

MHRA Board (part 2)

MINUTES OF THE MEETING

12 February 2016

Present:

The Board

Professor Sir Michael Rawlins	Chairman of MHRA
Mr Martin Hindle	Deputy Chairman
Dr Ian Hudson	Chief Executive
Dame Valerie Beral	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
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

Name redacted under s40(2) of the FOIA (personal data), Associate Director, Corporate Communications

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

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 Dr Barbara Bannister MBE, Non-Executive Director (NED), and Rachel Bosworth, Director of Communications

1.2 Sir Michael thanked staff for organising the morning's public Board meeting, which the Board thought was a success. While the morning's meeting would be evaluated, the Board decided in principle to open part of its discussions every second month to staff observers and members of the public.

Item 2: Declarations of interest

2.1 None was declared.

Item 3: Minutes of the last meeting, 9 December 2015, and matters arising

3.1 The draft minutes of the Board meeting of 9 December 2015 were agreed.

Matters arising

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

Item 4: Note of the Board / Corporate Executive Team Away Day, 15 January 2016

4.1 The draft note of the Board / Corporate Executive Team Away Day of 15 January 2016 was agreed.

DISCUSSION ITEMS

Item 5: NEDs' sponsor roles

5.1 Sir Michael presented a short paper that set out the areas of special interest for which individual Board members would provide advice and support to the Agency. This was endorsed by the Board.

Operational agenda and governance

Item 6: CEO's report

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

- *Zika* – An update was given on the work of the newly established cross-agency team. The Board heard that the Agency's work will focus on how it can support the development of new diagnostic kits, therapeutics vaccines and standards, as well as policy and development aspects. Professor Sir Alex Markham suggested that the Agency might find Andrew Jackson of Edinburgh helpful, as he is an expert in this field. Professor Dame Valerie Beral also shared her perspective on the current epidemic based on earlier outbreak in Micronesia.
- *Phase 1 Clinical Trial in France* – An update was given on the investigation by the French regulator, ANSM, into the serious adverse reactions that were observed during a Phase 1 Clinical Trial in France. The Agency is reviewing the data to see what lessons can be learnt, and will consult with our advisory committee structure. The update also covered the work of the cross-agency incident team that was set up after the incident to consider the implications for Phase 1 clinical trials in the UK. A paper will be brought to the Board in due course.
- *St. John's Wort* - An update was given on a Class 1 pharmacy, retail and patient recall of batches of St. John's Wort tablets.

Item 7: Minutes of the Corporate Executive Team (CET) of 8 December 2015

7.1 The minutes of the CET meeting of 8 December 2015 were noted.

Item 8: Any Other Business (AOB):

Deputy Chair of the Board

8.1 Following discussions with DH, Sir Michael proposed that the Board have a Deputy Chair who would deputise in Sir Michael's absence. Sir Michael advised that the deputy Chair would have no rights of succession, should the current Chair stand down; the Deputy Chair would act as in an interim capacity until a new chair was appointed.

8.2 It was agreed that Martin Hindle, NED, be appointed with immediate effect as Deputy Chair.

Department of Health Change Programme

8.3 Claire Armstrong reported that, to adjust to an affordable size, the Department is planning to reduce staff by around 30%. Further updates will be given at future Board meetings about where the reductions will take place. Claire Armstrong advised that the Department remains committed to retaining individual ALB sponsorship teams supported by a small central team

Board Effectiveness questionnaire

8.4 Deborah Oakley, NED, asked for an update on the Board Effectiveness questionnaire. Sir Michael advised that he had recently met with Karen Finlayson of Price Waterhouse Coopers, the Agency's internal auditors, to discuss the process of self-assessment. Further information would be available in due course.

Date of next meeting: 14 March 2016