MHRA Board

MINUTES OF THE MEETING

14 March 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
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

Ms Rachel Bosworth	Director of Communications
Mr Jonathan Mogford	Director of Policy
Ms Patience Wilson	Head of Corporate Strategy, Accountability and Partnership, Policy Division – item 4
Name redacted under s40(2) of the FOIA (personal data), Team leader, Business, Planning and Programme Management, Policy Division – item 4	
Dr Siu Ping Lam	Director of Licensing, item – item 6
Dr Martyn Ward	Group Manager, Licensing Division - item 6
Dr Sarah Branch	Deputy Director of Vigilance and Risk Management of Medicines Division, item 5

Name redacted under s40(2) of the FOIA (personal data), Senior Service Manager, Information Management Division, 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), Deputy Head of Directorate

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

Name redacted under s40(2) of the FOIA (personal data), DH Legal Services

Item 1: Introductions and Announcements

1.1 No apologies were received.

1.2 Sir Michael welcomed everyone to the meeting, includi Name redacted under s40(2) of the FOIA (personal data), who had joined Directorate as the unit's deputy head on the same day. Previously, Natalie had worked as Business and Strategy Manager in the Vigilance and Risk Management of Medicines Division.

Item 2: Declarations of interest

2.1 None was declared.

Item 3: Minutes of the last meeting, 12 February 2016, and matters arising

3.1 The draft minutes of the Board meeting of 16 October 2015 were agreed, although the Board asked that, in future, a fuller account of the Board's comments should be reflected in the minutes.

Matters arising

3.2 The Board reviewed the actions' list from previous meetings. It was noted that the paper on Board Effectiveness would be brought before the Board at its next meeting on 11 April.

DISCUSSION ITEMS

Item 4: Corporate Plan and draft Business Plan

4.1 Jonathan Mogford introduced the revised Corporate Plan Update, which the Board thought was 'in very good shape'. There was a shared a concern about the uncertainties that lie ahead, e.g. about the nature of new healthcare products and the wider funding environment. The Board thought this was especially applicable to the period following 2019/20. Accordingly, the Board endorsed the Corporate Plan Update.

4.2 The Board then considered the draft Business Plan for 2016/17. The Board's comments centred on the following areas:

- *Clinical Practice Research DataLink (CPRD)* – The Board noted that discussions are still continuing with DH about business plan targets for CPRD in 2016/17.

- Devices – The Board sought clarification as to whether there should be an item related to continuing to take forward the recommendations from the Stephenson review. In response, the Chief Executive advised that much progress has been made in relation to medical devices' work. The Devices Expert Advisory Committee (DEAC) is working well and the Agency's engagement with stakeholders, including the Royal Medical Colleges, is positive and was considerably greater than before. The Device Clinical team had been rebuilt and was performing well, nevertheless he indicated he would clarify whether all the actions were complete: if not an item could be included in the Business Plan.

- *Capital expenditure* – Peter Commins agreed that further information would be inserted into the Business Plan and a summary included in the budget paper coming to the Board on 11 April. The Board also raised the question of its role in the oversight of capital investments, and it was agreed that the existing mechanisms for supporting the Accounting Officer would be presented in the budget paper which would form the basis for further consideration by the Board of how they should be supplemented.

- *Medication errors* – The Board asked about the role the Yellow Card reporting system could play in tracking overdoses and fatalities from overdoses, and indeed the MHRA's position in relation to proactive collection of overdose information. Dr Hudson stated he would discuss further within the Agency.

4.3 Mr Mogford thanked the Chairman and the Board for their comments, which would be reflected in the final version of the Business Plan. Mr Mogford also asked that the minutes record his thanks to colleagues in Policy Division for their work on the Corporate Plan Update and Business Plan 2016/17.

Action: Finance Division to update budget paper with current governance mechanisms for capital spend.

Item 5: Public Health England's request to use Yellow Card reporting system

5.1 Dr Sarah Branch, Deputy Director of VRMM, presented on behalf of the authors, (Name redacted under s40(2) of the FOIA (personal data) and Mr Mick Foy, a progress report. The report was on work undertaken in response to a request from Public Health England (PHE) to use the Yellow Card (reporting)) Scheme as a means of collecting Adverse Drug Reaction (ADR) reports associated with the use of Novel Psychoactive Substances (NPS). The paper addressed the NPS reporting site and the respective roles and responsibilities of MHRA and PHE.

5.2 The Board heard that a one-year pilot of NPS reporting will run in collaboration between MHRA and PHE. The web-form will use Yellow Card functionality but the reporting site will be PHE-branded and will be located on a PHE website distinct from the Yellow Card Scheme website. A Memorandum of Understanding is currently being drafted by PHE's MOU team to clearly define PHE's and MHRA's responsibilities with regards to the operation of this reporting system and the safety analysis of the data. A joint PHE and MHRA Steering Group will also be established to oversee the project. A communications package will be developed by MHRA and PHE (with PHE taking the lead) to ensure this message is clear to stakeholders. All staff resource and IT technical changes will be funded by PHE.

5.3 The Chairman thanked Dr Branch for the paper and then sought the Board's views. These centred on the following areas.

- *Publicity* – The Board commented that this might be useful in raising the profile of the Yellow Card Scheme and the Agency, and enquired about the handling of Yellow Card data. Dr Branch explained that the Agency has weekly signal detection meetings, (with regular updates being given to the Commission on Human Medicines). For this project, the Agency will pass signal relevant information to PHE. The Board expressed an interest in seeing periodic data on the nature and type of data being submitted via the Yellow Card Scheme.

- *Toxicity reports* – Concern was expressed that the identity of the toxic substance might not be known after a patient has been admitted to an A&E department.

5.4 The Chairman and the Board commended the project, which they agreed the Agency should support for a one-year period, after which it should be evaluated.

Action: A paper to be prepared showing periodic data on the nature and type of data being submitted via the Yellow Card Scheme.

Item 6: Clinical trial activity

6.1 Dr Siu Ping Lam, Director of Licensing, introduced Dr Martyn Ward, who along with Dr Lam presented a report on clinical trial activity. The report covered: (i) the number of clinical trial applications for medicines that have been received by the Agency's Clinical Trials Unit (CTU), (ii) the CTU assessment performance, and (iii) the Agency's position in Europe, including initiatives to streamline approvals of multi-member state trials.

6.2 The Board heard that applications for clinical trial authorisations (CTAs) in the UK continue to increase with an 11% increase in total CTA applications in 2015 compared with the previous year. Moreover, the numbers of both commercial and non-commercial studies have increased in recent years. The Board noted that the historical decrease in Phase 1 studies had stabilised in recent years and in 2015 increased by 9% compared with 2014.

6.3 Dr Lam reported that the UK (MHRA) maintains a leading position in Europe as a preferred place to conduct clinical trials of medicines. Additionally, the Agency is taking a leading role in harmonising clinical trial assessment throughout Europe by acting as a reference competent authority for a high proportion of procedures submitted under the Voluntary Harmonisation Procedure (VHP).

6.4 The Chairman thanked Dr Lam for the report and then sought the Board's views. These centred on the following areas.

(a) Phase 3 – The Chairman asked why the UK's share of Phase 3 clinical trials was not larger. Dr Ward explained that the UK is competing in a global market; some of our competitors are able to challenge us on cost. Dame Valerie Beral asked if the fall off was due to the introduction of the Clinical Trials Directive of 2004. Dr Ward explained the trend towards a greater globalisation of clinical trials began around 2004, when the Clinical Trials Directive came into force, and certainly, the Directive was perceived as having a negative effect.

(b) Commercial trials – The Board noted that the number of commercial phase 1 clinical trials had fallen from 300 to 180. The Board asked if there was anything the Agency can do to reverse the trend. Dr Lam explained that the Agency is doing much to help those who wish to carry out clinical trials through its Clinical Trials Helpline and Innovation Office.

(c) Non-commercial clinical trials – The Board advised that fewer academics are carrying out such trials, as the costs of conducting research have increased substantially.

(d) Next steps / Innovation Office – The Board suggested that the Agency should talk to the National Institute for Health Research (NIHR) about sharing the data and seeing if there was more that the Agency could do to support research.

6.4 The Chairman thanked Dr Lam and Dr Ward for the report and suggested that the British Pharmacological Society, of which Professor David Webb is President, could be a useful tool for promoting clinical trials in the UK, working with the Agency.

Item 7: Public Board meetings – update

7.1 Mr Aidan McIvor, Secretary to the Board, provided an update on the feedback that had been received from staff observers and members of the public following the Agency's inaugural public board meeting on 12 February. The Board heard that eight members of staff and five members of the public session attended the public board. The feedback on the registration and meeting arrangements had been positive, although a number of respondents had asked for a glossary of terms to accompany the papers for future board meetings. Additionally, respondents and Board members commented on the deficiencies of the microphones. Name redacted under s40(2) of the FOIA (personal data) of Information Management Division, who joined the meeting for this item, will investigate possible solutions.

7.2 The Chairman and the Board welcomed the update and agreed that part of the Board meetings in April, September and December 2016 should be opened to the public.

STANDING ITEMS

Item 8: CEO's report

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

- *MHRA 2016 Annual lecture* – The Board heard that this year's annual lecture (on 1 March) by Dr Margaret Chan, Director-General of the World Health Organisation, was a major success.

- *St. John's Wort* – an update was given on the recall to Patient, Pharmacy and Retail of six contaminated batches of St John's Wort Pyrrolizidine alkaloids tablets.

- *Herbal Medicines* - An update was given on work taking place in response to the findings of the Report (from 2015) into the Regulation of Herbal Medicines and Practitioners by Professor David Walker.

- *Visit to Scotland* – An update was given on a visit to Scotland by Sir Michael Rawlins and Dr Hudson and Professor Webb to meet with the Chief Medical Officer (Scotland) and Chief Pharmaceutical Officer (Scotland). As well as the RCPSG

Item 9: Finance and Procurement report

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

- MHRA (Regulator) operating income: year to date was £89.5m.
- NIBSC operating income: year to date was £34.6m.
- CPRD operating income: year to date was £8.2m.
- Total operating income for the Agency was £132.3m; £5.8m above budget.
- Total operating costs were £111.7m, which are £1.7m below budget.

- The Agency's bank balance at the end of January 2016 was £218.3m.
- Capital expenditure for the year to end of January 2016 was £7.2m.
- Total Product Licensing deferred revenue at the end of January 2016 was £18.3m.
- The number of full-time equivalents (FTE) in January 2016 was 1,246, including 155 FTE on short-term contracts and 45 non-payroll employees.

9.2 Mr Commins updated the Board on a request for an extraordinary dividend payment of £100m to DH, and outlined the reasons for the payment. The Board endorsed the approach but emphasised the importance of understanding the financial implications of the agency's IT investment.

The Board was told about a possible write off of IT expenditure. The Board requested that a paper be provided to the annual accounts seminar.

9.3 Mr Commins then updated the Board about a possible accommodation move for the Agency in 2017/18.

Item 10: Audit and Risk Assurance Committee meeting of 14 March 2016 - update

10.1 Deborah Oakley, Chair of the Audit and Risk Assurance Committee (ARAC), provided an update on the ARAC meeting that was held earlier in the day. This covered ARAC's consideration of internal audit reports, payroll, external audit, information security update, external and internal fraud, whistle blower policy, and the Corporate Risk Register (CRR) including the consolidation of risks.

10.2 Deborah Oakley reported that the committee recommended that the Board should receive a written report following each of the quarterly ARAC meetings. In addition, the Board agreed to the committee's recommendation that the Board should have sight of the CRR after each ARAC meeting.

Action: Finance and Procurement to provide the Board with a copy of the CRR on a quarterly basis.

Item 11: Minutes of the Corporate Executive Team (CET) of 5 January 2016

11.1 The minutes of the CET meetings of 5 January 2016 were noted.

Item 12: Any Other Business (AOB):

12.1 No of AOB items were tabled

Date of next Board meeting: 11 April 2015