Medicines and Healthcare Products Regulatory Agency

MINUTES OF THE MEETING

17 March 2017

Present:

The Board

Professor Sir Michael Rawlins	Chairman of MHRA
Dr Ian Hudson	Chief Executive
Mr Jon Fundrey	Chief Operating Officer and Director of Finance
Dr Barbara Bannister MBE	Non-Executive Director
Mr Matthew Campbell-Hill	Non-Executive Director
Professor Bruce Campbell	Non-Executive Director
Mr Martin Hindle	Non-Executive Director
Mr Stephen Lightfoot	Non-Executive Director
Ms Deborah Oakley	Non-Executive Director
Professor Sir Alex Markham	Non-Executive Director

Others in attendance

MHRA executive and supporting officials

Mr Jonathan Mogford	Director of Policy
Ms Rachel Bosworth	Director of Communications
Mr John Quinn	Director of Information Management Division
Mr Andy Gregory	Assistant Director, EU, International and Strategy – items 1-4
Ms Patience Wilson	Assistant Director, Corporate Strategy, Accountability and Partnership – items 1-5
Mr Richard Humphreys	Deputy Finance Director – items 6 and 11
Redacted: Section 40: Personal data	Head of Strategic Communications and Marketing – item 8
Mr Aidan McIvor	Head of Directorate and Secretary to the Board
Redacted: Section 40: Personal data	Head of Science Strategy
Redacted: Section 40: 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
Mr Paul Wright	DH Legal Services

Item 1: Introductions and Announcements

1.1 Apologies were received from Professor Dame Valerie Beral, Non-Executive Director; Professor David Webb, Non-Executive Director; and Mrs Janet Davies, Acting Deputy Director of Healthcare Quality Division, representing the Welsh Assembly Government

1.2 The Chairman welcomed everyone to the meeting and made the following announcements:

(i) The Chairman asked that the minutes record the Board's gratitude to Ms Libby Green, who will return to the Foreign and Commonwealth Office in April 2017. Ms Green's successor at the Department of Health will be announced in due course.

(ii) The first Board lecture of 2017 will be given at the National Institute for Biological Standards and Control (NIBSC) by Dr Barbara Bannister on 22 May. Other Board lectures will take place later in the year as part of the Agency's Continuing Professional Development lecture programme.

(iii) The Chairman, together with a group from the UK and Venezuela, will meet with Pope Francis I at the Vatican in May 2017 to discuss the treatment of Huntington's disease, which is prevalent in South America.

Item 2: Declarations of interest

2.1 None was declared.

Item 3: Minutes of the Board meeting of 17 February 2017, and matters arising

3.1 Subject to a minor change suggested by Mr Paul Wright, Senior Legal Advisor, which the Board agreed, the minutes were adopted.

Matters arising

3.2 The Board reviewed the actions list from previous meetings.

DISCUSSION ITEMS

Item 4: Brexit - update

4.1 Jonathan Mogford presented an update on recent Brexit-related work. This included: {(i) redacted: Section 35: Government policy in development}; (ii) scenario and contingency planning, including for "deal" and "no deal" with the EU; (iii) the Agency's Brexit task force; preparations for the messaging for internal and external stakeholders when Article 50 is triggered. Mr Mogford also gave an update on formal and informal discussions at the recent Heads of Medicines Agencies meeting in Malta and at the European Medicines Agencies (EMA) Management Board in London.

4.2 {redacted: Section 35: Government policy in development}

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

- *The European Medicines Agency (EMA*) – The Board asked about the future of the EMA, which is currently located in Canary Wharf, London. Dr Hudson advised that the decision about the EMA's future location would be taken by EU governments. The Board asked if the Agency should have a view on the preferred next location for the EMA. The Board was advised that many locations are likely to be considered, it was not clear whether the UK will be able provide input.

- *International relations* – The Board asked what international relationships were being considered as part of the scenario planning. Dr Hudson advised that the

Agency is considering a range of post-Brexit relationships, e.g. with other major international regulators, with the British Commonwealth of Nations, {redacted: Section 35: Government policy in development}, and with major non-state actors, such as the Gates Foundation.

- *Industry's perspective* – In answer to questions from the Board, Dr Hudson updated the Board on regulatory discussions he and Jonathan Mogford had recently attended as guests of the Board of the Association of the British Pharmaceutical Industry (ABPI).

4.4 The Chairman thanked Mr Mogford for his report. A further update will come to the Board on 24 April.

Item 5: Business Plan 2017/18

5.1 Patience Wilson presented the draft Business Plan for 2017/18 to the Board for review and approval, advising that the draft had been reviewed by the Corporate Executive Team (CET) at its meeting on 3 March. Ms Wilson asked the Board to consider, in particular, (i) the top 10 priorities; (ii) the key achievements in 2016/17, (iii) and the revised structure of the Business Plan and changes to some of the performance targets and metrics. The final agreed Business Plan will be sent to DH for formal sign off, after which it would be published.

5.2 The Chairman thanked Ms Wilson for her presentation and sought the Board's views. Although the Board thought the draft Business Plan read well and covered the key priorities for the organisation, they had additional comments, which they asked to be taken into account before the final version of the Business Plan was sent to DH.

- *Executive summary* - It was suggested that the Business Plan could benefit from having an Executive Summary.

- It was suggested that there could be more reference to pressures on the NHS in the body of the text.

- *Operational Transformation* - The Board advised that the Business Plan should make an explicit link to delivering increased business efficiency, savings, and benefits (that flow from the Agency's work) and that the costs of the operational transformation programme should be more visible in the Business Plan.

- *Cyber security* – It was suggested that the plan should highlight the importance of cyber security, possibly in the top 10 priorities.

- *Devices funding* – The Board commented that there had been no progress on introducing devices fees and questioned whether this should continue to be a priority; Mr Mogford advised that securing sustainable funding for devices fees regulatory work was among the Agency's priorities and was a regular feature of discussions with DH.

5.3 Ms Wilson thanked the Board for their comments, and Dr Hudson confirmed that all these would be considered before the final version of the Business Plan was sent to DH for sign off.

5.4 The Chairman concluded by thanking Ms Wilson for presenting the draft Business Plan, which the Board formally adopted, subject to their comments being taken into account in the final version.

Item 6: Agency Budget

6.1 Jon Fundrey and Richard Humphreys presented the Agency's budget for 2017/18, which the Corporate Executive Team had reviewed and approved on 3 March. As part of his introductory remarks, Mr Humphreys outlined the budgetary position of the Agency's three centres: the Regulator, NIBSC and CPRD. This was followed by an overview of the several components of the budget, which included (i) devices fees, (ii) medicines fees, and future assumptions, (iii) operational transformation programme, and (iv) the accommodation relocation project.

6.2 Concerning NIBSC and CPRD, Mr Humphreys reported that NIBSC continues to be in a financially sustainable position, while CPRD's budget for 2017/18 has been set in line with the revised financial model and includes assumptions made on volumes and price.

6.3 The paper proposed a deficit budget in 2017/18 as a result of expenditure on Operational Transformation. The Board heard that, depending on decisions around investment in the Operational Transformation programme, the regulatory Centre will be close to breakeven in each financial year for the next five-year financial objective period (2018/2023). Mr Humphreys concluded by saying that the budget for 2017/18 did not include any assumptions about the implications of Brexit.

6.4 The Chairman thanked Mr Humphreys for his presentation and sought the Board's views, which centred on the following areas:

- *Opening comments* – The Board emphasised the importance of realising efficiency savings in order to make the investment affordable over the long term.

- *Headcount* - The Board sought clarification on the head count figures for permanent and fixed term staff, which Mr Humphreys gave.

- *Accommodation costs* - Mr Humphreys addressed questions about the costs of the accommodation relocation project, after which the Chairman advised that a visit to the new building by the Board would take place on 20 November 2017.

- *Software expenditure* – In answer to a question from the Board, Mr Humphreys explained the accounting treatment of the procurement of new software, which will provide the Agency with a new cloud-based service. Mr Humphreys advised that the auditors are currently considering this approach. Mr Humphreys went on to assure the Board about the governance arrangements for any significant IT-related expenditure, for which all business cases are subject to robust review and challenge by the Agency's Information Management Governance Board.

- *Emerging threats* – In answer to a question from the Board about emerging threats, Mr Humphreys shared with the Board a perspective on possible threats to the Agency's income for the financial year 2019/2020 and beyond.

6.5 The Chairman concluded by thanking Mr Fundrey and Mr Humphreys for the Budget paper, which the Board formally noted.

Item 7: Operational Transformation

7.1 John Quinn presented a progress report on the Operational Transformation Programme, the first since the Board/CET away day on 27 January. Mr Quinn reported that the focus has been on two areas: (i) reviews, audits and planning, and (ii) portfolio delivery. This work has included a mini review of e-business delivery by the National Audit Office and audits by Price Waterhouse Coopers (PwC) on cyber security and on the implementation of the IT strategy – follow up. Mr Quinn also reported on the work being carried out by PA Consulting, who are providing external challenge and support to the Agency.

7.2 As part of his report, Mr Quinn gave a detailed update on the cyber security audit. The Board heard that while cyber security and information assurance will continue to represent risks to Agency operations, good progress has been achieved in recent months. In particular, the Agency now has an IT Security Officer in post, who will lead on taking forward work on the auditor's recommendations. Mr Quinn concluded his report by updating the Board on progress on phase 1 of the Digital Platforms project, the first phase of the Information Processing Unit reform project, IT-related aspects of the accommodation project, and the Portfolio Plan.

7.3 The Chairman thanked Mr Quinn for his report and sought the Board's views. These centred on the following areas:

- *Opening comments* - The Board commended Mr Quinn on the progress he and his team have achieved to date, e.g. thanks to the introduction of new technology, the Agency no longer expends time, effort and money on sending out over 60,000 items of written communication.

- *Cyber security* – Deborah Oakley, Chair of the Risk and Audit Committee, said that, having read the PwC's report on cyber security, she was very impressed with the progress that has been achieved between 2014 and 2017.

- *External challenge* – the Board asked if PA Consulting would provide challenge around benefits. Mr Quinn confirmed that they would – around technical benefits.

Item 8: Falsified Medicines and Medical Devices Campaign

8.1 {Redacted: Section 40: personal data} presented a progress report on the falsified medicines and medical devices (FMMD) campaign and plans for the next year. {Redacted: Section 40: Personal data} explained that the Agency's campaign aims to reduce the harm caused to public health by changing consumer behaviour when purchasing medical products online. The campaign, which was launched in August 2016, is a long-term campaign aimed at changing the behaviour of specific target audiences. {Redacted: Section 40: personal data} then went on to outline the campaign approach and activity to date; the impact of the campaign; the spending controls associated with such campaigns, which need to be approved by DH; and next steps - the campaign plans for 2017/18.

8.2 The Chairman thanked {Redacted: Section 40: personal data} for the report and then sought the Board's views. The Board congratulated {Redacted: Section 40: personal data} and her colleagues on the success of the FMMD campaign, so far. Ms Bosworth said she would pass on the Board's positive feedback to the staff concerned. Ms Bosworth advised that the project was a truly cross-agency endeavour, with staff also from Devices Division and Inspection, Enforcement and Standards Division

playing a key role in the work. Many Board members thought that the campaign was an excellent way to also raise the profile of the Agency, especially in the NHS. The Board also advised that the Agency should build on the learning points from the first year of the campaign.

8.3 The Chairman concluded by thanking {Redacted: Section 40: personal data}for her report and all those involved with the project.

Item 9: Board / Executive interaction – next steps

9.1 Dr Hudson gave an update on work to take forward a range of suggestions at the Board / CET away day on 27 January about enhancing Board / executive interaction. Dr Hudson reported that Aidan McIvor, Head of Directorate, would take the lead on coordinating this work, liaising closely with Martin Hindle, Deputy Chairman. Mr Hindle said he had spoken with Mr McIvor before the Board meeting about this work and was in full agreement with Dr Hudson's approach.

Action: Directorate (Aidan McIvor) to coordinate and take forward work on Board / Executive interaction and to report back to the Board in October 2017.

STANDING ITEMS

Item 10: CEO's report

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

- *Concordat on Openness on Animal Research* – An update was given on a Concordat on Openness on Animal Research, which the Agency has been given approval to sign by the Minister. The agreement will be signed most likely in June 2017.

- Redacted: Section 5: Commercial confidentiality

- *International relations* – An update was given on the Mutual Recognition Agreement on inspections of medicines manufacturers that was signed in March between U.S. Food and Drug Administration and the European Union.

- *Valproate* – An update was given on developments on Valproate, including meetings with stakeholders.

- *UK Stem Cell Bank* - An update was given on the release of the UK Stem Cell Bank's first stem cell lines suitable for development into novel cell-based medicines.

- Medical Devices and In-Vitro Diagnostic (IVD) regulations – an update was given on the implementation of the new regulations in May 2017, after which there will be a three-to-five year transition period.

- *E-cigarettes* – An update was given on the number of notifications (over 30,000) that have been received under the Notification Scheme.

- *TGN1412 documentary* – An update was given on the television documentary about the first-in-human clinical trial (TGN1412) of March 2006 that was broadcast on BBC2 in February 2017.

- *NIBSC recruitment* - an update was given on succession planning at a senior level at NIBSC.

10.2 The Chairman thanked Dr Hudson for the update and sought the Board's views. These centred on the following areas:

- *Vigilance work* – In answer to a question about the Agency's vigilance work, Dr Hudson advised that a paper on Vigilance projects would come to the Board at its meeting on 24 April.

Item 11: Finance and Procurement report

11.1 Richard Humphreys presented the Finance and Procurement report for the first ten months of the financial year. After allowing for payment of dividends and financing, the Agency has a retained surplus of £5.2m which is £4.0m above budget. The Agency is forecast to deliver a retained surplus in 2016/17 of £9.8m which is £3.3m above budget; the forecast expenditure on Information Communications Technology is being continually reviewed.

11.2 Mr Humphreys went on to report that, in line with the internal audit report for recognising Tobacco Products Directive (TPD) income, 70% of the value of fees received for E-cigarette notifications has been deferred to when the review and publication work has been completed. This is expected to be done in 2017/18, with the balance (currently circa £0.5m) recognised in 2016/17. It was noted that the internal audit review on Electronic Cigarettes was still in draft form at the time of the Audit and Risk Assurance Committee (ARAC) meeting on 17 March, at which was informed about the accounting methodology. Mr Humphreys added that the income recognition is subject agreement with the National Audit Office.

11.3 The Chairman thanked Mr Humphreys for his report and invited questions from the Board; these centred on the following areas:

- *Corporate costs* – In answer to question from the Board, Mr Humphreys explained the Agency's approach to recognising corporate costs across the three centres: the Regulator, NIBSC and CPRD.

- *Operational Transformation expenditure* - The Board asked if IT expenditure to date (£25m) was over or under budget. Mr Humphreys explained that the expenditure on IT was part of a five-year programme of investment, rather than in-year expenditure. Mr Quinn added that the programme of expenditure is broadly on track. Moreover, all business cases are subject to robust review and challenge by the Information Management Governance Board.

Item 12: Audit and Risk Assurance Committee – oral update

12.1 Deborah Oakley, Chair of the ARAC, gave an oral update of the meeting of the ARAC, which took place earlier in the morning. A written report on the ARAC meeting would come to the next Board meeting on 24 April.

Item 13: Minutes of the Corporate Executive Team (CET) of 13 January 2017

Item 04 **MHRA 26/2017**

13.1 The minutes of the CET meetings of 13 January 2017 were noted.

Item 14: Any Other Business (AOB): None was tabled.

Date of next Board meeting: 24 April 2017