

Medicines and Healthcare products Regulatory Agency

Minutes of the Board meeting 21 October 2019

(12.30 p.m. – 2.30 p.m.)

Round Room

10 South Colonnade, Canary Wharf London E14 4PU

Present:

The Board

Professor Sir Michael Rawlins GBE Kt	Chair of MHRA
Professor David Webb	Deputy Chair
Dr June Raine CBE	Interim Chief Executive
Mr Jon Fundrey	Chief Operating Officer
Dr Barbara Bannister	Non-Executive Director
Ms Amanda Calvert	Non-Executive Director
Professor Bruce Campbell	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 and supporting officials

Dr Samantha Atkinson	Director of Inspection, Enforcement and Standards
Ms Vanessa Birchall-Scott	Director of Human Resources
Ms Rachel Bosworth	Director of Communications
Mr John Quinn	Director of Transformation
Mr Jonathan Mogford	Director of Policy
Mr Graeme Tunbridge	Interim Director of Devices
(Redacted: Section 40: personal data)	Diversity Lead, Human Resources
(Redacted: Section 40: personal data)	Head of Science Strategy
(Redacted: Section 40: 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.
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Department of Health and Social Care (DHSC)

Mr Alastair Hardistry	Head of MHRA sponsorship and EU Exit.
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Lay representatives from Expert Committees

Ms Susan Bradford	Lay representative from the Commission on Human Medicines
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Item 1: Introductions and Announcements

- 1.1 The Chair welcomed all to the meeting, including Alastair Hardistry, who had recently been appointed as Head of the MHRA sponsorship and EU Exit Team at DHSC. The Chair also welcomed Graeme Tunbridge, who was appointed as interim Director of Devices with effect from 18 October.
- 1.2 The Chair explained that the agenda had been reordered, e.g. the Chief Executive's report would be given first, as Dr June Raine had to leave the meeting early so that she could fly to Washington DC. Dr Raine would address a medical devices conference at the United States Food and Drug Administration.
- 1.3 Dr Raine said she was honoured and delighted to take on the role of interim Chief Executive.

Apologies

- 1.4 Apologies were received from Ms Sara Payne, lay representative from the Devices Expert Advisory Committee; and Carly McGurry, Deputy Director

Item 2: Declarations of interest

- 2.1 None.

Item 3: Minutes of the Board meeting of 16 September 2019 / Actions list

- 3.1 The minutes of the last Board meeting (16 September 2019) were adopted.
- 3.2 The Board reviewed and noted the Actions list. In regard to one of the actions (raising the profile of public meetings), Mr Aidan McIvor said, as Board Secretary, he was working closely with the Agency's Patient, Public and Stakeholders' Team to raise awareness of the Agency's programme of public board meetings through a wide range of networks.

DISCUSSION ITEMS**Item 4: Chief Executive's Report**

4.1 Dr Raine presented the highlights from the CEO's report for September 2019. These centred on the following areas:

- Isotretinoin – An update was given on the consideration of Isotretinoin by a Commission on Human Medicines (CHM) Expert Working Group.
- *Life Sciences Bill* – The Board noted that the Life Sciences Bill is now entitled Medicines and Medical Devices Bill.
- *Urogynaecological Mesh* – An update was given on current developments in this area, including a debate on surgical mesh at Westminster Hall on 5 September. The Board heard that following an EU review of data on urogynaecological surgical mesh by MHRA, relevant Notified Bodies and Competent Authorities have been asked to prepare action plans.

- *Independent Medicines and Medical Devices (IMMDS) Review* – An update was given on the Review which is expected to report during the first quarter of 2020
- *International meetings* – An update was given on Dr Raine's upcoming international visits: most immediately to speak at the Medical Devices Epidemiology Conference at the US FDA, and at the International Coalition of Medicines Regulatory Authorities (ICMRA) in Rome from 28-30 October.
- Hormone Replacement Therapy (HRT) and breast cancer – an update was given on a meeting which will take place during the w/c 28 October between MHRA, the Royal College of Obstetricians and Gynaecologists and the British Menopause Society.
- During the CEO's report, the Board noted the work of the Industry-Government Clinical Research Working Group (CRWG). The CRWG comprises representatives from DHSC, the Health Research Authority, the National Institute for Health Research, the Medical Research Council, the Devolved Administrations, the NHS, Industry members from the life sciences trade associations and national and global heads of research from biopharmaceutical companies and Clinical Research Organisations, the Association of Medical Research Charities and the Royal College of Physicians. The Group reports to the Innovation Data and Research expert Group (IRDG), a sub-group of the Life Sciences Council.

4.2 The Chair and the Board thanked Dr Raine for her report and invited comments from the Board. These centred on the following areas.

- *Format* – The Board welcomed the new format of the CEO's report, which included statistical tables and colour bar charts.
- *Marketing Authorisations (MA)* – The Board noted that the number of new MA applications has decreased compared to last year and asked if the trend was the same in Europe. The Board heard the volume of applications for generic products in Europe has fallen.
- *CEO's video blog* – The Board commended Dr Raine on the success of her weekly video blogs for staff.
- *Foetal dopplers* – The Board asked about the draft guidance for foetal dopplers. The Board heard the Agency has carried out a review of foetal doppler products, for home use available on the UK home market. As part of the review, the Agency engaged with manufacturers and reviewed labelling and instructions; the Agency has also engaged with stakeholders. A draft guidance is in preparation and will be published on GOV.UK.

Item 5: Exiting the EU – update

5.1 Jonathan Mogford provided a comprehensive update on the Agency's preparations for EU Exit (No Deal or a negotiated exit). The Board heard that teams across the Agency have undertaken a dry run of their No Deal readiness. The Agency is also working closely with DHSC and other partners across Government on a range of subjects related to EU Exit and the UK's future relationships with other countries.

5.2 Mr Mogford answered the Board's questions about the possible relationships the Agency may have with the EU and beyond after the UK's departure from the EU, depending on the nature of the departure. Mr Mogford also addressed the Board's

questions about the status of Northern Ireland in relation to the MHRA after the UK leaves the EU.

Item 6: Operational Transformation portfolio update

6.1 John Quinn gave a progress report on the Operational Transformation (OT) programme. This Board noted the new reporting format, which included updates on delivery progress, governance, programme expenditure, benefits realisation and the work of the Tiger Team. Mr Quinn prefaced his remarks by mentioning that significant progress has been achieved to ensure the Agency's IT platforms are ready for a 'no deal' exit from the EU. The Board heard that a full day of testing had been carried out and the Agency is ready for all eventualities.

6.2 Mr Quinn then went on to report that work is underway on the next version of the OT business case; the priority is to develop an outline economic case that addresses directly the comments raised previously by DHSC. The Board heard that a specialist economist has assisted with preparing a skeleton economic case template and to help develop an initial economic analysis. Mr Quinn reported that a meeting with DHSC economists was held in early October to check alignment and approach.

6.3 During the rest of the update, Mr Quinn reported that the OT portfolio status remains at red; a return to amber is not possible because the action plans required to bridge the current benefits shortfall are not in place for all workstreams. Mr Quinn also went on to report that Dr Janet Valentine has agreed to take over from Mr Wilkinson, who retired in October, as the CET champion for the Corporate Services workstream. Similarly, since Dr June Raine was appointed interim CEO in September, Mick Foy of VRMM is now leading the Safety and Surveillance workstream. Mr Quinn concluded by giving an update on the OT deep-dive sessions and next steps.

6.4 The Chair thanked Mr Quinn for the report and asked the Board for its comments, which centred on the following areas.

- *Tiger Team* - The Chair asked for fuller explanation of 'what is a Tiger Team?' Mr Quinn explained that the term 'Tiger Team' is a diversified group of experts brought together for a single project, need, or event. They are usually assigned to investigate, solve, build, or recommend possible solutions to unique situations or problems. The term is derived from the U.S. Apollo Space Programme in the 1960s where Tiger Teams were used with great effect.
- *Change management* – The Board advised that OT offered a significant opportunity to develop staff and offer OT-related opportunities. The Board also cautioned that such opportunities would require detailed workforce planning and the need to back-fill posts that had been vacated to allow staff to take on development opportunities. Mr Quinn concurred and advised that the Transformation Academy, which the Agency set up, will leave a legacy of highly motivated and skilled staff who will enable change. Mr Quinn went on to report on the number of OT apprenticeships the Agency has advertised, all of which have been taken up.
- *Accommodation* – The Board asked about the accommodation aspect of the OT business case. Mr Quinn advised that desk occupancy levels was in many ways dependent on the outcome of the EU Exit process.

Item 7: Diversity and Inclusion Annual Report

7.1 Ms Vanessa Birchall-Scott introduced (Redacted: Section 40: personal data), Diversity and Wellbeing Lead, who presented the Equality and Diversity Annual Report to the Board. The report covered (i) the work of the Diversity and Inclusion Group; (ii) a summary of key progress to date, in particular, on equality data, staff networks, talent and learning, and recruitment; (iii) future programme of actions; (iv) and the Gender Pay Gap Report. (Redacted: Section 40: personal data) also referred the Board to three annexes which accompanied the report: Annex A: Agency staff profile and analysis, and Annex B Performance and Rewards Summary and Annex C (draft) Gender Pay Gap report.

7.2 (Redacted: Section 40: personal data) advised that the gender pay data for this year's report is currently being analysed in a parallel exercise with DHSC and Public Health England, as data for all three organisations in the Health family are reported together. The Board noted that the draft Gender Pay Report is with Ministers awaiting clearance after which the report will be published on GOV.UK. (Redacted: Section 40: personal data) also highlighted the Agency's work on three new staff networks: parents, carers and LGBT (Lesbian, Bisexual, Gay or Transgender), as well as the work of the network of Mental Health Champions.

7.3 The Chair thanked (Redacted: Section 40: personal data) for the report and sought the Board's views. These centred on the following areas:

- *Opening comments* – The Board commended (Redacted: Section 40: personal data) on the success that had been achieved so far and the action the Agency is taking on pay strategy / gender pay gap, recruitment, well-being, talent and career paths, leadership, and diversity and inclusion.
- *Headcount by gender* – The Board noted that 58% of Agency staff were female and of 115 new starters in 2018-19, 65% were also female. The Board cautioned against the inevitable significant gender imbalance this would create should this pattern continue.
- *Disability profile* – The Board was very surprised that in answer to 'the disability profile' 94% of staff answered "not known/ prefer not say". Ms Birchall-Scott advised that non-disclosure remains a major issue for the Agency and across the Civil Service and is something the Agency is keen to remedy, e.g. obliging all new joiners to complete the personal data fields, although the option 'prefer not to say' will be available in all sections. The Board advised that some staff may be reticent to disclose details of a disability, especially around mental health, because of a perceived fear it could adversely affect their career. The Board advised this is something that needed to be addressed.
- *Social mobility* - The Board advised that social mobility can be an issue, e.g. around recruitment, and can be addressed through a range of outreach work with schools. Ms Birchall-Scott advised social mobility featured in the recent staff survey and the Agency plans to learn from the experience of other public sector organisations about their approach to this aspect of Diversity and Inclusion.

Item 8: Update on Audit and Risk Assurance Committee meeting of 21 October

8.1 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. Mr

Whitehouse prefaced his update by advising that there is not any assurance issue that the Board needs to be aware of, but there are risks which need to be managed.

8.2 The following highlights from the meeting were mentioned:

- *Internal audit* – ARAC reviewed internal audit reports on cash management and payroll control, both of which had a moderate assurance.
- *The Internal Audit Plan* - ARAC reviewed and agreed Internal Audit's Plan for 2019/20. As well as providing assurance on internal controls and overall governance, Internal Audit will evaluate progress in key functions.
- *Corporate Risk Register (CRR)* – An update was given on the work which Boryana Stambolova is doing with the Corporate Executive Team on strategic risks. Mr Whitehouse reported that ARAC thought that the CRR with its revised focus on strategic risk was a considerable improvement was. A more focused CRR will come to the Board in January 2020.
- Mr Whitehouse said he would bring a paper on risk appetite to the Board (date to be confirmed).
- *DHSC Audit and Risk Committee* – Mr Whitehouse reported that he, along with June Raine, Jon Fundrey and Boryana Stambolova have been invited to attend a meeting of the DHSC's Audit and Risk Committee on 13 November. Further refinement is needed to align with the Agency's operational risk management, but this is in progress. The revised CRR will come to the Board in January 2020
- *Deep Dives* – ARAC has embarked on a new initiative: carrying out 'deep dives' into specific areas of the Agency's work, which ARAC believes requires more scrutiny. The process began at ARAC's meeting on 21 October when ARAC considered a paper on the strategy to replace Sentinel. The deep dive provided assurance that the process to replace Sentinel is being handled well. Considerable risks remain; ARAC will continue to keep these under review and seek assurance periodically that they are being managed effectively and report to the Board

8.3 The Board noted the oral report, which it found to be most informative, and commented on the challenge of managing legacy systems and data that had been accrued over decades. This would be considered further at the forthcoming Strategy Day with a subsequent paper coming to the Board with input from the Audit and Risk Assurance Committee

Action: Mr Whitehouse, as Chair of ARAC, to bring a paper on risk appetite to the Board.

Item 9: Programme for Board / CET awayday (draft), 18 November

9.1 Dr Raine presented a draft programme for a Board / CET awayday on 18 November, which the Board endorsed.

Item 10: Forward programme of Board business for 2019/2020

10.1 The Board noted the forward of Board business for 2019/2020.

Item 11: Minutes of the Corporate Executive Team (CET) meetings

11.1 The minutes of the CET meetings of 5 August 2019 and September 2019 were noted.

Item 12: Any Other Business (AOB):

12.1 None was tabled.

Date of the next meeting (Board / CET Strategy and Planning Day): 18 November 2019.