# Medicines and Healthcare products Regulatory Agency

## Minutes of the Board meeting 23rd July 2020

(13:30 – 16:15)

By Zoom / conference call

**Present:**

*The Board*

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| Professor Sir Michael Rawlins GBE Kt | Chair |
| Professor David Webb | Deputy Chair and Non-Executive Director |
| Dr June Raine CBE | Interim Chief Executive |
| Mr Jon Fundrey | Chief Operating Officer |
| Dr Barbara Bannister MBE | Non-Executive Director |
| Ms Amanda Calvert | Non-Executive Director |
| Professor Bruce Campbell | Non-Executive Director |
| Ms Mercy Jeyasingham MBE | Non-Executive Director |
| Mr Stephen Lightfoot | Non-Executive Director |
| Ms Anne-Toni Rodgers | Non-Executive Director |
| Professor Liam Smeeth | Non-Executive Director |
| Mr Michael Whitehouse OBE | Non-Executive Director |

**Others in attendance**

*MHRA executive*

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| Dr Samantha Atkinson | Director of Inspection, Standards and Enforcement (IE&S) |
| Ms Vanessa Birchall-Scott | Director of Human Resources |
| Dr Sarah Branch | Interim Director of Vigilance and Risk Management of Medicines |
| Ms Rachel Bosworth | Director of Communications |
| Mr John Quinn | Business Transformation Director |
| Mr Jonathan Mogford | Director of Policy |
| Dr Christian Schneider | Director of National Institute for Biological Sciences and Control |
| Mr Graeme Tunbridge | Interim Director of Devices |

*Supporting officials – in order of attendance for specific items*

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| Ms Carly McGurry | Deputy Director, Change Strategy |
| Ms Boryana Stambolova | Deputy Director of Finance and Procurement |
| {Section 40: redacted: personal data} | Head of Future of Regulation and Strategic Partnerships, Policy |
| {Section 40: redacted: personal data} | Diversity and Wellbeing Lead, Human Resources |
| {Section 40: redacted: personal data} | Corporate Affairs, NIBSC |
| {Section 40: redacted: personal data} | Head of Science Strategy |
| {Section 40: redacted: personal data} | Executive Assistant to the Chairman |
| Mr Aidan McIvor | Secretary to the Board and Head of Directorate |

*Department of Health and Social Care (DHSC)*

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| Ms Dunia Alameddine | Senior Policy Advisor – MHRA Sponsorship and EU Exit Medicines and Pharmacy Directorate, DHSC |

*Devolved Administrations*

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| Ms Fiona Taylor | Principal Officer for EU Exit medicines contingencies, Northern Ireland |
| Alison Strath | Scottish Executive Government |

*Lay representatives from Expert Committees*

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| Ms Susan Bradford | Lay representative from the Commission on Human Medicines |
| Ms Sara Payne | Lay representative from the Devices Expert Advisory Committee |

**Item 1: Introductions and Announcements**

1.1 The Chair welcomed all to the meeting.

*Apologies and announcements*

1.2 Apologies were received from Elizabeth O'Neill, Deputy Director, MHRA, Medicines and Pharmacy Team, DHSC Legal Advisers, Government Legal Department

1.3 The Chair made the following announcements:

- The Chair welcomed Professor Liam Smeeth, who joined the Board on 1st July 2020.
- The Chair asked that the minutes record the Board's deep gratitude to Susan Bradford and Sara Payne, whose attendance at the Board as lay observers would end in July. This follows the recent appointment of Mercy Jeyasingham as the Board's Patient Representative.

- The Chair noted the agenda for today's meeting was in a new format that emphasised the core work of the Agency; a new format for the cover sheets for Board papers will be ready by the next Board meeting on 24th August.

- The next public session of the Board will take place on Monday, 21st September; the meeting be delivered by a webinar, details of which will be published on GOV.UK.

- The Conflict of Interest policy for Non-Executive Directors will be submitted to the Audit and Risk Assurance Committee in October.

**Item 2: Declarations of interest**

2.1 Stephen Lightfoot reported that he has been appointed as Non-Executive Chair of the Board of Sussex Primary Care Limited which is a wholly owned subsidiary of Sussex Community NHS Foundation Trust.

**Item 3: Minutes of the Board meeting of 20th June 2020.**

3.1 The minutes of the Board meeting of 20th June were adopted.

**Item 4: Actions List**

4.1 The Board noted the Actions list.

**Item 5: Chief Executive's Report**

5.1 Dr Raine presented the CEO's report, which was in a new format, and is now at the beginning of the agenda. As part of her report, Dr Raine updated the Board on the following areas: (i) COVID-19 vaccines and therapeutics; (ii) the Independent Medicines and Medical Devices Safety Review; (iii) EU Exit; (iv) Future of Regulation; (v) Diversity and Inclusion; and (vi) return to work sites. As part of the update, it was noted that the fees structure is being reviewed.

5.2 Dr Raine said the volume of work which the Agency is managing overall remains very high, and staff morale remains good despite the pressures. Dr Raine mentioned that the 'Ventilator team' within Devices Division had received a personal letter of thanks from the Prime Minister, which was much appreciated by the staff concerned.

5.3 The Chair thanked Dr Raine for her report and congratulated the staff in Devices Division for their significant efforts. The Chair also mentioned that the Agency had been praised for its work during the pandemic, in Parliament by the Prime Minister and by the Health Secretary. The Board noted that a range of intense activity in recent months by staff has brought many public health benefits, of which the supply of ventilators is one example. The Board also noted that work has started on calculating the costs of these activities, which will come to the Board later in the year.

5.4 The Board asked about remote working arrangements for expert committees. Rachel Bosworth, who is leading on accommodation work, advised that a report about accommodation and agile working will come to the Board on 24th August.

**Item 6: Balanced Scorecard**

6.1 The Board received an update on work to develop a 'balanced scorecard', which was one of the recommendations that came out of the recent Governance Review by Ernst & Young. The Board noted that work is underway to fully develop a strategic balanced scorecard; meanwhile, a more basic performance dashboard will be used

6.2 The Board agreed to use the dashboard in the shorter term and offered to advise on the indicators critical for inclusion. As part of this process, the evolving dashboard / balanced scorecard will be tested with members of the Audit and Risk Assurance Committee.

## Item 7: Independent Medicines and Medical Devices Safety Review – update

7.1 The Board considered a paper on the Independent Medicines and Medical Devices Safety (IMMDS) Review, 'First Do No Harm', which was published on 8th July 2020. The paper summarised the recommendations relevant to MHRA and outlined next steps. These included a proposal to create an Implementation Steering Group that would report to the Regulation and Patient Safety Committee of the Board. It was noted that the Department of Health and Social Care will prepare a response to the Report's recommendations from the Government.

7.1 The Board endorsed the paper's proposal to have an Implementation Steering Group, as well as the overall direction of travel set out in the paper. For example, changes should be made without delay to ensure the Agency is able to listen effectively to patients and involve them in every aspect of its work. The Board noted that the Agency is already taking steps to strengthen collaboration with all bodies in the healthcare system.

7.2 The Board recommended that work should proceed without delay on areas where the Agency can make a difference quickly. The Board went on to comment on the need to map how patients are currently involved with the Agency's work The Board concluded by asking about staff morale, especially those directly involved with the report's findings. The Board were advised that prior to and after the Review's publication, staff were kept fully informed.

## Item 8: Regulatory and Patient Safety Committee feedback and endorsement of terms of reference

8.1 Professor David Webb, Deputy Chair of the Board, and Chair of the newly established Regulatory and Patient Safety Committee, gave an update on a planning meeting for the new committee that was held by video-link earlier in the day. Professor Webb explained that the Committee had been established following the publication of the Government's Independent Medicines and Medical Devices Safety Review on 8th July 2020 and that its scope would be wide. Draft terms of reference for the new committee are still in preparation and will come to the Board for review on 24th August. The Board noted that there would be two independent members, who will be recruited in due course.

**Action:** Draft Terms of Reference for the committee to come to the Board on 24th August.

## Item 9: Board Terms of Reference

9.1 The Board considered draft Terms of Reference for its unitary Board status and offered comments on specific areas. These include the Board's composition (executive and non-executive), its quorum, the role of the Vice Chair as the 'Senior NED', and procedures for terminating a NED's appointment, and the need for the Terms of Reference to be reviewed by the Board's legal adviser.

9.2 It was agreed that Carly McGurry would revise the Terms of Reference, considering the Board's comments. The Board asked that Elizabeth O'Neill, Senior Legal Adviser, to review the Terms of Reference.

**Action:** Elizabeth O'Neill, Senior Legal Adviser, to review the Terms of Reference.

## Item 10: MHRA COVID-19 Vaccine Deployment Oversight Group

10.1 Dr Christian Schneider presented a paper on the new COVID-19 Vaccines Deployment Oversight Group, including the Terms of Reference for the group. Dr Schneider advised that the Vaccines Deployment Oversight Group would oversee and co-ordinate the Agency's activities in areas relevant to deployment of high quality, safe and effective COVID-19 vaccines. Moreover, it would function as a "firewall" around the Agency's key activities and provide adequate governance and oversight. The Group will be composed of at least one member of relevant Divisions and will require extra project management support (ideally sourced internally). Meetings will be held weekly.

10.2 The Board noted that MHRA's contribution to the UK's COVID-19 response including into the Government Vaccine Task Force has been to provide technical advice and expedited approval of UK clinical trial applications, and to provide advice on scale-up of manufacturing facilities. With a range of candidate COVID-19 vaccines in development, this impartial scientific advice will remain an important function of the Agency during the pandemic. However, as product-specific data begin to emerge from clinical trials, the Agency has a crucial role in the scientific evaluation of specific vaccines, and this function must be independent of factors like product procurement and immunisation policy.

10.3 The Board enquired about the legal oversight that had been sought when setting up the Oversight Group. Dr Schneider explained the process and thinking that had gone into setting up the group the management of conflict of interest and interactions with industry. At the Board's request, further legal advice will be sought, and Ministers will be kept informed of how the process would work in practice. The Board also asked that consideration be given to having a 'sunset clause' for the Oversight Group, so that it can be stood down when its role is no longer required. The Board concluded by endorsing the Terms of Reference for the Group.

**Action:** legal advice to be sought on the management of conflicts of interest.

## Item 11: Transition (including EU Exit)

11.1 The Board received an update on a range of EU and HM Government negotiations which are in progress. Work continues in preparing for 1 January 2021. Plans are being developed to engage and share proposals on regulatory arrangements with a wide range of stakeholders. Work also continues about the Northern Ireland Protocol, working across Whitehall on a range of implementation issues related to both medicines and devices to ensure consistency in approach. The Board noted as part of the Implementation Plan operational plans, underlying IT, fees and costs will be finalised. It was noted that new systems to allow the Agency to operate independently would take 60 days to build but depending on outcomes this would be abortive work. Meanwhile, parallel work is also taking place to build closer links with other global regulators.

11.2 The Board noted the tight timescale (five months until the end of the transition period) and the intense pace of recent activity. The Board also noted that while the 'size and shape' project has yet to begin, Licensing Division's future role from 2021 is under development. The Board observed that an innovative licensing offer will not take up all the slack after January 2021; a paper on this will come to the Board. The Board also asked for an update on current thinking on future fees. These will be reflected in upcoming papers.

**Item 12: Office of Life Sciences Joint Review on the future of Regulation**

12.1 The Board received an update on the joint Office of Life Sciences (OLS) / MHRA Review on the future of regulation, which was commissioned by the Life Sciences Council (LSC). The aim of this project is to define the future role of regulation in UK, with strong input into Life Sciences and innovation, a strengthened role for protecting patients, and a strong global voice. A joint project team has been set up which is preparing a recommendations paper by mid-August. Work is under way to identify relevant streams of work in the Agency and discussions are ongoing to agree on a consultation process with stakeholders, as well as to link this work with the Agency's change programme, innovative licensing offer and other projects under way. As with EU Exit, there are concerns over resources and funding for project management support for this work.

12.2 The Board welcomed the update and commented on the need to reflect the agenda around vigilance and patient safety in this work. The Board advised that one should not forget NIBSC when considering this area of work. The Board commented that the provision of scientific advice recognised as a very valuable service with a strong positive impact for public health and for patients. Mechanisms were needed to ensure that there was no conflict of interest. It was noted that NICE and UK Veterinary Medicines Directorate have addressed these issues through the establishment of separate legal entities. Concerning CPRD, the Board advised that it has enormous strength in primary care data.

**Item 13: COVID-19 Task Force progress report**

13.1 Dr Samantha Atkinson presented an update on the Agency's ongoing response to the COVID-19 pandemic. The Board noted that the closing date for a Government tender for a strategic stockpile of medicines will close on 5th August as well as discussions with DHSC on other aspects of medicines supply, including in care homes. Dr Atkinson went on to give an update on clinical trials work, with the move away from sequential to parallel processing, which has shortened timelines. Dr Atkinson went on to assure the Board that safety standards would not be compromised as result of these more agile and flexible ways of working. In conclusion, the Board noted that a paper on lessons learned from the pandemic will come to the Board on 24th August.

**Item 14: Business Plan 2020-21 Q1 Report**

14.1 {Section 40: redacted: personal data}, presented the Quarter 1 report for 2020/21. The Board noted that most objectives are on track, although the ongoing pandemic has delayed the delivery of several objectives. Ms Dhaliwal reported that contributor factors include funding delays, impacts of delayed EU legislation (EU Medical Devices Regulation), and the reprioritisation of work. This Quarter 1 paper focussed particularly on two areas of current importance to the MHRA: deliverables which support the response to the Independent Medicines and Medical Devices Safety Review (IMMDSR) and the governance review.

14.2 The Board welcomed the updated format of the Quarterly Report, especially the narrative, although it was concerned by the volume of activities. The Board also cautioned against delay to any objectives related to IMMDSR. In answer to a question about finance, Jon Fundrey confirmed that an update on finances will come to ARAC and the Board in October. The Board also observed that phase 2 of the Change Strategy ('size and shape') will help define the agenda following the phase 1 implementation of a more agile governance of the Agency.

**Item 15: Inclusion and Diversity**

15.1 Vanessa Birchall-Scott introduced {Section 40: redacted: personal data}, Diversity and Well-being Lead within HR, and {Section 40: redacted: personal data}, Corporate Affairs Administrator at NIBSC, who gave a presentation on the Agency's Diversity and Inclusion agenda. As part of this work, a new Black, Asian, Minority Ethnic (BAME) staff network has been set up which was prompted by recent heightened domestic and international events and awareness of diversity issues, as well as in response to Public Health England's COVID-19 disparities report. The Board noted that the BAME Staff Network will give voice to race equality as part of this process and will join other staff networks, such as Lesbian, Gay, Bisexual, Transgender + (LGBT+) in operating both independently and linking together under an umbrella Staff Inclusion Network on issues of common interest. Furthermore, it was noted these networks are chaired by staff.

15.2 The Board welcomed the update and advised that, as the Agency's Patient, Public and Stakeholder Engagement Strategy is developed, it should also consider diversity and inclusion. The Board asked that the Inclusion and Diversity network's title be widened to include the word 'Equality', so that it will be known as Equality, Inclusion and Diversity. The Board asked if staff attendance at work had been adversely affected by COVID-19; Ms Birchall-Scott advised that from the data available, the number of COVID-related staff absences have been minimal. Further analysis will take place, which will be informed by one-to-one meetings between all staff members and their line managers. The Board went on to comment on the importance of training and development opportunities for staff, and why an inclusive workplace culture can help retain current staff and recruit new joiners. The Board also referred to recent work by the King's Fund into the impact of COVID-19 pandemic on the NHS, patients, and NHS staff, many of whom are drawn from the BAME community.

**Item 16: Forward Programme of Board Business**

16.1 The Board noted the Forward Programme of Business.

**Item 17: Minutes of the Corporate Executive Team (CET) meetings**

17.1 The Board noted the final minutes of the CET meeting of May 2020 and the draft minutes of June 2020.

17.2 The Board noted the current gap of nearly six weeks between the date of a CET monthly meeting and when the Board has an opportunity to see the draft minutes of the CET meeting. The Board asked that, in future, the most recent draft minutes of a CET monthly meeting should come to the Board, rather than having the current gap of nearly six weeks.

**Action:** Directorate to provide the Board with the most recent draft minutes of CET meetings.

**Item 18: AOB**

*Civil Service Reform*

18.1 The Board noted an announcement by Alex Chisholm, Chief Operating Officer for the Civil Service and Permanent Secretary for the Cabinet Office, concerning Civil Service Reform. The Board noted that the Agency was engaged with this initiative.

**Date of the next meeting:** 24th August 2020