Medicines and Healthcare products Regulatory Agency

Minutes of the Board meeting 20 May 2020

(10.30 am – 12.30 a.m.)

By Zoom / conference call

Present:

The Board

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
Mr Michael Whitehouse OBE	Non-Executive Director

Others in attendance

MHRA executive

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

Ms Carly McGurry	Deputy Director, Change Strategy
Ms Boryana Stambolova	Deputy Director of Finance and Procurement
{Section 40: redacted: personal data}	Regulatory Affairs Group Manager, Devices
{Section 40: redacted: personal data}	Expert GMP Inspector, IE&S
{Section 40: name redacted – personal data}	GMCP Operations Manager, IE&S
{Section 40: name redacted – personal data}	Acting Head, Advanced Therapies Division
Ms Rachel Arrundale	Deputy Director, Corporate Strategy, Policy Division
{Section 40: name redacted – personal data}	Head of Science Strategy
{Section 40: name redacted – personal data}	Executive Assistant to the Chairman
Mr Aidan McIvor	Secretary to the Board and Head of Directorate

Legal Services

Ms Elizabeth O'Neill	Deputy Director, MHRA, Medicines and Pharmacy Team, DHSC Legal Advisers, Government Legal Department

Department of Health and Social Care (DHSC)

Ms Helen Gibson	Head of Medicines Regulation and EU Exit, Medicines and Devices Regulation and Prescribing, Medicines and Pharmacy Directorate, DHSC.
Mr Alistair Hardisty	Head of MHRA Sponsorship, DHSC (Leeds)

Devolved Administrations

Mr Chris Garland	Principal Pharmaceutical Officer, Northern Ireland
Ms Fiona Taylor	Principal Officer for EU Exit medicines contingencies, Northern Ireland
Dr Rose-Marie Parr	Chief Pharmaceutical Officer, Scotland
Dr Sara Davies	Consultant in Public Health Medicine Planning and Quality, Scotland

Lay representatives from Expert Committees

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

Observer

{Section 40: redacted: personal data} Associate Partner, Ernst and Young

Item 1: Introductions and Announcements

1.1 The Chair welcomed all to the meeting which was being held as a Zoom-enabled and telephone conference call because of the extraordinary circumstances around COVID-19.

Apologies and announcements

1.2 Apologies – none was received.

1.3 The Chair made the following announcements:

- *Board appointments* - The Chair announced that the Secretary of State had appointed two new Non-Executive Directors: Mercy Jeyasingham MBE, who joined the Board on 1 May 2020 as the Patient and Public Representative; and Professor Liam Smeeth, a medically qualified epidemiologist, who will join the Board on 1 July 2020.

- *Lay observers* - The Chair reported that Sara Payne and Susan Bradford would continue to attend the Board as lay observers until the end of July.

Item 2: Declarations of interest

2.1 None was declared.

Item 3: Minutes of the Board meeting of 27 April 2020.

3.1 The minutes of the Board meeting of 27 April were adopted. The Board also reviewed and noted the Actions list.

DISCUSSION ITEMS

Item 4: Coronavirus (COVID-19) – update

4.1 The Board received an update on the Agency's ongoing response to the COVID-19 pandemic from Dr Samantha Atkinson, who chairs the Agency's COVID-19 task force, with Vanessa Birchall-Scott providing an update on staff, business, and health and safety aspects; and Jonathan Mogford providing an update on UK regulatory flexibilities agreed to date and published. Rachel Bosworth concluded by updating the Board on accommodation and future ways of working.

Accommodation / agile ways of working

4.2 The Board noted staff have been working very differently in recent weeks, with staff working remotely. Ms Bosworth advised that the Agency is now considering what the 'new normal' will be post-COVID. This is likely to be based on a step-change in the way staff work, accommodation and the use of technology. This will be shaped by what has been learned during the period of remote working, as well as the Agency's plans for culture change. The Board noted four interlinked workstreams, overseen by the Programme Board. One of the workstreams concerns managing the shorter-term aspects of returning to on-site working, while a second is focused on future ways of working. It was noted there are strong links to the Agency's future Change Strategy and to the work under way on culture, values and behaviours.

4.3 The Chair said he was very impressed by how the Agency has responded to the pandemic, adding that he, along with Professor Webb, Deputy Chair, would write to staff to express the Board's gratitude. The Board asked for further information about the working arrangements at NIBSC during the pandemic. Dr Schneider addressed this question and, as part of his reply, he explained that staff work on a rota basis, on site, at NIBSC. The Board commended the work to ensure staff are fully supported and kept informed, e.g. through staff and managers' meetings. The Board asked if they could receive copies of the weekly COVID-19 updates to stakeholders, which Rachel Bosworth said would be done. The Board went on to offer its services, should the Executive wish to 'bounce ideas' off any Non-Executive Directors.

Action: The Chair and Deputy Chair to write to staff to express the Board's gratitude.

Action: Directorate to share copies of the weekly COVID-19 updates to stakeholders with the Board.

Item 5: Future Agency Change Strategy

5.1 Carly McGurry updated the Board on the Agency's developing implementation of the Change Strategy. Since the last Board meeting, Ernst and Young (EY) Consultancy were appointed to carry out a review of the Agency's governance structure, which is due to conclude in June. Ms McGurry also updated the Board on the informal meeting of the

Audit and Risk Assurance Committee of 12 June, where the Agency's developing implementation of the Change Strategy, linked to budget assumptions around the size and shape of the Agency, was also discussed. Ms McGurry advised that the EY Review would be the first milestone of a range of work that is taking place which will help to inform an overarching roadmap for the Agency for 2021 and beyond.

Item 6: Transitional Budget

6.1 Boryana Stambolova presented the 20/21 Transitional Budget for endorsement by the Board. The transitional budget was considered at an informal meeting of the Audit and Risk Assurance Committee (ARAC) on 12 May.

6.2 Ms Stambolova set the context for the budget: (a) the UK's departure from the EU, (b) the new Change Strategy, (c) likely recommendations from the Independent Medicines and Medical Devices Safety Review, and (d) opportunities stemming from the Agency's work with the Office of Life Sciences on innovative medicines. Ms Stambolova said the 2020/21 Transitional budget provided a financial framework for the Agency to continue to operate until the shape and cost the new role of the agency would be established. This would set a new baseline budget and funding structure.

6.3 Michael Whitehouse, Chair of ARAC, reported that at its informal meeting on 12 May ARAC supported the Transitional budget, but had made several comments, including that back-office costs appear high in comparison with other organisations. ARAC emphasised that the budget must be seen as transitional and it discussed the concept of a 'shadow' budget to be developed along with the "size and shape" change programme. The Board went on to comment on the importance of having transparency of costs, in particular, the need to separate out IT costs from the rest of the corporate overhead. Moreover, the Board thought the current structure of eleven divisions hampered attempts to understand financial expenditure. The Board also asked for periodic updates on the budget as the Change Strategy evolves. In conclusion, the Board endorsed the Transitional Budget.

Item 7: Exiting the EU – update

7.1 The Board received an update on the Agency's work with DHSC and wider Government on the future relationship with the EU, trade negotiations (free trade agreement); the Northern Ireland Protocol, and work with international forums, such as the International Coalition of Regulatory Medicines Authorities (ICMRA).

7.2 The Board noted that the Government's timetable for taking forward this work remains unchanged, with discussions/meetings being conducted 'remotely' although, as the Board observed, 31 December 2020 was just over six months away. It was noted that the scope of requirements for the Northern Ireland Protocol are still to be finalised. The MHRA will be the UK Regulator and it was essential to minimise market disruption and supply of medicines to patients in the UK. The Board commented on the importance of prioritisation for the Transition Delivery Plan, focussing on 'mission critical work'. The Board was advised that the Agency will continue to work closely with DHSC and wider Government on a range of issues, including supply issues. A further update will come to the Board on 22 June.

Item 8: Future of licensing models – item 8 was deferred to the June Board.

Item 9: Future Regulation of Devices

9.1 Graeme Tunbridge presented a paper on the Agency's vision for the regulation of medical devices from January 2021, as well as longer term ambitions for ensuring the safe regulation and use of medical devices. The first part of the paper focussed on the development of a responsive regulatory system that ensures devices can safely be placed on the market; the second part set out ambitions for the continued development of our safety and surveillance role to monitor devices that are in use to ensure their continued safety. Mr Tunbridge said this requires the Agency to make use of data, knowledge and improve transparency in order to respond earlier and more effectively to emerging issues, as well as to collaborate more closely with other parts of the healthcare system, including with patients. Mr Tunbridge concluded by thanking Professor Bruce Campbell for his advice on the paper.

9.2 The Board welcomed the paper and commented on the significant challenge posed by the disparity between the number of different types of medicines (approximately 15,000), when compared with medical devices (around 500,000) on the UK market. The Board observed that, while a medical device may function well, subsequent problems for a patient could be due to the lack of experience of the healthcare professional handling, operating, and/or implanting the medical device in question. This, as the Board observed, was an area outside the Agency's remit. Dr Davies of the Scottish Executive Government also commented on the challenge faced by a lack of knowledge and experience among some GPs when they prescribe the use of certain medical devices.

9.3 The Board emphasised the importance of partnership working, e.g. with healthcare professionals, in order to ensure patient safety. Here was also dependency on NHSX to provide a system for Unique Device Identifier (UDI) for medical devices. The Board recognised that work on the future regulation of medical devices is linked to the Independent Medicines and Medical Devices Review and the Agency's Change Strategy. This must be clearly articulated, emphasising that patients are at the heart of what the Agency does. Mr Tunbridge welcomed the Board's comments, which he said would be used in developing the strategy.

Item 10: Independent Medicines and Medicines Devices Safety (IMMDS) Review – update

10.1 Dr Raine updated the Board on preparations for the Agency's response to the Independent Medicines and Medical Devices Safety (IMMDS) Review. The Report of the IMMDS Review was due to be published on 24 March, however, it was postponed due to COVID-19. The Review Team has now announced a new publication date of 8 July. DHSC continues to coordinate a system-wide response to the IMMDS Review, while an Agency internal co-ordination group continues to prioritise and maintain an oversight of Agency's work on the report.

10.2 The Board welcomed the updated paper and commented that EU Exit provides a good opportunity to consider, revise and update the format and content of Patient Information Leaflets, which Rachel Bosworth advised the Agency was considering. There was discussion that, whatever the outcome, it would be important that the Agency's reporting systems were more responsive to issues raised and important that expectations were managed especially where the Agency does not have primary responsibility. The Board asked if copies of the IMMDS Review would be available before 8 July; Dr Raine reported that there may be a very restricted copy available on the morning of 8 July. A further update will come to the Board on 22 June, as part of the CEO's report.

Item 11: Oversight of Blood and Blood components

11.1 {Section 40: redacted: personal data} presented a paper proposing changes to the oversight of blood safety and quality in the Agency. {Section 40: redacted: personal data} explained that DHSC has the policy lead for blood, while MHRA is the Competent Authority for blood and blood components for transfusion in the UK. The UK blood sector (Blood Services and Hospital Blood Banks) is regulated by MHRA, Human Tissue Authority, Care Quality Commission and UK Accreditation Service. This responsibility is fulfilled through compliance assessment and inspections performed by the Good Manufacturing Practice Inspectorate and through haemovigilance activities in the Devices Information and Operations Group. The Board noted this undesirable regulatory duplication and lack of alignment with Agency core activity.

11.2 {Section 35: redacted: policy in development}

Item 12: UK Stem Cell Bank – update

12.1 {Section 5: redacted – Commercial – confidentiality}

Item 13: Business Plan 2019/20 – Quarter 4

13.1 Rachel Arrundale updated the Board on the final quarter of Business Plan, 2019/20. As with previous quarterly updates to the Board, the report was prepared on an exception basis and focussed on those areas of business activity that have been closed or postponed, rather than completed. The Board noted that the Agency has delivered most of its objectives during Quarter 4 and commented on the need for the Business Plan to be more closely linked to the Change Strategy. The Board noted that the business plan and change programme need to be costed and requirements incorporated into the Agency budgets. The Board also asked that for future Quarterly Reports a summary / narrative be included, as some Board members found the current version difficult to follow. Finally, the Board asked that further consideration be given to how realistic some of the Business Plan targets are.

Action: Policy to incorporate a summary with future Quarterly Business Plan reports to the Board.

Item 14: Annual Report 2019/20 – revised draft

14.1 Because of time pressure this item was not discussed; instead, comments were sought by close of 27 May.

Item 15: Chief Executive's Report

15.1 Because of time pressure, Dr Raine presented her monthly Report and invited members of the Board to send on any comments and/or questions after the meeting.

Item 16: Board meeting dates for 2021

16.1 The Board considered a list of proposed dates for Board meetings in 2021 and asked that further thought be given to having meetings mid-week, e.g. on a Wednesday or Thursday, rather than on Mondays. The Board noted that a paper will come to its meeting on 22 June about managing public-facing meetings, including public sessions of the Board, during the current pandemic.

Action: Directorate to prepare a revised set of meeting dates for 2021.

Item 17: Forward programme of Board business for 2020

17.1 The Board noted the forward programme of Board business.

Item 18: Minutes of the Corporate Executive Team (CET) meetings

18.1. The Board noted the final minutes of the CET meetings of March and April 2020.

Item 19: AOB

19.1 Elizabeth O'Neill, Head of Legal, flagged by reference to Item 4 (Coronavirus) that in introducing regulatory flexibilities the Agency had taken a risk-based approach in order to respond in an agile way to the supply crisis, which involved taking legal risk and interpreting its powers as generously as possible in order to safeguard human health.

Date of the next meeting: 22 June 2020 – by Zoom video link