

Medicines and Healthcare products Regulatory Agency

Minutes of the Board meeting 24th August 2020
(10:30 – 12:50)

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
Professor Liam Smeeth	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)
Dr Sarah Branch	Interim Director of Vigilance and Risk Management of Medicines
Ms Rachel Bosworth	Director of Communications
Dr Siu Ping Lam	Director of Licensing
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
Dr Janet Valentine	Director of Clinical Practice Research DataLink

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: name redacted – personal data}	Corporate Affairs Manager, NIBSC
{Section 40: name redacted – personal data}	Senior Data manager
{Section 40: name redacted – personal data}	Executive Assistant to the Chairman
Mr Aidan Mclvor	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)

{Section 40: name redacted – personal data} Senior Policy Advisor – MHRA Sponsorship and EU Exit Medicines and Pharmacy Directorate, DHSC

Devolved Administrations

Mrs Cathy Harrison Chief Pharmaceutical Officer, Northern Ireland

Ms Alison Strath Principal Pharmaceutical Officer, Scotland

Dr Sara Davies Consultant in Public Health Medicine Planning and Quality, Scotland

Item 1: Introductions and Announcements

1.1 The Chair welcomed all to the meeting.

Apologies and announcements

1.2 Apologies were received from Anne-Toni Rodgers, Non-Executive Director.

1.3 The Chair made the following announcements:

*Appointment of new Chair**Remarks by Sir Michael Rawlins, Chair*

- Sir Michael announced that the Secretary of State had appointed Stephen Lightfoot, Non-Executive Director, as the new Chair of the Agency. This followed an open, competitive recruitment campaign by the Department of Health and Social Care.
- Sir Michael said that he had decided to stand down early so that he could 'hand over the baton' as Chair to Mr Lightfoot, who would take up his new role on 1st September 2020.
- Sir Michael asked that the minutes record his congratulations to Mr Lightfoot and his deep pride in the Agency.

Remarks by Dr June Raine, Chief Executive

- Dr June Raine paid tribute to Sir Michael's long and distinguished service to the Agency, the UK and internationally. Dr Raine thanked Sir Michael for leading the Agency as its Chair since 2014, before which he had been the founding Chair of the National Institute for Health and Care Excellence (NICE), and before that Chair of the Committee on the Safety of Medicines.

- Dr Raine said patients across the UK and beyond owe an enormous debt of gratitude to Sir Michael and that MHRA will be forever in his debt. Dr Raine said that the Agency and Board will celebrate Sir Michael's retirement in a fitting way at an appropriate time in the future.

Remarks by Professor David Webb, Deputy Chair

- On behalf of the Board, Professor Webb thanked Sir Michael for his clear thinking, vision, leadership and excellent judgement which he had shown as Chair of the Agency, as Chair of NICE and at the Academy of Medical Sciences. Professor Webb said Sir Michael would be greatly missed and that the Board looked forward to hosting Sir Michael to a belated farewell dinner in the future, COVID-19 related circumstances-permitting.

Remarks by Mr Stephen Lightfoot, Chair designate

- Stephen Lightfoot said it was a huge privilege to have been appointed as Chair of the Agency. Mr Lightfoot paid tribute to Sir Michael's many achievements and his leadership at public sessions of the Board, where he had proved most effective at engaging with the public. Mr Lightfoot said he will build on Sir Michael's legacy and that the Board will host Sir Michael to a farewell dinner at a future date.

Board Terms of Reference

1.4 A revised set of Terms of Reference will return to the Board in September.

Item 2: Declarations of interest

2.1 None was made.

Item 3: Minutes of the Board meeting of 23rd July 2020.

3.1 The minutes of the Board meeting of 23rd July 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 the Board considered and noted. The Board asked about the Government proposals for a fundamental reshaping of the Government Communication Service. Dr Raine said this was an important opportunity for the Agency to set the agenda and for the regulator to continue to have a strong independent voice. The Board also asked about the National Institute for Health Protection, which was established on 18th August 2020. Dr Raine said an introductory meeting will take place (details to be confirmed), to which Stephen Lightfoot, Chair designate, will also be invited.

Action: Directorate to invite Stephen Lightfoot, Chair designate, to the introductory meeting between Baroness Dido Harding and Dr June Raine.

Item 6: Performance Dashboard

6.1 The Board considered the latest version of the Performance Dashboard. This is intended to provide the Board with more transparent information to support its assurance role and is intended to stimulate thinking about what are key metrics the Board should consider, and the Agency should be measured against. The Board noted this is an iterative process, or as some NEDs described it, 'a journey'. The Board recommended that more narrative be added; that the domains in the balanced scorecard should focus on strategic impact and give the Board assurance on what the Agency is achieving. The Board suggested that a comparison between what was achieved this last year and the current year (and possibly month by month) be incorporated. An updated version of the Dashboard will come to the next Board.

Item 7: Regulatory and Patient Safety Committee feedback and endorsement of terms of reference

7.1 The Board were updated on work to establish a new Regulation and Patient Safety Committee and considered a set of draft Terms of Reference for the new committee. The Board discussed both items and debated whether the new committee should be split into two, as some thought its current scope was too broad.

7.2 In view of the Board's discussion, the Chair asked Dr Raine and Ms McGurry to reflect further on the Board's views and to use ARAC as a model. The Chair said it was important to be clear about the Committee's scope, its powers to seek additional information, something which ARAC does, as well as assurances.

Action: Dr Raine and Ms McGurry to discuss offline the Board's comments.

Item 8: Transition (including EU Exit)

8.1 The Board considered a range of papers, including on the Future of Regulation, current developments around Transition and international engagement. The Board noted progress on discussions on medicines and medical devices; further negotiation rounds are expected in September with the aim of concluding the discussions for agreement ahead of the European Council in mid-October.

8.2 Jonathan Mogford addressed the Board's questions and commented on issues around the resourcing of a future Agency, all of which ties in with the 'size and shape' project. Dr Davies of the Scottish Executive Government said she welcomed the opportunity to contribute to the discussion and valued MHRA's wish to engage with the Devolved Administrations.

Item 9: Change Strategy

9.1 The Board considered a report on the implementation of the Phase One of the Change Strategy and of the initiation of Phase Two. The Board noted that Ernst and Young (EY) had won the bid to lead the Phase 2 ('Size and Shape') programme through an open and competitive process. Work on Phase 2 will begin on 7th September. The Board was briefed on the staff workshops on the Change Strategy during August as well as the process for selecting Chief Officers. Dr Raine reported that the interviews for these appointments will take place during the w/c 24th August. The Board also commented on the implementation process for Phase 2 and beyond, and for the need to be open about inevitable redundancies that will flow from a slimmer but more agile agency.

Item 10: COVID-19 Task Force lessons learned

10.1 The Board considered a “lessons’ learned” report from the COVID-19 Task Force. The Chair said that the Agency had won well-deserved praise from the Prime Minister and Secretary of State for its work during the pandemic. As part of its consideration, the Board highlighted the need to focus on ‘learning and not blaming’ from past experiences, and of the importance of getting external feedback. The Board noted the report and asked that the paper is sent to the next Audit and Risk Assurance Committee (ARAC) meeting for its consideration.

Action: “Lessons learned” report to be submitted to ARAC.

Item 11: Accommodation, infrastructure and agile working

11.1 Rachel Bosworth presented a report on the setting up of an Accommodation, Infrastructure and Agile Working Programme. This included arrangements for a gradual return of staff to the Agency’s offices in Canary Wharf in September 2020. The Board asked for an update on how the Statutory Committees and Expert Working Groups had adjusted to working remotely during the lockdown. Ms Bosworth reported that feedback from members of these groups had been very positive. The Board noted that after further easing of pandemic-related restrictions, the Agency will adopt a mixed approach as to how such meetings are held: face-to-face and on a virtual basis. The Board concluded by noting the report.

Item 12: Annual Health and Safety Report

12.1 The Board considered the Annual Health and Safety Report, which was presented by Dr Christian Schneider and {Section 40: name redacted – personal data}. The Board formally noted the report and commended the work that has been carried out over the past year to keep staff safe, whether working overseas (e.g. on inspections); in a laboratory setting, especially at NIBSC, since the onset of the pandemic; and elsewhere across the Agency. The Board noted that the Agency is benchmarked against other relevant organisations, such as Public Health England.

Item 13: Draft agenda for the next public session of the Board

13.1 The Board considered a draft agenda and decided that it would be best that the next public session be held in October.

Action: Directorate to postpone the public session to October.

Item 14: Forward Programme of Board Business

14.1 The Board noted the Forward Programme of Business.

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

15.1 The Board noted final minutes of the CET meetings of June, July and August 2020.

Item 16: AOB

16.1 None was tabled.

Date of the next meeting: 21st September 2020

