Agency Board

Minutes of the meeting
7 November 2014

Present:

The Agency Board

Sir Gordon Duff	Chairman of MHRA
Professor Barry Furr	Non-Executive Director
Mr Martin Hindle	Non-Executive Director
Professor Vincent Lawton	Non-Executive Director
Sir Alex Markham	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
Mr Peter Commins	Chief Operating Officer and Finance Director
Mr Jonathan Mogford	Director of Policy
Ms Rachel Bosworth	Director of Communications
Dr Stephen Inglis	Director of NIBSC
Dr Siu Ping Lam	Director of Licensing (item 5)
Mr John Quinn	Director of Information Management Division
[redacted]	Acting Head of Government and Corporate, Policy Division (items 4 & 6)
Mr Jon Ford	Head of Operations, CPRD (item 9)
[redacted]	Head of Science Strategy
Mr Aidan McIvor	Secretary to the Agency Board
[redacted]	Executive Assistant to the Chairman

Department of Health

Mr Simon Reeve	DH sponsor representative

Observers

Sir Michael Rawlins	Chairman designate

Item 1: Apologies and Announcements

1.1 Apologies were received from Dame Valerie Beral, Non-Executive Director; Ms Deborah Oakley, Non-Executive Director; Mr Mark Wilson, Deputy Director, Legal Services; [redacted], Legal Advisor; and [redacted], Legal Advisor.

1.2 The Chairman advised that, although Ms Oakley was unable to attend the Board meeting, she had sent on written comments on three of the discussion papers: IT Strategy, Investment at NIBSC, and Breast Implant Registry. Hard copies of Ms Oakley's comments were tabled at the meeting.

1.3 The Chairman then went on to explain that none of the legal advisors were able to attend the Board because of international meeting commitments. Mr Wilson and [redacted] were at a meeting of the Heads of Medicines Agencies' network of legal advisers in Rome, while [redacted] had to attend a hearing at the European Court of Justice in Luxembourg. While noting the reasons for the current absences, the Board expressed concern that legal advisors have been unable to attend a number of Board meetings in 2014. Dr Hudson said he would look into this.

Announcements

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

- *Sir Michael Rawlins* – The Chairman welcomed Sir Michael Rawlins to the Board meeting and congratulated him on his appointment as the next Chairman of the Agency. The Board heard that Sir Michael would assume the Chairmanship of the Agency on 1 December.

- *Chairman's departure* - The Chairman said that, as his tenure as chairman would end on 30 November, this was his last Board meeting. The Chairman expressed his thanks to the Board and Dr Hudson and the executive team for their support during his chairmanship and went on to wish Sir Michael his successor every success for the future.

- Professor Vincent Lawton asked that the minutes record the high esteem and gratitude of Board members for Sir Gordon. Professor Lawton said the Board would express its thanks in fuller terms at Sir Gordon's farewell dinner on 10 December.

- *Board lecture programme* - The Chairman thanked Mr Martin Hindle for giving the Board lecture earlier in the day. Mr Hindle's lecture was on "The pathway to non-executive directorship at MHRA".

- *Board meeting dates in December* and January – The Chairman reported that the Agency Board/CET away day, which was due to take place on 10 December, would now take place on 23 January 2015. The away day had to take place then because the Chairman designate, Sir Michael Rawlins, was in the U.S.A on 10 December. The Chairman went on to report the Board would meet in December under the chairmanship of Sir Michael; the date for the meeting had still to be confirmed.

Item 2: Declarations of interest

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

Item 3: Minutes of the Agency Board meeting of 17 September 2014

3.1 The draft minutes of the Board meeting of 17 September 2014 were adopted.

DISCUSSION PAPERS

Item 4: 2015-2016 Business Planning and AB/CET away day

4.1 [redacted] of Policy Division gave a progress report on preparations for the draft Business Plan for 2015-2016. The Board heard that to help develop a more consistent and thorough approach to business planning, a template for business planning had been prepared by the cross agency business planning group. That template had been sent to the Agency's three Centres (NIBSC, CPRD and the nine divisions that form MHRA regulatory) for completion. The Board heard that the completed templates are now helping to inform the key strategic activities for the agency Business Plan 2015/16. Attached to the update paper was an annex that listed fourteen draft priorities for the Agency business plan 2015-16, which the Board were asked to consider. After considering the annex, the Board expressed satisfaction with the general direction of the draft priorities.

4.2 [redacted] then went on to advise that the Board / CET away day on 23 January 2015 would consist of two parts: (i) the review of the draft Business Plan and (ii) a discussion of the Agency's approach to and engagement with key health stakeholders. Martin Hindle, NED, said he was very encouraged by the progress being made with business planning and, in particular, with the work of the cross-agency business planning group. The Board thanked [redacted] for his update and the Board endorsed the proposed format of the draft away day programme.

Item 5: Ebola – oral update

5.1 Jonathan Mogford, Director of Policy, and Dr Siu Ping Lam, Director of Licensing, gave an overview on the outbreak of Ebola in West Africa and the Agency's contribution to the response by the UK and the wider international community to the epidemic. Mr Mogford explained that six of the Agency's divisions were involved in Ebola-related work: Inspection, Enforcement and Standards (IE&S), Vigilance and Risk Management of Medicines (VRMM), the National Institute for Biological Standards and Control (NIBSC), Licensing, Policy, and Devices, with staff from Policy Division working on short-term secondments at DH on Ebola-related work. The Agency's work is being coordinated by a cross-agency group and officials are working closely with other government departments, the World Health Organisation and other regulators.

5.2 Mr Mogford went on to explain the international effort to assist West African countries to contain and fight Ebola. The UK's efforts are mainly focussed on Sierra Leone, while France and the USA provide similar support to Guinea and Liberia respectively. To date, there have been around 5,000 deaths from Ebola, with nearly 14,000 reported cases of Ebola in eight African countries. Mr Mogford went on to outline the work of the UK's cross-government vaccine programme and the issues which such a programme faces, namely scientific advice, regulation, production intelligence, indemnities, vaccine procurement and delivery, and international collaboration.

5.3 Dr Siu Ping Lam, Director of Licensing, then gave a short presentation on work on the development of Ebola vaccines, the status of the recent and planned clinical trials programme (Phases 1-3), and the challenges which lie ahead. Dr Lam reported that while it usually takes between six and seven years to complete the three stages of a clinical trial for a new vaccine, pharmaceutical companies and regulators are now trying to reduce that time frame to eight months for an Ebola vaccine. A number of trial vaccines are being developed by several pharmaceutical companies, some of which may be available for widespread use from April 2015. Healthcare workers and those engaged in burials would be among the first to receive the new vaccines.

[Section 35 redaction: formulation of government policy]

5.6 Dr Hudson thanked the Board for their comments and advised that a further update would be given at the next Board meeting in December.

Item 6: DH Triennial Review – oral update

6.1 Jonathan Mogford gave an update on the progress of the Triennial Review; this followed an initial update that the Board received on the Review at its meeting on 17 September. Mr Mogford reminded the Board 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.

6.2 Mr Mogford went on to explain the methodology and approach of the Review, its governance structure and overall timetable. During the update, Mr Mogford explained the role and composition of the Project Board and Challenge Group. The Project Board will oversee the delivery of the Triennial Review, while the Challenge Group will ensure that the Review is rigorous. Mr Mogford concluded his update by explaining that the Review's Project Board and Challenge Group will have their first meetings on 17 November. These will be followed by a call for evidence in late November. The stakeholder interviews for that part of the review covering the British Pharmacopeia Commission and the Commission on Human Medicines, will take place in December; those for the MHRA will take place in early and mid-January. The Review's report is expected to be published in mid-March 2015.

Item 7: Update on Information and Technology (IT) Strategy

[Section 43 redaction – trade secrets and prejudice to commercial interests]

Item 8: Update on NIBSC Investment Plan

8.1 Dr Stephen Inglis presented a paper on the investment programme at NIBSC. The Board heard that after significant period of organisational change and more recently a time of uncertainty about NIBSC's future location, the Institute is now in a position to plan and invest in its future development.

8.2 Dr Inglis explained that the investment strategy has been built around two key requirements: (i) to address the growing importance and rapidly global landscape for biological medicines and (ii) the need to plan for succession planning as several key senior members of staff approach retirement. The Board heard that the main areas of long-term scientific investment include the establishment of an advanced therapies division and filling gaps that have been identified in three particular areas. They are: bioinformatics, monoclonal antibodies and endocrinology standardisation. The Board also noted that Dr Inglis is likely to step down as NIBSC's director within the next eighteen months.

8.3 The Chairman thanked Dr Inglis for the update and commended him for setting up so successfully the Advanced Therapies Division under Professor Mary Collins of University College London. The Board also heard that good progress is being made in attracting high calibre candidates to senior positions at NIBSC. The Institute is developing strong links with universities which helps with recruitment and is considering the idea of offering scientific fellowships in conjunction with academic centres. Dr Inglis assured the Board

that the succession planning for senior staff is a high priority and that consideration was also being, through the Chief Executive, to succession for his own post. Professor David Webb, NED, and Chair of the Scientific Advisory Committee at NIBSC, endorsed Dr Inglis' update.

Item 9: Breast Implant Registry

9.1 Mr Jon Ford, Head of Operations at the Clinical Practice Research DataLink (CPRD), presented an update on the pilot study currently being carried into the feasibility of running a Breast Implant Registry. The Board heard that CPRD was invited by DH to undertake a study into the practicalities of running a Breast Implant Registry in 2013; this arose from one of the recommendations of the Keogh Review into the regulation of cosmetic interventions. The Board heard that the CPRD team had identified an efficient method of collecting data for a Breast Implant Registry using existing information flow. The data would then be stripped of patient identifiers, with patient pseudonyms being provided by the relevant hospitals. The data collection exercise will conclude at the end of December 2014, after which a report on the study is expected to be ready by February 2015.

9.2 The Chairman thanked Mr Ford for the update. The Chairman went on to highlight the difficulties of maintaining registries and ensuring that their records were kept up to date. The Chairman said that registries had a two-fold purpose: (i) to aid research and (ii) to facilitate long-term patient follow-up, which can only be done if the details of procedures / operations are registered. A number of Board members thought that, while the creation of a Breast Implant Registry was technically feasible, it was not clear if such a registry should sit within the Agency. The Board noted Mr Ford's comments about the reputational and operational risks associated with establishing such a registry. These included the management overhead and the need to clearly differentiate between anonymised data and patient identifiable data so that appropriate information governance practices could be put in place.. The Board also heard that a number of other organisations have more experience and better expertise in running registries.

9.3 Some Board members expressed concern that if such a registry was an 'ill fit' for the Agency, and if the presence of such a registry could prove difficult for CPRD because of the heightened sensitivity about Patient identifiable Data, then the Agency should not host it. The Chairman suggested that DH should consider the issues associated with registries in more detail. The Board heard that it would receive a further update in the early spring after the completion of the study.

STANDING ITEMS

Item 10: Audit and Risk Assurance Committee meeting of 15 October 2014 - update

10.1 Professor Vincent Lawton, Chair of the Audit and Risk Assurance Committee (ARAC), gave an account of the highlights from ARAC meeting of 15 October. These included the discussion of the statutory audit, the internal audit to review the audit tracker and Corporate Risk Register. At the meeting on 15 October, Professor Lawton also shared his reflections on the meeting of the Department of Health's ARAC, to which he had been invited to attend on 16 September. That meeting considered how the Agency's management of keys risks could impact on the wider health and social care network and DH itself.

Item 11: CEO's report for September and October 2014

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

- *The House of Commons Public Accounts Committee (PAC)* hearing on Tamiflu on 20 October. The hearing, which Dr Hudson attended as a witness, discussed trial registration and transparency, as well as the government stockpiling of antivirals for pandemic influenza.

- *Early Access to Medicines Scheme (EAMS)* – The second promising innovative medicines (PIM) designation was issued in October. On 5 November, the Office for Life Sciences hosted a meeting with industry and NICE and NHS England to discuss the success of the scheme so far.

- *One-stop-Shop* regulatory advice service for regenerative medicines was launched on 13 October. The service will coordinate all advice requests in relation to regenerative medicines.

- *Visit to India* – From 6-10 October, Dr Hudson, and Gerald Heddell, Director of Inspections, Enforcement and Standards Division, paid an official visit to India. During the visit, they met with state regulators in Maharashtra and Gujarat States, and national regulators in New Delhi. They also hosted meetings with industry in each state.

- *Vaginal meshes and tapes* – The Agency has submitted its final report to the Chief Medical Officer (England) on whether the risk/benefit assessment remains correct for vaginal mesh implants. The Agency's conclusion in the report is that from a regulatory perspective the benefits of the use of these devices outweigh the risks. The separate review by the Scottish Executive of the same safety issues continues.

- *Fake dental devices* – An update was given on a television news report by the BBC health team about the seizure of counterfeit and unapproved dental equipment. Over 12,000 items were seized.

- *NIBSC and University College London (UCL)* – On 30 September, NIBSC and UCL signed an agreement to promote further scientific collaboration in the field of advanced therapies.

- *Update on Devices Expert Advisory Committee (DEAC) Chair* – Interviews for the post of the Chair of DEAC will take place on 10 November.

- *Update on CET appointments*: After a competitive selection process, a successful candidate has been identified for the post of Director of Human Resources Division. An announcement will be made once the candidate's references have been checked. It was reported that Dr Janet Valentine will join the Agency as Director of the Clinical Practice Research Datalink on 3 January 2015.

Item 12: Finance and Procurement report

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

- MHRA (Regulator) income: for September 2014 was at £11.2m.
- NIBSC operational income: for year to end of September 2014 was at £10.1m.
- CPRD income: for year to end of September 2014 was at £0.7m.
- Operating income for the Agency for September 2014 was £75.6m, which is £4.2m above budget.
- Total operating costs for the year to end of September 2014 were £61.4m, which is £5.4m below budget.
- The Agency's bank balance at the end of September 2014 was £189.7m.
- Capital expenditure was £4.8m out of the full year budget of £13.9m.
- Total Product Licensing deferred revenue at the end of September 2014 was £18.1m.
- The number of full-time equivalents at the end of September 2014 *was* 1,206, with 120 short-term contracts and 49 non-payroll employees.

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

13.1 The minutes of the CET meeting of 2 September 2014 were noted.

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

14.1 The following updates were given:

(i) Professor Vincent Lawton - gave a lecture on innovation and regulation at a conference in Frankfurt, Germany, which had been organised by KPMG.

(ii) John Williams - attended a conference of surgeons in Prague in the Czech Republic.

(iii) Sir Alex Markham – attended a recent meeting of the CPRD Expert Advisory Group.

(iv) Martin Hindle – attended a meeting of the Agency's Conflict of Interests group meeting earlier in the day.

Item 15: Any Other Business (AOB):

(i) *Annual Lecture* – Dr Hudson reported that the 2015 Annual Lecture would take place on 25 March; the lecture would be given by Dr Dan Hartman of the Gates Foundation.

(ii) *Yellow Card 50th anniversary events* – The Board heard that to mark the 50th anniversary of the launch of the Yellow Card scheme, a series of events would take place on 25 November and 4 December. These would be followed by a conference in Edinburgh on 20 March 2015. Dr Hudson said that details of all three events would be sent to Board members.

Date of next Board meeting: 16 December 2014 – date to be confirmed.

Aidan McIvor
Head of Directorate