MHRA Board (in public session) Part 1

MINUTES OF THE MEETING

12 February 2016

Present:

The Board

Professor Sir Michael Rawlins	Chairman of MHRA
Dr Ian Hudson	Chief Executive
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

Mr Jonathan Mogford	Director of Policy
Ms Paul Inglefield	Associate Director, Corporate Communications
Dr Stephen Inglis	Director of National Institute for Biological Standards and Control (NIBSC)
Dr Christian Schneider	Director-designate, NIBSC
Name redacted under s40(2) of the FOIA – personal data	Biosciences Team Leader, Devices Division – item 3
Dr Krishna Prasad	Group Manager, Licensing Division – items 3 & 5
Mr Mick Foy	Group Manager, Vigilance and Risk Management of Medicines – item 3
Mr Tony Sant	Group Manager, Devices Division - item 4
Name redacted under s40(2) of the FOIA – personal data	Head of Talent and Learning, Human Resources –item 6
Name redacted under s40(2) of the FOIA – personal data	Senior Programme, Planning and Corporate Governance Officer, Policy Division –item 7
Mr Aidan McIvor	Head of Directorate
Name redacted under s40(2) of the FOIA – 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	Lawyer - DH Legal Advisor

Item 1: Introductions and Announcements

1.1 Apologies were received from Dr Barbara Bannister MBE, Non-Executive Director, and Rachel Bosworth, Director of Communications.

1.2 Sir Michael welcomed everyone to the meeting, in particular, the staff and public observers. Sir Michael explained that this was the Agency's first public board meeting which was part of a pilot programme, which would be evaluated. To inform the evaluation process, the Agency would send out an electronic questionnaire after the meeting.

Dr Stephen Inglis, Director of NIBSC

1.3 Sir Michael asked that the minutes record the Board's deep gratitude to Dr Stephen Inglis, who was attending his last MHRA Board meeting prior to his retirement at the end of March. Sir Michael commended Dr Inglis on his service to NIBSC, the Agency and public health Sir Michael went on to welcome Dr Christian Schneider, who will succeed Dr Inglis as Director of NIBSC on 1 April.

Item 2: Declarations of interest

2.1 None was declared.

DISCUSSION ITEMS

Item 3: Genomics and companions diagnostics – progress report

3.1 (Name redacted under s40(2) of the FOIA) and Dr Krishna Prasad of Licensing Division presented a progress report on work within the Agency on genomics and companion diagnostics. The Board heard that the National Institute for Biological Standards and Control (NIBSC) has developed a programme for the development of standards for genomic diagnostics and cancer. As part of this work, NIBSC has established a core facility for Next Generation Sequencing and bio-informatics. (Name redacted under s40(2) of the FOIA) r also reported on work to involve patients and the public in the Agency's approach to genomics, as well as on next steps.

3.2 Although there are no changes to medicines legislation, it is expected that the new IVD regulations will include a new pathway for the regulation of companion diagnostics and the Agency is involved in developing guidance in this area.

3.3 In terms of next steps, the Board heard that discussions are in progress with key stakeholders about collaborating on a range of issues, including the security of personal data. Moreover, work will take place on identifying costs and developing a business case to secure funding and re sourcing within the Agency, to take this work forward.

3.4 The Board welcomed (Name redacted under s40(2) of the FOIA) and Dr Prasad's comprehensive and detailed report, the direction of travel of which the Board endorsed fully. A further progress report will be given later in the year.

Item 4: Joint Patient Safety and Vigilance Strategy - update

4.1 Mr Tony Sant of Devices and Mr Mick Foy of VRMM presented an update on the Joint Patient Safety and Vigilance Strategy, which had come to the Board in September 2015. The Board heard that in October 2015, a cross agency project was launched to carry out a strategic review of common activities and look for synergies and the systems that are used to support vigilance activities. Although the Agency has a wide range of responsibilities regarding patient safety, the scope of the strategic review wouldn't cover some surveillance functions, e.g. blood products, or other surveillance and supervisory activities, such as inspections and compliance monitoring.

4.2 The Board heard that five strategic objectives have been set for the strategy and a governance system has been set up with a steering group and a coordination group. Moreover, three project teams with representation from relevant teams across the Agency have been tasked with addressing the strategic objectives. They are:

- Project Team 1: Addressing the way the Agency handles suspected adverse incidents and carry out signal detection
- Project Team 2: Looking at the way the Agency assess safety issues and use other data sources to support our assessments
- Project Team 3: Looking at how the Agency communicates safety issues and how we measure the impact of our safety communications.

4.3 Mr Foy and Mr Sant went on to advise that the project is still in an early stage, with relevant teams developing project plans and identifying key deliverables. At the same time, Agency officials are meeting with stakeholders, such as Care Quality Commission and the Health and Social Care Information Centre, to discuss common issues and collaborative working.

4.4 During the update, Mr Sant reported on the Medical Devices and Medicines Safety Officers' conference, which the Agency hosted on 8 February. Professor Campbell, Non-Executive Director, advised that he had attended the conference, which he thought was most successful. The conference illustrated the fruits of partnership working with NHS England, which highlighted the contribution to the protection of public health from these networks.

4.5 The Board welcomed the progress report and endorsed its direction of travel. Mr Sant and Mr Foy thanked the Board for its comments, e.g. about Unique Device Identifiers, and on how to make the reporting of adverse incidents easier for healthcare professionals. A further update will be given later in the year.

Item 5: Building Academic Relationships

5.1 Dr Stephen Inglis, Director of NIBSC, presented a progress report on the four priority areas identified for building the Agency's links with academia. They were: (i) regenerative medicine, (ii) clinical trial design, (iii) supporting emergency response to disease, and (iv) the use of real world data to inform medicines evaluation. Dr Inglis outlined work at present with University College London, Imperial College London, and the UK Regenerative Medicine Platform. Updates were also given on the Agency's interaction with academia on clinical trial design, developments in the areas of stratified medicine and genomics, as well as supporting the Agency response to disease, such as Ebola. Dr Inglis concluded by reporting that following the Nurse Report, which was published in December 2015, the Agency can bid for funding from research bodies, such as the Medical Research Council.

5.2 The Board welcomed the progress report and agreed that there are clear opportunities for, and benefits from, establishing formal partnerships with universities. A further update will be given later in the year.

Item 6: Skills Capability

6.1 (Name redacted under s40(2) of the FOIA) -of Human Resources gave a progress report on skills and capability planning. The update focussed on four areas of capability development that are a priority across the Civil Service. They are: (i) digital skills, (ii) project delivery, (iii) leading and managing change, and (iv) commercial skills and

behaviours. (Name redacted under s40(2) of the FOIA) explained challenges of retaining and recruiting staff, especially of a specialist nature. The Board then heard about the work being carried out for the four categories. For example, a questionnaire on digital needs will be sent to staff in early 2016; the Agency is working with Civil Service Learning to develop appropriate training solutions; and the Agency is working with other government departments and arms-length bodies to create a network of shared learning. Ms Reeve also reported on the use of social media in a changing recruitment environment.

6.2 The Board welcomed the update and endorsed the approach that (Name redacted under s40(2) of the FOIA) outlined. A further progress report will return to the Board later in the year.

Item 7: Monitoring report: targets and strategic activities (Quarter 3)

7.1 Mr Jonathan Mogford presented the third quarterly report of progress against the 2015-2016 Agency Business Plan. The report set out the Agency's position against targets, activities, metrics and further performance-related work.

Operational agenda

Item 8: CEO's report

8.1 Dr Hudson presented from the CEO's report for December 2015 and January 2016. This covered headlines, product-related issues, regulation and policy developments, communications, organisational topics, operational performance, international topics, and litigation.

Item 9: Finance and Procurement report

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

- MHRA (Regulator) income: year to date was £79.7m.
- NIBSC operational income: year to date was £31.7m.
- CPRD income: year to date was £7.5m.
- Operating income for the Agency was £119.1m, which is £7.1m above budget.
- Total operating costs were £99.1m, which are £2.6m below budget.
- The Agency's bank balance at the end of December 2015 was £213.2m.
- Capital expenditure for the year to end of December 2015 was £6.9m.
- Total Product Licensing deferred revenue at the end of December 2015 was £19.6m.
- The number of full-time equivalents in December 2015 was 1,236, with 152 short-term contracts and 45 non-payroll employees.

Item 10: Audit and Risk Assurance Committee – oral update

10.1 Deborah Oakley, Chair of the Audit and Risk Assurance Committee (ARAC), provided an update on the ARAC meeting of 14 January 2016. This covered ARAC's consideration of internal audit reports, the draft Governance Statement, whistleblowing, self-assurance, and the Corporate Risk Register.

Item 11: Any Other Business (AOB):

14.1 Sir Michael and the Board thanked members of the public and staff for attending the meeting. Details of the next public board meeting would be advertised in due course.

Date of next meeting: 14 March 2016