Medicines and Healthcare products Regulatory Agency Board

MINUTES OF THE MEETING

17 February 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
Professor Dame Valerie Beral	Non-Executive Director – by telephone
Mr Matthew Campbell-Hill	Non-Executive Director
Professor Bruce Campbell	Non-Executive Director
Mr Stephen Lightfoot	Non-Executive Director
Professor Sir Alex Markham	Non-Executive Director
Professor David Webb	Non-Executive Director

Others in attendance

MHRA executive and supporting officials

Mr Jonathan Mogford	Director of Policy
Mr Stephen Hallworth	Deputising for the Director of Communications
Mr Richard Humphreys	Deputy Finance Director – item 11
Redacted – Section 40 of Freedom of Information Act (FOIA) – personal data	Human Resources – item 7
Redacted – Section 40 of FOIA - personal data	Head of Imaging, Acute and Community Care, Devices Division - item 8
Redacted – Section 40 of FOIA - personal data	Policy Division – item 12
Mr Aidan McIvor	Head of Directorate
Redacted – Section 40 of FOIA - 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 Martin Hindle, Deputy Chairman; Deborah Oakley, Non-Executive Director; Rachel Bosworth, Director of Communications; 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) This year's MHRA Annual Lecture will be given by Dr Jeremy Farrar OBE, Director of Research at the Wellcome Trust, at the Francis Crick Institute on Tuesday, 23 May 2107.

(ii) Sir Andrew Witty had accepted the Chairman's invitation to attend a dinner with the Board on 24 July for an informal discussion. It was noted that Sir Andrew will have retired as Chief Executive Officer of GlaxoSmithKline by 24 July.

The Board welcomed the news and agreed to the Chairman's suggestion that the date of the next Board/CET away day be moved from 24 July to 25 July, subject to the venue, the Royal Society, being available on 25 July. The Chairman said he would personally bear the cost of Sir Andrew's dinner on the 24 July.

(iii) Items 9 and 13 of the agenda would be deferred to the next meeting.

Action: Directorate to make the necessary arrangements for the Board dinner on 24 July and requested the change of date of the away day, that is, subject to the venue's availability.

Item 2: Declarations of interest

2.1 None was declared.

Item 3: Minutes of the Board meetings (part one and part two) of 12 December 2016, and matters arising

3.1 The minutes of the Board meetings of 12 December (part 1 and part 2) were agreed.

Matters arising

3.2 The Board reviewed the actions list from previous meetings.

Item 4: Note of the Board/Corporate Executive Team (CET) away day, 27 January 2017

4.1 The minutes of the Board/CET away day of 27 January were agreed.

DISCUSSION ITEMS

Item 5: Brexit - update

5.1 Jonathan Mogford presented an update on recent Brexit-related work. This included: (redacted: Section 35: Government policy in development); (ii) engagement with industry, in particular, the series of 'Deep Dive' meetings with industry associations and company representatives; (iii) legal work, (redacted: Section 35: Government policy in development); (iv) engagement with staff and stakeholders; and (v) work with the media.

5.2 As regards staff and stakeholder engagement, the Board heard that the Agency held two stakeholder forums in December 2016 with eighteen health professional representative groups and, separately, with twenty patient representative groups and research charities. The Agency has also arranged Brexit briefing meetings with a wide range of other stakeholders, such as the Royal Medical Colleges, the Wellcome

Trust, NHS Confederation, and the pharmaceutical and medical technology sectors. Moreover, an internal network of members of staff from EU member states has been set up as a source of support and advice.

5.3 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 one which the MHRA would not be party to; that decision would be taken by EU governments in the future. Meanwhile, EMA officials are carrying out some scoping work on what a relocated EMA would need, e.g. suitable buildings, access to skilled staff, and transport needs (domestic and international). The EMA is likely to be concerned about retaining its staff, many of whom have settled in London.

- National Institute for Biological Standards and Control (NIBSC) – In answer to question about other emerging concerns, Dr Hudson advised that there is concern that NIBSC could lose some of its batch release work to other Official Medicines Control Laboratories in Europe. To address this concern, NIBSC officials are working closely with key customers.

5.4 The Chairman thanked Mr Mogford for his report. A further update will come to Board on 17 March.

Item 6: Clinical Practice Research DataLink (CPRD) – strategic progress report

6.1 Dr Janet Valentine presented a progress report on the CPRD Strategic Plan, 2016-2021, just over a year on since the Strategy was signed off by the Board. The report covered the following:

(i) The major organisation transformation / restructuring of CPRD;
(ii) Business efficiencies and improvement;
(iii) Population coverage;
(iv) Information governance;
(v) Data linkage and added value tools;
(vi) Interventional services;
(vii) Partnerships;
(vii) Priorities for year two;
(viii) Impact of Brexit;
(ix) Financial model update; and
(x) Risk and emerging issues.

6.2 Dr Valentine reported that one year on, the CPRD Plan has been characterised by a fundamental organisational transformation aimed at securing CPRD's services within a dynamic health data landscape. Highlights have included a major staff restructure bringing in the necessary capacity and skills to deliver both observational and interventional research services; achieving daily data extracts from GPs using *EMIS* software which opens up the possibility of recruiting GP and their patients from a pool of 55% of UK GP practices; and developing version 1 of the single clinical trials platform to support real world pragmatic trials, which is a world first and unique selling point for the UK. Now that the ground work has been laid in year one of the Plan, CPRD can look forward to building on these secure foundations in year 2; continuing to shape the essential developments that are required to provide a globally leading research data service.

6.3 The Chairman thanked Dr Valentine for the report and sought the Board's views. These centred on the following areas:

- *Opening remarks:* The Chairman and the Board thanked Dr Valentine for the report, which they thought was excellent, and praised Dr Valentine for the pivotal role she has played in transforming CPRD

- *CPRD's current location* – The Board noted that during Dr Valentine's presentation, reference was made to approaches from NHS Digital about CPRD being part of MHRA. The Board thought there were no grounds for CPRD to be detached from MHRA; moreover, the Board endorsed strongly the view that CPRD and MHRA were a perfect fit, which should not be disturbed.

- *Observational data* – In answer to questions about CPRD's observational research capability, Dr Valentine advised that this is progressing well, with new staff being recruited to take forward this work.

- *Clinical trials process* – Dr Valentine explained that CPRD's involvement in trials was largely as a recruitment broker, supporting patient recruitment in a primary care setting, based on screening of anonymised patient records. Patients identified could then go on to take part in clinical studies in primary or secondary care or studies in academic settings, however CPRD had no further involvement. CPRD also provided innovative integrated services for patient recruitment, data capture and trial management of post-marketing pragmatic trials in primary care, such as for the current clinical trial DECIDE.

- GPs' recruitment – The Board asked if GPs have sufficient incentives to contribute data to CPRD. Dr Valentine explained that there are a number of incentives in place, including payment to participate in clinical trials and a joint project with the Royal College of General Practitioners (RCCPs) providing feedback to practices on prescribing at an individual patient level. The Board expressed recognition of the exciting possibilities this feedback offered and consequent alignment with MHRA's vigilance activities.

- *Priorities for year two* – The Board noted that, although CPRD still has hundreds of TPP practices waiting to join CPRD, this was not currently possible. Dr Valentine aid that she and her team would work with the Department of Health, the RCGPs and the NHS to enable CPRD to have access to such data in year 2.

6.4 The Chairman concluded by thanking Dr Valentine again for her report.

Item 7: Health and Wellbeing

7.1 (Name redacted: Section 40 of FOIA – personal data) presented a progress report on the Agency's health and wellbeing programme. (Name redacted: Section 40 of FOIA – personal data) set the context for the report by explaining its background: the launch of the Agency's health and wellbeing proposal /action plan in January 2016, and the wider support for this initiative across the Civil Service. (Name redacted: Section 40 of FOIA – personal data) explained that research conducted by the Chartered Institute of Personnel and Development has highlighted that employees with good mental health and wellbeing generally have less sickness absence, greater levels of engagement and performance. Overall, the wellbeing programme and activities have been well received by members of staff who are taking an active part in all events.

7.2 (Name redacted: Section 40 of FOIA – personal data) reported that the top reasons for staff sickness in the Agency were: musculoskeletal, stress, and minor illnesses / infections. This has been informed by a review of absence rates, together with work on the Agency's revised HR policies. As part of this work, there has been a renewed effort from Human Resources to help managers with their approach to managing short and long term absences.

7.3 (Name redacted: Section 40 of FOIA – personal data) went on to report that there has been a decrease in the average number of sick days per employee, although the wellbeing index has remained unchanged. A health and wellbeing day was recently held at the Agency's offices in Victoria and NIBSC, along with other initiatives, such as the Alexander technique, neck and back massages, and a range of work to raise awareness of mental health at work. (Name redacted: Section 40 of FOIA – personal data) cited the programme mental health first aiders, as well as the 'Time to Talk' day, which was held on 2 February. (Name redacted: Section 40 of FOIA – personal data) concluded by outlined a range of work planned for 2017.

7.4 The Chairman thanked (Name redacted: Section 40 of FOIA – personal data) for his report and sought the Board's views. These centred on the following areas:

- Opening remarks – The Chairman and members of Board welcomed the report, commending (Name redacted: Section 40 of FOIA – personal data) and his colleagues on their work, and asked that they continue the "good work".

- *Sickness absence rates* – The Board commended the HR team for reducing overall sick rates of absence, but asked that in the next progress report greater detail be provided. Specifically, the Board asked for more detail by centre / division, and if possible by grade, as it was not clear from the report which group of civil servants were affected most, e.g. junior staff, middle managers, or members of the Senior Civil Service.

Item 8: Redacted: Section 5: commercial confidentiality

Item 9: Board / Executive interaction – next steps (deferred to 17 March 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:

- *MHRA and Human Tissue Authority (HTA)* – An update was given on the partnership agreement signed on 8 December 2016 between the MHRA and the HTA.

- *Unannounced audit* – An update was given on unannounced audit on NIBSC by UL (the notified body for NIBSC), the Notified Body for NIBSC CE marked in-vitro diagnostics.

- *Valproate and risks in pregnancy* - The Board was informed of a meeting that will take place on 22 February 2017 between the Parliamentary Under-Secretary for Health, Lord O'Shaughnessy, and Lord Norman Lamb MP, chair of the All-Party

Parliamentary Group (APPG) on antiepiletics in pregnancy. The meeting follows concerns raised by the APPG.

- *Cannabidiol* – An update was given on a meeting that was held with Epilepsy Action and the Multiple Sclerosis Society and, separately, with the mental health charity, MIND, about Cannabidiol to understand the extent of their concern / patient exposure.

- *Breast implant associated anaplastic large Cell Lymphoma (ALCL)* – An update was given on a statement that was issued in December 2016 by the Australian regulator, the Therapeutic Goods Association, on the breast implant associated anaplastic large cell lymphoma. Further information was sought by a Board member on the natural incidence. Dr Hudson promised to follow up in writing.

- *Falsified medicines and devices campaigns* – An update was given on a week of action targeting DMAA (dimethylamylamine) in medicines sold as sports supplements. The event was launched on 30 January 2017.

- *Visits to Royal Colleges* – An update was given on recent meetings between MHRA's Chairman and Chief Executive and the Royal College of Obstetrics and Gynaecology, Royal College of Surgeons, the Royal College of Midwives, the College of Optometrists, as well as with the Royal Pharmaceutical Society.

- *India* – An update was given on the visit by an MHRA delegation, which included Dr Hudson, to India in early January, 2017. During the visit, discussions were held with senior officials from the Indian Central Drugs Standard Control Organisation, and the Indian Pharmacopoeia Commission.

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

- *Relocation* – In answer to a question about when the Agency would leave Victoria, Mr Jon Fundrey gave a brief update on the relocation project, during which he confirmed that the Agency would relocate to Canary Wharf around mid-2018.

- *Medical devices - Occlutech LAA Occluder* – Following a request for an update, Dr Hudson said he would speak to relevant officials in Devices Division and follow-up in writing with the Board member concerned.

Action: Dr Hudson to follow-up on the requests for information on ALCL and *Occlutech LAA Occluder.*

Item 11: Finance and Procurement report

11.1 Richard Humphreys presented the Finance and Procurement report for the first nine months of the financial year. After allowing for dividends and financing, the Agency has a retained surplus of £7.2m which is £7.8m above budget. The Agency is forecast to deliver a retained surplus in 2016/17 of £9.7m which is £3.2m above budget; the forecast expenditure on Information Communications Technology is being continually reviewed. The report also included a comparison of financial performance between the first three quarters of 2016/17 and 2015/16 (Annex 1). By the end of Q3 2016/17 the Agency's retained surplus at £7.2m is £6.2m (46%) lower than at the end of Q3 2016/17.

11.2 The Chairman invited questions from the Board; these centred on the following areas:

- *Tobacco Products Directive (TPD) income* – In answer to questions about the TPD income, Mr Humphreys explained that £2.8m of TPD income has been invoiced to the end of third quarter of the financial year. That income will be deferred the next financial year, subject to the agreement with the National Audit Office.

- *Relocation costs* - In answer to questions about the relocation costs, Mr Humphreys advised that these are not currently available.

11.3: The Chairman thanked Mr Humphreys for his report.

Item 12: Quarter 3 report – progress against the Business Plan, 2016-17

12.1 Jonathan Mogford presented a progress report for the third quarter (October – December 2016) of the current Business Plan. The report provided an update on the Agency's Quarter 3 position against the targets, activities, metrics and further performance related work.

12.2 The Board heard that the Agency is on track for the majority of targets for Quarter 3. However, three were at 'significant risk of delay', while four other targets were at 'risk of delay'. The report explained reasons for the delays, e.g. for PM2(b) - Medicines licensing - assessment of applications, specifically - % of Decentralised Procedure Reference Member State in 70 days, the low volume of applications received means the overall year target will not be met. The Board also noted that five targets will have been completed early.

12.3 The Chairman and Board thanked Mr Mogford for his report and noted the work so far on achieving the current Business Plan's objectives.

Item 13: Audit and Risk Assurance Committee meeting of 20 January 2017 – oral report

13.1 This item was deferred until the next Board meeting (17 March 2017).

Item 14: Minutes of the Corporate Executive Team (CET) of 6 December 2016

14.1 The minutes of the CET meetings of 6 December 2016 were noted.

Item 15: Any Other Business (AOB):

- *Board meeting dates for 2018:* These are being prepared, about which Directorate staff would be in touch.

- *Board members' end of year appraisals* – The Chairman advised that Directorate staff would contact Board members to arrange the end of year appraisals, which could, if required, be carried out by telephone.

- *Legal lecture* – Paul Wright, Senior Legal Advisor, would give a talk entitled "The Judge over my shoulder" at 151 BPR on Monday, 20 February. As many of the Board could not attend the lecture, they asked that the set of slides that would accompany Mr Wright's talk be circulated.

- *Gates Foundation funding* – The Board asked if the Agency could apply for funding from the Gates Foundation to support a database for regulatory requirements for low and middle income countries. Dr Hudson said that this is something that the Agency would need to consider.

Action: Directorate to circulate copies of Mr Wright's presentation to the Board.

Date of next Board meeting: 17 March 2017