

## MHRA Agency Board

### MINUTES OF THE MEETING

16 July 2014

#### Present:

##### *The Agency Board*

Sir Gordon Duff	Chairman of MHRA
Dame Valerie Beral	Non-Executive Director
Mr Martin Hindle	Non-Executive Director
Professor Vincent Lawton	Non-Executive Director
Sir Alex Markham	Non-Executive Director
Ms Deborah Oakley	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
Name redacted: Section 40 of FOI Act (personal data)	Deputising for the Director of Communications
Name redacted: Section 40	Acting Head of Government, Corporate, Policy Division – for item 5
Mr John Quinn	Chief Information Officer
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*

Mr Simon Reeve	DH sponsor representative
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#### Item 1: Apologies

1.1 Apologies were received from Professor Barry Furr, Non-Executive Director, Professor David Webb; Non-Executive Director; Mr Jonathan Mogford, Director of Policy; and Mr Mark Wilson, Legal Advisor.

#### Item 2: Announcements

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

- *Board lecture programme:* The Chairman thanked Professor Sir Alex Markham for giving the Board lecture earlier in the day. Sir Alex's lecture was on "Stratified Medicines".
- *DH sponsor representative* - The Chairman welcomed Mr Simon Reeve, Head of Clinical and Cost-effectiveness at the Department of Health (DH) in Leeds, who would in future represent DH at Board meetings.

- *Board meeting dates in October, November and December* – The Chairman advised that, because of diary clashes, Jude Thompson would try to find new meeting dates for the Board in October and November. As for the Agency Board /Corporate Executive Team (CET) away day, the Chairman reported that it would now take place on 10 December. This would be followed by a farewell Board dinner to mark the Chairman's departure from the Agency.

### **Item 3: Conflicts of interest**

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

### **Item 4: Minutes of the Agency Board / CET away day of 21 May 2014**

4.1 The revised draft minutes of the Agency Board / CET away day were adopted.

### **Item 5: Minutes of the Agency Board meeting of 18 June 2014**

5.1 The draft minutes of the Board meeting of 18 June 2014 were adopted.

## **DISCUSSION PAPERS (in the order in which the items were taken)**

### **Item 6: Framework of Quality Assurance for Responsible Officers and Revalidation**

6.1 (Name redacted: Section 40), Head of Science Strategy, presented the first Revalidation Annual Report for the period April 2013 – March 2014. This was accompanied by an Annual Organisational Audit and a Statement of Compliance. The Statement of Compliance has to be submitted to DH by 31 August 2014.

6.2 (Name redacted: Section 40) described the approach the Agency has taken with respect to medical appraisals and revalidation. To date, sixteen physicians have successfully been revalidated including the Chairman and Chief Executive. Dr Hudson, thanked (name redacted: Section 40) for her work on setting up the medical appraisal system and the report, which the Chairman and Board thought was excellent. Dr Hudson said that he thought that the MHRA's appraisal and revalidation system was working extremely well, nevertheless there are some areas we should reflect on to see whether they needed to be updated, such as the tool for 360 degree feedback, the system for managing the process and how any investigations might be handled.

6.3 The Board thanked (name redacted: Section 40) for the report and agreed with its conclusions. Furthermore the Board agreed that some form of external assurance or audit process would be helpful. In addition, it was recommended that the Agency should consider whether 'buddying up' with another arms-length public body that employs medical doctors might be helpful. It was also discussed whether there are sufficient appraisers, particularly for the senior physicians within the Agency. It was noted that this was being addressed through the provision of appropriate training to members of the Board and external senior physicians who are medically qualified.

### **Item 7: Business Planning, 2015-16**

7.1 (Name redacted: Section 40) of Policy Division outlined the broad approach to developing strategic plans for the next business year and presented the specific proposals. The meeting heard that good progress had been made in working through the business planning process for 2014/15. One of the elements of the 2014/15 business

plan was to develop a strategic approach to engagement in the health and social care system. Linked to this, the work to implement the Stephenson Review into access to clinical advice in the devices domain envisaged a more collaborative approach with clinical expertise in the health system. (Name redacted: Section 40) advised that, in addition to proposed priorities for the 2015/16 business year, a substantive discussion about the progress of the health and social care system work would be valuable at the Agency Board/CET away day, which would now take place in December. The meeting heard that this should be accompanied by substantive discussions on the other strategic relationship priorities for 2014/15, namely: (i) healthcare professionals; (ii) patients and the public; and (iii) academia.

7.2 (Name redacted: Section 40) went on to report that a cross-agency group on business planning had been set up which would incorporate the expertise from the previous Outcomes Group. This would help embed business planning in the Agency, and assist in identifying opportunities for the future business plan as well as to use the Corporate Strategy and Business Plan to structure further how the Agency accounts for its activities, e.g. the Annual Report.

7.3 The Chairman and the Board welcomed the update. Martin Hindle, Non-Executive Director, endorsed the direction of travel of the business planning process. Mr Hindle went on to say that he agreed fully with the need to embed business planning in the Agency, which is something that he had discussed in the previous week with Jonathan Mogford, Director of Policy.

## **Item 8: Information and Technology Strategy**

8.1 Mr John Quinn, Chief Information Officer, presented a paper on the Agency's emerging Information and Technology Strategy. The meeting heard that many of the Agency's IT systems are approaching the end of their operational life. Consequently, an IT strategic plan is needed to set the future direction, manage the risks that this creates but also to use the opportunity to create business benefits. Mr Quinn went on to explain that there are five interdependent priorities that the Agency's Information and Technology Strategy must address. They are: data, corporate business management, business services, infrastructure, and IT reform. Mr Quinn advised that failure to address these critical issues risks the operation and reputation of the Agency. Mr Quinn then outlined how the emerging strategy intends to address the key risks, and what the resource and change implications would be.

8.2 Mr Quinn explained that there was a need for a more coherent architectural plan that would serve the data, information and technology needs of the entire organisation. In particular, there was an urgent need to upgrade the IT elements of the Agency's HR and finance functions. Mr Quinn then set out three options to address the future direction of the agency's infrastructure, desktop and support services. They were: (i) to move to the Atos shared service which would run on a 3-year fixed contract; (ii) to re-procure in a different model in line with the IT strategy; or (iii) in-source the infrastructure services. It was noted that all three options require a contract extension with the existing infrastructure provider. The CET's preferred option was for option (ii), to move towards Crown Hosting. The Atos shared service provision was more expensive for the Agency, and would not result in any improvement in service provision.

8.3 The Chairman and Board thanked Mr Quinn for his report, which they thought was very important. Some Board members asked about the risks such a programme of change would have on the Agency and in particular delivering the Business Plan. Mr Quinn advised that an incremental approach, as set out in Option 2, would mitigate such risks.

8.4 Having heard a full options appraisal, the Board agreed the recommended approach (Option 2). Mr Quinn thanked the Board for its steer, which he said aligns with the direction set by the Government Digital Service (GDS), namely to use smaller, more agile service providers. Mr Quinn said it would bring more control back into the Agency in a number of areas, including financial, risk and speed and quality of development.

8.5 The Chairman commended Mr Quinn on this report and endorsed the Board's decision. The Chairman asked that, in view of the importance of the IT Strategy, the Board should receive periodic updates on the delivery of the IT Strategy.

**Action:** The Board to receive periodic updates on the delivery of the IT Strategy.

## STANDING ITEMS

### Item 9: Audit and Risk Assurance Committee meeting, 30 June - oral update

9.1 Professor Vincent Lawton reported that the main business of the meeting on 30 June was to review the position of the MHRA's Statutory Accounts for 2013/14, particularly, the Internal Audit Annual report; to consider the NAO's draft report on the 2013/14 final audit; and to review changes since the Accounts Seminar of 21 May 2014. The ARAC also received an update from (Name redacted: Section 40), interim Director of HR, and John Quinn, Chief Information Officer, on work to address the pensions' data loss issue. ARAC was assured that good progress was being made. In addition, the ARAC considered the Conflicts of Interest annual compliance report and the Health and Safety annual report, both of which were endorsed subsequently. The ARAC also received an update on the Internal Audit Plan for 2014/15 – 2016/17 and reviewed the audit recommendations tracker and the Corporate Risk Register, including a note from Dr Inglis of NIBSC on the risk to income the Agency's work on influenza standards.

9.2 Professor Lawton went on to report that the internal auditors had given moderate assurance to the Accounting Officer that MHRA has had adequate and effective systems of control, governance and risk management in place for the reporting year 2013/14. Moreover, the external auditors (the National Audit Office) had advised that, subject to some further audit work, NAO was very likely to give the Agency an unqualified audit opinion. Professor Lawton concluded by saying that this has since happened and that the Annual Report and Accounts had been now been signed by Chairman, the Chief Executive and the Comptroller and Auditor General and would be laid before Parliament very soon.

### Item 9: CEO's report for June 2014

9.1 The highlights from the CEO's monthly report were given by Peter Commins. These centred on the following areas:

- *Bacillus cereus incident* – The investigation continues into the cause of the tragic outbreak of *Bacillus cereus* septicaemia associated with the use of total parenteral nutrition among newborn babies in neonatal intensive care units at hospitals in the South East of England. Additional information on this incident was set out at Annex A to the CEO's report.
- *Annual Accountability meeting* – The Annual Accountability meeting took place on 11 June, which was chaired by Earl Howe on behalf of the Secretary of State for Health. The tone of this year's meeting was very

positive as the Minister reviewed and commended the Agency on its work over the past year.

- *Roche judicial review* – An update was given on a judicial review that Roche had served on the Agency in January 2014.
- *Product issues* – Up-dates were given on: (i) Alteplase (Actilyse): the Commission on Human Medicines (CHM) has agreed to set up an expert working group to consider all sources of data relevant to the use of Alteplase. (ii) Statins: The Agency held a meeting with (name redacted: Section 40) of Oxford University to discuss public concern about the side effects of statins.
- *Nicotine Containing Products (NCPs)* –The DH Permanent Secretary has informed the Agency that MHRA should be the competent authority to oversee the requirements of the Tobacco Products Directive. A cross-agency working group has been set up to consider developments in relation to the wider DH policy on smoking cessation.
- *Vaginal mesh implants* - The Chairman and Dr Neil McGuire, Clinical Director (Devices) met with Mr Alex Neil, Scottish Health Secretary, on 25 June about concerns raised in Scotland about the safety of vaginal mesh and tape implants for pelvic organ prolapse and stress urinary incontinence. The Chief Medical Officer (England), Dame Sally Davies, has asked the Agency for an interim report on the issue by the end of the summer. This will take place alongside separate reviews by NHS England and the Scottish Government.
- *NIBSC Scientific Advisory Committee* – invitations to join the new Scientific Advisory Committee (SAC) were sent out in mid-June, to which all who were invited to sit on the SAC have since accepted. The SAC will hold its first meeting in October or November 2014.
- *Chairman's visit to U.S.A.* – The Chairman paid an official visit to Boston and New York from 3-14 June, which was arranged by UK Trade and Investment (UKTI). Some of the meetings were held at the Massachusetts Institute of Technology's (MIT), as part of MIT's New Drug Development Paradigm (NEWDIGS) programme. The visit programme also included meetings with 26 companies, which centred on the Earlier Access to Medicines Scheme, Adaptive Licensing, and the work of CPRD.
- *Chief Executive's visit to U.S.A.* - Dr Hudson paid an official visit to Minneapolis and San Diego from 23-27 June. The visit, which was arranged by UKTI, involved meetings with U.S. biotech companies and attendance at the BIO International Conference in San Diego, where Dr Hudson gave presentations on the Earlier Access to Medicines Scheme, Regulatory harmonisation and Paediatric Study Plans. The company discussions which UKTI arranged allowed Dr Hudson to describe some of the developments in the MHRA and the EU, such as the Earlier Access to Medicines Scheme (EAMS), Adaptive Licensing, the Agency's Innovation Office, and issues which the companies wished to discuss.

- *China* – A renewed Memorandum of Understanding was signed with the Chinese Food and Drug Administration (CFDA) on 17 June. Health Minister Earl Howe signed on behalf of the Agency, while Vice Minister Yin Li of China signed the MOU on behalf of the CFDA.

#### **Item 10: Operations and Finance report**

10.1 Mr Peter Commins gave the highlights for the first month of the financial year 2014/15. They were:

- MHRA (Regulator) income: for May 2014 was at £7.5m.
- NIBSC operational income: for May 2014 was at £5.9m.
- CPRD income: for May 2014 was at £1.3m.
- Operating income for the Agency for May 2014 was £23.1m, which is £0.2m above budget.
- Total operating costs for May 2014 were £20.5m, which is £1.8m below budget.
- The Agency's bank balance at the end of May 2014 was £178.6m.
- Capital expenditure was £1.4m out of the full year budget of £13.0m.
- Total Product Licensing deferred revenue at the end of May 2014 was £14.1m.
- The number of full-time equivalents at the end of May 2014 was 1,194, with 114 short-term contracts and 26 non-payroll employees.

10.2 Peter Commins reported that work continues with identifying the remainder of the fifty posts which the Agency had committed itself to disestablishing in 2014/15. The Board also heard that preparatory work has begun should the Agency be able to sub-let the third floor at 151 Buckingham Palace Road.

10.3 Peter Commins went on to report that interviews for the post of Director of Human Resources had taken place on 14 July, but none of the candidates had been successful. A new recruitment plan would be prepared; meanwhile, Peter Commins will discuss cover arrangements with (name redacted: Section 40), the interim HR Director.

10.4 The Chairman thanked Peter Commins for the update and went on to say that it was vitally important to the Agency that a high calibre candidate was selected eventually to lead the Human Resources Division.

#### **Item 11: Minutes of the Corporate Executive Team (CET) meeting of 3 June 2014**

11.1 The minutes of the CET meeting of 3 June 2014 were noted.

#### **Item 12: Non-Executive Directors' (NEDs) updates**

12.1 None were given.

#### **Item 13: Any Other Business (AOB): *Honours nominations***

13.1 Professor Vincent Lawton reported he had attended a meeting recently at the DH, which was chaired by the Permanent Secretary, Una O'Brien, about the need to get more junior staff recognised in the honours rounds. Professor Lawton asked the Agency's senior executive team to give this matter consideration.

**Action:** Dr Hudson to update the Board on what the Agency is doing to encourage the recognition of staff, especially more junior staff, through the honours round.

**Date of next Board meeting:** 17 September 2014.

**Aidan McIvor**  
**Head of Directorate**