Medicines & Healthcare products Regulatory Agency

AGENDA FOR BOARD MEETING HELD IN PUBLIC

2:00 pm – 4:30 pm on Tuesday 20 September 2022

Chair: Stephen Lightfoot

	AGENDA ITEM	**PURPOSE**	**PRESENTER**
2:00	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		
2:15	4. What are the most important activities and priorities from the CEO's point of view?	Context	June Raine
2:35	5. How much of the MHRA Delivery Plan was delivered in the first quarter of 2022/23 and are there any risks to its completion by 31 March 2023?	Assurance	John Taylor
2:55	6. What was the operational performance of the MHRA in the first quarter of 2022/23?	Assurance	Marc Bailey Laura Squire Alison Cave John Taylor
	PATIENT SAFETY		
3:20	7. How many of the key MHRA deliverables have been implemented since the Cumberlege Review was published 2 years ago and what difference have they made to patients?	Assurance	Alison Cave
3:40	8. What assurance can be provided by the Patient Safety and Engagement Committee?	Assurance	Mercy Jeyasingham

	DYNAMIC ORGANISATION		
3:55	9. What assurance can be provided by the Organisational Development and Remuneration Committee?	Assurance	Mandy Calvert
	EXTERNAL PERSPECTIVE		
4:10	10. What questions do members of the public have about the items on this Board Meeting Agenda?	Public Engagement	Chair
4:30	CLOSE OF MEETING	-	Chair

MHRA Board Declarations of Interest – September 2022

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
Stephen Lightfoot Chair of Board	NHS Sussex Integrated Care Board	Chair	Yes	Yes
	Sussex Community NHS Foundation Trust	Deputy Chair and Non-Executive Director	Yes	No
	Sussex Primary Care Limited	Chair and Director	No	No
	Gainsborough Property Development UK Limited	Director	No	No
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
	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

Name and MHRA Role	Name of Other Company or Organisation	Nature of interest	Paid	Current
Amanda Calvert Non-Executive Director	Astrazeneca	Ex-employee shareholder Immediate family member	No	Yes
	Quince Consultancy Ltd	Provides consultancy services including companies in the healthcare sector.	Yes	Yes
	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
	The Guinness Partnership Limited – Housing Association	Non-executive Director, member of Audit Committee and Chair of Health and Safety Committee	Yes	Yes
Dr Alison Cave Chief Safety Officer	None	N/A	N/A	N/A
Professor Graham Cooke Non-Executive Director and Deputy Chair	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
	NIHR	NIHR Research Professor	Yes	Yes
Dr Paul Goldsmith Non-Executive Director	Closed Loop Medicine Ltd	Shareholder, director & employee; ILAP applicant and user of CPRD	Yes	Yes
	Summit Inc	Shareholder	No	Yes
	Ieso Digital Health	Shareholder	No	Yes
	MDU Ltd	Director	Yes	Yes
	MDU Investments Ltd	Director	Yes	Yes
	NHS	Consultant Neurologist	Yes	Yes
	NHS	Clinical Senate Member	No	Yes
	Big Tent Foundation	Trustee	No	Yes
	Radix Group Limited	Trustee	No	Yes
	Sleepstation	Co-founder of original programme, 2012-2014	No	No
Claire Harrison Chief Technology Officer	None	N/A	N/A	N/A

Name and MHRA Role	Name of Other Company or Organisation	Nature of interest	Paid	Current
Haider Husain Associate 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 Ward Muslim Memorial Trust	Trustee	No	Yes
	Microsoft Corp	Shareholder	Yes	Yes
	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	Royal College of Podiatry	Consultancy	Yes	No
	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
Laura Squire OBE Chief Healthcare Quality & Access Officer	None	N/A	N/A	N/A
John Taylor Interim Chief Finance Officer	None	N/A	N/A	N/A

Name and MHRA Role	Name of Other Company or Organisation	Nature of interest	Paid	Current
Michael Whitehouse OBE Non-Executive Director	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	Yes
	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 21st June 2022

(13:30 – 16:00)

by Zoom Webinar

Present:

The Board

Stephen Lightfoot	Chair
Dame June Raine DBE	Chief Executive
Dr Marc Bailey	Chief Science, Research and Innovation Officer
Dr Junaid Bajwa	Non-Executive Director
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 Technology Officer
Haider Husain	Associate Non-Executive Director
Mercy Jeyasingham MBE	Non-Executive Director
Dr Laura Squire OBE	Chief Healthcare Quality and Access Officer
Dr Glenn Wells	Chief Partnerships Officer
Michael Whitehouse OBE	Non-Executive Director

Others in attendance

Carly McGurry	Director of Governance, MHRA
Natalie Richards	Head of the Executive Office, MHRA
Kathryn Glover	Deputy Director, Medicines Regulation and Prescribing, DHSC

INTRODUCTION

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

1.1 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 Raj Long, Non-Executive Director; Rachel Bosworth, Director of Communications; 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 for all MHRA Board members. Junaid Bajwa declared that he has been appointed to the Board of DIA Global; Haider Husain declared that he has been appointed to the Board of the Buckinghamshire, Oxfordshire and Berkshire West NHS Integrated Care Board; and Mercy Jeyasingham declared that she has been appointed to the South West London NHS Integrated Care Board. The Chair noted the new declarations and was satisfied that there were no conflicts of interest preventing any of the NEDs 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.

3.2 With regards to the action on complaints which are escalated to the parliamentary ombudsman; an action was taken to provide a report on stage 1 and 2 complaints to the ARAC for scrutiny.

Action 83: A report on stage 1 and 2 complaints will be considered by the ARAC
Carly McGurry / Michael Whitehouse

AGENCY PERFORMANCE

Item 4: How much of the MHRA Delivery Plan was delivered in the first year of 2021/22?

4.1 The Board considered a report on the how much of the MHRA Delivery Plan was delivered in the first year of 2021/22. The Board noted that the Executive Committee has concluded that overall, a huge amount has been implemented and we are on track to achieve the Delivery Plan's ambitions. Workload pressures have evolved over the year and are still live, including in areas where licence applications have been higher than anticipated. This has impacted capacity for some longer-term strategic deliverables, especially in relation to the delivery of technology projects. Out of a total of 58 specific deliverables there are 15 which now have revised due dates. These deliverables will receive extra focus this year.

4.2 The Board noted the report and conveyed thanks for all the work that has been undertaken in the Agency to ensure delivery. The Board provided further comments regarding extension of the valproate registry and increasing awareness of healthcare professionals; eliminating siloes across the agency; continuing technology platform improvements; progression of SafetyConnect; and capitalising on opportunities outside of Europe. The Board noted the report for assurance.

Item 5: What Assurance can be provided by the Audit and Risk Assurance Committee?

5.1 The Board considered the assurance report from the Audit and Risk Assurance Committee (ARAC). The ARAC had considered an update from the Finance Team and External Audit on their progress in finalising and auditing the MHRA's financial statements and Annual Report for 2021-22; the latest draft of the Agency's annual governance statement; and Internal Audit's most recent report on corporate governance. The ARAC also met on 21st June to review the audited Financial Statements and receive the National Audit Office report; an oral update on this meeting was provided to the Board. The Board noted the report for assurance.

Item 6: What were the financial results of the MHRA in 2021/22?

6.1 The Board reviewed the MHRA financial performance in 2021/22 as set out in the draft Annual Report and Accounts. The Board noted the Agency's financial performance and outturn for the last financial year and considered the implications for the current financial year, and provided comments relating to fee increases, change in trading fund status, and the transformation. The Board noted that this has been a challenging year.

Item 7: How will the performance and governance of the MHRA be reflected in the 2021/22 Annual Report?

7.1 The Board considered the draft report of the MHRA 2021-2022 Annual Report and Accounts. It was noted that the draft report has been reviewed by the Sponsorship Team at the Department of Health and Social Care (DHSC), ARAC, and by National Audit Office (NAO) auditors, who have provided guidance to finalise the narrative, key messaging and structure. The ARAC will review the report, seek assurance from the Agency and its auditors and, if appropriate, provide a recommendation for the Chief Executive, as Accounting Officer, to sign off the report. The Accounting Officer will additionally receive assurance from Chief Officers, through signed Annual Assurance Statements, that significant areas of internal controls have been followed for their areas during the financial year.

7.2 The Board noted that a 'lessons learned' exercise will be undertaken when the report has been finalised. The Board were content with the report and an action was taken for the Chair of the ARAC to approve the accounts on the behalf of the Board provided that there are no material changes from the draft accounts reviewed by the Board.

Action 84: The Board approved the content of the Annual Report. The Chair of the ARAC will scrutinise and approve the annual accounts on behalf of the Board.
Michael Whitehouse

Item 8: What are the most important current activities and priorities from the CEO's point of view

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

(i) Scientific Research and Innovation – including latest updates on establishing Yellow Card Biobank; the CPRD SPRINT service; global polio eradication; and the Coalition for Epidemic Preparedness Innovations on SARS-COV-2;

(ii) Healthcare Access – including updates on the first approval through the ACCESS consortium; the Innovative Licensing and Access Pathway; Hormone Replacement Therapy supply; vaccines and therapeutics for monkeypox; vaccine studies based on immuno-bridging; and quality standards for Advanced Therapy Medicinal Products; and revision of medical devices regulations;

(iii) Partnerships National and International – including updates on the Agency's membership of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; membership of the International Medical Device Regulators Forum; and the ACCESS Consortium Clinical Trials Working Group;

(iv) Patient Safety – including updates on Yellow Card enhancements – the SafetyConnect programme; a risk of leakage from an insulin pump; and the outcome of a prosecution of ITH Pharma;

(v) Patient Involvement – including updates on the valproate risk minimisation review; and product information for antidepressant medicines;

(vi) Dynamic Organisation – including updates on the Agency transformation programme; and the Health and Safety Annual Review; and

(vii) Financial Sustainability – including updates on the Agency Fees Review; and the Statutory Accounts.

8.2 The Board thanked Dr Raine for her report and provided comments relating to working with other regulators globally to align work towards more consistent and aligned regulations to the benefit of patients; the CPRD SPRINT service; the alignment of regulatory approvals with health technology assessments and implementation of NHS guidance; the oral polio vaccine; how research at the MHRA is able to benefit public health internationally; learning lessons from drug authorisations through Project Orbis to apply to future ways of working; publication of assessment reports; and communications. The Board noted Dr Raine's report for context.

GOVERNANCE

Item 9: What are the key requirements of the MHRA in the proposed new Framework Agreement with DHSC?

9.1 The Board considered a paper describing how the Framework Agreement between the Agency and the DHSC has been updated following a series of substantial changes to the Agency's operations. Although the new Agreement brings the requirements for both partners up to current expectations, the fundamental principles relating to the Agency's independence and the accountabilities of all actors remain similar. The Board endorsed the updates to the Framework Agreement.

PATIENT SAFETY

Item 10: What are the key priorities in the MHRA Enforcement Strategy and how does this help keep patients safe?

10.1 The Board considered a paper describing the key priorities in the MHRA Enforcement Strategy and how this helps keep patients safe. The structure and operating model for criminal enforcement in the MHRA are undergoing a substantial refresh as part of the agency's transformation programme. The design of the new Criminal Enforcement Unit (CEU) strengthens and refocuses existing capabilities in this area, brings on-stream new capabilities, and bakes-in innovation and disruptive thinking. Its revised operating model and risk-led prioritisation presents an opportunity to bring about a step-change reduction in the criminal threat to the public from medicines and medical devices offending ('medicrime') over the next three years.

10.2 The Board noted how the CEU will take the first steps towards realising this strategic ambition during this this transitional year. The Board provided comments relating to purchasing medicines online as a result of difficulty accessing GP services; issues where members of the public are not aware the website they are buying medicines online is an illegal website; partnering with other organisations in the health ecosystem; meeting data needs from a digital and technology perspective to tackle medicrime; ensuring proportionate and targeted measures to gain the greatest impact; disrupting the supply chain of illegal medicines and medical devices; and greater transparency when compliance issues are identified. The Board endorsed the three-year strategic mission of the CEU.

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.

ANY OTHER BUSINESS

12.1 No items of Any Other Business were raised and the Chair closed the meeting.

ACTIONS FROM MHRA BOARD MEETING IN PUBLIC – 21 June 2022

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.	Marc Bailey	~~21/09/21~~ ~~16/11/21~~ ~~15/03/22~~ ~~17/05/22~~ 15/11/22	
43	15/06/21: A revised assurance and governance framework for the new MHRA organisation should be presented to the Board.	Carly McGurry	~~15/02/22~~ ~~17/05/22~~ ~~20/09/22~~ 21/03/23	
46	15/06/21: The Board's comments on the future development &branding of ILAP, including its potential use for medical devices, should be considered so that a definitive proposal can be presented to the Board for approval. 16/11/21: Consider if ILAP should be rebranded as an "Innovative Therapy Pathway" and conduct a pilot with a medical device through this innovative regulatory route.	Laura Squire	~~19/10/21~~ ~~16/11/21~~ ~~19/04/22~~ ~~21/06/22~~ 19/07/22	Completed
51	20/07/21: Review Balanced Scorecard metrics and targets to provide more focus on outcomes, greater links to the Delivery Plan and (especially on innovation) and assurance that resources are available to deliver priorities 21/09/21: Review the outcome measures in the Balanced Scorecard and the RAG Ratings in the quarterly Delivery Plan reports before considering if the targets are ambitious enough. 19/10/21: Continue to evolve the Balanced Scorecard metrics to include outcome measures. Update the data set for Clinical Trials in the balanced scorecard. 16/11/21: Broaden the measures to include the impact and quality of our scientific work rather than volumes. Seek input from our customers on what MHRA	John Taylor	~~19/10/21~~ ~~16/11/21~~ ~~18/01/22~~ ~~15/03/22~~ ~~21/06/22~~ 20/09/22	On agenda

	services they value for inclusion in the Balanced Scorecard. 18/01/22: A new approach for Board Reporting on operational performance, risk management and opportunity progression to be recommended to the Board.			
52	18/01/22: The Board requested a review of the cross-agency actions that have delivered a meaningful and positive difference to patient safety and risk management in the two years since the Cumberlege Review was published.	Alison Cave	~~19/07/22~~ 20/09/22	On agenda
54	20/07/21: Review the progress and impact of the short, medium and long term deliverables of the agreed Culture, Equality, Diversity and Inclusion plans	June Raine	~~18/01/22~~ ~~15/02/22~~ ~~17/05/22~~ 20/09/22	Completed through Joint PSEC & ODRC Meeting
59	21/09/21: Board assurance committees to review their combined effectiveness and hold a board discussion on this topic.	Michael Whitehouse, Mercy Jeyasingham, & Mandy Calvert	~~15/03/22~~ ~~16/08/22~~ 13/12/22	
61	19/10/21: Prioritise the national and international initiatives to accelerate the diversification of patient recruitment for clinical trials, exploring options to maintain diversification of representation (eg gender balance). Consider development of a public dashboard of metrics for trial recruitment. 18/01/22: Review feedback from public consultation on clinical trial regulations and make strategic recommendations on areas for development	Marc Bailey	~~19/04/22~~ 19/07/22	Completed
62	19/10/21: Review the Corporate Risk Register to consider whether all strategic risks to Agency outcomes are accurately captured.	Carly McGurry	~~19/04/22~~ ~~17/11/22~~ 17/01/23	
64	16/11/21: Review opportunities for more partnership working with other regulators as part of the MHRA International Strategy	Glenn Wells	~~15/02/22~~ ~~19/04/22~~ ~~20/09/22~~ 18/10/22	
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	

71	18/01/22: Using the input from the public consultation and Board discussion, develop and publish a new regulatory framework for Artificial Intelligence as a Medical Device	Laura Squire	~~21/06/22~~ ~~20/09/22~~ 21/03/22	
73	15/02/22: Develop a Green Regulatory Strategy	Laura Squire & Glenn Wells	17/01/23	
79	19/04/22: Hold a discussion on the Yellow Card Biobank at an upcoming Board meeting	Alison Cave	21/03/23	
80	19/04/22: Implement the Budget as approved by the Board for 2022/23. Ensure the deficit is balanced by end of the year.	ExCo	31/03/23	
New Actions				
83	21/06/22: A report on stage 1 and 2 complaints will be considered by the ARAC.	Carly McGurry / Michael Whitehouse	13/12/22	
84	21/06/22: The Board approved the content of the Annual Report. The Chair of the ARAC will scrutinise and approve the annual accounts on behalf of the Board.	Michael Whitehouse	19/07/22	Completed. ARAC Chair gave recommendation for CEO to sign accounts

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

20 September 2022

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

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

'TOP 10' HEADLINES

- We approved the first bivalent COVID-19 booster vaccine which targets two different coronavirus variants: the original Wuhan coronavirus and the Omicron BA.1 variant
- Our surveillance activities with the UK Health Security Agency detecting poliovirus in wastewater have expanded to identify and assess local and national transmission
- Following assessment of evidence of safety, quality and effectiveness, Novavax COVID-19 vaccine was approved for use in adolescents aged 12- to 17-years
- The Clinical Investigations and Trials team has authorised a clinical trial of an antiviral drug in patients with monkeypox, the PLATINUM trial.
- We approved a new use for nivolumab (Opdivo) to include combination treatment with platinum-based chemotherapy for non-small cell lung cancer in adults
- The new online reporting system for medical device incidents being delivered as part of the SafetyConnect programme was the subject of industry engagement sessions
- Our technical support and training for the Gates Foundation African Union Smart Safety Surveillance project has strengthened safety monitoring of COVID-19 vaccines
- As part of embedding our transformed organisation, we are moving forward with implementation of our services which are being lead from within the business areas
- One Agency Leadership Group has reviewed the results of the Pulse Survey on staff satisfaction and is developing an action plan to make MHRA a good place to work
- We have commenced our consultation on amending statutory fees to gather the views of stakeholders on proposals for cost recovery in line with Managing Public Money.

1. SCIENTIFIC RESEARCH AND INNOVATION

Polio detection in sewage samples

1.1 Scientists at the MHRA have identified type 2 vaccine-derived poliovirus in sequential sewage samples from London as part of our role as a WHO Global Specialised Laboratory for Polio. The prevalence, distribution, and continued evolution of type 2 poliovirus isolates from wastewater samples indicates local transmission. This represents the first evidence of poliovirus natural transmission in the UK since 1984 and has generated broad public, scientific and medical interest. An immediate public health response has been implemented including enhanced surveillance and a vaccination campaign with inactivated poliovirus vaccine. Methods to track the spread and evolution of the virus facilitate widespread adoption of polio environmental surveillance in Europe and worldwide. We will continue working with UK Health Security Agency to expand environmental surveillance activities to assess if the virus has spread to other areas of the country.

Vaccines and therapeutics for Monkeypox

1.2 The Clinical Investigations and Trials team has authorised a clinical trial of an antiviral drug in patients with monkeypox. The PLATINUM trial, sponsored by Oxford University, will evaluate whether a two-week course of tecovirimat increases the rate of resolution of monkeypox skin and mucosal lesions, and/or increases the rate of viral clearance. PLATINUM will use a remote design and aims to recruit 500 participants with confirmed monkeypox.

1.3 In response to the monkeypox outbreak which has now reached over 70 countries globally and over 15,000 confirmed cases, the Global Diseases group in the Vaccines team (Scientific Research and Innovation - R&D) has signed a service order with the Coalition for Epidemic Preparedness Innovations (CEPI) for the development of research reagents for antibodies to monkeypox. These materials will be critical for the development and harmonization of serological assays for monkeypox to support research, vaccines and therapeutics evaluation and sero-surveillance worldwide.

Influenza vaccine requirements

1.4 On 21st and 22nd July 2022 we hosted the 34th meeting between World Health Organisation (WHO) Essential Regulatory Laboratories, Collaborating Centres and influenza vaccine manufacturers in London. The participants discussed influenza surveillance and requirements affecting future vaccine manufacture ahead of the autumn WHO influenza vaccine composition meeting, at which recommendations for the composition of vaccines for the southern hemisphere winter will be made.

Control Testing

1.5 Over 340 batches of vaccines and blood products were independently quality- assessed and certified. This included a new bivalent COVID-19 vaccine, vaccines for the year-round UK childhood vaccination programme and the 2022/23 influenza season. The team also established a new quality control assay for COVID-19 vaccine and tested 473 plasma pools that are used to manufacture blood products to confirm that they are free from contaminating Human Immunodeficiency Virus, Parvovirus B19 and Hepatitis A, B, C and E viruses.

UK Stem Cell Bank

1.6 In September 2022, the UK Stem Cell Bank (UKSCB) held a successful second workshop entitled “Facilitating clinical translation within the cell therapies community”, building on the success of its first workshop. This important second workshop brought together leaders from across academia, the NHS, regulation, and industry to explore the obstacles to the development of cell therapies in the UK. The UKSCB is committed to supporting the UK cell therapy manufacturing and research communities to realise the potential of government and industry investment in this innovative field.

Innovation Accelerator

1.7 In July 2022 we launched the webpage for the Innovation Accelerator following consultation with stakeholders about how the new service will support innovators in order to help them to navigate MHRA sources of support and to optimise their engagement with the regulatory framework. The webpage includes signposting to a refreshed Innovation Office enquiry page, a horizon scanning case study on Point of Care Manufacturing and the Innovative Licensing and Access Pathway (ILAP).

2. HEALTHCARE ACCESS

COVID-19 Booster Vaccines

2.1 The MHRA had another world first in August, approving the Moderna bivalent COVID-19 vaccine. This vaccine targets two coronavirus variants, hence designated as a "bivalent" vaccine: the original Wuhan virus from 2020 and the Omicron variant. The decision to grant approval was endorsed by the government's independent expert scientific advisory body, the Commission on Human Medicines (CHM), after a careful review of the evidence of safety, quality and efficacy. Our assessment, undertaken via a 'rolling review', was conducted in the shortest time possible. The second bivalent COVID-19 vaccine, from Pfizer-BioNTech, was approved on 3 September 2022. This decision was endorsed by the CHM, after a careful review of the evidence and taking into account the EU approval on 1 September.

Project Orbis

2.2 We are now a full participant in Project Orbis, a programme to accelerate access to new cancer medicines coordinated by the US Food and Drug Administration (FDA). In August a new use was approved (a variation) for nivolumab (Opdivo) to include combination treatment with platinum-based chemotherapy for the neoadjuvant treatment of resectable tumours (equal to or more than 4 cm or node positive) non-small cell lung cancer in adults.

Smoking cessation

2.3 We are working with Department of Health and Social Care (DHSC) on plans for the "Stoptober" campaign to ensure that material is compatible with the status of e-cigarettes which have not been licenced as medicines and consistent with medicines advertising rules where appropriate. This is part of the 'Smoke Free 2030' government initiative. In parallel we have provided advice to companies wishing to apply for marketing authorisations for the indication of supporting smoking cessation.

2.4 In collaboration with Action on Smoking and Health, we have supported development of a local authority briefing on youth vaping. This is designed for public health officials and trading standards officers, and contains useful information for councillors, schools, parents and retailers. This supports a report commissioned by Public Health England to summarise evidence on vaping products to inform policies and regulations.

First designation of new UK Approved Body

2.5 In August we designated a new UK Approved Body for medical devices, DEKRA Certification UK Ltd, after a thorough assessment of their systems, processes and technical competence. This is the first designation decision we have taken as a sovereign regulator and is an important first step in increasing capacity in the UK Approved Body system. UK Approved Bodies are responsible for undertaking conformity assessment of medical devices and in vitro diagnostics and play a key role in the delivery of the UKCA (UK Conformity Assessment) mark and establishing our future regulatory regime.

Remote and hybrid inspections

2.6 Progress continues with the development of remote and hybrid inspection approaches. This work assists the delivery of one of the prioritised service transformations within the agency. The use of technology supports the goal to enhance the use of data to support decision making and increase efficiencies during inspections. Following further trials of video technology for remote inspections a specification is under development to provide a solution for the delivery of facility tours (where practical) during remote and hybrid inspections. Planning is also underway to trial a fully hybrid overseas inspection of Bioequivalence and Biosimilar clinical trials. The inspection is planned for October and will involve bioanalytical data being inspected remotely using agency held software, before travelling to overseas to complete the inspection at the clinical and bioanalytical facilities.

Recognition of Good Manufacturing Practice inspections

2.7 As of 1 September 2022, we have agreed with Health Canada and the Veterinary Medicines Directorate to expand the existing approach of recognising Good Manufacturing Practice inspection results to include inspections that are conducted in countries outside of the respective Parties' territories for human and veterinary finished products. Such initiatives remove duplication of effort for sites of common interest and allow for re-deployment of inspector resource.

3. PARTNERSHIPS NATIONAL AND INTERNATIONAL

Access to medicines in Northern Ireland

3.1 We continue to support DHSC and Department of Health Northern Ireland (NI) to implement the Northern Ireland MHRA Authorised Route (NIMAR) list of medicines. Recently we clarified the regulations around advertising in NI for medicines placed on the NIMAR list. The position remains that Marketing Authorisation Holders should manage the supply of NIMAR products in a similar manner to medicines with a valid marketing authorisation for NI in accordance with the specific rules that apply to NIMAR. However, as NIMAR listed medicines hold a GB licence, they should only be advertised (i.e. actively promoted) in England, Scotland, and Wales. This does not preclude legitimate interactions and communications necessary to maintain medicines supply.

4. PATIENT SAFETY

Yellow Card Scheme enhancements

4.1 Several enhancements have now been made to the Yellow Card scheme 'platform', one of which includes the ability to ask tailored questions to reporters based on the information they provide. This functionality will allow us to collect specific additional information about a suspected adverse drug reaction (ADR) at the point of reporting which will ensure we can rapidly assess the data and reduce the need to send follow-up requests. In early August, we benefitted from this technology by introducing conditional questions that we now ask for those reporting suspected ADRs associated with monkeypox vaccines. Specifically, we now ask reporters whether the vaccine was given pre or post exposure, and follow-up in detail if the suspected reaction is myocarditis. The additional information supports signal assessment, and we will roll out this new technology further to benefit signal detection more widely.

SafetyConnect programme engagement

4.2 In August 2022 we organised industry engagement sessions to introduce the new online reporting system for incidents associated with medical devices being delivered as part of the SafetyConnect programme. The webinars covered changes to reporting of vigilance incidents for medical devices and what device manufacturers and those responsible for device vigilance activities need to do to prepare for using the new system. The two webinars were very well attended, with a total of 642 attendees. A recording of the webinars will be published in September along with a Q&A document and details of future workshops.

Risks of nebuliser use in asthma

4.3 Our August Drug Safety Update (DSU) publication provided advice on the risks of nebuliser use for asthma rescue medication delivery in children and adolescents. Nebuliser use has the potential to mask deterioration of asthma, which may delay seeking medical help and could result in a fatal outcome. The publication followed significant stakeholder engagement work to ensure that the messages in the DSU article would be understood by the relevant target audiences. We have subsequently received positive feedback from clinical groups on our messaging and its potential to save lives.

Mexiletine hydrochloride recall

4.4 A National Patient Safety Alert was issued to support the recall of three batches of Mexiletine hydrochloride hard capsules by the manufacturer, Clinigen Healthcare Ltd. This was due to a manufacturing defect leading to a potential risk of underdose or overdose. The company indicated that no alternative batches of Mexiletine hydrochloride 50mg, 100mg or 200mg hard capsules will be available until later in the year, so recall of affected batches from patients should only be considered where alternative products are available. We gave clear advice that patients should not stop treatment without consulting their relevant healthcare professional. The risks of suddenly stopping medication for ventricular arrhythmias are higher than the potential risk presented by too much or too little of the active ingredient in the capsule. For more information, please see the National Patient Safety Alert page.

African Union Smart Safety Surveillance project

4.5 Our technical and training support for the African Union Smart Safety Surveillance project, developed and funded by the Bill and Melinda Gates Foundation, and led by the African Union Development Agency (AUDA-NEPAD), has helped establish a sustainable safety monitoring system for priority medical products for patients in Nigeria, Ethiopia, Ghana, and South Africa, and more recently work has begun with Kenya. To date the programme has resulted in over 30,000 suspected adverse reactions being reported for COVID-19 vaccines but no new signals have been detected, thus enabling national communication campaigns to support vaccine uptake.

Criminal Enforcement

4.6 We continue to provide a significant contribution to Operation Pangea, an international initiative coordinated by Interpol with the purpose of combatting the trade in illicit health products. This year's global week of action, which ran from 23 to 30 June, saw countries across the world joining forces to seize non-compliant medical products. In the UK, 285,000 medicines and medical devices valued at over £850,000 were seized. Forty-eight social media accounts unlawfully offering to supply medicines were shut down. We continue to work closely with international partners and Border Force to prevent unlicensed medicines and non-compliant medical devices from entering the UK, and to bring the criminals behind this illegal trade to justice. As the CEU transforms its online capabilities, discussions have been held with several external partners to establish how the unit can collaborate effectively to tackle cyber-enabled offending and deploy new and innovative online interventions.

5. DYNAMIC ORGANISATION

Regulatory Management System

5.1 We are now in the discovery phase of the Regulatory Management System initiative, which will deliver the next generation digital technology to enable our patient safety focused regulatory services as a standalone regulator. This is an exciting and challenging initiative which will impact multiple stakeholders, expand our digital services and replace legacy IT systems. Current activities during this phase include carrying out user research across a range of external and internal stakeholders to understand their high-level needs, gaining a broad understanding of the functional and technical capabilities required in the new system, understanding our data compliance needs and identifying what will be in scope for the initial minimum viable product.

Data Centre Migration

5.2 This is a significant project as it involves migrating much of MHRA's technical hardware from current data centres to new government data centres. The main benefits are reductions and efficiencies in running costs, increased security capabilities along with less dependency on external suppliers which will enable the agency to make changes faster and at a reduced cost. The project is due to be completed by the end of November 2022.

Health and Safety Inspection

5.3 The Health and Safety Executive (HSE) carried out an inspection and reviewed the management of organisational change, with particular emphasis on 'human factors', looking at how the impact of changes has been considered for biosafety critical functions. The HSE report identified areas for strengthening such as full identification of all safety critical roles so that the impact of changes are fully risk assessed, ensuring that new structures and reporting lines do not develop new risks. The Agency Health and Safety team will address the findings by 30th November. The HSE has also investigated two incidents that were reportable under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 (RIDDOR), issuing two improvement notices. An action plan is in place to address the issues.

6. FINANCIAL SUSTAINABILITY

Fees consultation

6.1 We have commenced consultation to gather the views of stakeholders on proposals to increase our statutory fees. The MHRA's statutory fees have not been increased since the financial year 2016/17 for medicines and financial year 2017/18 for medical devices. Achieving full cost recovery in line with HM Treasury's principles on Managing Public Money will ensure the MHRA is resourced to provide the high-quality service that patients, the public and industry want and expect. The proposed adjustments will ensure we are financially sustainable in the long-term, enabling delivery of a responsive, innovative and efficient regulatory service that protects and improves patient and public health.

7. AGENCY PRIORITIES

7.1 In summary, the current key priorities for the Agency are:

i. Ensuring recruitment to key specialist posts in the transformed organisation is completed while enabling the One Agency Leadership Group to develop its full leadership role

ii. Progressing a major review optimising the Agency's services for all our stakeholders including patients and the public, with a focus on innovation in regulatory approaches

iii. Engaging with stakeholders to develop the future medical devices regulations and ensuring transitionary provisions support the introduction of the new regulatory system

iv. Continuing pandemic preparedness work as our priority on access to therapeutics, vaccines, and diagnostics for COVID-19 reverts to normal rather than emergency planning

v. Continuing to develop our national and international partnerships to enable safe access and continue to make UK an attractive environment to develop and deploy healthcare products, for the benefit of patients and healthcare systems.

Dr June Raine, CEO
September 2022

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

20 September 2022

Title	How much of the MHRA Delivery Plan was delivered in the first quarter of 2022/23 and are there any risks to its completion by 31 March 2023?
Board Sponsor	John Taylor
Purpose of Paper	Assurance

How much of the MHRA Delivery Plan was delivered in the first quarter of 2022/23 and are there any risks to its completion by 31 March 2023?

1. Executive Summary

1.1 This is the report on Delivery Plan implementation for the first quarter (Q1; April – June 2022) of the plan's second year. The Executive Committee (ExCo) has concluded that we are in a good position overall, with some notable items completed this quarter. Handling plans for the off-track items have been scrutinised and agreed mitigations are underway. The deliverables for the refreshed Delivery Plan are now included. Almost everything remains due within the plan's lifetime with some (previously agreed) exceptions where elements of work will roll over into future years. It is also worth noting that Q4 is now very loaded.

1.2 The Board is asked to note this report and provide comments on the assurance given.

2. Introduction

2.1 The ExCo manages the Agency's performance processes and oversees the implementation of the 2-year Delivery Plan. Each quarter, the leads for the items in the plan provide a Red, Amber, Green (RAG) assessment, based on their confidence in successful delivery, and an action plan for anything going off-track. Completed items are marked Blue. This information is scrutinised by the Delivery and Performance Committee (DPC), who then advise the ExCo and actions to help further manage performance are agreed, if needed. An overview is sent to the Board for assurance.

2.2 Operational metrics will accompany reports in future to provide better context on delivery and performance and improve the diagnosis of issues and prioritisation. These metrics, contained in the Balanced Scorecard, are also scheduled for discussion at the Board in September and will accompany these reports as soon as they are available.

2.3 A summary of discussions is provided here. Table 1 (page 4) is a summary of this quarter's completed items. Table 2 (pages 5-7) is an overview of the status of every item in the plan. Table 3 (pages 8-9) is a summary of the off-track deliverables and their agreed handling plans. Table 4 (page 10) shows items that the ExCo have agreed to revise for the refreshed Delivery Plan to ensure they align with the current agreed position.

3. Proposal

3.1 The DPC and the ExCo have reviewed the Q1 report and are content overall. The Q1 successes are shown in table 1 and include: delivery of our **leadership development plan** Q1 actions; a successful pilot of **patient "listening sessions**" for both pelvic mesh and sodium valproate; approval of the Technology Delivery Roadmap, which includes our **plan to overhaul legacy systems;** roll-out of a new **workforce planning approach;** the completion of work **supporting staff as we move to the One Agency structure**; and the shortlisting of areas to take forward in this year's tranche of **legislative reform.** There were 4 items due in Q1 that slipped into Q2 (i.e., Delivery Plan refresh; report on the teratogen review; COVID-19 flexibilities proposal; and culture action plan). The culture action plan was since published on the 10 August and an update will be provided on these in the Q2 report.

3.2 The risks to completion highlighted with off-track items in table 3 have been reviewed. These deliverables have mitigations in-hand or pending agreement. They are mostly showing slippage and so do not look to currently pose significant risks to overall delivery by March 2023. Almost everything remains due within the Delivery Plan's lifetime with some agreed exceptions where elements of work are planned to roll over into next year. It is worth noting that we now have a significant increase in the number of deliverables that will be complete in Q4 of this year.

3.3 The overview of the status of the whole plan in table 2 shows the deliverables of the refreshed Delivery Plan that were shared with the Board previously. There has been some additional amends to some deliverables, shown in table 4 on page 10, as the reporting process flushed out a few items that were already late, had been superseded by more recent developments, or where revised timings had already been agreed internally. Given the refreshed plan will be public and needs to be feasible and accurate, the ExCo agreed to incorporate these changes. Some final elements of fine tuning are still underway that will bring several items back on track and these changes will all be reflected in the Q2 report.

3.4 Work has begun developing a new 3-year Corporate Plan as required by the Framework Agreement agreed with DHSC. Groups are preparing for a dedicated One Agency Leadership Group workshop in October, the output of which will provide material for the new plan. The Board will receive an update for discussion in due course.

4. Recommendation

4.1 The Executive Committee has reviewed the status of the Delivery Plan in the first quarter of the second year, it has noted the progress made and scrutinised the handling plans for off-track items. The Board is asked to note this report and provide comments on the assurance given.

John Taylor

September 2022

THIS QUARTER'S COMPLETED ITEMS (BLUE)	
Deliverable	**Comment**
Finalise plan to **overhaul costly legacy systems** by end Q1	The Technology Delivery Roadmap, which covers our plan to overhaul legacy systems, was updated and agreed in June 2022. Major legacy systems have been mapped to projects on the roadmap (planned and in-flight) until FY2025/26 and are subject to future budget being secured. The plan will be updated quarterly as projects move through their delivery lifecycles. Significant savings delivery already completed in Q4, 2021/22. Further savings for FY2022/23 are planned as per Transformation business case profile and these have been built into the Agency's budgets.
Identify key **policy areas for second tranche of legislative** change and define timescales for laying SIs over 2022/23 and beyond by end Q1	We have now identified a shortlist of areas for the next phase of legislative reform. We will update this item to reflect the agreed list and timescales in the Q2 report.
Pilot **patient "listening sessions**" approach as a better method of seeking patient input, and define its role going forward by end Q1	This approach has been successfully tested and is now part of our toolkit. We piloted our first session in April on pelvic mesh and a further session was held on valproate. We are planning more sessions in Q3 and Q4.
Review workforce in Q1, identify follow-up actions to ensure we **embed workforce planning** by Q4	Our new proposed workforce planning approach and toolkit was approved by the People and Culture Committee in Q1 and was rolled out in July (moved from June to allow for production of necessary baseline data from Fusion once new structures go live on Fusion on 4/7/22). Wider work embedding this capability continues.
Continued delivery of **leadership development plan** from Q1 to Q4 to support Delivery Plan implementation	Actions for Q1 have been delivered: a continued rollout of bespoke leadership training for L2s, coaching for L1 and L2 leaders, (individually and in teams) and the reverse mentoring launch. Delivery will continue in Q2, plus socialising of Leadership in Action attributes.
Deliver HR support and guidance to **staff during restructuring** throughout Q1-Q4, 2021/22	We have now moved to the One Agency structure. There is some residual individual/ad hoc support ongoing (e.g. to those at risk of redundancy who have yet to leave) but this is modest and "business as usual" work. There is still an external recruitment challenge to address, and this is covered under the Transformation Programme item.
Refresh **culture action plan** by end Q1 and continue driving culture change needed for new operating model	We have now published the culture action plan for all staff. The plan is organised into 9 strands with each describing the aspirational culture we want to see and listing actions to move us closer towards that. After being approved by the People and Culture Committee, there was a slight delay following a final review by ExCo.

	Deliverables due by quarter			
	Q1 (Apr – Jun) →	**Q2 (Jul – Sep) →**	**Q3 (Oct – Dec) →**	**Q4 (Jan – Mar) and beyond →**
Scientific Innovation	Nothing scheduled in the Delivery Plan, focus on core business	Pilot mechanism for joint clinical trial approval and clinical trial and licensing scientific and compliance advice via Access Consortium; agree deliverables with partners and start pilot by end Q2	(↓) Improve UK clinical trials legislation, including encouraging the inclusion of underserved populations and increasing diversity in clinical research]; lay statutory instrument by end Q3	Integrate with the Health Research Authority and NICE Research's Clinical Research Network to provide a fast-track approval for defined clinical trials; support pilot to set up phase 1 oncology trials by end Q4
		(↑) Expand pilot providing a single decision on research using a medicine and device to a wider cohort and develop combined review process by end Q2	* Publish new Regulatory Science Strategy by end Q3	Risk-based approach to batch release: guidelines drafted by end Q3; implement independent testing based on risk-based strategy by end Q4
Healthcare Access	(↓) * Identify which flexibilities introduced in response to COVID-19 are safe to embed by end Q1	* Finalise Compliance Strategy through consultation with external stakeholders by end Q2	Embed visual technology capabilities as a standard part of inspections by end Q3	(→) Deliver a set of work packages to ensure that Artificial Intelligence as a medical device is underpinned by robust evidence to enable safer innovation by end Q4
	Identify key policy areas for second tranche of legislative change and define timescales for laying SIs over 2022/23 and beyond by end Q1		Consult on a national GB scheme to replace Falsified Medicines Directive (FMD) safety features regulation; lay Statutory Instrument as per Departmental timescales; and agree position on FMD for Northern Ireland post 3-year EU derogation by end 2023	(→) * Establish new devices framework to support safe innovation and ongoing access to products: lay statutory instrument and publish guidance and best practice by phased over mid-to late-2023
				* Ensure integrated UK regulatory pathways for products that combine medicinal products and devices; consultation by end Q4
			(↓) Lay statutory instruments for remaining elements of first tranche of legislative change proposals by end Q3	Agree policy on reliance and recognition to be implemented globally by Q4
Patient Safety	(↓) * Review of teratogen use during pregnancy by end Q1, independent patient / stakeholder input in Q2, and updated guidance and action to protect public health by end Q2, if required	Upgrade observational research infrastructure to enable timely and secure delivery of research data services: map out requirements and commence implementation of new systems by end Q2	(↓) * Deliver Safety Connect to ensure enhanced signal detection process by end Q3	Deliver expanded scope of NHSX funded synthetic data research project and launch the synthetic data service by end Q4
	Make available a valproate UK-wide digital annual risk acknowledgment form alongside defining the extension of valproate registry to UK-wide by end of Q4, 2021/22 [Revised deliverable agreed given outcome of the Commission on Human Medicines' review; to be added to the Q2 report]		(↑) Launch Yellow Card Biobank project to define a sustainable business model and commence pilot set-up activities to investigate the role of genetics in the development of adverse drug reactions by end Q3	
			(↑) * Agreed policy for an enhanced devices transparency regime by end Q3, with key elements delivered over 2022/23 and 2023/24	
			Improve model of Devices Expert Advisory Committee: launch consultation by end Q3; and establish statutory committee by July 2023	

KEY: Red: deadline past or not possible; Amber: off-track; Green: on-track; Blue: complete; Trend arrows: RAG change from previous quarter (↑ improve, → same, ↓ worsen); Asterisks: items given new deadline at end of year one

	Q1 (Apr – Jun) →	Q2 (Jul – Sep) →	Q3 (Oct – Dec) →	Q4 (Jan – Mar) and beyond →
Dynamic organisation	Review and revise plan and share with Department by end Q1, as part of annual business planning *[Plan has been finalised and shared with the Department the publishing date has been deferred]*	**(↓)** * Deliver Transformation including plan for benefits realisation, and restructure implementation; operationalisation of the future operating model and re-definition and optimisation of prioritised core services by end of Q2	Nothing scheduled in the Delivery Plan, focus on core business	Nothing scheduled in the Delivery Plan, focus on core business
	Deliver HR support and guidance to staff during restructuring throughout Q1-Q4, 2021/22			
	Review workforce in Q1, identify follow-up actions to ensure we embed workforce planning by Q4			
Collaborative Partnerships	Nothing scheduled in the Delivery Plan, focus on core business	Complete main elements of rebranding to ensure consistency and raise our profile by end Q2	Nothing scheduled in the Delivery Plan, focus on core business	Develop Risk Communication Strategy to ensure more coordinated, pro-active comms by end Q4
		Launch consultation on engaging with healthcare professionals by end Q2		Deliver a Partnerships Strategy by end Q4: setting out our long-term Partnerships approach for MHRA and the impacts that Partnerships can achieve
Financial Sustainability	Finalise plan to overhaul costly legacy systems by end Q1	* Improve our ability to exchange data with partners by adopting international standards; define adoption approach by end Q2; new system full implementation by end Q1, 2023/24	* Deliver Data Strategy, including a data sharing strategy, underpinned with robust security standards and privacy by design by end Q3	**(↓)** Deliver an enhanced clinical trials service by end Q4, 2022/23
		(↑) Fully scope what self-service functionality can be delivered via the Regulatory Management System by end Q2		Reduce corporate costs by 15% by the end of 2022/23
		Develop, consult on (Q2) and implement a new fee structure from Q1, 2023/24		Reduce non-pay costs of £60m by £6m per year through procurement and contract management by the end of 2022/23
				Deliver regulatory management core system by end Q1, 2023/24 *[nb – update due in Q2 following completion of the discovery phase]*
				Support revised devices regulations, deliver the digital self-service, automation and data platforms required by end Q1, 2023/24
				(↑) * Implement organisational design, creating a new, leaner organisational structure and balancing costs by end Q4, 2023/24

KEY: Red: deadline past or not possible; Amber: off-track; Green: on-track; Blue: complete; Trend arrows: RAG change from previous quarter (↑ improve, → same, ↓ worsen); Asterisks: items given new deadline at end of year one

	Q1 (Apr – Jun) →	Q2 (Jul – Sep) →	Q3 (Oct – Dec) →	Q4 (Jan – Mar) and beyond →
1 Patient involvement	Pilot patient "listening sessions" approach as a better method of seeking patient input, and define its role going forward by end Q1	(↓) Define deliverables on PROM to better understand our regulatory action's impact on patients by end Q2; and deliver by end Q4	Ensure and support patient presence on all committees and groups to improve patient representation and contributions by end Q3	Run 2 pilot separate involvement approaches for our key patient segments by end Q4
		(↓) Define deliverables to develop our understanding of patient perceptions of benefit / risk to improve regulatory decision-making by end Q2; and deliver by end Q4	Develop a more consistent, effective approach to public consultations by end Q3	
		Deliver staff training and support via new Patient Champion Network, to improve staff understanding and ability to deliver patient engagement by end Q2	Develop involvement strategies to meet the needs of key patient segments by end Q3	
2 Equity in Healthcare	(↓) * Review of teratogen use during pregnancy by end Q1, independent patient / stakeholder input in Q2, and updated guidance and action to protect public health by end Q2, if required (also shown above)	Improve diversity and representativeness of our patient group consultative forum to improve its contribution to regulatory decision-making by end Q2	(↓) Improve UK clinical trials legislation, including encouraging the inclusion of underserved populations and increasing diversity in clinical research; lay statutory instrument by end Q3	(→) Improve devices legislation by requiring better product clinical data to increase assurance of reduced bias and appropriateness for different populations; lay SI and publish guidance and best practice phased over mid to late- 2023
			(↑) Launch Yellow Card Biobank project to define a sustainable business model and commence pilot set-up activities to investigate the role of genetics in the development of adverse drug reactions by end Q3	Develop a prototype web-based tool that can detect and correct biases due to underrepresented populations for AI applications by end Q4
				Improve our ethnicity data by using a new algorithm and better integrating patient records with our CPRD databases by end of Q4
			Define deliverables for integrating Yellow Card data with NHS healthcare records to deepen our understanding of the representativeness of our data and the impact of demographics in adverse drug reactions by end Q3	Complete review of the available evidence on pelvic mesh benefit / risks by end Q4
				Provide translated materials on how to engage with Yellow Card in the 10 most commonly spoken languages in the UK by end Q4
				Improve UK regional representativeness of our CPRD data to include at least 10% of GP practices across all UK regions by end Q4
				Review of women's health regulatory inequities by end Q4
3 Embedding innovative WoW	Refresh culture action plan by end Q1 and continue driving culture change needed for new operating model	Publish new People Strategy by end Q2 to support Delivery Plan implementation and retain status as a world-leading regulator and employer	(↓) Launch key redesigned services and supporting process and systems, including design of a refreshed quality management system, by end Q3	Implement innovative devices pathway in conjunction with innovative medicines and build foundations for collaborative approach with Access Consortium by end Q4
		* Finalise compliance strategy via consultation with external stakeholders by end Q2	Embed operation of new established medicines pathway by end Q3	
		Develop, consult on (Q2) and implement a new fee structure from Q1, 2023/24	Deliver refreshed health & safety system, including high hazard assurance monitoring, by end Q3	
	Continued delivery of leadership development plan from Q1 to Q4 to support Delivery Plan implementation	Update talent management model by end Q2 to ensure we attract, develop and retain world-class scientific and regulatory capability	Implement new inclusive hybrid working policy by end Q3 to ensure an effective working approach that balances business and staff needs	
		Engage with staff to refresh vision statement and values and behaviours framework to align with the new operating model by end Q2		

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ISSUES AND HANDLING	
Deliverable (with trend arrow)	**Mitigation planned**
(↓) * Identify which **flexibilities introduced in response to COVID-19** are safe to embed by end Q1	This was due in Q1 and it has slipped to Q2 given the impact of competing COVID-19 work demands. The team is working to catch up and a proposal is due for ExCo approval shortly (date tbc at time of writing).
(↓) * **Review of teratogen** use during pregnancy by end Q1, independent patient / stakeholder input in Q2, and updated guidance and action to protect public health by end Q2, if required	The initial review was due Q1 and it has slipped to Q2. The team have adjusted the plan for delivery and are working to submit the proposal in September Medicines for Women's Health Expert Advisory Group *(*MWHEAG) (Q2), have patient/stakeholder input in October (Q3) and draft guidance for approval at November MWHEAG (Q3). These updated timing have now been agreed at the ExCo.
(↓) * **Deliver Transformation** including plan for benefits realisation, and restructure implementation; operationalisation of the future operating model and re-definition and optimisation of prioritised core services by end Q2	EY exited the programme on 15 July, and there are ongoing capacity and capability constraints within the Agency. This has created a difficult balance between BAU activity and capacity to project manage implementation of the transformation of Services and the Operating Model. The impact of this is the delay in benefits realisation both financial and non-financial. Significant cost reductions have been realised, but are currently below plan and there is further work to do to realise these savings. The operationalisation of the Services will be impacted by the delay in the planning and roll-out of the implementation plan as well as the delays experienced in the RMS Discovery. To mitigate this, the Transformation team are working collaboratively with D&T and Core area Chief Officers to identify the pool of resource and capabilities currently available in the Agency to drive Transformation workstreams. This will enable us to refresh and validate the detailed implementation plans for services and operating model, in consideration of current resourcing constraints, with meaningful delivery timeframes and dependencies identified. This issue has been escalated at ExCo and a paper was tabled at ODRC on 2 September 2022 alongside the consideration of contractors /contingent labour to supplement the needs for change/project manager roles to enable delivery.
(↓) Deliver an **enhanced clinical trials service** by end Q4	This is due in Q4 but, as per last quarter, no funding has been secured so the work is on hold. Q4 delivery at risk (hence move from Amber to Red) as 3 full quarters are estimated for delivery.
(↓) Improve **UK clinical trials legislation**, including encouraging the inclusion of underserved populations and increasing diversity in clinical research]; lay statutory instrument by end Q3	We succeeded in getting the Government response to the consultation out on time but the Q3 deadline is looking difficult given the volume of interest. We expect to slip into Q4 given these delays.

	(↓) Lay SIs for remaining elements of **first tranche of legislative change** proposals by end Q3	Same as item above.
	(↓) Launch **key redesigned services** and supporting process and systems, including design of a refreshed underpinning quality management system, by end Q3	See Red transformation item above; mitigation actively under discussion. Implementation phase to see transfer of services work to new teams. Work ongoing to validate and/or develop detailed implementation plans and Integrate roadmaps with overall Transformation plan.
	(→) Deliver a set of work packages to ensure that **Artificial Intelligence as a medical device** is underpinned by robust evidence to enable safer innovation by end Q4	We are in the process of seeking sign-off for a roadmap of this work which will set out the programme's deliverables. A schedule of deliverables will be provided that includes estimated delivery timings, we will report against these timings going forward. This will allow recalibration and we hope to convert this back to Green for the next quarter. There is a dependency on the legislative change work and there has been disruption over the last few months from diversion of key staff to cover wider staff exists. We are now returning focus to this, recent progress includes successful interview for a Software Clinician post and our roadmap entering final clearances prior to publication.
	(→) * Establish **new devices framework** to support safe innovation and ongoing access to products: lay statutory instrument and publish guidance and best practice by mid- late-2023 [and] **(→)** Improve devices legislation by requiring better product clinical data to increase assurance of **reduced bias and appropriateness** for different populations; lay statutory instrument and publish guidance and best practice by mid- late-2023	The main challenge is the number of vacancies and the impact this has on taking work forward. We are undertaking a recruitment drive to ensure HR can advertise asap. We are also in discussion with the Office of Life Sciences to explore whether we can use one of their analysts.
	(↓) * Deliver **Safety Connect** to ensure enhanced signal detection process by end Q3	This was due to launch in Q3 but full implementation has been phased in Q4 following an agreement at Strategic Change Committee.
	(↓) Define deliverables on PROM to better understand our regulatory action's impact on patients by end Q2; and deliver by end Q4	This is a deliverable in the patient involvement strategy. There are delays expected for the initial scoping, but the final deadline is Q4.
	(↓) Define deliverables to develop our understanding of **patient perceptions of benefit / risk t**o improve regulatory decision-making by end Q2; and deliver by end Q4	This is a deliverable in the patient involvement strategy. There are delays expected for the initial scoping, but the final deadline is Q4.

AGREED REVISED DELIVERABLES FOR THE REFRESHED DELIVERY PLAN	
Amended deliverable	**Comment**
Work with others in the healthcare system to implement new, strengthened safety measures for sodium valproate by end Q3, and to continue to drive down the number of exposed pregnancies. ~~Make available a valproate UK-wide digital annual risk acknowledgment form alongside defining the extension of valproate registry to UK-wide by end of Q4, 2021/22~~	Superseded – this objective was updated as the original object was overtaken by more recent events, ie the outcome of the Commission on Human Medicines' recent safety review. The new deliverable reflects the current agreed strengthened position.
Reduce corporate costs (including technology costs) by 15% by the end of 2024/25 • ~~Reduce corporate costs by 15% by the end of 2022/23~~ • ~~Reduce non-pay costs of £60m by £6m per year through procurement and contract management by the end of 2022/23~~	Superseded - since drafted, several decisions have superseded these original deliverables (i.e., the pathfinder work and the Technology Delivery Roadmap). The new deliverable is reflects the current agreed position.
Improve UK clinical trials legislation, including encouraging the inclusion of underserved populations and increasing diversity in clinical research; lay Statutory Instrument by end ~~Q3~~ Q4	Date amended given delays caused by volume of interest in the consultations.
Lay SI for remaining elements of first tranche of legislative change proposals by end ~~Q3~~ Q4	Date amended given delays caused by volume of interest in the consultations.
* Establish new devices framework to support safe innovation and ongoing access to products: lay SI and publish guidance and best practice by mid-late-2023 ~~early 2023 and publish guidance by end Q1, 2023/24?~~	Revised deadline to reflect current agreed legislative timescales.
Identify which flexibilities introduced in response to COVID-19 are safe to embed by end ~~Q1~~ Q2	Delivery slipped updated to ensure everything in the refreshed plan is possible - see table 1.
Review of teratogen use during pregnancy by end ~~Q1~~ Q2, independent patient / stakeholder input in ~~Q2~~ Q3, and updated guidance and action to protect public health by end ~~Q2~~ Q4	Delivery slipped updated to reflect final agreed project timings, agreed at the ExCo, and ensure everything in the refreshed plan is possible - see table 1.
Deliver Safety Connect to ensure enhanced signal detection process; ~~by Q3~~ roll out from Q3, 2022/23 to end Q4	Updated to reflect new timeline for roll out, already agreed by the Strategic Change Committee.

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

20 September 2022

Title	What was the operational performance of the MHRA in the first quarter of 2022/23?
Board Sponsor	John Taylor
Purpose of Paper	Assurance

What was the operational performance of the MHRA in the first quarter of 2022/23?

Balanced Scorecard

Once metrics agreed a Balanced Scorecard pro forma will be designed.

Q1 Performance Report

1. Finance

During the first quarter of 2022/23 (Q1) the agency has seen underperformance in key income streams, such as national applications and inspections income. This has been offset by significant underspend, so the agency is covering its costs.

There is a direct relationship between low income and lower staff numbers. The Q1 budget already assumed a high vacancy rate of 13%, reducing to 8% in Q2. We exceeded these rates in Q1 with a vacancy rate of c14% by the end of June when we take contingent labour into account. We are forecasting to reduce the vacancies during the year but will remain significantly under our pay budget with the reduced staff resources putting our service delivery and income at risk.

We also have large non-pay expenditure underspends within accommodation, deprecation, and Digital & Technology (D&T). However, these are timing variances, and our expenditure is forecast to catch up with the budget by the end of the year. Overall, we are forecasting to spend all our available income and funding by the end of the year.

A target for debt levels and overdue debt is still being worked on. This will likely be a % of income or the widely used days sales outstanding. Whichever is used will need the phasing of our revenue (especially for the service fee) to be built in.

Income - £33.7m v budget of £39.0m

Expenditure - £31.6m v budget of £37.7m

Staff Costs - £19.5m v budget of £21.3m

Debt 30 to 180 days = £7,626,618, over 180 days = £5,464,499

Productivity
Data unavailable – metric being rebuilt to fit with new structure, expected completion at end of Q3

Cost: Fee ratio
Data unavailable – will need to complete activity reporting before this can be reported. It is likely this will not be capable of reporting until Q1 of next financial year.

2. People

Current proposed people metrics to be included in the Board reporting. Note these are subject to change following the HR workshop which took place on 30th August with the outputs currently being finalised, this will include decisions on targets and 'what good looks like'. To be included in the Q2 performance report.

Establishment and Recruitment

Approximately 75% of all established posts are now filled by permanent staff (L2 and L3 over 80%). To address turnover recruitment continues at pace to both vacant posts and those filled by fixed term, contingent or contractors, on a priority basis. The process from receipt of a request to advertise through to onboarding is not reflected here, but ExCo are regularly updated.

Joiners – During Q1 : 29
Leavers – During Q1: 74 voluntary leavers
FTE End of June : 1168 (budget of 1,363)
Contractor FTE – End of June : 114
Permanent FTE – End of June : 1054

Engagement

A welcome, albeit small, increase in the engagement score (Q3 was 51%) as new Agency structures begin to embed and colleagues have more clarity about their roles going forward. The Civil Service People Survey will be launched at the end of September 2022 and further inform.

Engagement Q1 – 54.12%

Culture

Culture scores are still down on Q3 levels but show a small increase since Q4, this indicates that the Agency may have turned a corner if the upward trend continues. The One Agency Leadership Group is now established and the focus on staff feedback within a small number of identified priorities is helping to progress issues of leaders' visibility and positive role modelling. The plan to develop a decision-making framework by end of Q3 should lead to an improvement in this area.

Walk the talk:
Q3 – 13%
Q4 – 6%
Q1 – 10%

Timely decision making
Q3 – 28%
Q4 – 7%
Q1 – 11%

Diversity

The BAME figure is stable since last quarter reporting. The disabled staff figure has reduced marginally since the last quarter and will continue to be impacted by the influx of new staff, with a need for further reflection ahead of the next quarter.

BAME staff G7 and above – Q1 21% (civil service 13.2%)
Disabled staff G7 and above – Q1 6.5% (civil service (12.8%)

Sickness

Sickness absence is low compared to pre-COVID lockdown and is likely to have been impacted by the work from home opportunity.

Sickness absence per FTE – Q1 1.5 days
Average leave days per FTE – Q1 5.2 days

Learning

During 2021/22 our learning offer focused heavily on two curated curricula, full of online learning resources, whose use by staff we are unable to track. This is because currently we are unable to host learning on our learning management system. We are also increasingly placing a focus on the 70:20:10 (research-based) model for learning, which involves only 10% of learning time spent on formal training programmes, the rest of the time spent doing on the job learning and learning through others. None of that 80% is reflected in these formal training figures. The figure is also likely to have been influenced by the various impacts of Covid on availability of staff and of external training opportunities. We are reviewing both how we track learning at the Agency and the metrics that we use to assess learning impact.

Training days per FTE for last 12 months – 0.61 (target 5)

Redundancy

32 of the 38 people at risk were colleagues working their notice having accepted either voluntary or compulsory redundancy, and 6 are colleagues temporarily redeployed to other roles.

Number of people at risk at end of Q1 – 38 (target 0)

3. Patients, Public & Partners

The majority of patients, public & partners metrics will come from the new reputational index we are currently developing. Additional metrics may also come from the communications and partnerships workshops, planned to take place on the 12th and 15th September.

MHRA featured in 840 articles in Q1, reflecting a 37% decline compared with the last quarter. The continued decline in COVID-19-related coverage can be attributed as the main cause. Nevertheless, COVID-19 stories continued to be a large driver behind MHRA mentions following the approval of the Valneva vaccine. Other coverage was aided by the approval of new treatments and an investigation by MHRA. COVID-19 mentions accounted for 36% of all mentions, a significant drop compared to Q4's result of 73%.

Reporting remained highly positive with 99% of articles carrying favourable sentiment. Reporting saw a peak on the 10th – 16th of April following different Covid-related stories that included the approval of the new vaccine, as well as the approval for the use of Moderna's 'Spikevax' for children aged between 6 and 11 (Mirror, Independent).

Coverage in April did not all relate to COVID-19, with national publications reported on Pregabalin, in which a study found that it "may increase risk of birth defects if taken while pregnant", and the articles mentioned that the MHRA has ruled out its use in pregnant women "unless completely necessary" (Evening Standard, Independent). Other recurring headlines involved Aquiette, a drug for an overactive bladder, that could be made available 'over the counter' for the first time. Coverage of this news included the call by MHRA for "people with the condition, as well as healthcare professionals with experience of treating it, to share their views in the reclassification consultation" (ITV News, Guardian, Independent, Belfast Telegraph).

May continued to witness Covid coverage in the form of discussion on the declined use of the AstraZeneca vaccine (Wales Online, Hull Daily Mail), but there was recurring coverage of the approval of Faricimab, an injection that reduces vision loss, for NHS patients that followed approval by the MHRA and given the green light by the National Institute for Health and Care Excellence (The Times, Daily Express, Independent). June's most prolific story was news on the detection of Polio in sewage samples collected from the London Beckton Sewage Treatment Works by the UK Health Security Agency (UKHSA) and MHRA (Independent, Mirror, Kent Online).

Total article mentions:
Q2 – 1,602
Q3 – 1,708
Q4 – 1,334
Q1 - 840

% Favourable
Q2 – 86% slightly favourable, 13% strongly favourable, 1% slightly unfavourable
Q3 – 91% slightly favourable, 9% strongly favourable
Q4 - 93% slightly favourable, 6% strongly favourable, 1% slightly unfavourable, <1% strongly unfavourable
Q1 – 93% slightly favourable, 6% strongly favourable, 1% slightly unfavourable

Overall reduced Covid-19 coverage has seen a reduction in MHRA mentions which also coincides with a reduction in our strongly favourable coverage.

4. Service Performance

4.1 Science Research and Innovation

What are we measuring?	What does this say about performance?	Why do we need to know this?	What is indicative of good performance?	Quarter 1 performance Apr-Jun 2022	Quarter 1 contextual narrative
Clinical trial and clinical investigation numbers and assessment timeframes. These will be split between early and later development. Annually, we will report where UK lies in global league tables (data obtained from ABPI report) The team measures approvals of clinical trials, not launches of trials as these are a decisions, made by the company, NHS and NIHR All Assessments are now done in partnership with the Health Research Authority as a Combined Review	Indicator of UK clinical trial and investigation research activity and agency efficiency in processing applications. Expedited assessment of Phase 1 healthy volunteer trials (HVT) provides indication of support for innovation.	If numbers of trials and/or investigations drops as an annual figure in line with the ABPI-reported data, we can investigate and target support. If assessment timelines increase or targets are not met, we can realign agency resource and priorities to improve efficiency.	Consistent and reliable review times. For CTs statutory timeframe for initial assessment is 30 days with an internal target of 14 days for Phase 1 healthy volunteer trials. For CIs the reported timeframe is for final decision within 60 days. If there is a Northern Ireland site, the target is 45 days (65 days if an external assessor is required.)	<u>Clinical trials</u> **Total**: 214 applications assessed in 31 days (target 30 days). **Phase 1 HVT**: 28 applications assessed in 25.1 days (target 14 days). **Other trials**: 186 assessed in 31.9 days (target 30 days). <u>Clinical investigations</u> **Total**: 19 applications assessed in an average of 55 days.	The total number of clinical trial applications for Q1 is 6 less (down from 220 in Q1 2021-2022). The timeline for assessment performance is slightly above target. In this time period the DHSC acknowledged a temporary decrease in capacity of the UK's clinical research system. HVT studies are being prioritised and within statutory timelines; however, the internal target of 14 days was missed due to resourcing pressures. Clinical Investigation assessment performance is well within target and in line with Q1 2021-22.

ILAP Innovation Passport (IP) designation activity Scientific Advice	Demonstrates attractiveness of the pathway and trends in product type and applicant engagement Scientific Advice supports all innovators bringing products to market It provides future proofing of performance by ensuring that agency activities are aligned to new technological advances	ILAP is a flagship agency service, need to monitor progress with goals for expedited patient access It measures the support provided by the Agency to those developing new medicines and Devices	Steady / increasing IP designation, matching target to time for assessment, positive feedback from companies engaged with the ILAP Many diverse activities, metrics under development for Q2 2022-23	IP designations: 17 received, 16 approved via the ILAP Steering Group, 2 refused via the ILAP Steering Group. The average time between IP submission to IP meeting date was 129 calendar days (target 30 days)	Total number of IP designations remains steady from Quarter to Quarter, demonstrating strong interest from companies. We continue to see a good mix of large and small applicant companies, and products in both common and rare diseases Informal measurement shows that the Agency is very active in giving advice in Q1 2022-23
The time taken to certify batches of biological medicines such as vaccines and blood products for release onto the UK market	Indicator of efficiency of Agency processes Indicator of identity and number of biological medicines released for use in the UK	To provide confidence that MHRA certification does not delay supply of biological medicines to UK patients	Reliable and consistent turnaround times, which helps manufacturers supply planning <u>KPIs</u> Vaccines: 95% of batches certified within 43 working days	All KPIs were met <u>Average (mean) time for release</u> Vaccines (non-COVID): 4.5 days COVID-Vaccines: 2.9 days Blood products: 3.7 days	<u>Total number of batches for each category certified</u> Total: 334 batches Vaccines (non-COVID): 95 batches COVID-Vaccines: 32 batches Blood products: 207 batches

			Blood products: 99% of batches certified within 15 working days Metrics to show annual trends in Control Testing are being developed		<u>12 month rolling/moving average comparison:</u> Across all products, including COVID vaccines, more batches were released compared to previous years – 25% increase in certification compared to 2021 (~1000 batches compared to 800) and doubled compared to 2020 (~500 batches in 2020)
Total number of unique customers active (i.e. ordering Biological Reference Materials (BRMs)) Number of customers ordering for first time	Indication that Agency is providing what the stakeholders need and has effective marketing / communications activity	Provides us with assurance that we are developing and producing materials that are beneficial	New metric so will require some analysis of historic data to define a performance indicator and show annual and year on year trends	824 unique customers active in Q1 85 first time customers	The metrics will be developed to show the types of product and types of customer in order to understand how the BRMs benefit the Patient
Absolute number of scientific publications Other metrics are under development	Vibrant regulatory research programme addressing key public health needs for biological medicines;	Measure of scientific communication on public health benefits, how the Agency is making available its lab-based science	90 scientific publications p.a. – based on historical trends;	25 publications in Q1 which is consistent with rolling 5-year average (24.6)	New metrics aim to capture national and international scientific impact; Vision is to report with reference to specific ‘themes’ such

	R&D outcomes provide scientific framework for development of innovative biological standards and appropriate control testing; provides technical expertise to support multiple Agency activities and evidence of Agency being attractive partner for public health R&D collaborations Benchmarks against equivalent Research and Development organisations are being developed	outputs and supporting product lifecycle aims;			as public health; international guidance documents for biological medicines; grant progress/end reports; products in development; products developed (e.g. International Standards; ref material; assay); evidence of collaboration with leading scientific organisations
Safety Risk Assessments (RAs) within review date	All activities, especially high-risk, are fully considered and assessed before commencing work and all control measures are in place	Activities carried out by the organisation need to be risk assessed to ensure safe practice. This is especially important for high-risk activities to ensure control measures are appropriate and signed off	Percentage RAs within review date: High: 100% Medium: 90% Low: 80%	Q1 figures not available	Review needed to consider how to assess this under new structure (previously collected separately for the two Agency sites).Current focus is to ensure that all safety critical roles are filled with staff with up-to-date training.

4.2 Healthcare, Quality and Access

Healthcare Quality and Access (HQA) delivers a number of services which protect patients and the public. For Medicines these include:

- The assessment and approval of licences and variations for medicines incorporating **new active substances**, (including for EAMs and ILAP reported under SR & I).
- The assessment and approval of licences and variations for **established medicines.**
- Enabling the importation of **unlicenced medicines** for patients with needs that cannot be met by licenced products.
- Assessment of applications to **reclassify routes of sale and supply** of medicines, where safe to do so, to increase patient access.
- Assessment and approval of licences and variations for parallel important medicines, vital for protecting supply continuity and keeping costs of medicines to the NHS down.
- Approvals of advertising, patient information and is competent authority for registration of eCigarettes.
- HQA also gives advice on products falling on the borderlines between medicines, medical devices, and other products such as food stuff, biocides and equipment.

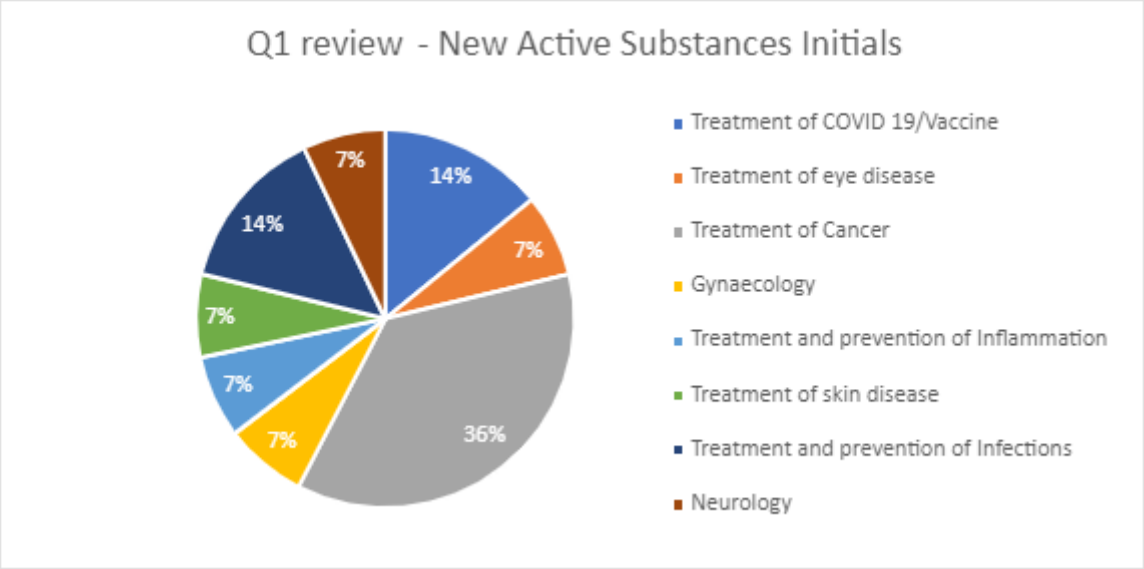
In addition, HQA ensures manufacturers, distributors, laboratories and clinical trials meet the standards set to keep patients and the public safe, both before approvals are given and once a product is on the market or a trial ongoing.

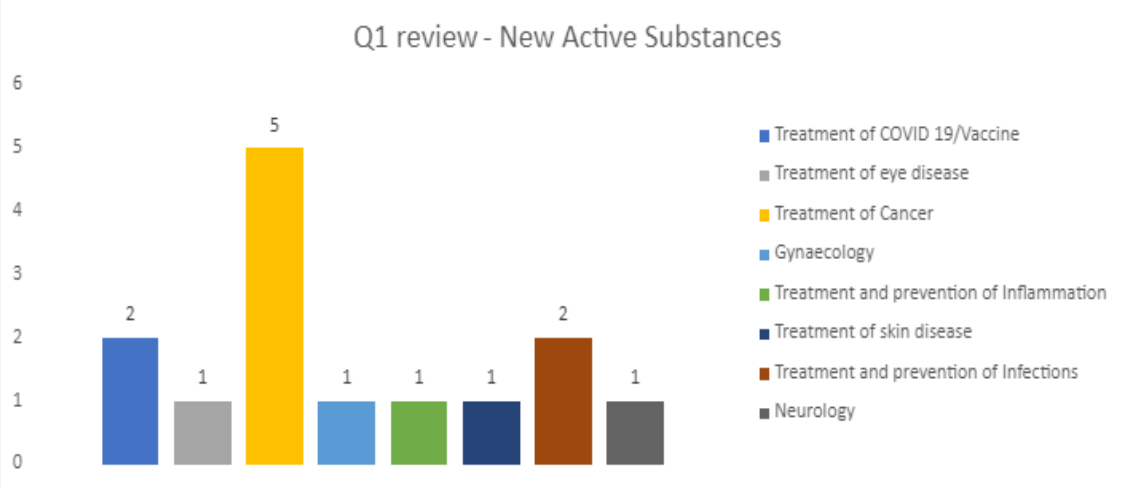
HQA is also leading on the implementation of the new Medical Device regulations, including setting standards and designating new Approved Bodies to carry out assessments of Medical Devices to ensure they reach the standards required to enter and remain on the market in the UK.

HQA publishes some performance metrics every month however these do not reflect performance under the new Agency structure and are not patient focused. In parallel with the development of a balanced scorecard we are reviewing our published metrics, including consulting with Industry to ensure metrics also better support them in planning submissions.
This paper highlights **6 key measures only** of the activities undertaken by the HQA group, those with the greatest impact on public health, along with Q1 performance. Performance in many areas is not at desired levels. Much of this is due to resource gaps particularly of Pharmaceutical Assessors, Non-Clinical Assessors and GMP Inspectors, where staffing levels remain below new operating model levels.

Measure 1: the number and nature of approvals of initial applications for medicines incorporating New Active Substances.

In the last 20 months, New Active Substance (NAS) work has prioritised COVID Products, (vaccines, monoclonal antibodies and antivirals). The chart below shows that we are now broadening our coverage across therapeutic areas with medicines for treatment of cancer making up the highest proportion of the **14 new licences** granted in the first quarter of 2022.





We continue to develop our collaborations with other global regulators and in Q1 of 22/23, 2 of the new licences resulted from the FDA Led project Orbis. 2 resulted from work with the Access Consortium involving Australia, Canada, Singapore, Switzerland and the UK.

Measure 2: the number and nature of approvals of type II clinical variations for medicines incorporating New Active Substances (NAS).

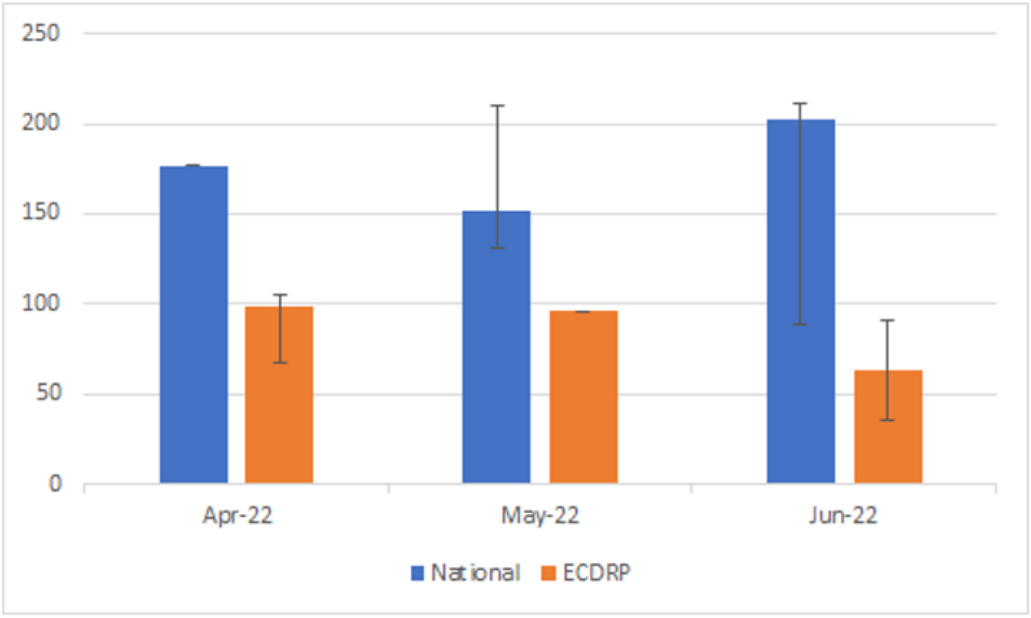
Type II variations are major changes to existing marketing authorisations. As examples, the approvals of the Moderna and Pfizer/BioNTech Bivalent vaccines, (Moderna as a world first), which have enabled the UK Autumn Booster campaign to vaccinate around 20m people to start on time, were both variations.

49 type II clinical variations to Marketing Authorisations for products involving NAS were granted in Q2 22/23. It is not yet possible to break these down into therapeutic areas without significant manual intervention. We will continue to explore ways to do this, and to ensure it is designed into the new Regulatory Management System.

Measure 3: Speed of Access for Medicines incorporating New Active Substances - Performance against Statutory Targets.

New active substance initial applications median time to determination (**time taken by the MHRA to process the application**) Apr-Jun 22 is shown below.

National	April	May	June	ECDRP	April	May	June
Median days	177	152	203	Median days	99	96	63
0.1	177	131	88	0.1	67	96	36
0.9	177	210	211	0.9	105	96	91



Statutory target for national apps – 210 days, MHRA target 150 days. Target for ECDRP – 67 days

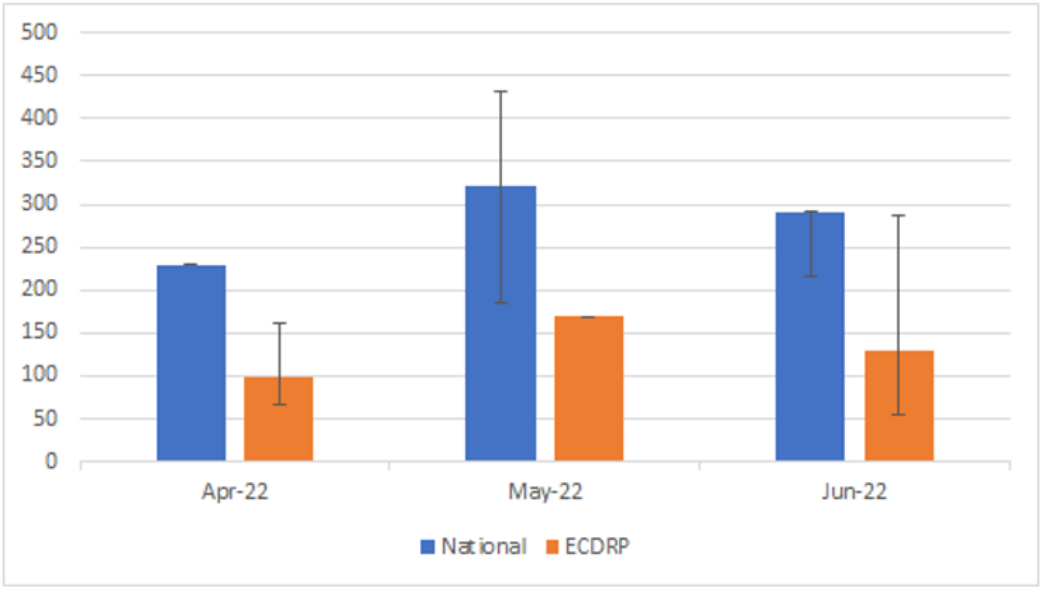
All were within the 210-target range

The median time has varied with work to recover backlogs being reflected in some older national applications being determined in June.

Whilst total elapsed time is not entirely in the MHRA's control, it is a vital measure for patients as it represents how long they are waiting for new treatments. Work is ongoing to reduce total elapsed time by limiting rounds of RFIs and ensuring only decision-relevant queries are raised.

New active substance initials median time to determination (**total elapsed days**) Apr-Jun 22 is shown below.

National	April	May	June	ECDRP	April	May	June
Median days	230	323	290	Median days	100	169	129
0.1	230	186	217	0.1	67	169	54
0.9	230	432	293	0.9	161	169	288

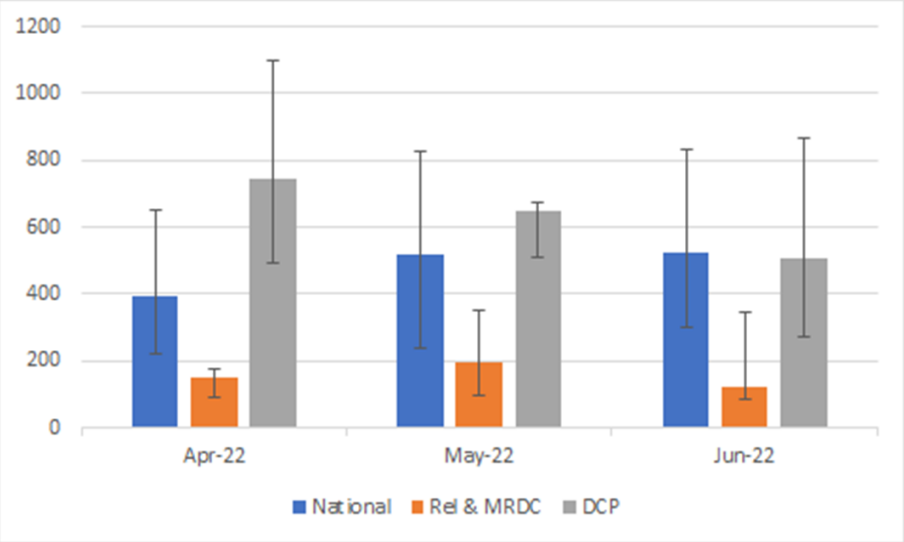


NOTE: MHRA will always expedite applications where there is an urgent public health need. In Q1, which in the first half of 2022/23 we have demonstrated this through our work on COVID, but also on Monkeypox and Polio.

Measure 4: Elapsed times for first Generic Medicines.

The expiry of patents and exclusivity periods for medicines presents opportunities to reduce the cost of these medicines, enabling them to be more affordable by the NHS thus increasing patient access. Whilst these medicines are prioritised manually by the MHRA, it is not yet possible to provide metrics which separately identify these therapeutic areas. Work continues to generate these reports and to ensure the capability to generate them is designed into RMS. In the interim, the graphs below show the MHRA and total elapsed times for all **259** established medicines initial applications granted in Q1 22/23.

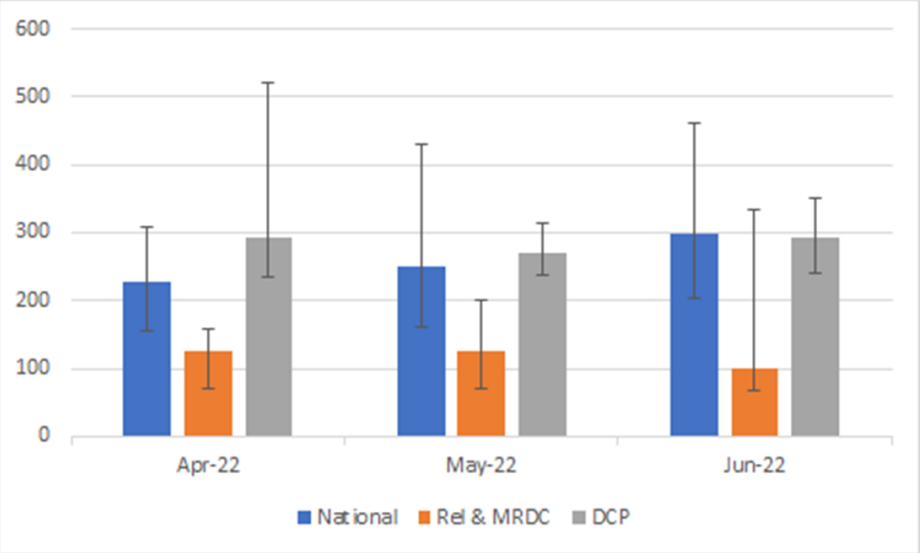
Established medicine initials median time to determination (total elapsed days) Apr-Jun 22



National	April	May	June	Reliance & MRDC	April	May	June	DCP	April	May	June
median days	393	517	523	median days	149	193	123	median days	747	649	505
0.1	282	238	298	0.1	89	96	85	0.1	493	510	273
0.9	708	825	834	0.9	174	350	345	0.9	1097	677	868

As for NAS, whilst total elapsed time is not entirely in the MHRA's control, it is a vital measure for patients as it represents how long they are waiting for new treatments. Work is ongoing to reduce total elapsed time but limiting rounds of RFIs, ensuring only decision-relevant queries are raised, and streamlining process. RMS will also improve this.

Established medicine initials median time to determination (time taken by the MHRA to process the application) Apr-Jun 22



National	April	May	June	Reliance & MRDC	April	May	June	DCP	April	May	June
median days	227	251	297	median days	125	126	101	median days	292	271	293
0.1	156	160	203	0.1	71	71	67	0.1	236	237	240
0.9	308	430	461	0.9	159	201	335	0.9	522	313	349

Statutory target for National Applications – 210 Days (MHRA Only), Target for ECDRP & other reliance – 67 days (MHRA Only)

Measure 5: Income from sales of Standards – British Pharmacopeia and Laboratory Services.

The British Pharmacopeia & Labs team produce and maintain published standards for medicines used for the research, manufacture and testing of pharmaceutical products, increasing the ease and speed of access for patients to new drugs.

Income in Q1 22/23 was £1.35m (up 4.3% from £1.29m in the same period last year).

Measure 6: Compliance Assurance activity.

<table>
<tr><th>Nature of activity</th><th>How does this improve compliance?</th><th>Q 1 Performance</th></tr>
<tr><td>Initial reviews of new Approved Bodies.</td><td rowspan="2">Ensures bodies approved to undertake assessments of conformity against regulations for Medical Devices used in the UK meet required standards</td><td>4 reviews undertaken, 75% completed within 2 weeks - target 90%</td></tr>
<tr><td>Designation of new approved bodies.</td><td>None approved Q1. 6 open applications (1 approved in September 22).</td></tr>
<tr><td>Inspectorate Blogs</td><td rowspan="2">Keeps industry up to date with latest standards and best practice, and lessons learned from inspections, ensuring they are aware of requirements.</td><td>12,041 Unique Visitors
25,682 Unique Page Views.</td></tr>
<tr><td>GXP Guide Sales</td><td>Orange Guide - £90,728
(£23,659 in Q4 21/22)
Green Guide - £56,368
(£2136 in Q4 21/22)</td></tr>
<tr><td>Site Inspections</td><td>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.</td><td>8 Clinical Trial sites inspected. 1 referral for critical findings.

17 Laboratories Inspected, 2 referrals for critical findings.

6 Pharmacovigilance (safety monitoring) systems inspected. 1 referral for critical findings.

86 Manufacturers Premises Inspected, 1 referral for critical findings.

112 Supply Chain sites inspected. 13 referrals for critical findings.</td></tr>
<tr><td colspan="3">Compliance Assurance - We have also developed a compliance assurance value metric that will provide a GxP wide indicator of the balance of inspection demand vs. capacity vs. achieved. The new medicines compliance strategy will drive changes to demand, (by refining risk-based approaches to match interventions with behaviour), and capacity (e.g. use of remote visual inspections enabling greater number of inspections per FTE). Full realisation of this metric is dependent on the RMS programme, however, an interim version will be available for the next quarterly report.</td></tr>
</table>

4.3 Safety and Surveillance

To deliver optimally on the Agency's central mission to protect public health, there is a need for robust processes to rapidly identify, assess and appropriately mitigate risks to patient safety posed by medical products throughout the product lifecycle. Whilst patient safety is a thematic thread that runs throughout the Agency, operational delivery of this area is focused in the four functional units of the Safety and Surveillance Group. The responsibilities of the units and how the performance of each is measured are set out below:

- **Patient safety monitoring**
  The engine room of the Group's patient safety effort, Patient Safety Monitoring conducts market surveillance and detects safety signals from data captured predominantly through the Yellow card Scheme in order to drive a proactive and proportionate remedial response to identified patient risk.

  Patient Safety Monitoring reports the number and percentage increase of Yellow Card reports received describing an adverse reaction to a medicine or an adverse incident involving a medical product. The level of engagement with the Agency's reporting channels and its movement over time can be considered useful proxies for patient and healthcare practitioner awareness. In turn, increasing awareness affords the agency increased confidence in its signal detection and understanding of adverse incidents.

  We aim to achieve incremental growth in combined reporting volumes each quarter.

What are we measuring?	Quarter 1 performance	Quarter 1 contextual narrative
The number and percentage increase of reports received describing an adverse reaction to a medicine or an adverse incident involving a medical product.	**Total reports received: 30,968:** <u>Medicines: 23,582</u> • Marketing Authorisation Holders: 8,357 • Healthcare Professionals: 5,941 • Members of Public: 9,284 <u>Devices: 7386</u> Increase on previous reporting period (%): N/A	From Q2 this measure will show the percentage growth on previous quarter.

- **Benefit risk evaluation**
  Using signals and insight generated from within the Group and beyond, our Benefit-risk groups are responsible for making real-time benefit:risk judgements on potential signals of harm and devising and implementing proportionate risk mitigation strategies for healthcare products.

  The benefit-risk groups report the total number of patient safety signals/issues under assessment broken down by origin. This illustrates the volume of signals and issues that warrant further in depth assessment in this quarter, including source trends, and issues proactively identified by assessors. Such in depth assessment involves an assessment of all available data on a safety signal and may include the conduct of additional epidemiological studies conducted through experts located within Scientific Data and Insight using a number of real world data sources. The measure also reports the

numbers of assessments undertaken which have warranted the need to seek independent expert advice from either the Committee on Human Medicines or its Expert Advisory groups.

The benefit-risk groups are also responsible for assessing and approving safety variations to marketing authorisations and Risk Management Plans (RMP) for medicinal products on the UK market. This provides insight into the number of marketing authorisations where the product information or the RMP is amended, and the volume and timeliness of additional work undertaken. It also provides an indicator of income generated.

The unit aims for the timely assessment of applications without building up a backlog.

The total number of patient safety signals / issues under assessment by Benefit Risk Evaluation assessors (broken down by source)	**Total number of patient safety assessments completed or ongoing in Q1: 173** By source: • Yellow Card -27[1] • Field Safety Notices (Devices) – 23 • Company - 11 • Stakeholder - 24 • Query – 18 • Other - 47 **Number of assessments taken to committee – 23**	As a new function, which merges medicines / devices patient safety expertise, this group conducts in depth assessments of safety signal assessments. From Q2 this measure will show the trend in numbers of safety signals assessed compared with the previous quarter.
Number of Variations (Type II and Type IB for RMPs only) to marketing authorisations which are assessed by the Benefit Risk Evaluation teams	**Variations received, assessed and determined** National • Received: 183 • Assessed[2]: 133 • Determined[3]: 136 79 % assessed within target time Reliance • Received: 129 • Assessed: 48 • Determined: 68 71 % assessed within target time	This metric provides a measure of the volume and timeliness of assessment of updates of product information for medical products and an indicator of income generated.

[1] This refers to the origin of the information which initiated the assessment such as a signal derived from yellow card data or a Field Safety Notice submitted by a manufacturer. The Company source refers to assessments arising from data submitted by a MA holder or manufacturer and includes significant assessments of variation applications. Assessments arising from Stakeholders includes those based on information from other regulators, clinical groups and public health bodies. Assessments may also arise from queries received from patients, HCPs, MAHs or manufacturers. 'Other' refers to assessments coming from sources not covered by these categories and includes internal requests for specialised input into safety assessments for example, a toxicological assessment.

[2] Assessed refers to the initial assessment. Applicants may be requested to provide additional information in order to conclude the assessment.

[3] Determination refers to the conclusion of the assessment following resolution of all outstanding issues

	<u>Concerned Member State</u> • Received: 119 • Assessed: 121 • Determined: 132 91 % assessed within target time *Target times[4]	

While not all assessments result in regulatory action, for some risk minimisation measures are recommended to strengthen the benefit:risk balance of a product. We report here the number of actions taken to mitigate an identified risk, including the number of patient/user engagement sessions held during the quarter. In addition, we report the number of stakeholder enquires received and responded to over the last quarter. This demonstrates how Safety and Surveillance is fulfilling its core objective of protecting patient safety through the minimisation of risks associated with adverse incidents, alongside its commitment to involve patients in our decision making.

Risk Management The number of actions taken to mitigate risk, including the number of patient/user engagement sessions delivered during the quarter	<u>Actions taken:</u> Suspension / revocation / withdrawal / recall: 1 Updates to Patient Information / Instructions for Use as a result of MHRA action: 7 MHRA advice to use alternative device: 1 Introduction of new risk minimisation materials: 3 Publication of Public Assessment Reports / reviews: 3 Recall of medicinal products: 16 total notifications/alerts • Class 1/NatPSA Recalls: 0 • Class 2 Recalls: 7 • Class 3 Recalls: 0 • Class 4 Caution in Use notifications: 6 • Company Led Recalls: 3 Number of patient / user engagement sessions: 12	Not all safety signals results in regulatory action. When measures to minimise risk are required a number of routes to manage the identified risk for patients are available.

[4] The Agency target for Type II variations is 97% to be assessed within 90 days. For Type IB variations, which includes many RMP updates, the target is 97% of applications to be assessed within 30 days.

- **The Criminal Enforcement Unit**

  This unit gathers information from all sources, converts this into actionable intelligence and then uses the resulting insight to identify, prevent and disrupt the most serious criminal threats to public safety.

  The unit reports on the number, distribution and impact of interventions it leads, coordinates or supports that are independently assessed to have diminished an identified criminal threat. As a proxy, this measure demonstrates the extent to which the agency is reducing the criminal threat.

  Maximum threat reduction value is achieved by delivering multiple interventions targeting different aspects of the criminal threat in different ways and with different levels of impact. This measure is directly linked to the purpose of the unit, which is to reduce the criminal threat to the public.

What are we measuring?	Quarter 1 performance	Quarter 1 contextual narrative
The number, distribution and assessed impact of CEU interventions that are assessed to have diminished an identified medicrime threat.	• **Major impact: 2** • **Moderate impact: 6** • **Minor impact: 309**	Interventions assessed as having minor impact tend to dominate as these are generally quick time and lower cost. This was particularly marked in Q1, reflecting the unit's current resourcing challenges.

- **Clinical Practice Research Datalink (CPRD)**

  CPRD captures, integrates and evaluates scientific and clinical data to generate insight to inform Group and Agency decision making, support horizon scanning and trend analysis in the market and to provide data services to external healthcare stakeholders

  Representativeness of the data is critical to ensure the insight generated is relevant to the UK population. Hence an important metric for CPRD is the percentage coverage of the UK population, including importantly that coverage by geographical region. Coverage is calculated using the number of research acceptable patients who have met the data quality checks as the numerator, across both the primary care databases CPRD operates, and the annual ONS UK population estimate as the denominator.

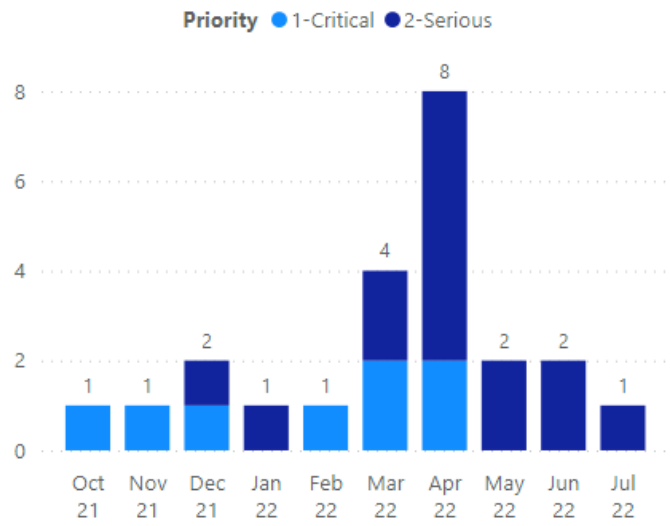
  CPRD aims for coverage of 27% of the total UK population by the end of Q4, with an objective to recruit at least 10% of GP practices in each UK region.

What are we measuring?	Quarter 1 performance	Quarter 1 contextual narrative
The percentage of the UK population covered by CPRD, including by region. This is calculated using the number of research acceptable patients who have met CPRD's data quality checks, across both primary care databases as numerator, and the annual ONS UK population estimate as denominator. In addition, the percentage of practices in each region contributing to CPRD is included as an indicator of regional representativeness .	25.05% overall Above 10% practice target for all regions except Eastern which has 9.4% practices contributing to CPRD	Coverage has increased from just under 25% coverage in the previous quarter; this represents an increase of 413,128 patients.

Meaningful performance measures are critical in documenting the success of the Safety and Surveillance Group internally and, most importantly, in demonstrating accountability to the public it exists to protect. The suite of measures captured by Safety and Surveillance Group reflect the alignment of its multiple delivery functions with the core purpose and strategic mission of the wider Agency.

Given the variety of needs to be met, both the metrics and their respective indicative success levels are intended to be accessible to a wide audience. Where feasible, the measures track the patient safety value they create rather than the contributory outputs. Work is on-going to strengthen the measures in this respect, but is challenging as in some cases the high-level results are not immediately measurable or are insufficiently proximate to the actions taken to achieve them.

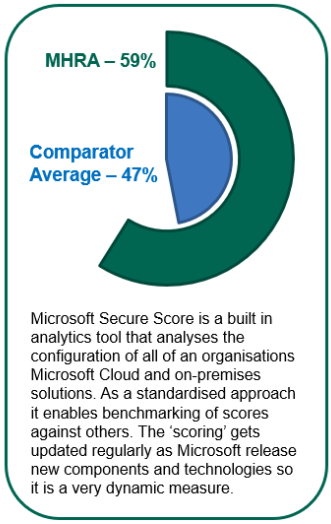
4.4 Digital and Technology



P1/P2 Incidents and Changes

- There was 1 P2 raised in July where Sentinel was unavailable due to the CPU hitting 100%. The issue resolved itself. Logs were collected for investigation and the service is being monitored.
- Meeting rooms are being checked for equipment daily. Connectivity issues via WiFi need to be reported to the helpdesk asap by walking up to the service desk.
- All services have now transitioned to CAE (our new WAN provider)
- Taleo Recruit was upgraded during July without any issues

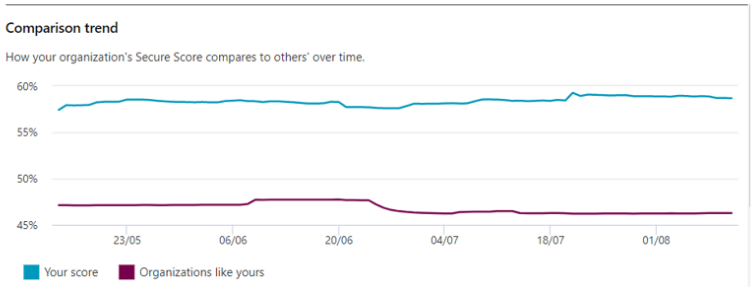
Data Security



In 2020 our Microsoft Secure Score was 23%. The average for organisations like ours is 47%. As this is where the majority of corporate information is hosted this represented a significant risk to the Agency.

The Digital Workplace 21 project was tasked with actioning the levers in M365 that could address this, such as Data Loss Prevention policies, records retention and sensitivity labels. At the project close in Feb 2022, the Secure Score was 56.6% and a further 8 points were added when we provided notice on the contract for support of RSA SecurID, giving a Secure Score of 64.6% - 19 percentage points higher than the average.

Our current secure score resides at 58.7%. This reduction is due to new technologies and components being introduced by Microsoft with update the scoring but work is planning to improve the score within the coming months by introducing things such as but not limited to: do not expire passwords, turning on Microsoft Defender credential guard among others.



John Taylor
September 2022

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

20 September 2022

Title	How many of the key MHRA deliverables have been implemented since the Cumberlege Review was published 2 years ago and what difference have they made to patients?
Board Sponsor	Alison Cave
Purpose of Paper	Assurance

How many of the key MHRA deliverables have been implemented since the Cumberlege Review was published 2 years ago and what difference have they made to patients?

1. Executive Summary

1.1 The Cumberlege Review (the Independent Medicines and Medical Devices Safety Review, IMMDSR) was published on 8th July 2020. Two years following the report is a key point to assess the Agency's progress in delivering the changes needed to put patients at the centre of everything we do. The Agency's key goals and objectives to deliver these changes are laid out in the Agency Delivery Plan 2021-23: "Putting patients first: A new era for our agency", which was published on 2nd July 2021. An updated Delivery plan, which defines further patient centred activity is soon to be published.

1.2 The Board has previously endorsed the Agency's planned short, medium, and long-term deliverables in response to the Cumberlege Review. This paper provides a further update on what has been achieved so far and the differences these have made or will make for patients.

1.3 The Board is asked whether enough progress has been made by the Agency so far, and to provide continued support given that the implementation of many of the deliverables are still ongoing.

2. Introduction

2.1 The Cumberlege Report sets out the evidence obtained during two years of hearings and other information gathering regarding how women who received sodium valproate, pelvic mesh implants and hormone pregnancy tests were failed by the healthcare system. The systems which should have identified risks were slow and public awareness of these systems was low, and the responses in terms of listening to and acting on women's concerns were inadequate.

2.2 The report contained nine strategic recommendations and fifty actions for improvement. Recommendation 6 of the IMMDS Review states: *The MHRA needs substantial revision, particularly in relation to adverse event reporting and medical device regulation. It needs to ensure that it engages more with patients and their outcomes. It needs to raise awareness of its public protection roles and to ensure that patients have an integral role in its work.* There are also twelve 'Actions for Improvement' identified for the Agency to implement. In July 21, a detailed summary of the work being taken forward by the Agency was provided which outlined the progress that had been made in the following range of areas: to strengthen the regulatory framework for medicines and devices, improve adverse event reporting, improve patient involvement, improve the safety of medicines in pregnancy and transform our culture.

2.3 The Agency has embarked upon an ambitious organisation-wide transformation to ensure it becomes a progressive and responsive patient-focussed regulator of medical products. The transformation will deliver a new organisational structure which is committed to improving how we listen and respond to patients and the public, will support the development of a more responsive system for reporting adverse incidents, and will strengthen the evidence to support timely and robust decisions that protect patient safety.

3. Progress on the implementation of the MHRA deliverables

Transforming culture and governance

3.1 The Agency has implemented its new integrated 'One Agency' structure, bringing together science, research and innovation, healthcare quality and access, and safety and surveillance for both medicines and medical devices. This organisational transformation includes the appointment of a new MHRA Chief Safety Officer, accountable for the safety and surveillance for all health care products, including medicines and medical devices. As a member of MHRA's Board, the Chief Safety Officer is also responsible for ensuring that the Agency's response to the IMMDS Review is delivered. The Agency will look to establish a strong and collaborative relationship with the new Patient Safety Commissioner, who has now been appointed.

3.2 Involving patients in our activities is the Agency's first priority and every member of staff now has an objective to help deliver better patient involvement. Other steps to address the cultural change required, included All Staff meetings and group work focussing on the shift from an internal science focus to an external outcome focus on the people we serve, and a series of seminars with the theme of why we should engage with patients more. The Organisational Development & Remuneration Committee has also considered the Agency's work on culture and a People and Culture committee has also now been established.

3.3 The Patient Safety and Engagement Committee (PSEC), which includes lay members, is now established (as part of the Agency's transformation and in response to the Cumberlege Review). The PSEC has been advising and providing assurance to the Board in relation to the Agency's responsibilities regarding patient safety and involvement. The PSEC has provided critical input on a large number of patient centred activities including the strengthening of the Yellow Card Scheme and the Patient and Public Involvement Strategy.

3.4 The Agency has consulted on improvements to its Code of Practice on managing conflicts of interest for its independent experts who provide advice on decisions about the safety and benefit risk of medicines and medical devices. The proposals aim to ensure that experts remain independent and impartial, that the processes to manage conflicts of interest are robust and clear to all, including any conflicts or bias that patients involved in discussions of the committees may hold. The Code also includes the designation of a 'patient expert' for the first time. The consultation closed in May and the Code was published on 8 September 2022. The Agency has also completed an internal review of policies and procedures on conflicts of

interest to ensure these remain robust. For example, staff cannot hold direct financial interests, employment or directorships in the pharmaceutical and healthcare industries, or carry out consultancy or other private work for those industries.

3.5 The Medicines and Medical Devices Act includes powers for an independent, statutory advisory committee for medical devices to be established to provide advice on the safety and performance of medical devices and to strengthen the vigilance system for medical devices. The Agency has been improving the systems and processes associated with its Devices Expert Advisory Committee (DEAC) and, following this review, is now establishing an interim group on the Safety of Medical Devices until a statutory committee is in place. A consultation on the proposal for the statutory Expert Committee on Devices will be held before the end of March 2023.

Patient Involvement

3.6 The Agency's "Patient Involvement Strategy 2021-25" was published in September 2021 and is an important part of the response to Recommendation 6 of the review. The strategy has been developed in consultation with patients on what was important to them and included input from the IMMDS Review's independent Patient Reference Group. The Agency will develop and introduce new systems, processes, and training to ensure the agency's teams have means of engaging and involving patients and the public, embedding the patient and public voice in decision making. The MHRA will work across the health sector to improve the effectiveness of patient engagement and share patient insight. A patient outcome evaluation framework will provide the agency with a robust understanding of progress in delivering the MHRA's vision of being a patient-focused regulator. Work is under way delivering the strategy and the MHRA will continue to listen to patients throughout delivery of it. As part of the revised Delivery Plan, we will be defining deliverables to develop our understanding of patient perceptions of benefit-risk to improve regulatory decision-making.

3.7 The Agency has been using a variety of mechanisms to support patient involvement in regulatory decisions, such as the consultation on sodium valproate through the Commission on Human Medicines (CHM). As another example, in November 2021, patient representatives from Allergy UK and Anaphylaxis Campaign and individual patient carers were included on an Expert Working Group of the CHM which made recommendations to improve the safe use of adrenaline auto-injectors. In addition, the MHRA issued a public call for information in November 2020 as part of a review on isotretinoin which received over 650 responses. The experiences of patients and their families were vital to the review. Patients and other stakeholders who had contributed to or had an interest in the expert review could watch part of the CHM meeting in December 2021, and could provide comments and ask questions online. In the future we aim to incorporate patients' views and lived experience in at least 50% of our substantial benefit risk reviews.

3.8 Throughout 2021 and early 2022, the MHRA ran two workshops (36 attendees), a survey (2,262 respondents), 10 focus groups (54 participants, representative of

the UK adult public) and a Citizen's Jury across four locations in the Devolved Nations (98 participants, broadly representative of the UK adult public) about a new biobank to investigate the role of genetics in adverse drug/vaccine reactions. The results of patient and public engagement has contributed towards the design of the biobank, ensuring that the biobank's approach to and continuing engagement with patients will be of a high standard.

Improving adverse event reporting

3.9 The MHRA is undertaking a major investment programme to upgrade its safety reporting systems. MHRA's SafetyConnect programme is using new technology to improve its responsiveness to reporters and a new modern vigilance database using artificial intelligence to support the more rapid identification of product quality defects and safety signals across medicines, medical devices and blood products. Throughout the development of the new system, the MHRA has engaged with patients and the public directly to gain user feedback and perceptions on the system via user needs sessions.

3.10 The upgraded reporting system is now at an advanced stage of testing prior to full implementation and the SafetyConnect programme will continue to enhance the service over the coming months. A new Yellow Card website went live in February 2022, building on the improvements made to the Coronavirus Yellow Card site that was deployed in May 2020 and enhanced throughout the pandemic. The Coronavirus Yellow Card site enabled the Agency to process the reports received more quickly and efficiently, for better safety signal detection for patient safety. Other recent enhancements include installing new functionality that enables reporters to update their own reports and for the Agency to raise requests for additional information from reporters. Improvements such as these, supported by SafetyConnect will help improve the dialogue with patients. These changes have enabled the integration of Yellow Card into other services such as the NHS App. The website has been made easier to use with new search and help functions as proposed by patients. There is also a new "News Feed" area so users can keep up to date with the latest research and analysis coming from the Yellow Card data. MHRA will continue over the coming year to use patient feedback to add new features to the Yellow Card website to further improve its usefulness and ease of use for patients and carers. We are working to further improve the comprehensiveness of our signal detection and assessment, for example through the Yellow Card Biobank, greater linkage and use of other data sources, such as device registries and incorporation of Unique Device Identifiers (UDIs).

Strengthening evidence for decision making – safety of medicines in pregnancy

3.11 A wider programme of work to improve the safety of medicines taken during pregnancy is being taken forward. The Agency is committed to improving the evidence base for the use of medicines in pregnancy, and ensuring that women have high quality, accessible information to enable them to make informed decisions about their healthcare.

3.12 In January 2021, the Agency published its strategy for its Safer Medicines in Pregnancy and Breastfeeding Consortium. The consortium brings together 16

leading organisations under a common pledge to meet the information needs of women and healthcare professionals, through accessible, clear and consistent advice. The consortium meets 3 to 4 times a year and it has added insight and value on a range of topics including enhancing the quality and consistency of information on the use of medicines in pregnancy and breast-feeding, including COVID-19 vaccines.

3.13 The Agency has also been engaging with wider organisations on the delivery of the recommendations of the Expert Working Group on Optimising Data on Medicines used during Pregnancy. This Expert Working Group published recommendations on how to ensure the UK makes better use of real-world data on medicines exposure during pregnancy and breastfeeding.

3.14 The MHRA has now completed the first stage of its work to support better evidence-based dosing for medicines used in pregnancy and in related training for obstetricians. This work secured funding from the Bill and Melinda Gates Foundation for a 2-year project. Improving this evidence will help ensure more is known about optimal efficacy and minimal toxicity of medicines and will give obstetricians further clarity on the optimal dose of a medicine when treating pregnant patients. After successful completion of the first stage of this project, further funding from the Bill and Melinda Gates Foundation has been awarded to fund work until March 2025. Several publications are in preparation and there will be a new online portal to publish these, as well as any new evidence produced going forward. The MHRA is also now planning further training for academic clinicians and clinicians (obstetricians, obstetric physicians, other specialists etc) who treat women needing to take medication during pregnancy in Q2 2022/23.

3.15 To ensure regulatory approaches for handling the risks of teratogenic medicines remain up to date, the Agency is conducting a review of current processes and guidance to establish if any elements can be strengthened. The first stage of this review looking at approaches in product information in UK and overseas to alert women to the need for contraception for teratogenic medicines is scheduled to complete by the Autumn of this year when its findings will be subject to independent patient and stakeholder input and expert advice and, if needed, follow up action and updated guidance will be carried out by Spring 2023.

3.16 Understanding how diseases, drugs and other exposures affect pregnant women and their children is an important public health priority. The MHRA has also now expanded the Clinical Practice Research Database (CPRD) Pregnancy Register (an algorithmic pregnancy register based on electronic healthcare records) which identifies all pregnancies recorded in CPRD thus greatly increasing the ability to study rare exposures in pregnancy and their outcomes ultimately improving healthcare advice to women. The expanded CPRD Pregnancy Register is being used by the Agency for studying the safety of COVID-19 vaccination during pregnancy and in another study to improve the understanding of dose-exposure-response relationship of hormonal contraceptives.

Sodium valproate

3.17 We are continuing to take forward work to ensure sodium valproate is only used where clinically appropriate, and to improve patient safety for women and girls of child-bearing potential for whom there is no alternative medicine by ensuring that a Pregnancy Prevention Programme is in place with annual reviews.

3.18 The Agency is working with NHS England to deliver a programme of work in place, which includes reducing prescribing and seeking safer alternatives to sodium valproate, pregnancy prevention and contraception, informed consent and shared decision making and improving data collection.

3.19 The Agency continues to evaluate the risks and benefits associated with any medical product, including sodium valproate. The latest evidence on the safety of sodium valproate was discussed at several Commission on Human Medicines (CHM) meetings between May and August 2022 where they reassessed the most appropriate regulatory measures to best minimise risks associated with sodium valproate. CHM's consideration was informed by two meetings involving stakeholder engagement with experts and those with personal experience of the medicine, many of whom are members of the MHRA's Valproate Stakeholder Network and actively involved in the implementation of the existing risk minimisation measures and evaluation of their effectiveness.

3.20 The MHRA and NHS Digital have established the 'Valproate Register' which contains data on all NHS prescriptions of valproate in women and girls of childbearing age in England dispensed in the community and identifies if they are pregnant and accessing NHS care for that pregnancy. Through the Registry, we monitor the implementation of and adherence to the Pregnancy Prevention Programme and understand changes in the use of sodium valproate over time and the impact of these changes on women and their children. The Registry has been expanded to include other antiepileptic drugs taken during pregnancy.

3.21 Working in partnership with DHSC, a 6-week consultation was launched in November 2021 on 'original pack dispensing and supply of medicines containing sodium valproate'. This included a proposal to amend the Human Medicines Regulations 2012 with a specific requirement that medicines containing sodium valproate are always dispensed in the original manufacturer's packaging. This will ensure patients, and particularly women of child-bearing age, always receive the patient information leaflet with warnings about taking the medicine while pregnant.

Strengthening the regulatory framework for medicines and medical devices

3.22 The Review was a key driver for the Medicines and Medical Devices Act 2021. Powers in the 2021 Act allow the MHRA to amend the Medical Devices Regulations 2002, which govern medical devices regulation in the UK, to improve safety for patients and to align with the best international healthcare standards.

3.23 The MHRA held a public consultation on proposals for a future medical device regime, which closed in November 2021. Analysis of the 900+ responses identified strong support for proposals that will enable MHRA to improve patient safety. The MHRA plans for the future regulatory framework for medical devices to improve

and safeguard public health, better assure the safety and quality of devices placed on our market and deliver on the need for improved regulation of implantable devices highlighted by the IMMDS Review. The government response was published in June 2022, and given the breadth of the consultation response and level of ambition, the Agency now intends to lay legislation to provide the legal basis for the changes from 2023.

3.24 Since January 2021, all medical devices have been required to be registered with the MHRA before they can be placed on the market in Great Britain. This has enhanced MHRA oversight of all devices being marketed in Great Britain for the first time, supporting its safety surveillance activity and allowing more rapid action where safety concerns are identified. The new medical devices legislation will also mandate manufacturers to submit additional data to the registration system to improve data quality and availability. A new policy is being developed for a significantly enhanced transparency regime for medical device regulation. The work is being scoped out and we will be delivering key elements over 2022/23 and 2023/24.

3.25 The future regulations will also introduce more stringent pre-market requirements for example mandating the reporting of all adverse incidents that take place during clinical investigations and performance studies. This previously only applied to serious adverse incidents however, the reporting of all incidents will enable the MHRA to have better oversight of the performance and safety of a device throughout the clinical investigation/ performance study. In the UK, medical devices mesh products will be reclassified to a Class III medical device, the highest risk class. This means that they will be subject to a higher level of scrutiny by Approved Bodies. All Class III devices undergo 100% review of technical documentation and clinical review (Class IIa and IIb devices are sampled).

3.26 The MHRA's Early Access to Medicines Scheme (EAMS) Statutory Instrument, which came into force on 15 April 2022, gives patients with life-threatening or seriously debilitating conditions access to medicines that do not yet have a marketing authorisation when they have a clear unmet medical need. The new provisions clarify the legal basis for the EAMS and strengthen safety measures for supply of innovative medicines to patients who need them, prior to full authorisation.

3.27 Following a public consultation in March 2022, the Agency is developing legislation to overhaul the UK's clinical trial framework. The ambitious proposals will ensure patients remain at the heart of clinical research and get access to safe, new treatments faster, whilst promoting the UK's status as a world leader in trials, supporting innovation and increased global competitiveness. The consultation also included proposals to encourage the inclusion of underserved populations including pregnant and breastfeeding women and increase diversity in clinical trial populations.

3.28 The Health and Care Act 2022 provides the power to establish a UK-wide medicine information system by NHS Digital. This will enable the collection of data for the MHRA to establish and maintain medicines registries, which will improve the health

and social care system's ability to monitor medicines and protect patients. Registries could also be used to generate high-quality evidence regarding medicine use, benefits and risks to inform regulatory decision making, support local clinical practice and provide patients and prescribers with the evidence they need to make better-informed patient safety decisions. Now that the power has come into force, the MHRA will start scoping how medicine information systems will work in practice, with the goal of developing proposals for public consultation.

4. Next steps

4.1 The Agency fully recognises that there is still more work to be done to achieve the changes recommended in the Cumberlege Report and will continue to work with other healthcare system partners. The Agency will continue to monitor the progress of the specific commitments and actions in the Delivery Plan 2022/23 designed to address the Review's concerns and further work will be needed to identify the impact of the changes for patients. In particular, the revised Delivery Plan 2022/23 includes the actions planned for the coming year that will deliver the step change needed in patient involvement in our work.

5. Recommendation

5.1 Is the Board assured by the continued progress which the Agency is making in implementing the deliverables to address the recommendations of the Cumberlege Review and that these deliverables will make a difference to patients?

Alison Cave
September 2022

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

20 September 2022

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

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

1. Executive Summary

1.1 PSEC discussed four areas at its meeting on the 7th of July 2022. These were the development of how the committee review risk/benefit from a patient's perspective; CPRD Data Governance/ Real world data and how patient input is being embedded into it; Clinical Trials Consultation response; and adding Patient Safety topics to the work programme. PSEC also held a joint meeting with the Organisation Development and Remuneration Committee (ODRC) on Equality, Diversity, and Inclusion on the 26th of July 2022. This is the first time both committees met together. The topic of Equality, Diversity and Inclusion was discussed from internal and external perspectives.

2. Introduction

2.1 The eighth meeting of the PSEC was held on the 7th of July 2022.

3. PSEC discussed each of the following items at the meeting on the 7th of July 2022;

Development of how the committee review risk/benefit from a patient's perspective

3.1 The topic of how patients perceive risk/benefit had been discussed at the last meeting. The Committee had decided to take discussions forward through a seminar or workshop in the Autumn as this would affect many areas of work including communication of risk through patient information leaflets. The patient and public involvement strategy was on the agenda for the next meeting, and it was suggested that patient's perception of risk/benefit also links to the strategy.

CPRD Data Governance/ Real world data and how patient input is being embedded into it

3.2 The MHRA works with 2000 GP practices through the Clinical Practice Research Datalink (CPRD) and has access to anonymised patient records. The use of this real-world data can be invaluable for research and the safety and effectiveness of drugs and devices. The Committee reviewed CPRD's patient engagement and involvement activities, and how these addressed the recommendations relating to patient engagement in the Goldacre Review and the steer provided in the draft versions of the national data strategy, *Data Saves Lives*. The committee were briefed about the uses and protection of data. PSEC was particularly keen to understand how patients found out if their data was part of CPRD, how representative the database was, and how CPRD worked with patient charities and researchers. The Committee made several suggestions on transparency and publicity to patients on CPRD. It was important to have clear information on how patients check if their data is being used, the security of the data, feedback on the general use of data and how they could opt out. Posters in surgeries were thought to be inadequate and it was better to improve our website. Interactive online sessions with patients to share information and gather feedback was welcomed. The Committee agreed that CPRD was an important data source for the safety of drugs and devices.

Clinical Trials Consultation response

3.3 On 17th January 2022 the MHRA launched a public consultation on updating The Medicines for Human Use (Clinical Trials) Regulations 2004, which transposed the EU Clinical Trials Directive 2001/20 EC into UK law. The consultation outlined a set of proposals, capitalising on the opportunity of having left the European Union, to reframe the UK legislation for clinical trials, responding to the needs of the sector to deliver a more streamlined and flexible regulatory regime, whilst protecting the interests of patients and trial participants. PSEC were briefed on the level and content of responses to the Clinical Trials consultation. Analysis had taken longer due to the volume of responses from 2138 respondents (88% from individuals and 12% from organisations) from all UK nations and across the world. Similar EU consultations had received 400 responses. Overall, there was strong support for the ambition to update and improve the legislation for clinical trials. The Committee noted the relatively high number of responses from patients, as well as health professionals and industry. Different strategies were used to reach a diverse audience including targeting traditionally under reached communities. Lived experience was taken into consideration when reviewing responses. Early involvement of PSEC and co-design was seen as positive to the success of the consultation.

Adding Patient Safety topics to the work programme

3.4 The Patient Safety and Engagement Committee's purpose is to provide independent consideration of patient safety and patient engagement. The Committee considers many aspects of patient safety mainly concerned with patient engagement, but the terms of reference clearly state that patient safety and patient engagement are two separate areas of scrutiny. The Terms of reference state that "the committee is responsible for monitoring and advising the Board on aspects of patient safety in the Agency's procedures for its initial assessments of medicines, medical devices and blood products, the continued surveillance of their use, and its processes for dealing with information" from this surveillance. The Committee therefore needed to review if enough patient safety topics were considered by the committee and add them to the work programme if not. The Chief Officers were asked to consider all aspects of the work of the agency and to ensure topics from the full pathway of work is considered at some point by the Committee.

4. Joint meeting between PSEC and ODRC on the 26th of July 2022

4.1 The Patient Safety and Engagement Committee and the Organisational Development and Renumeration Committee met to discuss how Equality, Diversity, and Inclusion (EDI) were being addressed by the Agency. Presentations were given on the internal and external focus of EDI. The internal focus looked at the Equality and Public Sector duty, the future use of the balanced scorecard, and how strategy also looked at well-being and keeping up with best practice. EDI is linked to the aspirations of the organisation and the meeting reviewed how this was being achieved in a time of change. The external focus was mainly on the implementation of the public and patient involvement strategy. Different ways of reaching diverse communities, and the use of partnerships were discussed. It was noted that sometimes issues raised by patients related to other parts of the health care system therefore working with other parts of the system was important. The meeting noted there was much less data on the external focus than internal focus.

5. Conclusion

5.1 PSEC were able to discuss CPRD and the Clinical Trials consultation responses in detail. There has been a shift in how patients and the public are engaged in both these areas which is positive. It was noted that the overwhelming response to the Clinical Trials consultation needed a great deal of time and resource for review, but this will benefit legislation and supporting guidance. PSEC is reviewing the balance of topics it discusses so that it ensures that it is covering its full remit. The joint meeting between PSEC and ODRC was not only a more effective use of resource to minimise duplication for staff, but joint discussions enhanced assurance.

Mercy Jeyasingham
Chair, Patient Safety and Engagement Committee
Non-Executive Director MHRA
September 2022

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

20 September 2022

Title	What assurance can be provided by Organisational Development and Remuneration Committee?
Board Sponsor	Amanda Calvert
Purpose of Paper	Assurance

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

1. Introduction

The Organisation Development and Remuneration Committee (ODRC) met on 2nd September 2022 and the agenda for the meeting covered:

- A review of the effectiveness of the new organisational structure and operating model
- A review of the progress for developing the processes for the 4 key services that the Agency delivers to achieve its objectives.
- An update on the progress of the development and roll-out of the competency development framework
- An item to note the progress of the people strategy

The ODRC held a joint meeting with the Patient Safety and Engagement Committee (PSEC) to consider Ethnicity, Diversity and Inclusion matters; assurance from this meeting is contained within the PSEC assurance report.

2. Effectiveness of the new organisational structure and operating model

2.1. A review of progress versus the project business case (PBC) objectives was presented. The PBC was approved by DHSC in August 2022. Four major outcomes were sought:

- Agency Restructure and Cost Reduction
- Operating Model design and implementation putting patients first and delivering support to the UK life sciences agenda
- Replacement of legacy systems and investment in new technology to support the new operating model
- One Agency Culture

2.2. **Agency Restructure & Cost Reduction –** There has been significant reductions achieved in headcount and associated costs and this has been balanced by an increase in income from licencing and service fees. Non-pay savings from reduction in accommodation and delays to some technology investments have been achieved.

2.3. The foundations have been laid for continued improvements in efficiency and effectiveness. These will be delivered as the recruitment to key roles is completed, the service design work is implemented and there is greater collaboration and alignment across different parts of the Agency.

2.4. **Operating Model and Organisation Structure –** The Agency successfully transitioned to its new structure on 1st June 2022. The new ways of working have

not yet been fully embedded and there are still some capability gaps within the organisational structure. Services design is explored later in this paper.

2.5. Several risks have been identified to improve and accelerate the transformation of the operating model to allow the Agency to achieve its objectives and be financially sustainable. It was recommended that there is a comprehensive review of risks and actions agreed and owned by senior leaders.

2.6. EY who supported the first phases of the transformation programme have now handed over to an in-house change team who are working closely with the Chief Officers and their teams.

2.7. Improvements in the governance structures have been identified and are being implemented. This includes a streamlined reporting structure and improvements in working across boundaries and forward planning.

2.8. **Replacement of legacy systems and investment in new technology –** The most critical technology project for the Agency is the replacement of the Regulatory Management System (RMS). To ensure the technology supports the future working of the Agency, the services design work and new processes need to be agreed quickly. This requires all groups to work together in a climate of uncertainty where external issues such as changes in legislation could have a big impact. Progress of this programme will be closely monitored by the SRO and leadership team.

2.9. **One Agency Culture –** It is recognised that the scale of change for people working within the Agency is unprecedented. It will take time to embed and embrace the changes and some improvements have been identified.

2.10. A staff communication and engagement plan is being rolled out. This will be critical to ensure that staff at all levels can be engaged and involved in the changes that affect them locally.

2.11. The new model requires greater levels of cross-team collaboration than previously, and alignment of objectives is required when dependencies are identified.

2.12. It has taken longer than expected to recruit and establish people into new roles. Improvements in HR processes and quality of people data will help this process in the future.

3. Review of Service Redesign to support the Operating Model

3.1. Underpinning the organisational restructure and operating model are business processes through which the Agency delivers its services which ensure that patients receive safe and efficacious medicines and devices. The committee sought assurance

that the services were fit for purpose, that risks were being mitigated to ensure they would be implemented to plan.

3.2. In July 2022, the Executive Committee (ExCo) prioritised 4 services:

- Proportionality of risk-based decisions for Established Medicines
- Innovative Licencing and Access Pathway (and Innovative Devices Access Pathway pilot to commence)
- Safety Signalling
- Risk Based Compliance

3.3. The committee welcomed the inputs from the Chief Officers who are leading and taking ownership of the implementation of these services and establishing the new ways of working.

3.4. The new services are all being designed so that a risk-based approach to delivery is embedded in the processes. For example; this approach has been successfully deployed to assess applications and grant licences for COVID vaccines.

3.5. A similar approach is being developed for inspections so that more attention is given to the facilities and suppliers who pose a higher risk to patient and public health whilst moving away from a standard one-size fits all approach.

3.6. Implementing the new ways of working identified to deliver these key services requires some staff with different sets of skills and capabilities. Many staff and potential recruits see this as an opportunity to develop, but there are challenges to offer remuneration and employment packages that are attractive compared to the private sector.

3.7. Technology is key to enabling the new services to be delivered. All 4 priority services have a dependency on the successful implementation of RMS. This is a complex technology project requiring collaboration, strong governance and leadership to focus on definition and delivery. Some lessons can be learned from the implementation of SafetyConnect.

3.8. Implementing the new services will require cross functional working on scale that the Agency is not used to. The embedding of appropriate project management resources will be key to success.

3.9. SafetyConnect remains the key business system that will build the foundation for future requirements for safety and surveillance of medicines and devices.

3.10. To secure successful implementation of all technology projects there will need to be a sustained and, in some cases, increased focus on communications to both internal and external stakeholders.

4. Competency Development Framework, Culture and Leadership

4.1. The competency development framework is under review to ensure it meets the needs of the Agency's new operating model.

4.2. There has been progress in the roll-out of the leadership development courses across multiple levels of leaders within the Agency. The One Agency Leadership Group is leading on initiatives to improve communications with all staff to improve key aspects of culture measured in pulse surveys.

5. People Strategy

5.1. Staff retention and recruitment remains challenging. As expected 2022 has seen a higher level of staff turnover due to the implementation of the new organisational structure and operating model.

5.2. The people strategy will be reviewed by ODRC when available and assurance given to the board in Q4 2022.

6. Concluding Remarks

The Agency has made significant progress in establishing the new organisational structure and operating model in the first half of 2022.

The basic design principles of the transformation hold firm and are still as relevant today despite the additional challenges now faced, particularly with the recruitment and retention of staff, rising inflation, economic pressures for industry and changes within the government.

Leaders will need to focus on implementing new ways of working, technology and services that will define the success of the Agency in the future. In turn they will need support to ensure there are effective governance and risk management processes in place to ensure obstacles can be quickly removed when they arise.

Amanda Calvert
Chair of Organisational Development and Remuneration Committee
September 2022