Medicines and Healthcare products Regulatory Agency

MINUTES OF THE MEETING

22 May 2017

Present:

The Board

Professor Sir Michael Rawlins	Chairman of MHRA
Mr Martin Hindle	Deputy Chairman
Dr Ian Hudson	Chief Executive
Mr Jon Fundrey	Chief Operating Officer
Dr Barbara Bannister MBE	Non-Executive Director
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
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 Rachel Bosworth	Director of Communications
Dr Christian Schneider	Director of the National Institute for Biological Sciences and Control (NIBSC)
Mr Gerald Heddell	Director of Inspection, Enforcement and Standards
Mr Richard Humphreys	Deputy Finance Director
{Redacted: Section 40: personal data}	Chief Financial Accountant
{Redacted: Section 40: personal data}	Team leader - Business Planning and Programme Management
{Redacted: Section 40: personal data}	Financial Accountant
{Redacted: Section 40: personal data}	Information Services Manager
{Redacted: Section 40: personal data}	Head of Corporate Services, NIBSC
{Redacted: Section 40: personal data}	Head of Science Strategy
Mr Aidan McIvor	Head of Directorate
{Redacted: Section 40: personal data}	Executive Assistant to the Chairman

Legal Services

Mr Paul Wright	Deputy Director, MHRA, Medicines and Information Team, DH Legal Advisers, Government Legal Department

Item 1: Introductions and Announcements

1.1 Apologies were received from Dame Valerie Beral, Non-Executive Director, and Dr Mark Timoney, Chief Pharmaceutical Officer of Northern Ireland.

1.2 Prior to welcoming everyone to the meeting, including staff observers from NIBSC, and officials from Finance and Procurement Division for the Annual Accounts Seminar,

the Chairman thanked Dr Schneider, Director of NIBSC, for making the Board so welcome. The Chairman went on to make the following announcements:

- Dr Barbara Bannister, Non-Executive Director, would give a lecture to staff on 'Infection Emergencies – a clinician's view'. The lecture would take place immediately after the Board meeting.

- There would be a health and safety tour of the facilities at NIBSC for members of the Audit and Risk Assurance Committee, along with other members of the Board, should they wish to join the tour.

- The Chairman reported that, he along with a group of Venezuelan patients, who were living with Huntingdon's Disease, and medical researchers from the UK and Venezuela, had met Pope Francis I at an audience in Rome on 18 May.

Item 2: Declarations of interest

2.1 Deborah Oakley declared an interest as a member of the Board of the Royal Free Hospital NHS Trust, which had signed a data-sharing agreement with DeepMind, a subsidiary of Google.

Item 3: Minutes of the last meeting, 24 April 2017, and Matters Arising

3.1 The minutes of the Board meeting of 24 April 2017 were agreed and the actions listed were reviewed under Matters Arising.

DISCUSSION ITEMS

Item 4: Brexit - update

4.1 Jonathan Mogford gave an update on Brexit-related work since the last Board meeting on 24 April. This has focused on scenario-planning work (including financial analytical work). At present, engagement with stakeholders has been constrained by the Agency's need to observe purdah during the election period.

4.2 Mr Mogford reported on discussions at the Heads of Medicines Agencies meeting in Malta from 10-12 May, where the UK was represented at all discussions, including on Brexit. The Board was also updated about a meeting at the European Medicines Agency (EMA) on 27 April, where contingency planning for Brexit was discussed. That meeting was attended by representatives of the EU Commission, the EMA and the heads of agencies from the EU27 grouping, but not the UK.

4.3 The Chairman thanked Mr Mogford for the update and sought the Board's views. The Board welcomed the progress report and understood the constraints that purdah places on the Agency. The Board considered the current thinking within the Agency on two possible scenarios: partnership working with the EU and a UK standalone regulatory model, both of which Mr Mogford had outlined at the public Board on 24 April. The Board asked a number of questions about links into EU databases and IT systems and how they would operate under either model, as well as about how batch release work at NIBSC would be affected. Dr Hudson and Mr Mogford addressed these questions.

4.4 During a broader discussion, which touched on emerging IT solutions and how they could help the NHS, the Chairman mentioned that he and Dr Hudson were due to

meet with Professor Jonathan Montgomery, Chair of the Health Research Authority, on 26 May to discuss a range of areas of mutual interest. The Board also considered the possible impact of Brexit on clinical trials in the UK and in particular on making the UK a sought-after destination to carry out Phase 2a and Phase 2b clinical trials. The questions were prompted by a section on clinical trials in the draft Annual Report. Dr Hudson advised that much progress has been made in this area, although more could be done in the areas of Research and Development (R&D) approval and 'recruitment into studies'.

4.5 A further update will come to the Board on 23 June.

Item 5: Annual Accounts seminar

5.1 The seminar was presented by Jon Fundrey, Chief Operating Officer; Richard Humphreys, Deputy Finance Director, {Redacted: Section 40: personal data}, Chief Financial Accountant; and {Redacted: Section 40: personal data} Financial Accountant. Mr Humphreys explained that the purpose of the seminar was to allow the Board to review the final draft Annual Accounts before they are submitted to the Agency's auditors and, in particular, the key statements; and to identify major changes from the previous year.

5.2 The seminar considered the timetable for the Annual Report and Annual Accounts, and the three main components of the accounts. They were (i) the Performance Report, the Accountability Report (Governance Statement and Internal Audit), (iii) Financial Statements (Statement of Comprehensive Income and Statement of Financial Position). The Board considered the Finance & Procurement Forward Look 2017/18.

5.3 Key points to arise from the presentation:

- National Audit Office's (NAO) final audit fieldwork will begin on 22 May and should be completed by mid-June, which, together with the draft Annual Accounts, will be reviewed by the Audit and Risk Assurance Committee on 23 June. Sign-off of the accounts is due to take place during the week commencing 3 July 2017. The Annual Report will be tabled in Parliament by the week commencing 10 July. Recess is due to begin on 20 July.

- The following developments were outlined, which will feature significantly in 2017/18: (i) planning and preparation for Brexit; (ii) Operational Transformation Programme; and (iii) the move to Canary Wharf during Q1 of 2018/19. Additionally, the Board was advised that Oracle Fusion Phase 1 was launched in April 2017, with Phase 2 to follow in August 2017, while a new Head of Internal Audit has been selected from the Government Internal Audit Agency. Furthermore, improved processes for the management of contracts are being rolled out.

- There are no significant accounting changes; the Period 9 accounts have been completed on time with an unqualified audit opinion from the NAO. Although the final internal audit opinion is still awaited, the draft opinion gives the Agency overall "moderate level assurance. This is derived from two components: the risk management and governance areas were deemed to be 'moderate', while the control areas were deemed to be 'limited'. The Agency has asked the Internal Auditors to carry out further field work, which may result in a change to the 'limited' rating. However, this will not change the overall rating of the 'moderate' for the Agency.

5.4 The Chairman thanked Richard Humphreys and his colleagues for their presentations and sought the Board's views. These centred on the following areas:

- *Fraud prevention* – The Board asked if the new finance platform will make it easier to prevent fraud. Richard Humphreys advised that lessons had been learned from earlier episodes of fraud and that the Agency had acted proactively to significantly tighten up controls and systems. The new robust control systems will help ensure that the risk of fraud can be significantly reduced.

- *IT spend* – in answer to questions about IT expenditure and the breakdown between ongoing expenditure and one-off project related costs, Mr Fundrey advised that the Agency is about to embark on a programme of prioritisation of IT projects.

- *Narrative* - The Board advised that the Annual Report should state clearly "that while the volume of work has gone up, fees have gone down".

- *Operational Transformation* – In answer to questions about the cost of the Operational Transformation programme, the Board heard that a paper would come to the Board in due course.

Draft Annual Report 2016/17

5.5 Ms Rachel Bosworth presented a revised draft of the Annual Report for 2016/17. The Board commended Ms Bosworth and her team on the work to date on the draft report and, in particular, on the use of infographics. The Board asked if the Agency's preferred position around Brexit could be weaved into the Annual Report, in particular, the forewords. Dr Hudson advised of the sensitivities around Brexit in an official publication, and the constraints within which the Agency, as with other parts of government must operate.

5.6 The Board went on to recommend that examples of current collaboration with the EU should be mentioned in the Annual Report, e.g. by way of text, photographs, and a map representing Europe. The Board also suggested that a picture of a patient (s) should appear as part of the cover or within the body of the report. Ms Bosworth thanked the Board for their comments, which would be taken into account. Ms Bosworth also advised that when the revised version of the Annual Report returned to the Board on 23 June, it will have been comprehensively proof-read.

5.7 The Chairman concluded by thanking all concerned for their presentations.

Item 6: Horizon-scanning paper

6.1 Dr Christian Schneider presented a progress report on recent scientific horizon-scanning work. This work has been led by a Horizon-Scanning Group, which has identified four topics of particular interest. They are: (i) veterinary advanced therapies, (ii) In silico clinical trials, (iii) Apps for health monitoring and Google DeepMind, and (iv) synthetic biology. As part of his report, Dr Schneider advised that the Agency's Innovation Office has had 372 enquiries, including one finding, which was brought to attention of Horizon scanning group: VapourSoft; a new mechanism involving a liquid gas cartridge to replace the role of a spring in an auto-injector.

6.2 Dr Schneider updated the Board on the recruitment of a lead for horizon-scanning. Dr Schneider also reported that an IT specialist would join the group.

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

- *Taking cost/time out of drug development* – The Board suggested that it might be beneficial to arrange a meeting with industry to seek their views on time and financial costs associated with R&D. The Chairman asked Dr Hudson and his colleagues on the CET to consider this.

- *New technology and regulatory needs* – The Board advised that it was important to think about the regulatory aspect of technology developments. In particular a question was raised about the skills available within Notified Bodies in relation to software and algorithms which drive clinical decisions.

- *Veterinary Medicines Directorate (VMD)* – The Board asked about the Agency's relationship with the VMD and whether there was scope for a possible merger. Dr Hudson explained that we work closely with VMD, e.g. at the Heads of Medicines Agencies meetings and at the EMA. As to a possible merger, this has been considered from time to time.

6.4 The Chairman concluded by thanking Dr Schneider for the update and asked that the Board be kept abreast of developments.

Action: CET to consider whether more might be done to reduce costs/speed development of new medicine

STANDING ITEMS

Item 7: CEO's report

7.1 Dr Hudson presented the highlights from the CEO's monthly report. These centred on the following areas:

- *Purdah* – An update was given on how purdah has affected the Agency, since Parliament was prorogued on 27 April for the General Election on 8 June.

- *Silimed* – An update was given on the work of the Independent Clinical Expert Advisory Group on Silimed implants and subsequent discussions at an EU level.

- {Redacted: Section 5: Commercial confidentiality}.

- *Medical Devices and In-Vitro Diagnostics Regulations* – An update was given on the publication in the Official Journal of the EU of the new EU regulations on 5 May 2017. These would enter into force twenty working days afterwards, triggering three and five year transition periods respectively.

- *Heads of Medicines Agencies (HMA) meeting, 10-12 May* – Further to the earlier update on Brexit, a more detailed update was given on the HMA meeting in Valletta, Malta.

- *Cyber-attack* – An update was given on action taken to protect the Agency from a cyber-attack following the cyber-attack on the NHS over the weekend of 13-14 May. Jon Fundrey, who gave the update, assured the Board that the Agency was well-placed in terms of IT security thanks to a programme of patching, security

upgrades and other protective measures that have been in operation over the past eighteen months. Mr Fundrey advised there had been a small number of incidents of IT virus contamination at NIBSC, which the Agency addressed quickly. This was due in part to the IT infrastructure at NIBSC being older than elsewhere in the Agency, as well as to NIBSC's links to certain external bodies, where there was a risk of possible contamination. Mr Fundrey assured the Board that robust measures had been brought into play to address IT security at NIBSC.

7.2 The Chairman thanked Dr Hudson and Mr Fundrey for the updates and sought the Board's views. These centred on the following areas:

- *Cyber–attack* – The Board commended Mr John Quinn, Director of Information Management Division, and his colleagues for the excellent work they have undertaken to protect the Agency from cyber-attacks, and asked that the minutes record the Board's congratulations to Mr Quinn and his colleagues for their work in this area. Mr Fundrey advised that a paper on cyber security would come to the Audit and Risk Assurance Committee at its meeting on 23 June.

- *Relocation* – In answer to a question from the Board, Mr Fundrey gave an update on the planned space / desk allocation at the Agency's future London offices in Canary Wharf.

- *World Health Organisation's (WHO) audit* – In response to a question from the Board, Dr Hudson gave an update on the WHO audit of NIBSC's vaccine evaluation laboratories. The audit took place during the week beginning 24 April.

Item 8: Quarter 4 report, Business Plan 2016/17

8.1 {Redacted: Section 40: personal data} presented a progress report for the fourth quarter of the Business Plan, 2016/17. The report provided an update on the Agency's Quarter 4 position against the targets, activities, metrics and further performance related work. Ms Bostock reported that 34 targets out of 39 were met from 2016-17; of the 103 activities due to be completed, 88 were completed and 15 were postponed, four of which were due to factors outside MHRA's direct control, which the Board noted.

8.2 The Chairman thanked {Redacted: Section 40: personal data} for her report and sought the Board's views. These centred on the following areas:

- *Devices fees* – In response to a question about devices fees, {Redacted: Section 40: personal data} advised that having sustainable devices fees was one of the Agency's top ten priorities
- {Redacted: Section 5: Commercial confidentiality}
- *Retention and recruitment of medical assessors* - In answer to a question about this area, Dr Hudson explained that the retention and recruitment of medical assessors presents a particular challenge for the Agency, especially in view of current pay constraints.

Item 9: Minutes of the Corporate Executive Team (CET) of 3 March 2017

9.1 The minutes of the CET meetings of 3 March 2017 were noted.

Item 10: Any Other Business (AOB):

General Election – manifestos of the main political parties

10.1 Mr Mogford gave an overview of the health and Brexit-related aspects of the manifestos of the main UK political parties, which had been published very recently.

Date of next Board meeting: 23 June 2017