MHRA Board (in public session) Part 1

MINUTES OF THE MEETING

11 April 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
Mr Matthew Campbell-Hill	Non-Executive Director
Professor Bruce Campbell	Non-Executive Director
Mr Peter Commins	Chief Operating Officer and Finance Director
Mr Martin Hindle	Non-Executive 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

Ms Rachel Bosworth	Director of Communications
Mr Jonathan Mogford	Director of Policy
Dr Siu Ping Lam	Director of Licensing – item 5
Dr Julian Bonnerjea	Head of Biologicals Unit – item 5
Mr John Wilkinson OBE	Director of Devices - item 6
Mr Mick Foy	Group Manager, Vigilance and Risk Management of Medicines – item 6
Ms Vanessa Birchall-Scott	Director of Human Resources – item 7
Mr John Quinn	Director of Information Management Division – item 8
Name redacted under s40(2) of the FOIA (personal data)	Head of Science Strategy
Mr Aidan McIvor	Board Secretary and Head of Directorate
Name redacted under s40(2) of the FOIA (personal data)	Executive Assistant to the Chairman

Legal Services

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 and Sir Alex Markham, Non-Executive Directors, as well as Mrs Claire Armstrong, Deputy Director (Medicines, Pharmacy and Industry Division) DH.

1.2 Sir Michael welcomed everyone to the meeting, in particular, the staff and public observers.

Item 2: Declarations of interest

2.1 None was declared.

Item 3: Minutes of the public Board meeting of 12 February

1.1 The minutes of the last public Board meeting were agreed.

DISCUSSION ITEMS

Item 4: CEO's report

4.1 Dr Hudson presented the CEO's report for March 2016. These centred on the following areas:

- *Sodium Valproate* – An update was given on the work surrounding Sodium Valproate, in particular, the launch of a Valproate toolkit and the establishment of the Valproate Stakeholder Network (VSN), both in early 2016. The Board heard that a major stakeholder meeting will take place on 15 April.

- *Adrenaline auto-injectors (AAIs)* – An update was given on work the Agency has undertaken on the safety of AAI devices since a review was published in 2014.

- *Early Access to Medicines Scheme (EAMS)* - An update was given on the number of scientific opinions (seven) that have been awarded. These have included treatment of lung cancer, melanoma and heart failure.

- *Launch of PRIME* – An update was given on the launch of the European Medicines Agency's Priority Medicines (PRIME) scheme on 7 March 2016. Agency officials will join the PRIME Oversight Group, which will have its first meeting in April.

- MHRA/Association of the British Pharmaceutical Industry (ABPI) conference: "Making the case for Medicines Manufacturing" – an update was given on the Agency's first jointly branded conference with the ABPI.

4.2 The Chair then invited questions from the Board.

- *E-cigarettes – An* update was sought on e-cigarettes. The Board heard that the Tobacco Products Directive will be transposed into UK law from 20 May 2016. The update also covered the planned fee arrangement and communications plans.

- *Zika virus* – An update was sought on Zika. The Board heard that, although there has been very limited media attention in recent weeks on Zika, the Agency has been busy with a range of work. An incident group has been set up, which is now liaising with key stakeholders, such as the World Health Organisation. The Board also heard that the Agency is working to remove from sale an unregistered homeopathic medicine that claims to be a treatment for Zika.

- *Assessment performance* – In answer to a question about assessment times, the Board heard that the timetable is driven by European procedures.

Additionally, the Agency is working with industry and the trade associations to reduce timelines on their side. The total time to approval includes both clock stop time, where the Agency is waiting for the company to respond, and the Agency assessment time. Considerable progress has been made on the latter over recent years.

4.3. The Board then invited questions from the staff and public observers.

- *E-cigarettes* – One member of the public asked for clarification about the legal status of vapour devices, which Dr Hudson gave.

4.4 The Chairman concluded by thanking Dr Hudson for his report.

Item 5: Review of the MHRA Innovation Office

5.1 Dr Lam, Director of Licensing, introduced Dr Bonnerjea who presented the report. The Board heard that the Innovation Office was established as one aspect of the MHRA's response to the Government's Life Sciences' agenda. The Board heard that the Innovation Office is a free service that has been operating successfully for the last three years. It has answered over 270 regulatory queries and held over 40 meetings, mainly with academics and Small and Medium Enterprises (SMEs).

5.2 Dr Bonnerjea went on to outline the future direction of the innovation Office, including becoming more proactive in approach, working more closely with outside organisations such as Tech Transfer Offices, which would require some additional resource.

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

- *Working with NICE* – The Board was surprised that the report did not mention NICE, especially in regard to medical devices. The Board also noted that the rate of uptake of the MHRA/NICE joint scientific advice service was low. The Board heard that much of the work that comes to the Innovation Office is at a very early stage, often before a product has been developed and before any data relevant to reimbursement have been generated. The Board also heard that the joint NICE/MHRA scientific advice service has been launched some years ago, with limited success (there have now been four joint meetings) and further collaboration in the area of devices is being discussed.

- *Streamlining advice / Frequently Asked Questions (FAQs)* – The Board asked if the new IT Strategy could offer opportunities to streamline the way advice is provided, e.g. FAQs. Dr Bonnerjea explained that under current rules about what can be published on GOV.UK, it is not possible to provide FAQs in the traditional format. However, Communications Division and Licensing Division are considering a range of options about the provision of information in more user-friendly way.

- *Response times* – Martin Hindle asked how requests and response times are tracked. Dr Bonnerjea explained that Licensing Division maintains a spreadsheet that monitors response times and has a target response time of 20 working days. Dr Bonnerjea added that occasionally a face-to-face meeting is needed with a client, which the Agency will provide. Mr Hindle commended Dr Bonnerjea on the work of the Innovation Office and offered to facilitate a meeting with the

Academic Health Science Network in Leicester, of which he is the chair. Dr Bonnerjea gratefully accepted the offer.

- *Customer journey* – The Board commented on the need to give due care to the customer journey and customer interface.

5.4 The Board then invited questions from the staff and public observers.

- *Success stories* – One member of the public asked if there are any success stories, which could be shared? Dr Bonnerjea replied that eight case studies have been published and more are planned to be published soon.

5.5 The Chairman concluded by thanking Dr Bonnerjea for his report and agreed in principle to the recommendation that a full-time equivalent be recruited, which would be subject to a business case being approved.

Item 6: Joint Patient Safety and Vigilance Strategy - update

6.1 John Wilkinson and Mick Foy presented an update on the Joint Patient Safety and Vigilance Strategy; earlier progress reports had come to the Board in September 2015 and February 2016. The Board heard that a cross-agency group has been underway since October 2015 to carry out a strategic review of common activities that the Agency uses to support activities. Mr Foy went on to report that work on the objective data capture for incident reporting and signal detection is more advanced. The Board were asked to endorse this as a priority area to gain from the synergies. As part of his report, Mr Foy also asked the Board to agree the eight deliverables proposed by the three Project Teams.

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

- *Nomenclature and Unique Device Indicators (UDIs)* – In answer to a question about nomenclature, Mr Wilkinson advised that a systematic approach to this work is taking place.

- *Post-market surveillance for devices* – The Board welcomed work in this area, but cautioned that since devices are continually being altered and upgraded the Agency will need a system that is nimble and granular to reflect such changes. John Wilkinson advised that the Agency already has mechanisms in place to pick up such changes, e.g. via the National Joint Registry.

- *National Reporting and Learning System* (NRLS) – In answer to a comment about the NRLS, Mr Foy advised that confirmation on the funding to cover the costs of its replacement system is awaited.

- *Key Performance Indicators (KPIs)* – The Board asked if KPIs will be in place to measure effectiveness of this work? Mr Wilkinson advised that the Agency is working with NHS England on this. Moreover, the Agency has signed up to the NHS Sign Up to Safety Campaign.

6.3 As part of his report, Mr Foy also asked the Board to note the four key deliverables proposed by Project Team 1. They were: (i) an app for reporting of incidents associated with counterfeits, defective medicines and devices; (ii) to develop a common standard for electronic reporting for device incidents; (iii) a proposal for a new workstream or category

for aggregated devices incident data; and (iv) implementation of a formalised signal detection methodology for single incident device reports with a signal management/case management system and consideration of whether the tools and resources can be shared.

6.4 The Chairman then invited questions from the staff and public observers.

- *Sodium Valproate* – A member of the public asked about Yellow Card Scheme and Sodium Valproate, which, at the Chairman's recommendation, Mr Foy said he would discuss with the questioner after the meeting.

6.5 The Chairman concluded the discussion by again welcoming the progress report and endorsing the direction of the travel set out in the update and the recommendations contained therein.

Item 7: People Survey

7.1 Vanessa Birchall-Scott presented a report to the Board on the high level results from the People Survey and plans for related action. The Board heard that members of staff were invited to participate in the annual Civil Service People Survey in October 2015. The response rate to the survey was 71%, which was 6% higher than in the previous year. The Agency's overall engagement index score was 63%, which was 4% higher than the previous year and higher than the Civil Service average. Ms Birchall-Scott outlined the nine themes covered by the survey, e.g. my manager or my team. This was followed by an update on the Corporate Executive Team's consideration of the People Survey results and the divisional and pan-agency action plans, as well as the work of the People Survey Focus Group.

7.2 The Chairman thanked Ms Birchall-Scott for the update and sought the Board's views. These centred on the following areas:

- *Opening remarks* – The Board welcomed the report and congratulated Ms Birchall-Scott on the Agency's high response rate and engagement scores. The Board advised that many organisations do not achieve such a high response rate.

- *Contrasts between the Agency's three centres* – Ms Birchall-Scott explained that across the three centres (MHRA Regulator, NIBSC and CPRD), there were differences and for example CPRD's scores reflected the fact that there had recently been a significant amount of organisational change. It was noted that in addition to a significant amount of leadership development related activities HR continues to support managers with managing change programmes.

- *Bullying and harassment* – The Board expressed concern that responses in this area had marginally increased from last year. Ms Birchall-Scott explained that this can be a difficult area to fathom, as it is often subject to the perception of individuals about behaviour. Divisions are examining the findings within their own teams.

- *Participation levels* - While welcoming the high response rate (71%), some Board members noted that the Agency should continue to encourage more staff to participate in the next annual survey.

7.3 The Chairman then invited questions from the staff and public observers.

- *Length of the survey questionnaire* – Ms. Birchall-Scott was asked whether extra questions could be added to the questionnaire, or if a shorter version of the survey questionnaire could be used. Ms Birchall-Scott explained that the Agency had to use the Civil Service-wide survey questionnaire.

7.4 The Chairman concluded the discussion by thanking Ms Birchall-Scott for the progress report and by noting the achievement of such a high response rate from staff.

Item 8: Digital, Information Management, Technology – quarterly update

8.1 John Quinn presented a quarterly update to the Board on progress on delivery of technology, information management, and the digital business plans. The Board heard that the infrastructure transition was the largest focus of work from the previous year, with the transition from a single supplier to multiple suppliers. A CET planning day was held which considered the long term future of the Agency's three themes of supply chain, surveillance, and innovation; and then considered what this meant for the Agency's future IT systems. John Quinn went on to report that Information Management Division (IMD) will produce a Digital Strategy paper for the May 2016 CET.

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

- *Opening remarks* – The Board congratulated Mr Quinn and his colleagues in IMD for delivering the transition from a single supplier to multiple suppliers seamlessly, without interruption to operational business and, in doing so, saving the Agency 20% in infrastructure costs. The Board was very impressed with the success of the infrastructure change.

- *Costs and business cases* – The Board asked if the planned IT investment programme was affordable and if it had been laid out in sufficient detail. Mr Quinn explained that the detail of each business case would be subject to rigorous scrutiny and challenge by the Information Management Governance Board, which adjudicated on all major business cases. Moreover, a process will be put in place to monitor and track each programme, which will allow the Agency to see where the savings will be made.

- *Investment decisions / risk management* – Mr Quinn advised that the question of whether to invest in a particular area contains risks, for if one does not invest, e.g. in upgrading Documentum, the money saved could be used elsewhere; but the risk is one that has to be carefully considered and managed. This is something the CET has discussed recently. Mr Quinn advised that he will present a paper to the CET in May, about which he will update the Board at the Annual Accounts Seminar on 9 May.

- *Technological change* – The Board asked about how technological advances can help with patient reporting, evaluation reports, adverse incidents reports. The Board heard that technological innovations, such as the Yellow Card App, illustrate what can be achieved in this area.

8.3 The Chairman then invited questions from the staff and public observers; none were received. The Chairman concluded the discussion by thanking Mr Quinn for his report.

Operational agenda

Item 9: Budget

9.1 Peter Commins presented the Agency's recommended Budgets for 2016/17, which represented planned growth in each centre. The Budget paper also included the following sections: (i) an update to the strategic financial position outlined in the report the CET and Board in January 2016 and set the position for the 2017/18 Regulator fees' round; (ii) the budgetary position for the Regulator, the National Institute for Biological Standards and Control, and the Clinical Practice Research Datalink (CPRD); (iii) DH funding; and (iv) the budget for the whole Agency, along with a sensitivity analysis.

9.2 The Board heard that 2016/17 is the fourth year in the current five year financial objective period that ends in March 2018 and the paper reflected the start of preparations of budgets for the period beyond 2018 given the intention to undertake substantial investment. In considering the budgets the CET had agreed the priority of preparing for the next financial duty period from 2018 and to use the current financial strength of the agency as the opportunity to prepare those plans. By 2018, the Agency will have exceeded its minimum required rate of return and any additional financial commitments during 2016/17 and 2017/18 could be absorbed by the significant surpluses already accumulated since 2013. Mr Commins went on to report that over the remainder of the current five year financial objective period the regulatory centre will be close to breakeven, which is line with the recommendation of the Triennial Review. NIBSC continues to be in a financially sustainable position, while the CPRD budget for 2016/17 has been set in line with revised financial model. Finally, the Board heard that the sensitivity analysis suggests that the income and costs budgets will be favourably exceeded for each centre during 2016/17 providing further security alongside the flexibilities of the trading fund regime which permits annual deficits to be incurred provided they are exceeded by surpluses within each period.

9.3 Mr Commins concluded his opening remarks by reminding the Board that the Agency will most likely have to relocate during 2017/18 which, should that arise, would lead to unplanned expenditure, and that the implementation of the Devices fees' regime has yet to receive approval from HM Treasury.

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

- IT investment – The Board asked for a breakdown of the latest estimated costs of the IT investment programme and that this be broken down between one off investment costs and on-going running costs in order to be assured that it was affordable. Mr Commins explained that the paper reflected the latest estimate of the profile of the spend across the next five years and that he would provide the requested breakdown of that current estimate at the Annual Accounts Seminar on 9th May. The CET will be considering the IT investment programme at its May meeting and any changes will be reflected in a June board paper. Regarding the use of historic reserves Mr Commins explained that the investment programme's costs until 2018 would be funded from income earned between 2013 and 2018, with costs beyond that point needing to be funded from income generated in the next five year period. The Board heard that the business cases for particular investment decisions would contain details of the planned costs and benefits

arising from each investment which would then be tracked as part of the overall programme.

- Decentralised Procedure (DCP) income – Clarification was sought of the assumptions around DCP income, namely that it will remain at around £16m per annum through 2016/17 and 2017/18. Mr Commins explained that it reflected the latest assessment of licensing and finance colleagues but added that from 2018/19 and beyond the picture was more uncertain. This would be one of the key assumptions tested in the process of preparing for the 2018 budgets.

- Academic institutions and CPRD – The Chairman asked if the Agency can help academic institutions use CPRD. Mr Commins replied that ensuring the affordability of CPRD to academia was an opportunity that the Agency was looking at and would consider as part of increasing its non-commercial customer base.

- Overspend of IT budget - The Board queried the £4m reported overspend on IT. Mr Commins explained that the variance reflected cumulative additional spend over and above the baseline 2014/15 budgets which had been issued pending the development of the IT change programme.

9.5 The Chairman then invited questions from the staff and public observers.

- Possible relocation to Canary Wharf - A member of the public asked why the Agency could not move out of Greater London to a less expensive location. Mr Commins explained that the Agency could relocate to a cheaper but more distant location, however, any financial savings that could be gained had to be weighed against the risks and costs associated with such a move. These included the need to retain highly skilled staff, many of whom live in London and its environs. Mr Commins went on to explain that many of the Agency's staff are required to attend scientific and other meetings on a regular basis at the European Medicines Agency in Canary Wharf, which would be difficult to maintain if the Agency was to relocate to a more distant location. Additionally, many companies and other key stakeholders value the ease of access to the Agency because of its current location.

6.4 The Chairman concluded the discussion by thanking Mr Commins his report and by recording the Board's endorsement of the draft Budget paper.

Action: Finance and Procurement Division to provide a breakdown of the costs of the IT investment programme as part of the Annual Accounts Seminar on 9 May.

Item 10: Finance and Procurement report

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

- MHRA (Regulator) income: year to date was £97.5m.
- NIBSC operational income: year to date was £38.0m.
- CPRD operational income: year to date was £8.9m
- Operating income for the Agency was £144.4m, which is £4.4m above budget.
- Total operating costs were £127.5m, which are £3.3m below budget.
- The Agency's bank balance at the end of February 2016 was £212.5m.

- Capital expenditure for the year to end of February 2016 was £7.3m.
- Total Product Licensing deferred revenue at the end of February 2016 was £18.9m.
- The number of full-time equivalents in February 2016 was 1,262, including 163 short-term contracts and 56 non-payroll employees.

10.2 The Chairman thanked Mr Commins for the update and sought the Board's views.

10.3 Expenditure - The Board queried the overspend on page 3 of the report which referred to other operating costs being £7.2m (14%) above budget mainly due to an increased unfavourable variance of £4m on the Regulator's IT expenditure and whether this was expected.

10.4 The Board heard that IT expenditure was £4m above budgets that reflected historic spend on IT given the formative nature of the plans, the only adjustments to those budgets being as elements of individual projects within the IT portfolio have been approved through the Information Management Governance Board. The Board heard that the overspend would be offset by 'favourable positive variances in all other non-pay expenditure categories.

10.5 The Chairman concluded the discussion by thanking Mr Commins his report.

Item 11: Audit and Risk Assurance Committee – report from 14 March meeting

11.1 Deborah Oakley, Chair of the Audit and Risk Assurance Committee (ARAC), asked that Board to note the report from the ARAC meeting of 14 March, about which she had given an oral update at the Board meeting of the same day (14 March). Ms Oakley highlighted that the committee had indentified a gap in overall responsibility for the prevention of fraud and a lack of visibility in training in fraud awareness. She also drew the board's attention to the committee's recommendation that the NED Whistle-blowing champion be named as the final point of escalation internally. This had been agreed subject to a check on the policy in place at other ALBs.

11.2 The Board noted the report and there were no questions from other non-executive directors or from the staff and public observers about the report.

Item 12: Any Other Business (AOB):

12.1 Sir Michael and the Board thanked members of the public and staff for attending the meeting.

Date of next public meeting: 12 September 2016