MHRA Agency Board

MINUTES OF THE MEETING

17 September 2014

Present:

The Agency Board

Sir Gordon Duff	Chairman of MHRA
Dame Valerie Beral	Non-Executive Director
Professor Barry Furr	Non-Executive Director
Mr Martin Hindle	Non-Executive Director
Professor Vincent Lawton	Non-Executive Director
Ms Deborah Oakley	Non-Executive Director
Professor David Webb	Non-Executive Director
Mr John Williams	Non-Executive Director

Others in attendance

MHRA executive and supporting officials

Dr Ian Hudson	Chief Executive – by telephone (items 1-8)
Mr Peter Commins	Chief Operating Officer and Finance Director
Mr Jonathan Mogford	Director of Policy
Ms Rachel Bosworth	Director of Communications
Name redacted: Section 40 of FOI Act (personal data)	Acting Head of Government and Corporate, Policy Division (items 7 and 9)
Name redacted: Section 40	interim Director of Human Resources (item 8)
Name redacted: Section 40	Policy Manager, Policy Division (item 9)
Name redacted: Section 40	Policy Officer, Policy Division (item 9)
Name redacted: Section 40	Head of Science Strategy
Mr Aidan McIvor	Secretary to the Agency Board
Name redacted: Section 40	Executive Assistant to the Chairman

Department of Health

Name redacted: Section 40	DH sponsor representative

Item 1: Apologies

1.1 Apologies were received from Professor Sir Alex Markham, Non-Executive Director; Mr Mark Wilson, Legal Advisor; (name redacted: Section 40); Mr Mark Jenkins-Rees, Legal Advisor; Mr Simon Reeve, DH sponsor representative.

Item 2: Announcements

2.1 After welcoming everyone, the Chairman made the following announcements.

- *Board lecture programme:* The Chairman thanked Professor Dame Valerie Beral for giving the Board lecture earlier in the day. Dame Valerie's lecture was on "History of medical research using linked NHS data".

- *Board meeting dates in October, November and December* – The Chairman reported that the Board would meet again on 7 November and 10 December (for the Agency Board / Corporate Executive Team away day). As the Board could not meet in person in October, a provisional telephone conference had been arranged on 15 October to attend to any urgent business. If, however, the Chairman and Chief Executive judged that there was no need to hold such a telephone conference, a cancellation notice would be issued on 14 October.

- *Board meeting dates for 2015* – The Chairman invited the Board to note the meeting dates for 2015. In response to requests from Board members that the Agency adopt a more flexible approach to meeting dates, Dr Hudson said he would ask Directorate to explore a range of options, including holding Board meetings on Fridays. At present, the Board normally convenes on a Wednesday.

Item 3: Conflicts of interest

3.1 The Chairman asked for any interests to be declared at the beginning of the meeting; none was declared.

Item 4: Minutes of the Agency Board meeting of 16 July 2014

4.1 A number of minor amendments were made after which the draft minutes of the Board meeting of 16 July 2014 were adopted.

Matters arising

4.2 The Board the reviewed the actions list from previous meetings; the following updates were given:

- *Action 1: Launch a Board lecture programme* – Chairman said that the Board lecture programme, which began in June 2014, had proved highly successful.

- *Action 2: E-working and Board meetings*, The Board heard that the electronic portal through which meeting papers could be accessed would be ready by the end of the year. The delay in the roll-out was due to changes in IT contracts. A further update would be given at the Board meeting on 7 November 2014.

- *Action 3: NIBSC /British Pharmacopoeia Strategy* – The Board heard that a paper on this subject would come to the Board on 7 November.

- *Action 4: The Board to receive periodic updates on the IT Strategy* – The Board asked for an update at its meeting on 7 November.

- *Action 5: The Board to receive an update on honours nominations* – Dr Hudson advised that the Agency trawls for nominations from divisional directors and staff twice a year. Moreover, a notice was placed recently on the Agency's intranet site, insite, inviting staff to submit honours nominations.

DISCUSSION PAPERS

Item 5: Innovation and Life Sciences

5.1 Jonathan Mogford, Director of Policy, gave a progress report on the Agency's work to take forward the Government's innovation, life sciences and growth agendas. The update covered the following areas:

- *The Early Access to Medicines Scheme (EAMS),* which was launched in April 2014 - The Board heard that the Agency has recently issued the first Promising Innovative Medicine (PIM) designation for an advanced therapy in the oncology setting. The Agency is working with other organisations in the healthcare system, notably NICE and NHS England, to ensure operational efficiency of the scheme.

- *Advanced licensing pilot* - Since the launch of the pilot scheme in March 2014, around thirty expressions of interest have been shown by companies with products in development. The pilot will remain open until further notice.

- *Advanced Therapy Medicinal Products (ATMPs)* - The Agency is leading discussions with other UK regulators about expanding the Innovation Office to include a One-stop-Shop advice service for regenerative medicines /advanced therapies. The Board heard that there are indications that the European ATMP Regulation may be reviewed in 2015. Discussions are taking place within the Agency to identify any opportunities to drive forward such a review.

- *Dementia, Anti-Microbial Resistance (AMR)* – The Agency is contributing to the work of the joint DH/Cabinet Office Dementia Innovation Unit's regulatory work stream. This includes the part-time secondment of a member of staff from Policy Division. The Agency is also working with DH on the delivery of the AMR Strategy.

- *Stratified Medicines* – The Agency is participating in a number of initiatives at national, European and global levels to develop work in this area.

- *Clinical Trials* – The Agency is now working to implement the new EU Clinical Trials Regulation that will deliver a streamlined and simplified process for authorisation of clinical trials.

- *Medical Devices* – Negotiations continue on the revision of the EU medical devices legislative framework and, as part of that process, the Agency continues to press for a system that safeguards patients and supports innovation.

5.2 Mr Mogford went on to report that the Agency's contribution to the Life Sciences Strategy and the Government's growth agenda was outlined to the Agency's new minister, Mr George Freeman MP, Parliamentary Secretary (Life Sciences) on 16 September. The Agency's delegation to the introductory meeting with the Minister was led by the Chairman and Chief Executive. The Board heard that the Minister, whose new appointment straddles the Department of Health and the Department of Business, Innovation and Skills, had warmly welcomed the work the Agency has done on early access to medicines and adaptive licensing. The Agency's public health role was explained at the meeting.

5.3 The Chairman thanked Mr Mogford for the paper and went on to share his own impressions of the meeting with the new Minister, which were very positive. The

Chairman said that UK's life sciences were a test bed for innovation and a link between innovation and the NHS. The Agency was well placed to play a key role in this area. This was a view also shared by the Board, who also commended Policy Division for its work in this area.

5.4 A number of Board members suggested that the paper's authors should have been present to hear the discussion; Mr Mogford explained that, normally such officials would be invited to attend the Board discussion, but on this occasion, however, the two key contributors were away. One was attending an external training course, while the other was working at the Cabinet Office, where he was on secondment two days a week. In answer to another Board member's question, the meeting heard that the Agency is working closely with NHS England and NICE. In particular, the Agency has a partnership agreement with NICE, and holds regular meetings with officials from NICE.

5.5 John Williams, Non-Executive Director (NED), said that the paper was timely and pertinent, and advised that he would chair a meeting in Prague in the following week on regulation and nanotechnology. Deborah Oakley, NED, observed that she didn't see Clinical Practice Research DataLink (CPRD) mentioned in the paper, which she went on to say has an important vigilance role and therein a link to innovation.

5.6 Mr Mogford thanked the members of the Board for their comments.

Item 6: Communications and Reputation Strategy

6.1 Ms Rachel Bosworth, Director of Communications Division, presented the final draft Communications and Reputation Strategy 2014-18. The Board heard that the strategy was underpinned by a stakeholder perceptions' audit that was carried out in late 2013. The strategy set out: (i) the reputation that the Agency is seeking to achieve; (ii) the Agency's core messages and strategic narrative; (iii) the Agency's main audiences; (iv) six key areas of focus; and (v) mechanisms for evaluation and measuring progress. The Board heard that the six key areas for focus over the next four years were: (i) promoting and marketing the agency and its products/services; (ii) improved customer experience; (iii) improved relationships and networks; (iv) profile with patients and the public; (v) employee communications and engagement; and (vi) thought leadership.

6.2 Ms Bosworth added that the aim of the strategy was to maintain and build the Agency's reputation as one of the global leaders in the regulation of medicines and medical devices; to be a key player in the UK health and social care system; and to make a major contribution to the UK life sciences and economic growth through our support for innovation.

6.3 The Chairman thanked Ms Bosworth for her presentation and invited the Board's comments, which centred on the following areas:

- *Public perception* –the Agency does not have as high a public profile as, for example, NICE. When trying to describe what the Agency does, one sometimes has to liken it to the U.S. Food and Drug Administration (FDA), "it's the UK's FDA".

- *Research* – Scientific research should be mentioned under "where do we want to be?" The Agency is a research-active and scientifically-active organisation. In particular, CPRD is a most important research tool. It should be noted that clinical academics also carry out clinical trials.

- *Resources* – The Board appreciates that the Agency's involvement in the pan-government GOV.UK project has made significant demands on Communication Division's resources in terms of other digital communications and social media development. It follows that it is very important to prioritise activities and manage the interdependence of the Strategy's various work streams.

- *Over-reach* – There was concern that the Agency might be trying to do too much and that it should prioritise what needed to be done.

- *Communications* – The Agency needs to be a listening organisation; that its interactions should be two-way: "talk to us"; we will talk to you" – it needs to be truly interactive. This should be added into the section setting out the reputation the Agency is seeking to achieve. Moreover, the Agency needs to create opportunities for people to communicate two ways via social media.

- *Executive summary* – The Board recommended that the Strategy should be distilled down to a short document that staff could use.

6.4 Ms Bosworth thanked the members of the Board for their helpful feedback, which would be incorporated into the final strategy before publication.

Item 7: DH Triennial Review

7.1 Mr Jonathan Mogford, Director of Policy, gave an oral update on the Triennial Review. The Board heard that Triennial Reviews enable the Department of Health to review all its Arms-Length Bodies (ALBs) on a rolling three-year cycle. The reviews consider function and form, as well as performance, capability, efficiency and governance. Jonathan Mogford went on to advise that Ministers and senior officials see reviews as an important part of DH's stewardship role. This particular review will cover the Agency (as an executive agency), as well as and the Commission on Human Medicines and the British Pharmacopoeia Commission.

7.2 The Board heard that the review will likely focus on the following: (i) the Agency's place within the ALB network, and EU and international systems; (ii) leadership, governance and strategic direction; (iii) value for money and efficient delivery; and (iv) the Agency's understanding of, and ability to respond to challenges. The review is likely to begin in October 2014 and should conclude by the end of February 2015.

7.3 The Chairman and Board thanked Mr Mogford for the update, adding that the Agency should be proactive in its approach to the review. It was widely felt that the review offered a rare opportunity for the Agency to demonstrate its vital contribution to public health, research, life sciences and the growth agenda. A further update would be given at the next Board meeting.

Item 8: Overview on remuneration policies

8.1(Name redacted: Section 40), interim Director of Human Resources Division, gave an overview on staffing and remuneration structures within the Agency. The Board heard that staff appointments are made within a pay range; that staff are contracted to work 37 hours per week; and that staff are entitled to 25 days' holiday leave per year, rising to 30 days after five years. (Name redacted: Section 40) went on to explain that there are three distinct pay groups within the Agency: senior civil servants, civil servants (Administrative Officer grade to Grade 6), and staff at the National Institute for Biological Standards and Control (NIBSC), a majority of whom are on Agenda for Change (NHS)

pay scales. (name redacted: Section 40) also explained the controls which Cabinet Office exercise in relation to the Agency, e.g. pay levels, pension provision, the Civil Service Code, and policies on recruitment and redundancy.

8.2 The Chairman and Board thanked (name redacted: Section 40) for her report.

Item 9: Monitoring Report for the Agency's 2014-15, Business Plan activities, targets for Quarter 1

9.1 (Name redacted: Section 40) of Policy Division gave a quarterly monitoring report on the Business Plan for the first quarter of the new financial year. The meeting heard that the agency is on track to meet 21 of 22 targets and has delivered on six of the ten activities due for completion this quarter. A further three activities due for completion in Quarter 2 have also been completed this quarter. The Board heard that one target has been given a red rating (PM6a on biological standards supply). This was because only 61% of all materials were supplied within six working days against the stated target of 93%. The reason for the below target performance was because of a surge in demand for the influenza standards occurring at the same time as significant staff illness. The Board heard that the backlog has been recovered but it will be impossible to meet this target at year end. A proposal is under consideration to increase resilience in future by recruiting a temporary member of staff in January to assist with the annual surge in demand for influenza standards.

9.2 In answer to a number of questions about major IT projects and IT-related work, Mr Mogford said that IT-related work would be reflected in a refresh of the Business Plan.

STANDING ITEMS

Item 10: CEO's report for July and August 2014

10.1 Dr Hudson presented the highlights from the CEO's monthly reports for July and August. These centred on the following areas:

- *Early Access to Medicines Scheme (EAMS)* – An update was given on the two Promising Innovative Medicines (PIM) applications which have made and granted.

- *Ebola* – An update was given on the Agency's work with the World Health Organisation and the European Medicines Agency and other regulators internationally on Ebola, including consideration of potential treatments and vaccines, standards, importation and about the expedited review of a clinical trial application for a vaccine.

- *Merger of medicines and devices enforcement functions* – An update was given on the merger of the Agency's medicines and devices enforcement functions on 1 September 2014.

- *Yellow Card* – An update was given on arrangements to mark the 50th anniversary of the Yellow Card scheme in latter part of the year.

- *Products issues* – Updates were given on: Domperidone, Isotretinoin and Methadone.

- *Adaptive licensing* – The European Medicines Agency has now received over 26 applications; of these, four are suitable further consideration.

- *NHS England and National Reporting and Learning System (NDLS)* – Work continues in this area, including monthly meetings of the National Medication Safety Network Webex meetings.

- *Clinical Practice Research DataLink (CPRD) Clinical Trials* – CPRD is developing a tool to enable services to be offered to organisations to help create more efficient and lower cost trials.

- *Alterplase* – The Lancet published Dr Shinton's study on stroke management and the use of Alteplase.

- *Vaginal meshes and tapes* – An update was given on the review which the Agency had prepared for the Chief Medical Officer (England).

- *Pertussis in pregnancy vaccination programme* – an MHRA paper detailing a CPRD study examining the safety of pertussis vaccination in pregnancy was published in the British Medical Journal.

- *Sissons Review* – In July 2014 the Agency published its formal response to the report by Professor Sir Patrick Sissons on the future direction of the scientific work on NIBSC.

- *Update on CET appointments*: After a competitive selection process, a candidate has been appointed to the post of director of Clinical Practice Research Datalink. The successful candidate, Dr Janet Valentine, will join the Agency on 3 January 2015. As regards the director of Human Resources, a recruitment campaign is being carried out.

- *Blackbay Judicial Review* – In July 2014, the Agency received confirmation from the High Court that an application for a judicial review from Blackbay had been rejected.

Item 11: Finance and Procurement report

11.1 Mr Peter Commins gave the highlights for the first four months of the financial year 2014/15. They were:

- MHRA (Regulator) income: for July 2014 was at £8.5m.
- NIBSC operational income: for year to end of July 2014 was at £7.3m.
- CPRD income: for year to end of July 2014 was at £2.8m.
- Operating income for the Agency for July 2014 was £48.7m, which is £0.9m above budget.
- Total operating costs for the year to end of July 2014 were £40.8m, which is £0.4m below budget.
- The Agency's bank balance at the end of July 2014 was £189.7m.
- Capital expenditure was £2.9m out of the full year budget of £13.0m.
- Total Product Licensing deferred revenue at the end of July 2014 was £17.0m.
- The number of full-time equivalents at the end of July 2014 was 1,199, with 110 short-term contracts and 42 non-payroll employees.

11.2 During his report Mr Commins referred to Agency's expenditure of £241,000 on network licences and IT hardware, about which a number of Board members asked for

further details. The Board heard that the purchase of the licenses was part of the overall IT budget of £3.3m. Mr Commins said he would provide fuller details on the purchase of the network licenses after the meeting.

11.3 Mr Commins went on to report that the Agency has now identified three-quarters of the fifty posts that are to be disestablished in 2014/15. The Board also received an update on plans to sub-let the third floor at 151 Buckingham Palace Road, about which good progress has been made.

Action: Peter Commins to provide a further update on the purchase of network licenses.

Item 12: Minutes of the Corporate Executive Team (CET) meetings

12.1 The minutes of the CET meetings of 1 July and 15 August 2014 were noted.

Item 13: Non-Executive Directors' (NEDs) updates

13.1 Professor Lawton reported that he had attended part of DH's Audit and Risk Assurance Committee (ARAC) meeting on 16 September. The invitation to attend came from Mr Mike Wheeler, Chair of DH's ARAC, who was keen to talk to chairs with the ARAC chairs of other arms-length bodies.

Item 14: Any Other Business (AOB):

Date of next Board meeting: 7 November 2014.

Aidan McIvor
Head of Directorate