MHRA Agency Board

MINUTES OF THE MEETING
22 June 2015

Present:

The Agency Board

Professor Sir Michael Rawlins	Chairman of MHRA
Professor Valerie Beral	Non- Executive Director
Mr Martin Hindle	Non-Executive Director
Professor Vincent Lawton	Non-Executive Director
Professor Sir Alex Markham	Non-Executive Director
Ms Deborah Oakley	Non-Executive Director
Professor David Webb	Non-Executive Director
Mr John Williams	Non-Executive Director

Others in attendance

MHRA executive and supporting officials

Dr Ian Hudson	Chief Executive
Mr Peter Commins	Chief Operating Officer and Finance Director
Ms Rachel Bosworth	Director of Communications
Mr Jonathan Mogford	Director of Policy
Mr John Wilkinson	Director of Devices
Mr Gerald Heddell	Director of Inspection, Enforcement and Standards (IE&S) – for items 1-4
[redacted]	Editor-in-Chief, British Pharmacopeia - for items 1-4
[redacted]	Head of Corporate and Regulatory Strategy – item 4
[redacted]	Secretary to the Commission on Human Medicines – item 4
[redacted]	Deputy Finance Director
[redacted]	Chief Financial Accountant
[redacted]	Customer Services Manager – for item 5
[redacted]	Head of Science Strategy
[redacted]	Executive Assistant to the Chairman

Department of Health (DH)

[redacted]	DH sponsor representative
Mr Mark Wilson	Legal Services

Item 1: Introductions and Announcements

1.1 Apologies were received from Mr Aidan McIvor, Secretary to the Board.

1.2 *July Board*: Sir Michael Rawlins reported he had asked the four new non-executive directors, who will join the Board on 1 September 2015, to attend the Board meeting on 20 July as observers.

1.3 *Honours:* Sir Michael said he was delighted that Ms Una O'Brien, Permanent Secretary at the Department of Health; Professor Munir Pirmohamed, Professor of Clinical Pharmacology, University of Liverpool; and Professor Ian Weller, Professor of

Genitourinary Medicine, Windeyer Institute of Medical Sciences, had been recognised in the recent Birthday 2015 Honours. Ms O'Brien was appointed Dame Commander of the Order of the Bath, while Professors Pirmohamed and Weller received knighthoods.

Item 2: Declarations of interest

2.1 None was declared.

Item 3: Minutes of the last meeting, 15 May 2015, and matters arising

3.1 The draft minutes of the Board meeting of 15 May 2015 were agreed.

Matters arising

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

DISCUSSION ITEMS

Item 4: Triennial Review

4.1 Sir Michael welcomed [redacted] of Policy Division, who presented an overview of the Triennial Review reports on the Agency, the British Pharmacopoeia Commission, (BPC) and the Commission on Human Medicines (CHM). The Board heard that the Triennial Review of the Agency had been signed off by Dr Will Cavendish, senior sponsor for the Agency at the Department of Health (DH), and the report was awaiting Ministerial approval.

4.2 The Board considered the individual reports and their recommendations, and were advised by Dr Hudson, Chief Executive, and Mr Mogford, Director of Policy, that the Agency did not anticipate any challenges in delivering the reports' recommendations. The Board heard that the Agency's response to the reports on CHM and the BPC were due in October, while the response to the report on the Agency was due in December 2015.

4.3 Sir Michael and the Board thanked [redacted] for guiding the Board through the reports and their recommendations. The Board welcomed the reports and endorsed Dr Hudson's view that their recommendations could be delivered. Moreover, in preparing the Agency's formal response to each report, the Board thought the Agency was in a strong position to respond. The Board welcomed the report on CHM and endorsed the proposal that the Chief Medical Officer should write, where applicable, to those CHM members who are employed by NHS Trusts to emphasise the importance of their work on CHM to public health.

4.4 The Board heard that the Agency will track work on the three reviews in line with work on business planning. Dr Hudson advised that the Board will receive regular progress reports in the months ahead.

Item 5: Strategic Fees and Cash paper

[Section 43 redaction – trade secrets and prejudice to commercial interests]

Item 6: Annual Report and Accounts 2014/15

6.1 [redacted], Customer Services Manager, and [redacted], Deputy Finance Director, presented the final version of the Annual Report and Annual Accounts 2014/2015, which

the Board agreed, noting that the accounts were still being finalised. The Annual Report and Accounts will be laid before Parliament and published before the summer recess.

Item 7: Monitoring Report for Q4 and year end business plan targets and activities

7.1 Mr Jonathan Mogford presented the Quarter 4 and end of year monitoring reports for the Business Plan for 2014/15. The Board heard that the Agency has met 19 of its 22 targets. As to the three targets that had not been met, the Board heard that PM6 (biological standards supply), 87% of all materials were supplied within 6 working days, although the target figure was 93%. For PM7a (to enable 280 research studies in 2014/15), the Board heard that 253 research studies had been enabled, while for PM7b (to double cover of primary care data within the CPRD system by the end of the financial year), the Board heard that the figure achieved was 8-11%, although the target was 8%-16%.

Item 8: Electronic cigarettes – Tobacco Products Directive (TPD) regime - update

8.1 Mr Jonathan Mogford provided an update on the implementation of the e-cigarette elements of the revised Tobacco Products Directive (TPD). The Board heard [Section 43 redaction – trade secrets and prejudice to commercial interests] DH has proposed that the Agency will act as the competent authority for the provisions relating to e-cigarettes. Mr Mogford went on to report that a Government consultation, including a draft Statutory Instrument and Impact Assessment announcing the appointment of the Agency as the Competent Authority, is expected to be announced in early July.

8.2 The Board welcomed the update and was advised by Ms Rachel Bosworth of the reputational and communications' challenges which the regulation of e-cigarettes pose for the agency. The Board heard that an MHRA/DH/Public Health England working group has been to set up to ensure co-ordinated communications during the consultation. Martin Hindle, non-executive director, who is a member of Public Health England's Advisory Board, said that he would raise the issue of TPD at PHE's Board meeting on 26 June.

8.3 The Board heard it would be inappropriate for the agency to speak on e-cigarettes until the consultation is closed and subject to the Government's decision after the consultation on who is to be appointed as the Competent Authority. It would be for DH to field any enquiries on the consultation that was about to be published, relating to the implementation of the TPD, including those elements that relate to the e-cigarette Competent Authority (CA) role.

8.4 Professor Lawton, Chair of the Audit and Risk Assurance Committee, asked that TPD be placed on the Corporate Risk Register.

Action: TPD to be added to the Corporate Risk Register.

STANDING ITEMS

Item 9: Audit and Risk Assurance Committee meeting of 22 June – update

9.1 Professor Vincent Lawton provided an oral update on the meeting of the Audit and Risk Assurance Committee (ARAC), which took place earlier in the day. The main business of the meeting was the draft Annual Accounts, the National Audit Office's Statutory Report, and the internal audit reports. The Board heard that some final work had to be completed by the auditors before the Annual Accounts could be signed by the

Chief Accounting Officer, Dr Hudson. Once Dr Hudson has signed off the Annual Accounts, they would be submitted to the Comptroller and Audit General for signature.

9.2 Sir Michael thanked Professor Lawton for his oral report, and asked that the minutes record the Board's gratitude to Professor Lawton for chairing ARAC since 2012. Professor Lawton would stand down from as ARAC chair and as a member of the Board on 20 July 2015. His successor, as chair of ARAC, would be Ms. Deborah Oakley.

Item 10: Minutes of the Audit and Risk Assurance Committee meetings

10.1 The Board noted the minutes of the Audit and Risk Assurance Committee meetings of 20 January and 23 March 2015.

Item 11: CEO's report for May 2015

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

- *[section 43 redaction – trade secrets and prejudice to commercial interests]*

- *Joint BIA/MHRA conference – An update was given on the 5th joint Bio-Industry Association (BIA) and MHRA conference on "Pathway of innovation from research to patient", which took place at the Wellcome Trust in London on 11 June.*

- *Operational Daniel* – An update was given on the conclusion of Operation Daniel, a long-running investigation into the sale of unlicensed medicines.

- *Product-related cases*: updates were given on high dose ibuprofen and arterial thrombotic risk, a class 2 drug alert that was issued on 6 May 2015, and heaters/coolers used in cardiac surgery.

- *Falsified medicines Directive – EU Common Logo* – Agency officials met with representatives from the Devolved Administrations, the General Pharmaceutical Council, and the Pharmaceutical Society of Northern Ireland to discuss the UK's new registration scheme for the use of the EU Common logo. From 1 July 2015, all legitimate websites that are entitled to sell medicines at a distance must carry the common logo.

- *Medical devices (2 Regulations)* – An update was given on the Medical devices regulations, which the European Council had agreed a 'General Approach' on 19 June. The new Regulations are due to come into force in 2016.

- *MHRA abridged applications symposium* – An update was given on a conference which the Agency hosted on 9 June 2015 on how to correctly submit an abridged application for a marketing authorisation.

- *Association of Medical Research Charities (AMRC)* –An update was given on discussions that took place between Agency officials and AMRC about joint working opportunities.

- International Coalition of Medicines Regulatory Authorities *(ICMRA)* – Dr Hudson, Chief Executive, and Mr Mogford, Director of Policy, attended a meeting of the International Coalition of Medicines Regulatory Authorities in Washington DC from 14-16 June. The meeting was hosted by the U.S. Food and Drug Administration.

Item 12: Finance and Procurement report

12.1 Mr Peter Commins gave the highlights for the first month of the financial year 2015/16. They were:

- MHRA (Regulator) income: for April 2015 was at £7.8m.
- NIBSC operational income: for April was £4.3m.
- CPRD income: for April 2015 was at £0.76m.
- Operating income for the Agency was £13m, which is £1.3m above budget.
- Total operating costs were £10m, which was £1.3m below budget.
- The Agency's bank balance at the end of April 2015 was £192.3m.
- Capital expenditure for the year to end of April 2015 was £0.4m.
- Total Product Licensing deferred revenue at the end of April 2015 was £18.3m.
- The number of full-time equivalents in April 2015 was 1,199, with 142 short-term contracts and 34 non-payroll employees.

Item 13: Minutes of the Corporate Executive Team (CET) of May 2015

13.1 The minutes of the CET meeting of 3 May 2015 were noted.

Item 14: Non-Executive Directors' (NEDs) updates

14.1 None was given.

Item 15: Any Other Business (AOB):

15.1 The Board considered a letter from the Chief Medical Officer, Dame Sally Davies, to the Academy of Medical Sciences about statins.

15.2 Professor David Webb thanked agency staff for the briefing material he had received prior to his attendance at a conference on traditional Chinese herbal medicines in China.

Date of next Board meeting: 20 July 2015