

**Medicines and Healthcare products Regulatory Agency**

**Minutes of the Board Meeting Held in Public of 23<sup>rd</sup> November 2020**

(10:30 – 13:00)

By Zoom Webinar

**Present:**

*The Board*

Stephen Lightfoot	Chair
Professor David Webb CBE	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
Professor Liam Smeeth	Non-Executive Director
Michael Whitehouse OBE	Non-Executive Director

**Others in attendance**

Rachel Bosworth	Director of Communications
{Name redacted: Section 40 – Personal data}	Secretary to the Board and Deputy Head of Directorate
{Name redacted: Section 40 – Personal data}	Executive Assistant to the Chair

*Government Legal Department*

Elizabeth O'Neill	Deputy Director, MHRA, Medicines & Pharmacy, GLD
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*Department of Health and Social Care (DHSC)*

Dr Alistair Hardisty	Head of MHRA Sponsorship and EU Exit, Medicines and Pharmacy Directorate, DHSC
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*Devolved Administrations*

Cathy Harrison	Chief Pharmaceutical Officer, Department of Health Northern Ireland
Alison Strath	Chief Pharmaceutical Officer, Scottish Government
Greig Chalmers	Head of Medicines Policy Branch, Scottish Government

**Item 1: Introduction**

*What are the priorities for this meeting and how will the meeting run?*

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.

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

1.3 The Chair and the Board congratulated Professor David Webb who was made a Commander of the Order of the British Empire in the Queen's birthday honours.

1.4 The Board sincerely thanked the previous secretary to the Board, Aidan McIvor, for his unfailing readiness to offer help and advice to the Board.

**Item 2: Are there any Apologies or Declarations of Interest**

2.1 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 updates were provided on the outstanding actions. It was agreed to bring forward the action on Devices Registries for an update at the Board meeting.

**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, EU Exit, international work and CPRD support for new pragmatic clinical trials; (ii) patient safety – including updates on medicines and medical devices issues, MedSafetyWeek, and on the Medical Devices Safety Bulletin; (iii) dynamic organisation – including updates on inspections, mental health and wellbeing, staff meetings and Civil Service Awards; and (iv) financial sustainability – including updates on the Agency Change programme and the Finance Transformation.

4.2 The Board thanked Dr Raine for her report and provided comments relating to remote inspections and news ways of working; the safety and efficacy of hand sanitisers; the EU Exit web seminars and responding to uncertainty in industry, and stakeholder engagement in relation to EU Exit; and resources the MHRA has to undertake independent surveillance of covid-19 vaccines. The Board were assured on each of these points.

**HEALTHCARE ACCESS****Item 5: What are the most promising scientific research projects within the Agency that could have the biggest impact on protecting and improving patient health?**

5.1 The Board considered a paper describing the most promising scientific research projects within the Agency that could have the biggest impact on protecting and improving patient health. The Board noted that scientific research performed by the Agency, strategically aligned to a patient-centric Science Strategy, will create important outcomes

enabling medical products developing, licensing and surveillance, and evolve current regulatory frameworks.

5.2 The Board considered the areas of interest which should be considered for the Agency's portfolio which then can be further developed for the Agency's Regulatory Science Strategy. It was noted that the areas identified in the paper are not the only areas of interest, given the Agency's wide scientific portfolio. The Board commented that this paper focuses a lot on NISBC and CPRD; other areas of the Agency's portfolio could be brought in. The Board endorsed the proposal to establish a Centre for Regulatory Science.

5.3 The Board commented that it is vital this work focuses on the particular strengths of the UK for regulatory science, and how to address any weaknesses; and provided additional comments regarding issues with real world evidence and secondary care data; the ability to translate data in to evidence and CPRD's role in recruitment for pragmatic trials. Mapping out future needs with regards to methodology and applications in the area of real world evidence will be key.

5.4 The Board requested more information on the work of CPRD; an action was taken to conduct a Board review of CPRD.

***Action 13: Jon Fundrey to facilitate a Board review of CPRD.***

5.5 The Board provided a range of additional comments on the topics including the growing number of tumour markers being identified and the requirement of genomic reference standards; ensuring the Agency has access to equipment at the cutting edge of science; development of medical devices; new sources of signals. The Board suggested the Agency should consider routine publication in scientific and medical journals; starting with the Covid-19 vaccines regulatory approval process.

5.6 The Board agreed it is important that the Agency communicates and collaborates across the UK in this work; the Board also agreed that consideration should be given on how to prioritise these projects internally, and also working with external stakeholders.

## **PATIENT SAFETY**

### **Item 6: What is the assurance that the MHRA Enforcement Group can protect patient health by working with global partners?**

6.1 The Board considered a paper providing assurance that the MHRA Enforcement Group can protect patient health by working with global partners. The Board noted that the work of the Enforcement Group directly impacts the security of the supply chain and the availability of unlicensed medicines and is therefore essential for public and patient safety.

6.2 The Board thanked the MHRA Enforcement Group for all the work they do to protect public health. The Board provided a range of comments regarding incentives and disincentives such as penalties; the enormous scale of this work and the importance of international collaboration; vaccine fraud; and the importance of taking a holistic approach to this work.

6.3 An action was taken to review the resourcing of the MHRA Enforcement Group as this is a key area of work the Agency does to protect public health. Performance indicators should also be considered.

***Action 14: Samantha Atkinson to review the resourcing of the MHRA Enforcement Group and link with Business Plan as part of Size & Shape programme.***

## FINANCIAL SUSTAINABILITY

### Item 7: What assurance can be provided by the Audit & Risk Assurance Committee on the current risks facing the MHRA and their proposed mitigations?

7.1 The Board considered a paper providing assurance by the Audit & Risk Assurance Committee (ARAC) on the current risks facing the MHRA and their proposed mitigations. The Board noted the Agency's likely end of year financial position and endorsed the need for sustained implementation of the necessary changes which the Shape and Size review is likely to recommend so that the MHRA remains an effective and highly respected regulator but also becomes financially resilient.

7.2 The Board considered the recommendations to strengthen further the Agency's approach to risk management. The Board agreed this work is vital to the future of the Agency, and agreed that it is important that managers are fully engaged in the new governance system to ensure all risks are identified and there are no weaknesses.

7.3 The Board supported the project underway to better align fees to the Agency's costs and endorsed the need for a clear fee strategy which is periodically reviewed by the Board to enhance accountability and governance.

***Action 15: Jon Fundrey to review Agency Fee structure to ensure closer alignment with costs of delivery***

## DYNAMIC ORGANISATION

### Item 8: What are the strategic priorities for the new MHRA Corporate Plan (April 2021 – March 2024) and 2021/22 Business Plan?

8.1 The Board considered the strategic priorities for the new MHRA Corporate Plan (April 2021 – March 2024) and 2021/22 Business Plan. The Board agreed that a single 2-year Agency Delivery Plan should be produced instead of the existing Corporate and Business Plans. This should include specific details on change management, IT roadmap within realistic budget and prioritised Regulatory Science programme.

8.2 The Board agreed it is important to focus on deliverability, setting out the challenges and opportunities for the Agency from a public health and patient safety perspective, as well as from a scientific and regulatory excellence perspective. It was agreed that colleagues from the Devolved Administrations should be regularly consulted while the plan is in development.

***Action 16: Jon Fundrey to produce a single 2-year Agency Delivery Plan to replace the existing Corporate and Business Plans. This should include specific details on change management, IT roadmap within realistic budget and prioritised Regulatory Science programme.***

## ANY OTHER BUSINESS

### Item 9: What is the proposed membership of the Board Assurance Committees and the special responsibilities of the Non-Executive Directors?

9.1 The Board reviewed the proposed membership of the Board Assurance Committees so that each committee can finalise their Terms of Reference in line with the MHRA Governance Framework and Assurance Map approved at the MHRA Board Meeting on 26 October 2020. The Board endorsed the membership and also endorsed the proposed special responsibilities assigned to each Non-Executive Director. It was agreed that lay members should be seconded on to the Patient Safety and Engagement Committee until new lay members can be recruited.

***Action 17: Second interim lay members on to Patient & Safety Assurance Committee until new lay members can be recruited***

**Item 10: What are the 2021 dates for Board Meetings to be held in public?**

10.1 The Board reviewed and endorsed the 2021 dates for Board Meetings to be held in public.

***Action 18: Directorate to send out meeting invitation for agreed Board Meeting dates in 2021***

**Item 11: Are there any other urgent items for discussion?**

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

**EXTERNAL PERSPECTIVE**

**Item 12: What questions do members of the public have for the MHRA Board?**

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

**SUMMARY OF ACTIONS FROM MHRA BOARD MEETING – 23 November 2020**

Action Number	Action	Owner	Date	Status
Carried Forward from previous meetings				
3	Present an overview of how Device Registries, Unique Device Identifiers and Device Databases are being developed in the health system and the MHRA role in their development to strengthen device regulation	John Quinn	23/11/20 19/01/21	On agenda
5	Arrange a Board Seminar to discuss how the MHRA could engage patients more widely, building on existing engagement activities by other organisations, and involve patients systematically in our regulatory decision making	Stephen Lightfoot	23/11/20	Delegate to PS&E Committee
7	Provide an update to the Board on the Memorandum of Understanding with NICE	June Raine	23/11/20	Chair & CEO Meeting in February
8	Hold a Board Seminar discussion on diversity and inclusion	Stephen Lightfoot	18/12/20	Delegate to OD & R Committee
12	The Terms of Reference of the Board Assurance Committees need to be finalised and agreed by the Board	Stephen Lightfoot Committee Chairs	18/12/20 19/01/21	On agenda
New Actions				
13	Conduct a Board review of CPRD	Jon Fundrey	16/03/21	
14	Review the resourcing of the MHRA Enforcement Group and link with Business Plan as part of Size & Shape programme	Sam Atkinson	18/12/20	Included in Size & Shape programme
15	Review Agency Fee structure to ensure closer alignment with costs of delivery	Jon Fundrey	15/06/21	
16	Produce a single 2-year Agency Delivery Plan to replace existing Corporate and Business Plans.	Jon Fundrey	20/04/21	
17	Second interim lay members on to Patient & Safety Assurance Committee until new lay members can be recruited	Mercy Jeyasingham	19/01/21	Completed

18	Send out meeting invitation for agreed Board Meeting dates in 2021	Directorate	18/12/21	Completed
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