Medicines and Healthcare products Regulatory Agency

Minutes of the Board meeting 20 January 2020
(1.30pm – 3.45 p.m.)
Round Rooms, 10th floor
10 South Colonnade, Canary Wharf London E14 4PU

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
Dr Barbara Bannister MBE	Non-Executive Director
Ms Amanda Calvert	Non-Executive Director
Professor Bruce Campbell	Non-Executive Director
Mr Stephen Lightfoot	Non-Executive Director
Mr Michael Whitehouse OBE	Non-Executive Director

Others in attendance

MHRA executive

Dr Samantha Atkinson	Director of Inspection, Standards and Enforcement
Ms Vanessa Birchall-Scott	Director of Human Resources
Ms Rachel Bosworth	Director of Communications
Mr Jonathan Mogford	Director of Policy
Mr John Quinn	Business Transformation Director
Dr Christian Schneider	Director of National Institute for Biological Standards and Control (NIBSC)

Supporting officials – in order of attendance for specific items

Ms Boryana Stambolova	Deputy Director of Finance and Procurement
Ms Patience Wilson	Deputy Director, Corporate Strategy, Policy Division
{Section 40: redacted: personal data}	Head of Business Planning and Programme Management, Policy Division
{Section 40: redacted: personal data}	Head of Patient, Public and Stakeholder Engagement, Communications Division
Mr James Pound	Group Manager, British Pharmacopoeia
{Section 40: redacted: personal data}	Editor in Chief, British Pharmacopoeia
{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

Legal Services

Ms Joanna Greenidge OBE	Deputy Director, MHRA, Medicines and Pharmacy Team, DHSC Legal Advisers, Government Legal Department

Department of Health and Social Care (DHSC)

Ms Carly McGurry	Deputy Director - Medicines and Devices Regulation and Prescribing, Medicines and Pharmacy Directorate, DHSC.

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

Item 1: Introductions and Announcements

1.1 The Chair welcomed all to the meeting.

Apologies

1.2 Apologies were received from Ms Anne-Toni Rodgers, Non-Executive Director; and Mr Jon Fundrey, Chief Operating Officer and Member of the Board.

1.3 The Chair asked that the minutes record the Board's gratitude to Ms Joanna Greenidge who will leave DHSC to take up a new position as Deputy Legal Director at the Department of Transport). It was noted that Ms Greenidge would be succeeded by Elizabeth O'Neill.

1.4 The Chair reported that a joint Board/Corporate Executive Team Strategy Day will take place on 24 February 2020 at the Royal Society of Medicine.

Item 2: Declarations of interest

2.1 None.

Item 3: Minutes of the Board meeting of 16 December 2019 public meeting and Minutes of the Board meeting 16 December 2019 closed meeting.

3.1 The minutes of the public and closed meetings of 16 December 2019 were adopted. The Board also reviewed and noted the Actions list.

DISCUSSION ITEMS

Item 4: Exiting the EU – update

4.1 Jonathan Mogford gave an update on recent work as the Agency prepares for the UK to leave the EU on 31 January 2020. The update covered the UK's Future Relationship with the EU; the Northern Ireland Protocol; and the move into the Implementation Period. The Board noted that work on these areas has been moving quickly and the scope of the work is significant with many interdependencies.

4.2 During the discussion the Board also considered the Implementation Period and how it would work in practice; how much work has been done in terms of targeted assessments; the Northern Ireland Protocol; and options to deliver a regulatory model for medical

devices, which were set out. The Board's questions on these areas of were addressed. A further update will come to the Board / Corporate Executive Team on 24 February.

Item 5: Future Agency Change Strategy

5.1 Dr Raine and Jonathan Mogford gave a progress report on the Agency's evolving Change Strategy. The Board noted that following the joint Board/CET Strategy Day on 18 November, the vision for the future Agency was launched for staff on 11 December. This was followed by a Senior leadership Group meeting on 17 December, which set out how the Agency Change Strategy will impact on healthcare. The work has been taken forward at pace with weekly CET strategy sessions around each of the 5 pillars, each of which is led by a CET director. In parallel, the Transformation Division will begin an impact assessment of the outputs of the Change Strategy on OT. The Board asked about the resources implications to ensure that the 'day job' can also be delivered. A fully worked programme will circulated ahead of the Board /CET Strategy Day on 24 February.

Item 6: Outline Business Plan and Budget for 2020/21

6.1 Patience Wilson and Boryana Stambolova presented an initial outline of the Business Plan and the ongoing work to bring business and budget planning together. The Board was informed about the outline business plan slide pack which set out the strategic context of the Change Strategy and the intent to deliver a real step-change in the Agency's practical impact on clinical practice across the health service, and on helping patients and the public to make informed decisions about medicines and medical devices.

6.2 Ms Stambolova set the 2020/21 budget in a wider context and explained the challenges of setting a budget when the final shape of the new Agency has still to be agreed. Ms Wilson advised there are still substantial gaps in the detail for the strategic goals under the 5 'pillars'. The planned workshops should help expand these areas.

6.3 The Board endorsed the approach set out in the package of papers and supported zero-based budgeting. The Board recommended that a well-developed workforce plan was needed (a paper on workforce planning will come to the CET in February). The Board asked that the replacement of the legacy IT systems should be weaved into the '5 pillars' and that 'our people '(staff) should also be brought into the Business Plan. The Board also asked that reference be made to shared decision-making involving patients and healthcare professionals.

Item 7: Patient and Public Engagement (PPE) Consultation Report Back

7.1 Rachel Bosworth and {Section 40: redacted: personal data} presented, for approval, the final draft report of the Patient and Public Engagement (PPE) consultation on how the Agency engages and involves patients and the public in its work. The consultation was part of the Agency's two-year PPE Delivery Plan. The longer-term PPE/ Implementation Strategy is being developed and a further short consultation on the draft PPE/Implementation Strategy is planned for February or March 2020.

7.2 The Board considered the report, an earlier draft of which it had seen in December 2019. The Board's comments were as follows:

- The Agency needs to improve the way it works with healthcare professionals. The Board heard that the Agency is working with the General Medical Council (GMC) and the General Pharmaceutical Council.
- When the Agency has made changes, patients, the public and healthcare professionals should be told what the Agency has done.
- The public should see change sooner and not have to wait two years for a change to be introduced.
- The Agency's web page on GOV.UK should be made more interactive. Ms Bosworth advised that as the Agency's page is. hosted by GOV.UK, there are limitations on what the Agency can do. This is something the Agency is discussing with the Government Digital Service. Ms Bosworth went to advise that the Agency has multiple websites, e.g. for NIBSC and CPRD.
- The Board formally approved the report and endorsed next steps set out in the paper's cover sheet.

7.3 {Section 40: redacted: personal data} thanked the Board for its comments and advised that, since the Board had formally approved the report, copies will be sent to Ministers and subject to Ministerial approval, the report would be published.

Item 8: Towards a new partnership with NICE

8.1 Jonathan Mogford presented an update on joint working with the The National Institute for Health and Care Excellence (NICE), including a CEO bilateral meeting that took place on 20 December 2019, along with MHRA / NICE quarterly meetings. The Board noted the update and endorsed plans for joint working.

Item 9: Regulatory Science

9.1 Dr Schneider gave an update on work to develop regulatory science within the Agency, which will enhance science-based regulation of medicines and medical devices. Dr Schneider's paper gave a high-level overview of the Agency's links with academia in the UK; the work of other regulators in this field; the opportunity for the Agency to lead in regulatory science; and a proposed Regulatory Science Partnership workshop in early 2020. The Board heard that the workshop, which would involve key stakeholders, would explore the creation of a UK Regulatory Science Network. The Agency's activities will be led by NIBSC with support from CPRD and the Agency's operating divisions.

9.2 In answer to a question about the current academic links, Dr Schneider advised that several UK universities are keen to collaborate. The Board recommended that the 'two-way' traffic in ideas between academia and NIBSC should be encouraged. Dr Schneider also mentioned that the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) engage on work on regulatory science. The Board recommended that the Agency should highlight its regulatory science work in prominent publications.

9.3 In conclusion, the Board noted the paper and endorsed the proposed Regulatory Science Partnership Workshop.

Item 10: British Pharmacopoeia: Enabling Life Sciences Innovation through Standards

10.1 Dr Atkinson introduced James Pound and {Section 40: redacted: personal data} who presented a paper on the role standards play in supporting and enabling life sciences innovation; the paper was accompanied by several case studies which illustrate the work

of the British Pharmacopoeia (BP). As part of the update, Mr Pound and {Section 40: redacted: personal data} went on to outline emerging areas of science and technology that the BP will need to consider to ensure that the BP's standards remain suitable and relevant for the future. The following examples were given: digital therapeutics, continuous manufacturing, process analytical technology, data standards, and personalised medicines and companion diagnostics.

10.2 The Board noted the paper and advised that it is important to continue to invest in advanced therapies so that the BP remains relevant. The Board went on to ask for an example of digital therapeutics; Mr Pound cited an American app which can be downloaded onto a personal device. The app can help manage one's lifestyle through the delivery of evidence-based therapeutic interventions to patients that are driven by high quality software programs to prevent, manage, or treat a broad spectrum of conditions

Item 11: Operational Transformation Programme Report

11.1 John Quinn presented the monthly update on the Operational Transformation (OT) Programme. The Board noted that good progress has been made over the past two months across a range of workstreams, however, the forecast shortfall in benefits for the current financial year remains and is unlikely to be resolved until the OT Business Case is updated. Mr Quinn advised there is a hard dependency on the delivery of a new Agency business strategy to set direction, targets and priorities. In the meantime, the OT Portfolio Board is closely monitoring benefits performance and project delivery. Mr Quinn went on to report that the European Systems Contingency project was stood down in late December; this has allowed staff to be deployed to elsewhere Transformation Division. Once a new Agency Business Strategy is agreed, an impact assessment on the OT portfolio will be carried out to ensure it can change to adapt to new priorities and direction. This is expected to run for 6 weeks following on from agreed strategy.

11.2 At the Board's request, Mr Quinn gave an update on the data legacy issues: large volumes of data have to be transferred from older systems before they are decommissioned. Mr Quinn advised that as part of the impact assessment, options will be developed on what degree of risk the Agency wishes to accept on access to data.

11.3 The Board asked for an update on Agency's accommodation review, which Rachel Bosworth gave. A paper on accommodation will come to the CET in March. The Board went on to ask if the Agency was able to recruit new staff for business-critical Transformation Division posts. Mr Quinn advised this was of concern, as the market for such staff is very competitive, and the Agency policy on salaries was restricting ability to attract staff at the right level. A business case is being made to the Treasury, to apply Government Digital Service recommended salaries to the roles in Transformation Division.

Item 12: Chief Executive's Report

12.1 Dr Raine presented highlights from the Chief Executive's report for December 2019. These included the following:

(i) Opioids and dependence – an update on the Commission of Human Medicine's consideration of recommendations of the Opioids Expert Working Group.
(ii) The Independent Medicines and Medical Devices Safety Review – an update on the Review team's report, which is expected to be published in the spring.
(iii) Adrenaline auto-injector – an update on an inquest in December 2019 into a fatality following the unsuccessful use of an adrenaline auto-injector. Updates were also given on the following:

(iv) Hormone Replacement Therapy (HRT) and breast cancer.
(v) Calea UK Limited and sterile product supply.
(vi) Medical devices issues, including Urogynaecological surgical mesh.
(vii) Performance update – Ministerial and correspondence.
(viii) Safer medicines in pregnancy and breastfeeding consortium.

12.2 In answer to question from the Board, an update was given on the Medicines and Medical Devices Bill.

Item 13: Update on Audit and Risk Assurance Committee meeting of 20 January

13.1 Michael Whitehouse, Chair of the Audit and Risk Assurance Committee (ARAC), gave an oral update on the ARAC meeting, which was held earlier in the day. The following highlights from the meeting were mentioned:

- *External Audit Report - External Audit Plan Report Plan and Fees, which was approved.*
- *Internal audit* – ARAC reviewed internal audit reports on (a) Clinical Investigations and Trials Audit Report, (b) General Data Protection Regulation (GDPR) Compliance Audit Report, both of which had a moderate assurance), as well as (c) the Forward End of Year view on the Agency's Control Environment.
- *The National Archives Assessment* – ARAC reviewed the final version of the report.
- *Governance Statement* – ARAC considered a first draft of the 2019/2020 Governance Statement.
- *Annual Review of Whistleblowing* – this was reviewed and discussed, along with a report on incidents of fraud and whistleblowing.
- *Corporate Risk Register* (CRR) – This was reviewed; a new version of the CRR will come to the Board in March.
- *Other business:* Procurement Waiver Report was noted.

13.2 Mr Whitehouse said it was important that the new version of the Corporate Risk Register will come to the Board in March so that there is alignment between the Agency's risk appetite and risk approach. Mr Whitehouse advised there are two systematic issues facing the Agency: IT legacy issues and management capacity, the latter of which is critical to the delivery of the Agency's Change Agency.

Item 14: Forward programme of Board business for 2020

14.1 The Board noted the forward programme of Board business

Item 15: Minutes of the Corporate Executive Team (CET) meetings

15.1. The Board noted the final minutes of the CET meetings in November 2019.

Item 16: AOB

MHRA Annual lecture

16.1 The Board endorsed the Chair's proposal that the MHRA Annual Lecture should be renamed *The Breckenridge Lecture* in memory of the Agency's founding Chairman, Sir Alasdair Breckenridge CBE, who died on 12 December 2019.

Glossary

16.2 The Board noted the glossary which had been circulated along with the papers for the meeting, and which the Board found helpful.

Date of the next meeting: 24 February 2020 (Board / CET Strategy Day).