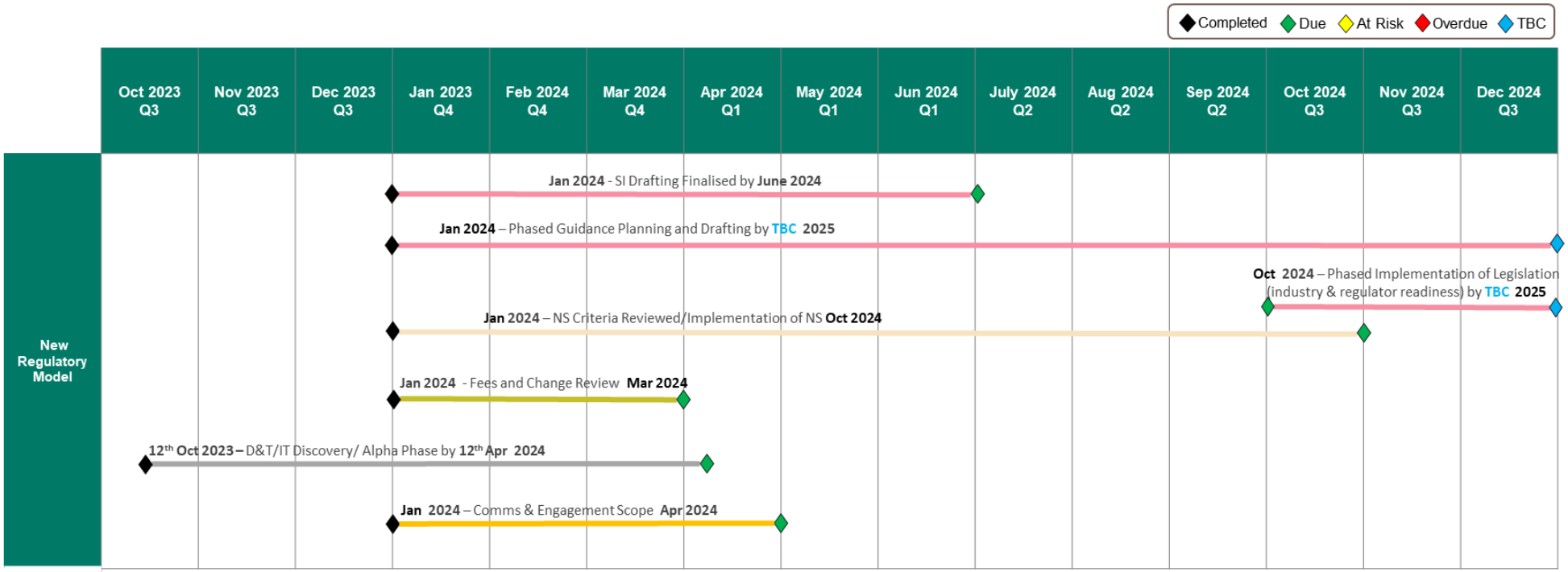
7.1 Is the approach adopted for maintaining ongoing sustainability of clinical trials assessment performance adequate and effective?

7.2 Does the update on the implementation of the new operating model give an acceptable level of assurance that the MHRA will meet the needs of patients, the ambitions of the life sciences vision, the Lord O'Shaughnessy review and ensure the UK is an attractive destination for clinical research?

Marc Bailey
March 2024

ANNEX 1 HIGH LEVEL PROVISIONAL PLAN

Clinical Trials New Regulatory Model Timeline of Delivery



NB: This is the current proposed timelines, however collaborative discussions and agreements with HRA need to take place, therefore the timelines may move

NB: CT will be operating on old fees regs till the new fees uplift go live in April 2025

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

19th March 2024

Title	How is the Yellow Card Biobank pilot progressing, to help the Agency move towards our goal of personalised medicines?
Board Sponsor	Alison Cave
Purpose of Paper	Strategic Direction

How is the Yellow Card Biobank pilot progressing, to help the Agency move towards our goal of personalised medicines?

1. Executive Summary

1.1. This paper provides an update on the Yellow Card Biobank pilot activities as we reach the end of the first financial year of operation.

1.2. Significant milestones met to date include establishment of formal governance arrangements including a memorandum of understanding with Genomics England, ethics approval for the operating model and consent process, establishment of a Scientific Advisory Board and Patient and Public Involvement Advisory Group, first participant recruitment and recent press announcement of our second study topic of Direct Oral Anticoagulants (DOACs) and excessive bleeding.

1.3. The board are asked to note progress to date and whether they are assured that delivery of key milestones is on track.

2. Introduction

2.1. The MHRA, in partnership with Genomics England launched a pilot in June 2023 for a Yellow Card Biobank to investigate the role of genetics in the development of adverse drug reactions (ADRs).

2.2. The commitment outlined in the MHRA Corporate Plan 2023 to 2026 included a pilot focused on two important drug safety issues over two years to demonstrate proof of concept and operational feasibility, and development of a future business model for scaling up in the longer term across all medicines and vaccines.

2.3. The aim of the Yellow Card Biobank is to better understand how a patient's genetic make-up can impact the safety of their medicines. Understanding the underlying mechanism of an adverse reaction would support the development of pharmacogenetic testing strategies to reduce the public health burden of ADRs. Better targeted testing may also retain the availability of medicines for those who can benefit and are less likely to suffer harm.

2.4. The Yellow Card Biobank aims to shorten the timeframe for translational learnings from pharmacogenomic research to be implemented in the NHS. Results generated by the Yellow Card Biobank would provide evidence to support the introduction of genomic tests into the National Genomic Test Directory to screen patients prior to prescription to prevent serious ADRs and move towards our goal of personalised medicines.

2.5. This pilot combines our extensive Yellow Card data on ADRs, with Genomic England's facilities and expertise in genomic sequencing to showcase the potential

of the Yellow Card Biobank to become a unique international resource for pharmacogenomic research into ADRs.

2.6. Two serious drug side effects were prioritised for the pilot on the basis of their significant impact on public health, patient quality of life and/or ability to help address a current unmet clinical need in the UK. The first topic, allopurinol, a highly prescribed gout treatment associated with severe (occasionally fatal skin) reactions, was announced in June 2023.

3. Progress Update

3.1. Since the launch of the pilot, set-up and operational activities have been progressing well and tracking against key milestones for governance, participant recruitment, communication activities and stakeholder engagement. The latest Plan On A Page can be seen in Annex 1. Progress against each of these key areas is detailed below.

Governance

3.2. A collaboration agreement between the MHRA and Genomics England has been formalised, establishing the governance arrangements for the pilot with Terms of Reference and membership of cross organisation governance meetings established and operating smoothly.

3.3. A Scientific Advisory Board has been established with Professor Cathie Sudlow appointed as the Chair of the Board. An initial orientation meeting was held in January 2024 and the first full meeting will be held in March 2024 with papers for discussion to include phenotypes and data collection and approaches for control.

Recruitment

3.4. The significant milestone of initiating participant recruitment was met in January 2024. This was slightly later than anticipated due to the need to secure additional ethics approval over and above the ethics approval Genomics England already have in place. Timelines have been revised to ensure this does not impact overall project delivery.

3.5. Our remote online electronic consent tool, REDCap has been set up and is operating well. To ensure accessibility, the online tool is supported by a telephone hotline to answer questions about the pilot and help participants navigate the consent process. There will be an external evaluation of the e-consent process as part of the second year of the pilot to inform the requirements for the future model.

3.6. The contract for sample collection has been awarded and we are on track to begin collecting samples from our already signed up participants by April 2024.

3.7. The target recruitment figure is 150 participants across the two study topics. In order to reach potential participants, multiple recruitment pathways will operate throughout

the pilot and be evaluated according to their success. The different recruitment pathways and their progress is outlined below:

3.7.1 Direct participant recruitment from patient Yellow Cards

3.7.1.1 Recruitment is underway with invite letters sent to eligible retrospective patient Yellow Card reports, screened by the Yellow Card Biobank team, for allopurinol and DOACs. To date a total of five patients out of 11 invited have signed up and consented to take part.

3.7.1.2 Conditional questions have been added to the Yellow Card website to prospectively capture highly specific relevant data for the two study drugs and enable potential patients to register their interest in taking part in the pilot in advance.

3.7.2 Recruitment through healthcare professional Yellow Cards

3.7.2.1 Documentation for healthcare professional Yellow Card recruitment is currently awaiting ethics approval but first contact with reporters from our pre-screened healthcare professional Yellow Card reports is expected to take place in March 2024.

3.7.3 Identification of participants through CPRD

3.7.3.1 Both the AURUM and GOLD databases available in CPRD are being searched to ensure coverage of devolved nations. Approximately 5500 potential participants have been identified for the DOACs study and invite letters are expected to go out to GPs for screening of their patients by the middle of March 2024. Identification of allopurinol patients is to take place in the next two weeks with invite letters to follow in late March/early April 2024.

3.7.4 Direct healthcare professional recruitment

3.7.4.1 We are looking to actively contact specialist centres and make use of Yellow Card Regional Centres to identify healthcare professionals to work with through this potential channel of recruitment. As a result of press coverage, we have also been approached directly by a number of healthcare professionals willing to refer their patients to the pilot which is encouraging. A healthcare professional DOAC engagement event is being held on 13th March 2024 to understand more about their ways of working and preferences for interacting with MHRA on this research project.

Communications

3.8 The second study topic of DOACs, an important group of anticoagulant medicines used to prevent strokes, and excessive bleeding was announced on 13th February 2024. The announcement gained good coverage from regionals (Glasgow Herald, Burton Mail,

Cambridge News, Paisley Daily) nationals (The Telegraph, Daily Mail), trade organisations (P3pharmacy.co.uk, thepharmaletter.com) and Medscape.

3.9 Other communication activities to support participant recruitment include a Yellow Card Biobank webpage added to the Yellow Card website containing current available resources and points of contact, and development of two video assets.

3.10 These promotional materials include an animation video explainer of what the Biobank is, and a talking heads video with a case example from a patient who has experienced an adverse drug reaction along with commentary from MHRA and Genomics England spokespersons. These two assets will be delivered by the end of March 2024.

Patient and Public Involvement

3.11 One of the core principles of the Biobank pilot is to ensure patient and public involvement in all of our activities. To date this has included patient review of the Yellow Card Biobank consent materials and establishment of a PPI Advisory Group.

3.12 We have recruited seven members across various areas of interest and experience including allopurinol and DOAC use. The first meeting of the PPI Advisory Group is to be held in March 2024 and topics for discussion will include opportunity for feedback on recent patient facing materials including the conditional questions on the Yellow Card webform and discussion on development of the Yellow Card Biobank pilot newsletter.

3.13 There has also been significant stakeholder engagement with patient groups & charities including SJS Awareness UK, the British heart Foundation, The British Skin Foundation, the British Association of Dermatologists, the British Society of Haemostasis and Thrombosis, and the Stroke Association.

3.14 SJS Awareness UK and the British Skin Foundation have approved use of their logos on our patient facing documents and the Stroke Association is reviewing this request for DOAC patient facing documents.

3.15 There are also ongoing activities to ensure interaction across the devolved nations and work with underserved communities to support diversity and inclusion within the Yellow Card Biobank.

Long term operations

3.16 In addition to the focus on current pilot activities there is a need to develop a sustainable future business model for long term operation of a Yellow Card Biobank.

3.17 The first stage of preparatory work in this area is underway with an internal cross agency meeting taking place in March to discuss future scientific and operational considerations. Further engagement with stakeholders on the topic will take place before the Business Case is developed and taken through the necessary MHRA governance channels.

4. Conclusion

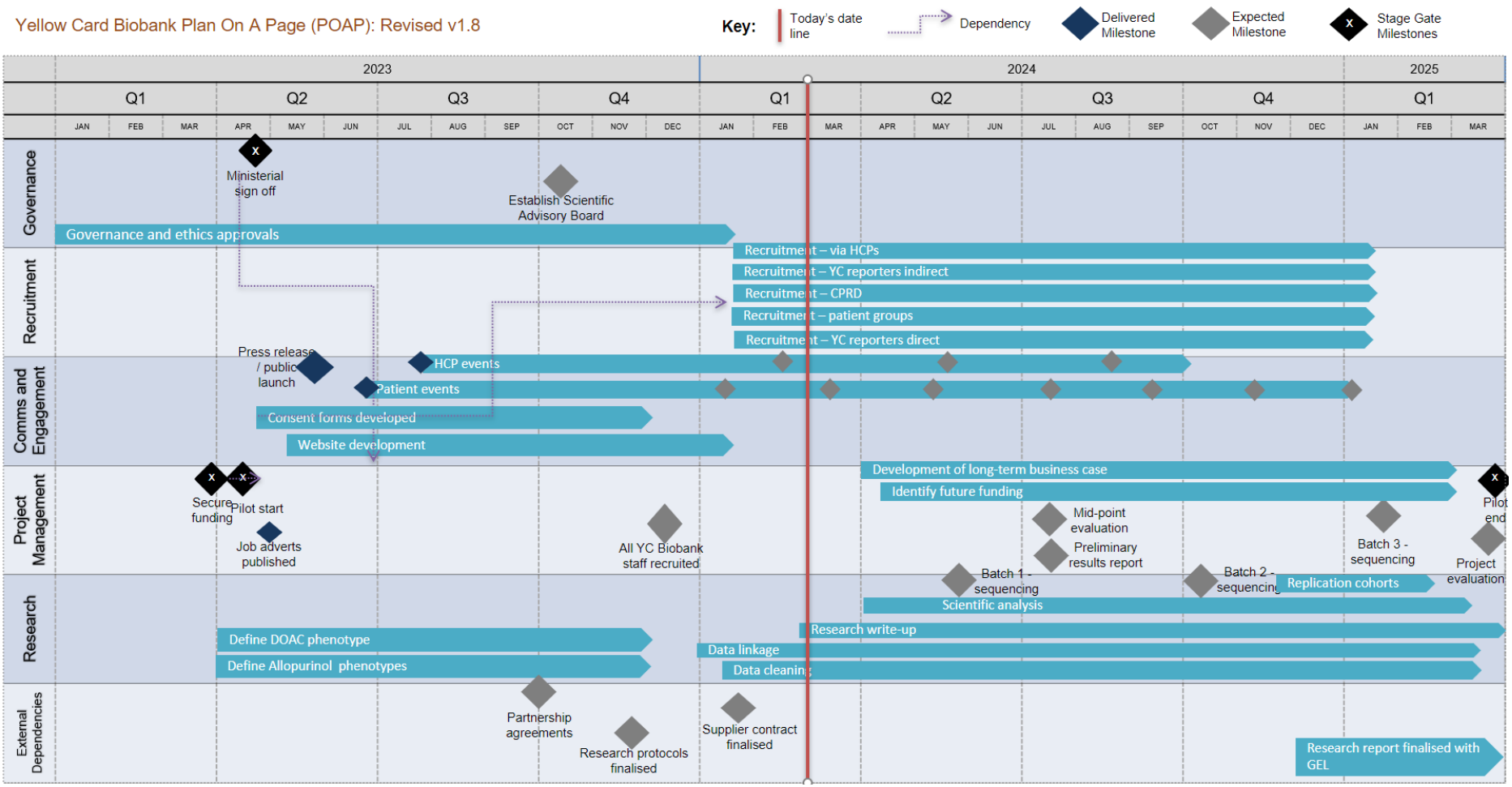
4.1. The Yellow Card Biobank pilot is progressing well with its objectives and a significant amount of activity is underway across all areas of the project. The major milestone of first participant recruitment has been met and the positive coverage of our recent press release announcing the second study topic has reinforced publicly the potential of the Yellow Card Biobank to improve patient safety outcomes and reduce the burden of ADRs on the NHS.

5. Recommendation

5.1. The Board is asked to note progress to date and whether it is assured that delivery of key milestones is on track.

Alison Cave
06 March 2024

Annex 1: Yellow Card Biobank Plan on a Page



Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

19th March 2024

Title	How well are the Agency's innovation pathways facilitating access to new innovative products and how are these pathways being optimised?
Board Sponsor	Marc Bailey
Purpose of Paper	Strategic Direction

How well are the Agency's innovation pathways facilitating access to new innovative products and how are these pathways being optimised?

1. Executive Summary

1.1 This paper sets out the two Innovative Pathways, the Innovative Licensing and Access Pathway (ILAP) and Innovative Devices Access Pathway (IDAP). It provides a high-level outline of their performance and work to optimise these.

1.2. It should be noted that work is ongoing to deliver a refreshed approach for ILAP. All parties are aligned with a shared vision/ambition for a refreshed ILAP and are working in partnership to undertake the work needed to launch a refreshed ILAP by the end of Q1 2024/25.

1.3. Scientific progress and integration of different combinations of therapeutic approaches, such as including companion diagnostics and Artificial Intelligence, increasingly blurs the traditional boundaries between medicines and devices. As we are seeing more of these products, 2024 will be a transition year for ILAP as it will support innovative medicines that are combined with these innovations. In recognition of the increasing use of both medicines and medical devices in therapies, it is our intention to explore opportunities to align ILAP with IDAP in 2025 coinciding with the end of the IDAP pilot.

2. Introduction

Innovative Devices Access Pathway (IDAP)

2.1. The Innovative Devices Access Pathway (IDAP) pilot was launched on 19 September 2023 to bring transformative medical technologies (including diagnostics and digital health technologies) to market that address unmet clinical needs within NHS. The aim of IDAP is to enable and improve patient access to innovative and transformative medical devices by providing an integrated and enhanced regulatory and access support and advice package to developers.

2.2. IDAP is delivered in partnership by Department of Health and Social Care (DHSC), Health Technology Wales (HTW), the Medicines and Healthcare products Regulatory Agency (MHRA), NHS England (NHSE), the National Institute for Health and Care Excellence (NICE), the Office for Life Sciences (OLS), and the Scottish Health Technologies Group (SHTG), underpinned by an MoU and grant funding provided by DHSC.

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

Government's Life Sciences Vision. Learnings from the pilot will inform the development of an enduring innovative pathway that can support medical technologies and medical/device combination products from 2025.

Innovative Licensing and Access Pathway (ILAP)

2.4. ILAP aims to reduce the time to market for innovative medicines by providing a single integrated platform for sustained collaborative working between the MHRA, partners and the medicine developer. By harnessing the collective expertise at the right time from the MHRA's partners, the National Institute for Health and Care Excellence (NICE), the Scottish Medicines Consortium (SMC) and the All Wales Therapeutics and Toxicology Centre (AWTTC), ILAP allows for enhanced coordination and monitoring of important product development activities.

2.5. The key aspects of the pathway are the assessment and subsequent award of an Innovation Passport (IP), and the Target Development Profile (TDP). The IP acts as the gateway to entry into the pathway and triggers the MHRA and partners to create the TDP and access to a variety of ILAP 'tools'. The TDP provides a roadmap which defines key regulatory and development features and identifies potential pitfalls specific to the product.

2.7. NHS England has now indicated its intention to formally join the ILAP partnership for the refresh, alongside representatives from NHS bodies in Scotland and Wales. All parties are aligned with a shared vision/ambition for a refreshed ILAP and are working in partnership to undertake the work needed to launch a refreshed ILAP by the end of Q1 2024/25.

3. Performance of Innovative Pathways and optimisation

Innovative Devices Access Pathway (IDAP)

3.1 The IDAP pilot was launched in September 2023 and strong interest from industry with 81 applications received for the eight available awards. The eight products selected for the pilot were announced on 14 February 2024 (IDAP.gov.uk). Collectively these represent a balanced portfolio of technologies that address unmet needs across development stages, organisation types, device types and geographical spread which will provide a range of insights crucial to shaping the future direction. Health minister Andrew Stephenson said: *"These cutting-edge technologies could help thousands of patients with a range of conditions, including cancer, stroke, and Alzheimer's, while easing pressure on our hospitals and reducing healthcare inequalities. Our investment in these pioneering companies is part of our long-term plan for a faster, simpler and fairer health care system, and demonstrates our clear commitment to ensuring the UK is the most innovative economy in the world."*

3.2. The selected eight applicants will now receive non-financial support from the IDAP partners who will work with the companies to develop a TDP which provides a pre-market roadmap for the technology including engagement with other IDAP tools. This will define the regulatory and access requirements for each product. This stage of the pilot began in March and will continue throughout the next quarter. It is the expectation of the pilot that the support provided via the IDAP TDP and tools will improve patient access or will help by simplifying and accelerating the route to market for these innovations. The pilot is designed to capture evidence to enable refinements to be developed in order to optimise a future innovative pathway that supports medical technologies alongside medicines.

3.3 Following completion of the pilot we will be seeking to develop and scale up the IDAP to enable manufacturers to provide their innovative devices to healthcare professionals and patients at the earliest, safe opportunity. This will support the priorities outlined in to MedTech Strategy and the McLean Review to make further progress to create innovative access routes for devices by creating clear, scalable, end to end pathway that meets the needs of the UK health and care system and industry.

Innovative Licensing and Access Pathway (ILAP)

3.4. ILAP was launched on 1 January 2021, ILAP has had significant interest and some early successes in supporting innovative products, representing innovative medicines serving a range of different therapeutic needs such as rare diseases, common cancers, dementia, and mental health. Summary figures below:

Number of IP applications received: 225
Number of IP applications Granted: 153
Number of TDPs delivered: 27

3.5. Of the 153 products with an IP a total of 24 have had a Marketing Authorisation granted and 4 have had promising innovative medicine (PIM) designation.

3.6. The Pro-innovation Regulation of Technologies Review (McLean Review published May 2023), lessons learned from running the ILAP, a Task and Finish Group with HTA bodies and direction from senior leadership across the partners, have highlighted a number of challenges and opportunities for improvement for ILAP. The key recommendations from the McLean review were:

- “Too many products are being assigned to ILAP which is overwhelming regulator capacity and leading to slow processing of applications.”
- “Ensuring appropriate governance and decision making for the products to be granted an ILAP designation, so as not to overwhelm the system.”

3.7. A group of industry stakeholders has been established using the Trusted Advisor Model to help inform the approach to ILAP to further optimise the pathway in advance of introducing any changes to ILAP. We are working with this group to test details of the proposals set out below in more detail. This feedback will be

crucial to inform the approach before the proposed revisions to ILAP can be applied from the end of Q1 2024/25.

3.8 Insight provided through engagement with Commission for Human Medicines (CHM) and industry through the Trusted Advisor group and from the Patient Access to Medicines Partnership (PAMP) have indicated that, while there is strong support for the ambition of ILAP, there is more to do to improve the value proposition and provide clarity on the offer.

3.9. Our intention is to deliver a reliable process for ILAP decisions, with ILAP products meeting a strict set of criteria focussing on transformative promise and unmet need to be published ahead of the revised process going live and supported by a comprehensive communications package which clearly sets out the benefits for applicants. Specifically, this includes:

- **Collaboration Agreement and Governance**: This will formalise the partnership and clarify the roles and responsibilities of the partners involved, learning from the model that has worked for IDAP. The partners have agreed the high-level governance structure and work is progressing to formally initiate the new arrangements. This will ensure the responsibilities for implementing ILAP and for providing strategic oversight going forward are in place. These will include DHSC representation as appropriate.
- **Revision to the ILAP selection criteria**: Building on the work of the ILAP Task and Finish Group in 2023 and incorporating more recent learning from IDAP the partners have developed a proposal for a revised set of ILAP criteria with the intent of focussing the pathway to products that provide the promise of transformation in healthcare, where ILAP could add significant value to accelerate development. The addition of the NHS is adding a new perspective to further refine the criteria by incorporating suggestions on how the ILAP advice could anticipate needs identified by the Standard of Care and the wider Patient journey.
- **Refinement to the process for product entry**. Alongside revisions to the entry criteria partners have developed proposals for a new process for reaching decisions on entry to ILAP, building on the approach and lessons learnt from IDAP. This will provide developers applying to ILAP with a reliable process with certainty on timelines for decisions.
- **Review of the Target Development Profile**. The current approach for the Target Development Profile is being considered by a cross-partner working group involving appropriate experts, to enhance the quality of these and ensure they add significant value to support product development. This is being informed by advice from the CHM and the industry Trusted Advisor Group to ensure this ‘product’ adds value and provides advice that is consistent, high-quality, and scientifically robust.
- **Review of ILAP Toolkit**. Work is underway to review the current suite of ILAP “tools” (targeted advice to help with specific aspects of regulatory and HTA approval) to optimise these and ensure they represent a significant value proposition to companies to expedite the pathway for transformative products and meet company expectations. In the very short term (from Q1 2024/25) we would

expect to provide ILAP products with access to a core of set of “tools”. We will then take a step wise approach to build from this and further increase, strengthen and enhance the toolkit following the initial relaunch.

- **Patient involvement.** We are engaging with existing members on the patient reference group to seek their feedback on their experience and their views on how best to involve patients and the public going forward in the pathway. Work is also ongoing with Partners to consider approaches to ensure the Patient Voice is embedded as part of the refresh. We will be arranging a workshop with patients to test the proposals to further optimise the pathway in this regard.

3.10. It is essential we provide a smooth transition as we seek to introduce changes to ILAP as part of the refresh to provide clarity on how their applications will be assessed (e.g. which criteria will apply) and what support they can expect as part of ILAP. It is clear that we need to honour commitments made and cannot seek to retrospectively apply new criteria or approaches to applications received before the launch of the refresh. It will be necessary to communicate the new criteria in advance of the new application process going live in order to give potential applicants time to consider their application and to signal when the change will happen. A comprehensive strategic communications plan is being developed to ensure a smooth transition and provide transparency to companies.

4. Recommendation

4.1 The Board is asked to note the current performance of the innovation pathways and work ongoing to optimise these going forward.

4.2. The Board is asked to consider what opportunities could be pursued to further enhance the customer experience of ILAP and IDAP as we seek to develop these into enduring and sustainable innovative pathways for the future.

4.3. The Board is asked to consider if there are additional areas that need to be considered as we seek to explore future opportunities for creating more streamlined access to innovative pathways for all types of healthcare products.

Marc Bailey
19 March 2024

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

19th March 2024

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

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

1. Executive Summary

1.1 PSEC discussed two substantive items which were: “Isotretinoin: approaches to patient engagement, their impact and lessons learned”; and “How are patients being involved in the development of the New Medical Device regulations and how will the new rules improve Patient Safety”.

1.1.1 The Committee reviewed the process of patient and public engagement in the review of Isotretinoin. It focussed on lessons learnt for similar issues that will arise in the future in terms of concerns on the risks and benefits of medicines. In particular how people are involved, who is involved, what changes this leads to, and how those changes are implemented. PSEC concluded that in future consultations should use timely feedback, the best use of resources and ensure all views are gathered.

1.1.2 The Committee reviewed how patients and the public were consulted on the new Medical Devices Regulations. It also considered the new approaches to patient safety introduced by the new regulations. PSEC noted the limited interest in the new regulations as patients and the public do not know how they will relate to them. However, there was an expectation that the Agency ensure safety. Further work probably needs to be done with patients who have suffered harm in the past. The Committee also were encouraged by many of the safety features in the new regulations including giving patients more information on implantable devices.

2. Introduction

2.2 The Patient Safety and Engagement Committee met on 15th February 2024.

3. PSEC discussed each of the following items at the meeting

3.1 **Isotretinoin: approaches to patient engagement, their impact and lessons learned**.

The committee reviewed the process of patient and public engagement in the review of Isotretinoin. The communications and patient engagement teams worked with Safety and Surveillance to reach those people using isotretinoin as well as family and friends. This was done through a range of methods including social media. The consultation time was extended from the usual 12 weeks to 14 weeks. PSEC ascertained whether a range of views from those who had benefited as well as those who had reported risks were obtained, and it was confirmed there were both types of responses. The work on Isotretinoin had needed many resources over several years. The consultations did lead to recommended

changes, but implementation is complex and further guidance is needed to support implementation. PSEC concluded that in future consultations should use timely feedback, the best use of resources and ensure all views are gathered. Assurance on implementation cannot be given as this is still to be done. However, lessons have been learnt through this consultation.

3.2 **How are patients being involved in the development of the New Medical Device regulations and how will the new rules improve Patient Safety.**
Consultation on the new regulations for Medical Devices attracted limited responses from patients and the public so a more targeted approach using specific representatives was undertaken. This produced consistent responses in that their expectation was that the Agency would do appropriate "due diligence" to ensure devices used in the UK were safe. However, specific groups who have been let down in the past were not consulted, and it was agreed this was an omission. PSEC also reviewed the new safety features in the new regulations including new duties on manufacturers for post market surveillance and the provision of information to patients such as the implant card. This will enable patients to identify the implanted device and get other information. It can also be used to identify themselves as needing special care, for instance in security checks and with first responders in emergency situations. A key recommendation from the Independent Medicines and Medical Devices Safety Review was the Unique Devices Identifier and PSEC was informed how this will be implemented through Regulatory Connect, our future IT system.

3.3 **PSEC's Forward Plan**
The Committee discussed several items for PSEC as well as the spread of topics over the rest of the year. Preliminary agendas for the meetings in May, August and November 2024 were agreed.

3.4 **Any other business**
The Chair of PSEC will be meeting with the Patient Safety Commissioner to discuss the work of the assurance committee and will ask for further feedback.

4. Conclusion

4.1 The Committee were updated on the state of the Isotretinoin review and lessons learnt through this work, as well as how the new regulations on Medical Devices were consulted on and how they will protect patient safety.

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

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

19th March 2024

Title	What were the results of the 2023 People Survey and what actions are being taken to address these?
Board Sponsor	Liz Booth
Purpose of Paper	Assurance

What were the results of the 2023 People Survey and what actions are being taken to address these?

1. Executive Summary

1.1. Good improvements in scores across the board compared to both 2022 and 2021 Civil Service People Surveys but noting that improvements are from a low base.

1.2. Engagement index score is now 58% (2022: 48%) still disappointing but improving.

1.3. Propensity to 'stay' now almost at civil service benchmark.

1.4. Three primary areas of corporate focus driven by data, narrative comments from colleagues, our strategy and culture action plan. These are:

- Support people to raise concerns and protect wellbeing
- Increase productivity and provide support to manage workloads
- Build confidence in and transparency of leadership decision making

1.5. Some areas of concern that will be prioritised in future years are: Career paths; Access to learning; Pay and Access to tools.

2. Introduction

2.1. The Civil Service People Survey is an annual survey conducted electronically in September / October amongst 103 civil service departments and agencies with the first outputs available to organisations in December.

2.2. This year 923 MHRA colleagues completed the survey.

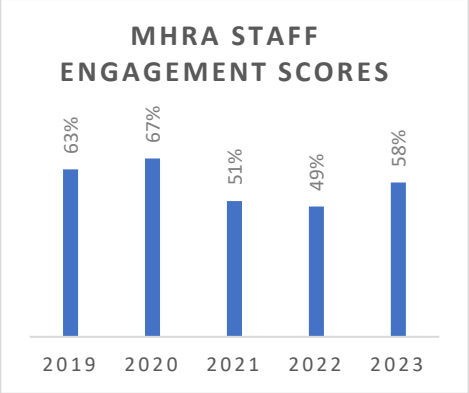
3. Results

3.1. Engagement index trend

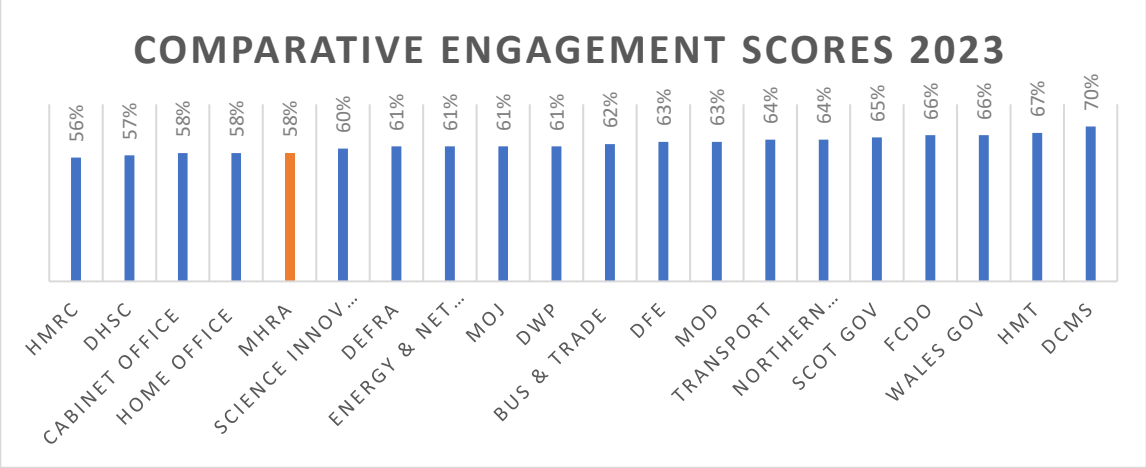
3.1.1. The Engagement Index is the composite measure that assigns a score to individual responses to five key statements:

- I am proud when I tell others I am part of my organisation
- My organisation inspires me to do the best in my job
- I feel a strong personal attachment to my organisation
- I would recommend my organisation as a great place to work
- My organisation motivates me to help it achieve its objectives.

3.1.2. In 2023 we saw a recovery to 58% from the very poor scores that coincided with the transformation programme.



3.1.3. This places the Agency in the lowest quartile and thus remains a cause for concern. Comparison with the main government departments is below.



3.1.4. It is achievable to target a four percentage point increase in the score for 2024 against what appears to be a downward trend in engagement in the civil service generally since 2020.

3.2. Propensity to Stay

3.2.1. The Agency demonstrates an improving picture with 76% of colleagues (2022: 66%) reporting that they are intending to stay for three years or more against a civil service propensity to stay for three years or more of 78%. This is triangulated by actual turnover which is now in the target range.

3.2.2. However, there was some variance in the push factors for those reporting an intention to leave. Colleagues were able to cite multiple factors and the top four factors for the MHRA were as follows.

	% of MHRA colleague citing the factor	% of civil servants generally citing the factor
Perceived poor pay and benefits	50%	50%
Perceived poor leadership	39%	30%
Perceived unmanageable workload	35%	21%
Dislike of culture	35%	26%

N=221

3.2.3. This data informed our action plan.

3.3. Variation between team results

3.3.1. Some variation in the results between teams is noted and Chief Officers and Directors will look in detail at their results (with all data cuts available on INsite) and take local decisions about the need for additional local action plans.

Core Themes Heatmap (percent favourable results)

Comparison: vs Current

Breakout: One level below

	MHRA0000 Medicine...	MHRA1000 Corporate	MHRA2000 Partners...	MHRA3000 Digital & ...	MHRA4000 Enablem...	MHRA5000 Scientific...	MHRA6000 Safety & ...	MHRA7000 Healthcar...
Response Counts	923	93	24	98	85	180	215	224
My Work	78%	80%	79%	80%	77%	78%	75%	79%
Organisational objectives and purpose	79%	81%	81%	86%	86%	67%	76%	85%
My Manager	77%	81%	77%	78%	84%	73%	77%	77%
My Team	83%	82%	82%	88%	79%	78%	83%	85%
Learning and development	47%	54%	50%	57%	50%	36%	51%	44%
Inclusion and fair treatment	78%	84%	75%	82%	82%	71%	79%	79%
Resources and workload	66%	71%	70%	73%	71%	62%	63%	65%
Pay and benefits	27%	33%	42%	28%	38%	25%	28%	20%
Leadership and managing change	39%	46%	38%	52%	48%	28%	40%	37%

4. Action plan

4.1. Corporate Action Plan

4.1.1. In coming to conclusions about where to focus the Agency's corporate action plan the following were considered:

- the quantitative results
- narrative comments from survey participants as part of the survey
- propensity to stay data
- comparisons with 2022 results
- comparisons with the 2023 civil service benchmark.

4.1.2. Following considerable debate, the One Agency Leadership Group (OALG) took the decision to focus primarily on the 2023 civil service benchmark.

4.1.3. The corporate level people survey action plan was published in January 2024 and members of the OALG have assumed responsibility for aspects of its delivery.

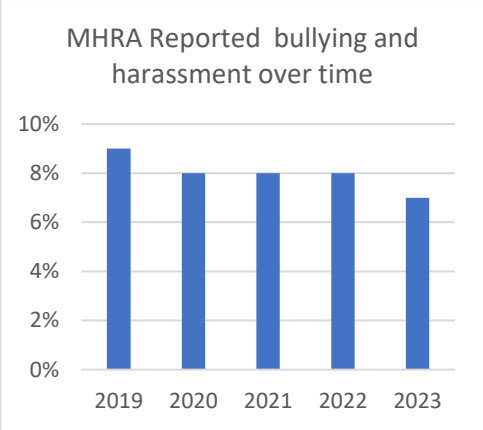
4.2. Themes

4.2.1. Three themes emerged strongly, all of which are interlinked.

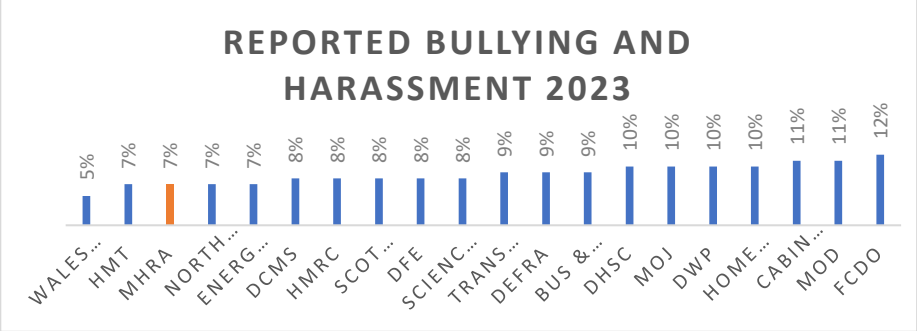
4.3. Theme: Support people to raise concerns and protect wellbeing

4.3.1. There are a cluster of questions (B46, B56, B57, W09, W10 LQA3) that speak to being supported, feeling safe to challenge, and to providing an environment free of harassment. Whilst there are significant gains against many of these questions, there is an approximate 12 percentage point deficit compared to the civil service benchmark and this is a gap that the Agency will focus on closing. This is necessary to achieve objective four of the Agency's corporate plan.

4.3.2. One focus will be reducing perceptions of bullying and harassment within the Agency. This is an area where the Agency has made steady progress over time.



4.3.3. Although the Agency compares favourably with primary government departments, this area is key to staff engagement and is necessarily a focus.



4.3.4. There will also be a focus on wellbeing. There are many tools and resources already in place but the Survey indicates that these are not communicated well enough. For example, only 46% of colleagues feel they have good support for wellbeing and a third report that they never discuss their wellbeing with their line manager.

4.3.5. Finally, our aspirations demand we have a culture where colleagues feel able to challenge decisions and behaviour. Only 37% of MHRA colleagues think it is safe to challenge the way things are done, with 35% not sure and 28% feeling that it is not safe. Without this “psychological safety” we will struggle to create and maintain true excellence in regulation and science. This requires a confident and questioning workforce that embraces a diversity of view to make the best decision for public health.

High level corporate commitments

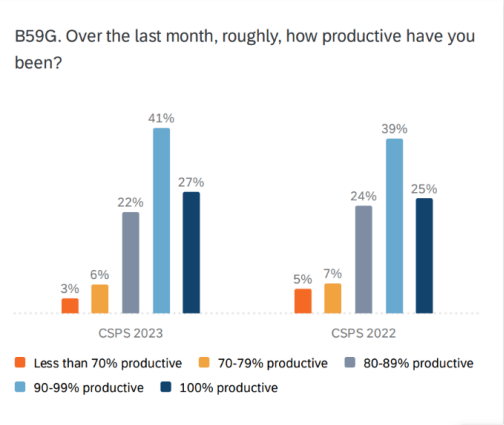
- Roll out a new wellbeing survey in collaboration with the Staff Partnership Group to monitor wellbeing concerns regularly and introduce new wellbeing tools in response to feedback.
- Refresh our approach to reporting bullying and harassment to make sure that everyone knows what to do if a concern is raised with them. This might include introducing a respect policy; publicising a freedom to speak up guardian and/or providing an anonymous reporting line.

4.4. Theme: Increase productivity and provide support to manage workloads

4.4.1. Established backlogs in key areas already indicate concern about productivity and informally we know that many colleagues are struggling with workloads.

4.4.2. Reported data is an improvement on the past two years when only a third of colleagues felt they had an acceptable workload, and this year 49% believed they did. However, this is 15 percentage points behind the civil service benchmark and is a matter of real concern. Work life balance has recovered to 2020 levels but also remains considerably behind the civil service benchmark.

4.4.3. Productivity is slightly improved with 31% of colleagues reporting that they were less than 90% productive (2022: 36%).



4.4.4. Fifty percent of MHRA colleagues feel that the organisation is pursuing efficiency as a priority which is typical of civil service responses. This suggests that optimising business processes was not achieving full traction in October 2022. This is possibly due to some delays in implementing new IT systems or may be as a result of change fatigue. The focus on Return to Green in selected areas will focus on efficiency and productivity in those key areas. The clear aspiration to be a world class regulator requires that optimal efficiency and productivity extends to all parts of the Agency, but that this is not achieved at the expense of colleague wellbeing.

High level corporate commitments

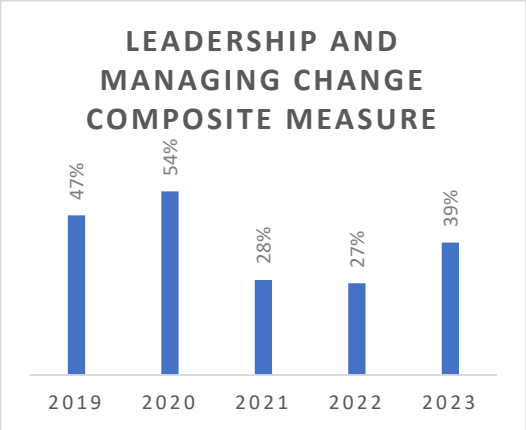
- Identify areas where colleagues feel routinely overworked and determine and address the causes.
- Set realistic goals to reduce excessive workloads and develop our processes to ensure we are measuring productivity against expectations.
- Refresh the guidance for manager 1:1s with their teams, to include discussions on performance, workload and wellbeing.
- Further develop workforce plans so that we are developing people to fill the next level of management.

4.5. Theme: Build confidence in and transparency of leadership decision making

4.5.1. Responses to the group of questions about leadership and the management of change demonstrate that colleague perceptions of leadership are not at the level normally associated with a high performing organisation.

4.5.2. As in almost every other category this is a much improving picture, but the shadow of the transformation programme is a long one.

4.5.3. Below is the time series for the group of questions about leadership and managing change.



4.5.4. In 2024/25 the Agency continues to be focused on change including Return to Green, SafetyConnect Phase 2, and RegulatoryConnect. This requires all leaders and particularly change programme leaders to focus on listening to colleague feedback and communicating the changes we are making as a result.

4.5.5. There are four question responses of particular note. These are:

- Only 60% (2022: 44%) of our colleagues think senior managers are sufficiently visible compared to civil service benchmark of 71%
- 19% (2022: 8%) of colleagues feel that change is well managed compared to the benchmark of 34%
- 48% (2022: 34%) think the organisation keeps them informed about the matters that affect them compared to a benchmark of 64%
- Overall confidence in the decisions made by senior managers is 44% (2022: 27%) compared to a benchmark of 56%

High level corporate commitments

- Increase the involvement of shadow ExCo and the Staff Partnership Group to set the agendas of senior-level meetings and to raise the topics that colleagues want discussed. Ensure notes are widely available.
- Trial 'talk-back briefings' after key meetings. For example, a couple of members of ExCo talk informally to all staff immediately at the conclusion of the meeting, about topics covered, decisions made and to take questions.
- Greater recognition for the work of individuals and teams, including through agency awards.

5. Areas for future focus

5.1. The OALG agreed the requirement for an achievable action plan, noting the limited time available until the next survey.

5.2. The OALG identified several areas for future focus:

5.2.1. Career paths
5.2.2. Access to learning
5.2.3. Pay
5.2.4. Access to tools

5.3. The relevant teams will continue to work on these areas in the background in preparation for the 2024 survey action plan.

6. Communication

6.1. It is noted that the high-level corporate commitments are intended as examples of activities to enable changes in the three key areas. The intention is to build on these as we discuss the plan with colleague representatives and receive feedback from colleagues.

6.2. There will be a monthly blog summarising actions taken in the preceding month.

6.3. The three themes will be referenced in routine communications demonstrating that they are at the heart of our aspirations.

7. Equalities

7.1. All significant actions area of course subject to equalities impact assessment.

8. Recommendation

8.1. The Board is asked to note the views of MHRA staff contained within the 2023 People Survey.

8.2. The Board is asked for comment, advice, and help to implement the action plan.

Liz Booth
March 2024