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Medicines and Healthcare products Regulatory Agency**MINUTES OF THE BOARD MEETING**

25 June 2018

Present:*The Board*

Professor Sir Michael Rawlins GBE	Chair of MHRA
Mr Martin Hindle	Deputy Chair
Dr Ian Hudson	Chief Executive
Mr Jon Fundrey	Chief Operating Officer
Mr Matthew Campbell-Hill	Non-Executive Director
Professor Bruce Campbell	Non-Executive Director
Mr Stephen Lightfoot	Non-Executive Director
Professor Sir Alex Markham	Non-Executive Director
Ms Deborah Oakley	Non-Executive Director
Professor David Webb	Non-Executive Director

Others in attendance*MHRA executive and supporting officials*

Mr Jonathan Mogford	Director of Policy
Mrs Rachel Bosworth	Director of Communications
Mr John Quinn	Director of Transformation Division
Mr Richard Humphreys	Deputy Finance Director (until Friday, 29 June 2018)
{Redacted: Section 40: personal data}	Head of International Office
Ms Boryana Stambolova,	Deputy Finance Director (from Monday, 2 July 2018)
{Redacted: Section 40: personal data}	Editor-in-Chief, British Pharmacopeia
{Redacted: Section 40: personal data}	Head of Analytical Science
{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

Mr Martin Charnley	Senior Lawyer, MHRA, Medicines and Information Team, DHSC Legal Advisers, Government Legal Department.
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Item 1: Introductions and Announcements

1.1 Apologies were received from Dr Barbara Bannister, Non-Executive Director; Professor Dame Valerie Beral, Non-Executive Director, who for technical reasons was unable to join the meeting by telephone from Oxford; and Mrs Carly McGurru of the Department of Health and Social Care (DHSC).

1.2 The Chair welcomed everyone to the meeting and made the following announcements:

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- *Cost-savings:* In view of the financial challenges facing the Agency, the following cost-cutting measures would be introduced: (i) a sandwich lunch will only be provided for Board members when an all-day meeting takes place, e.g. when the Board and the Audit and Risk Assurance Committee meet on the same day; (ii) the next Board/Corporate Executive Team awayday, which was due to take place at the Royal Society, will now take place in-house at the Agency's new offices (this will save the Agency £5,000); and the Board dinner on 16 July will be self-financing, except for the guests of honour. The Chair went on to advise that other measures along these lines would take place later in the year and during 2019.
- The Agency's new offices / relocation – The Chair noted that meeting was taking place during the Agency's relocation from Victoria and Canary Wharf and commended all concerned for the success to date of the relocation.

Item 2: Declarations of interest

2.1 Deborah Oakley, Non-Executive Director, asked that the minutes record that she had been appointed to the Board of NHS Digital, and as part of her new role, Ms Oakley will Chair NHS Digital's Audit Committee. Ms Oakley reported that the appointment will become effective on 1 July, with Ms Oakley stepping down from MHRA's Board on 31 August 2018. As the Board will not meet in August, Ms Oakley's last MHRA Board meeting will take place on 16 July.

Item 3: Minutes of the Board meeting of 21 May 2018

3.1 The minutes of the Board meeting of 21 May 2018 were adopted.

Item 4: Actions list / matters arising

4.1 The Actions list was reviewed.

DISCUSSION ITEMS**Item 5: Exiting the EU – update**

5.1 Jonathan Mogford presented an update on the UK's negotiations to leave the EU. The update covered (i) the Withdrawal Agreement, including the Implementation Period; (ii) the UK's future relationship with the EU (this will be set out in White Paper, which is expected to be published during the first half of July); and (iii) work the Agency is doing on 'No deal' contingency planning, as well as on the future shape of the Agency.

5.2 Sir Michael (Chair) thanked Mr Mogford for the update and sought the Board's views. These centred on the following areas:

- {Redacted: Section 35: Formulation of Government policy}
- The Board asked about real-world trials using CPRD and was assured by Dr Hudson that there was a significant interest in this work.
- {Redacted: Section 35: formulation of Government policy}

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- Professor David Webb, who was recently appointed by the Chair to be the Board's lead member on Brexit-related discussions and developments, gave an update on his meeting with the Minister on 22 May.

Item 6: MHRA post-Brexit: Opportunities and likely impact

6.1 Jon Fundrey gave an update on work that has been commissioned by Health Minister Lord O'Shaughnessy on the likely impact on the Agency of three Brexit scenarios: (i) continued collaboration with the EU system, (ii) continuation of the Implementation Period (IP) arrangements, and (iii) stand-alone mode. Mr Fundrey went on to set out the advantages and disadvantages of the respective scenarios and estimates the likely impact on the corporate and regulatory functions of the Agency. Mr Fundrey advised that CPRD remains unaffected by Brexit, while the impact on NIBSC concerns batch release and possibly access to EU grant funding. Mr Fundrey concluded by advising that Lord O'Shaughnessy had asked the Agency to carry out scenario planning for worse case outcomes in time for a meeting with the Minister in July. This work is now taking place.

6.2 The Chairman thanked Mr Fundrey for the update and sought the Board's views. These centred on the following areas:

- *Opening comments* – The Board thanked Mr Fundrey for his report, which was interim in nature, then commented on the link between this work and the Operational Transformation (OT) Programme. Dr Hudson said that OT will allow the Agency to look afresh at processes, and systems of the Agency.
- {Redacted: Section 35: Formulation of Government policy}
- {Redacted: Section 35: Formulation of Government policy}

Item 7: Strategic Finance – update

7.2 Jon Fundrey gave an update on changes to the Agency's income profile over the current budget year and during 2019/2020 the income loss during the Implementation Period (IP). To address the upcoming changes, Mr Fundrey reported on the recent budget challenge process by CET peers which identified definite and possible savings and income generation opportunities across the Agency. Mr Fundrey explained that CET has agreed a savings target of £13m for the nine divisions that comprise the Regulator. Of that £13m, savings of £6m will need to be found within the corporate divisions / Regulator, with £7m being allocated to fund Operational Transformation. In addition, CPRD and NIBSC will aim to attain financial break-even. Mr Fundrey distinguished between the short-term Budget Challenge exercise, the current commission from Lord O'Shaughnessy on the shape of the Agency in the worst-case scenario post IP and the longer-term solutions to be provided by Operational Transformation.

7.2 The Chair thanked Mr Fundrey for his update and sought the Board's views; these centred on the following:

- *Recruitment panel* – In answer to a question from the Board, Mr Fundrey explained the structure and governance arrangements for the newly created recruitment panel.
- {Redacted: Section 35: Formulation of Government policy}

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- {Redacted: Section 35: Formulation of Government policy}

7.3 A paper on Strategic Finance will come to the Board on 16 July.

Item 8: Operational Transformation

8.1 John Quinn gave an update on the Operational Transformation Programme (OT) programme. Mr Quinn explained that the seven work streams have been established and work is being taken forward, with CET directors providing sponsorship for each work stream. The Board heard that the recent meetings of the Agency's Senior Leaders Group, where OT featured significantly, were well-attended, the feedback from which has been very positive. Mr Quinn also mentioned the series of blogs by CET workstream sponsors, which have been published on Insite. The workstreams will inform a business case that will set out the Vision, Design, Plan, Accountabilities and Resource requirements. The business case will be underpinned by a roadmap with key milestones, targets, benefits and costs. Mr Quinn advised that the timeline for this part of the OT programme is very tight, as the target for completing the draft business case is 23 July.

8.2 The Chair thanked Mr Quinn for the progress report and sought the Board's views. These centred on the following areas:

- *Opening comments:* The Board commended Mr Quinn on the project plan and especially the proactive role involvement of the CET, which clearly many Board members said demonstrate a clear willingness to take ownership of the challenge.
- *Board input / offers of support* – Several Board members expressed concern that OT was exerting particularly heavy pressure on a relatively small number of officials, all of whom had many other responsibilities and demands on their time. In view of this, several Board members offered their support, e.g. as a 'critical friend' or sounding board with whom CET directors could talk through issues and challenges. Mr Quinn thanked the Board for the offer about which he would discuss with the Board members concerned outside the meeting.
- *Impact on research* - The Board asked if the aim was to find 25% of savings equally across all seven workstreams, and how this would impact on the Agency's research work. The work heard that these points would be discussed in July. Dr Hudson cautioned that when carrying out this important work, the Agency had to challenge itself while at the same time ensure it would not be weakened, e.g. by losing expert staff.

Item 9: International Office - update

9.1 {Redacted: Section 40: personal data} Head of the International Office, presented a paper that set out the priorities for the International Office over 2018/19. {Redacted: Section 40: personal data} advised that the International Office will focus on four key priorities: (i) exploring future collaborations, (ii) developing the MHRA's international role in the regulatory landscape, (iii) maintaining agreements to support core business, and (iv) supporting the work of Inspection, Enforcement and Standards Division and Devices Division in securing a safe global supply chain.

9.2 The Chair and Board thanked {Redacted: Section 40: personal data} for the progress report and commended her on the work of the International Office. In

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response to a question about the status of the Agency's MoU with India, 1 {Redacted: Section 40: personal data} advised that the MoU would expire in October 2018. Discussions are taking place about its renewal. {Redacted: Section 40: personal data} went on to explain that the International Office works closely with partners across Government the Foreign and Commonwealth Office in London and the UK's network of embassies and High Commissions.

Item 10: Draft Annual Report and Accounts 2017/18

10.1 Rachel Bosworth presented the draft Annual Report and Accounts for sign off. Ms Bosworth reported that the revised draft of the Annual Report reflected the Board's earlier comments and was now in a final stage. Ms Bosworth said the Annual Report would be subject to further proof-reading.

10.2 The Chair thanked Ms Bosworth and her team for their work on the draft Annual Report. Several Board members said they had some minor comments, which they would send on after the meeting. Subject to the minor changes being made, the Board endorsed the draft Annual Report for sign off.

Annual Accounts / Audit and Risk Assurance Committee (ARAC) - update

10.3 As regards the Annual Accounts, the Chair invited Deborah Oakley, Chair of the Audit and Risk Assurance Committee (ARAC), to give an update on the ARAC meeting which was held earlier in the day, where the draft Annual Accounts were considered, and to explain what action was required to conclude work on the Annual Accounts.

10.4 Ms Oakley reported that the main business of the meeting was to consider draft Annual Accounts, the National Audit Office's Statutory Report, the internal audit reports and to review the Corporate Risk Register. Ms Oakley went on to report that ARAC considered a paper on CPRD and access to data from external parties, as well as the Agency's programme of work on cyber security. Ms Oakley commended John Quinn and his team on the progress that had been achieved so far.

10.5 Ms Oakley reported that the Head of Internal Audit had given a moderate rating for the end of year assurance as well as for internal controls and governance. She went on to report that the National Audit Office was expected to issue an unqualified opinion, subject to completion of final field work. Additionally, ARAC could not approve the draft Accounts in view of queries that had been raised about the value of the NIBSC estate. Accordingly, Ms Oakley recommended, subject to the Board's agreement, that ARAC reconvene by way of a telephone conference call on 9 July to reconsider the draft Annual Accounts, including any additional information about the valuation of the NIBSC estate.

10.5 Sir Michael Rawlins, Chair of the Board, asked the executive and non-executive directors present if they would be content to delegate this matter to ARAC by way of a telephone conference call on 9 July, or whether an extraordinary meeting of the Board should be arranged to consider the draft Annual Accounts. The Board unanimously agreed to authorise ARAC to meet by telephone conference call on 9 July to consider and address any remaining concerns.

10.6 Subject to ARAC's agreement on 9 July, ARAC would formally recommend that Dr Hudson as Accounting Officer could sign the Annual Accounts. Once Dr Hudson had signed off the Annual Accounts, they would be submitted to the Comptroller and Audit General for signature after which they would be laid before Parliament.

FINAL*Chair of ARAC*

10.7 Martin Hindle, Deputy Chair and a member of ARAC, noted that this was the last occasion when ARAC was chaired in person by Ms Oakley. Accordingly, Sir Michael Rawlins, Chair of the Board, and Mr Hindle asked that the minutes formally record the Board's gratitude to Deborah Oakley for her past services as Chair of ARAC.

Action: Officials from Finance and Procurement Division to arrange a telephone conference call for ARAC to take place on 9 July.

Item 11: British Pharmacopoeia (BP) – NIBSC Herbals Project

- 11.1 {Redacted: Section 22: Information intended for future publication}

Item 12 Chief Executive's Report

12.1 Dr Hudson presented the highlights from the CEO's report for May 2018. These centred on the following areas:

- *Fake meds campaign* – Dr Hudson reported that the Agency's 'Fed meds campaign' had won the Chartered Institute of Public Relations annual wards (2018) for the 'best healthcare campaign'. The Chair and the Board asked that Rachel Bosworth convey the Board's congratulations to those concerned.
- *Surgical mesh* – An update was given on developments following a third-party review of the NHS Digital Review by the London Tropical School of Hygiene and Medicine. A meeting has been arranged between officials from Devices Division and Mesh UK Charitable Trust.
- *Counterfeit medicines* – An update was given on the seizure of a large variety of prescription only medicines in Bolton on 2 May. The raids, which were carried out by officials from the Enforcement Group in liaison with the Greater Manchester Police, resulted in four arrests.
- *Clinical Practice Research Datalink's (CPRD) 30th anniversary* – An update was given on events to mark '30 Years of UK data – improving public health'. While CPRD was founded in 2012, its predecessors reach back to the database that Dr Alan Dean, a GP in Essex, set up, which led eventually to the creation of the General Practice Research Database (1994-2012). The Board noted that the 30th anniversary celebrations will culminate with an event for GPs that will coincide with the Royal College of GPs conference in October 2018.

12.2 The Chairman thanked Dr Hudson for his report and invited questions from the Board. These centred on the following areas:

- *Campaigns* - The Board asked how the Agency knows if a campaign has been successful. Ms Bosworth explained that while we know a campaign has most likely reached its target audience, we do not know whether it may have changed behaviour.
- *Cumberledge Review* – In answer to a question from the Board, Dr Hudson reported that the terms of reference of the Review were being prepared.

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13.1 Professor David Webb gave an oral update on the meeting of the Remuneration Committee, which took place by telephone on 18 June. Professor Webb reported that the Remuneration Committee had a very a productive meeting, the recommendations of which were agreed unanimously.

Item 14: Review of the Board members' Declarations of Interest – to note

14.1 The Board reviewed the annual Board members' declarations of interest. It was noted that the list was incomplete as a declaration, which Deborah Oakley had made was absent, while Matthew Campbell-Hill advised there were several declarations which he would like to add to list. Mr Campbell-Hill said he would this after the meeting. The Chair asked that Directorate staff liaise with Ms Oakley and Mr Campbell-Hill after the meeting to ensure that the list of declarations is brought up to date. The Chair also asked the Directorate liaise with Dame Valerie Beral about nay declarations of interest she would wish to make as a user of CPRD data.

Action: Directorate to liaise with Dame Valerie Beral, Deborah Oakley and Matthew Campbell-Hill to ensure that the Board members' declarations of interest are up to date.

Item 15: Minutes of the Corporate Executive Team (CET) of 8 May 2018

15.1 The minutes of the CET meeting of 8 May 2018 were noted.

Item 16: Draft agenda for the Board meeting of 16 July 2018

16.1 The Board noted the draft agenda for the next Board meeting on 16 July.

Item 17: Forward Programme of Board Business, 2018-2019

17.1 The Board noted the Forward Programme of Board Business for 2018/2019.

Item 18: Any Other Business (AOB):

19.1 The Chairman then asked if there were any items of AOB; none was tabled.

Date of next meeting: 16 July 2018