MHRA Board

MINUTES OF THE MEETING

20 November 2015

Present:

The Board

Professor Sir Michael Rawlins	Chairman of MHRA
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 Martin Hindle	Non-Executive 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
Dr Stephen Inglis	Director of National Institute for Biological Standards and Control (NIBSC)
Mr John Quinn	Director of Information Management Division
Dr Janet Valentine	Director of Clinical Practice Research DataLink item 4
[Redacted Section 40 personal data]	Senior Policy Officer, Policy Division – item 9
[Redacted Section 40 personal data]	Investigation Team Leader, Inspection, Standards and Enforcement Division – item 6
[Redacted Section 40 personal data]	Strategic Communications and Marketing Manager, Communications Division – item 6
[Redacted Section 40 personal data]	Campaigns lead, Communications Division – item 6
[Redacted Section 40 personal data]	Head of Science Strategy
Mr Aidan McIvor	Head of Directorate
[Redacted Section 40 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	DH Legal Services

Item 1: Introductions and Announcements

1.1 No apologies were received.

1.2 Sir Michael welcomed everyone to the meeting.

Item 2: Declarations of interest

2.1 None was declared.

Item 3: Minutes of the last meeting, 16 October 2015, and matters arising

3.1 The draft minutes of the Board meeting of 16 October 2015 were agreed.

Matters arising

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

DISCUSSION ITEMS

Item 4: Clinical Practice Research DataLink Strategy

4.1 Dr Janet Valentine presented the draft CPRD Strategic Plan 2016-2021 for agreement. The strategy set out the CPRD strategic objectives for the next five-year period, as well as the strategic activities proposed within each year. The Board heard about plans to implement the current and planned improvements, including on population coverage, data linkage, growing the intervention studies service, enhancing information governance and data security, working with the regulator, and developing partnerships. Dr Valentine also reported on the development of key performance indicators, the CPRD staff restructuring exercise, and the financial model for the next five years.

4.2 Sir Michael and the Board thanked Dr Valentine for the Strategy, which they all thought was excellent and bode well for the future, especially in terms of the Board's confidence in the strategic leadership and direction of CPRD. Many on the Board commended Dr Valentine on the remarkable, positive difference she has made to CPRD in less than a year of having taken up post

4.3 While commending the quality of the strategic analysis, Professor Campbell asked that the strategy should give appropriate attention to medical devices. Dr Valentine said she would take this comment into account. Deborah Oakley asked for a more detailed breakdown of the CPRD finances, in particular, the profile of spend on capital investment (IT), running costs and the detail around projected sources of income and timing. Peter Commins agreed to provide this information to the next meeting. The board also inquired how potential conflicts of interest would be handled and how often these were expected to arise given the projected growth in clinical trials. In conclusion, the Chairman said that the Board endorsed the CPRD Strategy.

Action: Peter Commins (Finance) to give an update on CPRD's finances at the board meeting on 9 December.

Item 5: Moving towards greater transparency around animal work

5.1 Dr Stephen Inglis, Director of NIBSC, presented a paper that proposed the Agency should move towards greater transparency about its laboratory work the animals. Dr Inglis gave an overview of the role of animals in laboratory research for public health and how that work has evolved greatly over the past decade. The Board heard that NIBSC is fully signed up to the 'Three Rs' agenda: Reduce, Replace and Refine, and has made a very large global contribution to this, for example in the area of polio vaccine analysis, although for some life-saving medicines effective testing is still only possible through the use of animals. In addition, NIBSC is held as an exemplar of best practice by the Home Office team that monitors compliance with the extensive legal measures around use of animals to support scientific research.

5.2 [Redacted Section 35 Government policy]

5.3 Dr Stephen Inglis set out the potential benefits and possible risks associated with a move towards more openness. The paper contained three options, which Dr Inglis, asked the Board to consider, one of which, option 2, recommended that the Agency opt to increase its level of transparency proactively. It was noted that the Chief Medical Officer was in favour of this strategy.

5.4 [Redacted Section 35 Government policy]
Action: NIBSC to roll out option 2 and further explore option 3.

Item 6: Major communications campaign – the risks surrounding falsified medicines and medical devices

6.1 Rachel Bosworth, Director of Communications Division, presented an update on the development of a major public-facing communications campaign on the risks surrounding fake and illegal (FAIL) medicines and medical devices. The planned campaign will be long term – over a 2-3 year period – and will aim to build on and complement the excellent work to date to raise awareness of these dangers.

6.2 The Board heard that the nature of the long-term campaign and the specific activities and areas of focus will be informed by the extensive research which is already well underway. Rachel Bosworth reported that the research has identified the types of products that are most susceptible to fake or illegal manufacture and purchase by the public, and the demographic profile of the types of people that are most likely to purchase products online (the single largest source of fake and illegal products). Potential partnerships are being identified to enhance the impact of the campaign, working across government, with industry and other stakeholder organisations. The extensive research will ensure that the resources appointed to the project can be targeted for maximum impact.

6.3 Sir Michael and the Board welcomed the report. The Board advised that the Agency should make use of the print and broadcast media, as well as social media to help promote the campaign's messages. Rachel Bosworth explained the Agency would work with television programme makers to 'seed' story lines around the dangers posed by buying counterfeit healthcare products, as well as with national newspapers about the damage caused to people by, for example, counterfeit lifestyle products.

6.4 In regard to costs, Rachel Bosworth explained the process required by Cabinet Office to obtain approval for expenditure for £100,000 and above. The board noted that the lifetime cost of the campaign will exceed £100,000 (it is likely to be £600,000-£900,000).

6.5 Ms Bosworth thanked Sir Michael and the Board members for their comments and asked that if Board members had any additional comments they could send them on.

Item 7: Digital, Information Management, Technology – quarterly update

7.1 Mr John Quinn presented the quarterly update to the Board on progress on the delivery of the Agency's IT Strategy and summarised the status of the strategy's seven interlocking priorities: (i) Information Management Division's operating model; (ii) infrastructure, (iii) e-business, (iv) tactical business systems, (v) service operations, (vi) information, and (vii) digital business services.

7.1 The Board heard that the agency needed to keep pace with developments in the digital domain; for simply updating or replacing current applications with 'like for like' would be

very costly. Mr Quinn went on to advise that only by conducting a root and branch review of the processes that underpin the digital services will the Agency accrue the significant cash and non-cash benefits available and so minimise overall net costs. The Board heard that the move away from a single infrastructure provider (Accenture) had provided an ideal springboard to consider how the organisation can make full use of digital approaches to transform how we operate, particularly in terms of meeting the needs and expectations of customers.

7.2 Sir Michael thanked Mr Quinn for the quarterly update and asked if the Agency was taking the necessary measures to 'future-proof' that the new IT system and structure 'does not fall over'. Mr Quinn assured the Chairman and the Board that the IT Strategy is well-balanced and has been informed by the lessons from earlier major IT infrastructure projects. The board emphasised that the investment in IT was an opportunity to transform the way the agency works and therefore engagement from across the entire organisation was crucial. The board wished to be re-assured that the program was affordable. Ms Oakley drew attention to the Finance paper which highlighted the need for the IT investment to produce long term savings. Mr Quinn and Mr Commins also addressed questions from the Board about costs; although a fuller consideration, including benefits' assessment would come to the Board in March 2016.

Action: Quarterly update, including a benefits' assessment, to return to the Board in March 2016.

Item 9: Business Plan – monitoring report for Quarter 2

9.1 {Redacted: Section 40: personal data} of Policy Division presented the Quarter 2 monitoring report for the Business Plan for 2015/16. The report covered performance against targets, an update on the progress of strategic activities, a list of metrics for each of the last 4 quarters and a cumulative total for the 2015/2016 business year, and information on further performance related work. The Board heard that the Agency is on track to meet all of its published targets, with the exception of the following three: PM2(b)(c); PM7(b); and PM8(b).

9.2 The Board heard that for PM2(b)(c), (% DCP RMS in 70 days and Type IB % in 30 days), this was attributed to resource constraints; the recruitment of additional assessors is in progress. For PM7(b) (increasing population cover of primary care data to 20%), the Board heard the Agency anticipates reaching a population coverage of 8.7% by the end of Q2, with a further increase by the end of Q3, when data will begin flowing from the TPP GP software provider. The agency will, however, not achieve the target (20%) within the CPRD system by the end of the financial year. For PM8(b) (FOI requests), the Board heard that Policy Division has introduced a new process resulting in 99.7% of FOIs being replied to within target.

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:

- *HPV vaccine* – [Redacted Section 35 Government policy]

- *Ebola* – An update was given on the two types of Ebola reference reagents which have been produced by NIBSC and which have been endorsed by the WHO Expert Committee on Biological Standardisation at its meeting in October 2015.

- *India* - An update was given on the Chairman's official visit to India in October, during which a Memorandum of Understanding was signed with the Central Drugs Standard Control Organisation of India.

- *NICE and HRT* – [Redacted Section 35 Government policy]

- *Product-related issues*: – [Redacted Section 35 Government policy]

- *Product recalls*: an update was given on a number of product recalls which were carried out by the Defective Medicines Reporting Centre.

- *PRIME* - An update was given on a publication consultation on the Priority Medicines (PRIME) scheme which was launched by the European Medicines Agency on 23 October, and which will run until 23 December.

- *JAP audit* - An update was given on a Good Manufacturing Practice (GMP) audit which the Agency underwent in October. The audit was carried out under the Joint Audit Programme (JAP) for EU GMP inspectorates.

- *Heads of Medicines Agencies (HMA) meeting, Dubrovnik* – An update was given on the HMA meeting in Croatia in October.

- *The Accelerated Access Review (AAR)* – An update was given on the AAR interim report, which was published on 27 October; the final report is expected to be published in April 2016.

- *Ministerial Industry Steering Group (MISG)* - An update was given on the MISG New Technologies Forum on umbrella and basket protocols, which took place on 27 October.

- *GcMAF* - An update was given on an investigation, which is ongoing.

- *Ghana* - an update was given on training which a member of the staff from the Agency's Enforcement Unit delivered in Accra, Ghana from 7-8 October. The training was about the EU Falsified Medicines Directive.

- Litigation – Updates were given on two judicial review appeals.

Item 11: Finance and Procurement report

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

- MHRA (Regulator) income: year to date was £52.8m.
- NIBSC operational income: year to date was £20.9m.
- CPRD income: year to date was £5.3m.
- Operating income for the Agency was £79.1m, which is £3.9m above budget.
- Total operating costs were £66.5m, which are £0.5m below budget.
- The Agency's bank balance at the end of September 2015 was £222.1m.
- Capital expenditure for the year to end of September 2015 was £3.5m.

- Total Product Licensing deferred revenue at the end of September 2015 was £17.7m.
- The number of full-time equivalents in September 2015 was 1,204, with 140 short-term contracts and 33 non-payroll employees.

Item 12: Minutes of the Audit and Risk Assurance Committee of 22 June 2015

12.1 The minutes of the Audit and Risk Assurance Committee meeting of 22 June 2015 were noted.

Item 13: Minutes of the Corporate Executive Team (CET) of 15 September and 13 October 2015

13.1 The minutes of the CET meetings of 15 September and 13 October 2015 were noted.

Item 14: Non-Executive Directors' (NEDs) updates

14.1 The following updates were given:

- Dr Barbara Bannister reported that she had attended a two-day conference in London on clinical Pharmacokinetic/Pharmacodynamic (PKPD) studies and their potential value in streamlining medicines assessment.

- Mr Matthew Campbell-Hill will give a presentation at a conference on UK Cyber Health.

Item 15: Any Other Business (AOB):

15.1 No of AOB items were tabled

Date of next Board meeting: 9 December 2015