Medicines & Healthcare products Regulatory Agency

AGENDA FOR BOARD MEETING HELD IN PUBLIC

9:30 am – 12:00 pm on Tuesday 11 July 2023

Chair: Stephen Lightfoot

	AGENDA ITEM	**PURPOSE**	**PRESENTER**
9:30	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
	ANNUAL REPORT		
9:40	4. What assurance can be provided by the Audit and Risk Assurance Committee?	Assurance	Michael Whitehouse
9:50	5. How well does the 2022/23 Annual Report and Accounts reflect the performance, governance and financial results of the MHRA over the last year?	Approval	Carly McGurry
	AGENCY PERFORMANCE		
10:10	6. What are the most important current activities and priorities from the CEO's point of view?	Context	June Raine
10:30	7. What was the operational performance of the MHRA for this year up to 31 May 2023?	Assurance	Rose Braithwaite
	SCIENTIFIC EXCELLENCE		
10:50	8. What are the strategic priorities in the MHRA Science Strategy to enable the faster access of safe and innovative products to patients in the UK?	Approval	Glenn Wells

	PATIENT SAFETY		
11:10	9. How well has SafetyConnect and other MHRA actions over the last three years helped to address the concerns raised by the Cumberlege Review?	Assurance	Alison Cave
11:30	10. What assurance can be provided by the Patient Safety and Engagement Committee?	Assurance	Mercy Jeyasingham
	EXTERNAL PERSPECTIVE		
11:40	11. What questions do members of the public have about the items on this Board Meeting Agenda?	Public Engagement	Chair
	GOVERNANCE		
11:50	12. What are the new arrangements for chairing the MHRA?	Information	Chair
12:00	CLOSE OF MEETING		

MHRA Board Declarations of Interest – July 2023

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

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

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

Name and MHRA Role	Name of Other Company or Organisation	Nature of interest	Paid	Current
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
Rose Braithwaite Chief Finance Officer	Mental Health Foundation	Treasurer	No	Yes
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
	Fennix Pharmaceuticals	Founder of start-up company planning to develop oral chemotherapy product into Phase 2 trial. Not yet trading.	No	Yes
	High Value Manufacturing Catapult	Non-Executive Director	Yes	Yes
Dr Alison Cave Chief Safety Officer	None	N/A	N/A	N/A
Professor Graham Cooke Non-Executive Director & Deputy Chair	Imperial College NHS Trust and Chelsea & Westminster NHS Foundation Trust	Honorary NHS Consultant	Yes	Yes
	NIHR	NIHR Research Professor	Yes	Yes
	NIHR	Influenza platform trial in the UK	Yes	Yes
	NIHR	Chair DSMB (PROTECT-V trial)	No	Yes
	Pfizer	Pneumonia study with Imperial College Healthcare Partners	Yes	Yes
	30 Technology Ltd	Consultant/Advisor	Yes	Yes
	DNAnudge Ltd	Consultant/Advisor	No	Yes
	Seventh Sense Biosystems	Consultant/Advisor	Yes	Yes
	Debevoise and Plimpton LLP	Consultant/Advisor in relation to COVID protocols	Yes	No
	Sanofi CoV	Chair of End Point Review Committee for vaccine trial	Yes	Yes
	WHO	Chair of Committee for Selection and Use of Essential Medicines	No	Yes
Dr Paul Goldsmith Non-Executive Director	Closed Loop Medicine Ltd	Shareholder, director & employee; MA submission	Yes	Yes
	Summit Inc	Shareholder	No	Yes
	Ieso Digital Health	Shareholder	No	Yes

Name and MHRA Role	Name of Other Company or Organisation	Nature of interest	Paid	Current
	MDU Ltd	Director	Yes	Yes
	MDU Investments Ltd	Director	Yes	Yes
	NHS	Consultant Neurologist	Yes	Yes
	NHS	Clinical Senate Member	No	Yes
	Radix Big Tent Foundation	Trustee	No	Yes
	Sleepstation	Co-founder of original programme, 2012-2014	No	No
Claire Harrison Chief Digital & Technology Officer	None	N/A	N/A	N/A
Haider Husain Non-Executive Director	Healthinnova Limited	Chief Operating Officer	Yes	Yes
	Milton Keynes University Hospital NHS Foundation Trust	Non-Executive Director	Yes	Yes
	British Standards Institute	Panel Chair BS30440 – Use of AI within Healthcare	No	Yes
	Dementia Carers Count	Trustee	No	Yes
	World Wars Muslim Memorial Trust	Trustee	No	Yes
	Microsoft Corp	Ex-employee shareholder	No	No
	BBC	Family Member	No	Yes
	NHS Buckinghamshire, Oxfordshire and Berkshire West Integrated Care Board	Associate Non-Executive Director	Yes	Yes
Mercy Jeyasingham MBE Non-Executive Director	NHS South West London Integrated Care Board	Non-Executive Member	Yes	Yes
Raj Long Non-Executive Director	Gates Foundation	Employee – Deputy Director	Yes	Yes
	Bristol-Myers Squibb	Ex-Employee Shareholder	Yes	Yes
	RESOLVE (Sustainable solutions to critical social, health, and environmental challenges)	Scientific Advisory	No	Yes
	Novartis	Ex-Employee Shareholder	Yes	Yes
	EC IMI NEURONET EC Innovative Medicines Initiative (IMI) Non-Product	Scientist Advisory Board	No	Yes
	Gates Venture – EC Innovative Medicines Initiative (IMI) Non-Product – IMI European platform for Neurodegenerative Disorders	Advisory	Yes	Yes
	HUYA Bio	Access Advisory	Yes	No
	PAVIA – PV Africa Board (EC Funded)	Advisory Board	No	Yes
	WHO – Sustainable COVAX Manufacturing Strategy for Regional Health Security	Advisory Expert	No	Yes
	UK Health Security Agency	Associate Non-Executive Board Member	Yes	Yes

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

Medicines and Healthcare products Regulatory Agency

Minutes of the Board Meeting Held in Public on 16 May 2023

(10:00am – 12:30pm)

Large Meeting Room, NIBSC, Blanche Lane, South Mimms

Present:

The Board

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

Others in attendance

Rachel Bosworth	Director of Communications and Engagement, MHRA
Kathryn Glover	Deputy Director, Medicines Regulation and Prescribing, DHSC
Carly McGurry	Director of Governance, MHRA
Natalie Richards	Head of the Executive Office, MHRA
James Pound	Deputy Director, Standards & Compliance (for item 9)

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; Alison Strath, Chief Pharmaceutical Officer for Scotland; Greig Chalmers, Head of Chief Medical Officer's Policy Division in the Scottish Government; and Cathy Harrison, Chief Pharmaceutical Officer for Northern Ireland.

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

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

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

AGENCY PERFORMANCE

Item 4: How well has the MHRA achieved the deliverables in its two-year Delivery Plan 2021-23 "Putting patients first: A new era for our agency"?

4.1 The Board considered a paper describing the MHRA's performance against the deliverables which were set in the two-year Delivery Plan 2021-23. The Board noted the significant amount of work which has been delivered by the Agency. The Board provided comments relating to the delivery of the new organisational structure; preparedness for the future; assurance of the delivery of the Regulatory Management System (RMS), and the evolving scope and complexity of this project; the Board agreed that the Audit and Risk Assurance Committee (ARAC) should do a deep dive on RMS.

4.2 The Board provided further comments relating to system alignment with other bodies in the health ecosystem and the work of the Partnerships group; identifying areas for learning from the 2-year delivery programme and building these into the new Corporate Plan; the ability to be agile and take rapid and risk assessed decisions such as in the pandemic and then learning from the outcomes; international comparators and international collaboration; and how external factors impacted MHRA's ability to deliver on certain aspects. The Board agreed to close this Delivery Plan and agreed that ExCo should consider carefully where any outstanding items should fit within the Corporate Plan as a continuation of this Delivery Plan. The Board thanked all members of staff for all the achievements throughout this challenging 2-year period.

Action 97: ARAC will undertake a deep dive on RMS; all Board members will be invited to attend. ***Michael Whitehouse***

Item 5: What are the most current important activities and priorities from the CEO's point of view?

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

(i) Scientific Research and Innovation – including latest updates on innovation; future vaccines manufacturing research hub; cancer vaccines; mycobacterium tuberculosis standard; influenza; haemophilia A anti-drug antibodies; microbiome related biological products; research into emerging diseases; collaboration with the National Measurement Institutes in diagnostic assays; CEPI funding; tuberculosis research funding; and a vaccine research award;

(ii) Healthcare Access – including updates on personalised immunotherapy; innovative medicines; innovative devices; and product lifecycle management;

(iii) Partnerships – including updates on the Access Consortium; clinical trials legislation; and health service alignment;

(iv) Patient Safety – including updates on the Report of the Commission on Human Medicines' Isotretinoin Expert Working Group; the Criminal Enforcement Unit; CPRD asthma studies; increased reporting requirements for devices; and the Interim Devices Working Group;

(vi) Dynamic Organisation – including updates on the Business Plan and the upcoming BSI audit; and

(vii) Financial Sustainability – including an update on fee changes.

5.2 The Board thanked Dr Raine for her report and provided comments relating to accelerating clinical trial recruitment using CPRD as an enabler as the Agency; increasing CPRD coverage and linkage to the NHS app; publication of MHRA performance metrics on gov.uk; development of a self-service process through RMS; raising the UK's profile through the Access Consortium, and a proactive transition to the next Chair of Access; the development of the Science Strategy and how MHRA NEDs will be engaged to input in to the strategy; ensuring there is added value from system alignment; data sharing; the benefits of the health ecosystem working together, taking into account that the MHRA's remit covers the whole of the UK unlike some other organisations; and horizon scanning. The Board noted the report with thanks.

Item 6: What was the operational performance of the MHRA for the year up to 31 March 2023?

6.1 The Board considered a report describing the Agency's performance against the Key Performance Indicators in the fourth quarter (Q4) of 2022/23. The Board considered the report and provided comments relating to the clinical trials backlog and the work being done to address this issue including moving assessor resource into this area and using secondments from NIHR; scientific publications; grant funding;

transparency; the time required to undertake a reliance procedure and the importance of communication to manage expectations; increasing CPRD linkage to other datasets and ensuring high quality of all data in CPRD; and the decrease in staff turnover rate. The Board noted the report for assurance with thanks.

DYNAMIC ORGANISATION

Item 7: What assurance can be provided by the Organisational Development & Remuneration Committee?

7.1 The Board considered an assurance report provided by the Organisational Development & Remuneration Committee (ODRC). The ODRC met on 14 March 2023 and undertook a review of the updated Terms of Reference (TOR) and membership of the ODRC; a review of feedback from the leadership team and the forward workplan for 2023/24; a review of the approach to improve communications to all staff to facilitate the delivery of the Agency's corporate and business plans; and a review of the proposals to improve governance and establish new roles and ways of working across the Agency. The Board noted that staff engagement is vital, and the ODRC will hold a future meeting with the One Agency Leadership Group to build on this. The Board noted the assurance report with thanks.

FINANCIAL SUSTAINABILITY

Item 8: What assurance can be provided by the Audit and Risk Assurance Committee?

8.1 The Board considered an assurance report provided by the Audit and Risk Assurance Committee (ARAC). The ARAC met on 21 April 2023 and discussed a progress update on resolving issues raised by the Health and Safety Executive (HSE) at the South Mimms site; the Agency's financial position at the year-end together with progress in preparing draft financial statements; the outcome of NAO/KPMG's interim audit and the resilience of the remaining audit timetable; a presentation from Internal Audit on the outcome of three further reports and the implications for their annual assurance assessment; the Agency's draft annual governance statement which will be published with the Annual Report in July; and the annual reports on the Agency's handling of fraud and complaints. The Board noted the improvements which need to be made with regards to audits, however noted progress. The Board noted the assurance report with thanks.

HEALTHCARE ACCESS

Item 9: What are the strategic priorities for a progressive MHRA Compliance Strategy to enable new product innovation?

9.1 The Board considered the Agency's new medicines compliance strategy, which is a commitment in the existing Agency Delivery Plan, a key deliverable in the new Agency Corporate Plan and will be delivered over a three-year programme to 2025/26. The scope of this first phase of the compliance strategy is for medicines, with a follow-on phase to expand to include medical devices subject to the development of the new UK medical devices regulatory regime. The Board noted that compliance is a critical component of the medicines regulatory framework and the strategy established a range of proposals that will drive benefits to patient safety and access by focussing our resources where risk is greatest and enabling medical product innovation.

9.2 The Board noted the update and provided comments relating to consideration of other sectors when developing this strategy, such as food or aviation; working as a system to increase compliance; partners in innovation including academic, domestic and international partners; international recognition frameworks; learning from COVID-19 regulatory flexibilities; the use of digital technology such as remote visual technologies to undertake inspections remotely; linkage with the Agency's data strategy; measures of success; ensuring the strategy is able to adjust for technological improvements; and lifting barriers in regulation. The Board thanked all members of staff who have been involved in developing this strategy and approved the strategy.

CORPORATE PLAN

Item 10: How well does the final draft Corporate Plan capture our strategic ambitions for the next three years?

10.1 The Board reviewed the draft Corporate Plan for 2023-2026, which represents the Agency's high-level vision and sets out the Agency's ambitions for the next 3 years. The Board noted the draft has been updated following earlier comments from the Board. The Board reviewed this draft and provided comments relating to the positive work on transparency building through publication of signals through to public hearings, and feedback from patients on this process; greater involvement of patients; and the work to refine the key priorities. The Board thanked all who have been involved in developing this Corporate Plan. The Board approved the draft Corporate Plan, which will now be submitted to the Department of Health & Social Care (DHSC) for final clearance.

Action 98: The Board approved the draft Corporate Plan; this should now be submitted to DHSC for approval. A Business Plan for 2023/24 should now be prepared to deliver the actions in the first year of the 3-year Corporate Plan.

Rose Braithwaite

EXTERNAL PERSPECTIVE

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

11.1 The Board answered a range of questions which had been submitted by members of the public before and during the meeting. These questions concerned the performance of the MHRA; the barriers to CPRD recruitment and how participation by GPs can be increased UK-wide.

ANY OTHER BUSINESS

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

ACTIONS FROM MHRA BOARD MEETING IN PUBLIC – 16 May 2023

The actions highlighted in red are due this month

Action Number	Action	Owner	Date	Status
Carried Forward from previous meetings				
29	16/03/21: Present an Agency Science Strategy to the Board. 15/11/22: Revise the Science Strategy to include clear prioritisation; and greater inclusion of in-house expertise on behavioural science with a complementary expert group. Include vaccines work as a specific area of expertise, alongside biologics and the UK Stem Cell Bank, to create a distinctive offering to make the UK an internationally recognised centre of excellence in this field. A review of scientific committees should also be undertaken. Present a further update to the Board in March 2023. 21/03/2023: Science Strategy to be presented to the Board in July	Marc Bailey	~~21/09/21~~ ~~16/11/21~~ ~~17/05/22~~ ~~15/11/22~~ ~~21/03/23~~ 11/07/23	On Agenda
70	18/01/22: Develop and present a Data Strategy to the Board.	Alison Cave & Claire Harrison	~~17/05/22~~ ~~18/10/22~~ ~~15/11/22~~ ~~18/04/23~~ 19/09/23	
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~~ ~~21/03/23~~ 16/05/23	The Board noted there is a stream of work ongoing to deliver this new regulatory framework; this action can be closed.
73	15/02/22: Develop a Sustainability Strategy.	Glenn Wells	~~17/01/23~~ 16/01/24	
88	15/11/22: Present the Agency's Compliance Strategy to the Board. 16/05/23: The Board reviewed the Compliance Strategy and endorsed the progression of this work.	Laura Squire	~~21/02/23~~ 16/05/23	Completed

89	17/01/23: PSEC to review the implementation of sodium valproate safety measures at a future agenda.	Mercy Jeyasingham	~~21/03/23~~ ~~18/04/23~~ 20/06/23	Completed
93	21/03/23: Submit the 2023/24 MHRA Budget to DHSC for final approval.	Rose Braithwaite	16/05/23	Completed
94	21/03/23: Publish H&S annual report on website and include H&S KPIs in quarterly performance report to Board.	Marc Bailey	16/05/23	Completed
96	21/03/23: Clarify how MHRA partnerships, strategic plans and substantial contracts are approved in ExCo Terms of Reference and circulate final version to Board.	Carly McGurry	16/05/23	Completed
New Actions				
97	16/05/23: ARAC will undertake a deep dive on RMS; all Board members will be invited to attend.	Michael Whitehouse	19/09/23	
98	16/05/23: The Board approved the draft Corporate Plan; this should now be submitted to DHSC for approval. A Business Plan for 2023/24 should now be prepared to deliver the actions in the first year of the 3-year Corporate Plan.	Rose Braithwaite	11/07/23	Verbal Update

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

11 July 2023

Title	**What assurance can be provided by the Audit Risk and Assurance Committee?**
Board Sponsor	Michael Whitehouse
Purpose of Paper	Assurance

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

1. Executive Summary

1.1 The Audit Risk and Assurance Committee (ARAC) met on 4 July 2023. The main focus of the meeting was consideration of the NAO's completion report summarising the outcome of their final audit of the MHRA's Financial Statements for 2022-23. The Committee received an update on progress in implementing the recommendations of the Health and Safety Executive (HSE). We also considered Internal Audit's remaining reports for 2022-23 together with their Annual Assurance assessment for the year. We reviewed the risk register focusing in particular on cyber security risk and how this is being managed.

1.2 The Committee welcomed Stephen Wright, who is the MHRA's new head of Internal Audit, and Charlotte Dickinson, the Agency's new Deputy Director of Finance.

2. Annual Report and Financial Statements

2.1. The National Audit Office (NAO) supported by KPMG have substantially completed their external audit of the MHRA's Financial Statements for 2022-23 apart from some final end year testing of income. The NAO are not anticipating any material issues (the ARAC Chair and the Director of Finance will meet the NAO on Monday 10 July to receive final confirmation) and expect to recommend that the Comptroller and Auditor General (C&AG) issues a clear audit opinion. The Board should therefore be able to approve the MHRA's Annual Report and Financial Statements at its meeting on 11 July.

2.2. The plan is that the Accounting Officer will sign the Financial Statements on 12 July which will be laid in Parliament on the 19 July before the Summer Recess. The Agency should meet its statutory reporting responsibilities.

2.3. The Financial Statements form part of the MHRA's Annual Report. The NAO are not formally required to audit the Annual Report but have to ensure that information presented in the Report and any supporting commentary is consistent with the Financial Statements. The NAO also check to ensure that the Governance Statement, which forms part of the Annual Report, complies with HM Treasury's guidance and other appropriate standards. No outstanding issues remain. Both the NAO and Internal Audit commended the transparency of the Agency's governance statement.

2.4. ARAC recommends that the Board approve the MHRA's Annual Report for 2022-23.

2.5. The Committee commend the excellent work which colleagues in Finance, the Governance Office and Communications have done in ensuring that the Agency successfully meets its external reporting requirements for 2022-23.

3. Health and Safety Executive (HSE)

3.1. The Committee were pleased to note that the HSE had confirmed that the Agency had successfully implemented the Executive's recommendations to ensure that health and safety is reliably addressed in any future organisational change. The Agency's health and safety policies are being updated and a revised strategy will be presented to the Board in November. ARAC has agreed to consider an early draft.

3.2. Work is in progress to ensure that health and safety is a specific responsibility in the personal objectives of MHRA staff.

3.3. The Agency has encountered difficulties in securing skilled personnel to retain its full SAPO (Specified Animals Pathogens Order) licence to operate. This has been ongoing for some considerable time and remains an organisational risk. We were told that staff were being trained to ensure that the Agency was fully SAPO compliant but that this took time. We asked to be updated at our next meeting.

4. Internal Audit

4.1. We received five Internal Audit reports which completed the programme for 2022-23. These are:
- Agency Fees (substantive assurance);
- Regulatory Management System Governance (RMS) (moderate assurance);
- Information Security Training (limited assurance);
- Management of Backlogs (advisory); and
- Patient Involvement (advisory).

4.2. Internal Audit are required to provide the Accounting Officer with independent annual assurance on the reliability of internal controls including risk management. For the second year Internal Audit provided limited assurance. Compared to the previous year, 2022-23 represents an improvement and Internal Audit consider that some important advances have been achieved notably in the implementation of a more robust risk management approach. There needs, however, to be more comprehensive evidence that these improvements are now embedded in the MHRA and that they will be sustained.

4.3. Over the last 3-4 years the MHRA has undergone major transformation and had to respond to significant external challenges. As new approaches take time to be understood and accepted, it is not unusual for overall assurance ratings to slip. It is important, however, that over the remaining period of the current financial year the Agency works consistently to improve the overall level of assurance.

4.4. Internal Audit have highlighted in their Annual Report a number of systemic improvements which the Agency needs to implement. These include: the setting of risk appetite; having a reliable assurance framework; embedding the requirements of Cabinet Office functional standards; responding swiftly to recommendations intended to improve performance and promoting a culture of greater compliance. The Agency accepts these and has work underway or planned. ARAC will monitor progress and report to the Board.

4.5 The Committee received a progress report on implementing Internal Audit recommendations. There are some recommendations that are currently outstanding, and more are likely to reach this stage over the next few months. At a previous ARAC meeting we discussed whether some of these recommendations were dependent on external factors such as new legislation or new digital solutions which increased the time it would take to fully implement them.

4.6. The Committee supported the Executive's decision to revisit outstanding recommendations and to consider the practicalities of some of the existing timelines. This process is underway and we asked to receive an updated schedule of intended actions and any increase in operational risk which delaying implementation might result in. We will seek ongoing assurance that there is no weakening of controls.

4.7. A number of Internal Audit reports which we received did not have a management response or proposed action plans. Going forward the Committee will expect the Senior Responsible Officer to attend the ARAC meeting to discuss how they intend to implement recommendations that have been accepted and the dependencies which may need to be managed to secure the intended performance improvement or the strengthening of controls.

5. Risk management

5.1. ARAC reviewed the risk register and noted that it continued to include the key strategic and operational performance risks which the Agency faces. We questioned why nearly all of the risks were assessed as red even after mitigating actions were taken into account. We advised that it would be helpful to understand the direction of travel which the mitigating action had the potential to help achieve. This would help the Board understand whether the mitigating action was both sufficient and proportionate.

5.2. The Committee discussed in detail the Agency's exposure to cyber risk. While we can take assurance that the Agency has a wide range of defensive actions in place we would like additional assurance that taken as whole these represent a comprehensive strategy that is sufficiently agile and appropriately resourced. This is part of the remit of an Internal Audit review which will be considered by ARAC in September.

5.3 ARAC was briefed on and support the work being undertaken to promote a better and more consistent understanding and application of risk management across the Agency.

6. Next meetings

6.1. ARAC will next meet on 4 September to hold a horizon scanning discussion and on 12 September.

Michael Whitehouse
Chair, Audit Risk and Assurance Committee
July 2023

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

11 July 2023

Title	**How well does the 2022/23 Annual Report and Accounts reflect the performance, governance and financial results of the MHRA over the last year?**
Board Sponsor	Carly McGurry
Purpose of Paper	Approval

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

1. Executive Summary

1.1 The annual report and accounts for the Agency have been prepared in accordance with the relevant requirements and been subject to audit by the National Audit Office (NAO). The Executive Committee (ExCo) and the Audit & Risk Assurance Committee (ARAC) have both reviewed and approved the documents. The Board is asked to approve the draft and advise the CEO to sign the report and accounts, prior to submission to the NAO for certification.

2. Introduction

2.1 Every year, MHRA, in keeping with other government bodies, has to lay an annual report and audited accounts in Parliament, in order to set out our performance throughout the year and account for our use of public funds (including those arising from charges to service users).

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

2.3 Board members will recall that in recent years, the Board has relied on ARAC to confirm that the report and accounts are in good order and are recommended for signature by the Chief Executive and Accounting Officer. This year, the draft report comes to the Board in full for approval, supported by the approval of ARAC at its meeting held on 4 July, as detailed in the assurance report from the same.

3. Proposal

3.1 We are subject to strict controls over what must be included in the documents, how it must be presented and where in the document it is positioned. This can sometimes mean that elements of the report can appear repetitive, but we have worked closely with Communications colleagues and taken advice from both GIAA and NAO colleagues on how best to provide and cross-reference material. The accounts are also subject to a detailed audit by the National Audit Office, who will take a close interest in the governance statement and will check for a balanced and consistent report throughout.

Performance

3.2 The performance section in the first half of the report is where we have most flexibility to set out the achievements of the Agency in the way we consider appropriate. We have worked hard to capture all that has been achieved by the Agency, including but not limited to objectives in the Delivery Plan. We have also updated all of the key performance indicators in the document. We are not able to do this each year as it will prevent a comparison of trends, so we have used this opportunity to reset the indicators included whilst simultaneously seeking to make the data as useable as possible. The indicators included for operational areas are the same as those included in the Agency's new business plan which creates the basis for an effective performance monitoring cycle from this year onwards.

Governance

3.3 The governance statement, and in particular the statement on internal controls seeks to set out where we are this year, in the context of a longer, multi-year journey as part of transformation to bring our governance and controls up to the right level. This recognises the progress we have made within this twelve month period and sets out priority areas for action for next year, which are also called out in brief in the draft business plan, so that all priorities for the coming year are brought together. This area of the report also contains the Head of Internal Audit's opinion on the Agency this year. While there are clearly identified areas for continued improvement within the statement, it also recognises the positive trajectory that we are on.

Finance

3.4 Following the MHRA's reclassification from a trading fund, the Agency is now inside the accounting boundary of the Department for Health and Social Care (DHSC). As a result, the presentation of the accounts is very different from last year. Specifically, the funding from DHSC is no longer shown as income in our Statement of comprehensive income (SOCI on page 130) but instead is included as a reserve movement in the general fund within the Statement of financial position (page 131). It is shown as a separate line in our Statement of changes in taxpayers' equity (page 133) which provides details of how our balance sheet reserves have moved during the year. This means that the Agency is showing negative comprehensive expenditure in the SOCI, equivalent to a loss of £33.1m, which are costs in the year more than our trading income. However, this loss is covered by the £33.2m of DHSC resource funding or 'grant-in-aid' that we have received during the year. DHSC also provide budgetary cover for all of our depreciation non-cash resource costs (RDEL).

3.5 As with the rest of central government, MHRA has adopted IFRS16 for lease accounting in the 2022/23 accounts. This financial standard requires that right of use assets be included in the statement of financial position. The main asset not previously included is the 14-year lease for the Canary Wharf building. As a result of this change the rent for the property will no longer go through accommodation costs but be shown as depreciation in the annual statements.

3.6 To show readers how we compare to last year following the change in status and the adoption of IFRS16, the prior year comparators have been updated and put in the same format. For the SOCI this includes three years' worth of information as we have had to restate the opening balances for last year (1st April 2021).

4. Recommendation

4.1 The Board is asked to endorse the draft annual report and accounts and advise the CEO to sign and submit them to the Comptroller and Auditor General for his approval, prior to laying them in both Houses ahead of summer recess.

Carly McGurry
July 2023

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

11 July 2023

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

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

'TOP 10' HEADLINES

- Our Corporate Plan 2023-26 has 4 strategic priorities: maintaining public trust; healthcare access including to innovation; scientific and regulatory excellence; and customer service
- The Commission on Human Medicines has advised on plans for a new, risk-proportionate system for clinical trial applications, in light of O'Shaughnessy Review recommendations
- Under our Chairmanship of the Access Consortium (Australia, Canada, Singapore and Switzerland), a new 'Promise pathway' for innovative medicines has moved to pilot stage
- We announced that use of CE markings on medical devices will be accepted until mid-2028 or mid-2030, depending on device type, after parliamentary approval of the changes
- Under the Windsor Framework, from 1 January 2025 we will licence medicines on a UK-wide basis, and guidance on the implications for packaging and labelling is in preparation
- We launched a public health campaign on best use of adrenaline autoinjectors to provide information on carrying two of these life-saving products in case of an anaphylaxis event
- Our collaboration to develop the digital Pathfinder Pregnancy Prevention Programme for lenalidomide, a myeloma treatment, has led to shortlisting for a Patient Safety Award
- We have held meetings with patient charities and healthcare organisations to support safe implementation of the strengthened oversight provisions for antiepileptic sodium valproate
- Following Yellow Card reports, we issued warnings about correct dosing with calcium gluconate in the management of high blood potassium levels, a medical emergency
- The work of the Criminal Enforcement Unit led to a defendant receiving a custodial sentence for the illegal possession and intent to supply prescription medicines.

SCIENCE, RESEARCH AND INNOVATION

Global Training Hub for Biomanufacturing

1.1 The head of the R&D Viral Vaccines team was invited to be part of the faculty of the Global Training Hub for Biomanufacturing (GTH-B). This 2-week course is organised by the International Vaccine Institute (IVI) and supported by the Korean Ministry of Health and Welfare and the World Health Organisation (WHO). The aim is to help strengthen the capabilities of low- and middle-income countries in local production of vaccines and biologics, address vaccine inequity, and enhance pandemic preparedness. The lecture on Standards and Control provides an excellent opportunity to raise awareness on the importance and role of reference material, especially International Standards. The visit also offered an opportunity to discuss current and future projects with collaborators at IVI.

Vaccine Standardisation

1.2 The International Alliance for Biological Standardization (IABS) meeting on Vaccine Standardisation (WHO, IABS, Health Canada, FDA, EDQM, Vaccine Manufacturers etc) was held to discuss both technical and regulatory considerations specific to the use of reference standards in the quality control of human and veterinary vaccines. Presentations were given by three experts from MHRA SR&I.

Nipah virus research

1.3 Scientists in the Viral Vaccines teams in R&D and Standards Lifecycle were invited to the Coalition for Epidemic Preparedness Innovations (CEPI) stakeholder 'Nipah portfolio and technical program' meeting in Kuala Lumpur, Malaysia on 19-20th June to discuss the status and future landscape of clinical research, vaccines, and diagnostics development for Nipah, with an outwards look to preparedness and prevention strategies for emerging viruses. Senior Scientists in the Viral Vaccine Standards group presented the development of the WHO International Standard for Nipah virus antibody, and colleagues in the Viral Vaccines group (R&D) offered their expert opinion as part of a panel discussion.

Attenuated oral polio vaccine

1.4 There has been great interest in the publication by the R&D Vaccines Poliovirus team of a study in *Nature*: 'Genetic stabilization of attenuated oral vaccines against poliovirus types 1 and 3'. The paper reports the development of novel oral polio vaccine candidates that may help the eradication programme by reducing the likelihood of vaccine-derived outbreaks occurring for poliovirus types 1 and 3. Creation of the vaccines used an approach previously used to make the new type 2 polio vaccine nOPV2, currently being deployed extensively. Testing in mice showed them to be effective and genetically stable and they are now being assessed in human trials. The paper was also selected for comment in a *Nature* editorial, a *Nature* News and Views item, as well as on the Agency LinkedIn site and in the UK media.

Measles and rubella elimination

1.5 We attended the UK national verification committee for measles and rubella elimination. The collation and submission of evidence is the responsibility of the UK Health Security Agency (UKHSA). Evidence is reviewed at the meeting ahead of agreeing the final report for the WHO.

Group A streptococcus

1.6 A collaboration between the MHRA R&D Conjugate Vaccines group, Sheffield University, LSHTM and MRC Unit on Group A Streptococcus has resulted in a publication in the *Journal of Infectious Diseases*, "Streptococcus pyogenes colonization in children aged 24-59 months in The Gambia: Impact of Live Attenuated Influenza Vaccine and associated serological responses". This publication helps to highlight risk factors and prevention of Group A Strep colonisation.

Alzheimer's Disease

1.7 We participated in the Alzheimer's Disease Vaccine Roadmap Workgroup meeting. Here, companies presented an overview of their Alzheimer's Disease vaccine pipeline and development status, while regulatory bodies offered their views on future regulation of such products. This work is progressing in line with the Life Sciences Vision mission on Dementia and we are collaborating with the Office of Life Sciences on the regulatory requirements.

Scientific collaborations

1.8 A University College London MSc student, supervised in the R&D Vaccines team, successfully completed their final project, "The Role of Standardisation of Serological Assays in Fighting Emerging Viral Infections". The project was an analysis on how many COVID-19 vaccine clinical studies reported the immunological responses in WHO International Standard units. The work highlighted the scarce use of the international units, despite an unprecedented high global distribution of the Standard, suggesting more education is needed on the use of this reference material.

Multiplex immunoassay development

1.9 Collaboration between the R&D Microbial Toxins (Vaccines) team and Serum Institute of India has led to development and validation of a bead-based assay to test antibodies against multiple antigens simultaneously, using WHO reference standards. Results have been published in *Frontiers in Immunology*. The multiplex immunoassay can estimate levels of serum immunoglobulin G (IgG) antibodies for pertussis, diphtheria and tetanus toxoids. The assay demonstrated increased sensitivity, reproducibility and high throughput capabilities, allowing design of robust studies evaluating natural and vaccine-induced immunity.

Outreach presentations to students

1.10 We gave a presentation to MSc students at the University of Leeds School of Molecular and Cellular Biology about some of the R&D work at MHRA and talked with students about potential scientific careers. A STEM event was organised at the Beech Hyde Primary School. The MHRA staff talked to students about bacteria, viruses and vaccines, with activities such as creating organisms with modelling clay, and playing a card game that demonstrates how viruses and bacteria can spread and how vaccines are important in stopping that spread.

HEALTHCARE ACCESS

Licensing performance

2.1 In our ongoing work to meet predictable performance timelines for medicines authorisations by January 2024, an engagement session was held with industry representatives going through progress with new ways of working under discussion with the Task and Finish group. This presentation highlighted some of the new processes which we are working on, including how we can ensure that the applications are received and processed 'right first time'. Specifically, the validation process, Customer Experience Centre processes, potential checklists for internal company use, and an understanding of the training program for assessors were discussed along with a Q&A session. It is now planned to continue the 'right first time' sessions with open MHRA clinics for different stages of the application process. The MHRA publishes performance statistics on 15th of each month.

Adrenaline autoinjectors

2.2 We launched a public health campaign on adrenaline autoinjectors, which seeks to give patients, healthcare professionals and the general public information on the best use of these life-saving medicines in the event of an anaphylaxis event. The campaign launched in alignment with World Allergy Awareness Week and will capitalise on seasonal milestones and opportunities from June until end of October to leverage influential voices across traditional and social media to engage target audiences.

Patient engagement

2.3 The biological products team and patient engagement team collaborated to carry out three separate patient engagement activities regarding a new gene therapy product for treatment of sickle cell disease and transfusion dependent beta thalassemia. Individual meetings with a total of four patient representatives were attended by assessors and discussions on the patient lived experience and thoughts on gene therapy were explored. One of the patient representatives is the CEO of the sickle cell society charity. This was an exceptionally useful and productive exercise for the assessors and the patients.

Medtech regulatory reform

2.4 We announced that CE marking on medical devices would be accepted until mid-2028 or mid-2030 depending on device type. Also, the In-Vitro Diagnostics (IVD) Expert Advisory Group has fed back on future classification rules. There are opportunities to refine the future classification rules considering the needs and trends of IVDs. The IVD Classification rules started with the International Medical Device Regulators Forum rules that were developed pre-pandemic and had not considered the new direction for IVDs following the pandemic.

PATIENT SAFETY

Sodium valproate harm reduction

3.1 Several meetings were held with key stakeholder groups including patient charities, healthcare professional bodies and standards organisations to gain support for the implementation of the strengthened oversight of initiation of valproate in view of the serious harms in pregnancy and growing evidence of male reproductive adverse effects. The key change advised by the Commission on Human Medicines is the requirement for two prescribers to confirm that alternative anti-epileptics are ineffective or not tolerated. The MHRA presented a summary of the latest data on the harms of valproate and awareness was raised of the serious nature of the harms.

Lenalidomide pregnancy prevention programme

3.2 Lenalidomide is an important anti-cancer medicine that is structurally related to thalidomide, a known teratogenic medicine which causes birth defects. A joint pregnancy prevention programme for lenalidomide products, the 'Pathfinder PPP', was approved by MHRA following collaboration with NHS England and the British Generics Manufacturers Association. This programme has been shortlisted as a finalist for the Health Service Journal Patient safety awards, to be announced in September 2023, under the "Improving Medicines Safety" category. This new digitally enabled programme could be a prototype for risk minimisation for other teratogenic medicines.

Calcium gluconate dosing recommendations

3.3 Following Yellow Card reports of medication error, new warnings were issued on the correct dosing of calcium gluconate in the management of high blood potassium levels (hyperkalaemia). Calcium salts (either calcium chloride or calcium gluconate) are used to stabilise the myocardium and prevent cardiac arrest in patients experiencing severe hyperkalaemia. However, the two salts are not equivalent in terms of calcium dose. Healthcare professionals were advised to ensure the correct dose of calcium gluconate is administered to avoid underdosing. If treated sub-optimally, hyperkalaemia can be fatal.

Clinical Practice Research Datalink

3.4 The public health impact of use of CPRD data is measured using a combination of qualitative and quantitative measures. The CPRD publishes summaries of all approved protocols and the resulting publications on its website. As of 8 June 2023, there were a total of 3,307 peer-reviewed publications using CPRD data. More recently, CPRD conducted an exercise to measure the number of high-impact publications in ten top-ranked journals based on impact factors in the last 5 years (1 June 2018 to 1 June 2023) and found 135 (10.6%) of the publications in this period, met this criterion.

Criminal enforcement

3.5 The month of June 2023 saw the completion of a complex and long-running investigation by the Criminal Enforcement Unit (CEU) in which a defendant was sentenced at the Nightingale Court in Wolverhampton to five years imprisonment for the illegal possession and intent to supply of prescription medicines. The defendant had been identified as associated with a website that was illegally trading in such medicines. When officers from the CEU, supported by West Midlands Police, searched his home address he was found to be in possession of over 23,000 doses of powerful medicines including zopiclone, zolpidem and zolpidem tartrate. Subsequent analysis of bank accounts indicated that the defendant had received more than £2m from the illegal sale of medicines. Separately, CEU operational activity, in partnership with Merseyside Police, led to the seizure of a significant quantity of illegally traded medicines, most notably, unlicensed botulinum toxin.

DIGITAL AND TECHNOLOGY

Adverse event reporting

4.1 Our legacy adverse event reporting systems are being decommissioned through the SafetyConnect programme. As such, the integration of Yellow Card with electronic healthcare record (EHR) systems has been migrated to the Yellow Card Vigilance Hub. The delivery of this functionality within the Hub has also enhanced management of incoming reports so they conform to regulatory data requirements. These enhancements will support the integration of a wider range of safety reports from different systems. In addition to EHR migration, this recent production release has enhanced the Manufacturers Online Reporting Environment (MORE) for device incident reporting based on industry feedback. Enhancements include performance improvements, simplification of web-forms, improved validation error alerting and auto-population of organisation data to save time for users.

Signal detection and case management

4.2 The Medicines HALO case management and signal detection systems are scheduled to go live this summer, requiring one of the most complex data migrations in the Agency's recent history. For medicines alone, the programme will migrate circa 13 million case records, which have 47million reactions reported against 60m drugs from Sentinel to the new case management and signal detection platform. Backlog refinement and detailed planning is also under way for the delivery of a new Haemovigilance case management system and Devices Signal Detection. Data migration of c300,000 records from legacy systems has commenced requiring close collaboration with external partners such as Serious Hazards of Transfusion (SHOT), and with blood establishments. This phase of the programme will deliver a case management system for internal users and a new reporting platform for external users and further reduce the Agency's dependency on Lotus Notes infrastructure.

Regulatory Management System

4.3 A joint meeting of the Executive Committee and Regulatory Management System (RMS) Project Board took place on 14 June to review the current programme scope, timelines and budget. Following a summary of the current delivery challenges, a new baselined plan was proposed together with associated end-to-end finances. Following this joint meeting a further discussion on the ambition of the RMS project has been held with the Agency Board, taking into account new priorities such as new regulatory pathways. Following the move of the Senior Responsible Officer to a new role, a new SRO for RMS has been appointed.

NIBSC e-mail change

4.4 This month, a D&T project team has worked collaboratively with the Comms team and key suppliers to deliver a change to @nibsc.org email addresses to support the 'One Agency' objective. The @mhra.gov.uk email address is now the primary email address for all MHRA staff. The new email addresses have also been updated in applications, such as MS Outlook and Fusion. To ensure a smooth transition for our customers, partners and stakeholders, colleagues will still be able to receive emails sent to old @nibsc.org email address until further notice. The team are continuing to work closely with the Comms team, key suppliers and stakeholders from South Mimms to work through mop-up activities and the next phase of work, which will look at making the change for shared mailboxes. This will require further analysis and testing to ensure a smooth transition.

Freeze Dryer Project

4.5 Planning is under way to ensure works on the freeze dryer project can be completed by December 2023. Key activities include working with procurement to produce the tender documentation for the next freeze dryer upgrades, which will include updating the Supervisory Control and Data Acquisition (SCADA), Programmable Logic Controller (PLC) and Human Machine Interface (HMI) on the C150 and CS15 Freeze Dryers. The route to market is currently being reviewed to ensure expenditure within the 23/24 financial year.

Laptop Refresh

4.6 Digital and Technology Group is nearing completion of the Laptop Refresh project, with nearly 1,000 colleagues now set up with a brand-new Microsoft Surface 4 laptop in exchange for an end-of-life Lenovo laptop. The project team is continuing to work with the remaining 20 users available to organise a laptop exchange in July. The remaining ~45 colleagues who are not available for reasons such as sick leave will be notified to the Helpdesk to organise a laptop exchange at a convenient time. The team is also continuing to work through the final closure activities, including the decommissioning of Lenovo laptops.

COMMUNICATION AND ENGAGEMENT

Customer insight projects

5.1 We coordinated a debrief of all customer insight projects covering: reputation analysis (across public, industry and healthcare audiences); Customer Experience Centre satisfaction (current customers); Patient Engagement sessions (software as a medical device; safety messaging). Overall, the results highlighted consistent themes across our audiences. Our next steps are to further refine these reports with follow up questions and alignment with our upcoming business plan before informing stakeholders of the salient insights.

Patient and public enquiries

5.2 The Customer Experience Centre (CEC) compiled the most common patient and public enquiries for the Patient and Public Health Committee to keep up to date on themes and trends. Covid related queries continue to dominate much of our patient and public queries on authorisation, safety and surveillance data. Other low volume but high-profile topics include isotretinoin, Emerade adrenaline auto-injector and information on pending applications about assessment timeframes, where a member of the public may have heard in the media about a new treatment for a condition. The CEC works closely with relevant groups and teams to ensure we have lines to take in response to these types of queries. Over the last six months, the CEC has handled on average 5,500 enquiries per month.

PARTNERSHIPS – NATIONAL AND INTERNATIONAL

International recognition framework

6.1 The development of the framework for international recognition, to support speedy access to medicines approved by other stringent regulators has reached a point where this was shared with representatives from innovative medicines and established medicines industry. Companies welcomed the thinking and development of the ideas and appreciated being consulted. There is an agreement that the framework is globally aligned but also pragmatic in that lifecycle management is also being incorporated which is over and above the approach of other regulators. The next steps comprise publishing guidance in August following frequently asked questions and some worked examples being completed in July.

International cooperation

6.2 Several key staff attended the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) assembly and International Pharmaceutical Regulators Programme (IPRP) Management Committee at the 46th ICH conference in Vancouver. The Agency contribution was welcomed, in particular in the work on pregnancy and lactation requirements. While MHRA participates in 20% of the ICH working groups, further collaboration in topics which will be developed and used by the agency is under consideration. The opportunity both to contribute and to develop our staff with expertise in the different ICH topics will receive prioritisation and focus in the agency.

Access Consortium

6.3 Under the UK Chairmanship, the Access Consortium (Australia, Canada, Singapore, Switzerland and the UK) presented a session at the Drug Information Association (DIA) 2023 Global Annual Meeting to create awareness of the Access worksharing procedures which compare favourably with the performance of other major regulators. The session also provided an opportunity to announce the new expedited 'Promise' pathway. The Access session was well-received, and several new ideas were raised in the audience Q&A which will be evaluated taken forward. The Access Heads of Agency meeting was held in the margins of the DIA 2023 Global Annual Meeting and progressed a number of current topics including options for a dedicated Access Consortium website, based on an analysis of requirements from all Access partners.

Windsor Framework

6.4 On 9 June we announced plans for medicines under the Windsor Framework. The Windsor Framework sets out a long-term set of arrangements for the supply of medicines into Northern Ireland. They will ensure that medicines must be approved and licensed on a UK-wide basis by the MHRA, with medicines using the same packaging and labelling across the UK. The European Medicines Agency will have no role in approving or licensing new drugs for provision in Northern Ireland. These new arrangements will take effect from 1 January 2025, with existing arrangements for supplying medicines to Northern Ireland applied in the meantime. accompanied by new guidance and stakeholder communications to engage those impacted in the changes of which they need to be aware.

DYNAMIC ORGANISATION

Corporate Plan 2023-26

7.1 We have published our Corporate Plan for the next three years, setting out how we plan to keep patients safe by enabling access to innovative, safe and effective medical products. This clear and concise plan sets out the central priorities for the agency over the next three years with 4 strategic priorities: to maintain public trust through transparency and proactive communication; to enable healthcare access to safe and effective medical products; to deliver scientific and regulatory excellence through strategic partnerships; and to become an agency where people flourish alongside a responsive customer service culture.

Health and Safety

7.2 The Agency's policy on Managing Organisational Change has been updated to ensure that the risks of changes are assessed early in a change process. A risk assessment checklist based on guidance from the Energy Institute has been added as an Appendix to the policy. We are developing a document which maps the safety critical roles and activities undertaken across the Agency. This will be used to support a new change management process, to ensure it is robust and the impact of any changes to safety critical roles and activities are fully assessed and managed. We have included this key activity in the 2023-24 Health and Safety Action Plan, with a target date of end Quarter 3. This will be monitored by the South Mimms Main Health and Safety Committee, with oversight from the Health and Safety Strategy Group.

Cost of living

7.3 In early June the Cabinet Office announced a one-off non-consolidated cash payment of £1,500 to all delegated grade civil servants (not part of the Senior Civil Service). The cost of this will be met within our existing budget. The precise payment and eligibility criteria are being finalised across the civil service and if this can be concluded, we plan to pay the amount with the July salaries at the end of this month.

AGENCY PRIORITIES

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

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

ii. Lead the development of a new reformed Medtech Regulatory Framework in line with the recommendations of the Life Sciences Council Advisory Group

iii Refresh the Innovative Licensing and Access Pathway together with partner organisations and establish the Innovative Devices Access Pathway, in line with the Mclean Report

iii. Refocus the regulatory management system programme taking account of evolving priorities and the opportunity to better integrate with the work on process transformation

iv. Strengthen the visibility and accessibility of the Agency leadership, building on the positive experience of the newly introduced Shadow Executive Committee, and other local initiatives.

Dr June Raine
July 2023

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

11 July 2023

Title	**What was the operational performance of the MHRA for this year up to 31 May 2023?**
Board Sponsor	Rose Braithwaite
Purpose of Paper	Assurance

What was the operational performance of the MHRA for this year up to 31 May 2023?

1. Executive Summary

1.1 Financial performance at the end of May shows at an Operating Surplus of £2.2m.

1.2 The May financial position includes most of the 2022-23 year-end corrections flagged in the April report with the resulting decrease in Other Operating costs.

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

1.4 Our customer debt has reduced by £2.7m to £10.1m in May, reflecting a significant reduction in Agency outstanding debts. This means that we are reporting £1.5m better than the target of £11.6m for total debt (one month of budgeted trading income). Our continued focus on clearance of debt aged over 6 months has enabled us to report debt older than 6 months of £2.2m at the end of May. This means that we continue to meet our aged debt target of having less than 20% of our total budgeted debt in that bracket (i.e. less than £2.3m).

1.5 The people resource within the Agency remains critical in terms of capability, capacity, and quality and ultimately to Agency performance for patient, business and financial outcomes. We continue with a concerted effort to finish recruiting into the new structure and are now seeing the benefits of this with a vacancy rate at 10%. We are now focussing on delivering incremental improvement by targeting highest impact recruitment and reducing sickness absence.

2. Financial Performance

AGENCY PERFORMANCE - REVENUE

Table 1 - Agency revenue performance to the end of May 2023

£million	May 23 Actual	May 23 Budget	Variance vs Budget %	YTD Actual	YTD Budget	Variance vs Budget %	2023/24 Full year Budget
Trading Income	11.7	11.8	-1%	22.1	23.4	-6%	138.9
Income from DHSC	1.7	1.7	0%	3.4	3.4	0%	20.6
TOTAL INCOME	13.4	13.5	-1%	25.5	26.8	-5%	159.5
Staff Costs	6.8	7.6	-11%	13.6	15.3	-11%	94.9
Operating Costs	4.4	4.8	-8%	9.9	9.6	3%	60.4
Project costs	0	0.7	-100%	0.1	1.1	-91%	3.8
TOTAL EXPENDITURE	11.2	13.1	-15%	23.6	26	-9%	159.1
OPERATING SURPLUS	2.2	0.4	14%	1.9	0.8	4%	0.4

Income

2.1 The Agency receives most of its funding from trading income realised in the performance of its regulatory obligations, supplemented by direct funding from its sponsor department, the Department for Health and Social Care (DHSC). The trading income budget for the financial year 2023/24 is £138.9m. The most material element of this, £43.9m or 32% of trading income, is the Periodic fee for those holding a marketing authorisation. The periodic fee funds safety and surveillance and other activity that is not directly fee-earning.

2.2 Other significant income streams for the Agency include:

- Licence Applications, Renewals and Variations income is budgeted at £24.5m, 18% of trading income. Much of this income is realised in Healthcare Quality & Access (HQA) in the assessment of applications.
- The Sale of Goods and Services by the Scientific Research and Innovation (SR&I) Group, including the sale of standards and grant and contracts income is budgeted at £26.8m, 19% of trading Income.
- Income from Clinical Practice and Research Datalink (CPRD) data access licence fees is budgeted at £16.3m, or 12% of trading income.
- Income from Inspections such as Laboratory, Manufacturing, Distribution and Clinical Practice inspections amongst others, is budgeted at £8m, 6% of trading income.
- The sale of the British Pharmacopoeia and associated standards is budgeted at £5.6m, 4% of trading income.

2.3 The Agency also realises income through other regulatory activity such as the regulation of clinical trials and medical devices and the provision of scientific advice.

2.4 The trading income budget is slightly lower than that previously approved by Board because of a reduction in DHSC Covid funding £0.6m and a £0.9m reduction in the CPRD income budget after further analysis on expected activity.

2.5 Trading income in May was £11.7m, only 1% below budget, a significant improvement on April's result, leading to an overall YTD trading variance of 6% in the first two months of the financial year. Compared to April, the most material improvement in May's results was an increase in income from the Sale of Goods and Services in the Scientific Research & Innovation (SR&I) group. Otherwise, most groups performed around budget, except for Healthcare Quality & Access (HQ&A) which is down on income because of a lag in Inspections invoicing and a delay in the impact of the new, higher, fees (see para 4.9 below).

Staff Costs

2.6 Staff costs in May were £0.8m below budget. Half of this variance is due to the pay award profiling which is across the entire year in advance of final agreement and the use of average salaries to create the budget when first set. The balance represents a small number of vacancies for recently approved posts that have been agreed to support backlog clearance that are currently going through the recruitment process.

Non-Pay Costs

2.7 Spend on other operating costs was £0.4m (7%) under budget in May. This was expected due to the large number of corrections to 2022/23 costs that had incorrectly fallen into April 2023. The YTD position is a 3% overspend to budget. A few corrections still need to be implemented which will reduce spend further. The small overspend YTD is due to Contracted Out Services spend in Digital and Technology and Laboratory Costs spend in SR&I.

Project Expenditure

2.8 Project expenditure represents the resource spend on various projects being implemented during the year including Regulatory Management System (RMS) and SafetyConnect. Revenue change costs were £0.7m under budget in May, following a correction of April postings, a £0.7m underspend to budget was experienced in the month, and a £1.2m underspend to the budget YTD representing an 80% shortfall to budget. Schemes are being discussed at the Strategic Change Committee to better understand the delivery profiles for the rest of the year.

AGENCY PERFORMANCE – CAPITAL

2.9 All of the capital budget has to be provided either by DHSC or from other Government Departments via the Commissioner Pays model which allows for the transfer of capital budget between departments. The Agency capital bid to DHSC is summarised in Table 2 below. This does not include capital funding being provided by OLS (now MedTech) for the Innovative Devices Access Pathway (IDAP). The allocation of capital funding across the DHSC remains under review.

Table 2 - Agency capital funding

Capital	Budget 23/24 (£'000)
SR&I Capital	6,000
Safety Connect Programme	1,096
Regulatory Management System (RMS)	13,924
CPRD schemes	2,812
D&T Capital	1,660
Total	**25,492**

2.10 £13.9m of the capital funding received is allocated to the development of the new Regulatory Management System (RMS). As in previous years, we have also received £6m of baseline capital funding from DHSC to support essential work at our South Mimms site. Other significant capital investment in for 2023/24 includes the development of CPRD's Trusted Research Environment and associated platforms that will enable improved business development in future years.

2.11 Capital costs are currently reporting a £1.6m underspend to plan (details are in table 3). This is mostly due to lower than budgeted expenditure on RMS with all other variances being very small. This is a timing difference with the budget profiling based on the original plans that have subsequently changed. RMS costs will significantly increase during the year, mostly in Q2 onwards and we are due to sign a critical contract early in July. RMS comprises 55% of the total approved capital budget.

Table 3 - Agency capital performance to the end of May 2023

Capital	May Actual £m	May Budget £m	Variance vs Budget %	YTD Actual £m	YTD Budget £m	Variance vs Budget %	23/24 Forecast £m	23/24 Budget £m
SR&I Capital	0.1	-		0.4	0.1	300%	6.0	6.0
Other Capital	1.0	2.0	-50%	2.1	4.0	-48%	19.5	19.5
Total	1.1	2.0	-45%	2.5	4.1	-39%	25.5	25.5

Customer Debt Levels

2.12 The Agency has debt balances of £10.1m outstanding at the end of May, a reduction of £2.7m compared to April (see table 4 below).

Table 4: Agency aged debt balances March & May 2023

Aged Debt	Apr £	Apr %	May £	May %	Increase/ Decrease £
0-30 Days	6,174,285	48%	3,418,126	34%	-2,756,160
31-60 Days	3,102,878	24%	2,177,005	21%	-925,873
61-90 Days	216,416	2%	1,323,862	13%	1,107,446
91-180 Days	1,372,469	11%	988,572	10%	-383,897
181-365 Days	755,926	6%	765,510	8%	9,584
365+ Days	1,259,525	10%	1,476,338	15%	216,812
Total	12,881,500	100%	10,149,413	100%	-2,732,088

2.13 The Agency performance against agreed cash management KPI's are advised below, both targets have been achieved in May:

Debt management Performance:

			On target / Off target		
KPI's	**May £m**	**Target £m**	**May**	**April**	**Comments**
Total Debt	10.1	<11.6		£1.3m above target	Less than one month budgeted trading income should remain outstanding
> 6 month old debt	2.2	<2.3			Less than 20% of targeted total debt should be in excess of 6 months old

All figures rounded to one decimal place

3. People Performance

3.1 We had 1,168 people in establishment posts in May 2023 (FTE, permanent, fixed term and contingent workers covering established posts), an increase of 15 compared to April.

3.2 There has been a further reduction in our turnover of staff to 12% so within the levels considered 'healthy' by the CIPD (10-15%). Despite a challenging employment market for all sectors, we continue to see an increase in the number of joiners versus leavers, reflected in our decreased turnover. We welcomed 20 new starters to the Agency in May versus 6 voluntary leavers, in addition we had one Contingent Labour placement appointed into a permanent role.

3.3 Chief Officers and hiring managers prioritise their recruitment based on their business needs. In May there were 37 new advertising campaigns opened for 45 roles.

3.4 In respect of our 130 'vacancies' these are split by Group as follows:

Group	Vacancies Count	Vacancies FTE	Employee Count	Employee FTE	% of vacancies FTE
Corporate	14.0	13.5	102.0	101.2	13.3%
Digital and Technology	23.0	23.0	99.0	97.8	23.5%
Enablement	14.0	13.4	95.0	91.7	14.6%
HQA	28.0	27.0	354.0	342.7	7.9%
Partnerships	1.0	1.0	27.0	26.6	3.8%
S&S	25.0	24.5	279.0	272.2	9.0%
SR&I	25.0	25.0	245.0	239.4	10.4%
Grand Total	**130.0**	**127.4**	**1,201.0**	**1,171.5**	**10.9%**

3.5 The highest percentage of vacancies are within the Digital and Technology Group (D&T). However significant progress has been made since last year when vacancy levels were as high as 44%. Where necessary resource requirements are filled using professional services contracts and contingent labour, although the bulk of these are used to deliver on projects where roles are temporary. There are some other areas where recruitment continues to be challenging particularly where industry experience is needed (eg GMP within HQ&A). Changes in our targeting of recruitment resulted in improved responses and appointments from the last campaign. A further campaign launched at the end of June.

3.6 Sickness absence is currently reducing at 6.8 days per FTE (annualised April 2022 – May 2023) and by Group this was:

Group	Average by FTE
Corporate	11.6
D&T	1.8
Enablement	9.1
HQ&A	8.2
Partnerships	10.7
S&S	3.5
SR&I	7.2
Agency-wide	**6.8**

3.7 The long and short-term sickness split by Group is not given as it could inadvertently identify colleagues, particularly in the smaller Groups or where absence is attributable to one person. 60% of all Agency absence is long term, which is any absence over 21 days.

4 Group Performance

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

4.2 Income for the groups now includes Periodic fee income directly allocated to each operational group to provide a more comprehensive presentation of fee-earning areas financial performance. Further work is being done to complete the corporate recharge allocation which will be applied to the group analysis from next month.

Scientific, Research and Innovation (SR&I)

May 2023 Scientific, Research and Innovation	Period Actual £m	Period Budget £m	*Variance vs Budget %*	YTD Actual £m	YTD Budget £m	*Variance vs Budget %*	23/24 Forecast £m	23/24 Budget £m
Total Income	3.7	3.8	-3%	6.8	7.4	-8%	40.9	40.9
Total Costs	2.0	2.0	0%	4.0	4.0	0%	24.1	24.1
Total Operating Surplus	**1.7**	**1.8**	**-6%**	**2.8**	**3.4**	**-18%**	**16.8**	**16.8**
All figures rounded to one decimal place								

4.3 SR&I had a total operating surplus of £1.7m, which is £0.1m (6%) below budget. In terms of the YTD position, because of a slow start to the year in April, the operating surplus is 18% behind budget. Both are due to lower-than-expected income.

4.4 May's income of £3.7m was only 3% under budget, a significant improvement on April's 18% negative variance, due to higher income from the Sale of Goods and Services as sales improve. The performance of Sample Testing also improved. Grant income, however, remains low against the budget.

4.5 Operational expenditure in May was £2m and £4m YTD, and both were in line with budget with small underspends in staff costs making up for overspends in Laboratory Costs.

4.6 The most recent validated set of performance metrics for the Clinical Trials assessments teams up to the end of May 2023 were published on the MHRA website on 15 June 2023 and have already been circulated to the Board.

4.7 In June 2023 the working total of clinical trial applications and amendments received by the MHRA and those authorised were at similar levels based on the working figures with 63 new trial applications and 385 amendments received and 46 new trials and 321 amendments authorised. The final performance data for June is being validated and will be published on the MHRA website on July 15 2023.

4.8 In parallel, a new and innovative risk-proportionate process has been developed and tested that enables the team to dynamically allocate the most appropriate resourcing to each application. This allows for the robust scrutiny of each application, ensures the safety, efficacy and quality of the trial to our usual high standards, and delivers our decision sooner. This approach has been evaluated and endorsed by external experts in clinical trials. It will be presented more widely to the clinical trials community in line with the target to return to normal levels of service by 1 September 2023.

Healthcare Quality and Access (HQ&A)

May 2023 Healthcare, Quality and Access	Period Actual £m	Period Budget £m	*Variance vs Budget %*	YTD Actual £m	YTD Budget £m	*Variance vs Budget %*	23/24 Forecast £m	23/24 Budget £m
Total Income	4.4	4.8	-8%	9.0	9.7	-7%	58.9	58.9
Total Costs	2.4	2.6	-8%	5.2	5.3	-2%	32.7	32.7
Total Operating Surplus	**2.0**	**2.2**	**-9%**	**3.8**	**4.4**	**-14%**	**26.2**	**26.2**
All figures rounded to one decimal place								

4.9 HQ&A finished May with a total operating surplus of £2.0m, this was £0.2m (9%) behind its budgeted surplus.

4.10 Income in May was 8% behind budget, contributing to a YTD under performance of 7%. Some of this is due to the invoicing schedule for inspections, with income being recognised towards the end of the quarter. The remaining variance to budget is mostly explained by an incorrect assumption in the budget profiling that the uplift in the Agency's fees and charges would mean a rise in income from the start of the year when the new fees took effect. A lag should be expected before the impact of the fees increase can be seen, as much of the work in early 2023/24 will be on assessments submitted under the old fees and charges. We will assess the impact of this as part of our reforecasting at the end of the first quarter.

4.11 HQ&A expenditure in May was slightly below budget by £0.2m (8%), reducing the YTD overspend to 2% on budget. Staff costs, T&S and Training continue under budget.

4.12 The latest published performance metrics for HQ&A on New Marketing Authorisation Applications and Variations up to the end of May 2023 were published on the MHRA website on 15 June 2023 and have already been circulated to the Board.

4.13 Validation metrics show all processing times reducing after significant numbers of personnel changes, with validation for national applications tracking to be within 14 days of submission by Q2 23/24, which will then support ongoing real-time assessment activities. Validation of variations is being worked on as the next priority.

4.14 We are seeing increases in the number of approved variation submissions, and stability or reduction in the time taken before decision. We are on track to deliver against our commitment to handle variations within statutory timeframes from 1 July 2023; this has been our highest priority. We anticipate applications being cleared from our backlog after this date for approximately 3 months.

4.15 For national applications for Marketing Authorisations for Established Medicines, the number of applications assessed remained stable in May with the reduction in mean time to first RFI (Request for Information) which we saw in April being maintained.

4.16 We continue to improve our communications with applicants tracking the trends and questions through our Customer Experience Centre to track the impact. Whilst the numbers of status request updates remain high, the total numbers of requests were seen to reduce in May.

4.17 Full performance data for June will be available for publication on our website in line with our usual schedule on 15 July 2023. However emerging data indicates and improving position; 60 Marketing Authorisations for new generic medicines were granted in June, up 38% on May. Whilst the average gross time for assessment for national MA was slightly higher than in May, this is due completing older applications. Our approval rate for determination of 1B variations for Generic Medicines is up 16% in June.

Safety and Surveillance

May 2023 Safety and Surveillance	Period Actual £m	Period Budget £m	*Variance vs Budget %*	YTD Actual £m	YTD Budget £m	*Variance vs Budget %*	23/24 Forecast £m	23/24 Budget £m
Total Income	5.5	5.0	10%	10.2	9.9	3%	59.4	59.4
Total Costs	1.9	2.6	-27%	4.1	5.1	-20%	32.1	32.1
Total Operating Surplus	**3.6**	**2.4**	**50%**	**6.1**	**4.8**	**27%**	**27.3**	**27.3**
All figures rounded to one decimal place								

4.18 Safety and Surveillance (S&S) had a significant operating surplus of £3.6m, which is £1.2m (50%) better than budget. The YTD operating surplus is 27% better than budget. This is driven both by higher than budgeted income, and lower spend.

4.19 Income in May was £5.5m, 10% over budget, driven by higher Variations and Periodic fee income.

4.20 Spend in May was £1.9m, £0.7m under budget, contributing to an overall YTD underspend of £1m. This is due to lower spend on staff and IT costs. Both are expected to increase in the coming months.

Corporate recharges & non-fee earning groups

4.21 We have a number of non-fee earning groups which directly support our three fee-earning areas. These include Partnerships, Digital & Technology, Corporate and Enablement Groups. These form the basis of Agency corporate charges that, as in each year, will be shared across Agency operational areas to recognise where costs should be borne. Periodic fees previously reported within Corporate recharges are now directly allocated to each fee earning group as part of trading income.

4.22 Further work is being done to check and challenge the recharging model before it will be reported within individual group figures for future reporting. Details will be included from Q2 after this work is completed.

4.23 Financial performance for each of the non-fee earning group has been outlined below:

Corporate overhead groups	May 2023	Period Actual £m	Period Budget £m	*Variance vs Budget %*	YTD Actual £m	YTD Budget £m	*Variance vs Budget %*	23/24 Forecast £m	23/24 Budget £m
Partnerships	Total Income	-	-	n/a	-	-	n/a	-	-
	Total Costs	0.2	0.2	0%	0.3	0.4	-25%	2.6	2.6
	Total Operating Deficit	**- 0.2**	**- 0.2**	0%	**- 0.3**	**- 0.4**	-25%	**- 2.6**	**- 2.6**
Digital and Technology	Total Income	0.1	0.1	0%	0.2	0.2	0%	1.1	1.1
	Total Costs	2.9	2.3	26%	4.8	4.7	2%	31.4	31.4
	Total Operating Deficit	**- 2.8**	**- 2.2**	27%	**- 4.6**	**- 4.5**	2%	**- 30.3**	**- 30.3**
Corporate and Enablement	Total Income	0.3	0.2	50%	0.5	0.3	67%	1.9	1.9
	Total Costs	2.1	2.7	-22%	5.1	5.3	-4%	31.4	31.4
	Total Operating Deficit	**- 1.8**	**- 2.5**	-28%	**- 4.6**	**- 5.0**	-8%	**- 29.5**	**- 29.5**
Total Corporate	Total Income	0.4	0.3	33%	0.7	0.5	40%	3.0	3.0
	Total Costs	5.2	5.2	0%	10.2	10.4	-2%	65.4	65.4
	Total Operating Deficit	**- 4.8**	**- 4.9**	-2%	**- 9.5**	**- 9.9**	-4%	**- 62.4**	**- 62.4**
All figures rounded to one decimal place									

4.24 Partnerships has no income stream of its own. The operating deficit is reporting close to plan with only minor variances mainly due to lower staffing costs.

4.25 Digital and Technology finished May with a £0.6m adverse variance to budget. In terms of expenditure, the overspend of 27% was due to Contracted-Out Services costs remaining higher than budget because, as in 2023/24, we continue to have several companies that are required to provide key services for areas of work where we have yet to fill staff vacancies or to deal with peak workloads for projects such as RMS.

4.26 Corporate and Enablement reported a £1.8m operating deficit in May, which was £0.7m better than budget. Taking into account April's result, the YTD Operating Deficit is £4.6m, which is £0.4m (8%) better than budget. Income remains above target because of higher than budgeted Interest payments. Expenditure in May was £0.6m lower than budget because of corrections to April's results as part of the year-end process, including VAT and accrual corrections. Accommodation costs, however, remain above target because of spend on building repairs and maintenance. Overall, YTD spend is £0.2m (4%) below budget.

5 **Recommendation**

5.1 The Board is requested to note the updated report on Agency Performance, and that we anticipate eliminating backlogs by the dates provided to industry for meeting statutory timelines for compliant applications.

Rose Braithwaite
June 2023

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

11 July 2023

Title	**What are the strategic priorities in the MHRA Science Strategy to enable the faster access of safe and innovative products to patients in the UK?**
Board Sponsor	Glenn Wells
Purpose of Paper	Approval

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

1. Background

1.1 The MHRA both as a Public Sector Research Establishment (PSRE) and as a regulator, must deliver a scientific programme capable of enabling its regulatory functions and its role in supporting innovation.

1.2 This will be made possible through conducting intramural research such as the work carried out at South Mimms. This will be expanded through extramural collaborations with the UK (and international) research and innovation sectors.

1.3 In addition, and in line with Government policy, MHRA will support the development of Centres of Excellence in Regulatory Science and Innovation (CERSI) to capture further the world leading UK research community to ensure that the agency has access to cutting edge innovations to support its roles.

2. Summary

2.1 The MHRA Science Strategy document presented to the Board sets out the importance of building current capabilities, expanding and enhancing them through internal investment and leveraging of the UK research and innovation expertise across the sector.

2.2 The document has been created with support from Agency teams and the input of our Non-Executive Directors (NED), noting that it was not possible to engage with all NED colleagues before submission of the paper.

2.3 Consistent with the strategic nature of the document, reference is made to the need to accompany it with robust business planning and where needed bespoke implementation plans.

3. Recommendation

3.1 It is recommended that the Board approve the strategy allowing for amendments to be made following Board discussion and further stakeholder engagement.

Glenn Wells
July 2023

MHRA Science Strategy

Foreword

I am delighted to be setting out our scientific priorities for the next three years in our new science strategy. We aim to be bold and ambitious, to capitalise on our core strengths, and to build our capabilities in emerging segments, such as Artificial Intelligence (AI) and Software as a Medical Device (SaMD). This Strategy is a companion piece to our Data Science Strategy, which will be published shortly and sits alongside our wider agency priorities as set out in our Corporate Plan 2023-26.

We emerge from our transformation as an agency, structured around the product lifecycle and we have brought our data, research, scientific, commercial and regulatory functions under a single agency. This provides us with opportunities that are unique among global regulators and offers us the chance to deliver and exceed on our public health mission for patients in the UK.

Delivery of this science strategy will require close working with our partners, customers and stakeholders. Their involvement and collaboration are vital to the success of the ambitions set out here, as is the development of our excellent staff and scientists. The next three years bring challenges and opportunities; however, we will maintain our steadfast focus on patients and the public and ensure that our scientific endeavours deliver for them.

Dr June Raine DBE
Chief Executive Officer, MHRA

Introduction and strategic context

The MHRA is the UK's regulator of medicines, medical devices, and blood components for transfusion in the UK and is an Executive Agency of the Department of Health and Social Care (DHSC). With public health as the focus, its statutory functions support an end-to-end scientific, regulatory approach from early product development, through to enabling patient access to medical products.

Structured around the product lifecycle, the Agency is better able to make comparisons of data generated by the different statutory functions and more readily identify regulatory improvements and additional scientific knowledge requirements. In parallel the Agency supports a network of partnerships and collaborations including with international regulators to understand approaches to regulating new innovative products, responding to patient need and aligning with policy requirements.

The science strategy will look to strengthen and continue our key research activities that we deliver now as part of our UK and global offer. These include:

- **Our Centre for Biological Reference Materials** is the specialist facility for our formulation science research and development (R&D) and production of biological reference materials including lyophilised products and infectious materials.

- **Our WHO Essential Regulatory Laboratory of the Global Influenza Surveillance and Response System (GISRS)** generates reassorted viruses and distributes the resultant candidate vaccine viruses and serum standards for seasonal flu vaccines
- **The Influenza Resource Centre (IRC)** has played a key role in influenza vaccine standardisation and control for over 30 years.
- **Our WHO Collaborating Centre of Poliovirus Research and Surveillance** undertakes a national and global programme of polio vaccine development and assessment, R&D, surveillance and vaccine quality testing for other countries and at the behest of the WHO. Specialist expertise in essential in vivo testing of vaccines is unique to the MHRA.
- **National Control Laboratories**. We are designated as the UK's National Control Laboratory for Biological Medicines and Official Medicines Control Laboratory for Chemical Medicines, responsible for independently assessing batches of small molecule products, vaccines and blood products before they are used.
- **UK Stem Cell Bank.** The UK Stem Cell Bank is a unique strategic asset, placing the UK at the centre of the advanced therapy landscape, providing ethically sourced, quality assured human stem cell lines of adult, foetal or embryonic origins to prepare clinical-grade seed stocks for the development of stem cell therapies.
- **Clinical Practice Research Datalink.** The Clinical Practice Research Datalink (CPRD) is a real-world research service supporting retrospective and prospective public health and clinical studies.

MHRA will continue to innovate across these key areas of research as part of this Science Strategy.

MHRA is a critical part of the UK health and life sciences ecosystem promoting innovation in the UK as well as a globally respected regulator. This has been recently highlighted by the Life Sciences Vision and the recommendations arising from the Pro-innovation Regulation of Technologies Review: Life Sciences and the Commercial clinical trials in the UK: the Lord O'Shaughnessy review.

These three publications highlight the need for the MHRA to operate a robust and internationally competitive regulatory regime, maintaining expertise and capacity and capability to address current and emerging healthcare challenges.

This new Agency science strategy aims to grow this reputation for scientific excellence by both applying the science that is unique to the Agency and partnering with leading scientific experts to nurture new research areas for innovative medicines and healthcare products. The strategy will provide a framework on which the Agency can act on the relevant emerging and existing scientific areas identified by our experts and supported by horizon scanning that can be applied to improve regulation and support preparedness planning for future threats to public health.

This document sets out our scientific ambition for the next three years covering 2023-2026: continuing to deliver the best for patients, as part of the UK and global health systems and contributing to the growth of a vibrant UK life sciences sector.

Vision

The MHRA is a patient-focused and science-driven organisation, using research-based evidence to enable its regulatory role and to support innovation within and provide advice and guidance to innovators. MHRA is also a Public Sector Research Establishment (PSRE) with a globally proven reputation for scientific expertise and knowledge of developing products that are applied to regulatory and healthcare needs, creating unrivalled combination of world-leading specialist scientific expertise and regulatory disciplines.

MHRA research outputs are central to protecting the UK population and global public health through for example, our World Health Organisation (WHO) Collaborating Centre and International Laboratory for Biological Standards, of which we are the leading member. The MHRA will continue to align its regulatory science research programme strategically to anticipate and respond to UK and global public health needs, applying our global leadership, expertise and will develop/grow new scientific expertise to ensure innovative medicines and devices are fit for patient use. The science strategy builds from the vision and strategic goals outlined in our Corporate Plan, including the five priority themes:

- Vaccines and immunotherapies
- Biotherapeutics, cell and gene therapies
- Diagnostics and Genomics
- Data Science
- Artificial intelligence (AI) and software as a medical device

Our five scientific priority themes reflect the continued significant advances in medicines and medical devices and examples of how our ambitions for delivering across these themes will be achieved are given below.

Building our science base

Scientific knowledge and expertise are fundamental to us achieving our goals. Our scientists have a diverse expertise enabling them to perform cross-disciplinary translational laboratory research and data analysis, provide expert advice, and examine medical products both pre- and post- regulation to assure public and patient health. The MHRA makes evidence-based decisions and needs to generate and support the generation of this evidence, to provide the foundation of its ability to regulate effectively and ensure the safety of the UK population.

Over the next three years the MHRA will deepen is knowledge, capability and capacity across a range of scientific disciplines through research and will conduct or support this activity as follows:

Across the MHRA, **Our Research** activity will be focussed on addressing evidence generation to allow the agency to deliver its statutory function and provide the ability to address current and emerging medical technologies and challenges. Over the next three years, the MHRA will build on current scientific endeavours, enhancing this activity and aligning to our five core science themes. This will include not only our laboratory and data science research but will include actionable horizon scanning across the entire R&D lifecycle, ensuring that the agency is ready to support and regulate the most innovative healthcare products, enabling patient access to life changing technologies.

Recognising the world leading science in the UK, **Our Collaborations and Partnerships** will be used to deepen our scientific expertise and extend our research capacity and capability. The MRHA will work across the UK health and life sciences sector and build strategic partnerships internationally to support its science and evidence needs. Moreover, working closely with the UK research and innovation system will allow real time horizon scanning, enabling the agency to prepare for emerging innovations and their regulation, potentially reducing the time to market access.

Innovation in regulatory science is essential and requires long-term funding and commitment. Following the recommendation in the Pro-innovation Regulation of Technologies Review: Life Sciences, MHRA will support the creation of a network of **Centres of Excellence in Regulatory Science and Innovation (CERSI)**. The MHRA will continue to work with stakeholders to explore the establishment of centres addressing the five priority themes learning from international initiatives for example the US FDA CERSI programme.

Focus on the five priority themes

Vaccines and immunotherapies

Vaccines against infectious disease and those used as immunotherapies against cancers, are a powerful and oftentimes cost-effective component of a healthcare arsenal. Ideally used to prevent disease, vaccines can be used to control infection outbreaks and help stem the rise in antimicrobial resistance. The MHRA is at the forefront of biological medicine developments and has active research programmes looking at innovative vaccine platform technologies, such as mRNA-based vaccines for infectious diseases and cancer.
Our scientific programme will support the evaluation of product development and trial data to inform regulatory decisions and addresses key attributes of vaccines that are central to making informed regulatory decisions. Defining correlates of protection against infectious agents and developing the most relevant standardised assays to measure effectiveness will not only support the development of products but also the regulatory pathway.

Through Our Research and Our collaborations and Partnerships, by 2026 we will:

- Develop the capability to routinely investigate correlates of protection for so-called ‘escalating infectious diseases’ to enhance our understanding of the efficacy of vaccination and the predictability of multiple antigen responses.

- Develop and validate novel biological reference materials and novel assays for the evaluation of effectiveness, quality and safety of new platform technologies with multi-antigen efficiency targeting existing and new pathogen threats.

- Develop capabilities in the physical and bioinformatics standards required to meet HLA genotyping and epitope characterisation by high throughput sequencing, that will best support the use of cancer immunotherapies.

- Deliver the ambition of the 100 Days Mission, through strengthening our Pandemic and Escalating Infectious Disease programme so we are ready to respond promptly and confidently to global public health emergencies.

Biotherapeutics, cell and gene therapies

Advanced therapy medicinal products (ATMP), comprising gene therapy medicinal products, somatic cell therapy medicinal products and tissue engineered products represent a range of different therapeutic modalities but share many regulatory challenges. The MHRA has specialist facilities and capabilities that enable it to be a leader in the regulatory science of complex biological medicines including monoclonal antibodies (mAbs) with immunoinhibitory or immunostimulatory properties for the treatment of diseases like cancer, and advanced therapy medical products (ATMP) such as chimeric antigen receptor (CAR)-T cells.

Our scientific programme will focus on safety and efficacy of cell and gene therapy medicinal products our research on novel immunotherapeutic medicines, which include monoclonal antibodies, bi-specific antibodies, antibody-drug conjugates and cellular immunotherapies (e.g. CAR T cells) and 'cancer vaccines'. We aim to better understand when and why treatments may cease to work for certain patients, as this will be critical for effective clinical monitoring and decision making for switching to different products for disease management.

Through Our Research and Our collaborations and Partnerships, by 2026 we will:

- Develop the capability to routinely test new immunotherapies for safety and effectiveness, including sustained activity against their target, and the potential to stimulate adverse events; we will develop solutions to support the analytical assessment of product safety and efficacy of innovative therapeutic treatments for important pathologies such as cancer and inflammatory disease

- Through our UK Stem Cell Bank we will develop innovative solutions to address the challenges of quality and safety assurance for novel stem cell therapies, providing quality assured, ethically sourced and regulatory-compliant stem cells as starting materials for the development of cell therapies, broadening and fostering our interactions with a broad range of stakeholders.

- Have implemented a flexible regulatory framework that will provide clear guidance to manufacturers and support the development, clinical trials and manufacturing of cell, gene and personalised medicines to facilitate timely patient access.

Diagnostics and Genomics

Genomics is integral to genetic testing and Precision Medicine, with a recent report on personalised prescribing calling for a concerted national effort to make pharmacogenomic-based prescribing a reality for all in the UK. The UK has a world leading role in genomics, exemplified by the sequencing effort during COVID-19, and genomically targeted drugs, especially in cancer, will become increasingly common to optimise effectiveness and success rates. In parallel, pharmacogenomics offers the opportunity to understand the biological mechanisms of adverse drug reactions (ADRs), which has the potential to save healthcare systems millions of pounds in direct care and more in reducing mortality and morbidity.

As a regulator, MHRA must keep pace with the rapidly evolving landscape of genomics, genetic testing, and diagnostics. Genetic testing already is being aligned with diagnostic

regulatory frameworks but the regulation of genomics data for advancement of diagnostic devices needs to accelerate.

Our science programme will focus on deepening our capability and capacity to support innovate diagnostic technologies, validation of novel biomarkers and to develop systematic processes to understand the underlying mechanisms of adverse drug reactions and adverse events for medical devices to move from reactive mitigation to proactive identification and avoidance.

Through Our Research and Our collaborations and Partnerships by 2026 we will:

- Create a programme for rapid assessment of new diagnostic tests alongside developing suitable reference materials and to support the evaluation of clinical biomarkers identified by developers and manufacturers, including infectious (pathogens) and non-infectious (e.g. liquid biopsy, circulating tumour DNA) diseases.

- Based on the outcomes of the Yellow Card Biobank-Genomics England pilot project for assessing genetic associations with ADRs, develop an evidence base relevant to the use of vaccines, immunotherapies and personalised medicines through interrogation of patient surveillance data and clinical samples.

- Develop world leading biological measurement capabilities supporting global and UK healthcare for diagnostics, genomics as well as vaccines and ATMP, through work with international organisations such as the International Bureau of Weights and Measures (BIPM) (CCQM) and the International Federation of Clinical Chemistry and Laboratory Medicine.

Data Science

Real world data (RWD) is becoming an ever-increasing part of regulatory decision making. The convergence of new treatments, diagnostics, wearables, sensors and connectivity when coupled with electronic health records and advances in technology, offer opportunities to deliver a better evaluation, characterisation and stratification of the performance of medical products in development and in clinical practice.

New designs for clinical trials and investigations especially pragmatic trials, offer opportunities for faster, and more generalisable results at a reduced cost, a world class exemplar being the Recovery trial during COVID-19 which has saved millions of lives globally. The emergence of new analytical technologies, specifically artificial intelligence (AI) and machine learning approach (ML), is realising its potential through its use in modalities such as MRIs, mammographies and software integrated implantables.

Data science must evolve as novel diagnostics emerge along with data mining, data analytics, data pooling, data governance and data privacy for prognostic diagnostics and personalised treatment pathways.

Our science programme will focus on the development and delivery of a robust regulatory framework to ensure performance and safety.

Through Our Research and Our collaborations and Partnerships, by 2026 we will:

- Demonstrate Proof-of-Principle of the potential and the value of the use of bioinformatics in the Yellow Card Biobank, as a unique international resource of genomic information on ADRs.

- Demonstrate the utility of artificially generated information to emulate clinical trials and better reflect groups in society that are less well represented in clinical trials and investigations, including different age groups, social demographics and ethnicities.

- Develop the evidence base to and associated framework for assessment of in silico clinical trials through collaborative partnerships.

- Characterise and exploit the utility of The Observational Medical Outcomes Partnership (OMOP) common data models for broadening access to real world data to support regulatory decision making throughout the product lifecycle

Artificial intelligence (AI) and software as a medical device

Software as a Medical Device (SaMD) encompasses a range of applications including Artificial Intelligence (AI) and Machine Learning. These growing areas of innovation present a clear opportunity to support our healthcare ecosystem in a wide breadth of applications; including, but not limited to, use in treatment discovery, diagnostics, clinical treatment decision-making and condition management, as well as, as a tool to support regulatory functions in the future as our understanding of these technologies develop.

The SaMD and AI Change Programme announced by the MHRA earlier in 2023 highlights the significant body of work required ensure public and patient safety is protected whilst enabling the benefit of such technology to be realised through regulatory reform.

Our science programme will support this work examining quality, safety and efficacy characteristics of these devices including their capability to offer consistent benefit to all populations and serve diverse communities.

Through Our Research and Our collaborations and Partnerships we will:

- Develop and Pilot an AI airlock, and similar approaches, as enablers to improve our ability to robustly assess the scientific validity of AIaMDs during the development pipeline prior to deployment.

- Research the explainability of AI decisions in collaboration with clinicians and utilise this to develop practical working principles on interpreting complex medical device algorithms.

- Research the quality, fidelity, and privacy metrics of synthetic data to inform our ability to support the validation of AI and Machine Learning Algorithms.

- Develop a consensus view on identifying and handling significant change due to concept drift when assessing AI models in healthcare.

Centres of Excellence in Regulatory Science and Innovation

A recommendation from the Pro-innovation Regulation of Technologies Review: Life Sciences, led by the post of Government Chief Scientific Advisor, was the creation of a network of CERSI to push the boundaries of regulatory science and innovation in the UK. MHRA will work with policy teams across Government and with funders of research to engage with academia and industry on the creation of CERSI in areas of national priority.

Cross cutting areas of interest

Complementing the five priority themes, MHRA will engage on cross-cutting areas of work to be addressed through the full range of our science/research activities. The agency will seek funding to support these internally and in collaboration.

Life Science Vision: Healthcare Missions

The Life Sciences Vision (LSV) published in 2021 set out to support MHRA to be "…an independent, sovereign regulator able to act with great agility and a focus on getting vaccines, drugs, and technologies to patients as safely and quickly as possible."

The LSV also sets out Healthcare Missions in the following areas:

1. Improving translational capabilities in neurodegeneration and dementia.
2. Enabling early diagnosis and treatments, including immune therapies such as cancer vaccines.
3. Sustaining the UK position in novel vaccine discovery development and manufacturing.
4. Treatment and prevention of cardiovascular diseases and its major risk factors, including obesity.
5. Reducing mortality and morbidity from respiratory disease in the UK and globally.
6. Addressing the underlying biology of ageing.
7. Increasing the understanding of mental health conditions, including work to redefine diseases and develop translational tools to address them.

MHRA will support these missions through work on our strategic themes and by providing advice and support to innovators working to deliver novel approaches to addressing these challenges.

Antimicrobial Resistance

Antimicrobial Resistance represents a significant threat to public health and the UK government is committed to tacking the issue through the current National Action Plan and renewed commitment to partnerships in the recent Atlantic Declaration. MHRA already has significant expertise in microbial research and will build on this through collaboration with partners in the UK across the life sciences sector and internationally, to increase harmonisation across regulators.

Net Zero

MHRA has committed to delivering a Net Zero Strategy to include adapting the science estate to reduce carbon emission and to create standards, controls and reference materials that can keep pace with the changes to the develop of healthcare products including greener chemistry and novel materials.

In addition to developing frameworks to enable regulatory support essential to promote sustainability, MHRA will also deliver a programme of work to reduce the carbon footprint of its research facilities.

Pandemic Preparedness

As part of the national and international preparedness and response community, MHRA will build on recent experience to develop partnership with regulators and public health bodies to ensure that agency science expertise is current on emerging threats and agile to respond at pace and scale to initiatives such as the 100 Day Mission.

Policy Research and Evaluation

MHRA has commenced a programme of regulatory reform to reflect its role as a sovereign regulator and is now engaging with a range of government policies. This body of work will be supported by research to support policy decision and by robust evaluation of agency policy and will be delivered in collaboration with the UK and if appropriate international research and innovation community.

People and Locations

MHRA will continue to invest in the development of staff to ensure we have the right capability to deliver our public health role alongside developing rewarding careers. We are building a workplace where continuous training and development are supported and expected.

We will develop graduate schemes and apprenticeship programmes to increase our talent pool. In addition, MHRA will increase its capacity and capability through secondments and fellowships, drawing in talent from the wider life science sector. MHRA will continue to promote shared learning opportunities across the health family, including secondments and loans.

MHRA will continue to invest in facilities for Our Research to ensure the agency can continue to support innovation in the UK and internationally.

Accountability

The MHRA Board is responsible for advising on the strategic direction of the agency and ensuring that its targets are met.

A Scientific Advisory Board (SAB) will be established in year one. The SAB will oversee activity and performance against business plans:

- The SAB will comprise internationally recognised experts to provide direction for and review of the agency scientific research activities.

- The Independent Scientific Advisory Committee for MHRA database research (ISAC), which is a non-statutory expert advisory body established in 2006, will continue to give advice on research-related requests to access data from the Clinical Practice Research Datalink (CPRD).

The SAB will provide the reassurance required by many funding bodies for the scientific direction, monitoring and evaluation, and governance of external funding.

Our strategy spans three years, and it will be evaluated and refreshed with input from the SAB as needed to ensure it continues to align with and deliver the mission of the MHRA.

The Chief Science, Research and Innovation Officer will be responsible for the implementation of the Science Strategy. The implementation of this strategy will be integrated with the MHRA annual business planning cycles and will where needed be supported by Implementation Plans.

Overall accountability will be through the MHRA Executive Committee and the MHRA Board as appropriate.

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

11 July 2023

Title	**How well has SafetyConnect and other MHRA actions over the last three years helped to address the concerns raised by the Cumberlege Review?**
Board Sponsor	Alison Cave
Purpose of Paper	Assurance

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

1. Executive Summary

1.1 The Cumberlege Review (the Independent Medicines and Medical Devices Safety Review, IMMDSR) was published on 8th July 2020. Three years following the report is an appropriate milestone to consider how well the Agency's actions have helped to address the concerns raised by the Review and delivered on the ambition to put patients at the centre of everything we do.

1.2 In response to the Cumberlege Review, the Board endorsed the Agency's planned short, medium, and long-term deliverables. This paper provides an update on what has been achieved by the Agency so far and the differences these deliverables have made or are expected to make for patients.

1.3 The Board is asked whether the actions taken have helped to address the concerns, and to provide continued support, given that the implementation of some of the deliverables are ongoing.

2. Introduction

2.1 The Secretary of State asked for the Review to explore how the healthcare system in England responds to reports about harmful side effects from medicines and medical devices. In doing so, the Cumberlege Report sets out the evidence obtained during two years of hearings and other information gathering regarding how women who received 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 response to the Review, the Agency has been taking action in a 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 contributed to the IMMDSR update report on government implementation published in December 2022, which provides an overview of progress on the Review recommendations and Actions for Improvement.

2.4 The Agency's key goals and objectives to deliver these changes were 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. The Delivery Plan was refreshed following the mid-point review of the original plan, which defines further patient centred activity. The Agency's ambitious organisation-wide transformation to become a progressive and responsive patient-focussed regulator of medical products has now delivered a new organisational structure which is committed to improving how we listen and respond to patients and the public, supports 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.

How has the implementation of the MHRA deliverables helped address the concerns?

3 Transforming culture and governance

3.1 The Agency has implemented a 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 included the appointment of a new MHRA Chief Safety Officer (CSO), accountable for the safety and surveillance for all health care products, including medicines and medical devices. As a member of MHRA's Board, the CSO is also responsible for ensuring that the Agency's response to the IMMDS Review is delivered.

3.2 In mid-2022 we recruited senior staff with expertise bringing greater patient focus to policy, practice and research, in order to support staff across the Agency. The Agency has committed to changing the culture so that staff develop greater insight into what the public and patients are experiencing and thinking. As part of this workstream, every member of staff was required to complete mandatory e-learning on patient involvement. Other steps taken to address the cultural change included All Staff and Business Group meetings and presentations on patient involvement. Working with the University of Oxford, the Agency has developed a suite of films of patients talking to camera about their experiences of different health issues, medicines and devices. These are now available on the staff intranet. The Organisational Development & Remuneration Committee has also considered the Agency's work on culture and a People and Culture committee has also been established. It is hoped that these actions have helped ensure that patient safety is the primary focus of our staff.

3.3 The Patient Safety and Engagement Committee (PSEC), which includes lay members and is chaired by one of our Non-Executive Directors Mercy Jeyasingham, was established and has been advising and providing assurance to the Board in relation to the Agency's responsibilities regarding patient safety and engagement. The PSEC has provided critical input on a 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 a working relationship with the new Patient Safety Commissioner (PSC) for England with regular meetings between the PSC and the CSO. The Agency was grateful that the PSC gave the keynote address at the Medicines Safety Officer and Medical Devices Safety Officer network conference (jointly hosted by MHRA and NHS England), with the theme of 'Improving Patient Safety'. The Agency additionally provided evidence to the Scottish Parliament on the Patient Safety Commissioner bill hearing, on how we would collaborate with any individual or team should the post be established.

3.5 The MHRA completed a public consultation on proposals to improve the Code of Practice on managing Conflicts of Interest for its independent experts who provide advice to the licensing authority on decisions about the safety and benefit risk of medicines and medical devices. The revised Code was published alongside the consultation results and next steps on 8 September 2022, and came into force immediately.

3.6 The revised Code of Practice prevents the holding of financial interests by members of the main statutory expert advisory bodies, with the exception of the British Pharmacopeia Commission. The Code also clarifies the role of patients as experts at committees for the first time, to support the important contribution that those with lived experience can make to committee deliberations. The Code continues to ensure that the processes to declare and manage conflicts of interest are robust and clear to all. The MHRA has also completed an internal review of policies and procedures on conflicts of interest to ensure these remain robust.

3.7 Strict conflict of interest policies for staff ensures MHRA staff do not hold financial interests in any of the industries regulated by the Agency, and updated policies have improved the guidance available to staff and managers to support declaration of any potential conflicts. These actions taken in relation to Conflicts of Interest should help provide assurance about how decisions relating to healthcare products are made independently and without any financial or other conflicts.

3.8 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 established an interim group on the Safety of Medical Devices. A consultation on proposals for the establishment of a statutory Expert Committee on Devices is planned for later this year.

3.9 We will be increasing the transparency of safety signals and the basis of our benefit-risk decisions by regularly publishing the safety signals on medicinal products and a public statement following approval of all new chemical entities within one week, plus a summary of the evidence for the regulatory approval within one month.

4 Patient Involvement

4.1 The Agency's "Patient Involvement Strategy 2021-25" was published in September 2021 and is an important element of the response to Recommendation 6 of the review. The strategy was 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 committed to developing and introducing new systems, processes, and training to ensure the agency's teams have means of engaging and involving patients and the public to embed 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. For example, the Agency is a member of the Arms-Lengths Bodies People and Communities Forum, and works closely with the Health Research Authority on the Shared Commitment to Public Involvement. The Shared Commitment aims to drive up standards by improving the quality of public involvement across the health and social care research sector.

4.2 The Agency has been using a variety of mechanisms to support patient involvement in regulatory decisions. For example, the insights we hear inform our continued benefit-risk assessment of medicines and devices and shape our approaches to reducing harm. We know we have much more to do. We held a patient and public engagement session focused on medical devices where patients shared their thoughts and experiences on important safety issues. During a safety review of a medicine, patients shared their experience of the drug and what aspect of treatment has had the greatest impact. They shared insights into how the risks associated with the medicine should be managed. The Commission on Human Medicines heard directly from patients, carers and those who support them (e.g., charities) to understand patient views and experiences on the safety of a medicine being discussed. As outlined in the new Corporate Plan, we are starting to plan for piloting public hearings on major safety issues to bring the experience of patients and stakeholders into consideration openly and transparently. Our Corporate Plan also commits to increasing patient input of their experience into scientific assessments before product authorisation; and into at least half of our substantial risk-benefit reviews after authorisation. The Agency is also working to ensure diverse voices are heard where there are safety concerns on specific types of medicines and medical devices.

4.3 During scoping of the Yellow Card biobank, in 2021 and 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) to seek views on the establishment of a new biobank to investigate the role of genetics in adverse drug/vaccine reactions. The results of this patient and public engagement have 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. As part of the pilot phase, we will be looking at the genetic factors underpinning severe skin reactions with allopurinol, including Steven Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN). In order to engage directly with patients who have experienced these rare conditions, at the end of June 2023 the Yellow Card biobank team attended a Drug Safety

Patient and Public Involvement Group event. In July, the team will also be running a workshop to further understand healthcare professional's views on key aspects of the project including recruitment pathways for the chosen pilot topic and promotion of Yellow Card reporting.

4.4 Our enhanced customer service centre enables us to offer patients and the public one place through which they can make contact. The customer service centre offers advice and guidance where it can and shares any issues quickly within the Agency as required. We are able to take a Yellow Card over the phone, working through the form with the caller and discussing their concerns. In some cases the individual does not have a specific case to report but have more general concerns, which will be shared within the Agency.

4.5 Over the past 12 months the centre has responded to 2930 enquiries related to product safety, quality and efficacy reporting, 1847 of which have been related to COVID-19.

5 Improving adverse event reporting

5.1 MHRA is undertaking a major investment programme to upgrade its safety reporting systems and has delivered several improvements to the patient journey, with further improvements to be implemented. 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.

5.2 The SafetyConnect programme is a large and very complex programme of work that is split into multiple projects and is being delivered in phases. The MHRA has engaged with patients and the public directly to gain user feedback and perceptions on the system via user needs sessions and will seek further input from patients and the public as the system is developed and enhanced further.

5.3 The Coronavirus Yellow Card site enabled the Agency to process the reports received more quickly and efficiently, for better identification of potential patient safety issues (signal). 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. As part of the new design, we changed how a member of the public reports. In the old design, the person completing the form had to know whether a product was classified as a medicine or a device. Patient feedback highlighted that this was confusing for people. As a result people no longer need to know how their medical product is classified to submit a report.

5.4 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. Based on feedback from patients and other reporters, the Agency has been developing 'account areas' for registered users, where they will benefit from

improved information provision and can easily access and update their reports, add products to their 'watchlists' and see safety updates (see Annex 1 for example user account area). These new account areas will be available for people to register to within the coming months (and when the new features are implemented anyone who is already registered as an account user will see the new changes to their account the next time they log in) and we will continue to develop the account area further (eg providing better targeted safety related updates and linkages to relevant devices transparency data).

5.5 Work has also been progressing to improve the data visualisation of the Yellow Card reports, with the first phase being delivered in December 2022 for COVID vaccination data. These changes deliver improvements in format, accessibility and allow individuals access to more granular data than has been published to date. This new public data visualisation platform will be rolled out across medicinal products and devices in 2023.

5.6 We have deployed new functionality to both enable patient reported follow ups, and for the MHRA to customise the questions asked both during the initial report and to schedule routine follow ups where there is a need for longer term data collection. Attachments can now be added to reports (eg photographs). Improvements such as these helps to improve the dialogue with patients and our ability to conduct responsive safety surveillance for an emerging issue, or for selected new products, where additional questions can be asked in response to a specific safety concern.

5.7 The changes implemented have also enabled the integration of Yellow Card into other services such as the NHS App, however further work on this integration needs be taken forward to optimise the benefits and improved access for patients and other reporters.

5.8 The creation of common teams combining expertise across all medical products for the delivery of our safety services associated with the collection, management and signal detection and assessment of adverse incident data for all product types has been realised now through the delivery of the Agency's Transformation Programme, the design work and benefits modelling being part of early SafetyConnect work. The benefits of the new team structures will be fully realised as the roll-out of the SafetyConnect programme progresses.

5.9 The new signal detection functionality delivered through SafetyConnect, will enable automation of different signal detection approaches for medical devices, using the same robust signal management capability as for medicines. For the first time we will be able to assess safety at different levels of the Global Medical Device Nomenclature (GMDN), and automatically flag patterns of reporting in relation to both medical device problems and associated health effects.

5.10 The Agency will progress with the SafetyConnect programme and further system improvements will be delivered. We are working to further improve the data sources available to support 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 Unique Device Identifiers (UDIs). The MHRA is

working with DHSC on the new Medical Device Outcome Registry, which will collect information on all procedures involving high risk (Class III/IIb) devices, such as pacemakers, hip replacements and breast implants. The MHRA is also working closely with DHSC on creating a Product Information Master database which will act as single online database that collects, manages, and exports device product information. The central reference system aims to minimise fragmented and manual data requests that are currently the norm and so supports the Cumberlege Report's recommendation of 'collect once, use often' in data capture and processing. The emphasis on making core product characteristic data more accessible also aligns with the Goldacre Review's emphasis on open and consistent data collection.

5.11 The MHRA actively encourages reporting of any safety concerns to the Yellow Card scheme to help improve the safe use of medicines and medical devices for everyone. A sharp increase in reporting (mainly from patients) has been seen due to better awareness of the scheme following significant communications activity during the COVID-19 vaccination campaign. During the pandemic, we worked with our key partners to provide information about the Yellow Card scheme relating to COVID-19 treatments to recipients, coupled with an MHRA campaign and outreach work that generated extensive media coverage and exposure of the scheme including through social media.

5.12 In 2022, the Yellow Card scheme received the highest number of reports to date from members of the public (includes reports from patients, carers and parents) reporting 15,470 suspected Adverse Drug Reaction (ADR) reports, accounting for 23% of all reports. Reports from members of the public increased by 86% (7,156 reports) over the last five years, since 2018. Reporting rates from healthcare professionals also increased, accounting for 31% of direct Yellow Cards (20,791 ADR reports). These figures exclude COVID-19 reports for purposes of comparison with previous years. Since the Cumberlege Review, compared to 2020, overall reporting in 2022 to the Yellow Card scheme increased by 75%. This increase is in part due awareness from COVID-19 pandemic coupled with MHRA's Yellow Card strategy work, including national campaigns and local outreach through the MHRA's Yellow Card Centres where efforts continue to be made, proactively, to encourage and educate people about the importance of reporting.

5.13 Further communications and engagement activities to promote the Yellow Card scheme and improve audience reporting are in development to support the delivery of the agency's corporate plan objectives for vigilance activities.

6 Strengthening evidence for decision making – safety of medicines in pregnancy

6.1 The Agency has worked to improve 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. 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 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.

6.2 The Agency engaged with wider organisations on 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.

6.3 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 held further training for academic clinicians and clinicians (obstetricians, obstetric physicians, other specialists etc) who treat women needing to take medication during pregnancy.

6.4 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 looked at approaches in product information in UK and overseas to alert women to the need for contraception for teratogenic medicines. It highlighted that relatively few medicines in the UK have formal named pregnancy prevention plans. The Summary of Product Characteristics (SmPCs) of other medicines, that do not have a formal pregnancy prevention plan, but are contraindicated for use in pregnancy, contain variable information and it is not always clear for what reason the contraindication is listed. These initial findings were presented to the Medicines for Women's Health Expert Advisory Group (MWHEAG). We intend to explore pregnancy-related additional risk minimisation measures further and inform and develop guidance for industry during the year.

6.5 Understanding how diseases, drugs and other exposures affect pregnant women and their children is an important public health priority. The MHRA has expanded the Clinical Practice Research Datalink (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.

7 Valproate

7.1 This is an ongoing safety issue and we are continuing to take forward work to ensure 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.

7.2 The Agency is working with NHS England to deliver a programme of work in place, which includes seeking safer alternatives to valproate where the benefit risk is considered negative, improved pregnancy prevention and contraception, informed consent and shared decision making and improved data collection.

7.3 The Agency continues to evaluate the risks and benefits associated with any medical product containing valproate (as sodium valproate, valproate semisodium, or valproic acid). The latest evidence on the safety of valproate was discussed at several Commission on Human Medicines (CHM) meetings where they reassessed the most appropriate regulatory measures to better minimise risks associated with 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.

7.4 The MHRA and NHS Digital have established the 'Medicines and Pregnancy Registry' 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 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.

7.5 Working in partnership with DHSC, the outcome of a consultation on 'original pack dispensing and supply of medicines containing sodium valproate' was published in March 2023. The legislative process is now underway to amend the Human Medicines Regulations 2012 with a specific requirement that medicines containing 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.

8 Mesh

8.1 The use of mesh for stress urinary incontinence (SUI) and pelvic organ prolapse (POP) procedures continues to remain subject to a national period of high vigilance restriction (paused). The Agency continues to support the ongoing development of the mesh registry established in response to the IMMDS review. This registry is in its infancy so limited data has been captured to date.

8.2 We are continuing to progress our review into the use of mesh used for rectopexy procedures. An update regarding this work was published in December 2022.

8.3 Engagement activities for mesh work is ongoing. The Agency held a pelvic mesh patient and public listening session in April 2022. Early in 2023 the Agency also met with representatives from patient campaign groups such as Rectopexy Mesh Victims and Support, Sling the Mesh and Mesh Rectopexy Support and Action groups to discuss feedback that followed on from the December 22 update. This feedback indicated that the scope of the rectopexy review should be widened to include rectopexy fixation devices, alongside highlighting their concerns on the suitability of the Yellow Card scheme for capturing mesh related device issues. The MHRA also met with the Pelvic Floor Society who have agreed to support the Agency in the rectopexy review.

8.4 An in-depth review into the risk and benefits of mesh used for rectopexy procedures is ongoing. This is an extensive piece of work that requires reviewing data provided from a number of medical device manufacturers.

9 Strengthening the regulatory framework for medicines and medical devices

9.1 The Review was a key driver for the Medicines and Medical Devices Act 2021 (MMDA). 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.

9.2 The MHRA held a public consultation on proposals for a future medical device regime, which closed in November 2021. The MHRA carried out pre-consultation engagement with patient representatives, which led to the development of the consultation with supportive guidance and sections tailored to the member of public responses. The consultation was widely promoted to all audiences with engagement sessions open to all registrants and targeted at members of the public to gather their views. Analysis of the 900+ responses identified strong support for proposals that will enable MHRA to strengthen patient safety. We received a representative proportion of responses from patient groups and individuals. All responses to the consultation were carefully considered and informed the Government response. Focus groups of patient representatives have been set up to ensure further engagement in the next steps for legislative implementation, to gain feedback on emerging policies, guidance development and changes following consultation.

9.3 The MHRA is working to ensure that the future regulatory framework for medical devices will 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. The new medical devices legislation will bring in requirements for manufacturers of implants and class 3 devices to produce and publish a Summary of Safety and Clinical

Performance which will be accessible to the public. The Agency has also issued guidance on when software applications are considered to be a medical device and how they are regulated and problems with software can be reported to MHRA using the Yellow Card scheme or via the Yellow Card app.

9.4 The Medicines and Medical Devices Act 2021 introduced powers under section 39 that enable the MHRA to share information for the purpose of warning members of the public about concerns that the Secretary of State has in relation to the safety of a medical device. The provision will also enable the MHRA to disclose information with international regulators with regards to concerns relating to the safety of a medical device. This will enable greater transparency surrounding device safety issues with patients and healthcare professionals as well as, enabling the MHRA to gather information on safety issues with key international stakeholders (pursuant to international agreements).

9.5 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 including providing the UDI. The MHRA intends to lay a further statutory instrument later this year that will put in place strengthened post-market surveillance requirements ahead of the wider future regulatory regime reform. These post-market surveillance requirements are expected to apply from mid-2024 and will introduce clearer and more stringent post-market surveillance requirements that are risk proportionate, with improved regulatory oversight and includes details on what should be covered in trend reports and tighter timelines for adverse incident reporting.

9.6 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 device 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).

9.7 Powers in the MMDA also allow the MHRA to amend legislation relating to the regulation of medicines.

9.8 Following the outcome of public consultation, published in March 2023, the Agency is bringing forward legislation to overhaul the UK's clinical trial framework. The ambitious regulatory framework ensures 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.

9.9 The Health and Care Act 2022 provides the power to establish a UK-wide medicine information system by NHS Digital. This will provide for the collection of data 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 and their 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 could work in practice, with the goal of developing proposals for public consultation.

10 Next steps

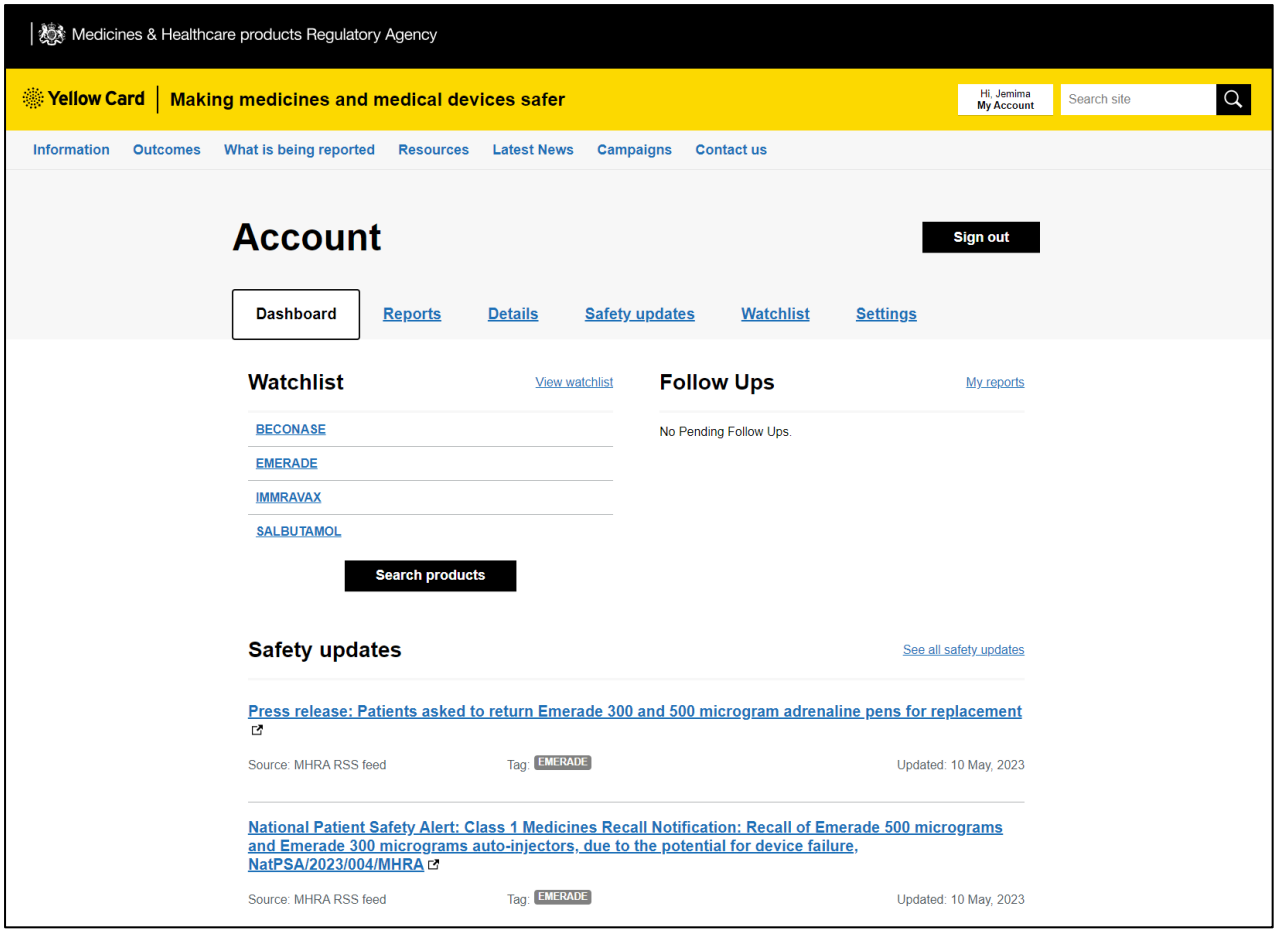
10.1 The Agency recognises that there is still more work to be done to achieve and embed the changes required to address the concerns in the Cumberlege Report and will continue to work with other healthcare system partners. The Agency will continue to monitor the progress of the specific commitments and actions outlined above and the new activities outlined in the Agency Corporate plan for 2023-26.

11 Recommendation

11.1 Consider if the Board is assured that the actions taken by the Agency so far in response to the Cumberlege Review are helping to make a difference to patients.

Alison Cave
July 2023

Annex 1 – example of new User Account area



Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

11 July 2023

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 three main areas at its meeting on 12 May 2023. This included the forward plan for the Committee, the minimisation of risk associated with sodium valproate, and the evaluation of the patient and public involvement strategy by the agency.

2. Introduction

2.1 The tenth meeting of the Patient Safety and Engagement Committee was held on the 12 May 2023. This was the first meeting for the year due to difficulties with diary co-ordination of key members. It is hoped setting dates well in advance will prevent this issue occurring in the future.

3. PSEC discussed each of the following items at the meeting on 12 May 2023.

3.1 **PSEC Forward Plan**

Future and recuring topics for the committee were discussed. It was important to make sure that PSEC covered the main areas of work of the agency, therefore a suggested list of future agenda items was discussed in detail and committee members identified what topics were missing, what items needed to be a priority, and the optimum scheduling for topics. It will be more appropriate in the future to discuss ILAP with IDAP (noting these programmes might change name). PSEC members have commented over the years on some subjects that have not been holistically tackled by the agency, such as patient information leaflets and it was agreed there might be some value in scheduling work on this for discussion at a future committee. A revised draft forward plan will be circulated to the committee before the next meeting covering proposed subjects for the next year.

3.2 **Sodium Valproate**

PSEC discussed a paper on the implementation of new regulatory measures to minimise the risks of sodium valproate, a treatment for epilepsy and bipolar disorder which has significant and well-established risks to the unborn child when used in pregnancy. The Commission on Human Medicines heard in May and June last year from patients, charity groups and healthcare professionals on their experiences, as well as on opportunities for risk minimisation. PSEC discussed current evidence and the nuances of prescribing a drug with known side effects that is still used by some pregnant women. Influencing and informing the wider health system and therefore enabling patients to make informed choices was discussed in some detail by the committee. The committee noted the need to continue to monitor the impact of the new regulatory measures to reduce the risks associated with valproate given it is a drug that is considered very effective, especially in the treatment of some forms of epilepsy.

3.3 **Evaluation of the Patient and Public Involvement (PPI) strategy in the MHRA**
PSEC discussed how the Patient and Public Involvement Strategy 2021-2024 should be evaluated in terms of progress and outcomes. The committee agreed an evaluation framework that viewed patient involvement as a research process that is underpinned by organisation values and principles. It was suggested these principles, based on Boivin et al (2018), should be grounded in clarity, reflexivity, methodological rigour, transparency, pragmatism, and reciprocity. The Patient and Public Involvement team are working with academic centres and acknowledge that the MHRA has some way to go to reflect best practice. PSEC agreed that at this stage the evaluation should be on the work of the PPI team as well as the work of the rest of the organisation, including patient views on strategy. In the future the evaluation can be extended to health system partners.

4. Conclusion

4.1 The topics discussed at PSEC were mainly strategic and less focused on specific areas of work. The Forward Plan and Evaluation of Patient and Public Involvement strategy enables PSEC to ensure that it is delivering on its purpose of assurance to the Board. However, the discussion on Sodium Valproate, one of the main concerns of the Independent Medicines and Medical Devices Review report, enabled the committee to consider not only new evidence of effects and usage, but also the need to engage with the wider health system.

Mercy Jeyasingham
Chair Patient Safety and Engagement Committee
June 2023