Medicines and Healthcare products Regulatory Agency

Minutes of the Board Meeting Held in Public of 26th October 2020

(10:30 – 13:00)

By GoToWebinar conference call

Present:

The Board

Stephen Lightfoot	Chair
Professor David Webb	Deputy Chair
Dr June Raine CBE	Chief Executive
Dr Samantha Atkinson	Interim Chief Quality and Access Officer
Dr Barbara Bannister MBE	Non-Executive Director
Amanda Calvert	Non-Executive Director
Professor Bruce Campbell	Non-Executive Director
Jon Fundrey	Chief Operating Officer
Mercy Jeyasingham MBE	Non-Executive Director
John Quinn	Interim Chief Technology Officer
Anne-Toni Rodgers	Non-Executive Director
Dr Christian Schneider	Interim Chief Scientific Officer
Michael Whitehouse OBE	Non-Executive Director

Others in attendance

Rachel Bosworth	Director of Communications
Natalie Richards	Secretary to the Board and Deputy Head of Directorate
{Section 40: name redacted - personal data}	Executive Assistant to the Chair

Government Legal Department

Elizabeth O'Neill	Deputy Director, MHRA, Medicines & Pharmacy, GLD

Department of Health and Social Care (DHSC)

Elizabeth Woodeson CBE	Director of Medicines and Pharmacy, DHSC
Dr Alistair Hardisty	Head of MHRA Sponsorship and EU Exit, Medicines and Pharmacy Directorate, DHSC

Devolved Administrations

Kerry Chalmers	Medical Devices and Legislation Head of Unit, Scottish Government
Christopher Garland	Principal Pharmaceutical Officer, Northern Ireland

Item 1: Introduction

What are the priorities for this meeting?

1.1 The Chair set out his expectations and priorities for this public Board meeting which was being live streamed to the registered audience and recorded. Following a governance review in the summer of 2020 a unitary Board has been created, formed of the Chairman, Chief Executive, 7 Chief Officers and 7 independent Non-Executive Directors. This Board does not take regulatory decisions on individual products – it advises on the strategic leadership of the Agency. The agenda is structured around the Agency's four key strategic priorities: patient safety, healthcare access, dynamic organisation, and financial sustainability.

1.2 The Chair thanked Sir Michael Rawlins, the previous Chair of the MHRA, for his significant contribution to the MHRA over the last 6 years and to public health.

1.3 The Chair welcomed all to the meeting, including the broad range of members of the public attending in the audience.

Item 2: Are there any Apologies or Declarations of Interest

2.1 Apologies were received from Professor Liam Smeeth, Non-Executive Director.

2.2 There were no declarations of interest.

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 agreed these have each been appropriately actioned.

CURRENT CONTEXT

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

4.1 Dr June Raine presented the Chief Executive's monthly report, which covered topics within the four strategic priorities: (i) healthcare access – including updates on Covid-19 vaccine, therapeutics and diagnostics, and international work; (ii) patient safety – including updates on medicines and medical devices issues and on the Agency's patient and public engagement and involvement strategy; (iii) dynamic organisation – including updates on staff and accommodation, and the Agency's diversity and inclusion strategy; and (iv) financial sustainability – including updates on the Agency change programme and the Spending Review bid.

4.2 The Board thanked Dr Raine for her report and provided comments relating to the Spending Review bid and the Agency's future funding; the key role of NIBSC in the deployment of Covid-19 vaccines; the Agency's role in relation to Covid-19 tests; the strategy to establish real-time safety vigilance; and international collaboration. Communication with patients and the public was raised; it was noted that the Agency aims to test communications with patient representatives and relevant charities prior to publication.

4.3 The Board agreed with the priority issues presented and requested further information on the MHRA's wider work in the health system; an action was taken to provide an update to the Board on the Memorandum of Understanding with NICE.

Action 1: June Raine to provide an update to the Board on the Memorandum of Understanding with NICE by 23 November 2020

4.4 The Board noted that a new Diversity and Wellbeing lead has been appointed at the Agency; an action was taken to hold a Board seminar discussion on diversity and inclusion.

Action 2: Stephen Lightfoot to arrange a Board Seminar discussion on diversity and inclusion by 18 December 2020.

HEALTHCARE ACCESS

Item 5: What is the assurance that the MHRA can regulate multiple Covid-19 vaccine applications in parallel with priority, rigour and independence?

5.1 The Board considered a paper providing assurance that the MHRA can regulate multiple Covid-19 vaccine applications in parallel. The Board considered the MHRA's preparedness to deliver vaccine regulation as a priority, while also ensuring scientific rigour and independence are maintained. The report covered the work the MHRA has undertaken in four priority areas: (i) Early engagement and scientific rigour; (ii) Independence; (iii) Capacity; and (iv) Public and patient safety.

5.2 The Board agreed that the work the Agency is doing in parallel to regulate Covid-19 vaccines does not risk compromising standards: these applications are assessed in depth. The Board provided comments regarding OMCL batch release of the vaccines and was assured that batch release will be scaled up for a mass batch release programme.

5.3 The Board raised concerns regarding misinformation on social media and asked how to ensure the correct information and communication reaches patients; an action was taken to explore what can be communicated to patients on how and why the MHRA made its decisions when new Covid-19 vaccine applications have been determined.

Action 3: Sam Atkinson to explore what can be communicated to patients on how and why the MHRA reaches its decision when Covid-19 vaccine applications have been determined by 23 November 2020.

5.4 The Board provided comments on potential international data sharing and harmonisation of learnings. The Board was assured that the MHRA stands ready to deliver in support of the wider fight against Covid-19.

Item 6: What is the assurance that the MHRA will be ready to operate on Day 1 of EU Transition?

6.1 The Board considered a paper providing assurance that the MHRA will be able to operate on Day 1 following the end of EU Transition. The Board noted that the underlying objective of the Transition programme is to ensure that patients in all parts of the UK will continue to have access to existing and new medicines and devices and to meet healthcare needs from 1st January 2021.

6.2 The Board considered the measures which the MHRA is putting in place in order to be ready to operate on Day 1 of EU transition. The Board expressed its thanks to the GLD Legal team for their extensive work on EU Exit. The Board was reassured by the pragmatic work the MHRA has been undertaking to maintain continuity of supply to Northern Ireland. The Board agreed on the importance of strong independent assurance on the Agency's work and noted the results of the recent audit by the Infrastructure and Projects Authority of Cabinet Office.

6.3 The Board provided a range of additional comments on the topics of the standstill, the Falsified Medicines Directive, the Statutory Instruments, and quality and integrity of medicines. The Board was assured on the MHRA's preparations to be able to operate on Day 1 after EU Transition.

PATIENT SAFETY

Item 7: What is the MHRA doing to address the recommendations of the Cumberlege Review?

7.1 The Board considered a paper providing an overview of the actions which the MHRA is taking in relation to the recommendations from the Independent Medicines and Medical Devices Safety (IMMDS) Review, led by Baroness Cumberlege. The Board noted the activities the MHRA has been undertaking in response to the report; and noted that the Agency is working with DHSC and other healthcare partners in preparation for the government response to the Review and to improve collaborative working across the healthcare system.

7.2 The Board provided comments on patient engagement and involving patients systematically in regulatory decision-making; providing specific feedback to reporters; bringing together and linking data from across the system; how the MHRA works with the NHS and pharmacy services to increase awareness through initiatives such as Medicines Safety week and World Patient Safety day; and engagement across the system with healthcare professionals. The Board was assured on the progress MHRA is making in taking action in relation to the recommendations from the IMMDS Review.

Action 4: Stephen Lightfoot to arrange a discussion on how to involve patients systematically in our regulatory decision-making in a Board Seminar by 23 November 2020.

DYNAMIC ORGANISATION

Item 8: What are the key responsibilities and assurance map of the new MHRA Unitary Board, Board Committees and Management Committees?

8.1 The Board considered the overall shape, key responsibilities and priorities of the revised MHRA Governance framework, which is being rolled out to establish more agile decision-making. The Board agreed that the Patient & Safety Assurance Committee of the Board is an important addition to scrutinise patient safety and engagement and to provide assurance to the Board.

8.2 The Board provided comments on the new Committees and emphasised the importance of linkage in the work of the Committees at the Executive level. The Board recommended scenarios should be drawn up by ARAC to stress-test the MHRA Governance framework to ensure the structure is robust in the event of a significant unexpected event.

Action 5: Michael Whitehouse to arrange for ARAC to draw up scenarios to stress-test the MHRA Governance framework to ensure that the structure is robust by 18 December 2020.

8.3 The headline Terms of Reference for each of the committees was discussed; it was agreed that the detailed Terms of Reference and membership of the Board Assurance Committees need to be finalised and agreed by the Board. The Board agreed the

assurance framework should adequately provide clear routes of assurance in all directions across the Agency.

Action 6: Stephen Lightfoot to ensure that the membership and Terms of Reference of the Board Assurance Committees are finalised and agreed by the Board by 18 December 2020.

ANY OTHER BUSINESS

Item 9: What are the key items for discussion at the next MHRA Board Meeting?
9.1 The Board agreed this would be discussed further separately.

Item 10: Are there any other urgent items for discussion?

10.1 The Board noted that there were no other urgent items for discussion at this time.

EXTERNAL PERSPECTIVE

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

11.1 The Board answered a range of questions from members of the public.

SUMMARY OF ACTIONS FROM MHRA BOARD MEETING – 26 October 2020

	ACTION	Who	When
1.	Provide an update to the Board on the Memorandum of Understanding with NICE	June Raine	23/11/20
2.	Arrange a Board Seminar discussion on diversity and inclusion	Stephen Lightfoot	18/12/20
3.	Explore what can be communicated to patients on how and why the MHRA made its decision when new Covid-19 vaccine applications have been determined	Samantha Atkinson	23/11/20
4.	Arrange a discussion on how to involve patients systematically in our regulatory decision making in a Board Seminar	Stephen Lightfoot	23/11/20
5.	ARAC to draw up scenarios to stress-test the MHRA governance framework to ensure that the structure is robust	Michael Whitehouse	18/12/20
6.	The membership and Terms of Reference of the Board Assurance Committees need to be finalised and agreed by the Board	Stephen Lightfoot	18/12/20