Medicines & Healthcare products Regulatory Agency

AGENDA FOR BOARD MEETING HELD IN PUBLIC

10:00 am – 12:30 pm on Tuesday 19 September 2023

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 operational performance for the MHRA for Quarter 1, 2023/24?	Assurance	Rose Braithwaite
10:50	6. How effectively is the MHRA maintaining performance on clinical trials and how has a sustainable clinical trial function been established from 1 September?	Assurance	Marc Bailey
	DYNAMIC ORGANISATION		
11:35	7. What is the progress in delivering an excellent culture with strong leadership at the MHRA?	Strategic Direction	Chief People Officer / Malgosia Malach
	ASSURANCE		
11:55	8. What assurance can be provided by the Patient Safety and Engagement Committee?	Assurance	Mercy Jeyasingham
12:05	9. What assurance can be provided by the Organisational Development and Remuneration Committee?	Assurance	Mandy Calvert

	EXTERNAL PERSPECTIVE		
12:15	10. What questions do members of the public have about the items on this Board Meeting Agenda?		Chair
12:30	CLOSE OF MEETING		

MHRA Board Declarations of Interest – September 2023

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
	NIHR	NIHR Research Professor	Yes	Yes
	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	Yes
	30 Technology Ltd	Consultant/Advisor	Yes	Yes
	DNAnudge Ltd	Consultant/Advisor	No	Yes
	Seventh Sense Biosystems	Consultant/Advisor	Yes	Yes
	Debevoise and Plimpton LLP	Consultant/Advisor in relation to COVID protocols	Yes	No
	Sanofi CoV	Chair of End Point Review Committee for vaccine trial	Yes	Yes
	WHO	Chair 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

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	Tbc			
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.	Yes	Yes
	University of Manchester digital Experimental Cancer Medicine Team	Quince Consultancy providing strategy and data protection consultancy	Yes	No
	Cambridge Judge Business School	Member of Advisory Board	No	Yes
	Fennix Pharmaceuticals	Founder of start-up company planning to develop oral chemotherapy product into Phase 2 trial. Not yet trading.	No	Yes
	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	Yes
	MDU Investments Ltd	Director	Yes	Yes

Name and MHRA Role	Name of Other Company or Organisation	Nature of interest	Paid	Current
	NHS	Consultant Neurologist	Yes	Yes
	NHS	Clinical Senate Member	No	Yes
	Radix Big Tent Foundation	Trustee	No	Yes
	Sleepstation	Co-founder of original programme, 2012-2014	No	No
Claire Harrison Chief Digital & Technology Officer	None	N/A	N/A	N/A
Haider Husain Non-Executive Director	Healthinnova Limited	Chief Operating Officer	Yes	Yes
	Milton Keynes University Hospital NHS Foundation Trust	Non-Executive Director	Yes	Yes
	British Standards Institute	Panel Chair BS30440 – Use of AI within Healthcare	No	Yes
	Dementia Carers Count	Trustee	No	Yes
	World Wars Muslim Memorial Trust	Trustee	No	Yes
	Microsoft Corp	Ex-employee shareholder	No	No
	BBC	Family Member	No	Yes
	NHS Buckinghamshire, Oxfordshire and Berkshire West Integrated Care Board	Associate Non-Executive Director	Yes	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
	EC IMI NEURONET EC Innovative Medicines Initiative (IMI) Non-Product	Scientist Advisory Board	No	Yes
	Gates Venture – EC Innovative Medicines Initiative (IMI) Non-Product – IMI European platform for Neurodegenerative Disorders	Advisory	Yes	Yes
	HUYA Bio	Access Advisory	Yes	No
	PAVIA – PV Africa Board (EC Funded)	Advisory Board	No	Yes
	WHO – Sustainable COVAX Manufacturing Strategy for Regional Health Security	Advisory Expert	No	Yes
	UK Health Security Agency	Associate Non-Executive Board Member	Yes	Yes
	EU Innovative Health Initiatives (IHI)	Advisory Expert for this EU public-private partnership funding health research and	Yes	Yes

Name and MHRA Role	Name of Other Company or Organisation	Nature of interest	Paid	Current
		innovation funded by European Commission		
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 11 July 2023

(09:30am – 12:00pm)

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

Present:

The Board

Stephen Lightfoot	Chair
Dr June Raine DBE	Chief Executive
Dr Marc Bailey	Chief Science, Research & Innovation Officer
Dr Junaid Bajwa	Non-Executive Director
Rose Braithwaite	Chief Finance Officer
Dr Alison Cave	Chief Safety Officer
Amanda Calvert	Non-Executive Director
Professor Graham Cooke	Non-Executive Director and Deputy Chair
Dr Paul Goldsmith	Non-Executive Director
Claire Harrison	Chief Digital & Technology Officer
Haider Husain	Non-Executive Director
Mercy Jeyasingham MBE	Non-Executive Director
Raj Long	Non-Executive Director
Dr Laura Squire OBE	Chief Healthcare Quality & Access Officer
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

INTRODUCTION

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

1.1 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 Kathryn Glover, Deputy Director of Medicines Regulation and Prescribing, DHSC; 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. No new declarations were made this month. The Chair reviewed the existing 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**.**

ANNUAL REPORT

Item 4: What assurance can be provided by the Audit and Risk Assurance Committee?

4.1 The Board considered an assurance report from the Audit and Risk Assurance Committee (ARAC). The ARAC met on 4th July 2023 and considered the National Audit Office's completion report summarising the outcome of their final audit of the MHRA's Financial Statements for 2022-23; an update in implementing the recommendations of the Health and Safety Executive; the internal audit reports for 2022-23 together with their Annual Assurance assessment for the year; and reviewed the risk register focusing on managing the Agency's cyber security risks.

4.2 The Board noted the ARAC Chair's commendation for all staff involved in the timely completion of the financial statements and the annual report and accounts. The Board provided further comments relating to ensuring patient involvement in internal audits is reviewed by the Patient Safety and Engagement Committee; the work ongoing to revisit the Agency's risk appetite cross-Agency to ensure understanding on risk management; it was noted the Board is due to review risk at the Board in November.

Action 99: Patient involvement in internal audit should be reviewed by the Patient Safety and Engagement Committee. ***Carly McGurry***

Item 5: How well does the 2022/23 Annual Report and Accounts reflect the performance, governance and financial results of the MHRA over the last year?

5.1 The Board reviewed a paper describing the 2022/23 Annual Report and Accounts. The annual report and accounts for the Agency have been prepared in accordance with the relevant requirements and been subject to audit by the National Audit Office (NAO). The Executive Committee (ExCo) and the Audit & Risk Assurance Committee (ARAC)

have both reviewed and approved the documents. The Board reviewed the draft Annual Report and Accounts.

5.2 The Board noted that this year's Annual Report and Accounts sets a new standard of quality and timeliness; noted the achievements of the Agency throughout the year; and expressed their sincere thanks to all members of staff involved in producing this report. The Board endorsed the Annual Report and Accounts and advised Dr June Raine as CEO to sign the report and accounts, prior to submission to the NAO for certification.

Action 100: The Board endorsed the Annual Report and Accounts; these should now be signed and submitted to the NAO for certification.

June Raine

AGENCY PERFORMANCE

Item 6: What are the most current important activities and priorities from the CEO's point of view?

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

(i) Scientific Research and Innovation – including latest updates on a Global Training Hub for Biomanufacturing; vaccine standardisation; Nipah virus research; attenuated oral polio vaccine; measles and rubella elimination; Group A streptococcus; Alzheimer's disease; scientific collaborations; multiplex immunoassay development; and outreach presentations to students;

(ii) Healthcare Access – including updates on licensing performance; adrenaline autoinjectors; patient engagement; and medtech regulatory reform;

(iii) Patient Safety – including updates on sodium valproate harm reduction; the lenalidomide pregnancy prevention programme; calcium gluconate dosing recommendations; the Clinical Practice Research Datalink; and criminal enforcement;

(iv) Digital and Technology – including updates on adverse event reporting; signal detection and case management; the Regulatory Management system; the NIBSC e-mail change; the freeze dryer project; and the laptop refresh;

(vi) Communication and Engagement – including updates customer insight projects; and patient and public enquiries;

(vii) Partnerships – National and International – including updates on the international recognition framework; international cooperation; the Access Consortium; and the Windsor Framework; and

(viii) Dynamic Organisation – including updates on the Corporate Plan 2023-26; Health and Safety; and cost of living.

6.2 The Board thanked Dr Raine for her report and provided comments relating to educational outreach and linkage with communications activities; progress in eliminating backlogs; customer insight; improving communication of safety messages to healthcare professionals; FOI requests; embedding the role of the MHRA in education of healthcare professionals; utilising the MHRA's expertise to build partnerships with a purpose; international recognition; the significant steps forward on the Agency's technology agenda; and leading development of reform of the medtech development framework. The Board noted Dr Raine's report with thanks.

Item 7: What was the operational performance of the MHRA for the year up to 31 May 2023?

7.1 The Board considered a report describing the Agency's operational performance for this year up to 31 May 2023. It was noted the financial performance at the end of May showed an operating surplus of £2.2m. It was noted that the Agency's new reporting requirements as an ALB within the accounting boundary of the DSHC mean the Agency must manage all expenditure and income within the financial year; it is not possible to access any previous year reserves. Customer debt has reduced to £10.1m in May reflecting a significant reduction in outstanding debts; there is continued focus on clearance of debt over 6 months. The Agency continues to meet the aged debt target.

7.2 The Board noted that people resource within the Agency remains critical in terms of capability, capacity, quality and ultimately to Agency performance for patient, business and financial outcomes. A concerted effort continues to finish recruiting to the new structure; the benefits of this are now beginning to be seen. Focus is now on delivery of incremental improvement by targeting highest impact recruitment and reducing sickness absence. The Board noted the update and provided comments relating to ensuring the level of capital spend remains consistent throughout the year; delivery of the Regulatory Management System; and the work of the finance team to build relationships with operational leads within the Agency to drive improvements in the financial management system.

7.3 The Board discussed clinical trials performance and actions being taken to address the backlog, noting that patient safety remains the highest priority. These actions have included increasing recruitment into the clinical trials assessment team, movement of assessment staff from other areas of the Agency into the clinical trials team, process improvements, and increased communication with applicants. Marc Bailey informed the Board that he was very confident that a return to statutory timeframes would be seen from 1st September. The Board noted that a communications strategy will need to be developed with active continuous stakeholder engagement to mitigate any reputational issues.

7.4 The Board discussed established medicines performance; the Board noted the actions taken to address the backlog in this area including that a task and finish group, a focus on recruitment, and training. The Board noted the first commitment in relation to performance has been met; and the educational events with industry continue to increase the quality of initial applications. The Board were assured by this update.

7.5 The Board discussed performance in relation to people and noted the significant improvement in recruitment figures. The Board noted the performance report with thanks, and requested a proposal at the next Board meeting on the proactive communications and engagement activities which will maintain trust in the Agency from industry and research customers.

Action 101: Present an update to the Board on the performance and proactive communications and engagement activities which will maintain trust in the Agency from industry and research customers. Marc Bailey

SCIENTIFIC EXCELLENCE

Item 8: What are the strategic priorities in the MHRA Science Strategy to enable the faster access of safe and innovative products to patients in the UK?

8.1 The Board considered the MHRA Science Strategy, which sets out the importance of building current capabilities, expanding and enhancing them through internal investment and leveraging of the UK research and innovation expertise across the sector. The Board noted that the MHRA both as a Public Sector Research Establishment (PSRE) and as a regulator, must deliver a scientific programme capable of enabling its regulatory functions and its role in supporting innovation. This will be made possible through conducting intramural research such as the work carried out at South Mimms. This will be expanded through extramural collaborations with the UK (and international) research and innovation sectors. In addition, and in line with Government policy, MHRA will support the development of Centres of Excellence in Regulatory Science and Innovation (CERSI) to capture further the world leading UK research community to ensure that the agency has access to cutting edge innovations to support its roles.

8.2 The Board gave thanks to all Agency teams and Non-Executive Directors who have been involved in developing this strategy. The Board provided comments relating to ensuring a focus on strategic partnerships; maintaining a focus on public health; ensuring delivery is carefully tracked through the Corporate Plan; capacity building; the benefit of the end-to-end regulatory process; understanding opportunity costs; establishing the scientific advisory boards from the beginning; implementation of the O'Shaughnessy and McLean reviews recommendations; and undertaking a systematic review of the Agency's current R&D portfolio to ensure alignment to these priority areas. The Board endorsed the Science Strategy.

Addition to action 29: Present an update to the Board on progress against each of the themes in the Science Strategy at the end of 2023.
Glenn Wells / Marc Bailey

PATIENT SAFETY

Item 9: How well has SafetyConnect and other MHRA actions over the last three years helped to address the concerns raised by the Cumberlege Review?

9.1 The Board considered paper describing how well SafetyConnect and other MHRA actions over the last three years have helped to address the concerns raised by the Cumberlege Review. The Cumberlege Review (the Independent Medicines and Medical Devices Safety Review, IMMDSR) was published on 8th July 2020; the Board considered how well the Agency's actions have helped to address the concerns raised by the Review and delivered on the ambition to put patients at the centre of everything we do. In response to the Cumberlege Review, the Board endorsed the Agency's planned short, medium, and long-term deliverables. This paper provides an update on what has been achieved by the Agency so far and the differences these deliverables have made or are expected to make for patients.

9.2 The Board reviewed the actions and provided comments related to the deliverables in Corporate Plan; the involvement of the Patient Safety and Engagement Committee in overseeing this work; working with the Patient Safety Commissioner; increasing awareness of the Agency and the Yellow Card Scheme; increasing reporting from healthcare professionals in secondary care; linking with primary care networks; and linking with the Communications and Reputation Strategy. The Board thanked all members of staff involved in delivering this work. The Board suggested that the Patient Safety Commissioner should be invited to a future Board meeting.

Action 102: Invite the Patient Safety Commissioner to a future Board meeting.
Alison Cave

Item 10: What assurance can be provided by the Patient Safety and Engagement Committee?

10.1 The Board considered an assurance report from the Patient Safety and Engagement Committee (PSEC). PSEC discussed three main areas at its meeting on 12 May 2023: the forward plan for the Committee, the minimisation of risk associated with sodium valproate, and the evaluation of the patient and public involvement strategy by the Agency. The Board noted the report for assurance.

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 when the MHRA will return to competitive timing of clinical trial approvals; and international recognition.

GOVERNANCE

Item 12: What are the new arrangements for chairing the MHRA?

12.1 The Board noted that Stephen Lightfoot is stepping down as Chair today following 8 years on the Board as a Non-Executive Director, and 3 years as Chair. The Chair noted that until a new Chair has been appointed, Michael Whitehouse, Amanda Calvert and Graham Cooke will act as interim co-chairs. The Chair thanked all those observing this meeting, his Board colleagues, and in particular paid tribute to the staff working at the MHRA. Dr Raine expressed her sincere thanks to Stephen Lightfoot for everything he has done for the Agency in his time as Non-Executive Director and as Chair.

ANY OTHER BUSINESS

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

ACTIONS FROM MHRA BOARD MEETING IN PUBLIC – 11 July 2023

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~~ 21/11/23	
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~~ 19/09/23	
73	15/02/22: Develop a Sustainability Strategy.	Glenn Wells	~~17/01/23~~ 16/01/24	
97	16/05/23: ARAC will undertake a deep dive on RMS; all Board members will be invited to attend.	Michael Whitehouse	19/09/23	
98	16/05/23: The Board approved the draft Corporate Plan; this should now be submitted to DHSC for approval. A Business Plan for 2023/24 should now be	Rose Braithwaite	11/07/23	Completed

	prepared to deliver the actions in the first year of the 3-year Corporate Plan. 11/07/23: The Corporate Plan was launched on the 4th July 2023; the Business Plan is currently going through DHSC approvals process and will be published shortly.			
New Actions				
99	Patient involvement in internal audit should be reviewed by the Patient Safety and Engagement Committee.	Carly McGurry	21/11/23	
100	The Board endorsed the Annual Report and Accounts; these should now be signed and submitted to the NAO for certification.	June Raine	19/09/23	
101	Action: Present an update to the Board on the performance and proactive communications and engagement activities related to clinical trials which will maintain trust in the Agency from industry and research customers.	Marc Bailey	19/09/23	
102	Invite the Patient Safety Commissioner to a future Board meeting.	Alison Cave	17/10/23	

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

19 September 2023

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

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

'TOP 10' HEADLINES

- We have published our Business Plan 2023-4, setting out the objectives of the first year of our Corporate Plan 2023-26, including the introduction of our new science strategy
- From 1 September clinical trial applications are now handled within statutory timelines, having dealt with a backlog which arose during training of new assessors to fill vacancies
- We have progressed our Agency strategy to combat antimicrobial resistance via research on the microbiome and a multi-stakeholder meeting on the regulation of phage products
- An independent expert review concluded that UK-sourced plasma can be used for the manufacture of albumin medicinal products, in addition to manufacturing immunoglobulins
- We approved the Bimervax Covid-19 vaccine, the 9th Covid vaccine in the UK, and have also approved an adapted vaccine, Cominarty, that targets the Omicron XBB.1.5 variant
- We published guidance for industry on the new international recognition procedure covering the application process, reference regulators and related evidence requirements
- We launched the Yellow Card Centre Northern Ireland, the sixth UK satellite centre with a vital outreach role encouraging reporting of adverse incidents and suspected reactions
- We received over 900 responses to a public consultation on moving codeine linctus from pharmacy availability to prescription only, a further step to minimise risk of opioid addiction
- Following collaborative work with the National Institute for Health and Care Excellence and the Office of Life Sciences, the Innovative Devices Access Pathway will be piloted
- We have designated three new Approved Bodies for medical devices in the UK, doubling the UK's capacity to certify devices, in line with a Life Sciences Council announcement.

DYNAMIC ORGANISATION

Business Plan 2023-24

1.1 Following the publication of the Agency's Corporate Plan 2023-26, we have now published the Business Plan 2023-24 which provides detail on how we will deliver our objectives for the first year of the Corporate Plan. Over this year and into the next there will be a number of important developments including optimisation of our service delivery times in priority areas, improved patient access to innovative products by formalising new recognition pathways for UK and the introduction of new legislation and guidance on critical topics such as clinical trials, Medtech and Point of Care Manufacture. These will realise some of our opportunities as an independent regulator and help make the UK an attractive place to develop and launch new medicines and medical devices. A key focus will be the introduction of our science strategy.

SCIENCE, RESEARCH, AND INNOVATION

Clinical trials

2.1 All new compliant clinical trial applications received from 1 September will be reviewed within statutory timelines. Since mid-July, we have reviewed over 1500 clinical trial applications including dealing with a backlog of approximately 1000 applications. In doing so, we have introduced new approaches to interacting with researchers, including the Clinical Trial Hotline, a new service providing companies and sponsors with bespoke updates on the status of initial applications and amendments. Proactive emails have been sent to all applicants and sponsors with initial clinical trials applications in the backlog. To date, over 200 proactive updates have been issued and all queries that have come through the hotline are being picked up and responded to within 5 days with no queries outstanding. We have worked with stakeholders across Government and with trade associations to cascade core messaging and respond to offers of support. A stakeholder Task and Finish Group has provided valuable insights and contributions.

Innovative Devices Access Pathway

2.2 Woking with the National Institute for Heath and Care Excellence (NICE) and the Office of Life Sciences (OLS) we have made significant progress in developing plans for the Innovative Devices Access Pathway (IDAP) pilot. This includes seeking agreement from partners on the patient involvement strategy and developing the necessary documentation for the recruitment of patients to the first activity. Patients will attend IDAP Delivery Group meetings between 1st November and 6th December where IDAP applications will be shortlisted and the eight products to enter the pilot will be selected. We will be hosting a patient education event on 2 October and preparations for this are under way.

Control testing

2.3 All newly manufactured vaccine batches, blood products and plasma pools for the UK undergo independent control testing assessments by our laboratory scientists. This is to ensure these medicines are consistently safe and effective before they are used. Batches are certified if they meet their key biological specifications. The Control Testing programme runs continually and covers over 60 different biologicals. During April-August, we certified 1982 batches and plasma pools. This included the first 107 batches of influenza vaccine for the 2023/24 immunisation campaign as well as new products such as RSV vaccines, a new Hepatitis B vaccine and XBB1.5 COVID-19 vaccines. The team set up several new test methods for the laboratory assessments with very tight deadlines to enable fast supply to patients.

Microbiome

2.4 One approach being explored to address the threat of antimicrobial resistance (AMR) is the development of novel biological medicines that obviate the need for antibiotics. These fall predominantly into two categories: microbiome and phage products. Microbiome-targeted products aim to restore the symbiotic microbiological communities that co-exist in our gut, on our skin, and at other body sites which together comprise our microbiome. When these communities become unbalanced, pathological species may thrive, such as recurrent Clostridium difficile infection, and these products restore the microbiome communities and health without the need for antibiotics. A group at the South Mimms laboratories secured additional funding to work across the Agency and beyond to develop guidance for innovators and manufacturers working on these materials. On August 24th a virtual meeting was held with 17 participants from 10 organisations to review the draft microbiome product guidance document before going out for public consultation.

Bacteriophages

2.5 A second approach to combat AMR is to employ bacteriophages (phages) which are viruses that attack and destroy pathogenic bacteria in a selective, targeted manner. On 30th August a workshop was held with academics, innovators, manufacturers, and representatives of the Veterinary Medicines Directorate and the Food Standards Agency to identify the common and distinct challenges of regulating phage products and the types of reference materials and regulation that will be needed to assure these products. Taking a One Health stance is likely to prove essential in dealing successfully with AMR and establishing links with colleagues in other UK regulatory agencies addressing this topic will minimise the risk of providing contradictory guidance. The next steps are to produce similar draft guidance as has been done for microbiome targeting products.

Communications

2.6 The Communications team has started a project to deliver efficiencies and reduce the amount of paper processes for Standards sales order processing. The paperless pilot which ran throughout August on UK orders has been a success. Our next steps will be to roll out wider training across the team which will increase capability to reduce backlogs and process more orders ready for dispatch. We also produced communications around our research into polio detection methods, which received widespread coverage in the trade press and performed strongly online with the 'Guardian' developing an in-depth piece into the research: The Guardian: New technique cuts time to detect polio in half, study finds

HEALTHCARE ACCESS

COVID-19 vaccines

3.1 The Bimervax COVID-19 vaccine was authorised and becomes the 9th COVID-19 vaccine authorised in UK. Bimervax combines a part of the SARS-CoV-2 virus spike protein with an 'adjuvant' – an additional ingredient designed to trigger a stronger immune response. It can be given as a booster injection in the upper arm to those aged 16 years and over. The clinical evidence for this authorisation is based on data from a study of 765 adults who had received primary vaccination with 2 doses of the Comirnaty COVID-19 vaccine and who were given a booster dose of either Bimervax or Comirnaty. The vaccine demonstrated a strong immune response, and the most common side effects were mild, and resolved within a few days of vaccination. We also approved an adapted Cominarty vaccine that targets the Omicron XBB.1.5 variant. This new line extension granted by the MHRA is valid in Great Britain only and was approved via the European Commission Decision Reliance Route.

UK Plasma

3.2 The Biological Products unit reviewed the safety of using UK-sourced plasma for the manufacture of albumin medicinal products with particular reference to the risk of variant Creutzfeldt-Jakob disease. Based on current epidemiological data, manufacturing process capability, expert advice and information collected for previous reviews, it was concluded that UK-sourced plasma can safely be used for the manufacture of albumin medicinal products, in addition to the already approved use for the manufacture of immunoglobulins. Further information is available on our website: Use of UK plasma for the manufacture of albumins and vCJD risk - GOV.UK (www.gov.uk)

Established medicines

3.3 We are making significant progress in clearing the established medicines backlog. We are also ensuring that any new compliant type 1b variations from 1 July are processed within statutory guidelines. Our current performance for Type IB variations from 1 July is close to our industry commitment, 99% in July and 93% in August. Our primary focus over the past 3 months has been to increase our throughput of licence determinations for national applications. This has increased since May and we are now granting about 40 applications a month for established medicines. This is including backlog clearance.

Approved Body designation

3.4 In August, following a detailed assessment process to ensure that they are able to undertake impartial and objective conformity assessments, we designated three new Approved Bodies: TUV Rheinland, TUV SUD and Intertek. An approved body is an organisation that has been designated by the MHRA to assess whether manufacturers and their medical devices meet the requirements set out in the Medical Devices Regulations 2002. This brings the number of Approved Bodies to seven and represents a significant increase in the current capacity for the certification of medical devices (including In Vitro Diagnostics) in GB. In line with the recommendation of the medical devices advisory group of the Life Sciences Council in March, this increase in approved body capacity supports manufacturers to bring their products to the UK and supports patients to access safe and effective products. The detail scope of the designation of all designated Approved Bodies is published on the MHRA website: UK approved bodies for medical devices - GOV.UK (www.gov.uk)

PARTNERSHIPS – NATIONAL AND INTERNATIONAL

The Windsor framework

4.1 The Windsor Framework, once commenced on 1 January 2025, will ensure that all medicines can be licensed on a UK-wide basis by the MHRA, and medicines will use the same labelling and packaging across the UK. Working closely with DHSC and legal, we are making good progress to implement the Windsor Framework. The first set of guidance on labelling requirements was published at the end of July, and drafting of guidance for UK-wide licencing is in progress.

International Recognition Framework

4.2 As we progress to our new International Recognition Framework, we have opened the required consultation to amend the Human Medicines Regulations 2012 so that the powers that enable the European Commission (EC) Decision Reliance Procedure, ECDRP will no longer be available as a route for UK marketing authorisation from 31 December 2023 and therefore the legal basis for this will be removed from the statute. Teams across the organisation have worked closely to develop the recognition processes for medicines through creation and coordination of a series of meetings with international regulators to allow knowledge exchange between technical teams. Having taken place over many months, the handover from development to implementation has now begun with major milestones reached such as the publication of guidance for applicants at the end of August. The guidance covers the application process, reference regulators, timelines and evidence requirements. Further information is available on our website: International Recognition Procedure - GOV.UK (www.gov.uk)

Access partnership

4.3 The Access Partnership (Australia, Canada, Singapore, Switzerland and UK) continues to expand the scope of its work. Following the success of the UK Chair of the consortium in the first 6 months of 2023, during which the Promise Pathway for innovative medicines was further developed, the chair has now passed on rotation to Australia Therapeutic Goods Administration (TGA). On 4th September the TGA senior leadership visited MHRA and spent the day exchanging information and perspectives on key topics in regulation. We have an ongoing work-sharing arrangement with TGA on the Vaxxinity COVID-19 vaccine, on which we expect to reach a decision later this year.

Devolved administrations

4.4 The MHRA Partnerships Group has now established closer working with colleagues in the Devolved Nations, through dedicated time allocated per week to individuals to attend meetings with UK wide teams to increase the level and quality of communication and collaborative working on policy and operational issues.

PATIENT SAFETY

Clinical Practice Research Datalink

5.1 The Clinical Practice Research Datalink team is establishing a new Scientific Advisory Group (SAG) that will provide advice on the overall scientific direction and strategic priorities for CPRD. This is not a governance group or a statutory committee. The SAG will comprise academic and industry experts in real world data research as well as key stakeholders including NHS England, the Clinical Research Networks (CRN), GPs, healthcare research services from the devolved nations, Office of Life Sciences, Health Research Authority, Health Data Research UK, and patient representatives. The first meeting of the SAG is scheduled for November 2023.

Valproate

5.2 In August we published a statement regarding the required re-analysis of a post-authorisation safety study which investigated the risk to children born to men who took valproate in the 3 months before conception. This followed the identification of errors which may affect the study results. An article in Drug Safety Update was published to ensure that healthcare professionals are aware of the latest developments. The article reinforced the message that patients should not stop taking valproate without discussing their medication with their specialist, as their condition may get worse. Drug Safety Update also included a reminder that girls and women of childbearing potential should continue to follow the conditions of the pregnancy prevention programme.

Codeine linctus

5.3 Codeine is an opioid medicine, and is therefore associated with the potential risk of addiction. Recent safety information has revealed use of codeine linctus in the UK is an ingredient of a recreational drink and carries a risk of overdose which can be fatal. We therefore launched a consultation on moving codeine linctus from pharmacy availability to prescription only status. Over 900 completed responses were received. It was the first public consultation to include optional evaluation questions at the end to monitor user experience, which was completed by 867 users (95% response rate). We have summarised themes and areas of improvement arising from the user experience questions for future consultations. Responses on the use of codeine and potential safety measures are now being reviewed and policy options developed.

Safety of breast implants

5.4 In early August we published a statement relating to an emerging risk of Squamous Cell Carcinoma and various lymphomas (not BIA-ALCL) of the breast implant capsule in those with breast implants. An FDA update in early 2023 reported an increase in cases being reported in the literature. Following engagement with our Plastic, Reconstructive and Aesthetic Surgery Expert Advisory Group (PRASEAG) and international regulatory colleagues, a statement was placed on the MHRA website alongside other breast implant advice pages to inform UK patients of this potential risk. This informs patients of our current vigilance activities, what actions we are taking, encourages reporting and instructs surgeons to include these additional potential risks when consenting a patient. Although no UK reports have been received, the three main breast implant associations in Britain (Association of Breast Surgery, British Association of Aesthetic Plastic Surgeons, and the British Association of Plastic, Reconstructive and Aesthetic Surgeons) have also produced a joint statement aligned to our actions. We remain vigilant on Yellow Card data and UK literature for new cases of these diseases associated with breast implants and continue to engage with our expert advisory group to provide best advice for UK patients.

Bed rails

5.5 In October 2022, we received a report regarding the death of a child due to entrapment in bed rails. Following the review of this report, it was agreed that the Bed Rails Guidance should be updated in conjunction with feedback received from stakeholders. In January 2023, we chaired a stakeholder round table to discuss updates to the guidance with extensive engagement with representatives from across the healthcare sector including the Devolved Administrations, Care Quality Commission, Health & Safety Executive, Royal College of Occupational Therapists, NHS Estates, NHSE, Hospice UK, British Healthcare Trade Association, National Association of Equipment Providers, National Association of Medical Device Educators and Trainers and National Association for Safety and Health in Care Services . The guidance on the Safe Use of Bedrails was published in August 2023. Publication of the guidance was supported by a National Patient Safety Alert to ensure that the guidance is embedded in local procedures and processes.

Variant COVID-19 tests

5.6 In August, we provided updated guidance to manufacturers of COVID-19 tests regarding the requirements for demonstrating diagnostic assurance with SARS-CoV-2 variants in circulation. The guidance outlines the requirements for manufacturers to have in place a Post-Market Surveillance Plan to continuously monitor the influence of newly emerging variants on assay performance. This proactive post-market surveillance activity sees MHRA working with UK Health Security Agency, the NHS and Devolved Administrations as part of the Pathogen Diagnostic Assurance Group to review the manufacturers' reports and ensure that the COVID-19 tests registered in the UK continue to perform as intended.

Yellow Card Centre Northern Ireland

5.7 A new regional centre to promote Yellow Card reporting has been launched in Belfast. The Yellow Card centre in Northern Ireland will be the sixth UK satellite centre acting on behalf of the Agency alongside centres in Wales, Scotland, Northern and Yorkshire, North-West, and West Midlands. The new Yellow Card Centre Northern Ireland will have a vital educational and outreach role, aiming to encourage patients and healthcare professionals to report any suspected adverse incidents associated with medical devices and suspected adverse reactions to medicines to the Yellow Card scheme. The centre will routinely deliver local training and education and promote safety messages from the MHRA to healthcare professionals and patient groups.

British Pharmacopoeia

5.8 On 23 August the new website pharmacopoeia.com was launched in beta. The MHRA marketing team has been instrumental in feeding into development requirements, representing the customer voice in review meetings and ensuring the new site supports the BP brand effectively. We delivered communications to introduce the new site to users. The new site offers improvements to navigation, new self-serve user purchase journey and updated digital tools to help users get more out of their BP online subscription. More improvements will be released through the beta phase over the coming weeks.

Criminal Enforcement Unit

5.9 Early August saw a film crew from the BBC daytime TV series 'Defenders UK' film interviews with Criminal Enforcement Unit (CEU) staff as part of an upcoming episode showcasing the work of the MHRA in protecting the public from the criminal trade in unlicensed medical products. At the end of August, the Criminal Enforcement Unit carried out two targeted operations at an international parcel hub alongside Border Force partners. Over the course of the two days, approximately 800,000 doses of illegally traded medicines were prevented from entering the UK. The CEU has established a new partnership with a leading online service provider which will allow for the disruption of illegally trading websites by removing access to a key promotional facility.

DIGITAL AND TECHNOLOGY

Regulatory Management System

6.1 Following the Agency Board discussion in July 2023, the Regulatory Management System Programme has focussed on completing a detailed analysis of the existing scope and delivery plan to define the functionalities that can be delivered as part of a release by March 2024. There has been significant effort from all parts of the programme team to create a release-based approach that will enable the delivery of services and features that are desirable, feasible and viable. This planning exercise is expected to complete in September 2023 and will include Releases 1 and 2, and a clear end-to-end plan and financial and resource forecasting.

SafetyConnect

6.2 User Acceptance Testing of the SafetyConnect vigilance system continues and some complex data formatting issues have been identified. We are engaging with suppliers to undertake a root cause analysis and agree a resolution. Performance Testing continues, with suppliers working hard to analyse issues through to resolution. This phase of the project will enable case management for medicines, defective medicines, and e-cigarettes, allowing the Agency to switch-off Sentinel case management for the Adverse Drug Reaction and Signal Case folder which constitutes 30-40% of volume. Phase 3 is in the early design and delivery stage. The first run of data (migration of circa 300k records) from Lotus Notes is complete.

Intellicase system replacement

6.3 The Digital & Technology project team has been working with the Criminal Enforcement Unit to develop the business requirements and solution approach to support the procurement of a replacement to the Intellicase system. Project Management is now in place to manage project delivery, governance, and assurance and the first Project Board meeting took place on 24 August. Preparations are now under way to go out to the market in early September to procure a solution and the tender documents are currently being finalised.

Laptop refresh

6.4 The final clean up and closure of the Laptop Refresh project is well underway. The project has successfully exchanged over 1,000 laptops. This has allowed us to modernise our hardware offering and ensure improved performance and efficiency for Agency staff. The final clean-up of all cables, docks, and associated peripherals has been completed. The project is now working on formally handing over to the IT Helpdesk team, this includes the remaining laptop deployments which were not completed by the project due to absence of staff members. The project team is also finalising the commercial activities to sustainably decommission the old laptops with the intention of getting a rebate and contributing the agency's environmental goals. This will contribute towards the agency's waste management objective by reducing the overall amount of waste generated and increasing the proportion which is reused and recycled.

Freeze dryers

6.5 The freeze dryers replacement project has progressed with the touch screens for the user interface being developed ready for go-live in December 2023, completing this phase of the project. These screens allow basic control and monitoring of the freeze dryer. Phase 2 is now being initiated with resource being secured to produce the requirements needed for the tender documentation for the next freeze dryer upgrade. This includes updating the Supervisory Control and Data Acquisition (SCADA), Programmable Logic Controller (PLC) and Human Machine Interface (HMI) on the C150 and CS15 Freeze Dryers.

AGENCY PRIORITIES

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

i. Maintain the Agency's focus on delivering its core business functions, meeting assessment targets for all key services and eliminating any backlogs

ii. Deliver the Agency's Business Plan 2023-24 which outlines objectives for year one of the Agency's Corporate Plan 2023-26.

Iii Refresh and reset the Innovative Licensing and Access Pathway together with partner organisations and establish the Innovative Devices Access Pathway, in line with the McLean Report recommendations

iii. Refocus the Regulatory Management System programme replacing legacy IT systems, taking account of Agency priorities and the need to integrate process transformation

iv. Deliver a new international recognition framework which allows the Agency to streamline approvals for safe and effective medicines, and progress plans for international recognition for medical devices.

Dr June Raine, CEO
September 2023

Medicines & Healthcare products Regulatory Agency

BOARD MEETING IN PUBLIC

19th September 2023

Title	How effectively is the MHRA maintaining performance on clinical trials and how has a sustainable clinical trial function been established from 1 September?
Board Sponsor	Marc Bailey
Purpose of Paper	Strategic Direction

How effectively is the MHRA maintaining performance on clinical trials and how has a sustainable clinical trial function been established from 1 September?

1. Executive Summary

1.1 There have been delays in clinical trial assessment by the MHRA since September 2022 which increased over time despite efforts to reduce and eliminate these delays. The main causal factor was the loss of a significant number of experienced staff in the Clinical Investigations and Trials team and this was associated with difficulties in recruiting new staff with relevant skills.

1.2 As a result of the increasing scale of this assessment backlog a crisis response was initiated in July 2023 to rapidly address these delays. The aim of this response was to ensure the elimination of the backlog and that all newly received compliant applications from 1 September 2023 were approved within statutory timeframes. Since mid-July 2023, we have assessed over 1,600 applications. All newly received compliant clinical trial applications received from 1 September 2023 are being processed within statutory timeframes.

1.3 This paper sets out how the cross-agency crisis response has addressed the backlog, presents the ongoing measures to ensure continued clinical trial approval performance and outlines the foundations of a new clinical trial process based on the public consultation outcome announced in March 2023. This is aligned with the UK Government ambitions as set out in the Life Sciences Vision and O'Shaughnessy Review to ensure that the UK is an attractive location for clinical trials and the benefits this brings to UK patients and the healthcare system.

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, as it integrates medical research on medicines' efficacy with innovation in treatment delivery, access and patient safety. Statutory timeframes for the assessment of clinical trials anticipate approval within 30 calendar days (initial application) and 35 calendar days (substantial amendments).

3. Action taken

3.1 A range of measures were urgently implemented as part of the Agency's crisis response to restore clinical trials assessment performance. Key measures are set out below.

a. Redeployment of resources
Staff were redeployed from across the Agency to support assessment of clinical trials from July - September 2023.

b. Improved processes and data
The clinical trials team developed a revised risk-stratified assessment process that initially triaged trials by clinical trial phase and then by complexity and risk into high, medium, and low/limited risk categories. Depending on the risk, trials were then subject to a risk-proportionate assessment process that enabled an accelerated timeframe for assessment. Ensuring the safety of trial participants is the core principle of our clinical trials assessment process and this has been maintained through the risk-proportionate implementation of improved assessment processes.

c. Use of external resource
External resources have been brought in to provide additional capacity to support improved clinical trial performance and in the longer term create buffering capacity to increase resilience in this critical function, as well as increase access to specific technical expertise if this is required. This included the use of external contracts and the development of a unique collaborative enterprise with the National Institute for Health and Care Research (NIHR) that has enabled the agency to access their extensive network of expert clinicians to support the assessment process.

4. Maintaining current performance of clinical trials

4.1 In mid-July 2023 there were 966 clinical trial applications in the backlog that had exceeded their statutory timeframes for approval. We will have eliminated those remaining by mid-September whilst managing the workflow of applications received prior to 1 September. All compliant applications received from 1 September are being processed within statutory timeframes and robust reporting processes are in place to monitor performance.

4.2 Very significant progress has been made with restoring and improving service performance for clinical trials approval. However, it is critical that we ensure continued stability of assessment performance. To ensure there is no adverse impact on performance, a range of the measures implemented during the crisis response will be retained in the medium term.

5. Performance management

5.1 The revised framework for management and reporting of clinical trials performance will be maintained in the medium term to ensure that performance is fully stabilised and support local management. Short/medium-term improvements to our systems for

data reporting and analysis using the existing case management system will also be identified and implemented where appropriate.

5.2 Redeployed staff are returning to their respective 'home' groups on a phased basis whilst we manage the balance of assessments received prior to 1 September 2023 alongside those newly received applications from 1 September 2023. To ensure continued stability it will be necessary to retain a small residual amount of redeployed resource with the CIT team pending completion of new recruitment.

5.3 Contracted resource to support clinical and non-clinical assessment will be retained until at least the end of December 2023 or earlier if capacity is demonstrated to be robust to its withdrawal. We will continue to maximise the use of the NIHR clinical network to support assessment both in the medium term and in section 3.4 as part of building longer term resilience into our clinical trials assessment function.

6. New approach to UK Clinical Trials regulation

6.1 We are now working to ensure that we optimise the clinical trials approval process in line with the proposals set out in the UK Government response to the consultation on legislative proposals for clinical trials, the Life Sciences Vision, and the O'Shaughnessy review while maintaining and developing the international attractiveness of the UK as an attractive environment for clinical trials.

6.2 Building on the programme of reform set out in the UK Government response to the consultation on legislative proposals for clinical trials published in March 2023 as well as the innovation and learning from the crisis response, we will continue to drive the implementation of risk-proportionate regulation to make it easier and faster for applicants to gain approvals and to run clinical trials in the UK, as part of our work to support delivering the Government's Life Sciences Vision

6.3 As a first step in our programme of reform we will launch a new clinical trials notification scheme pilot in September 2023 that will allow researchers to proceed with low-risk trials without the need for further assessment (both initials and amendments). Higher risk trials will still require more extensive assessment. This new approach is based on the principle of ensuring participant safety through risk-proportionality to ensure that the participant risk is either equal or lower than in standard clinical care or from consideration of risk in light of information arising from the trial being already underway, completed or approved to commence in USA or EU.

6.4 It is expected that approximately 20% of trials will be eligible for the scheme which will run over the next 4 months. This pilot is being developed with input from our external experts on the Commission on Human Medicines as well as from representatives of the commercial and non-commercial clinical trials sectors under the Clinical Trials Task and Finish Group. Implicit to the development of our new ways of working will be the co-development of guidance with stakeholders.

7. IT Infrastructure

7.1 The underpinning infrastructure for clinical trials requires improvement and investment to ensure longer term sustainability. This also includes how we maintain the level of information and transparency with applicants on their application status. We will identify and implement where appropriate short/medium term improvements to our existing case management system to improve reporting and performance management. In the longer term, working with UK regulatory partners, we will identify what infrastructure is required to support an optimised approval process and one that would vastly increase transparency to applicants on progress and timings for approvals in line with recommendations of the O'Shaughnessy review.

8. Organisation and people

8.1 The organisational structure of the CIT team will be reviewed and, if necessary, reconfigured to ensure its design is an enabler to our ambitions and robust to performance delivery. The extensive capacity modelling developed during the crisis response has identified the need to increase the capacity of the CIT team for both clinical and non-clinical assessors as well as for the operational support team.

8.2 We will work to rapidly recruit these additional staff in Q3 of FY 23/24 using the innovation and access funding provided by the Chancellor earlier this year. This will be not only to support assessment activity but also the vitally important upstream pre-submission scientific advice support for applicants that is a core component of our offer as an enabling regulator providing an end-to-end service to those developing and marketing new products.

8.3 The newly developed collaboration with the NIHR clinical network will also be maintained as an important tool for specialist support from this vast network of experts and as an element of our plans to ensure resilience for this function.

9. Impact of the crisis response on other key Agency objectives

9.1 Impact assessments for the redeployment of staff were conducted by SRI, HQA and S&S and suitable prioritisation and mitigation plans developed and implemented. The Agency prioritised resource to ensure delivery of key activities including those that support the life sciences vision missions e.g. that for dementia treatments, COVID-19 vaccines, and key critical safety activities.

9.2 Whilst the Agency ensured that all feasible steps were taken to mitigate the risk to service delivery and to patients, it is recognised that there has been a temporary unavoidable impact on some areas that have not been prioritised. The Agency has kept these plans under regular review and strategically coordinated the phased return of redeployed staff aligned with these priorities.

9.3 The Clinical Trials team has continued to deliver scientific advice throughout this period, and the process has been updated to include an exchange of written advice prior to any meetings to ensure that the request for advice is fully understood and assessor resource is used as efficiently as possible. The process requires further improvement to ensure that it is timely and fit-for-purpose and that the advice given can be demonstrated to improve the content and quality of the subsequent clinical trials application or amendment.

10. Communications and stakeholder engagement

10.1 External stakeholders have emphasised that effective communications and enhanced information for applicants are essential to the MHRA's short- and long-term work in clinical trials.

10.2 We launched enhanced customer services support for clinical trial applicants as part of our crisis response, underpinned by significant workarounds to our data systems, communicating proactively with applicants on their individual trial status, on a regular basis. We intend to continue delivering this and further enhancements that embed a more customer-centric culture to the clinical trials service as it evolves to deliver longer term sustainability.

10.3 We have also been engaging regularly with a network of stakeholders who are representative of the clinical trials sector to provide consistent messaging and updates on measures the MHRA were taking to reduce backlogs, supported by the regular provision of additional datasets demonstrating the positive impact in regulatory assessments.

10.4 This was reinforced by our commitment to publishing data indicating our month-on-month performance, which is accompanied by analysis to support companies with their planning, by providing a more predictable view of service levels in the clinical trials area. We are committed to continuing to be transparent with our performance data and to providing key stakeholders with the means to brief consistently across the sector; encouraging them to share MHRA information through their own channels when appropriate to build reassurance or create desired behaviour change. We will consult with stakeholders to ensure that the data we communicate is decision relevant and reflects the performance metrics which are meaningful for applicants considering their options. We will also contribute to end-to-end data transparency across system partners involved in trial approval and set up including HRA, NIHR and the NHS, consistent with our legal obligations.

11. Proactive communications strategy

11.1 We have developed a coordinated strategy for communicating the restoration of our regulatory performance and ensuring that the UK's attractiveness as a destination for clinical trials is enhanced.

12. Recommendation

12.1 The Board is asked to consider the following key questions:

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

ii. Are the initial proposals for long-term sustainability and improvement of clinical trials assessment sufficiently ambitious to ensure the attractiveness of the UK as a destination for clinical trials?

iii. Are there additional communications or partners we need to consider, to ensure we maximise our impact in reassuring stakeholders that trials will be approved in the required timeframe and the attractiveness of the UK for clinical trials?

James Pound
September 2023

Medicines & Healthcare products Regulatory Agency

MHRA Performance Report

Operational Performance
Quarter 1, 2023/24

Finance Division

Medicines & Healthcare products Regulatory Agency

Part 1: Business Plan Progress

- Status of Business Plan objectives by Strategic Priority
- Status and mitigation of off-track items

	Key action	Q2 (Jul – Sep) →	Q3 (Oct – Dec) →	Q4 (Jan – Mar) →
1. Maintain public trust through transparency and proactive communication	1.1 Embed **patient involvement across our regulatory pathways** that is meaningful, proportionate, and impactful, to help ensure medical products reach patients without delay, accompanied by efficacy and safety info that better meets the needs of all patients.	Nothing scheduled in the Business Plan, focus on core business	1.1.1 Ensure patient involvement activities remain ethical, meaningful and impactful by embedding new tailored guidelines for priority agency functions by end Q3.	1.1.2 Develop a new risk communication strategy to ensure more coordinated, proactive risk and safety communications to patients, the public and healthcare professionals, by end Q4.
				1.1.3 Design a new approach to recruit and train additional lay committee members (non-clinical, academic or scientific) to ensure our independent advisory bodies benefit from greater lay perspectives and challenge by end Q4.
	1.2 **Enable diverse patient voices** to provide evidence on safety concerns on specific types of medicines and medical devices.	Nothing scheduled in the Business Plan, focus on core business	1.2.1 Establish a consistent, inclusive and systematic approach to ongoing patient involvement in our benefit and risk evaluation assessments by end Q3.	1.2.2 Complete a review of regulatory opportunities to address health inequalities by end Q4.
			1.2.3 Identify two safety topics affecting underserved groups by end Q3 and engage with patients so they can raise concerns and to inform our approach by end Q4.	1.2.4 Broaden our communications channels to reach under-represented and under-served populations, ensuring the contribution of more diverse voices by end Q4.
	1.3 **Increase transparency of safety signals and the basis of our benefit-risk decisions** by regularly publishing the safety signals on medical products and a public statement following approval of all new chemical entities within one week, plus a summary of the evidence for the regulatory approval within one month.	1.3.1 Make Yellow Card incident report data available in the new COVID-19 interactive format for medicines by end Q2 and devices by end Q3.	Nothing scheduled in the Business Plan, focus on core business	1.3.2 Pilot publication of safety signals assessed by our Pharmacovigilance Expert Advisory Group on our Yellow Card website and the publication of accessible lay summaries of our benefit and risk evaluation assessments by end Q4.
				1.3.3 By end Q4, establish the governance of the Yellow Card Biobank and successfully demonstrate procedures in action for participant recruitment, sample collection and sample storage.
				1.3.4 By end Q4, regularly publish a public statement following approval of all new chemical entities within one week and provide a summary to provide the evidence for the regulatory approval within one month.

KEY: Red: late or not possible; Amber: at risk; Green: on-track; Blue: complete; Trend arrows: RAG change from previous quarter (↑ improved, → no change, ↓ worsened)

	Key action	Q2 (Jul – Sep) →	Q3 (Oct – Dec) →	Q4 (Jan – Mar) →
2. Enable healthcare access to new, safe and effective medical products	2.1 Deliver **predictable and reliable operational performance** having defined our priority improvements for our core services to ensure swift and robust decisions on medical products, safety signals and compliance.	Nothing scheduled in the Business Plan, focus on core business	Nothing scheduled in the Business Plan, focus on core business	2.1.1 Identify service improvements across all priority areas with robust plans for implementation and effective change management to be in place by end Q4.
				2.1.2 Eliminate current service backlogs by end of 2023/24.
				2.1.3 Deliver phase one of our innovation-enabling and risk-proportionate medicines compliance strategy including the development of a pilot project for an outcome-based model by end Q4.
				2.1.4 Fully embed our new SafetyConnect vigilance system and realise patient and operational benefits by end Q4.
	2.2 Develop and embed **system cooperation with UK partner organisations, including the NHS**, to ensure the gap continues to be narrowed between regulatory and health ILAP technology approval with a clear path to patient deployment.	Nothing scheduled in the Business Plan, focus on core business	2.2.1 By end Q3, work with stakeholders to lay the foundation for electronic Patient Information (ePI) by 2026 to ensure more accessible information for patients.	2.2.3 Establish the ILAP and the IDAP by delivering a partnership governance that delivers ILAP activities and the IDAP pilot project by end of Q4.
			2.2.2 Establish the UK healthcare systems priorities for medicines and medical devices in terms of patient need and proactive supply chain management and to inform our priorities by end Q3.	2.2.4 Work with the HRA to implement the 60-day review period of clinical trial applications in line with the recommendation of the O'Shaughnessy.
	2.3 Launch the improved **regulatory management system** to make our services more streamlined, as the first phase of the replacement of legacy IT systems, enabling all new product licences, variations, inspections, and process licences to be efficiently handled, maximising the use of self-service for low-risk decisions.	Nothing scheduled in the Business Plan, focus on core business	Nothing scheduled in the Business Plan, focus on core business	2.3.1 Launch the first release of our new regulatory management system by end Q4.

KEY: Red: late or not possible; Amber: at risk; Green: on-track; Blue: complete; Trend arrows: RAG change from previous quarter (↑ improved, → no change, ↓ worsened)

	Key action	Q2 (Jul – Sep) →	Q3 (Oct – Dec) →	Q4 (Jan – Mar) →
3. Deliver scientific and regulatory excellence through strategic partnerships	3.1 Introduce the **MHRA Science Strategy**, establish and build on partnerships in key priority areas with national and international partners with measurable benefits that support prompt and robust regulatory decision-making	Nothing scheduled in the Business Plan, focus on core business	3.1.1 Publish a Data Quality Strategy, including proposals for revised and extended data quality checks, for our Clinical Practice Research Datalink services and refresh our data quality webpage by end Q3.	3.1.2 Launch our MHRA Science Strategy, including engagement with key stakeholders, and delivery of key themes by Q4.
				3.1.3 Establish processes to identify future areas of innovation, working with national and international partners to align priorities with patient need by end Q4.
	3.2 **Re-prioritise standards, control testing and underpinning research** to ensure support for priority areas of our MHRA Science Strategy and Corporate Plan.	3.2.1 Run a trial from Q2 to end Q4 aimed at improving our distribution approach, increasing the volumes of standards we provide globally and raising awareness of our offer.	Nothing scheduled in the Business Plan, focus on core business	3.2.2 Develop a new strategy for the BP and associated laboratory services for consultation by end Q4 including income investment plans to improve services
				3.2.3 Link the Innovation Accelerator activities with academia and other stakeholders by Q4 to provide support for the CERSI recommendation in the McLean Report.
				3.2.4 Implement a new risk-proportionate approach for the independent control testing of biological medicines to expand our ability to perform laboratory assessments by end Q4.
	3.3 Legislate on **Point of Care Manufacture** and drive international regulatory progress in key scientific areas commensurate with scientific and technological advances such as mRNA technology, artificial intelligence and in silico data generation.	Nothing scheduled in the Business Plan, focus on core business	Nothing scheduled in the Business Plan, focus on core business	3.3.1 Deliver a new framework for UK PoCM, lay legislation before Parliament and publish guidance by end Q4.
				3.3.2 Establish active bilaterals and wider collaborations nationally and internationally with work programmes in place on healthcare product innovation areas of interest by end Q4.
	3.4 **introduction of new guidance and legislation and work to build our status as an independent regulator** in a global environment and to ensure the UK remains a great environment to develop novel and innovative medical products. There are also some milestones for this year:	Nothing scheduled in the Business Plan, focus on core business	3.4.1 Implement Windsor Framework for a commencement date of 1 January 2025: issue essential guidance by end Q3, place legislation before Parliament in 2024 and issue further guidance and comms as needed up to the commencement date.	3.4.2 Prepare legislation by Q4 to deliver reform of the UK clinical trials regulatory framework.
		3.4.3 Lay regulations for transition provisions by end Q2 to maintain the supply of devices in GB and for future regulations to strengthened PMS by end Q4 to strengthen requirements for devices on the market and increase patient safety, and clarifying plans, including consulting if needed, for international recognition of devices approved in other jurisdictions by end Q3.		3.4.4 Launch a new international recognition route by 1 Jan 2024 for medicines utilising pre-existing approvals from Australia, Canada, the European Union, Japan, Switzerland, Singapore and the US.

KEY: Red: late or not possible; Amber: at risk; Green: on-track; Blue: complete; Trend arrows: RAG change from previous quarter (↑ improved, → no change, ↓ worsened)

	Key action	Q2 (Jul – Sep) →	Q3 (Oct – Dec) →	Q4 (Jan – Mar) →
4. Become an agency where people flourish alongside responsive customer service	4.1 Deliver a range of **core and specialist learning opportunities** and implement and review the agency leadership development plan, to ensure we have the right capabilities across the organisation.	4.1.2 Refresh our Culture Action Plan by end Q2 and deliver its actions by end Q4 to support our strategic priorities and the delivery of our redesigned services.	4.1.1 Introduce an MHRA-wide workforce plan by end Q3 to ensure our workforce needs are known and can be acted on.	4.1.3 Deliver a plan for core learning and development for 2023/24 that identifies and strengthens capabilities in priority areas by end Q4. 4.1.4 Update our Leadership Development Plan by end Q2 and deliver new actions to strengthen leadership capability across the agency by end Q4.
	4.2 **Attract and develop talent** by strengthening existing or creating new recruitment channels such as a graduate scheme and increasing apprenticeships.	4.2.1 The first graduate scheme cohort to commence our new 3-year programme and complete the on-boarding of 8 new graduates by end Q2.	Nothing scheduled in the Business Plan, focus on core business	4.2.2 Increase the number of apprenticeships towards the target of 40 by end Q4. 4.2.3 Update our talent management approach, aligning it to workforce planning and ensuring a clear link with business planning by end Q4
	4.3 Develop a **new financial plan** to ensure we continue to deliver value for money, invest in people, maintain our financial sustainability and recover the costs of all our services, with updates to our fees to be in force by 1 April 2025.	4.3.2 Produce new improved financial management reporting using DataRails by end Q2 to ensure better data and more informed decision-making.	4.3.1 Staff activity recording to go live by end Q3 to ensure we have a greater understanding of our costs to serve.	4.3.3 Develop new pricing for services and products by Q4 to improve cost recovery across the Agency, and consult on and deliver the next uplift in our fees by 1 April 2025.

KEY: Red: late or not possible; Amber: at risk; Green: on-track; Blue: complete; Trend arrows: RAG change from previous quarter (↑ improved, → no change, ↓ worsened)

Off-track objective	Status and mitigation
1. Maintain public trust through transparency and proactive communication	
1.2.1 Establish a consistent, inclusive and systematic approach to **ongoing patient involvement** in our benefit and risk evaluation assessments by end Q3.	This work has been impacted by clinical trial deployment and delivery depends on how long that runs for. We have therefore marked it as at risk.
1.2.2 Complete a review of **regulatory opportunities to address health inequalities** by end Q4.	Partnerships Group will be coordinating a x-Agency piece of work to scope this objective, this is due to start shortly. Part of this work is the review of Women's Health Regulatory Inequities. This has been impacted by clinical trial deployment: if redeployment extends much further into the autumn, it will delay this project
1.3.2 Pilot **publication of safety signals assessed** by our Pharmacovigilance Expert Advisory Group on our Yellow Card website and the publication of accessible lay summaries of our benefit and risk evaluation assessments by end Q4.	Work has begun but this activity is at risk due to resources being diverted to SafetyConnect and the clinical trial redeployment. We hope to get back on track, but it will need to be kept under review in light of how things on CT redeployment.
1.3.4 By end Q4, regularly **publish a public statement following approval of all new chemical entities** within one week and provide a summary to provide the evidence for the regulatory approval within one month.	This is on track but there is one area associated with the publication requirements of UK Public Assessment Reports (UKPAR), where we have a current backlog.

Off-track objective	Status and mitigation
2. Enable healthcare access to new, safe and effective medical products	
2.2.2 Establish the **UK healthcare systems priorities for medicines and medical devices** in terms of patient need and proactive supply chain management and to inform our priorities by end Q3.	Strategy being developed and Cross-Agency Group being established but resource diverted to manage two major incidents impacting on current medicines supply. Support to DHSC winter planning due to be provided. Demand and durations of major incidents is uncertain, we will provide an update on the status for the next quarter.
2.1.3 Deliver phase one of our innovation-enabling and risk-proportionate medicines **compliance strategy** including the development of a pilot project for an outcome-based model by end Q4.	The Strategy is in place and workstream leads are now developing detailed implementation plans. This objective is assessed as Amber given a potential impact from a key RMS dependency and given the impact of needing to manage multiple major incidents. We Expect to return to Green in Q3.
2.2.3 Establish the **ILAP and the IDAP** by delivering a partnership governance that delivers ILAP activities and the IDAP pilot project by end of Q4.	The partnership agreement for delivering Governance for ILAP is in development. Delivery of pathway, post partnership agreement is at risk due to lack of resource. However, funding has been secured and recruitment commencing represents our path to Green. We will provide an update for the next report.
2.1.2 Eliminate current service **backlogs** by end of 2023/24.	The DPC is taking forward a piece of work to monitor and address backlogs. Backlogs have been identified and quantified and the DPC will be reviewed and taking forward options to address them. The Committee is keeping ExCo updated. ExCo has approved additional resource that will be contributing to this work, they should start in Q2. Once the new resource is in place and remedial action is in train, we will look to move this back to Green.

Off-track objective	Status and mitigation
3. Deliver scientific and regulatory excellence through strategic partnerships	
3.2.1 Run a trial from Q2 to end Q4 aimed at **improving our distribution approach**, increasing the volumes of standards we provide globally and raising awareness of our offer.	Discussions with trial participants on-going. Go-live delayed due to concerns over backlogs within sales compromising service quality. Resource to clear backlog secured and path to Green is dependent on recruitment sufficient to provide confidence of high-quality service to support the trial
3.1.3 Establish processes to **identify future areas of innovation, working with national and international partners** to align priorities with patient need by end Q4.	Work is currently stalled due to limited resource but funding has been secured and recruitment commencing. There is sufficient time return to Green when staff are in place. We are in the process of developing a specific innovation-focused work stream for systems alignment, in collaboration with national partners.
3.3.1 Deliver a new **framework for UK PoCM**, lay legislation before Parliament and publish guidance by end Q4.	There are some ongoing HR issues to resolve relating to an individual the MHRA is hoping to recruit to finalise the legislation and accompanying guidance. If this is process is delayed much further this will impact on timings for the SI. We are currently working with HR to resolve the issue and hope that it will be addressed asap, and will provide an update for the next quarter.
3.4.2 Prepare legislation by Q4 to deliver reform of the UK **clinical trials regulatory framework**.	Drafting of the new legislation is in progress but is impacted by clinical trial deployment resources. To mitigate delays, we are preparing a workshop, aimed for Autumn, with external experts to consider the SI drafting.
4. Become an agency where people flourish alongside responsive customer service	
None identified	

Medicines & Healthcare products Regulatory Agency

Part 2: Operational Performance

Summary – Top Key Performance Indicators

	KPI (slide number)		Q1 23/24	Q4 22/23	Q3 22/23	Q2 22/23
Science, Research and Innovation	IP approvals through ILAP SG (17)		7	24	10	
	IP refusals (17)		5	2	1	
	Diagnostic standards (17)	Shipped: Customers:	4315 130	5987 143	6662 127	
	Number of TDPs requested (17)					
Safety and Surveillance	Public assessment reports (13)		88	84	58	92
	Safety signals identified for further assessment (29)		29	23	30	
	Safety variations assessed (29)		348	372		
	Actions taken to minimise risk to patients (18)		11	38	32	29
Healthcare, Quality and Access	New licences (23)		9	9		
	Established medicines number of abridged complex determined (24)		30	35		
	CT site inspections (28)	Inspections Referral for critical findings:	13 2	10 2		
	Supply chain site inspections (17)	Inspections Referral for critical findings:	84 10	123 8		

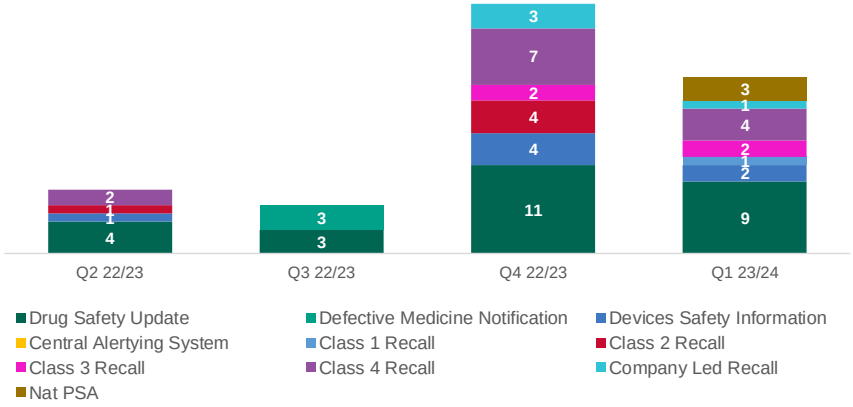
Summary – Top Key Performance Indicators

	KPI (slide number)	Q1 23/24	Q4 22/23	Q3 22/23	Q2 22/23
Corporate	Forecast Income (36)	184.5 m			
	Voluntary turnover (34)	12%	14%	16.3%	16.7%
	Incidents and accidents (35)	23	15	14	9
Enablement	CEC queries (15)	16k	18k	17k	16k
	Complaints (7)	188	226	159	124
Digital and Technology	Security score (29)	65.5%	60.2%		

Patients, Public, Partners and Customers

Delivery Plan Priority – Patient and Public Involvement

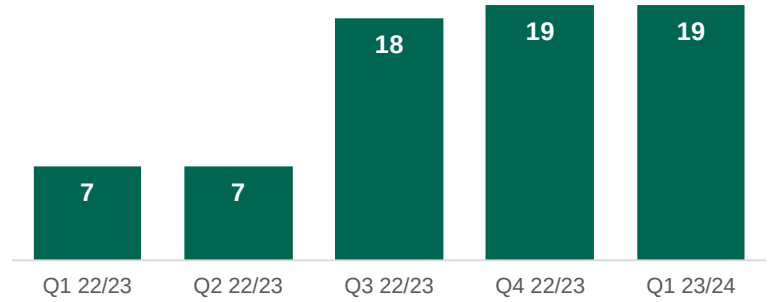
Q1 Communication to Healthcare Professionals



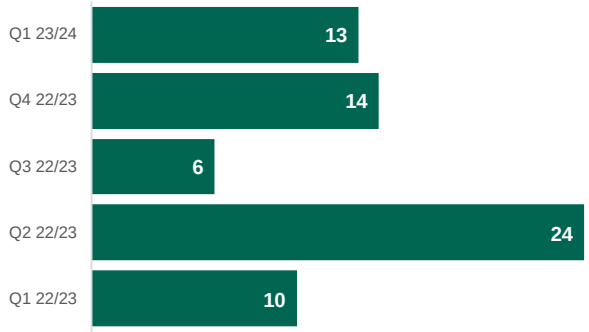
Patient Engagement Training Completed by Staff

953 staff (78%) have completed the training from a total workforce of 1208. The remaining 255 are comprised of 110 who have started and not completed, together with 145 who haven't yet started. This group are being contacted individually to ensure they complete their e-learning.

Internal requests for patient engagement activities



Scientific Papers Published



Reputational Index

The customer insight and reputation research has been completed. We have received the first-round reports and are now working to clarify some areas and to consider dissemination and action plans based on the findings.

Public Assessment Reports

- 0 PARs on self-mediation reclass procedures – 0 in Q4
- 0 on safety – 0 in Q4

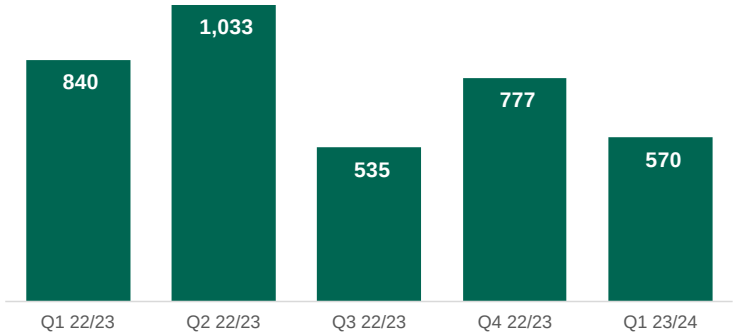
PARs published for new marketing authorisation – *(Target is 60 calendar days from licence grant, plus any clock off time)*

- Q2 - 92 (78; 85% completed on time)
- Q3 - 58 (33; 57% completed on time)
- Q4 – 84 (56; 67% completed on time)
- Q1 – 88 (33; 38% completed on time)

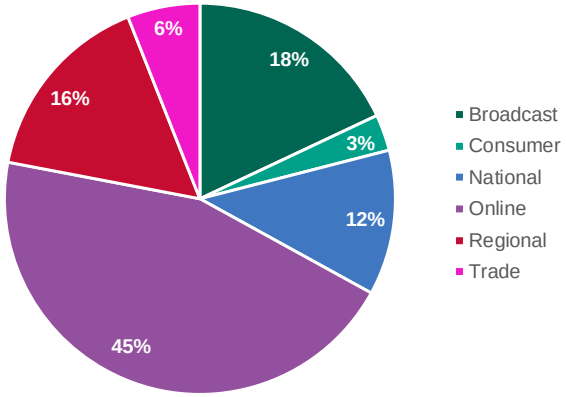
Patients, Public, Partners and Customers

Delivery Plan Priority – Patient and Public Involvement

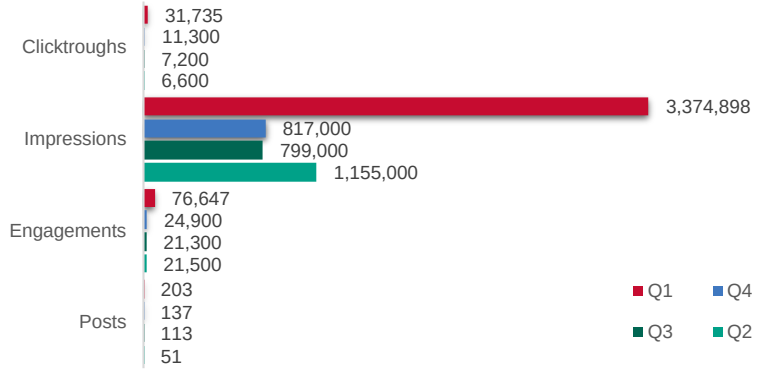
Media Article Mentions



Q1 Articles by Media Type



Social Media Reach – by quarter



This quarter, MHRA generated 570 mentions in coverage, representing a quarter-on-quarter decrease of 27-percentage-points. Covid-19 vaccines remained a prominent driver of coverage this reporting period, with high-readership outlets such as The Independent and Daily Telegraph reporting on the introduction of the COVID-19 vaccination for children under the age of 4, noting that the decision was approved by the MHRA in December of 2022. Elsewhere, reports that the husband of BBC presenter Lisa Shaw who passed away due to complications resulting for the AstraZeneca Covid-19 vaccine will be taking legal action was reported in prominent high-readership outlets such as BBC and ITV. The publication noted MHRA commented that, "All vaccines being used in the UK have undergone robust clinical trials and have met the Medicines and Healthcare products Regulatory Agency's (MHRA) strict standards of safety, effectiveness and quality“ adding that “vaccines were the "best way" to protect against disease from Covid and that the vaccine damage payments scheme was available for "individuals who have, in extremely rare circumstances, been severely disabled or died due to receiving a government-recommended vaccine for a listed disease”.

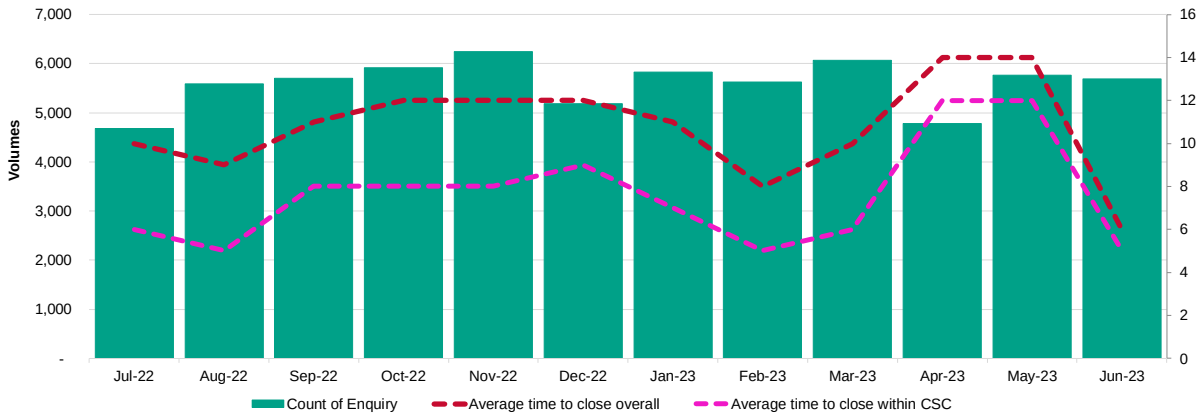
Dr. Allison Cave became the most prolific spokesperson this quarter, generating 9 mentions. Coverage surrounded the recommendations to improve the safety of the anti-acne medication Rizuderm “which will be taken forward by the Medicines and Healthcare products Regulatory Agency (MHRA)” (The Telegraph). The Independent reported on the spokesperson's comments that “Uncontrolled and severe acne can have a significant impact on a patient’s mental wellbeing and can lead to permanent scarring” and “for these individuals, isotretinoin may be the only effective treatment option” further noting that “for patients under the age of 18 there is additional scrutiny on isotretinoin prescribing”.

Almost all coverage this reporting period contained a sentiment that was at least slightly favourable in tone, with reports surrounding the introduction of a new partnership between the MHRA and international regulatory bodies to increase the speed of access for innovative new medications prominent in outlets such as the Daily Express. The Pharma Letter reported that the “new international recognition routes will sit alongside the MHRA’s own unique innovation pathway for medicines” and will “mark the start of a new international recognition framework for medicines that will be in place by the first quarter of 2024”.

Patients, Public, Partners and Customers

Delivery Plan Priority – Patient and Public Involvement

Customer Experience Centre – Queries per Month



Count of enquiry refers to any telephone call, email or letter received at the Customer Experience Centre, including Freedom of Information requests and formal complaints.

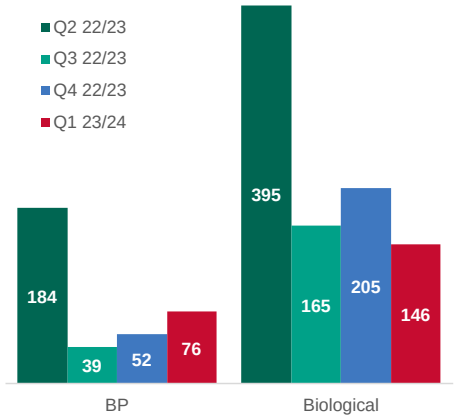
Average time to close overall: this is the average number of days before an enquiry receives a response, including those which are answered fully within the Customer Experience Centre and those where input is sought from another team within the agency.

Average time to close (CEC): refers to those enquiries which are handled entirely within the Customer Experience Centre with no involvement in response from any other team within the agency.

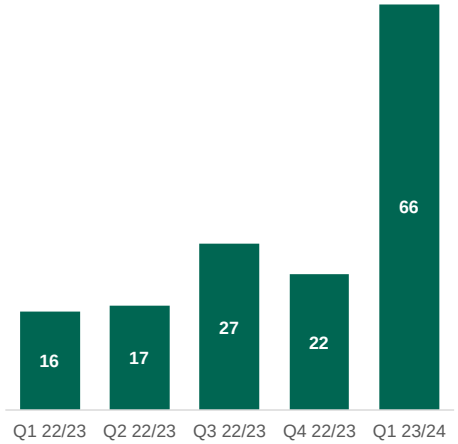
Query volumes reduced at the beginning of Q1 23/24, this is in line with previous year April 2022, Easter bank holidays and shorter month. Volumes increased again in May and June with average response times increasing as we work on clearing backlogs, particular focus on outstanding

Freedom of information requests with our new FOI manager now onboarded since June. Much of this work to bring FOI's back into compliance will continue during Q2.

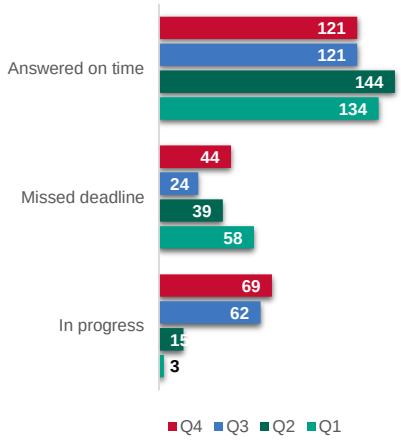
New Customers - Standards



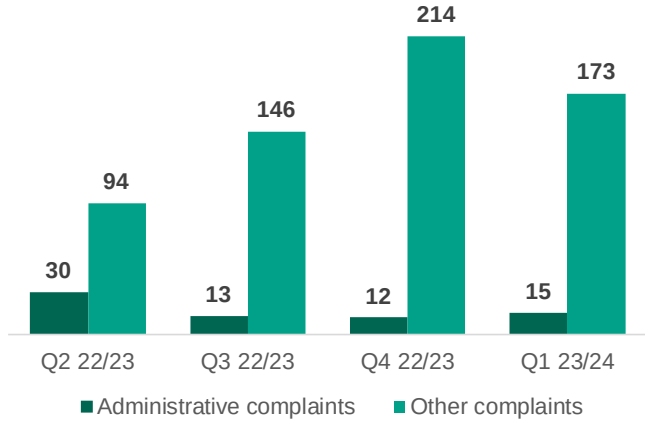
Parliamentary Questions Received



Freedom of Information requests received and responded to in 20 days

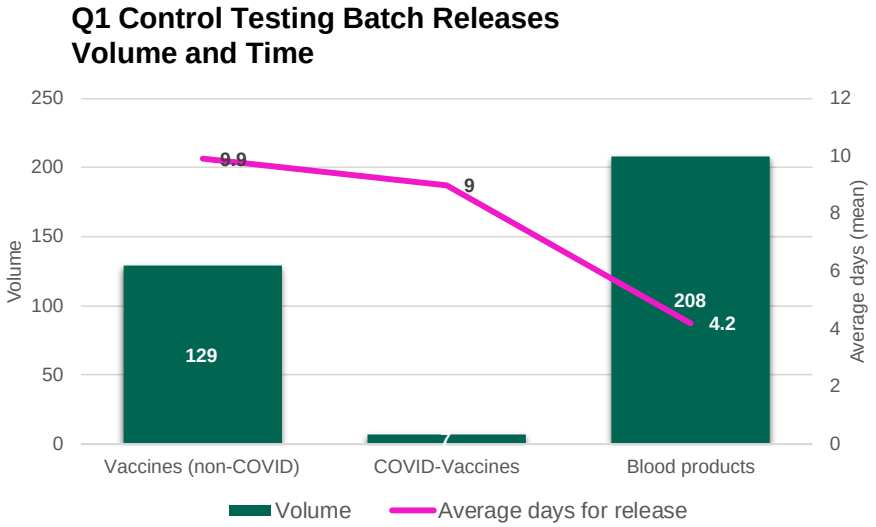


Complaints



Performance – Science, Research & Innovation Group

Delivery Plan Priority – Scientific Innovation



95% of vaccine batches certified within 43 days ✓

99% of blood product batches certified within 15 days ✓

12 months rolling/moving average comparison

The overall control testing workload across all products was stable – only 1% increase, including COVID vaccines compared to 2021/22 (1514 batches in 2022/23 vs. 1493 in 2021/22) and 77% increase compared to 2020/21 (893 batches).

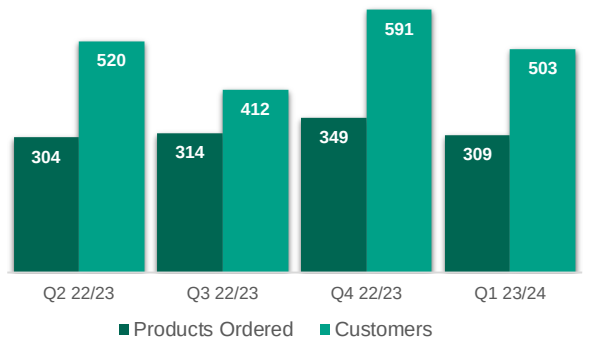
Changes to the breadth of Control Testing

Most of our testing is now for the UK market
Compared to pre-EU exit, we are testing a wider range of different products
We are evolving from a specialised, high throughput laboratory to one with a wider scope that better reflects the variety of biological medicines on the UK market
In 2022/23, 49% of batches for the UK (743) underwent lab-testing compared to <35% in 2019 and <15% in 2020, when NIBSC testing still included batches for the non-UK/EU market)
We are aiming to further reduce the proportion of batches that are released in the UK based on certificates issued by EU control testing laboratories
All plasma pools that are used to manufacture UK blood products underwent testing for adventitious blood viruses (2843 In 2022/23 – up 2% on 21/22 [2798] and up 123% on 20/21 [1254])

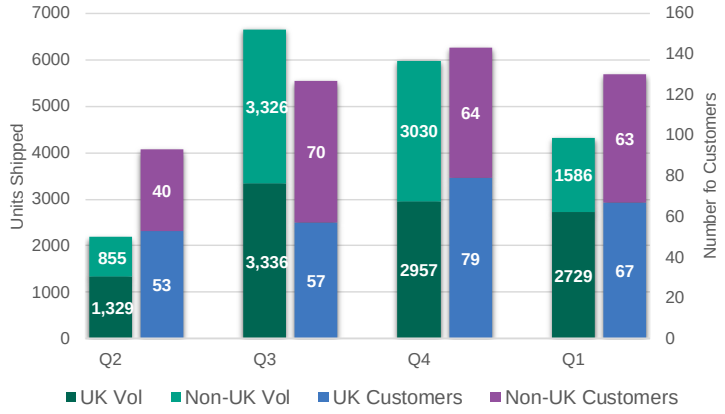
Performance – Science, Research & Innovation Group

Delivery Plan Priority – Scientific Innovation

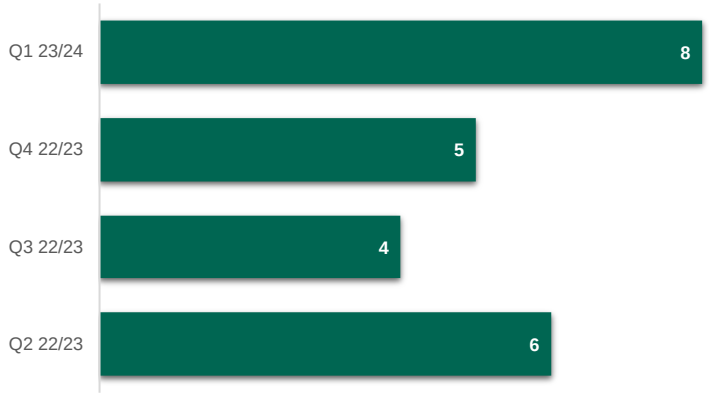
International Standards – Different Products and Customers



Diagnostic Standards – Volume Shipped and Customers



TDP Requests



ILAP

Q1 IP applications – **14** (12 in Q4)

Q1 IP MHRA review meetings – **16** (16 in Q4)

Q1 IP approvals through the ILAP steering group – **7** (24 in Q4)

Q1 IP refusals - **5** (2 in Q4)

International Standards

No significant change from the long-term average. Continuing to engage with same number of discrete customers across the same proportion of the WHO International standards range. Trending graphs are on subsequent slides.
Backlog (ca. 6 weeks) is too big to allow informative measurement of this trend in a quarterly manner.

ILAP

The ILAP refresh work increased pace in Q1, focusing on an ILAP partnership agreement and triage of historic IPs.

30 minute Innovation Surgeries continue to provide a time efficient engagement opportunity with requesters, helping to signpost to agency activities and resolve queries

Performance – Science, Research & Innovation Group

Delivery Plan Priority – Scientific Innovation

Grants and research contracts progress

In this quarter, 5 grants were awarded

Report period	Title	Funder	Duration / months	Value
23/24 Q1	Pilot study to develop a phage reference reagent	UKRI	12	60,000
	RSRU III (Pandemic Preparedness, Neurodegenerative Disease and regeneration medicine, cancer and chronic inflammatory disease, overcoming AMR, Bio-Informatics and mRNA vaccine reference standards)	NIHR	60	£5,500,000
	Environmental surveillance of Polio	UKHSA	12	434,000
	Future Vaccine Manufacturing Hub (RNA, GMMA, baculovirus, yeast platforms)	UKRI	36	£517,000
	Digitalisation and Automation of Medicines R&D and Manufacture (Digital Lyophilisation),	UKRI	24	£85,000

Grant application and success rate (from Research Grants office):

- Success rate is comparable to previous quarters
- Application numbers are higher than previous quarters and may reflect relevant funding calls at the start of the financial year

	2022					2023				
	Q1 Apr-Jun	Q2 Jul-Sep	Q3 Oct-Dec	Q4 Jan-Mar	Q1-Q4 Total	Q1 Apr-Jun	Q2 Jul-Sep	Q3 Oct-Dec	Q4 Jan-Mar	Q1-Q4 Total
Grants applied for										
Successful	4	4	5	2	15	5				
Pending - ongoing	1	0	4	1	6	17				
Unsuccessful	5	3	3	1	12	1				
Closed as not going ahead	0	2	0	0	2	0				
Win rate (%)					42.86					35

Grant forecast secured income at each Quarter (from Research Grants office):

- Trends will be available in future reports
- Forecasts reflect multi-year, phased funding nature of research grants

Financial Year	22/23	23/24	24/25	25/26	26/27	27/28
Secured grant income / £m: Q1	4.1	5.7	2.8	1.5	1.3	1.2
Secured grant income / £m: Q2						
Secured grant income / £m: Q3						
Secured grant income / £m: Q4						

Grant and research contract utilisation in 23/24 Q1 (from Finance):

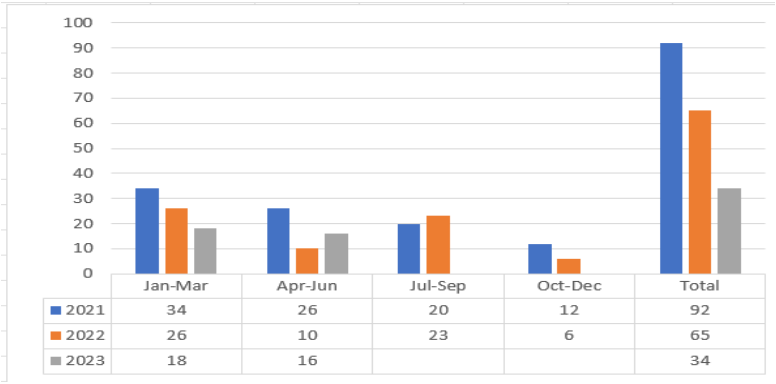
- Utilisation is on target

	2023				
	Q1 Apr-Jun	Q2 Jul-Sep	Q3 Oct-Dec	Q4 Jan-Mar	Q1-Q4 Total
YTD actual	1,262,671				
YTD budget	1,279,811				
YTD variance	(17,140)				

Performance – Science, Research & Innovation Group

Delivery Plan Priority – Scientific Innovation

Communicating our science and its impact: Scientific publications



	Jan-Mar	Apr-Jun	Jul-Sep	Oct-Dec	Total
2021	34	26	20	12	92
2022	26	10	23	6	65
2023	18	16			34

Experts have continued to present data at conferences, as invited speakers and lecturers. We have published scientific data in scientific journals and through information pieces for our website. In this period, we have had PhD student success.

Scientific Publications

The number of publications in peer-reviewed scientific journals is presented. The total number for the calendar year to date is similar to the same period in 2022 and less than for 2021. This is not unexpected given the staffing changes experienced across the teams. Such changes have been noted historically during periods of significant change to the former NIBSC. Staff continue to be encouraged to submit data for publication.

Scientific engagement

The Microbiome lead (R&D Diagnostics) made valuable contacts with colleagues involved in the regulatory science and regulation of Microbiome related biologicals as a result of presentations at back-to-back meetings in US and Asia. The trip was funded in part by the Regulators Pioneer Fund award to the Lead.

Scientists in R&D Diagnostics and R&D Vaccines attended the Microbiological Society's annual meeting in Birmingham. They presented 3 oral presentations and 2 posters on topics pertaining to diagnostics, pathogenesis and correlates of immune protection of emerging diseases including SARS-CoV-2, Chikungunya virus, Mpox and Crimean Congo Haemorrhagic Fever virus. A PhD student presented her data on the development of pseudotyped viruses as safe reference materials for high consequence pathogens.

The DD R&D was an invited speaker at the UKHSA's COVID Vaccine Unit (formerly the vaccine task Force) away day. The talk included the work undertaken by a large team of scientists at the South Mimms laboratories, at a time when pandemic restrictions were in full force, to ensure COVID-19 vaccines were available for the national vaccination programme in line with Government targets.

The 7th annual PhD student symposium took place at the South Mimms Laboratories. Six students presented their work to around 70 attendees including the university supervisors. The work highlighted the diverse nature of the scientific research undertaken at SML which underpins the Agency's work on improving patient and public health. Seven students presented posters of their work allowing colleagues to interact with them in person. A guest speaker, Professor Jonathan Ball from the University of Nottingham gave a talk on "Engaging with the media" which was both informative and entertaining. We are looking to expand the scale of this Symposium next year to allow PhD students from across the whole Agency to participate together.

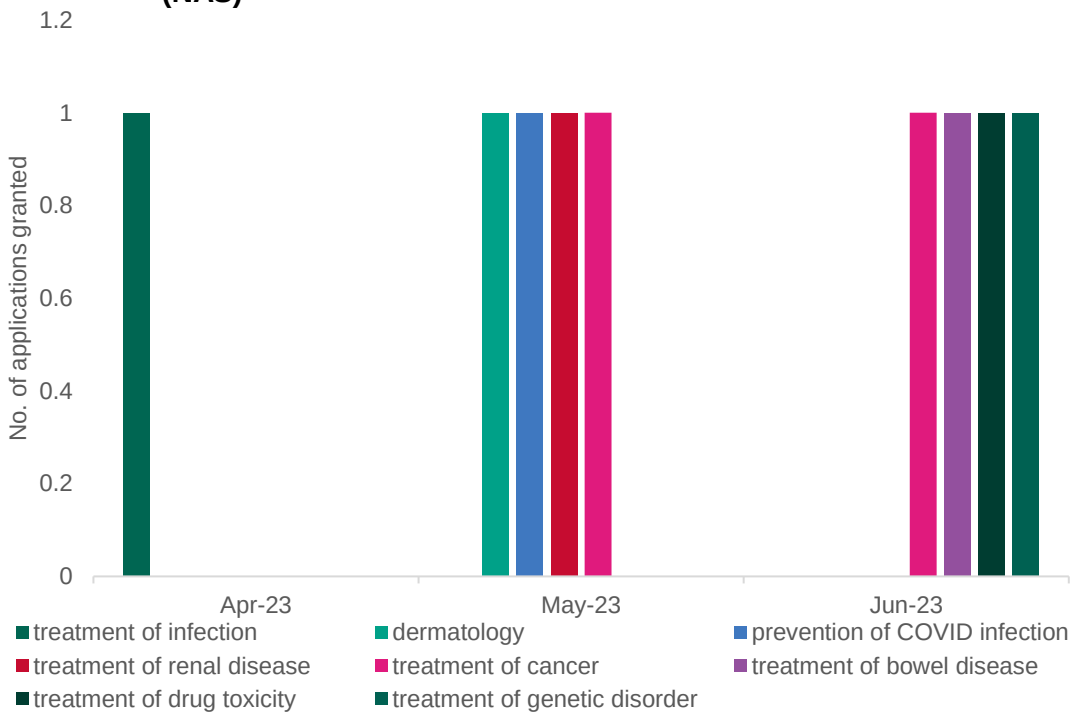
A Principal Scientist from the R&D Conjugate Vaccines group gave a presentation to MSc students at the University of Leeds School of Molecular and Cellular Biology about some of the R&D work we do at MHRA, and talked with students about scientific careers.

A Principal Scientist from the R&D Conjugate Vaccines group organised a STEM event at The Beech Hyde Primary School which was also attended by scientists from SR&I. The MHRA staff talked to students about bacteria, viruses and vaccines. The activities included presentations, creating viruses and bacteria with modelling clay, and playing a card game that demonstrates how viruses and bacteria can spread and how vaccines are important in stopping that spread.

Performance – Healthcare, Quality & Access Group

Delivery Plan Priority – Healthcare Access

New Licences – Q1 2023 New Active Substances (NAS)



NAS resulting from ORBIS & ACCESS during Q1 2023 (none approved Apr/June 23)

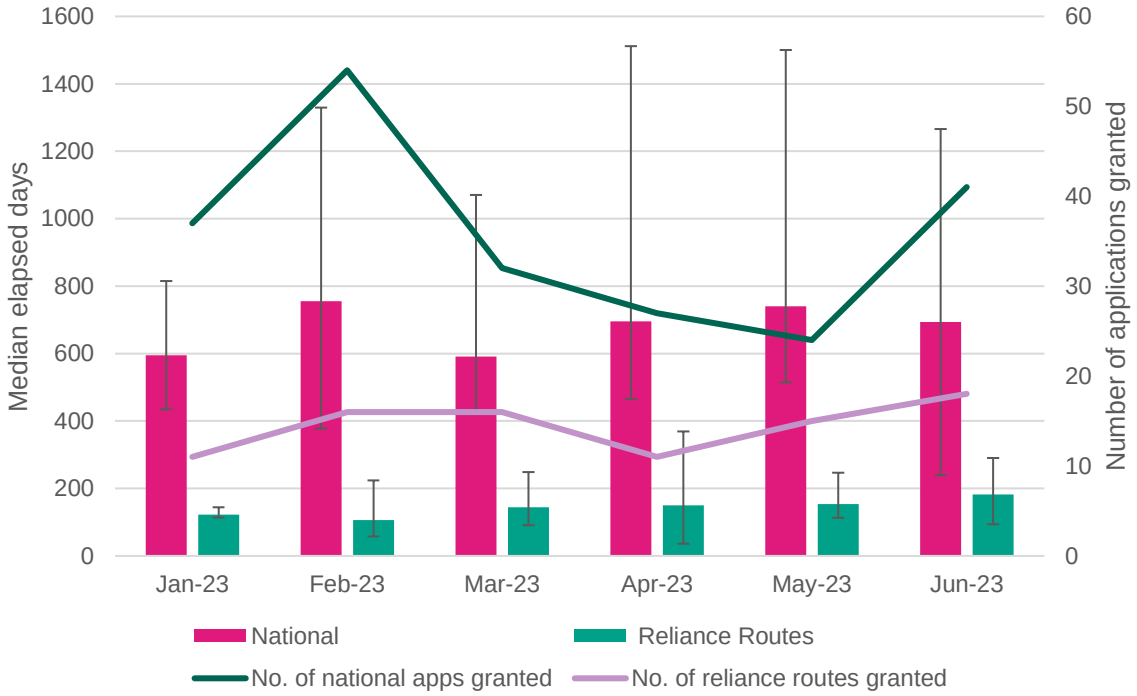
Product	Active substance	Submission	Proposed Indication
Vafseo 150 mg film-coated tablets	VADADUSTAT	ACCESS	Vafseo is indicated for the treatment of symptomatic anaemia associated with chronic kidney disease (CKD) in adults on chronic maintenance dialysis.

In Q1 2023, 9 new active substance licenses were granted via the national and reliance routes. These products included a vaccine for the prevention of COVID19 infection and a medicine to treat a rare genetic disorder. In addition, two positive scientific opinion were issued under the Early Access to Medicines Scheme, one for the treatment of endometrial cancer and one for treatment of diffuse large B-cell lymphoma. Currently, 15 national new active substance applications are under assessment.

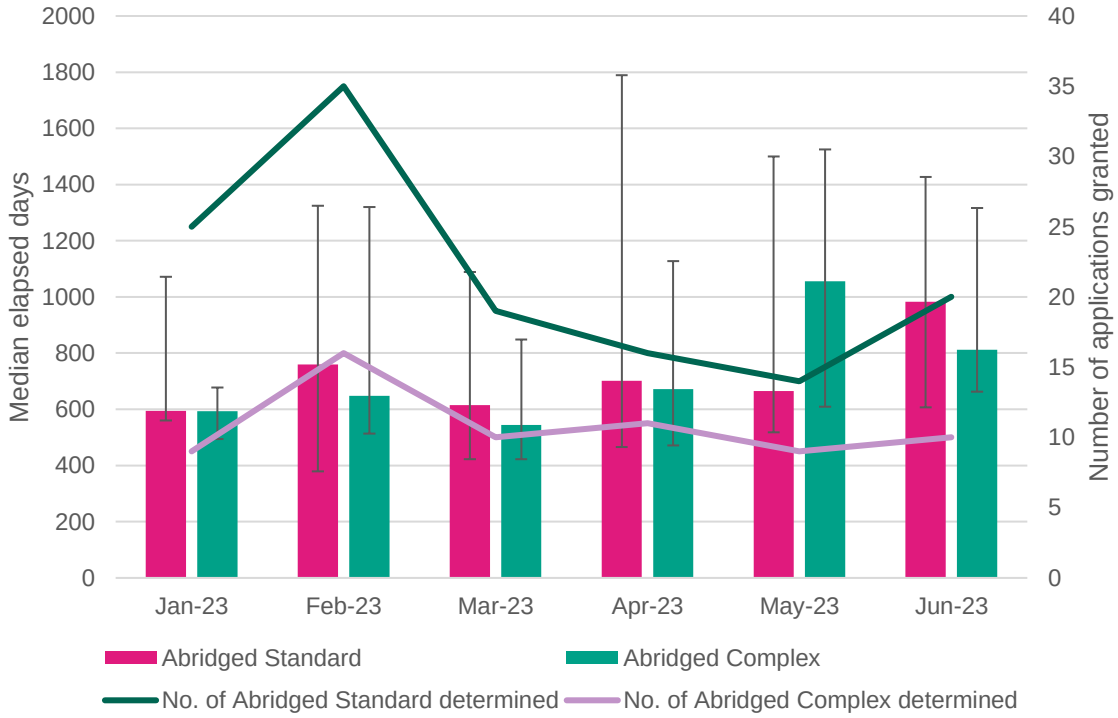
Performance – Healthcare, Quality & Access Group

Delivery Plan Priority – Healthcare Access

Established Medicine Initials – Median days elapsed to determination with 10% to 90% interpercentile range includes number of applications determined (Jan-June 23)



Established Medicine – Standard/Complex initial national applications – median days elapsed to determination with 10% to 90% interpercentile range and number of applications determined (Jan- June 23)

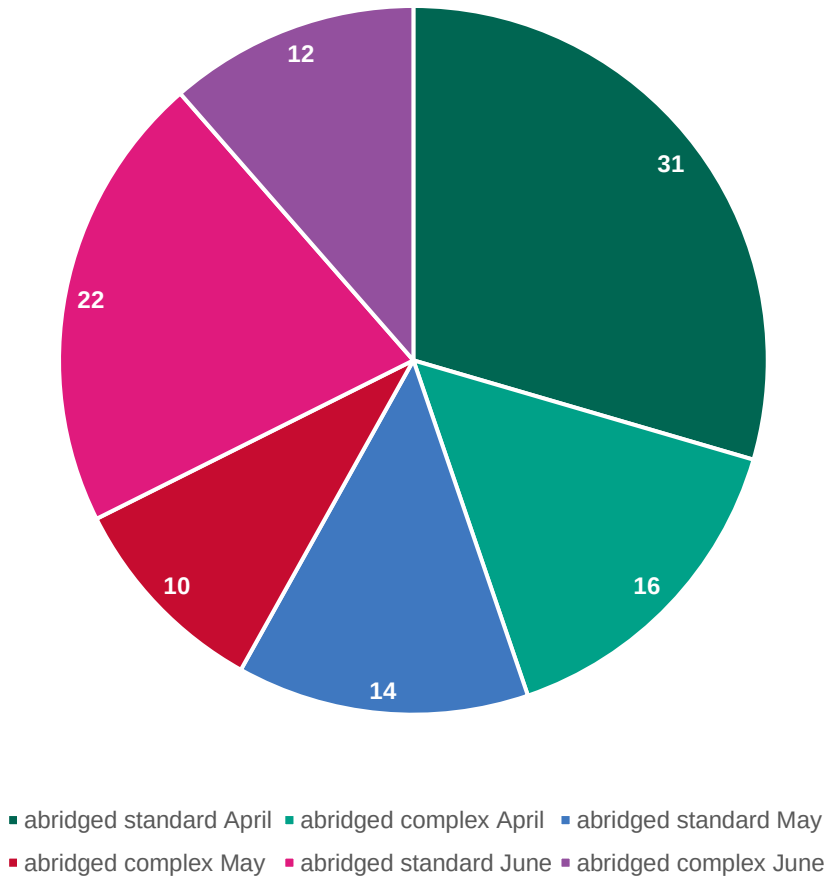


Focus on clearing applications through activities generated in the Task and Finish Group. First actions which are driving change over the period agreed with ExCo at the end of the period. Further actions are under review. Processing times will vary and not follow trend lines for 2023 as older applications are processed, giving the broad ranges between 10-90% percentiles.

Performance – Healthcare, Quality & Access Group

Delivery Plan Priority – Healthcare Access

Established Medicine – Standard/Complex initial national applications number of applications determined April to June 2023 (Q1)



Parallel Import Licence Applications granted - April to June 2023

Measure	April 2023	May 2023	June 2023
Initial Parallel Import Applications received	39	55	72
Initial Parallel Import Licences granted	46	72	81
Minimum time to grant (months)	9.1	7.8	7.8
Median time to grant (months)	12.4	11.2	12.1
Time to start assessment (months)	11	10	9.7
Variations received	1030	864	693
Variations granted	451	727	1104
Time to grant leaflets (months)	3.6	3.3	3.0
Time to grant pharmaceuticals (months)	3.2	2.9	2.9

Time taken to grant initials (median time) and variations in Q1 2023 remains stable and consistent with previous months. Ongoing initiatives to streamline processes and improve efficiency continue to demonstrate a significant upward trend in applications granted.

Unlicensed Medicines

A key activity that HQA regulates, is the **importation of unlicensed** medicines for patients with needs that cannot be met by licensed products. There are significant numbers of these per quarter and the numbers have been steadily growing.

However, it is not possible at this time to produce the metrics for this quarter; this is due to technical changes in the system and is currently being investigated. Relevant metrics will be published once the ongoing work to generate meaningful data from the system is completed.

Performance – Healthcare, Quality & Access Group

Delivery Plan Priority – Healthcare Access

Standards and Compliance

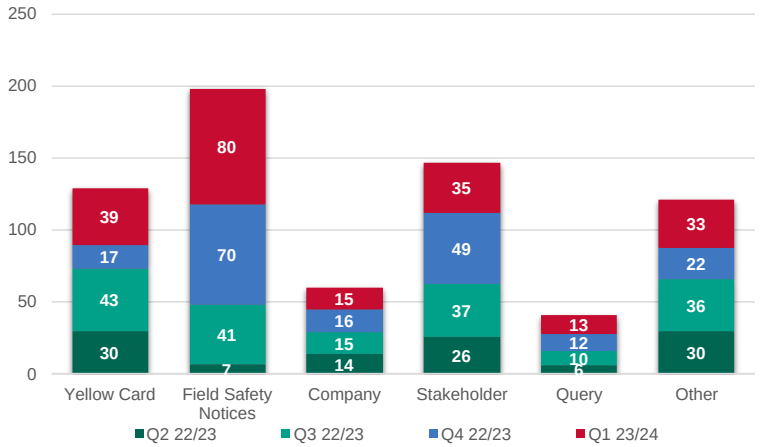
Nature of activity	How does this improve compliance?	Q 2 Performance
Initial reviews of new Approved Bodies.	Ensures bodies approved to undertake assessments of conformity against regulations for Medical Devices used in the UK meet required standards	1 new applications received in Q1. 0 initial reviews undertaken since Q1 (1st application received in last week of Q1), Target is to completed 90% within 2 weeks
Designation of new approved bodies.		8 open applications for designation We are expecting 1 further organisations to submit in the coming months, with 1 other preparing an application
Inspectorate Blogs	Keeps industry up to date with latest standards and best practice, and lessons learned from inspections, ensuring they are aware of requirements.	Unique Visitors 25,419 Unique Page Views 33,821
GXP Guide Sales		Orange Guide – Q1 23/24 £24,974, of which £8,740 royalty received from Pharmaceutical Press (PP) Green Guide –Q1 23/24 £12231, of which £4,281 royalty received from PP [Δ 75% from Q1 22/23 (new version launch) but Δ 13% from Q1 21/22]
Site Inspections	Inspections can be desk based (remote), hybrid (assisted by remote technology) or full physical inspections. Inspections detect system problems which could put patients at risk.	13 (Q4 10) Clinical Trial sites inspected. 2 (Q4 2) referral for critical findings. 13 (Q4 16) Laboratories (GLP/GCP/GMPQC) Inspected, 0 (Q4, 1) referrals for critical findings. 5 (Q4 4) Pharmacovigilance (safety monitoring) systems inspected. 1 (Q4 2) referral for critical findings. 57 (Q4 39) Manufacturers Premises Inspected, 1 (Q4 6) referrals for critical findings. 84 (Q4 126) Supply Chain sites inspected. 10 (Q4 8) referrals for critical findings.
British Pharmacopoeia Total Sales (Publication plus Reference Standards)	Combined sales revenue from the BP publication and sales of British Pharmacopoeias Reference Substances (BPCRS) gives an indication of our product reach and customer demand	Total Revenue (Q1) = £1,431,080.4 [Δ 7.9% vs same period last year (£1,326,714.6)] Total revenue (YTD) = £1,431,080.4 [Δ 7.9% on same period last year (£1,326,714.6]

Performance – Safety & Surveillance

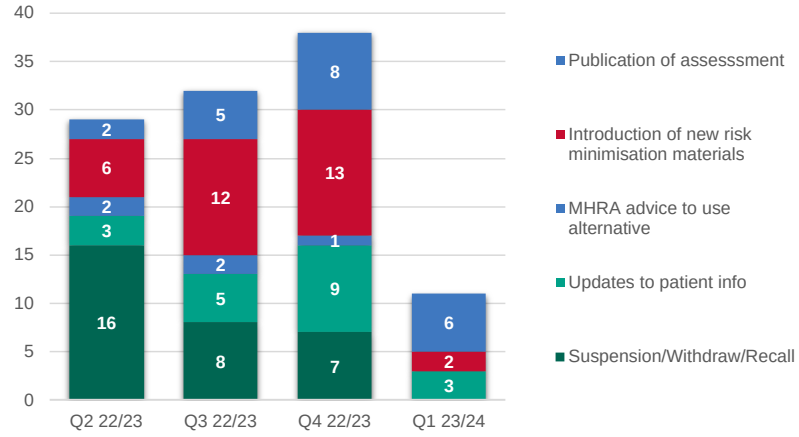
Delivery Plan Priority – Patient Safety

Yellow Card – Q1 reports

Benefit Risk Evaluation



Actions Taken to Minimise Risk to Patients*



Safety Signals

For medicines

The total number of drug -event combinations:

- Black Triangle/Additional Monitoring substances: 22,786 -23,902 in Q4.
- Established substances**:** 41,236 – 47,893 in Q4

The total number of new safety signals identified for further assessment* **29 – 23** in Q4

Variations Q1	National	Reliance	CMS
Received	223	165	61
Assessed	140	109	99
Completed	195	84	182

Current total backlog = 1,671

Performance – Safety & Surveillance

Delivery Plan Priority – Patient Safety

Assessed threat reduction impact	Q1 22/23	Q2 22/23	Q3 22/23	Q4 22/23	Q1 23/24
MAJOR	2	0	0	1	0
MODERATE	6	6	2	6	4
MINOR	309	280	250	257	491
TOTAL	317	286	252	264	495

Accompanying narrative

The number of interventions assessed as having a minor impact on the criminal threat has risen considerably against the first quarter of 22/23. This is likely to be attributable to impact of a near-full staffing complement on the CEU's capability and capacity.

Interventions assessed as having a minor impact will almost always dominate CEU performance reporting as they are generally quick time and delivered at zero-low cost to the Agency. Moderate and major interventions are far less common as these often require greater resources and time to achieve the intended threat reduction impact.

Detail

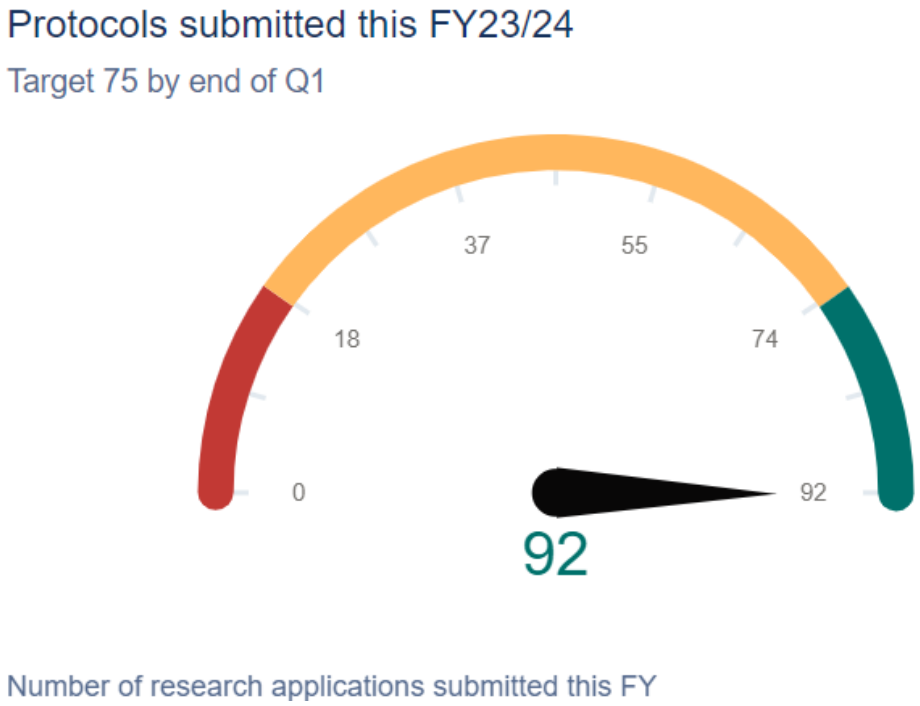
Interventions completed in quarter assessed as having a moderate threat reduction impact:

- Sentencing of Kieran Banks – sentenced to 5 years imprisonment for the supply and conspiracy to supply POMs and Class C controlled drugs.
- Arrest of subject and recovery of significant quantity of unlicensed medicines and controlled drugs of Class A, B & C, linked to two illegally operating websites purporting to be legitimate online pharmacies.
- Warrant and inspection resulted in the seizure of various beauty products classified as unlicensed medicines or POMs.
- Seizure of unlicensed medicines, prescription-only medicines and stolen medicines from an Aesthetics business.

Interventions completed in quarter assessed as having a minor threat reduction impact:

- This included multiple takedowns of illegally trading webpages, social media listings and marketplace listings, bank account closures, account freezing orders and warning letters sent to low-level first-time offenders.

CPRD - Total number of new RDG applications submitted in 2023/24



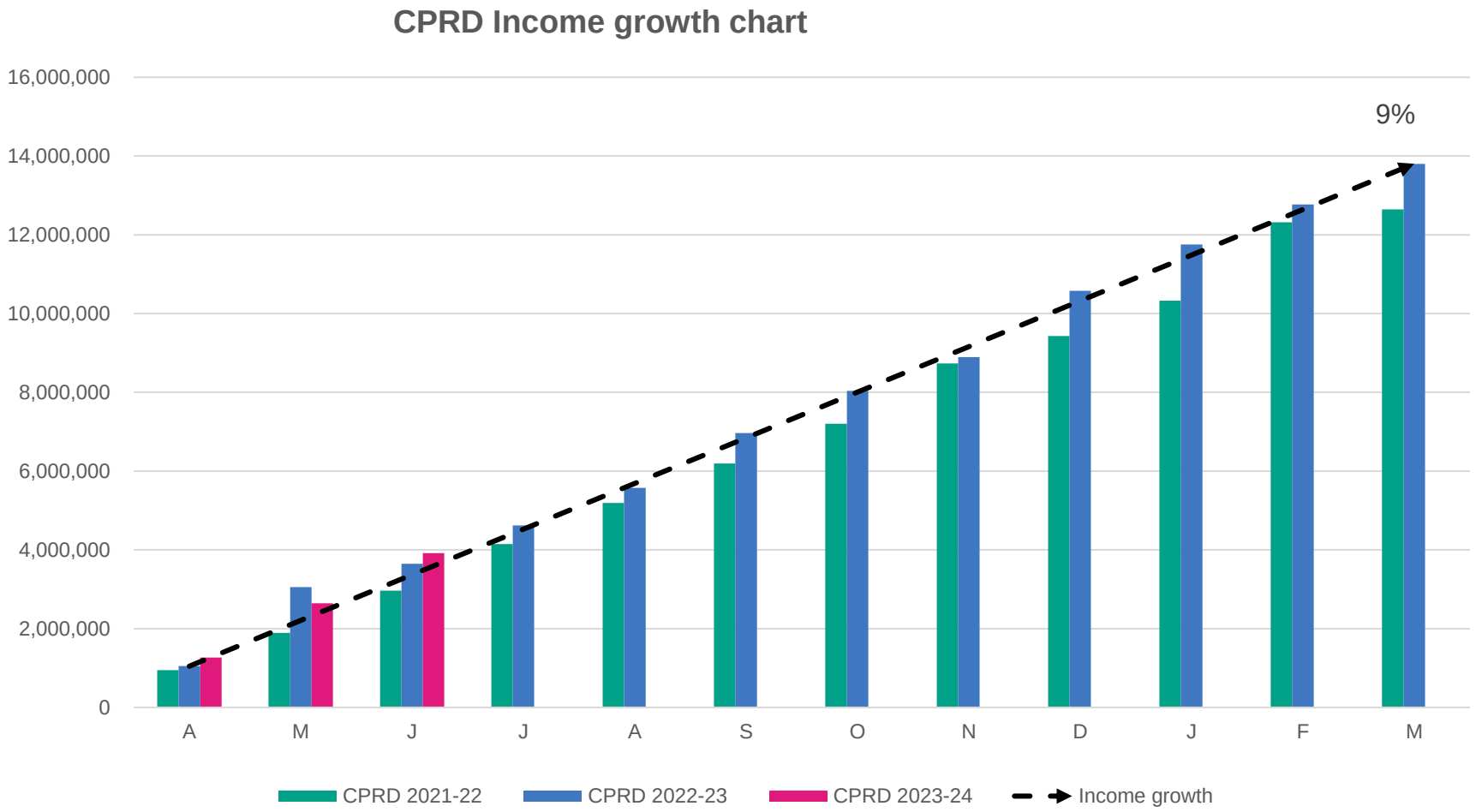
Target by end of quarter	Q1	Q2	Q3	Q4
Protocols target	75	150	225	300
Protocols submitted this FY	92			

This indicator could provide an early signal of waning interest in CPRD data which in turn could impact income from data licence fees.

To consider:

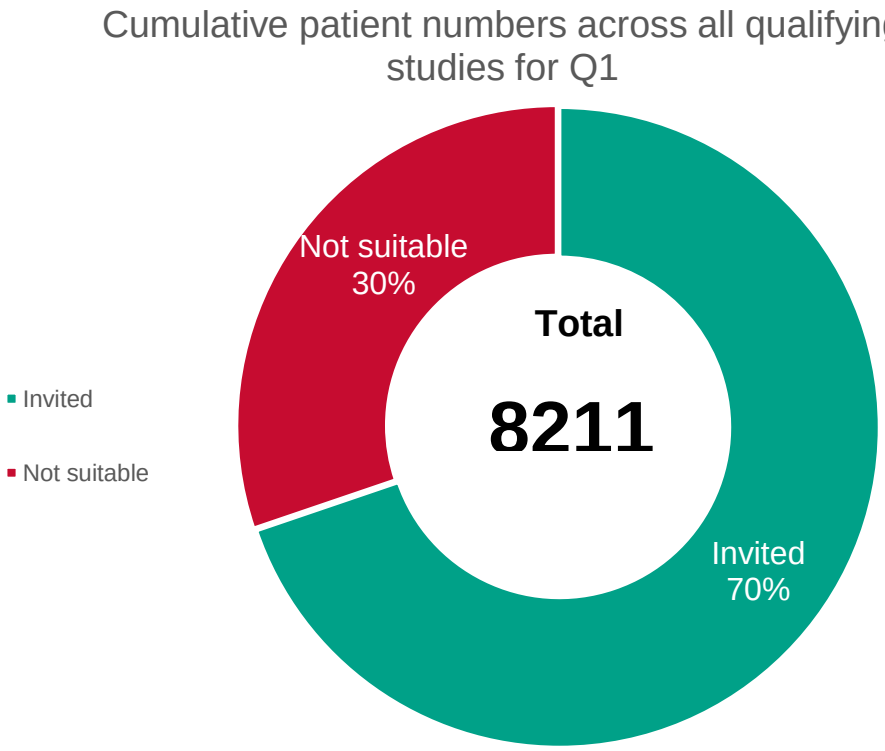
Needs careful interpretation as we routinely receive amendment requests to expand the scope of approved studies and recent applications related to machine learning typically have a much broader scope of use.

CPRD - Income growth



- This chart represents the CPRD income growth target in 23/24 and comparisons with 2021/22 and 2022/23, and the bars represent cumulative income across any given financial year.
- The dotted line represents the target income phased across 12 months and incorporates a 9% income growth as compared to 22/23

CPRD - Interventional Research Metric



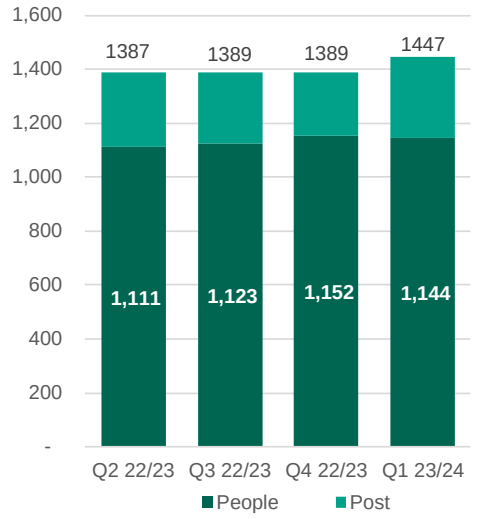
Proportion of GP reviews resulting in patient invitation to participate in a clinical study for all recruitment activities for CPRD Interventional Research services (Target 75%)

Target	Q1
75%	70%

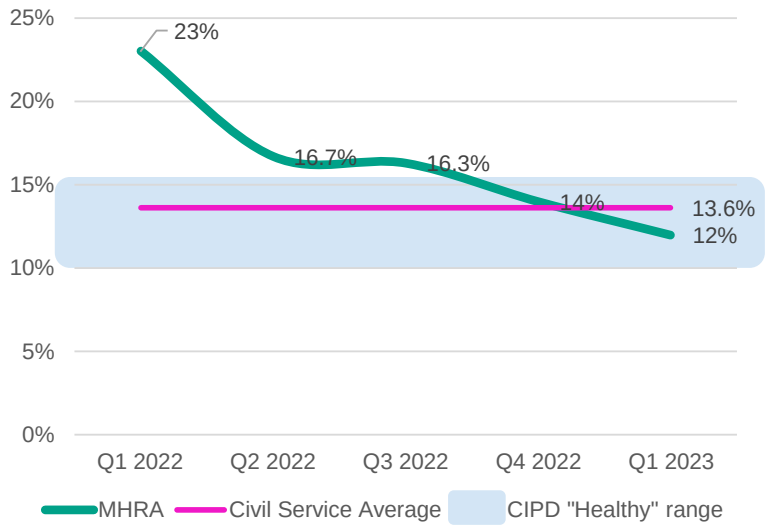
People

Delivery Plan Priority – Dynamic Organisation

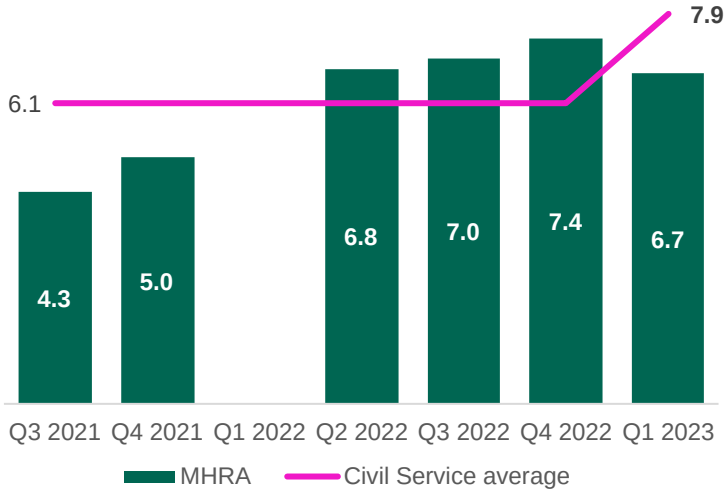
Recruitment
Posts filled v structure



Voluntary Turnover – Annualised



Sickness Absence Days – Annualised



There are a total of 1447.3 posts in Fusion in June, an increase of 5 since May. Permanent positions include apprentices, PhD Student, NEDs & Chairman and Fast Streamers but not posts filled by contractors/fixed term.

We report a stabilisation in our turnover at 12% as we increasingly fill vacancies, with a slowdown in the rate of leavers versus starters. Reassuringly our turnover now falls into the category considered 'healthy' by the CIPD.

Note: The Civil Service average is 13.6% and the Chartered Institute of Personnel Development (CIPD) report a "healthy" turnover as between 10% and 15%.

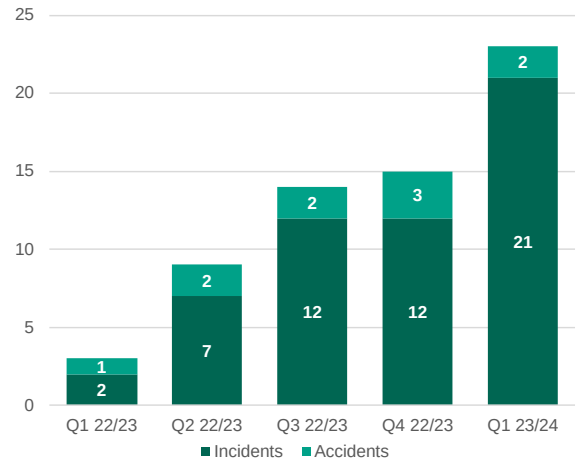
Absence is reducing slightly which is a positive sign.

Absence in the Civil Service as a whole is however increasing, with latest data presented in March 23 for 22-23 showing an increase in the average working days lost increasing from 6.1 days to 7.9 days. Absence by department has also increased, from a minimum of 2.5 days to 12.1 days (was previously in a range from 1.1 to 9.7 days reported.

People

Delivery Plan Priority – Dynamic Organisation

Incidents and Accidents



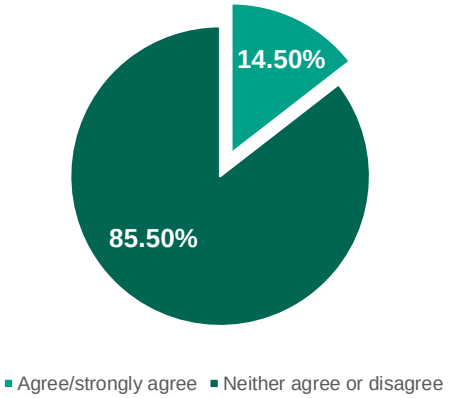
There have been 814 corporate training attendances (i.e. trainings developed or commissioned by the central Agency Talent and Capabilities team) by staff between April 2022 and March 2023 (some staff may have attended more than one). Please note this data does not include the majority of the training provision which is via the Government Campus (Civil Service Learning). The Government Campus provides both mandatory and a broad range of generic training, and related data is is currently unavailable to us for technical reasons. This data will be included again from Q1, 2023/24. Agency developed training run by Groups/Functions, which has not been recorded centrally, is also not reported here. There will be further efforts to capture and record this for Q1, 2023/24.

85.5% of corporate training participants from April 2022 to March 2023 agree or strongly agree that the learning undertaken was applicable to their role and performance in role.

69% of L2 and 3s have attended leadership training between January and December 2022. 100% of participants show increased confidence in their leadership capability immediately post-training. There was a further training date in March 2023 for recent arrivals in L2 and L3 posts. However, currently the data showing is the same as for the last reporting period, as we have not yet received the evaluation data form the training provider).

Across all corporate trainings between April 2022 and March 2023 (not just senior leader training), 80.7% of staff report increased confidence in the training subject matter immediately post-training.

Applicability of learning across 2023 training programme

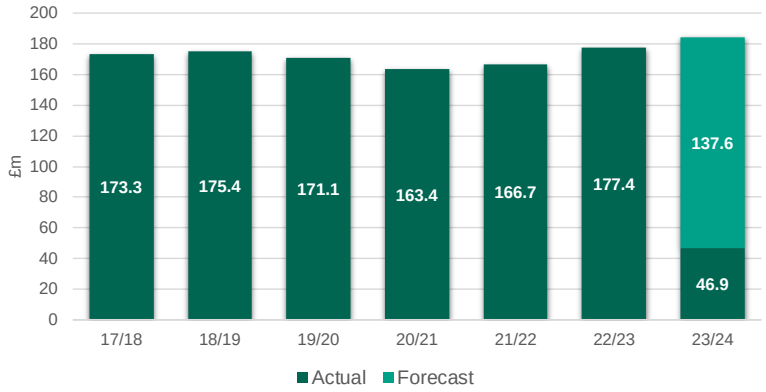


Majority of the incidents reported are facilities type issues due to proactive reporting culture encouraged by Health and Safety through the Safety Champions

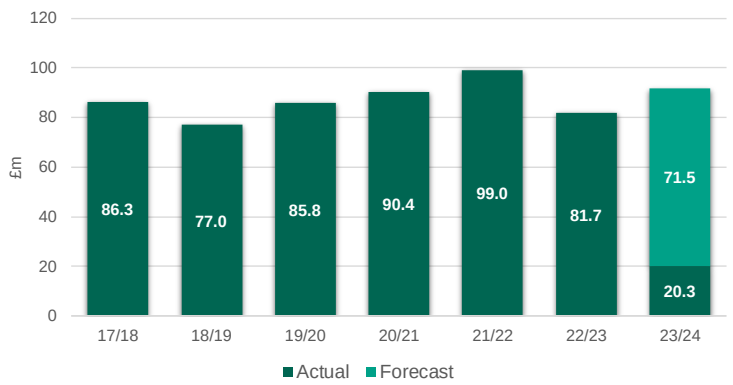
Finance

Delivery Plan Priority – Financial Sustainability

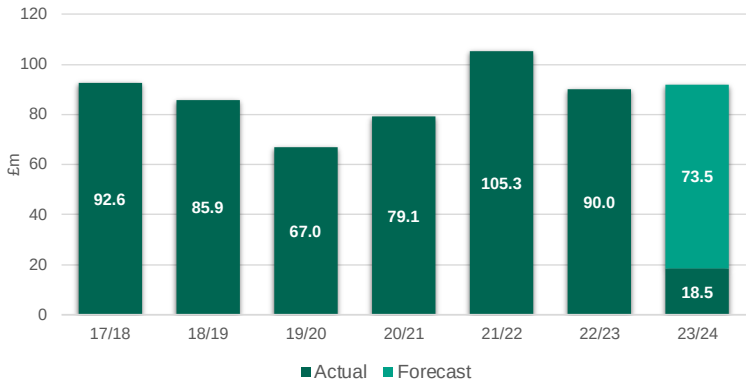
Income – 23/24 forecast **£184.5m** v budget £185.6m



Pay Costs – 23/24 forecast **£91.8m** v budget £94.9m



Non-Pay Costs – 23/24 forecast **£58.2** v budget £59.4m



Numbers include £25.5m of DHSC capital funding.

Small underperformance in CPRD income (£1.1m), grants (£0.8m) and standards (£1.0m) have been offset by increased performance in Licensing (£1.8m). This offset in licensing is despite having a budgeted £2.8m increase in income from 21/22. This increase was supposed to be delivered in the last financial year but due to recruitment issues this wasn't able to be achieved. However now most of these employees are in post we are seeing more than the expected increase, demonstrating how we can deliver growth but it often takes longer than we anticipate.

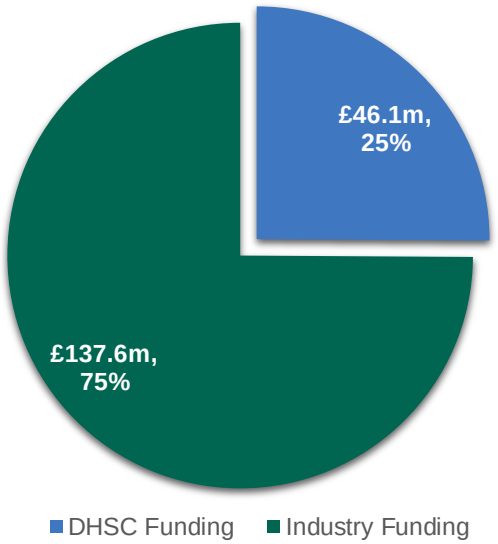
Additional investment in the agency led to an increase in budgeted FTE, this in turn has led to higher vacancy rates during Q1. However, recruitment combined with unbudgeted one-off bonuses and pay rises mean the forecasted end of year pay variance is only 3% favourable to budget.

Majority of change costs are profiled towards the end of the financial year, this is why non-pay costs are currently only £18.5m v a full year budget of £93.5m, we are now forecasting costs to end the year at £92.0m

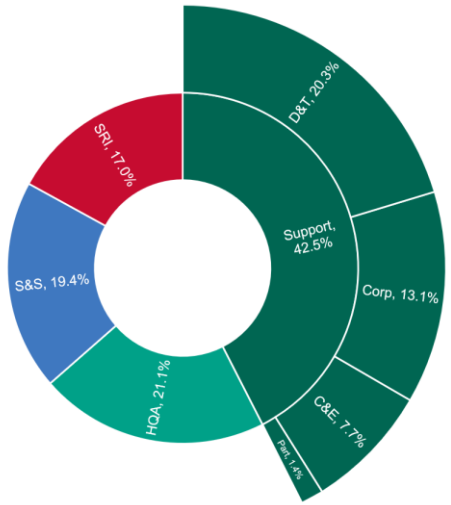
Finance

Delivery Plan Priority – Financial Sustainability

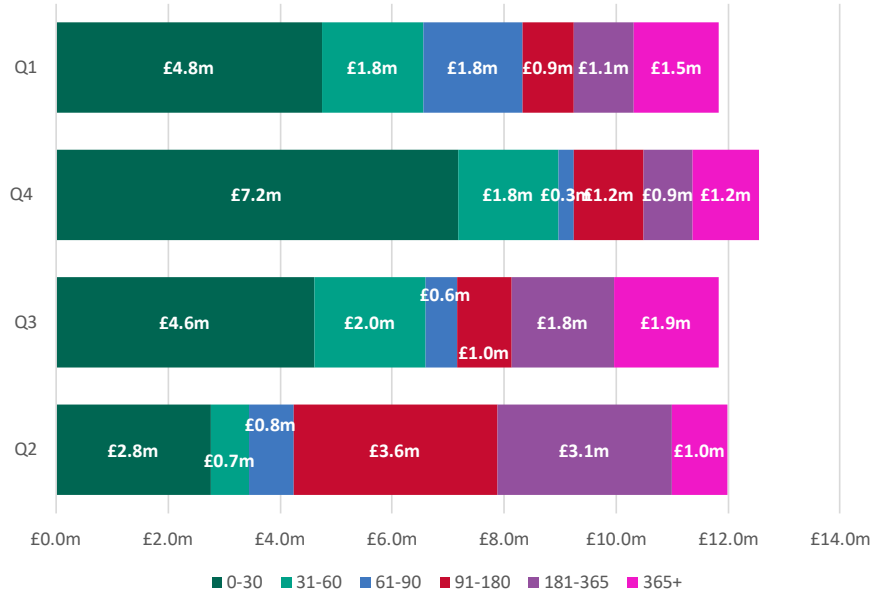
DHSC / Industry Income Split



Support Expenditure %



Debt by Days Due exc Service Charge



The agency has an ambitions to reduce DHSC reliance and reduce relative expenditure within the support groups.
DHSC funding for 23/24 has reduced to 25% of our total income, down from 29% last year. This is despite £15m of funding for RMS meaning we should see further decreases in future years.

Forecast support spending is down from 49.8% last year to just 42.5% this year, this is due to reduced accommodation costs as well as increased expenditure within the revenue generating areas. This shows improved efficiency within support in-line with the agency's ambitions.

While total debt has decreased, we've seen increases in debt over 30 days from £5.4m to £7.1m and debt over 180 days from £2.1m to £2.6m. However, both these value are lower than we saw during Q2 and Q3 last year.

Total debt is now £11.8m, just over our £11.6m (equivalent to 1 month's trading income) target, while debt over 6 months is £2.6m, £0.3m over our £2.3m (20% of 1 month's income) target.

Digital & Technology

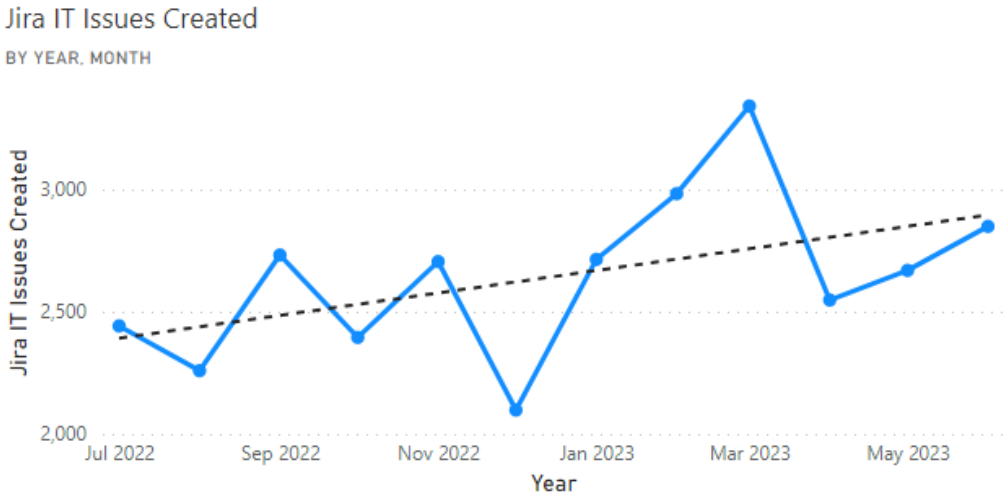
Delivery Plan Priority – Dynamic Organisation

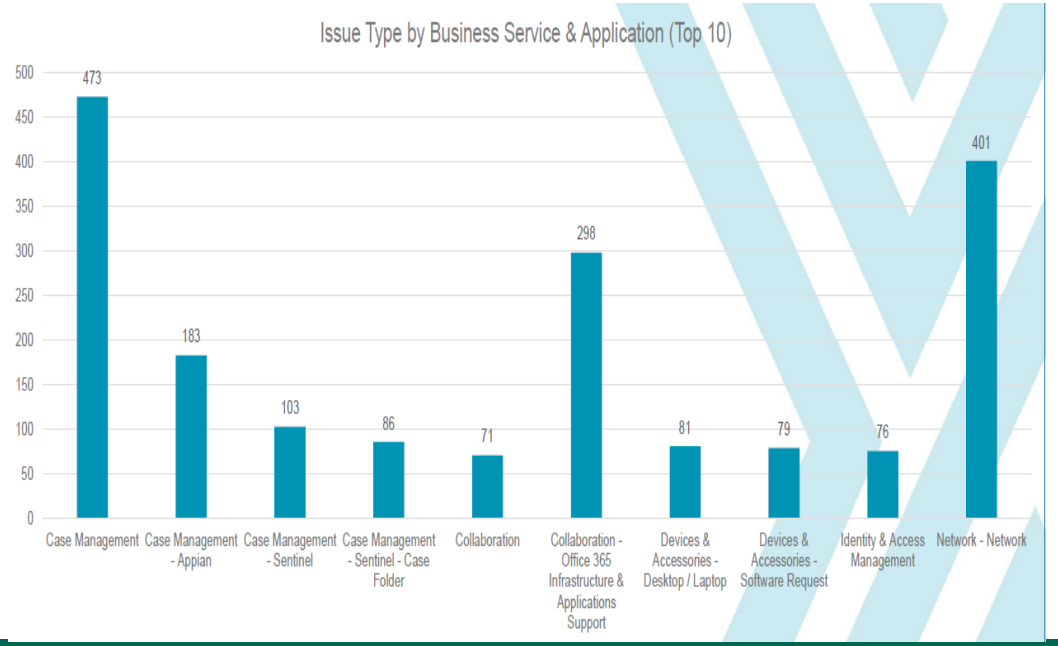
IT Service Desk Volumetrics

Q1 profile of raised Jira tickets
(April-June)

Issue Type	No. Created	Resolved	%
Service Request	5,452	5,446	99.9%
Incident	1,732	1,702	98.3%
Change	447	463	103.6%
Other	435	444	102.1%
Total	8,066	8,055	99.9%

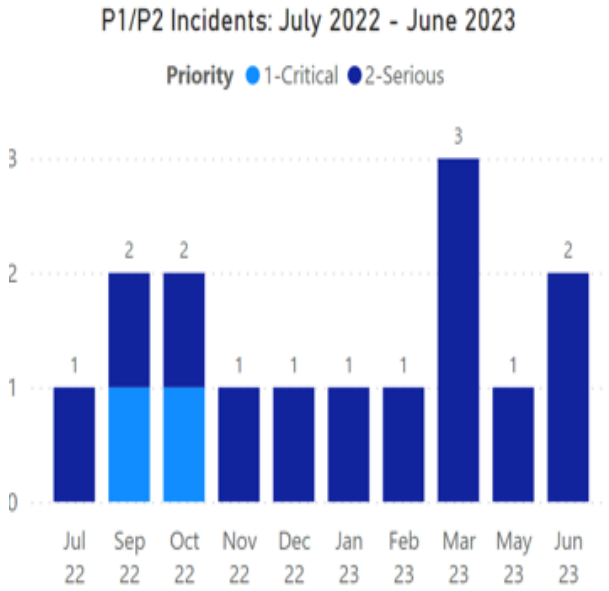
From April 2023 to June 2023 the MHRA IT helpdesk received a total of 8,066 requests for support and closed/resolved 8,055 requests.





Digital & Technology

Delivery Plan Priority – Dynamic Organisation



P1/P2 Incidents

There were no P1/P2 issues in April
In May there was 1 P2 raised where there was an issue where administrators could not remote onto the nibsc.org. The server was resized, and access was restored.
In June there were 2 P2 issues. On related to a vulnerability issue with the MOVEit transfer software. A security issue was picked up by MOVEit and an emergency patch had to be installed. There was also an issue with Sentinel Printing. The server was rebooted, and the service was recovered.

Service Management Highlights

During June a new desktop Service Desk provider, XMA took over the running of our Desktop and helpdesk services. Most of the staff who worked for the previous supplier have moved over to XMA.

The new supplier will be introducing new software which will enable MHRA Service Management to see Realtime information and improve services to users, and will deliver a suite of more relevant service performance indicators. New measures will be incorporated into the D&T performance report during the year as they become available.

Work is also underway to introduce a Service Catalogue, improve the joiners / leavers / movers process and implement other user focused Helpdesk improvements.

Medicines & Healthcare products Regulatory Agency

BOARD MEETING IN PUBLIC

19th September 2023

Title	How effectively is the MHRA maintaining performance on clinical trials and how has a sustainable clinical trial function been established from 1 September?
Board Sponsor	Marc Bailey
Purpose of Paper	Strategic Direction

How effectively is the MHRA maintaining performance on clinical trials and how has a sustainable clinical trial function been established from 1 September?

1. Executive Summary

1.1 There have been delays in clinical trial assessment by the MHRA since September 2022 which increased over time despite efforts to reduce and eliminate these delays. The main causal factor was the loss of a significant number of experienced staff in the Clinical Investigations and Trials team and this was associated with difficulties in recruiting new staff with relevant skills.

1.2 As a result of the increasing scale of this assessment backlog a crisis response was initiated in July 2023 to rapidly address these delays. The aim of this response was to ensure the elimination of the backlog and that all newly received compliant applications from 1 September 2023 were approved within statutory timeframes. All newly received compliant clinical trial applications received from 1 September 2023 are being processed within statutory timeframes.

1.3 This paper sets out how the cross-agency crisis response has addressed the backlog, presents the ongoing measures to ensure continued clinical trial approval performance and outlines the foundations of a new clinical trial process based on the public consultation outcome announced in March 2023. This is aligned with the UK Government ambitions as set out in the Life Sciences Vision and O'Shaughnessy Review to ensure that the UK is an attractive location for clinical trials and the benefits this brings to UK patients and the healthcare system.

2. Background

2.1 Clinical Trials regulation under the "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, as it integrates medical research on medicines' efficacy with innovation in treatment delivery, access and patient safety. Statutory timeframes for the assessment of clinical trials are 30 calendar days (initial application) and 35 calendar days (substantial amendments).

3. Action taken

3.1 A range of measures were urgently implemented as part of the Agency's crisis response to restore clinical trials assessment performance. Key measures are set out below.

a. Redeployment of resources
Staff were redeployed from across the Agency to support assessment of clinical trials from July - September 2023.

b. Improved processes and data
The clinical trials team developed a revised risk-stratified assessment process that initially triaged trials by clinical trial phase and then by complexity and risk into high, medium, and low/limited risk categories. Depending on the risk trials were then subject to a risk-proportionate assessment process that enabled an accelerated timeframe for assessment. Ensuring the safety of trial participants is the core principle of our clinical trials assessment process and this has been maintained through the risk-proportionate implementation of improved assessment processes.

c. Use of external resource
External resources have been brought in to provide additional capacity to support improved clinical trial performance and in the longer term create buffering capacity to increase resilience in this critical function, as well as increase access to specific technical expertise if this is required. This included the use of external contracts and the development of a unique collaborative enterprise with the National Institute for Health and Care Research (NIHR) that has enabled the agency to access their extensive network of expert clinicians to support the assessment process.

4. Maintaining current performance of clinical trials

4.1 In mid-July 2023 there were 966 clinical trial applications in the backlog that had exceeded their statutory timeframes for approval. We will have eliminated those remaining by mid-September whilst managing the workflow of applications received prior to 1 September. All compliant applications received from 1 September are being processed within statutory timeframes and robust reporting processes are in place to monitor performance.

4.2 Very significant progress has been made with restoring and improving service performance for clinical trials approval. However, it is critical that we ensure continued stability of assessment performance.

5. Performance management

5.1 The revised framework for management and reporting of clinical trials performance will be maintained in the medium term to ensure that performance is fully stabilised and support local management. Short/medium-term improvements to our systems for data reporting and analysis using the existing case management system will also be identified and implemented where appropriate.

5.2 Redeployed staff are returning to their respective 'home' groups on a phased basis whilst we manage the balance of assessments received prior to 1 September 2023 alongside those newly received applications from 1 September 2023. To ensure continued stability it will be necessary to retain a small residual amount of redeployed resource with the CIT team pending completion of new recruitment.

5.3 Contracted resource to support clinical and non-clinical assessment will be retained until at least the end of December 2023 or earlier if capacity is demonstrated to be robust to its withdrawal. We will continue to maximise the use of the NIHR clinical network to support assessment both in the medium term and as part of building longer term resilience into our clinical trials assessment function.

6. New approach to UK Clinical Trials regulation

6.1 We are now working to ensure that we optimise the clinical trials approval process in line with the proposals set out in the UK Government response to the consultation on legislative proposals for clinical trials, the Life Sciences Vision, and the O'Shaughnessy review while maintaining and developing the UK as an attractive environment for clinical trials.

6.2 Building on the programme of reform set out in the UK Government response to the consultation on legislative proposals for clinical trials published in March 2023 and the innovation and learning from the response, we will continue to drive the implementation of risk-proportionate regulation to make it easier and faster for applicants to gain approvals and to run clinical trials in the UK, as part of our work to support delivering the Government's Life Sciences Vision

6.3 As a first step in our programme of reform we will launch a new clinical trials notification scheme pilot in September 2023 that will allow researchers to proceed with low-risk trials without the need for further assessment (both initials and amendments). Higher risk trials will still require more extensive assessment. This new approach is based on the principle of ensuring participant safety through risk-proportionality to ensure that the participant risk is either equal or lower than in standard clinical care or from consideration of risk in light of information arising from the trial being already underway, completed or approved to commence in USA or EU.

6.4 It is expected that approximately 20% of trials will be eligible for the scheme which will run over the next 4 months. This pilot is being developed with input from our external experts on the Commission on Human Medicines as well as from representatives of the commercial and non-commercial clinical trials sectors under the Clinical Trials Task and Finish Group. Implicit to the development of our new ways of working will be the co-development of guidance with stakeholders.

7. IT Infrastructure

7.1 The underpinning infrastructure for clinical trials requires improvement and investment to ensure longer term sustainability. This also includes how we maintain the level of information and transparency with applicants on their application status. We will identify and implement where appropriate short/medium term improvements to our existing case management system to improve reporting and performance management. In the longer term, working with UK regulatory partners, we will identify what infrastructure is required to support an optimised approval process and one that would vastly increase transparency to applicants on progress and timings for approvals in line with recommendations of the O'Shaughnessy review.

8. Organisation and people

8.1 The organisational structure of the CIT team will be reviewed and, if necessary, reconfigured to ensure its design is an enabler to our ambitions and robust to performance delivery. The extensive capacity modelling developed during the response has identified the need to increase the capacity of the CIT team for both clinical and non-clinical assessors as well as for the operational support team.

8.2 We will work to rapidly recruit these additional staff in Q3 of FY 23/24 using the innovation and access funding provided by the Chancellor earlier this year. This will be not only to support assessment activity but the vitally important upstream pre-submission scientific advice support for applicants that is a core component of our offer as an enabling regulator providing an end-to-end service to those developing and marketing new products.

8.3 The newly developed collaboration with the NIHR clinical network will also be maintained as an important tool for specialist support from this vast network of experts and as an element of our plans to ensure resilience for this function.

9. Impact of the crisis response on other key Agency objectives

9.1 Impact assessments for the redeployment of staff were conducted by SRI, HQA and S&S and suitable prioritisation and mitigation plans developed and implemented. The Agency prioritised resource to ensure delivery of key activities including those that support the life sciences vision missions e.g. that for dementia treatments, COVID-19 vaccines, and key critical safety activities.

9.2 Whilst the Agency ensured that all feasible steps were taken to mitigate the risk to service delivery and to patients, it is recognised that there has been a temporary unavoidable impact on some areas that have not been prioritised. The Agency has kept these plans under regular review and strategically coordinated the phased return of redeployed staff aligned with these priorities.

9.3 The Clinical Trials team has continued to deliver scientific advice throughout this period, and the process has been updated to include an exchange of written advice prior to any meetings to ensure that the request for advice is fully understood and assessor resource is used as efficiently as possible. The process requires further improvement to ensure that it is timely and fit-for-purpose and that the advice given can be demonstrated to improve the content and quality of the subsequent clinical trials application or amendment.

10. Communications and stakeholder engagement

10.1 External stakeholders have emphasised that effective communications and enhanced information for applicants are essential to the MHRA's short- and long-term work in clinical trials.

10.2 We launched enhanced customer services support for clinical trial applicants as part of our crisis response, underpinned by significant workarounds to our data systems, communicating proactively with applicants on their individual trial status, on a regular basis. We intend to continue delivering this and further enhancements that embed a more customer-centric culture to the clinical trials service as it evolves to deliver longer term sustainability.

10.3 We have also been engaging regularly with a network of stakeholders who are representative of the clinical trials sector to provide consistent messaging and updates on interventions the MHRA were taking to reduce backlogs, supported by the regular provision of additional datasets demonstrating the positive impact in regulatory assessments.

10.4 This was reinforced by our commitment to publishing data indicating our month-on-month performance, which is accompanied by analysis to support companies with their planning, by providing a more predictable view of service levels in the clinical trials area. We are committed to continuing to be transparent with our performance data and to providing key stakeholders with the means to brief consistently across the sector; encouraging them to share MHRA information through their own channels when appropriate to build reassurance or create desired behaviour change. We will consult with stakeholders to ensure that the data we communicate is decision relevant and reflects the performance metrics which are meaningful for applicants considering their options. We will also contribute to end-to-end data transparency across system partners involved in trial approval and set up including HRA, NIHR and the NHS.

11. Proactive communications strategy

11.1 We have developed a coordinated strategy for communicating the restoration of our regulatory performance and ensuring that the UK's attractiveness as a destination for clinical trials is enhanced.

12. Recommendation

12.1 The Board is asked to consider the following key questions:

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

ii. Are the initial proposals for long-term sustainability and improvement of clinical trials assessment sufficiently ambitious to ensure the attractiveness of the UK as a destination for clinical trials?

iii. Are there additional communications or partners we need to consider, to ensure we maximise our impact in reassuring stakeholders that trials will be approved in the required timeframe and the attractiveness of the UK for clinical trials?

James Pound
September 2023

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

19th September 2023

Title	What is the progress in delivering an excellent culture with strong leadership at the MHRA?
Board Sponsor	Kerry McEyeson
Purpose of Paper	Assurance

What is the progress in delivering an excellent culture with strong leadership at the MHRA?

1. Executive Summary

1.1 The paper and attached PowerPoint presentation seek to provide assurance to the Board the agency is making progress towards delivering an excellent culture with strong leadership.

1.2 The presentation starts with some definitions of culture which support the approach taken to view culture as a dynamic process to work with, rather than a static object that can be easily measured and "fixed". It explores what is meant by culture in an agency context and summarises what has been done as well as signposting what is being done in the service of building an excellent culture.

1.3 Recognising the significance of leadership in creating cultures, the presentation moves on to consider how MHRA's leaders are influencing culture, emphasising expected leadership behaviours of agency' leaders. It sets out the leadership development offer in 22/23 to build leadership capability and continued plans to keep investing in this.

1.4 The presentation concludes with suggested actions for the Board itself to consider that would help deliver a healthy culture and great leadership.

2. Introduction

2.1 The agency recognises culture and leadership are key determinants of its success, (slide 5). This continues to be visible through its Corporate Plan (a priority is for the agency to be a place "where people flourish alongside a responsive customer service culture"), having previously being a priority in the agency's Delivery Plan 2021-2023). Culture is also a strategic risk, (risk 7 is the culture of the agency does not enable the required changes in support of the agency's strategic purpose and priorities). And culture and leadership are priority themes in the agency's People Strategy together with related actions, ("Developing exceptional people and people leaders" and "Investing in a healthy culture")

3. Key Challenges

3.1 Culture is often seen as a barrier to change because it is difficult to be clear about what is meant by it (slide 3), or if anything can be done to change it. The key challenge when working with culture is accepting it's a continually dynamic process to work with and not something that can be measured with precision, with problems or faults readily identified and then fixed. Culture is also experienced differently by everyone who works in the agency and there will be different cultures at play across the agency.

3.2 As leaders' power and visibility means they have a greater impact on culture than others, it is important for leadership to have a shared understanding of the culture

all of us are striving to co-create and to role model behaviours in support of the desired culture. Ultimately though everyone of us has a shared responsibility for shaping the desired culture and leaders have the added responsibility to enable the conditions for this to happen.

3.3 Given the pressures the agency is currently dealing with, a challenge for leaders is prioritising time to focus on their own development and growth, alongside that of their teams. To create space for teams to come together to talk about anything other than progress against the task (the "what"), can understandably be considered a luxury rather than an essential. However, it is only by giving due consideration to the "softer" people measures that will ensure delivery of the tangible (the task at hand).

4. Summary of measures taken

Culture (slide 7)

4.1 Culture is underpinned by values and the agency refreshed its values following consultation with all staff about these led by agency leaders. As behaviour is seen as an immediate and reliable indicator of cultural understanding and assumptions the One Agency Leadership Group (OALG) was then tasked to discuss with their teams how they would live the agency values in delivering expected outcomes and to arrive at 3 behaviours for each value the whole team could commit to practice. Additionally, each Group/Function was asked to distil from these a single behaviour for each Value to be practiced by the whole Group/Function. These have been collated in the Agency Behaviour Framework. The expectation is the process itself to define the behaviours will have increased the likelihood of permanent behaviour change in support of values and culture change. And it will be easier for leaders to hold themselves and others to account for displaying the right behaviours and living agency values.

4.3 Culture is also kept visible through the agency's Culture Action Plan which has been in place since 2021. The updated Culture Action Plan was published on the agency's intranet this month. It has been aligned to both the Corporate Plan and People Strategy and refocused on 4 key culture priorities, setting out actions for each priority to enable the supporting culture over the next 3 years. It will be reviewed annually in line with the agency's Business Plan.

4.4 Regular "temperature" checks on culture are carried out in a variety of ways – ranging from a simple "check-in" at meetings, to formal agenda items at meetings, to surveys, with senior leaders sighted on findings.

Leadership (slides,10-12)

4.5 Leadership development continues to be a priority for the agency. The positive impact of OALG, in place since January 2022, is showing through, (e.g: leading values and behaviours work).

4.6 A Leadership Development Plan is in place, including a comprehensive learning and development offer. Investment in developing the capability of leadership

teams is ongoing through offers of coaching to provide insight in how they work together and the Leadership Skills Core Programme.

4.7 Recognising that leadership is a learned skill, the leadership learning offer is now extended beyond OALG membership through the launch of a new "line manager as leader" programme.

4.8 The agency has set out the attributes/behaviours associated with good leadership and will shortly be launching a campaign seeking nominations of colleagues of all grades who are seen to be demonstrating these behaviours.

5. Measurable outcomes

5.1 The People Strategy and Leadership Development plan set out the expected measurable outcomes in relation to culture and leadership. A detailed project plan in support of the Culture Action Plan is being compiled and this will also show the outcomes expected. Most of the measures in the plans relate to increases in survey scores.

6. Recommendation

6.1 In order to facilitate an excellent culture with strong leadership at the agency, the Board is asked to:

- Enable the conditions required for a healthy culture and then cultivate a healthy culture;
- Set the high leadership standard for all to follow;
- Consistently role model expected leadership behaviour and hold itself and others to account for doing this;
- Engage with leaders and staff on how they are leading, living values etc;
- Assess leadership capability when selecting into leadership roles;
- Prioritise leadership development for itself and others, and
- Ensure culture/people considerations are taken account of in all discussions in Board meetings.

Kerry McEyeson
19th September 2023

Medicines & Healthcare products Regulatory Agency

What is the progress in delivering an excellent culture with strong leadership at the MHRA?

BOARD MEETING HELD IN PUBLIC

Kerry McEyeson, Deputy HR Director

and

Malgosia Malach, Head of Organisational Development, Talent and Capabilities

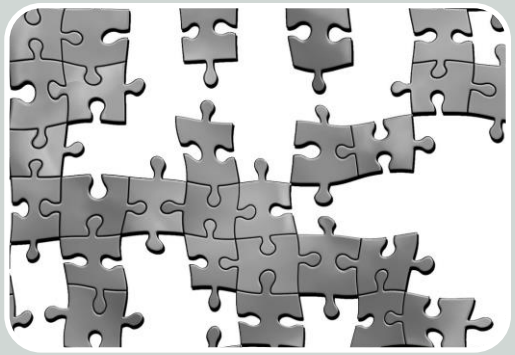
19th September 2023

Contents

Some culture definitions

How things are done around here. (Ouchi & Johnson, 1978)
The social glue that holds an organisation together. (Baker, 1980)
The values and expectations that organisation members come to share. (van Maanan & Schein, 1979)
“Cultures are the stories we tell ourselves about ourselves and then forget they are stories.” *(Geertz, 1975).*

What do we mean by culture?

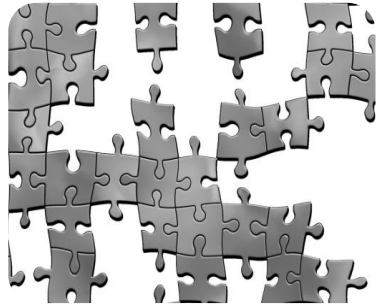


Cultures are concerned with meaning

Cultures act as a guide

Leaders are cultural provocateurs

What importance does MHRA put on culture?



An enabling culture is seen as a prerequisite for achieving all the agency's strategic objectives.

- People Strategy, priority 4, is "invest in a healthy culture"
- Corporate Plan, priority 4 is building towards an agency "where people flourish alongside a responsive customer service culture"
- Strategic Risk 7 – is that the culture of the Agency does not enable the required changes in support of the Agency's strategic purpose and priorities.

'Culture eats strategy for breakfast', (Peter Drucker).

Progress on culture is measured through regular surveys

- In-house Culture and Pulse Survey conducted in June 23
- Annual Civil Service People Survey is expected to launch today

Culture & Pulse Survey Summary (June 2023)

- Increased **engagement index** score from 49% to **62%**.
- Improved positive scores in '**Pulse'** questions, except for clarity of future vision from senior leaders, only **27%** positive.
- Although an improvement on the last Survey, **56%** of respondents remain either indifferent, anxious or concerned about the agency's future.
- Limited progress in responses to culture questions since last culture survey in 2021.
- Increase in numbers of 'neither agree nor disagree' responses to most of the questions. Possibly as high numbers of new joiners, who are still to make up their mind?
- Results reinforce what is already known and being addressed – decision-making approach, unrealistic workloads, barriers to effective working across boundaries, behaviours and ways of working.
- Signs of 'green shoots' of recovery, a turned corner, and on balance optimism that things can improve.

What is in place to guide culture across MHRA?

- Refreshed values launched in April, following OALG led whole agency consultation.

- Supporting Behaviours Framework in place.

- Culture Action Plan aligned with Corporate Plan and refocused around four priorities:
  - Living our values
  - Leading the agency to success
  - Leveraging future opportunities in how we work
  - Learning and innovating together

- One Agency Leadership Group (OALG) now “normed”. Meeting agendas regularly focus in on leadership and cultural challenges

- Bi-monthly meetings of the Our Culture & Ways of Working Group (whole agency representation):
  - “Culture Temperature check” is a standing agenda item

- New starters invited to share impressions of what it is like working at the agency as part of the Corporate Induction offer and comments shared with leaders to inform future thinking and improvements.

What else is planned?

An offer from the OD team to work with each member of One Agency Leadership Group in Q3 to run a culture enquiry into their team's culture and set local culture benchmarks.

- Expected benefits from this are:
  - At a local level:
  - **empowering** those attending to commit to taking individual and collective action as a result of their heightened awareness of the culture they belong to, and
  - **Informing the insights** of leaders to influence their culture locally.

- At a Group/Function and agency Level:
  - Showing how **cultural patterns are experienced** and are changing across the wider system;
  - Sharing these with the leadership team(s), encouraging them to take **individual and collective action** to influence the culture

Plans to increase visible ownership by senior leaders of 2023 People Survey actions and beyond.

How should our leaders be influencing culture?

Expectations for leaders:

- Holding themselves and others to account for displaying the right behaviours and living agency values;
- To live out Leadership in Action attributes
- Ensuring that demonstrated behaviours are talked about at monthly 1-1 review meetings;
- Noticing and rewarding desired behaviours and outcomes
- Role modelling – “Walking the talk”
- Being visible and accessible
- Taking ownership and responsibility for decisions

Suggested future actions:

- All Groups/Functions to have a local culture risk
- All OALG members to have a reverse-mentor

Behaviours associated with good leadership

- Regular opportunities for all colleagues to deep dive into a single “Leadership in Action” (LiA) attribute are part of the leadership development offer.
- Starting position is everyone, regardless of grade/role can exhibit leadership behaviours, so the LiA campaign is being reviewed to enable this.
- 13 leaders have thus far been recognised for exhibiting one of the LIA attributes, over 3 separate campaigns.

Leadership development remains a priority. This is what was offered in 2022/23:

Leadership and management development resources accessed through the new online learning library, including content on leadership of change and innovation.

Agency-wide career development guide.

Workshops for line-managers on career development and developing talent in their teams (3 Chief Officers signed up).

3 x leadership development days for ExCo.

One Agency Core Leadership Skills programme - 111 senior leaders have participated.

Individual and team executive coaching for One Agency Leadership Group (OALG)

Reverse mentoring offer – 39 pairings with senior leaders (including ExCo and NEDs)

5 colleagues participating in cross Civil Service Accelerated Development Schemes.

Leadership goal is mandatory for delegated grades as part of performance review process

360’feedback for senior civil servants applied to their performance review

Plans to continue building leadership capability

- Continued delivery of Leadership Development Plan actions. These include:
  - Raising leadership and management capability including at more junior levels (new “line manager as leader” programme and one more cohort for the One Agency Core Leadership Skills programme by Roffey Park)
  - Unlocking potential by improving communication and collaboration through team coaching, mentoring, use of Strength Development Inventory (SDI) psychometric
  - Strengthening talent pipelines to senior leader level (mentoring, coaching, development programmes, SDI)
  - Reverse mentoring to increase leaderships’ insights into agency and promote positive change.
- Proposed ExCo Strategic Priorities Awayday by end of 2023.

How can the Board influence an excellent culture with strong leadership?

The Board is asked to:	
	Enable the conditions required for a healthy culture and then cultivate a healthy culture
	Set the high leadership standard for all to follow
	Consistently role model expected leadership behaviour and hold itself and others to account for doing this
	Engage with leaders and staff on how they are leading, living values etc
	Assess leadership capability when selecting into leadership roles
	Prioritise leadership development for itself and others, and
	Ensure culture/people considerations are taken account of in all discussions in Board meetings

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

19th September 2023

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

Medicines & Healthcare products Regulatory Agency

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

1. Executive Summary

1.1 PSEC discussed three substantive items and noted a fourth on the Patient Engagement Audit Report. Those three items were:

1.1.1 Is the Committee assured that patients have been sufficiently involved in the review of the safety of fluoroquinolones?

1.1.2 Is PSEC assured regarding the patient engagement plan for the Agency's review into rectopexy mesh?

1.1.3 The Yellow Card Biobank consent process

1.2 The reports were comprehensive and well received by the Committee. The Committee also discussed the difference between patients and the public, how their interests and views might differ.

2. Introduction

2.1 The eleventh meeting of the Patient Safety and Engagement Committee was held on the 9th August 2023.

3. PSEC discussed each of the following items at the meeting on the 9th August 2023;

3.1 **Is the Committee assured that patients have been sufficiently involved in the review of fluoroquinolones?**

The review of fluoroquinolones had commenced due to concerns about the effectiveness of current measures to minimise the risk of disabling and potentially long-lasting or irreversible side effects associated with fluoroquinolones. Ensuring that patients' voice is accurately represented is vital to the Agency's commitment to be patient orientated. A range of measures had been taken to ensure that patients were involved in this review. Patients were involved in helping to set the scope of the wider engagement exercise and facilitated by UK patient support groups, which included some healthcare professionals, patients who had adverse drug reactions (ADRs) and those caring for loved ones who had ADRs. The Committee were also interested in data on the benefits of fluoroquinolones. The Committee discussed the potential for serious psychological side effects, highlighted by a recent Coroner's Regulation 28 report to prevent future deaths, and officers confirmed that this had been raised by CHM and is subject to further exploration. Lastly, the consideration of whether there was a genomic basis for working out who suffered from adverse drug reactions was discussed with the potential for the Yellow Card Biobank to be able to provide

data which would support the Agency's and patients' understanding of the risk profile. The Committee were assured that patients had been and were continuing to be involved in the review through a number of different methods of engagement.

3.2 **Is PSEC assured regarding the patient engagement plan for the Agency's review into rectopexy mesh?**

The Independent Medicines and Medical Devices Safety review provided a basis for the patient engagement plan for rectopexy mesh. The Agency heard a number of concerns raised by patients throughout its engagement with patients, including the lack of clear information shared between healthcare professionals and patients, and the need to adequately understand the benefits as well as the risks. There was an emphasis placed on the manufacturers' role too in ensuring that they adhere to regulations and guidance, adequately labelling their products. The Committee discussed the upcoming devices regulations, which will take a risk-based approach to post-market surveillance. Guidance and new demands on manufacturers as well as a more proactive approach from the Agency, such as supporting the development of a register, will increase patient safety.

3.3 **The Yellow Card Biobank process**

Officers highlighted three main components of the Yellow Card Biobank consent process: recontacting Yellow Card reporters, a consent sheet, and having electronic consent being able to be provided supported by a hotline. The Committee raised questions around whether it would be possible to include under 18s, however due to the speed that this was being put together and legal complications of including minors this was not possible. Genomics England were to be consulted on how they gain consent as they might have examples of good practice that we could learn from, and the committee highlighted that it was pivotal that the capacity from individuals for giving consent was assessed. Public trust in the system was also highlighted as particularly important as if the public could not trust the process, they would not engage, and the evidence provided by the Biobank would be damaged. The Committee reflected that public trust in the Covid vaccine was high, and lessons could be learned from that experience to apply to the Yellow Card Biobank.

3.4 The Committee noted the recommendations from the internal audit report that reviewed the Patient Engagement Strategy one year on from its publication.

4. Conclusion

4.1 The Committee made recommendations on each of the papers but was assured that officers were heading in the right direction on the three substantive items. The quality of papers was commended by the committee which allowed for good, probing questions.

Mercy Jeyasingham
Chair Patient Safety and Engagement Committee
Non-Executive Director MHRA
August 2023

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

19 September 2023

Title	**What assurance can be provided following the meeting of ODRC on 10th July and 28th July 2023**
Board Sponsor	Amanda Calvert
Purpose of Paper	Assurance

What assurance can be provided from the meeting of the Organisational Development and Remuneration Committee?

1. Introduction

1.1 The Organisation Development and Remuneration Committee (ODRC) met on 10th July 2023 with the following objectives:

- To review the progress that has been made in delivery of the RMS programme
- To review the Executive Team Remuneration

1.2 The Organisation Development and Remuneration Committee (ODRC) met on 28th July 2023 with the following objectives:

- Review the progress that has been made on the development leadership, values and culture across the Agency.
- Review and discuss feedback from the leadership team and agree the forward workplan for 2023/24

2. Delivery of RMS Programme

2.1 The committee reviewed the paper and presentation that was made to the Agency Board meeting in July 2023. It was noted that a new SRO had been appointed and there were challenges in delivering the current Minimum Viable Product.

2.2 Several suggestions were discussed that could ensure that this programme does not slip further. The importance of simplifying processes and giving priority to delivery of the MVP were reinforced.

2.3 The delivery team were encouraged to discuss options with Health Canada who are undertaking a similar programme of work.

3. Executive Remuneration

3.1. The ODRC held a confidential discussion on executive remuneration. The results of the discussion will be fed back to HR to take forward.

4. Progress on Leadership, Culture and Values

4.1. The chair of ODRC attended the One Agency Leadership Group in person on 25th July to meet with members of the team in person, learn more about the challenges and successes that members of the team were facing and to share some of their leadership insights and the work done by ODRC. There was opportunity to work together in small teams to share and develop commitments that can help develop the culture across the Agency.

4.2. It was encouraging that there are some improvements being seen in the culture and pulse survey of staff feedback which focused on culture, engagement and “pulse”.

The “pulse” questions showed improvement in all areas except clarity of future vision from senior leaders and there was an improved engagement index score of 62% against a benchmark of 58%.

4.3. Whilst there are pockets of progress in some teams and signs of improvement in organisational culture, the results are still below the civil service average. The two main areas of concern remain effective working across boundaries and managing workloads.

4.4. The committee welcomed the more granular team approach being developed by each OALG leader to run facilitated workshops with local teams to develop their “to-be” culture. In addition, the Culture Action Plan will be aligned to the Corporate Plan and cascaded through the organisation to everyone’s individual targets.

4.5. It was encouraging to see that 75% of staff reported in the survey that their manager had been supportive in helping staff members to adapt to changes within the Agency.

5. Leadership Development and People Plan

5.1. The people strategy 2023-2026 was published in July 2023 and is fully aligned to the corporate plan objective “an agency where people flourish alongside a responsive customer service culture”.

5.2. The committee welcomed the 5 themes of the plan and the partnership approach outlining what people can expect from the Agency and what the Agency expects from them.

5.3. There was discussion on what the ODRC and the Board need to do to support the delivery of the strategy. It was agreed that we all need to demonstrate the leadership behaviours and set the tone in everything that we do which can be done through telling stories that resonate and translate the priorities into actions, holding leaders to account, myth-busting and fact checking.

5.4. Workload and a long-hours culture continue to be major issues for many staff members.

5.5. It was discussed how leaders can make time to streamline ways of working within their teams to address these more fundamental issues. Delivery of RMS will be key as will addressing the backlogs and putting in place more sustainable risk-based approaches to licence and clinical trials applications.

5.6. HR have developed some great tools for managers to use including the culture action plan and behaviours framework which can help to address some of these challenges.

5.7. There are pockets of good practice where some of the challenges have been successfully addressed and some examples were discussed. The committee encouraged these approaches to be shared across different teams.

5.8. The importance of the corporate plan and how objectives are cascaded down through teams' objectives through to individuals performance targets was re-iterated and the committee were assured that this was happening.

6. Concluding Remarks

6.1. The July ODRC meetings focused primarily on the progress being made around people development, leadership and culture with the board discussing in detail the progress of the RMS programme. Whilst not directly a "people objective", the delivery of the RMS programme remains a key factor to achieve the corporate plan strategic priority 4; "An Agency where people flourish alongside a responsive customer service culture".

6.2. The ODRC chair joined the July OALG meeting and there was great opportunity share the priorities and work of ODRC, meet members of the team in person and work together to develop ways forward for everyone to improve their own leadership effectiveness and lead by example.

6.3. The board can be assured that there is a comprehensive people strategy in place that is aligned to the corporate plan. Whilst the Executive Committee are responsible for the delivery and implementation of the strategy ODRC will continue to monitor progress, act as a critical friend and undertake deep dives into different strands over the strategy starting with the "value diversity and promote well-being and inclusion" at the September meeting.

6.4. The committee are pleased to see the investment that has been made in leadership development over the past 12-18 months. HR have developed a comprehensive set of tools for leaders to use including the culture action plan, a refreshed behaviours framework and leadership training programmes which are all building capability. Whilst this is enabling leaders to be more confident in their roles, data collected in surveys is less positive, although individual line manager relationship with staff continues to be positive. Progress varies from team to team and it is encouraging to see that there are pockets of significant progress.

6.5. There has been an unprecedented level of change in the organisation over the past 18 months. For example, with the exception of the CEO, there is now a completely different Executive Committee and this has inevitably led to a feeling of instability for some staff. However, there are now signs that the Agency is turning a corner, especially with key leadership roles now being filled, new talent making a difference to performance, a greater focus on patients and a degree stability in the organisation allowing people to build confidence in their new roles.

6.6. There are still some areas that are under resourced leading to a long hours and stress on individuals. This is changing as posts are filled and new ways of working get established.

6.7. Additional resources have been brought in to address the backlogs in clinical trials and within HQA. Whilst the Agency generally responds well to crises, these work patterns cannot be sustained for the long term. Learning the lessons from these latest crises will be key to establishing more sustainable ways of working to deliver the corporate plan objectives.

6.8. The delivery of the people strategy will be key to both the well-being and development of staff members and is a key enabler to delivering the corporate plan. Strengthening the HR leadership with the appointment of a chief people officer is an important appointment and will strengthen the HR capability to support leaders in delivering the people plan objectives across their teams.

6.9. Leading by example and communication that resonates with staff members remains extremely important and this is something that every board member can do in all their interactions.

Amanda Calvert
Chair of Organisational Development and Remuneration Committee
August 2023