# MHRA Board (part 2)

## MINUTES OF THE MEETING

11 April 2016

**Present:**

*The Board*

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| Professor Sir Michael Rawlins | Chairman of MHRA |
| Mr Martin Hindle | Deputy Chairman |
| 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 Stephen Lightfoot | Non-Executive Director |
| Ms Deborah Oakley | Non-Executive Director |
| Professor David Webb | Non-Executive Director |

**Others in attendance**

*MHRA executive and supporting officials*

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| Mr Jonathan Mogford | Director of Policy |
| Ms Rachel Bosworth | Director of Communications |
| Dr Siu Ping Lam | Director of Licensing Division – item 4 |
| Dr Martin O'Kane | Head of Clinical Trials Unit – item 4 |
| Mr Gerald Heddell | Director of Inspection, Enforcement and Standards – item 5 |
| Mr Alastair Jeffrey | Head of Enforcement Group – item 5 |
| Name redacted under s40(2) of the FOIA (personal data), | Chief Financial Accountant – item 6 |
| Name redacted under s40(2) of the FOIA (personal data), | Customer Services Manager – item 7 |
| Name redacted under s40(2) of the FOIA (personal data), | Head of Science Strategy |
| Mr Aidan McIvor | Head of Directorate and Secretary to the Board |
| Name redacted under s40(2) of the FOIA (personal data), | Executive Assistant to the Chairman |

*Legal Services*

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| Mr Mark Wilson | Deputy Director, MHRA, Nutrition and EU Team, DH Legal Advisers, Government Legal Department |

**Item 1: Introductions and Announcements**

1.1 Apologies were received from Dame Valerie Beral, Non-Executive Director; Sir Alex Markham, Non-Executive Director; Mrs Claire Armstrong, Deputy Director, Medicines, Pharmacy and Industry Division at DH.

1.2 The Chairman thanked staff for organising the morning's public Board meeting, which the Board thought was a success. The Chairman asked that, in future, Board meetings in public session should begin at 10.30 a.m.

**Action:** Directorate to ensure that, if a public or standard Board meeting takes place in the morning, the start time must be 10.30 a.m.

**Item 2: Declarations of interest**

2.1 None was declared.

**Item 3: Minutes of the last meeting, 14 March 2016, and matters arising**

3.1 It was noted that a number of suggested amendments that been provided earlier had not been reflected in the draft minutes. The Chairman asked the Board Secretary to attend to the oversight.

**Action:** Directorate to revise and recirculate draft minutes of 14 March 2016.

*Matters arising*

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

**DISCUSSION ITEMS**

**Item 4: French First-in-Human Clinical Trial of BIA 10-2474**

4.1 Dr Lam and Dr O'Kane presented an update on the investigation into a first-in-human clinical trial in France where one of the five trial participants died.

Redactions have been made under s27 (damage to international relations) and s41 (breach of confidence) of the FOIA.

4.5 Chairman thanked Dr Lam and Dr O'Kane for the update and asked that a further report come to the Board after the final report into the (reference redacted) clinical trial has been published.

**Action:** Licensing Division to bring a paper to the Board after the publication of the French report.

**Item 5: Enforcement Group Control Strategy**

5.1 Gerald Heddell and Alastair Jeffrey presented the Control Strategy for the Agency's Enforcement Group. Mr Jeffrey explained that the Control Strategy is a publicly available document that sets out the objectives of the Enforcement Group. These include the long term priorities for crime prevention, intelligence and enforcement opportunities.

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

- *Resource allocation* – The Board asked how work and resources are prioritised and allocated. Mr Jeffrey explained that the Control Strategy stemmed from the 51 recommendations that came out of the Enforcement Group's Strategic Threat Assessment (STA) report, which the Board considered in October 2015. The Action Plan for Control Strategy is in turn informed by a Strategic Tasking and Coordinating Group that meets every six months. The group comprises senior

managers from across the Agency and it is they who decide on prioritisation of resources.

- *Devices* – The Board asked if the Control Strategy's work would cover medical devices. Mr Jeffrey reported that it would and that the Agency is in the process of recruiting a new specialist member of staff (crime analyst) part of whose duties will cover medical devices.

- *Crime mapping / horizon-scanning* – The Board asked how the Agency's approach to this. Mr Jeffrey reported that the Agency is working with the National Crime Agency, the Border Agency, HM Revenue and Customs, the Home Office, and a range of law enforcement agencies to map evolving trends of organised crime, such as the increasing trade in counterfeit healthcare products. The Board heard that criminal gangs can reap similar profits in trafficking counterfeit healthcare products without the same legal sanction associated with Class A drugs.

- *Protection of staff* – The Board asked what measures are taken to protect staff involved with this work. The Board heard that risk assessments are carried out on operational activities, such as surveillance or raids; that the Agency works closely with the police and other law enforcement agencies; that staff are issued with protective equipment, such as stab-proof vests; that appropriate training is provided in the use of equipment; and that due care is taken of the staff members' physical and psychological well-being. The Board heard that, staff have to be assessed to ensure they can carry out particular roles. Mr Jeffrey advised that in future the Enforcement Group's operational risk assessments will be peer-reviewed.

- *Health and safety aspect* – Deborah Oakley, Chair of the Audit and Risk Assurance Committee (ARAC), noted that the ARAC was due to receive an annual assurance report in respect of H&S at its next meeting in June. She requested that measures in place in to protect staff involved in enforcement be included in the report.

- Redacted under s42 of the FOIA (legal privilege)

**Action:** Personal protection issues for Enforcement Group staff members to be fed into the Agency's Health and Safety Strategy and into the annual H&S report to ARAC.

**Item 6: Board Effectiveness Review**

6.1 (Name redacted under s40(2) of the FOIA) presented the draft Terms of Reference (ToRs) and questionnaire from the Agency's internal auditors, PwC, which the Board was asked to endorse. (Name redacted under s40(2) of the FOIA) explained that once the ToRs and questionnaire had been approved, work on the Board Effectiveness Review could begin.

6.2 Deborah Oakley, Chair of the Audit and Risk Assurance Committee, sought clarification about how the Board had changed since it became a unitary Board in September 2015 and what expectations DH had when the recommendation was made. The Board heard that the lines of accountability for the Chairman and Chief Executive remain unchanged: for the Chairman they are to the Secretary of State and for the Chief Executive they are to the Permanent Secretary; and the Board's role was to advise. As

regards succession planning, which was asked about, the Board heard that DH takes the lead in this area. The process is well-planned and timely.

6.3 The Board endorsed the ToRs and questionnaire, subject to a few suggested changes, thereby enabling work to begin on the Board Effectiveness Review.

**Item 7: draft Annual Report and Accounts, 2015-2016**

7.1 (Name redacted under s40(2) of the FOIA) gave an update on preparatory work for the draft Annual Report and Accounts 2015-16. The Board heard that the Board would have two opportunities to comment on the draft Annual Report: at its meetings on 9 May and 17 June.

**Item 8: Inviting observers from the devolved administrations**

8.1 Dr Hudson presented a short paper on subject of observers from the Devolved Administrations attending MHRA Board meetings. Dr Hudson explained that the Framework Agreement between MHRA and DH, which was published on 15 March 2016, states that the Chair may invite officials from the Devolved Administrations to attend Board meetings as observers. Dr Hudson went on to comment that, unlike some other UK-wide public bodies, MHRA's Board doesn't have designated representatives from the UK home countries among its non-executives, hence the proposal.

8.2 The Board welcomed the paper and endorsed the proposal that Sir Michael should invite officials from the Devolved Administrations to attend future Board meetings as observers. While endorsing the proposal, the Board asked that that thought be given to ensure that there was a meaningful two-way engagement with the observers. On a point of detail, Professor Campbell emphasised the need to reflect medical devices' aspect of the Agency's work when writing to the Devolved Administrations.

**Action:** The Chairman to write to the Devolved Administrations to invite officials to attend future Board meetings as observers.

**Operational agenda and governance**

**Item 9: CEO's report**

9.1 Dr Hudson asked if the Board had any questions about the CEO's monthly report about which he had spoken at the public session of the Board. The Board noted that parts of the report were not made available at the public session; they had been omitted from the public session for reasons of confidentiality.

9.2 The Board asked Dr Hudson to provide an update on the following:

- *Advances in primary care data acquisition* – An update was given on advances in primary care acquisition from all three major GP software suppliers. As part of the update, the Board heard that while bespoke software developments by EMIS and TPP are at a very early stage, there is every expectation that CPRD will be able to receive data extracts from all three major software providers by the end of 2016.

- *Early Access to Medicines Scheme (EAMS)* – An additional update was given on progress to date on EAMS. The Board noted the recently completed PWC review of the Scheme with positive comments about the MHRA.

**Item 10: Minutes of the Corporate Executive Team (CET) of 2 February 2016**

10.1 The minutes of the CET meeting of 2 February 2016 were noted.

**Item 11: Any Other Business (AOB):**

*The next public Board meeting*

11.1 The Board asked that, in future, public observers who ask questions at public Board meetings should introduce themselves and, if applicable, state who they represent.

11.2 The Board asked that when questions are asked that refer to statistical tables, the questioner should make it clear which table they are asking about.

**Date of next meeting:** 9 May 2016