MHRA Board

MINUTES OF THE MEETING
9 December 2015

Present:

The Board

Professor Sir Michael Rawlins	Chairman of MHRA
Dr Ian Hudson	Chief Executive
Dr Barbara Bannister MBE	Non-Executive Director
Mr Matthew Campbell-Hill	Non-Executive Director
Professor Bruce Campbell	Non-Executive Director
Mr Peter Commins	Chief Operating Officer and Finance Director
Mr Martin Hindle	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 – by telephone

Others in attendance

MHRA executive and supporting officials

Ms Rachel Bosworth	Director of Communications
Dr Stephen Inglis	Director of National Institute for Biological Standards and Control (NIBSC)
Mr Jonathan Mogford	Director of Policy
[Redacted Section 40 Personal]	Principal Scientist (Biotherapeutics), NIBSC – item 5
Mr Richard Humphreys	Deputy Finance Director – items 7 & 11
[Redacted Section 40 Personal]	Head of Business Analysis – item 11
[Redacted Section 40 Personal]	Head of Science Strategy
Mr Aidan McIvor	Head of Directorate
[Redacted Section 40 Personal]	Executive Assistant to the Chairman

Department of Health (DH) and Legal Services

Mrs Claire Armstrong	Deputy Director (Medicines, Pharmacy and Industry Division)
Mr Mark Wilson	Lawyer - DH Legal Advisor

Item 1: Introductions and Announcements

1.1 Apologies were received from Dame Valerie Beral, Non-Executive Director

1.2 Sir Michael welcomed everyone to the meeting and went on to explain that a number of officials would attend for specific items during the meeting.

Whistleblowing Champion

1.3 Sir Michael invited declarations of interest from members of the Board in becoming a whistleblowing champion for the Agency. Sir Michael explained that the role was to

provide oversight and assurance to the Agency's whistleblowing policy and procedure, and challenge the Agency, as appropriate.

1.4 It was agreed that Stephen Lightfoot, who is a member of the Audit and Risk Assurance Committee, would serve as the Agency's Whistleblowing Champion.

Item 2: Declarations of interest

2.1 None was declared.

Item 3: Minutes of the last meeting, 20 November 2015, and matters arising

3.1 The draft minutes of the Board meeting of 20 November 2015 were agreed.

Matters arising

3.2 The Board then reviewed the actions list from previous meetings.

Audit and Risk Assurance Committee (ARAC) revised terms of reference -

3.3 Under action point 4 of the Actions' list, the Board considered and endorsed the revised terms of reference for ARAC.

DISCUSSION ITEMS

Item 4: Horizon scanning

4.1 Dr Stephen Inglis, Director of the National Institute for Biological Standards and Control (NIBSC), introduced Dr Simon Hufton, Principal Scientist (Biotherapeutics) at NIBSC, who presented a report on the work of the Agency's Horizon Scanning Group (HSG).

4.2 The Board heard that the HSG was set up in late 2013 to provide a system for collecting 'signal reports' from across the Agency on areas of emerging interest. These are reviewed periodically by scientific area leads and the HSG. In May 2015, the HSG presented its first report to the Corporate Executive Team (CET) who asked the group to continue their work including identification of specific priority areas to be taken forward. The Board noted that over 60 signal reports have now been generated and logged and to date four areas of particular interest have emerged from the signals: i) Faecal microbiome therapy (FMT); (ii) Clustered regularly interspaced short palindromic repeats (CRISPR) technology; (iii) Chimeric antigen receptor (CAR) T-cell immunotherapy; and (iv) RNA interference.

4.3 The Board welcomed the report, and asked that horizon-scanning should also cover digital technologies. In response to a question from Professor Campbell, Dr Hudson, Chief Executive, advised that medical devices would feature as part of this programme.

Item 5: Triennial Review

5.1 Mr Jonathan Mogford, Director of Policy, presented the six-month formal update on progress to date on taking forward the recommendations in the recent Triennial Review reports on the Agency, the British Pharmacopoeia Commission, and the Commission on Human Medicines. The update was informed by a spreadsheet that tracked progress against each of the Triennial Review's recommendations. The Board heard that good

progress has continued to have been made across the recommendations and plans are in place for remaining work.

5.2 The Board endorsed the formal six-month report subject to one amendment relating to the IT work which would be submitted to Cabinet Office via the Department of Health.

Item 6: Open board meetings – practice arrangements / next steps

6.1 Mr Aidan McIvor, Head of Directorate, gave an update on arrangements for the pilot programme of open board meetings, which will begin in February 2016. The Board noted the progress report on the research Mr McIvor had carried out, including attending several open board meetings at other organisations. The Board noted the update on registration, accommodation, security issues, agenda management, questions and answers after each discussion item. The Board asked that an equivalent number of staff (up to ten persons) should be able to attend the part 1 (open) board meetings as external observers. Mr McIvor said he would act on the Board's feedback.

Item 7: Board Effectiveness Review

7.1 Mr Richard Humphreys, Deputy Finance Director, gave an update on work that will take place to assess the Board's performance. Following the Board discussion of Board Effectiveness Evaluation at the Annual Accounts Seminar in May 2015, there was a pause, so as to allow the Triennial Review exercise to conclude and for the Board's new members to join in September. Now that the Board has a unitary structure and a full complement of members, work on the Board Effectiveness Review can begin again.

7.2 Mr Humphreys outlined the work that the Head of Internal Audit will carry out and the planned timelines between now and the end of the financial year. The Board agreed with the proposed approach.

Item 8: Draft programme for the Board / Corporate Executive Team away-day

8.1 Mr Jonathan Mogford outlined the draft programme for the Board/Corporate Executive Team (CET) away day on 15 January 2016. The Board heard that the objectives for the away day were to: (i) review strategic finance objectives; (ii) review and test out emerging material for the corporate plan; (iii) discuss in more detail two key underpinning agendas for longer term thinking in the Board about the future growth and development of the Agency. The Board welcomed the update and endorsed the draft programme for the away day.

Item 9: Draft timetable for the draft Annual Report 2015/16

9.1 The Board noted the timetable for the production of the Annual Report and Accounts 2015/16 and the arrangements for the layout of the report, which was presented by Ms Rachel Bosworth, Director of Communications.

STANDING ITEMS

Item 10: CEO's report

10.1 Dr Hudson presented the highlights from the CEO's monthly report. These centred on the following areas:

- *TOPRA* - Dr June Raine, Director of Vigilance and Risk Management of Medicines Division received a 'Lifetime Achievement Award' on 18 November.

The award was given by The Organisation for Professionals in Regulatory Affairs (TOPRA) in recognition of Dr Raine's contribution to the delivery of a world-class European pharmacovigilance system. The Board asked that the minutes record their congratulations to Dr Raine on being given the TOPRA lifetime achievement award.

- *Metal on Metal study* – An update was given on a data linkage for the metal on metal hip study that will be carried out by researchers at University College London (UCL). The study will be informed by National Joint Registry / CPRD primary care data that was sent to UCL on 20 November 2015.

- *GcMAF - [Redacted Section 35 Government policy]*

- *Litigation* – An update was given on a judicial review appeal.

- *People Survey* - An update was given on the Corporate Executive Team's consideration of the results of the People Survey and the follow-up action to be carried out at a divisional and cross-agency level.

- *Innovation Office* – In response to a board member's question, an update was given on the work of the Agency's Innovation Office.

Item 11: Finance and Procurement report

11.1 Mr Peter Commins gave the highlights for first seven months of the financial year 2015/16. They were:

- MHRA (Regulator) income: year to date was £62.0m.
- NIBSC operational income: year to date was £24.7m.
- CPRD income: year to date was £6.0m.
- Operating income for the Agency was £92.8m, which is £5.7m above budget.
- Total operating costs were £77.3m, which are £2.2m below budget.
- The Agency's bank balance at the end of October 2015 was £217.9m.
- Capital expenditure for the year to end of October 2015 was £5.2m.
- Total Product Licensing deferred revenue at the end of October 2015 was £18.2m.
- The number of full-time equivalents in October 2015 was 1,225, with 152 short-term contracts and 39 non-payroll employees.

Annual Strategic Finance update

11.2 Mr Commins presented a paper that set out the latest financial context in advance of the January 2016 Board / CET away day as part of the refresh of the Corporate Plan. The paper examined the strategic trends which will affect the Agency as it enters the next five-year objective period from 2018. Mr Commins advised that the annual budget setting process is underway and will separately address short term activity and manpower changes in the coming year.

Item 12: Minutes of the Corporate Executive Team (CET) of 4 November 2015

12.1 The minutes of the CET meeting of 4 November 2015 were noted.

Item 13: Non-Executive Directors' (NEDs) updates

13.1 The following updates were given:

- Sir Michael reported that he had attended a roundtable discussion on ethics for regulators under the chairmanship of Lord Bew, Chair of the Committee on Standards in Public Life (CSPL). The roundtable discussion on 24 November was followed by a visit to MHRA on 2 December by CSPL officials. The Board heard that the CSPL officials had met with Sir Michael and Dr Hudson to learn more about the Agency's work and its governance structure.

- Sir Michael reported that he, along with John Wilkinson, Director of Devices, had met with the Association of British Healthcare Industries on 8 December.

- Dr Barbara Bannister reported she had attended a two-day conference organised by ISARIC (International Severe Acute Respiratory and Emerging Infections Consortium) to review the response to the Ebola pandemic and to identify opportunities to improve the speed and effectiveness of the response. Dr Bannister said that during the conference she had met contributors from the WHO, major Aid Agencies, national public health leaders and scientists from Italy and other participating countries. Many were very interested in the work of CPRD. Dr Bannister offered to pass on the scientists' contact details, which Dr Hudson accepted, for CPRD to follow-up.

Item 14: Any Other Business (AOB):

Board members' sponsor roles

14.1 Sir Michael reported that he was keen that each member of the Board should act as a sponsor to a particular part of the work of the Agency. The Board welcomed this suggestion and the following areas of Board sponsor activity were agreed:

- Dr Barbara Bannister: broader public health
- Dame Val Beral: Vigilance and Risk Management of Medicines
- Professor Bruce Campbell: medical devices
- Matthew Campbell-Hill: Communications
- Martin Hindle: business planning and conflicts of interest
- Stephen Lightfoot: operational transformation
- Sir Alex Markham: CPRD
- Deborah Oakley: Audit and Risk Assurance Committee
- Professor David Webb: NIBSC

Date of next meeting (Board/CET away day): 15 January 2016