MHRA Board

MINUTES OF THE MEETING
14 October 2016

Present:

The Board

Professor Sir Michael Rawlins	Chairman of MHRA
Mr Martin Hindle	Deputy Chairman
Dr Ian Hudson	Chief Executive
Dr Barbara Bannister MBE	Non-Executive Director
Professor Dame Valerie Beral	Non- Executive Director
Mr Matthew Campbell-Hill	Non-Executive Director - by video link
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
Ms Rachel Bosworth	Director of Communications
Mr Richard Humphreys	Deputy Finance Director
Ms Vanessa Birchall-Scott	Director of Human Resources – item 7
Mr Andy Gregory	Deputy Director, Policy – item 4
Name redacted under Section 40 of the FOIA (personal data)	Head of Imaging, Acute and Community Care, Devices Division - item 5
Name redacted under Section 40 of the FOIA (personal data)	Head of Operations, Enforcement Group – item 6
Name redacted under Section 40 of the FOIA (personal data)	Head of Learning and Development – item 8
Name redacted under Section 40 of the FOIA (personal data)	Head of Science Strategy
Mr Aidan McIvor	Head of Directorate
Name redacted under Section 40 of the FOIA (personal data)	Executive Assistant to the Chairman

Department of Health (DH) and Legal Services

Ms Libby Green	Deputy Director (Medicines, Pharmacy and Industry Division), DH
Name redacted under Section 40 of the FOIA (personal data)	DH Legal Services

Item 1: Introductions and Announcements

1.1 Apologies were received from Mrs Janet Davies, Acting Deputy Director of Healthcare Quality Division, representing the Welsh Assembly Government

1.2 The Chairman welcomed everyone to the meeting.

Item 2: Declarations of interest

2.1 None was declared.

Item 3: Minutes of the last meetings, 17 June 2016, and matters arising

3.1 The minutes of the Board meeting of 12 September (parts 1 and part 2) were agreed.

Matters arising

3.2 The Board reviewed the actions list from previous meetings.

DISCUSSION ITEMS

Item 4: EU Referendum - update

4.1 Jonathan Mogford presented an update on Brexit-related work. The Board heard that the volume and pace of the work continues to be high, with increasing interest from the DH and the Department for Exiting the European Union {redacted under Section 35: Formulation of Government policy}. Alongside this, the Health Select Committee has called for an inquiry at which the Agency will need to submit written evidence. The Board heard that discussions with industry continue, with a Ministerial Industry Steering Group (MISG) taking place in late November. {redacted under Section 35: Formulation of Government policy}.

4.2 Mr Mogford then went on to report that at the International Medicines Regulators summit in Interlaken, Switzerland, the UK (MHRA) had been elected to chair the International Coalition Medicines Regulatory Authorities (ICMRA) for the next two years, with Australia and Mexico acting as co-Chairs. The Board heard that the atmosphere at the summit was very positive, with the heads of other European competent authorities saying how keen they are to continue to work closely with the UK.

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

- *ICMRA* - Sir Michael and the Board congratulated Dr Hudson on the election of MHRA as Chair of ICMRA. The Board thought this was a strong vote of confidence in the UK.

- *Continued work within the EU:* Dr Hudson commented that at an operational level MHRA will continue to work very closely with European counterparts; the wish for continued close collaboration is shared by the Agency's counterparts in the European medicines network. Dr Hudson went on to advise that at a higher, political level, the Agency would, of course, be subject to decisions taken at the centre of government.

- {redacted under Section 35: Formulation of Government policy}.

- *International comparisons* – In response to comments from Board members about how other non-EU regulators operate, e.g. their legislative base, funding and operating models, Mr Mogford advised that the Agency is carrying out research in these areas to inform its thinking and had had meetings with a number of member states whilst in Interlaken.

- {redacted under Section 35: Formulation of Government policy}.

4.4 A further update will come to Board on 14 November.

Item 5: Redacted under Section 5: Commercial confidentiality}.

Item 6: Enforcement Group Control Strategy

6.1 {Name redacted under Section 40 of FOIA (personal data} presented a paper that set out the control measures in place to support members of staff who undertake high risk activities as part of their role within the Agency's Enforcement Group. {Name redacted under Section 40 of FOIA (personal data} outlined the role of the Enforcement Group and, in particular, the roles its investigators and field intelligence officers undertake, and the risks they may encounter. {Name redacted under Section 40 of FOIA (personal data} then outlined how such risks are mitigated through risk assessment plans, the use of personal protection equipment, first aid, health screening, training, and, in particular, how to deal with violent confrontation. {Name redacted under Section 40 of FOIA (personal data} concluded by reporting on the range of mitigations to reduce the risks to staff are being fed into the Agency's Health and Safety Strategy.

6.2 The Chairman thanked {Name redacted under Section 40 of FOIA (personal data} for the update and sought the Board's views. These centred on the following areas:

- *Number of assaults on staff* – In answer to questions from Board, {Name redacted under Section 40 of FOIA (personal data} advised that no member of staff has been assaulted in the course of her/his duties with the Enforcement Group. {Name redacted under Section 40 of FOIA (personal data} said that he was conscious of the risk of some staff being complacent, e.g. their reluctance to wear stab-proof vests while on operational duty, although the wearing of such equipment is mandatory and staff are complying.

- *Near misses* – The board asked if a record is kept of near misses; the Board heard that no near misses have been recorded, which the Board found surprising, when contrasted with the experience of NHS Hospital Trusts. The Board commented that near miss recording and associated learning was an important way to prevent actual incidents occurring.

- *Feedback* – The Board asked if feedback has been sought from staff on their level of well-being. The Board heard that staff members were content with the protection and support provided to them. Moreover, the Agency's processes and protective measures have been peer-reviewed and have been demonstrated to be in line with those of the UK civil police service. The Board was reassured by this.

- *Legal protection* – In answer to a question from the Board, [Name redacted s40 (personal data)] assured the Board that all staff members are entitled to the same

level of legal protection as a police officer. The Board also heard of the range collaboration that the Agency has with the UK civil police and other law enforcement agencies in the UK. {Name redacted Section 40 of the FOIA (personal data)} concluded by advising that if an operation is deemed to be too high risk to MHRA staff, it will not be undertaken.

Item 7: Equality and Diversity Report

7.1 Vanessa Birchall-Scott presented the annual update on the Agency's equality and diversity activities. The update outlined work that has taken place in 2015/2016, as well as the Agency's quality and diversity objectives for the current financial year. Ms Birchall-Scott said that there is a strong commitment from the CET to meet the legal and moral aspects of the Agency's responsibilities.

7.2 To help with this work, a cross agency Equality and Diversity group was set up in October 2015, which meets quarterly. The group has implemented a number of initiatives and these include an Agency pledge and objectives, an Equality and Diversity page on INsite and the establishment of an equality and diversity staff data sub group, which carried out a review of the data available in 2015 and will do the same for the 2016 data provided to CET. A range of further initiatives are planned, including Equality and Diversity training.

7.3 The Chairman sought the Board's views; these centred on the following areas:

- *Part-time working* – The Board observed that the Agency had few part-time posts. Ms Birchall-Scott concurred advising that, compared with the National Health Service, a small percentage of the Agency's posts were part-time. Ms Birchall-Scott went on to explain that the Agency's flexible approach to employment, which includes home-working arrangements, which has been helped thanks to technological changes.

- *Sexual orientation* – The Board noted that when asked to indicate sexual orientation, 38% of staff opted to identify themselves as 'not known/ prefer not to say'. Ms Birchall-Scott explained the assurances provided to staff through INsite, and via the Equality and Diversity Group's divisional representatives, the latter of whom will continue to assure staff that all responses will be treated in strict confidence,

- *Equality Impact Assessments* – In answer to a comment from the Board, Ms Birchall-Scott said that Equality Impact Assessments were being prepared by divisional representatives.

- *Training* – The Board heard that the Agency is rolling out a range of training, as well as new recruitment software. The Board heard that all members of staff receive mandatory training on unconscious bias.

- *Bonus allocation* – In answer to a question about how staff bonuses are reviewed, Ms Birchall-Scott explained the bonus allocations are reviewed every quarter by the CET. The review looks at the breakdown of bonus allocation by gender and ethnicity. The Board heard that there is greater transparency around employee-related equality data, e.g. data linked to special bonuses, the latter of which were published in June 2016's Team Brief.

7.4 The Chairman and Board concluded by thanking Ms Birchall-Scott for the update.

Item 8: Health and Safety for Non-Executive Directors

8.1 [Name redacted section 40 (personal data)] presented a health and safety briefing for members of the Board. The briefing covered basic health and safety information, e.g. on fire evacuation, the legislation: the Health and Safety at Work Act 1974 and the Health and Safety (Display Screen Equipment) Regulations 1992. Ms Reeve went on to outline mandatory information and training, e.g. responsible for info-data protection, confidentiality of data, as well as about learning opportunities online.

8.2 The Chairman and Board welcomed the update. In answer to a question about whether Board members could access online training remotely, they were advised that, at present, the training could only be accessed at Agency locations via laptops. Remote access to such training will be available once Office 365 is rolled out in the first quarter of 2017.

STANDING ITEMS

Item 9: CEO's report

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

- *International Medicines Regulators Summit & ICMRA* – An update was given on annual global summit of medicines regulatory authorities in Interlaken, Switzerland from 10-13 October where, in addition to the main meeting, several bilateral discussions were held with other regulators; moreover, on the first day of the summit MHRA signed a Memorandum of Understanding with SwissMedic. An update was also given on ICMRA, which was earlier under item 4.

- *New Chief Operating Officer* – The meeting heard that Jon Fundrey, Chief Operating Officer designate, would join MHRA on 31 October.

- *Cannobidiol* - An update was given on the sale of products extracted from Cannabis, which contain significant quantities of Cannabidiol.

- *Metal on Metal hips*– An update was given on the work of an Australian research group's study of an Australian patient database, which includes patients with metal on metal hip replacement, for associations with cardiac failure.

- *Regenerative medicines* – An update was given on the House of Commons Science and Technology Committee inquiry into regenerative medicines. The Board heard that the Committee would take oral evidence on 19 October.

- *NIBSC*– An update was given on renewed interest by an animal activist organisation and broadcast media in animal work being carried out at NIBSC.

- *Litigation* – An update was given on a request for a Judicial Review against MHRA.

Item 10: Finance and Procurement report

10.1 Richard Humphreys presented the finance and procurement report for the year to 31st August. The regulator variance was £0.4m ahead of budget; £1.1m ahead for NIBSC and £0.1m ahead for CPRD. Overall, after five months, the Agency has a retained surplus of £4.6m, £2.9m above budget. The 2016-17 deferred income was at £18m. The Board heard there have been no new approvals at Information Management Governance Board, so no significant changes in the Information Management portfolio schedule. The Board heard it is too early to tell if the Agency was experiencing a drop in income, as the Agency expects to see more products coming off data protection at the end of 2016-17.

10.2 The Chairman invited questions from the Board; these centred on the following areas:

- *Income risk assessment* – The Board asked how much income came from the European Union (EU). Mr Humphreys explained that EU income came from research grants (for NIBSC) and European Medicines Agency income, which is around £12m per annum. In answer to a question about how much income came directly or indirectly through regulatory activities, Mr Humphreys said he would provide an update at the next meeting.

- *Parallel imports* – The Board commented that, with the fall in the value of British Pound, the impact on parallel imports could be significant, but it was too early to be sure.

10.3 The Chairman thanked Mr Humphreys for the report.

Action: Richard Humphreys to provide an update on income derived directly and indirectly through regulatory activities at the Board meeting on 14 November.

Item 11: Audit and Risk Assurance Committee – oral report

11.1 Deborah Oakley, Chair of the Audit and Risk Assurance Committee, gave a short oral update on the meeting of the Audit and Risk Assurance Committee, which met earlier in the day. As part of the oral update, Ms Oakley reported that ARAC had considered the NAO's Audit Plan for 2016/2017, the final Management Letter for 2015/16 including several high risk recommendations, two internal audits; a very re-assuring HSE visit to NIBSC and an update on Cyber Security. A written report of the ARAC meeting would come before the Board at its meeting on 14 November. Ms Oakley also reported on several forthcoming conferences and seminars for non-executive directors, which members of the ARAC would attend, including one on cyber-security. A short written briefing had been requested on recruiting to the position of information security officer.

Item 12: Corporate Risk Register

12.1 The Board noted the Corporate Risk Register.

Item 13: Minutes of the Corporate Executive Team (CET) of 31 August 2016

13.1 The minutes of the CET meetings of 31 August 2016 were noted.

Item 14: Any Other Business (AOB):

14.1 None was tabled.

Date of next Board meeting: 14 November 2016