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