Medicines & Healthcare products Regulatory Agency

AGENDA FOR BOARD MEETING HELD IN PUBLIC

11:00 – 13:30 on Tuesday 19 April 2022

Chair: Stephen Lightfoot

	AGENDA ITEM	**PURPOSE**	**PRESENTER**
11:00	INTRODUCTION 1. What is the purpose of this meeting, who are the Board Directors and are there any absences?	Information	Chair
	2. Are there any new Declarations of Interest?	Information	All
	3. What were the minutes and actions from the last meeting?	Approval	Chair
11:15	AGENCY PERFORMANCE 4. What are our most important activities and priorities from the CEO's point of view?	Context	June Raine
11:35	PATIENT SAFETY 5. What assurance can be provided by our Patient Safety & Engagement Committee?	Assurance	Mercy Jeyasingham
11:50	DYNAMIC ORGANISATION 6. What assurance can be provided by our Organisational Development & Remuneration Committee?	Assurance	Mandy Calvert
12:05	GOVERNANCE 7. What assurance can be provided by our Audit & Risk Assurance Committee?	Assurance	Michael Whitehouse
12:20	FINANCIAL SUSTAINABILITY 8. What are our financial plans for the Agency to achieve financial sustainability in 2022/23?	Approval	Jon Fundrey
12:40	EXTERNAL PERSPECTIVE 9. How are we going to provide more opportunities for public engagement with the Agency?	Strategic Direction	Rachel Bosworth

13:00	10. What questions do members of the public have about the items on this Board Meeting Agenda?	Public Engagement	Chair
13:30	CLOSE OF MEETING	-	Chair

MHRA Agency Board Declarations of Interest – April 2022

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 Designate	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
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.	Yes	Yes
	University of Manchester digital Experimental Cancer Medicine Team	Quince Consultancy providing strategy and data protection consultancy	Yes	No
	Cambridge Judge Business School	Member of Advisory Board	No	Yes
	The Guinness Partnership Limited – Housing Association	Non-executive Director, member of Audit Committee and Chair of Health and Safety Committee	Yes	Yes
Dr Alison Cave Chief Safety Officer	None	N/A	N/A	N/A
Jon Fundrey Chief Operating Officer	None	N/A	N/A	N/A

Name and MHRA Role	Name of Other Company or Organisation	Nature of interest	Paid	Current
Dr Paul Goldsmith Non-Executive Director	Closed Loop Medicine Ltd	Shareholder, director & employee; ILAP applicant and user of CPRD	Yes	Yes
	Summit Inc	Shareholder	No	Yes
	Ieso Digital Health	Shareholder	No	Yes
	MDU Ltd	Director	Yes	Yes
	MDU Investments Ltd	Director	Yes	Yes
	NHS	Consultant Neurologist	Yes	Yes
	NHS	Clinical Senate Member	No	Yes
	Big Tent Foundation	Trustee	No	Yes
	Radix Group Limited	Trustee	No	Yes
	Sleepstation	Co-founder of original programme, 2012-2014	No	No
Professor Graham Cooke Non-Executive Director and Deputy Chair	30 Technology Ltd	Consultant/Advisor	Yes	Yes
	DNAnudge Ltd	Consultant/Advisor	No	Yes
	Seventh Sense Biosystems	Consultant/Advisor	Yes	Yes
	Debevoise and Plimpton LLP	Consultant/Advisor in relation to COVID protocols	Yes	Yes
	Sanofi CoV	Chair of End Point Review Committee for vaccine trial	Yes	Yes
	WHO	Chair of Committee for Selection and Use of Essential Medicines	No	Yes
	NIHR	NIHR Research Professor	Yes	Yes
Claire Harrison Chief Technology Officer	None	N/A	N/A	N/A
Haider Husain Associate Non-Executive Director	Healthinnova Limited	Chief Operating Officer	Yes	Yes
	Milton Keynes University Hospital NHS Foundation Trust	Non-Executive Director	Yes	Yes
	British Standards Institute	Panel Chair BS30440 – Use of AI within Healthcare	No	Yes
	Dementia Carers Count	Trustee	No	Yes
	World Ward Muslim Memorial Trust	Trustee	No	Yes
	Microsoft Corp	Shareholder	Yes	Yes
	BBC	Family Member	No	Yes
Mercy Jeyasingham MBE Non-Executive Director	Royal College of Podiatry	Consultancy	Yes	No

Name and MHRA Role	Name of Other Company or Organisation	Nature of interest	Paid	Current
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	Yes
	PAVIA – PV Africa Board (EC Funded)	Advisory Board	No	Yes
	WHO – Sustainable COVAX Manufacturing Strategy for Regional Health Security	Advisory Expert	No	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	Yes
	National Audit Office	Board Member and Chief Operating Officer until 17 April 2017	No	No
Glenn Wells Chief Partnerships Officer	None	N/A	N/A	N/A

Medicines and Healthcare products Regulatory Agency

Minutes of the Board Meeting Held in Public on 15 February 2022

(10:00am – 12:15pm)

by Zoom Webinar

Present:

The Board

Stephen Lightfoot	Chair
Dame June Raine DBE	Chief Executive
Dr Marc Bailey	Chief Science, Research and Innovation Officer
Dr Alison Cave	Chief Safety Officer
Amanda Calvert	Non-Executive Director
Professor Graham Cooke	Non-Executive Director and Deputy Chair
Jon Fundrey	Chief Operating Officer
Dr Paul Goldsmith	Non-Executive Director
Claire Harrison	Chief Technology Officer
Haider Husain	Associate Non-Executive Director
Mercy Jeyasingham MBE	Non-Executive Director
Raj Long	Non-Executive Director
Dr Laura Squire OBE	Chief Healthcare Quality and Access Officer
Dr Glenn Wells	Chief Partnerships Officer
Michael Whitehouse OBE	Non-Executive Director

Others in attendance

Rachel Bosworth	Director of Communications, MHRA
Natalie Richards	Head of the Executive Office, MHRA
Kathryn Glover	Deputy Director, Medicines Regulation and Prescribing, DHSC
Cathy Harrison	Chief Pharmaceutical Officer for Northern Ireland

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.

1.2 The Chair welcomed everyone to the meeting, including a broad range of observers representing patient groups, healthcare professionals, government, industry, media and MHRA staff.

1.3 The Chair apologised for the technical difficulties that prevented the live stream from operating at the start of the meeting.

Item 2: Are there any Apologies or Declarations of Interest

2.1 Apologies were received from Junaid Bajwa, 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 Carly McGurry, Director of Governance.

2.2 The Board reviewed the Declarations of Interest for all MHRA Board members. Paul Goldsmith declared an additional declaration to those currently recorded; the company Dr Goldsmith works with has submitted an ILAP application and uses CPRD services. Haider Husain declared that he chairs a panel at the British Standards Institution (BSI) on establishing standards on the use of AI within healthcare; however this role has no involvement in the Health and Safety standards that BSI sets for the MHRA. The Chair was satisfied that Paul Goldsmith and Haider Husain could continue to participate in the full agenda of this meeting.

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

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

AGENCY PERFORMANCE

Item 4: What are the current issues from the CEO's point of view?

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

(i) Healthcare Access – including latest updates on COVID-19 vaccines and therapeutics; the Innovative Licensing and Access Pathway (ILAP); Clinical Trials; Influenza vaccine; vaccines against plague; women's health; and smoking cessation;

(ii) Patient Safety – including updates on the safety of COVID-19 vaccines; the SafetyConnect vigilance database; the MHRA's Criminal Enforcement Unit; compliance; orphaned device manufacturers; the safety review of Isotretinoin; and the Patient Involvement Strategy;

(iii) Partnerships – including updates on Project Orbis; the Access Consortium; and strategic data partnerships;

(iv) Dynamic Organisation – including updates on the Transformation Programme; optimising Agency services; Health and Safety; and the new Applications Outsourcing contract; and

(v) Financial Sustainability – including updates on fees strategy; the transition from Trading Fund status; and the Spending Review.

4.2 The Board thanked Dr Raine for her report and provided comments on the priority deliverables for the Agency; the Patient Involvement Strategy and how it will be vital that this is cross-cutting across all areas of the Agency; the Agency's role in tackling COVID-19 in developing countries and working with the World Health Organization; the work of the Criminal Enforcement Unit including the work in improving intelligence and moving towards prevention; and generating a systematic approach to early signal detection of signals under SafetyConnect.

4.3 The Board provided further comments regarding the Agency's location strategy in relation to the Levelling Up White Paper which has recently been published; data access; the Agency's fees strategy to deliver a financially sustainable Agency; further work with the Access Consortium including understanding the full impact on public health and access to new products; utilising CPRD in clinical trial research, hypothesis testing and other opportunities such as data linkages, expansion to secondary and tertiary care, and development of analytical platforms; expansion of ILAP and specific areas to focus on such as patient recruitment; COVID-19 therapeutics to tackle variants of concern and innovative regulatory pathways, noting the MHRA's recent published guidance on variants of concern. The Board thanked Dr Raine for this comprehensive report.

Item 5: How much of the Delivery Plan have we achieved from April to December 2021?

5.1 The Board considered a paper describing how much of the Delivery Plan the MHRA has achieved from April to December 2021. The Board noted that there has been successful delivery of seven items, two of which were completed before they were due. These involved deliverables on innovation, access, safety and partnerships, and reflect the move to the establishment of the 'One Agency' future operating model. The Board noted that three items have been brought back on track from amber to green, and the Agency has improved the delivery confidence of a further two from red to amber. However, a combination of transformation staffing impacts and dependencies have reduced progress and six items, due in Q3, are now expected to be achieved in the final quarter of the year. The number of items that are off-track has risen from 16 to 25; 15 of these are new and 10 have rolled over from Q2 and have mitigations in hand.

5.2 The Board noted the update and provided comments regarding the change from Trading Fund status and the work on the effective use of the Agency's reserves, including retention of some ringfenced funds such as the NIHR funding for CPRD, and access to proceeds of crime funds; the 900 responses to the consultation on the medical devices legislative framework change proposals; ensuring the Delivery Plan work is closely connected with the Agency's risk management framework; moving towards a continuous improvement approach to technological changes to maximise the use of resources; the progress on the common data model; and the volume of work the Agency is progressing, as well as undergoing a fundamental organisational change through the transformation. The Board noted the report for assurance.

DYNAMIC ORGANISATION

Item 6: How are we performing on Health and Safety compared to best practice?

6.1 The Board considered a report describing how the MHRA is performing on Health and Safety compared to best practice. The Board noted that the Agency strives to achieve excellence in all aspects of its business activities. There is internal and external assessment of Health & Safety (H&S) performance, which demonstrates the Agency's commitment to achieve best practice. The MHRA's relationships with the Regulators (Health & Safety Executive (HSE), Environment Agency and Home Office) and feedback from the British Standards Institution (BSI) remains positive. The Board reviewed suggestions for building on existing good practice and committing to the requirement for continual improvement to ensure a robust health and safety management system that can be considered as an example of best practice.

6.2 The Board reviewed the report and provided comments regarding the importance of ensuring staff who have H&S targets as part of their roles should have these reflected in their personal objectives; the health and wellbeing of staff given the change in the working environment with more working from home; it was noted that mental health is supported by H&S legislation and the Agency has a series of welfare programmes which are continuing, with thanks to HR colleagues for working very hard in this area. This also ties into the work on the Agency's accommodation strategy.

6.3 The Board provided further comments including an ambition to work towards Net Zero and the environmental agenda; it was noted that medicines and medical devices have a huge impact on the environment, during manufacturing and importation and notably waste disposal; it was agreed that a Green Regulatory Strategy should be developed to address this issue. The Agency's environmental statistics are reported in the Annual Report; it was noted that the Agency is a significant electricity consumer and refrigerants are used extensively at the laboratories at South Mims. The Board agreed to develop an environmental strategy.

Action 73: Develop a Green Regulatory Strategy

Laura Squire & Glenn Wells

6.4 Further comments were provided regarding the H&S report; the Board agreed that H&S leadership training should be scheduled for the Board; and regular Health & Safety reporting should be included in the Board Schedule of Business. The Board noted the H&S report with thanks.

Action 74: Include regular Health & Safety reporting and training on the Board Schedule of Business ***Stephen Lightfoot***

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

7.1 The Board considered the assurance report from the Organisational Development and Remuneration Committee (ODRC). At its last meeting the ODRC reviewed the ODRC Role and Terms of Reference; a review of services that will be provided by the Agency and priorities for establishing them in the new Agency operating model; a review of the Board's input on leadership from December 2021 and how to develop and deliver an effective leadership development programme to staff most effectively; and a review of the results on effectiveness of senior leadership culture from the balanced scorecard.

7.2 The Board noted the report and provided comments regarding the setting of the priority services, ensuring focus on those which will have the biggest impact on public and patient health; the priority services in the areas of Science Research & Innovation, Healthcare Quality & Access, and Safety & Surveillance were described.

7.3 The Board provided further comments regarding the One Agency Leadership Group; leadership training and career progression for staff, leading by example and reverse mentoring. The reverse mentoring scheme will be relaunched and Board Directors should also be able to participate.

Action 75: Provide details of Agency's Reverse Mentoring Scheme to Board Directors

Jon Fundrey

7.4 The Board noted the assurance report and were encouraged by the continued progress in the area of services.

FINANCIAL SUSTAINABILITY

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

8.1 The Board considered the assurance report from the Audit & Risk Assurance Committee (ARAC). At its last meeting the ARAC reviewed the Agency's financial sustainability, preparation for the change in Trading Fund status, risk management, external audit, the Annual Report timetable, internal audit, and Human Resource Controls. A joint meeting with the Patient Safety and Engagement Committee (PSEC) also took place to provide assurance to the Board on the development, governance and data standards of SafetyConnect.

8.2 The Board noted the report and provided comments regarding the importance of systematic financial reporting across the organisation; an action was taken to ensure monthly financial income and expenditure reports versus budget are available for every cost centre manager in the Agency.

Action 76: Ensure that monthly financial income and expenditure reports versus budget are available for every cost centre manager in the Agency

Jon Fundrey

8.3 The Board provided further comments regarding SafetyConnect: risks related to the scale of data transfer; the importance of partnerships and integration with the NHS, industry and medical practitioners; and use of technology to improve patient safety. The Board were content with the assurance provided from this report.

EXTERNAL PERSPECTIVE

Item 10: What questions do members of the public have for the MHRA Board?

9.1 The Board answered a range of questions, which had been submitted by members of the public before and during the meeting. Although most of these questions were answered, it was not possible to address them all in the available time. An action was taken to answer all remaining questions in writing to the people who raised them.

Action 77: Send written responses to observers whose questions were not answered during the February Board Meeting ***June Raine***

ANY OTHER BUSINESS

10.1 No additional business was raised and the Chair closed the meeting with thanks to all of the contributors and members of the public observing the meeting.

ACTIONS FROM MHRA BOARD MEETING IN PUBLIC – 15 February 2022

The actions highlighted in red are due this month

Action Number	Action	Owner	Date	Status
Carried Forward from previous meetings				
29	16/03/21: Present an Agency Laboratory Strategy to the Board as part of the Agency Science Strategy.	Marc Bailey	~~21/09/21~~ ~~16/11/21~~ ~~15/03/22~~ 17/05/22	
38	18/05/21: PSEC and ARAC to agree how to provide assurance to the Board on the development, governance and data standards of SafetyConnect	Mercy Jeyasingham & Michael Whitehouse	~~20/07/21~~ 15/03/22	Completed and Reported to Board on 15 February
43	15/06/21: A revised assurance and governance framework for the new MHRA organisation should be presented to the Board.	Carly McGurry	~~15/02/22~~ 17/05/22	
46	15/06/21: The Board's comments on the future development &branding of ILAP, including its potential use for medical devices, should be considered so that a definitive proposal can be presented to the Board for approval. 16/11/21: Consider if ILAP should be rebranded as an "Innovative Therapy Pathway" and conduct a pilot with a medical device through this innovative regulatory route.	Laura Squire	~~19/10/21~~ ~~16/11/21~~ ~~19/04/22~~ 21/06/22	
51	20/07/21: Review Balanced Scorecard metrics and targets to provide more focus on outcomes, greater links to the Delivery Plan and (especially on innovation) and assurance that resources are available to deliver priorities 21/09/21: Review the outcome measures in the Balanced Scorecard and the RAG Ratings in the quarterly Delivery Plan reports before considering if the targets are ambitious enough. 19/10/21: Continue to evolve the Balanced Scorecard metrics to include outcome measures. Update the data set for Clinical Trials in the balanced scorecard.	Jon Fundrey	~~19/10/21~~ ~~16/11/21~~ ~~18/01/22~~ ~~15/03/22~~ 21/06/22	

	16/11/21: Broaden the measures to include the impact and quality of our scientific work rather than volumes. Seek input from our customers on what MHRA services they value for inclusion in the Balanced Scorecard. 18/01/22: A new approach for Board Reporting on operational performance, risk management and opportunity progression to be recommended to the Board.			
52	20/07/21: Review how multiple data sources including Unique Device Identifiers, Registries, NHS data and real world data can be captured and used to strengthen safety surveillance. Incorporate this into the planned review of SafetyConnect 18/01/22: The Board requested a review of the cross-agency actions that have delivered a meaningful and positive difference to patient safety and risk management in the two years since the Cumberlege Review was published.	Alison Cave	~~16/11/21~~ ~~18/01/22~~ ~~17/05/22~~ 15/03/22 19/07/22	Assurance provided by ARAC and PSEC
54	20/07/21: Review the progress and impact of the short, medium and long term deliverables of the agreed Culture, Equality, Diversity and Inclusion plans	Jon Fundrey	~~18/01/22~~ ~~15/02/22~~ 17/05/22	
58	21/09/21: Update MHRA/DHSC Framework Agreement to coincide with the change in Trading Fund status.	Carly McGurry	~~31/03/22~~ 19/04/22	Verbal Update
59	21/09/21: Board assurance committees to review their combined effectiveness and hold a board discussion on this topic.	Michael Whitehouse, Mercy Jeyasingham, & Mandy Calvert	~~15/03/22~~ 16/08/22	
61	19/10/21: Prioritise the national and international initiatives to accelerate the diversification of patient recruitment for clinical trials, exploring options to maintain diversification of representation (eg gender balance). Consider development of a public dashboard of metrics for trial recruitment.	Marc Bailey	~~19/04/22~~ 19/07/22	

	18/01/22: Review feedback from public consultation on clinical trial regulations and make strategic recommendations on areas for development			
62	19/10/21: Review the Corporate Risk Register to consider whether all strategic risks to Agency outcomes are accurately captured.	Carly McGurry	~~19/04/22~~ 17/11/22	
64	16/11/21: Review opportunities for more partnership working with other regulators as part of the MHRA International Strategy	Glenn Wells	~~15/02/22~~ ~~19/04/22~~ 20/09/22	
65	16/11/21: PSEC to seek assurance on how safety risks are considered by the MHRA in those situations where patients are willing to accept more risk than healthcare professionals.	Mercy Jeyasingham	19/04/22	On Agenda
66	16/11/21: Assurance to be provided to ODRC on actions being taken to improve culture survey scores (ie walking the talk and taking timely decisions) in the Balanced Scorecard	Executive Committee	15/02/22	Completed
67	16/11/21: Update the RAG rating on the use of financial reserves in the Delivery Plan	Jon Fundrey	15/02/22	Completed.
70	18/01/22: Develop and present a Data Strategy to the Board	Alison Cave & Claire Harrison	~~17/05/22~~ 18/10/22	
71	18/01/22: Using the input from the public consultation and Board discussion, develop and publish a new regulatory framework for Artificial Intelligence as a Medical Device	Laura Squire	~~21/06/22~~ 20/09/22	
72	18/01/22: Send written responses to observers whose questions were not answered during January Board Meeting	June Raine	15/02/22	Completed
New Actions				
73	15/02/22: Develop a Green Regulatory Strategy	Laura Squire & Glenn Wells	21/02/23	
74	15/02/22: Include regular Health & Safety reporting and training on the Board Schedule of Business.	Stephen Lightfoot	15/03/22	Completed
75	15/02/22: Provide details of Agency's Reverse Mentoring Scheme to Board Directors	Jon Fundrey	~~15/03/22~~ 21/06/22	Scheme to be relaunched in Q1

76	15/02/22: Ensure that monthly financial income and expenditure reports versus budget are available for every cost centre manager in the agency	Jon Fundrey	01/04/22	Verbal Update
77	15/02/22: Send written responses to observers whose questions were not answered during February Board Meeting	June Raine	15/03/22	Verbal Update

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

19 April 2022

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

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

'TOP 10' HEADLINES

- Our Transformation Programme progresses, with new teams coming together and advancing work on services including the Innovative Licensing and Access Pathway
- With the end of Trading Fund status, the MHRA is now within the accounting boundary of DHSC and a balanced budget for the 2022/23 financial year has been agreed
- The Early Access to Medicines Scheme has now become law under the Medicines and Medical Devices Act, improving safe supply of innovative medicines to patients
- The public consultation on proposals to strengthen the UK clinical trials legislation has had a wealth of responses and the emerging themes will influence the final legislation
- Our collaborative research has found the SARS-CoV-2 Omicron sub-variant BA.2 dominant in London Beckton sewage through the wastewater research programme
- We approved Evusheld for pre-exposure prophylaxis in adults unlikely to mount an immune response or for whom COVID-19 vaccination is not recommended
- CPRD received significant positive coverage in the Open Data Institute's report on their study to improve understanding of data institutions and the impact they have
- The Good Practice Symposia week in March attracted 1800 delegates across 40 countries, demonstrating the strength of our international partnerships
- Agency staff supported the Coalition for Emergency Preparedness Innovations conference and its joint statement to deliver the 100 Days Mission
- The Delivering High Standards in Medicines Advertising Regulation 2021 Annual Report was launched at a 'best practice' webinar for the pharmaceutical industry

1. HEALTHCARE ACCESS

Clinical Trials

1.1 The consultation on a range of proposals to improve and strengthen the UK clinical trials legislation closed on 14 March. The consultation has had high levels of engagement, with over 2000 responses submitted, and these are currently undergoing analysis with the aim of publishing the government response by the end of June and introducing legislation in the autumn.

1.2 The consultation included proposals for the involvement of people with relevant lived experience in the design, management, conduct and dissemination of a trial; and proposals to encourage the inclusion of underserved populations and increase diversity in clinical trial populations. Supporting this, on 11 March, the MHRA joined with the Health Research Authority, the National Institute for Health Research (NIHR) and a host of organisations across the UK to sign up to a shared commitment to improve public involvement in research.

Early Access to Medicine Scheme

1.3 The Early Access to Medicines Scheme Statutory Instrument (SI), the first SI under the Medicines and Medical Devices Act has completed the Parliamentary process. The SI has now been signed and made, with the final SI to be published and the new provisions to come into force on 15 April 2022. These provisions will strengthen safety measures for supply of innovative medicines to patients who need them, prior to full authorisation.

Consultation on the future regulation of medical devices

1.4 Work continues to distil the themes from the public consultation on the Medical Devices legislation, taking into account the breadth and nature of this rapidly evolving sector and its importance in safe healthcare. We are aware of the concerns of industry about the risks of a truncated implementation period due to the pre-election restriction on government announcements, and continue to work to ensure that there is a realistic timeframe to enable system readiness before any new rules take effect in full.

COVID-19 vaccines and therapeutics

1.5 Significant work has continued to maintain and update the licences for the five approved COVID-19 vaccines. New manufacturing sites, new raw materials, amendments to analytical tests, extensions to shelf lives, and updates to patient and healthcare professional information have been approved. All 5 vaccines approved in Great Britain now have Conditional Marketing Authorisations (CMAs) and supply of the vaccines has now transitioned to those CMAs where there was previously emergency supply under Regulation 174 of the Human Medicines Regulations 2012. We also continue to provide scientific advice to companies developing new COVID-19 vaccines, including those for variant vaccines, and several are undergoing rolling reviews.

1.6 In March we approved Evusheld (tixagevimab/cilgavimab), to be used in patients before being exposed to the risk of COVID-19 infection in order to prevent disease, as pre-exposure prophylaxis for use in adults who are unlikely to mount an immune response from COVID-19 vaccination or for whom vaccination is not recommended. The rolling review approach was used in order to reach a regulatory decision on benefit risk in the shortest time possible, with advice provided by the COVID-19 Therapeutics Expert Working Group and Commission on Human Medicines (CHM).

COVID-19 vaccine independent batch release testing

1.7 By the end of March 2022, 220 batches of COVID-19 vaccines have been tested and released through NIBSC Independent Control Testing certificates. This is the equivalent of over 220 million doses available to UK and overseas vaccination programmes.

SARS-CoV-2 RNA detection in wastewater

1.8 As part of our wastewater surveillance programme, detecting evidence of viruses of public health concern, we have found that the SARS-CoV-2 Omicron sub-variant BA.2 is now dominant in the London Beckton sewage. This possibly explains rising numbers in COVID-19 cases driven by this more transmissible variant from mid-February.

Medicines Licensing

1.9 The volumes of national marketing authorisation applications granted remain consistently high, with the average number of initial applications and variations (Type 1B and Type II) determined per month significantly higher in March and throughout this reporting year 2021/2022 compared to last year. Requests for expedited variations to maintain product supply also remain high. We actively participate in the ACCESS Consortium's Generic Medicines Working Group, looking at operational aspects to make the pathway accessible and attractive to applicants. We also work with the FDA Generics Cluster towards harmonization on scientific and technical recommendations for specific generic medicines as well as on broader approaches in this sector. Progressing older applications to a timely close is a major operational priority. The Do and Resolve Group constituted to focus on this work continues to make good progress.

Project Orbis

1.10 The MHRA is now a full participant in Project Orbis, coordinated by the US Food and Drug Administration (FDA). We have completed assessment of several novel products and new indications. In March, a new drug licence was granted for Exkivity (mobocertinib) for the treatment of adult patients with EGFR exon 20 insertion mutation-positive locally advanced or metastatic non-small cell lung cancer who have received prior chemotherapy. In addition, a variation for Jakavi (ruxolitinib) to include the new indication for the treatment of acute or chronic graft versus host disease in patients aged 12 years and older was approved. (Jakavi is already authorised for myelofibrosis and polycythaemia).

Enabling continuous medicines and vaccine supply

1.11 The Product Information Quality Unit continues to prioritise label and leaflet assessments to address supply issues related to the current COVID-19 pandemic and leaving the EU, working closely with the DHSC Medicines Supply Team. Recent labelling exemptions authorised under Regulation 266 of the Human Medicines Regulations 2012 have permitted initial supply of the Cominarty vaccine for the 5-11 year age group with EU packs, and provision of a single pack of Beromun® (Tasonermin) 1mg Powder for Solution for Infusion to supply a single patient for treatment at the Royal Marsden Hospital, demonstrating that this Agency collaboration benefits patients from a population level down to the individual.

Data Institute Report: Measuring the impact of data institutes

1.12 The Clinical Practice Research Datalink (CPRD) is the only healthcare data service to be featured in the Open Data Institute's study to improve understanding of data institutions, by quantifying the impact they may have. The report includes significant positive coverage of CPRD, providing good visibility for its research services including via Twitter: "CPRD demonstrates how safe data access controls can support access to uniquely valuable datasets, which would otherwise be unavailable to stakeholders. . . CPRD lowers the cost of recruiting to trials and provides high-quality data. This benefits patients as participating in trials means they can get access to treatments before they are available on the market."

Updated GMP/GDP guidance published

1.13 The 2022 edition of Rules and Guidance for Pharmaceutical Manufacturers and Distributors (the "Orange Guide"), now in its 11th edition, has been updated and published together with its sister publication, Rules and Guidance for Pharmaceutical Distributors (the "Green Guide") which is in its fifth edition. Both guides are the first edition after the UK left the EU and incorporated the Agency's transformation, amended extracts from the Human Medicines Regulations 2012 and the Medicines for Human Use (Clinical Trials) Regulations 2004, good manufacturing and distribution practices and matters relating to brokering medicines and distributing active substances. These guides are an important tool in informing our stakeholders on how they can comply with our regulatory requirements for GMP and GDP.

2. PARTNERSHIPS NATIONAL AND INTERNATIONAL

Medicines advertising regulation

2.1 The Advertising Standards team has published its 2021 Annual Report **'**Delivering High Standards in Medicines Advertising Regulation', showcasing regulatory work done by the Agency, collaborating with a range of other bodies. It highlights key ongoing work of the unit such as vetting of advertising material for COVID-19 therapeutics and supporting the launch of innovative reclassifications into the pharmacy in the important area of women's health. The report was accompanied by a webinar hosted for the pharmaceutical industry, which gave key stakeholders an opportunity to hear from us about best practice in advertising compliance in the POM and OTC sectors. The webinar will be formally evaluated but early anecdotal signs are that the webinar provides useful and engaging content.

Long COVID study with National Institute for Health Research

2.2 The MHRA's Clinical Practice Research Datalink (CPRD) is collaborating in an NIHR funded study into non-hospitalised community long COVID cases, which aims to establish the evidence base for appropriate therapies and to evaluate the symptom burden and underlying pathophysiology. A methodology paper for this study has been published online in BMJ Open, detailing the used of anonymised primary care records from the CPRD to select an initial target cohort of up to 2500 individuals.

Agency role in Global Pandemic Preparedness

2.3 The Coalition for Epidemic Preparedness Innovations (CEPI) held their Global Pandemic Preparedness Summit on 7 and 8 March in London. This was attended by a number of Agency staff for whom it was an opportunity to strengthen international networks. This coincided with the issue of a joint statement by the UK Government and members of the life sciences industry to deliver the 100 Days Mission, to develop vaccines against emerging diseases in as little as 100 days. The Agency has multiple Research and Development collaborations on vaccines against emerging diseases supported by CEPI.

Working with other organisations to support vaccine development

2.4 The MHRA partnership between CEPI, NIBSC/MHRA and the University of Malaya, for the production of WHO Standard for Nipah antibodies to support vaccine development, has been expanded to include the International Centre for Diarrhoeal Disease Research, Bangladesh. We have contracted with Synexa Life Science, South Africa for provision of convalescent serum from unvaccinated Omicron-infected individuals. This material will be important to understand Omicron-specific immune responses and will be included in the proposed WHO international reference panel for COVID-19 convalescent plasma for Variants of Concern.

Working towards global polio eradication

2.5 A team from the NIBSC WHO Collaborating Centre on Polio visited the WHO Polio Laboratory at the Institut National de Recherche Biomédicale (INRB) in Democratic Republic of Congo to review the implementation of a new method for direct detection of poliovirus from clinical samples developed by NIBSC in collaboration with Imperial College London and funded by the Bill and Melinda Gates Foundation. This method will substantially reduce the time between sample collection and final characterization of viruses which will be critical for the early implementation of public health interventions such as immunisation campaigns and will hopefully help completion of global polio eradication.

Good practice symposia

2.6 We held the Good Practice Symposia week in March, attracting 1800 delegates across 40 countries, demonstrating our global influence and the strength of our international partnerships. Delegates included global regulators and stakeholders alike, with the week commencing with the joint MHRA, USA FDA and Health Canada Good Clinical Practice Symposium. This event provided a global regulatory perspective on how maximising our understanding and use of risk-based approaches can build resilience into clinical trials, allowing flexibility in the protocol and clinical trial conduct, while still ensuring participant safety and reliable results. This was followed by the Good Pharmacovigilance Practice Symposium that discussed current challenges in pharmacovigilance faced by industry, including lessons learnt following the end of the EU Exit Transition period and adaptations to inspection processes implemented by the MHRA and USA FDA in response to the COVID-19 pandemic.

International Engagements

2.7 MHRA representatives visited Washington, USA, joining NIHR in some Department for International Trade meetings with organisations to promote the UK as the world-leading location to run clinical trials, with progressive and proportionate regulatory approaches to trial approvals and legislation, support for innovation via the Innovative Licensing and Access Pathway, as well as the NIHR provided services. This was in addition to supporting the Association of Clinical Research Organizations 20th Anniversary Event, highlighting the work of the industry alongside USA FDA and NIHR colleagues conducted throughout the pandemic. The MHRA also delivered the keynote speech (virtually) at a UK China Pharma forum organised by the Foreign, Commonwealth and Development Office. Excellent feedback was provided from all events regarding the UK clinical trials environment and the MHRA approach.

3. PATIENT SAFETY

SafetyConnect reporting system

3.1 The programme to implement the new, responsive SafetyConnect reporting system is at an important stage. The final vigilance case management system has been deployed for informal testing, with formal testing beginning on 18 April. The sprints to configure the final version of the new signal detection system have started. We have also reached an important milestone in the signal detection research project and have completed the expected deliverables on time and within budget. This project has developed a number of signal detection methods which we will be applying for all healthcare products when we go live with our new signal detection system. We have also developed a range of training master classes on signal detection and the methods developed which we will be rolling out as part of our business readiness activities.

Expert advice on medical devices

3.2 The final meeting of the Devices Expert Advisory Committee (DEAC) took place in March. We are about to begin recruitment for an interim committee on devices. This committee will provide expert clinical and scientific advice, as well as patient perspectives, on devices pending the introduction of a statutory committee in 2023. The establishment of a statutory expert advisory committee on medical devices has been made possible by new powers introduced within the Medicines and Medical Devices Act, and will be an important step forward in formalising safety decision-making procedures for emerging safety issues with medical devices.

Several medical devices safety issues were managed this month:

3.3 Due to an electrical fault, Philips Medical Systems V60, V60plus and V680 non-invasive ventilators have the potential to shut down without alerting the user. We consulted a UK-wide incident management team and then issued an urgent National Patient Safety Alert (NatPSA) to advise hospitals to identify and deploy alternative devices and stop use of the Philips devices. The impact of the alert will be assessed by conducting a survey of the Medical Device Safety Officer Tetwork. This NatPSA was drafted and published in conjunction with the new Risk Communications team.

3.4 The Devices Expert Advisory Committee (DEAC), with two additional diabetes experts, discussed evidence presented by the MHRA on Roche Diabetes Care's Accu-Chek Insight insulin delivery pump and events of insulin leaks leading to cases of hyperglycaemia and diabetic ketoacidosis. The Committee endorsed MHRA's proposal to issue a National Patient Safety Alert advising that patients be proactively moved to alternative insulin therapy delivery methods.

3.5 An investigational review of LifeVac and DeChoker, two airway clearance devices on the UK market currently subject to marketing restrictions, concluded in March 2022. The outcome of this review is currently being communicated to the manufacturers and shall be published in due course.

Safety review on paracetamol and hypertension

3.6 We recently reviewed a publication raising concerns that paracetamol may increase blood pressure in patients with existing hypertension, and sought independent expert advice from the Pharmacovigilance Expert Advisory Group (EAG) of the CHM. The experts agreed with our assessment of the study limitations (short duration and small patient group) and that pain itself can have an effect on blood pressure, therefore the study was not representative of the whole population who experience pain. Further evidence is needed to determine the effect of paracetamol on blood pressure within the wider population. Alternative analgesic medicines have cardiac and gastrointestinal risks, therefore we do not recommend patients to change their pain medicine without the advice of their healthcare professional.

COVID-19 testing

3.7 Following the government announcement to end free COVID-19 testing for the public on 1 April 2022, we are moving to mainstream our safety and surveillance activities to 'business as usual'. We are moving our emphasis onto pandemic preparedness. This includes continuing cross-Agency partnership, as well as external partnership with UK Health Security Agency (UKHSA) and developing a project group consisting of internal and external stakeholders to update our guidance to manufacturers on their requirements regarding continued assurance regarding Variations of Concern.

Criminal Enforcement Unit

3.8 Online interventions, including the removal of marketplace listings and websites illegally selling medicines, continue to be successful in reducing internet-based threat. Introducing enhanced capabilities to tackle cyber-enabled offending during 2022 will further bolster the Unit's online disruptive impact and result in deployment of innovative interventions. Partnership with West Mercia Police resulted in one arrest, suspected criminal profits and a significant quantity of falsified and unlicensed medicines being removed. A separate MHRA investigation into a UK based pharmaceutical company concluded in a fine and a costs order. This case will have a significant deterrent value across industry as it highlights the potential consequences of non-compliance with regulations.

4. PATIENT INVOLVEMENT

Safety review of isotretinoin

4.1 The Isotretinoin Expert Working Group's review of psychiatric and sexual side effects was considered by the CHM in December, with patient representatives and families in attendance for the discussion. We are now considering the advice that was received from the CHM and a number of regulatory steps are needed before we can publish the findings and recommendations. There will be ongoing engagement with patients and other stakeholders as the process reaches its conclusion, after the restrictions on government announcements due to the elections.

5. DYNAMIC ORGANISATION

Transformation Programme

5.1 An All Staff Meeting was held where the Agency's senior leadership and NEDs focused discussions on the future of the Agency, providing a forward look on the Agency's Transformation and progress on our key objectives to put patients first, enable scientific innovation, accelerate healthcare access and strengthen patient safety. In line with the need to promote staff engagement, the theme was 'Starting a big conversation'. Internal selection and external recruitment activity are ongoing to fully populate the new teams, with progress being continually monitored and mitigation actions being undertaken with senior leaders where necessary. We are currently driving a revitalised internal recruitment and selection strategy following review with senior leadership, to accelerate selection outcomes and deliver our commitment to ensure job security for staff at-risk of being displaced.

5.2 Delay in placing staff in new roles and in external recruitment are factors underlying the low scores in a recent staff survey, indicating low morale amongst staff and a need for robust leadership during this transitional phase to populate the new structure. The new One Agency Leadership Group is working urgently on an action plan to address these concerns. Individual and team coaching for senior leaders has taken place, together with a bespoke One Agency leadership skills development programme connected to the Agency Delivery Plan goals and aligned to the requirements of the new operating model.

6. FINANCIAL SUSTAINABILITY

Financial Sustainability

6.1 We have had confirmation from the Department of Health that they anticipate awarding us transformation funding in the indicative Spending Review figures, in addition to our baseline funding for service delivery for the 2022/23 financial year. This aligns to the work that we have been doing to prioritise which new IT systems we invest in with the available funding, ensuring that we finish delivering SafetyConnect, our new responsive safety reporting system for all healthcare products, and start working on the core Agency Regulatory Management System. We will also be retaining the reserves built-up from working with the NIHR to fund work on the Scalability and Observational Research Trusted Research Environment (IRSP).

6.2 We have finalised our business planning work and the Executive team has agreed a balanced budget for the 2022/23 financial year. We continue to progress the work on the review of statutory fees, with a focus on ensuring that the fees applied in financial year 2023/24 allow for full cost recovery and an appropriate degree of inflation.

7. AGENCY PRIORITIES

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

i. Completing the staffing of the new transformed organisational structure with appropriately skilled people in the remaining vacant roles so to fully operationalise the 'One Agency' model

ii. Enabling the new One Agency Leadership Group to provide dynamic leadership in order to realise the current opportunities, including a major review and optimisation of the Agency's services to all our stakeholders including patients and the public

iii. Operating to a balanced budget for the 2022/23 financial year and progressing the fees review at pace to ensure a financially sustainable Agency

iv. Finalising plans for the revision of the medical devices regulations, ensuring that patient safety is a priority, regulation is risk proportionate, and that system readiness is factored into implementation timescales

v. Keeping up the momentum on pandemic preparedness work as the Agency's priority on access to vaccines, diagnostics and therapeutics for COVID-19 reverts to 'business as usual'

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

Dr June Raine DBE
CEO
April 2022

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

19 April 2022

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

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

1. Executive Summary

1.1 PSEC discussed four areas at its meeting on 1 April 2022. These were principles for consultations; complaints' handling standards and procedures; risk perception in patients; and the results of the public engagement on the Yellow Card Biobank. Each area was at a different stage of development. The principles of consultations and the complaints' handling standards and procedures would need further input from the Committee over time. The work on risk perception in patients, due to the potentially diverse areas it could cover, needs further thought and input from several sources across, and perhaps external to, the agency. The public engagement work on the Yellow Card Biobank is complete for this stage of the project and the Committee were pleased, not only in the thorough way this was conducted, but also the plans to involve patients in the ongoing development of the Yellow Card Biobank.

2. Introduction

2.1 The seventh meeting of the Patient Safety and Engagement Committee was held on 1 April 2022.

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

3.1 **How can we ensure that PSEC has assurance on the consultations run by MHRA?**
The Committee discussed a paper that set some core principles for consultations. The principles intended to introduce consistency and quality of the consultations carried out by the MHRA. Suggested principles would cover purpose, content, reach, response, and impact. The Committee wanted the principles to be more patient-focused. It was important to have some information at the planning stage, perhaps captured through standard pro-forma, noting how the content was put together, intended audiences and how they would be reached - therefore how this would affect the responses, and how results would be used.

Suggestions from PSEC also included a register of consultations with details of how many were reached and what methods were most effective. This information could be sent to the Committee on a regular basis. It was also important that the whole organisation learn from how consultations are planned, methods used to not only reach groups but analyse data such as meta-analysis or gap analysis, and the impact. There was further discussion on capturing enough demographic data without making consultations too long and onerous. It was also important to not lose flexibility in devising consultations. The Committee will continue to review this area to seek assurance as it develops.

3.2 **How do we handle complaints from patients and the public, and how can this be enhanced?**

The MHRA complaints' process currently covers administrative complaints only. The Parliamentary Health Service Ombudsman (PHSO) can review complaints about the MHRA, once internal procedures have been followed. It is consulting on new complaints' standards for the organisations it covers. The definition of a complaint and how to make a complaint will be broadened. The Committee discussed updating the MHRA complaints' standards and procedures to reflect these changes. The new definition will cover not just administrative complaints but also complaints about decision-making and services. At present at the MHRA, there might be some confusion for complainants and staff on what is a complaint and how it should be resolved. For instance, the Yellow Card scheme covering adverse drug reactions might be seen as a complaint but would not be covered by the complaints' procedure. Therefore, it is important that there is clear guidance and support for complainants as well as training for staff. Making the complaints process clearer to complainants and training for staff are both part of the PHSO's new draft standards. The Committee strongly recommended an external scrutiny stage as part of the complaints' procedure, but also suggested only one stage before this, to make complaint resolution as timely as possible. It also wanted to have updates on complaints including not just numbers but patterns of complaints, how they have been resolved and how quickly, as well as how the organisation was using them to improve administration, services, and decision-making. PSEC also offered to comment on draft standards and procedures, via email if necessary.

3.3 **Discussion on patient and public risk perception**

An earlier discussion at PSEC on how patients and the public perceive risk and how that differs from health professionals led to a board action point 65: "PSEC to seek assurance on how safety risks are considered by the MHRA in those situations where patients are willing to accept more risk than healthcare professionals". Individual patients may see the risks and benefits of a particular intervention in relation to their own situation and could best discuss this with their health professional, although this does not necessarily happen. However, the Committee needed to review its original discussion to ensure the relevance of this to the MHRA. PSEC decided there were areas where, either patient perception of risk, or the communication of risk, was useful to the work of the MHRA. For instance, the Committee view was that communication of risk through the Patient Information Leaflet is not always effective. Patients often do not know the risks of using alternatives or not using anything at all. The Committee also discussed the use of risk prediction tools and learning from other organisations such as ethics committees. This is obviously an area that needs much more thought. The Committee recommends further work on this - maybe through a seminar or workshop.

3.4 **What has been learnt from patient and public engagement events for Yellow Card Biobank and how can the Agency build on scoping work and continue to engage with patients and the public as it moves into set up?**

The MHRA is exploring whether a Yellow Card Biobank could be developed to capture genetic information from patients experiencing Adverse Drug Reactions (ADRs). This would create a resource to help the MHRA identify who is most at risk of ADRs due to genetic influences and develop the use of screening tests to optimise the use of medicines and reduce the number of side effects. Stakeholder engagement has been a key part of a 15-month scoping project. The Committee reviewed results of engagement with the public.

The methodologies used include Citizens' Juries covering 98 participants, 10 focus groups with 54 participants, and an online survey with 2262 responses. The Citizens' Juries were able to utilise short films and explanations about the project. The online survey had the least amount of explanation. Overall, the public was supportive of the project, and the areas of most concern was data and cyber security, and to some extent the use of data by outside organisations, which were more easily addressed through discussion and explanation. PSEC agreed that a more detailed breakdown of how demographics reflected different concerns can be used for more targeted engagement. The Committee were pleased with the range of methods used and the on-going work to include patients and the public in developing the project further. It congratulated the project team for the work undertaken so far.

4. Conclusion

4.1 PSEC were able to discuss how it would prefer to monitor Patient and Public Consultations and suggested several ways in which consistency and quality could be improved. This area is still in development but will be co-ordinated through the Patient Engagement Team. PSEC will continue to review consultations as they develop. PSEC agreed that the organisation should follow the PHSO standards and analyse complaints and outcomes more proactively. Complaints' handling will come back to the Committee so it can review the new standards and procedures once they have been developed. The Committee could also be contacted via email if needed as procedures were being developed at points between the PSEC meetings. PSEC recommends further work on how patients view risk and how risk is communicated. Finally, the Committee were pleased with the range of methodologies used to engage the public in the development of the Yellow Card Biobank project. It will be interested in how patients are actively involved as the Biobank is established.

Mercy Jeyasingham
Chair of Patient Safety and Engagement Committee
April 2022

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

19 April 2022

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

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

1. Introduction

The Organisation Development and Remuneration Committee (ODRC) met on 4 April 2022 and the agenda for the meeting covered:

- Agency progress on the recruitment of people to roles in the new organisation
- A review of the design proposals to deliver key services that will enable the Agency to deliver on its objectives
- The progress of the leadership and culture plans to support the development of the new organisation and operating model
- Review of the progress made to deliver the recommendations from the internal audit of culture.

2. Recruitment of people to roles in the new operating model

2.1. It was recognised that there had been significant slippages versus plan to get people appointed to new roles within the new organisational structure. Whilst there is little impact on current services to patients, the delays are having an impact on the morale of staff and causing delays in establishing new ways of working.

2.2. Almost three quarters of the permanent roles within the new organisation had been appointed at the time of the ODRC Meeting and the number of appointments is growing every day. Many of the roles not filled with permanent staff are currently being undertaken by fixed term contract or temporary staff and there are a number of permanent staff who have been displaced from previous roles who could potentially be redeployed.

2.3. The committee requested that an alternative approach to recruitment be considered so that the majority of roles within the new organisation can be appointed with staff on permanent contracts by the end of April. This would require the redeployment of existing staff who have been displaced where there is a good match of their skills, appointing fixed term staff into permanent roles that they are already doing and offering temporary workers fixed term probationary contracts where possible. An initial review of the Agency's headcount indicated that this could fill about 90% of the roles within the Agency and would provide certainty for everyone concerned.

2.4. It was recognised that such a process was not without risk, but the committee suggested that the benefits outweighed the risks and they would provide support to manage the risks as required.

2.5. Where roles require to be advertised externally to acquire new skills and capabilities, it was recommended that platforms such as LinkedIn should be utilised to ensure that the best possible pool of potential candidates are reached.

2.6. There was concern that some staff had resigned from the organisation in 2022. It was requested that a review of the reasons for resignation be undertaken and a plan to address the loss of skills developed.

2.7. It was stressed that the whole package of benefits of working for the agency should be made more visible to all current and potential new staff members. Many people are looking for other benefits including training, pensions, hybrid-working and career development opportunities, as well as base salary.

3. Services Redesign

3.1. Significant progress has been undertaken on the redesign of 5 services that are key to delivering improved services to patients and improving public health.

- Proportionality of risk benefit decisions for established medicines
- Innovation Accelerator, including maximising value from Scientific Advice and Horizon Scanning
- Expansion of the Innovative Pathway to include medical devices
- Safety signalling, detection, and management for medical devices
- Transforming the Compliance model using innovative approaches and technology

3.2. The work on services is starting to deliver new ways of working to deliver core activities such as faster decisions on established medicines through a combination of identifying non-value adding activities, listening to customers and stakeholders, identifying where technology can help and doing things differently.

3.3. A new compliance strategy is being developed that tailors the scale and type of interventions based on the level of risk. For inspections this will have a major impact on ways of working and improving patient safety.

3.4. It was encouraging to see that teams are working collaboratively with external organisations to co-create solutions and new ways of working.

3.5. The committee will continue to review progress, to ensure that benefits to patients are delivered and that the opportunities and ways of working enable more satisfying jobs for staff.

3.6. Assurance was given that the teams have sufficient people and resources to deliver the new ways of working and services.

4. Leadership and Culture Programme

4.1. The committee recognised that the leadership development programme has been well-designed and the roll-out has started reaching further down into the organisation than has been done previously. However, the benefits of this training will not be realised across the Agency until all staff are appointed into their new roles and feel a degree of psychological safety.

4.2. Feedback indicated that many leaders and staff are still not fully clear about their new roles and responsibilities. A One Agency Leadership Group of influential leaders from all levels across the Agency has been established to bring energy and accelerate the changes in ways of working and lead people towards working as One Agency rather than in silos.

4.3. There are two priority actions:

i) To appoint people to the vacant roles in the new organisation that are needed to deliver the One Agency Vision

ii) Communicate and engage all staff on what they need to be doing in their new roles and how they are enabling the delivery of the Agency Vision. It was stressed that these actions need to be led by line managers with support from HR, rather than being led by HR.

4.4. The roll-out of the culture programme and the leadership and development programme to existing and newly appointed staff will continue.

4.5. An e-learning programme on how to increase patient engagement will be rolled out early in the new financial year and will be mandatory for all staff.

4.6. A governance framework is being developed and will shortly be available to support the work on leadership and culture.

4.7. It was emphasised that leaders' primary responsibility is to set a vision for their teams and constantly engage, listen and coach their staff. The principles are in place, but leaders now need to start implementing them.

4.8. The committee will continue to review progress against the implementation plan, both in terms of metrics, success stories and areas of challenge where additional support is required.

5. Review of Internal Audit on Culture

5.1. The results of the internal audit of culture that indicated limited assurance were considered. A tracker for addressing the recommendations was then reviewed. The committee noted that many of the actions are overdue and revised timescales will need to be agreed with the Audit & Risk Assurance Committee (ARAC).

6. Concluding Remarks

The Agency is at a critical point in the implementation of its ambitious transformation programme. The priority is to complete the appointment of staff into new roles within the organisation, give clarity to everyone on what their role is and support them to be successful in delivering the ambitious Delivery Plan. The transition to the new ways of working will not be easy, but the Agency has a strong record of being able to deliver in the face of adversity. Leading by example and walking the talk will be essential for all leaders in the organisation, including the ODRC and the Board.

Amanda Calvert
Chair of Organisational Development and Remuneration Committee
April 2022

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

19 April 2022

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

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

1. Executive Summary

1.1 The Audit and Risk Assurance Committee (ARAC) held an additional meeting on 7 March 2022 to consider four Internal Audit reports. These were: Safety Connect; Implementation of the recommendations from the Independent Medicines and Medical Devices Safety Review; Order to Cash; and Preparedness for the change in the Agency's Trading Fund status. We also considered a paper from Human Resources on payroll controls. We reviewed the implications of the findings of this work for the Accounting Officer's annual Governance Statement for 2021-22 which is published as part of the Annual Report. Finally, we made a number of recommendations for Internal Audit's proposed work programme for 2022-23.

2. Internal Audit Reports

SafetyConnect

2.1 Internal Audit provided Substantial Assurance. The aim of SafetyConnect is to improve the MHRA's ability to monitor proactively and act on patient safety insights across the full product life cycle for the greatest public health benefit through the investment in a major new IT system. The expected programme outputs are: common ways of working across vigilance teams; common improved technology platform for incident management and signal detection; and an improved patient engagement platform for reporting suspected adverse incidents. We were pleased to note that Internal Audit found that programme management processes were well embedded and robust. There was good evidence of compliance with the Agency's Framework for Assurance of Projects and Programmes, together with examples of good practice. At this late stage in the implementation of this new system, Internal Audit did not identify any risk which could prevent SafetyConnect delivering its key outputs for the benefit of patients.

Implementation of the Recommendations from the Independent Medicines and Medical Devices Safety Review

2.2 In July 2020, Baroness Cumberlege published the Independent Medicines and Medical Devices Safety Review (IMMDSR). The report was critical of the health care system and its failure to respond to the concerns of patients. It made 9 strategic recommendations and 50 Actions for Improvement (AFI). Of the report's recommendations, one was specifically relevant for the MHRA stating that the Agency needed to improve its adverse event reporting and medical device regulation, whilst also ensuring that it engaged much more with patients and their outcomes. Patient engagement is now a key strategic priority for the Agency and SafetyConnect (detailed in paragraph 2.1) is a fundamentally important programme to help strengthen patient engagement and adverse impact monitoring. The Agency asked Internal Audit to review progress and provide independent assurance that the IMMDSR recommendations directly within the MHRA's purview are being addressed. This is Internal Audit's second review.

2.3 Internal Audit concluded that their work justified a limited rating. Internal Audit found good evidence that the MHRA is taking action to implement all of the recommendations of the IMMDSR and that failure to do so was a risk on the Agency's Corporate Risk Register, which is regularly reviewed by the Executive team.

2.4 The justification for Internal Audit's limited assurance was twofold. The first is that many of the IMMDSR recommendations cut across a number of aspects of the Agency's work and that progress was currently reviewed as part of separate reporting mechanisms. A fully integrated reporting capability is needed which makes the interdependencies between actions more transparent. The aim should be to ensure that all the actions are taken as a whole (including those which are not the responsibility of the MHRA) to deliver the overall improvement for patients which Baroness Cumberlege identified in her report. MHRA in isolation cannot mitigate whole system risk, indeed it is not within our remit, but we need to be aware of how the whole system operates from a medical products perspective, and thus form partnerships and strategies which are broader than the traditional approach.

2.5 The second justification for the limited rating was that the Agency had only confirmed resources for specific projects and not all the resources needed to address the IMMDSR recommendations across the Agency.

2.6 The Agency has accepted Internal Audit's recommendations and is considering how best to enhance its monitoring of progress. On resourcing, we recommend that the Board in considering the Agency's 2022-23 budget and medium term financing seeks assurance that sufficient resources are allocated to patient engagement.

Action: The Executive to highlight separately in presenting 2022-23 budget to the Board for approval, the level of resources allocated to patient engagement.

Order to cash

2.7 Internal Audit rated this as unsatisfactory. MHRA received £136.5 million of its income from fees in 2020-21. Fees and charges are accounted for by the Accounts Receivable Team using the Oracle Fusion financial management software. Invoices for MHRA services are generated across the Agency using local systems, not all of which are integrated with Oracle Fusion. The Finance team had recognised that the Order to Cash (O2C) processes had a number of weaknesses and asked Internal Audit to carry out an independent review against the Government Finance Functions principles for O2C. These principles are based on leading practices from the public and private sectors.

2.8 Internal Audit rated Order to Cash as unsatisfactory because the weaknesses in the framework of governance and control could have a significant impact on the Agency's ability to recover income. The main weaknesses are an accounts receivable system which is not fully integrated with feeder systems, thus requiring the manual input of emailed authorisation documents; inefficiencies in the system with O2C and in particular master data not being correctly maintained independent of those providing services; the need for a comprehensive debt management policy; and fragmented management of order to cash processes. Responsibility for these issues does not exclusively rest with Finance but are cross-agency.

2.9 We are concerned by Internal Audit's findings. The Agency has accepted all of the recommendations and assigned responsibility for implementation. Our next meeting is on 26 April 2022 (reporting to the Board on 17 May) and we have asked the Agency to provide a realistic assessment of how long it will take to remedy these weaknesses together with an implementation plan.

Action: The Executive to identify by when the weaknesses identified by Internal Audit can be realistically addressed together with a plan for doing so.

Preparations for change in Agency Trading Fund status

2.10 Internal Audit rated the Agency's preparedness for the transition from Trading Fund status as unsatisfactory. Internal Audit had originally planned to undertake its review in August, but this was delayed and while we received an interim update at our January meeting, the Agency's preparations were not sufficiently advanced for Internal Audit to undertake an assessment. The unsatisfactory rating is based on the finding that at the time of Internal Audit's work (late January / February) there was a lack of a clear governance structure for managing the change; an Agency-wide project plan was needed identifying all areas of the MHRA that will be impacted by the change; and that planning for the project should have commenced much earlier.

2.11 We were told that an experienced project manager has now been appointed, together with a Programme Governance Board entitled as Business Enablement, which will provide direction and governance to three closely related projects: Loss of Trading Fund status, Chart of Accounts reorganisation and Time Recording, which are critical in ensuring that the Agency's staff have the tools and support to manage costs and take informed business decisions. We welcome these initiatives, but the time to implement them is now significantly reduced which inevitably increases risk. The next six months will be critical and will require focused proactive leadership and management.

2.12 The redesign of the Chart of Accounts, which is essential to provide the enhanced management cost information required to support operational managers, is unlikely to be completed until July and in the interim, this is requiring a manual workaround. While the transformation which the Agency is undergoing, together with considerable effort devoted to responding to COVID-19, has placed significant demands on its leadership, major projects such as the change in Trading Fund status require much more proactive management initiated sufficiently early to best manage risk. It is important that this lesson is learned and owned by the Agency.

2.13 We have asked for a further update at our April meeting and recommend that progress at least for the next six months is routinely reported to the Board by the Chief Operating Officer. We also intend to gain ongoing enhanced assurance about the performance of financial management and control processes (paragraph 3.3)

3 Financial Controls

Payroll Controls

3.1 In response to some examples which indicated that payroll controls were not always operating as intended, and some concern over differences in human resource data, we asked for an update summarising the controls in place. We received a comprehensive paper setting out how the Fusion system is shared by Human Resources and Finance, and how the Agency interacts with CGI Payroll, an outsourced company providing services across the Civil Service. To provide further assurance that the controls are operating as intended, the first substantive Internal Audit review in 2022-23 will be on payroll processing.

Enhanced assurance over financial management and control

3.2 Over the last two years, the Agency's Finance team has initiated its own transformation programme in keeping with the strategic intention of the Government's Finance Function for the Civil Service finance profession to better support departments and agencies to be more strategic in their financial decision-making. To do so, routine financial information needs to be comprehensive and easy to access and interrogate. The MHRA's core financial system is Fusion (Oracle based) and MHRA Finance recognise that it needs to develop the way Fusion can be interrogated to enhance cost and activity management reports to support the Agency's management and its people better. The first stage of this is the redesign of the Chart of Accounts (paragraph 2.9).

3.3 It is important that the Board is confident that the quality of financial management is sufficiently robust and that the control weaknesses, such as identified in the Internal Audit of Cash to Order, are rectified and not more widespread. We consider that this assurance requires a more systematic assessment of the Agency's Finance Function. To help do this, there are a range of external benchmarks and best practice criteria such as the Government Finance Functions principles.

3.4 We have agreed with Finance that the best time to carry out such a review will be in August/September 2022 once the Agency's Financial Statements for 2021-22 have been laid in Parliament. This review would initially be a self-assessment by the Agency, supported by Internal Audit and External Audit, which ARAC would then review. In addition, we support the Deputy Director of Finance's suggestion that each year Internal Audit should review an aspect of the finance and human resources function on a rolling basis. This programme will be informed by the Committee's review.

Action: ARAC to hold a meeting in August / September 2022 to gain wider systemic assurance over financial management and control.

4 Governance Statement

4.1 Each year the Accounting Officer must prepare and publish, as part of the Annual Report and Financial Accounts, a Governance Statement which summarises the controls in place to ensure that resources have been used cost-effectively over the last twelve months. The Statement also includes the assurance provided by Internal Audit. In the light of the two unsatisfactory ratings awarded by Internal Audit it will be important that the Governance Statement sets out the action and timetable which the Agency has in place to remedy the identified weaknesses. The Statement should also set out the action taken in response to the systemic issues identified in Internal Audit's summary report for 2020-21.

5 Internal Audit draft programme of work for 2022- 23.

5.1 We reviewed Internal Audit's work programme for 2022-23. We suggested this should include a targeted review on how conflicts of interest are being managed (best time would be in Quarter 4 of 2022-23), the management of the new contract with the outsourced digital supplier and the progress with the Digital Road Map. We asked that the plan be re-submitted at the Committee's next meeting on 26 April 2022 for final agreement.

Action: Internal Audit's programme of work for 2022-23 to be agreed by the Executive and resubmitted to ARAC in April 2022 for formal agreement

Michael Whitehouse
Chair of ARAC
April 2022

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

19 April 2022

Title	**What are our financial plans for the Agency to achieve financial sustainability in 2022/23?**
Board Sponsor	Jon Fundrey
Purpose of Paper	Approval

What are our financial plans for the Agency to achieve financial sustainability in 2022/23?

1. Executive Summary

1.1 A budget is proposed that will enable the MHRA to deliver all of our services and the work outlined in the second year of our Delivery Plan.

1.2 The budget has a deficit of £0.7million, which means that we will have pressure within our budget of less than 0.5% at the beginning of the year. The Executive Committee has agreed that will be managed in-year to balance the budget by the end of the financial year.

2. Introduction

2.1 The MHRA ceased to be a Trading Fund on 31 March 2022 and is an Executive Agency of the Department of Health and Social Care (DHSC). This means that our income and expenditure is based on an annualised budget that is part of the Department's annual Parliamentary Estimates. The MHRA no longer has the option to use any surplus generated in prior years to fund services or change activities.

2.2 This paper contains the proposed budget for 2022/23 to provide our services and the work outlined in the second year of our Delivery Plan.

3. Proposal

3.1 The current proposed budget has a deficit of £0.7million (see table below). This means that we will have pressure of less than 0.5% at the beginning of the year. The deficit will be held in a central cost centre so that when we identify in-year underspends we can offset them against it. The Executive Committee are content with this proposal as several potential opportunities to close the deficit have already been identified. This includes additional savings on our facilities costs and some additional income. The Agency has also, in recent years, usually had a favourable performance against its budget.

	21/22 Budget	21/22 Forecast	22/23 Budget
Income	£169.1m	£165.1m	£161.4m
Spending Review	£0.0m	£0.0m	£18.6m
Staff Costs	(£99.0m)	(£90.3m)	(£90.6m)
Non-Pay Costs	(£66.1m)	(£62.1m)	(£67.1m)
Change Costs	(£36.8m)	(£36.4m)	(£23.0m)
Total	**(£32.8m)**	**(£23.7m)**	**(£0.7m)**[1]

[1] The £18.6m of indicative Spending Review funding includes £17.4m for transformation and £1.2m for the South Mimms site.

Income

3.2 DHSC has provided us with assurances that we will receive our expected base-line funding of £27.5million for 2022-23. This includes funding for the South Mimms site specialist facilities and sufficient scientific capability to deliver its statutory functions, as well as funding to provide pre-market support for innovative devices.

3.3 DHSC will also be providing us with £17.4million of funding to support the Agency's transformation. Of this £10.5million is capital funding to support the key digital improvements including finishing work on SafetyConnect and commencing the development of a new Regulatory Management System.

3.4 DHSC is also providing a further £3.4million to pay for the continued work that the Agency is doing to support COVID-19 testing and vaccines.

3.5 The final Spending Review (SR) allocations are waiting for Secretary of State approval. In the meantime, DHSC has provided us with these indicative figures to support the finalisation of our budget.

3.6 We have budgeted for £128.1million of trading income, in-line with our forecast for the current year. Although we are currently working on increases to our statutory fees these need to go through consultation and secondary legislation. We do not therefore anticipate that new fees will come into force before the end of the financial year and so no fee increases have been included in the budget.

3.7 Overall income is £4million lower than last year as we no longer require funding from the Department for our dividend as we paid back our Public Dividend Capital (PDC) on 1 April as part of our change in Trading Fund status.

3.8 We will continue to seek alternative sources of funding as we go through the year. We have already submitted bids for £9.9million of research and develop funding to progress our work on the Yellow Card Biobank, Innovative Access Pathways and mRNA-based therapeutics.

Expenditure

3.9 Pay costs reflect the new organisational structure and include the additional cost of continuing to deliver the work on COVID-19 testing and vaccines that is being funded by DHSC. It also includes an allocation to cover the annual pay rise and the additional 1.25% of employer's national insurance contributions.

3.10 Other expenditure has increased by £3.3million for on-going technology maintenance which in the prior year was classified as change costs. It includes a £1million increase in irrecoverable VAT after a review of how we recover VAT on our IT contracts. It also reflects a modest increase in our people-related costs for travel, conferences, and training as we return to some pre-pandemic working methods. However, it does include £2.5 million of savings from downsizing our office space in Canary Wharf and £2 million of savings from the retender of the IT Application Outsourcing contract.

3.11 Change costs include the key digital projects that the Executive Committee has prioritised. This includes £0.1 million for the Valproate Registry, £1.6 million for continued work on SafetyConnect and £9 million to start the development of a new Regulatory Management System. It also includes additional work during the year on reviewing our operating processes.

4. Recommendation

4.1 The Board is asked to approve the proposed budget for 2022/23.

Jon Fundrey
April 2022

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

19 April 2022

Title	**How are we going to provide more opportunities for public engagement with the Agency?**
Board Sponsor	June Raine and delivered by Rachel Bosworth
Purpose of Paper	Strategic Direction

How are we going to provide more opportunities for public engagement with the Agency?

1. Executive Summary

1.1 There has been a significant increase in the agency's engagement with patients and public over the last twelve months, and our Patient Involvement Strategy has been a key driver of this change. There is however still more for us to do to further develop our engagement approaches, in particular to ensure that we receive a diverse range of input from all sectors of the communities we serve.

1.2 This paper updates the board on some of the progress achieved over the last year, and proposes that we gather additional insight from patients, particularly from those groups we engage with less, as the basis for further development of our engagement approaches. We will seek the views and input of the Patient Safety & Engagement Committee (PSEC) in developing this work.

2. Introduction

2.1 Our Patient Involvement Strategy 2021 – 25, published in early October 2021, has been well received by patients and partners. We now have over twenty activation workstreams to deliver the ambition that we set out when we launched the strategy. There is now added impetus behind this as the resource in the Public, Patient and Stakeholder Engagement team is increasing as part of our transformation programme, and as we drive ownership of greater patient focus deep into the agency. This will be driven forward by our Public, Patient and Stakeholder Engagement team, but success will be achieved by ensuring that everyone in the agency recognises, embraces and helps deliver our patient first ethos.

2.2 One of the five strands of the Patient Involvement Strategy focuses on how we improve our involvement and engagement with the public and patients and we have made some good progress in this area already. The "One Agency: Delivering for Patients" programme, and the introduction of patient-focused values and behaviours for all our staff has driven a significant increase in requests from Agency staff for help and guidance in engaging patients. This has included patient engagement through consultations, workshops, piloting of innovative research techniques and listening to patient testimony on different issues. Some examples of our recent engagement with patients are highlighted in Section 3 below.

2.3 If we are to achieve this significant shift and put patients first, then we need to systematically involve patients and their carers in our regulatory processes on key topics and ensure their engagement and involvement is truly two way. We intend to build this in as we transform our business processes. We are actively considering introducing public hearings on safety issues, building on the pilot with Isotretinoin highlighted below; introducing more face-to-face briefings for patients and patient groups, for example on new technologies; refreshing and extending the Patient Group Consultative Forum; and extending the use of citizens' panels, building on the Yellow Card Biobank pilot. We are also considering how we will interface with the new Patient Safety Commissioner when they are appointed.

3. Examples of current engagement

3.1 At the start of last year we overhauled our approach to online consultation, changing to a new system that enabled us to professionalise our approach to consultations, provide us with far richer data outputs, and with heightened data security. Over the last year, we have run 10 online consultations, with a further five currently in planning. Since introducing the new system, we have seen a steady increase in the depth and breadth of responses, receiving over 1,000 responses to individual consultations including our recent consultation on medical device regulation, and over 2,000 responses on clinical trials. Alongside this, patients are providing detailed narrative responses to explain their views and this has been extremely valuable in informing next steps, for example in the development of our Patient Involvement Strategy. There is still much more that we can do to build this engagement further, and we have recently discussed with PSEC the need to introduce some principles to guide our approach to consultation, and allow us to create bespoke standards so that we can improve effectiveness. This work was informed by the Cabinet Office Consultation Guide 2019.

3.2 Over the last eighteen months, the Agency and the Commission on Human Medicines (CHM) have undertaken a review of Isotretinoin, which is used to treat people with severe acne when other medicines have been ineffective. Involving and engaging patients has been central to our approach. We have piloted new approaches, which included enabling patients and patient representatives to provide live testimony online to the Isotretinoin Expert Working Group. Patients and patient representatives were then invited to observe the evidence of the Expert Working Group being delivered to the Commission on Human Medicines, as they considered the recommendations of the review. This connectivity with patients has been hugely valuable in providing real examples of lived experience alongside the comprehensive data analysis carried out in the review, which is soon to be published.

3.3 We have also piloted the Citizens' Jury concept in our work on the Yellow Card Biobank initiative, which captures genetic information from patients experiencing Adverse Drug Reactions (ADRs). Four full-day Citizens Jury sessions were held in separate geographical locations in Newport, Long Eaton, Glasgow and Belfast in February and March 2022. Participants were asked to vote on a series of questions, such as whether they support the Yellow Card Biobank, whether they

would be likely to donate, the preferred recruitment approach, confidence in data security and whether they would like the option to have results returned and if so, what results to return.

3.4 This month (April 2022) we are piloting the first of our Patient Listening sessions, hearing directly from patients on the topic of surgical mesh which has been a focus of patient questions at recent MHRA Board Meetings held in Public. These sessions are intended to provide us with a far richer insight into the experiences of patients, which we will feed into our deliberations on what regulatory actions are required on these products. There will be no set agenda with these sessions and there will be an open invitation for patients to share their experiences with us.

3.5 Our Customer Service Centre launched in March 2020, and now receives just under 1000 patient requests or questions on a wide variety of topics every month, and this number continues to grow.

3.6 The Board's decision in September 2020 to hold all of our Board Meetings in public has proved very popular, with an open invitation for patients, stakeholders and staff to observe the meeting in full to build greater transparency and public awareness of Board discussions. The use of videoconferencing technology, initiated during the COVID-19 pandemic, has enabled members of the public from all over the country to observe the meetings and typically around 60 - 80 people have registered to watch each Board Meeting live. In addition, the Board Meetings have been recorded and published on the Agency's external website and internal intranet site with around 200 – 300 views after each meeting. Time has also been allocated at the end of each Board Meeting for members of the public to ask the Board any questions they wish. The number of questions being submitted in advance, and during the meeting on the chat function, have increased to such an extent that they now cannot all be answered within the allocated time. Questions not answered in the meeting have been answered in writing after the meeting, although it has become apparent that very similar questions are being raised at each meeting by specific patient interest groups. This suggests that alternative opportunities for more detailed engagement and in-depth dialogue need to be created with specific patient interest groups.

3.7 All of this has been encouraging, but we are on a journey. We know we still need to do more to provide a diverse range of patient engagement opportunities – whether digital or face-to-face, open equally to all demographics and all geographies. We are keen to explore additional opportunities for engagement, either direct or in partnership with other organisations, and to provide a better experience for patients. That said, it is important to remember that we must do more than create opportunities – we must also improve the engagement experience for patients and create a dialogue which can then inform regulatory decisions. We are currently exploring the creation of issue-themed web pages where patients can quickly find the answers to frequently asked questions that have been raised with our Customer Service Centre. This will improve the experience for patients by answering common questions more quickly.

3.8 All of this is engagement where the agency reaches out to connect with the public and patients. We are also exploring turning this approach on its head and provide patients with the opportunity to develop short patient-led content which would be shared with our staff. This could include short five-minute videos from patients to present different perspectives on a particular topic, medicine or device. This would be used to drive debate and discussion in every team meeting across the agency – putting patients into the very heart of the MHRA.

4. Proposal

4.1. We want to ensure that these additional opportunities for engagement have a sound strategic base, and that they collectively deliver a range of engagement opportunities that are representative of the wide spectrum of patients and public with whom we need to connect. Some patients want to be kept informed of our work, either generally or in specific areas of interest; some want to be involved in our work; and some want to provide input, for example into safety reviews. Our Patient Involvement Strategy highlighted three distinct groups shown below, and we are working to build a deeper understanding of the needs of each group, as the engagement approach should be different for each.

AUDIENCE	
Public/Patient	The vast majority of people are to be found in this group. They might have heard of the MHRA but have not had any reason to engage with us directly.
Reporting Patient	These are patients who have had contact with us perhaps through submitting a Yellow Card report, or by asking a question of the Customer Service Centre.
Involved Patient	These are patients who actively work with us in workshops, or research and are likely to be members of our Patient Group Forum.

4.2 We need to base the development of additional engagement opportunities needs on insight so that we know our engagement approaches enable us to connect with and understand the diverse patient population effectively.

To help us develop this approach, we propose to carry out a mix of consultation and focus groups with the three different audiences across the UK, ensuring we have a representative sample including those often excluded from formal channels of engagement. This engagement would seek to explore preferences, and further test engagement approaches with each of these groups.

4.3 This will help us to deliver an approach to engagement that recognises the different needs of the three broad groups and ensure that future engagement is properly representative of the patients and communities we serve.

We will work closely with a wide range of patient representative organisations and health sector partners to access a broad and diverse audience sample. The outputs from focus groups and consultation will then be drawn together to inform our framework of engagement approaches with public and patients. This will provide us with improved understanding and insight of patients when we engage in future.

4.4 With the return to in-person Board Meetings, it is proposed that all MHRA Board Meetings will continue to be live-streamed and recorded so that a video of each meeting can be published on the MHRA website and internal intranet site. However, with the increased range of other public engagement opportunities, it is proposed that only public questions relating to the items on each Board Meeting are answered in the meeting and any other questions are answered in writing after the meeting. This will also enable individual members of the public with specific product-related questions or comments to be directed to one of these other engagement opportunities as appropriate.

4.5 We will seek the views and input of PSEC in developing the detailed plans for the next stages of this work.

5. Recommendation

5.1 The Board is asked to note the good progress made so far in improving our engagement with patients and provide direction and support for the additional actions required to further develop our engagement approach.

Rachel Bosworth on behalf of June Raine
April 2022