MHRA Board (in public session) Part 1

MINUTES OF THE MEETING

12 December 2016

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
Dame Valerie Beral	Non-Executive Director
Mr Matthew Campbell-Hill	Non-Executive Director
Professor Bruce Campbell	Non-Executive Director
Mr Stephen Lightfoot	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 National Institute for Biological Sciences and Control (NIBSC)
Ms Vanessa Birchall-Scott	Director of Human Resources
{Name redacted under Section 40 of Freedom of Information Act (FOIA): personal data}	Human Resources Division
Mr Richard Humphreys	Deputy Finance Director
{Name redacted: Section 40 FOIA}	Head of Science Strategy
Mr Aidan McIvor	Head of Directorate
{Name redacted under Section 40 of FOIA} -	Executive Assistant to the Chairman

Legal Services

Mr Paul Wright	Deputy Director, MHRA, Nutrition and EU Team, DH Legal Advisers, Government Legal Department.

Item 1: Introductions and Announcements

1.1 Apologies were received from Professor Sir Alex Markham, Non-Executive Director.

1.2 The Chairman welcomed everyone to the meeting, in particular, the staff and public observers.

Item 2: Declarations of interest

2.1 None was made.

Item 3: Minutes of the public Board meeting of 12 September

3.1 The minutes of the last public Board meeting were agreed

DISCUSSION ITEMS

Item 4: Brexit and MHRA

4.1 Jonathan Mogford gave an oral update on the Agency's Brexit-related work since the last meeting of the Board in public session in September. Mr Mogford said the Agency has been working closely with Government to analyse the best options and opportunities available for the safe and effective regulation of medicines and medical devices in the UK. Mr Mogford went on to say that the Agency is working closely with a range of stakeholders, such as the industry trade associations, and with European and international counterparts.

4.2 At present, the Agency is considering the following: (i) Being a UK sovereign regulator and supporting the Accelerated Access Review, (ii) Looking at opportunities to improve and develop the regulatory system that we will in inherit when the UK leaves the EU, and (iii) how the Agency can develop its links, including work-sharing, with global partners. Meanwhile, the day to day business of the Agency will continue, with the safeguarding of public health remaining as the Agency's priority.

4.3 The Chairman thanked Mr Mogford for the update and invited comments from the Board. The Board commended the Agency for the work that has been done so far, in particular, the engagement with stakeholders, including industry. The Board asked if the Agency was sufficiently resourced, e.g. in terms of staff, to deal with the additional work load associated with Brexit. Dr Hudson advised that the Agency was currently able to manage the additional work, but would keep the resourcing aspect under review. The Board commented on the need to continue to keep the regulatory system fit for purpose; Mr Mogford said this chimed with the recently published Accelerated Access Review, which recommended closer cooperation between the Agency, the NHS England, and NICE. Mr Mogford went on to advise that Agency is working closely with the Office of Life Sciences, as part of the Agency's cross-government Brexit work.

4.4 The Chairman then invited questions from the staff and public observers.

- {Name redacted: Section 40 FOIA} of the Organisation for Anti-Convulsant Syndrome asked about the Agency's approach to adhering to the regulatory decisions of the European Medicines Agency. Dr Hudson advised that during the coming two plus years, while the United Kingdom remained a member of the EU, the Agency would similarly remain a full participant in the EU medicines regulatory network.

- {Name redacted: Section 40 FOIA} of Brightwake asked about the Agency's approach to engaging with Small and Medium Enterprises (SMEs). Mr Mogford advised that the Agency was actively engaging with a wide range of stakeholders, including the representatives of SMEs. Mr Mogford went on to say that the level of that engagement would increase in 2017, in order to gain a more nuanced view of the spectrum of opinions across industry.

4.6 The Chairman concluded by thanking Mr Mogford for the update.

Item 5: Chief Executive Officer's report

5.1 Dr Hudson presented highlights from the Chief Executive Officer's (CEO) report. These centred on the following areas:

- *International relations* – an update was given on Memorandums of Understanding that had been signed recently between the Agency and Macedonia, Switzerland and the Republic of Korea.

- *Head of (European) Medicines Agencies (HMA) meeting* – An update was given on the HMA meeting that Dr Hudson and Mr Mogford attended in Bratislava, Slovakia from 28-30 November

- *SCOPE* – An update was given on the Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) initiative. This project is now coming to an end, with many excellent deliverables, not least a successful Adverse Drug Reaction Reporting (ADR) campaign in November in which 22 countries participated.

- *Clinical Trial Regulation* – An update was given on the implementation of the Clinical Trial Regulation 536/2014, in particular, the new EU portal.

- *Reclassification seminar* – An update was given on a seminar between MHRA and the Proprietary Association of Great Britain that was held on 17 November. The aim of the seminar was to help improve the quality, content and structure of the reclassification of medicines.

- *Fake medicines and devices campaign* – An update was given on the Agency's fake medicines and devices campaign. This included an update on the storyline about a character in the television series, "Coronation Street", who suffers side effects from buying slimming pills via the Internet. The storyline will continue through December.

- *Counterfeit medicines meeting in Geneva* – An update was given on the annual meeting of the World Health Organisation's Member State Mechanism for Substandard / spurious / falsely-labelled / falsified / counterfeit medical products (SSFFC) in Geneva on 21 November.

- *Patient and public engagement* – An update was given on a meeting of the Patient Group Consultative Forum (PGCF) on 11 November.

- *Trade association meetings* – An update was given on a series of bilateral meetings with UK pharmaceutical trade associations that were held in November.

- *E-cigarette notification scheme* – an update was given on the notification scheme for electronic cigarettes. Dr Hudson reported that, to date, the Agency had received over 10,000 notifications under the scheme.

5.2 The Chairman then invited comments from the Board, which centred on the following:

- *International relations* – The Board commended the Agency on its programme of strengthening ties with other international regulators.

- *Fake medicines and devices campaign* - The Chairman and the Board congratulated Communications Division on the success of using a popular television series, "Coronation Street" to raise awareness of the dangers of buying unlicensed slimming pills, and asked Rachel Bosworth to pass on their thanks to the relevant team members.

- *E-cigarettes – In answer to questions from the* Board, Dr Hudson explained how the scheme was operated and financed. Dr Hudson advised that the Agency would review the operation of the scheme after one year

5.3. The Board then invited questions from the staff and public observers, none was asked. The Chairman then concluded by thanking Dr Hudson for his report.

Item 6: Talent Management

6.1 Vanessa Birchall-Scott presented an update on the Agency's Talent Management Strategy, 2015-2020. Ms Birchall-Scott explained that the aims of the strategy were: (i) to develop future leaders into senior roles; (ii) improve succession planning; (iii) improve access to internal and external learning opportunities (Civil Service and DH); (iv) develop career pathways to increase internal movement and broadening career opportunities; and (v) demonstrate the Agency's commitment to developing talent. As part of her report, Ms Birchall-Scott gave an update on progress with examples of career conversations using the 9 box grid for more senior staff and career pathways for more junior staff, explaining that a number of the initiatives would be rolled out and the Agency Talent Review Board would be supplemented with a similar remit for each Division/Centre senior management team.

6.2 Having thanked Mrs Birchall-Scott for her paper, the Chairman sought the views of the Board, which centred on the following areas:

- *9 Box grid* – In answer to a question about the numbers of staff who have used the 9-box grid, Ms Birchall-Scott advised that it was 56. Ms Birchall-Scott reported that staff had received extensive training in its use. Moreover, as part of the monitoring and evaluation process, there will be more spot checks to ensure greater consistency in its use. Finally, Ms Birchall-Scott reported that staff who used the 9-box grid system had found it helpful.

- *Coaching* – In answer to a question about appraisal and career conversations, Ms Birchall-Scott reported that the appraisal and personal development and career related discussions were generally separate.

- *Reward and recognition* – In answer to questions about reward and recognition, Ms Birchall-Scott explained the range of financial rewards available to staff. The examples cited were an annual bonus to the Agency's top 25% performers, a non-consolidated payment of up to a maximum of £3,000 for a one-off major piece of work for delegated grade staff, as well as a new Cabinet Office scheme for up 10 % of SCS staff.

6.3 The Board then invited questions from the staff and public observers, none was asked.

Item 7: Apprenticeships

7.1 {Name redacted: Section 40 FOIA} presented an update on the Agency's approach to the Government's apprenticeship initiative. Ms Birs outlined the background to the initiative, which was re-launched at the end of 2015 with the aim of delivering three million apprenticeships in the UK by 2020. The Agency, as with all other Government departments, has been set a target of a minimum of 2.3% of its 2015 headcount in apprenticeships roles by 31 March 2017 for each a year thereafter. {Name redacted:

Section 40 FOIA}. {Name redacted: Section 40 FOIA} then reported on the work that has been carried out so far, as well as on 'next steps' during 2016/17. reported that the majority of the apprenticeship posts (the Agency's target for 2016/17 is 28) will be met by converting existing posts in to apprenticeships. So far, the Agency has received expressions of interests from 45 applicants.

7.2 The Chairman thanked {Name redacted: Section 40 FOIA} for her update and sought the views of the Board, which centred on the following areas:

- *Remuneration* – The Board asked about the level of remuneration the new apprenticeships would receive. {Name redacted: Section 40 FOIA} reported that the successful applicants would receive the 'on entry' starting salary for the grade concerned.

- *Training* – In answer to a question about training, {Name redacted: Section 40 FOIA} advised that, in addition to 'on the job' training, all apprentices would receive one day's formal training per week. This would lead to a defined qualification.

- *Length of stay on the scheme* - In answer to a question about how long apprentices could remain on the scheme, {Name redacted: Section 40 FOIA} reported that apprentices would be expected to remain for a minimum of one year and could remain on the scheme for up to five years.

- *Agency-wide scope* – The Board asked if NIBSC would recruit any apprenticeships. In reply, {Name redacted: Section 40 FOIA} advised that at least one laboratory technician role at Administrative Officer grade had been identified, with possibly more to follow. Across the Agency, other posts suitable for the apprenticeship scheme have been identified, e.g., in Information Management Division, Finance and Procurement, and Human Resources. {Name redacted: Section 40 FOIA} added that the scheme was in an early stage and further work still needed to be done, e.g., to identify where the skills gaps were across the Agency. The Board thought the scheme would be particularly helpful for NIBSC.

7.3 The Board then invited questions from the staff and public observers. A member of staff asked how the Agency would ensure fairness in the performance management of new apprentices. {Name redacted: Section 40 FOIA} advised that the appointments would be based on merit; and, as with other members of staff, the apprentices' performance would be assessed fairly and in a structured manner.

7.4 The Chairman concluded the discussion by commending {Name redacted: Section 40 FOIA} and her colleagues for their work so far on the apprenticeships' scheme.

Item 8: National Institute for Biological Standards and Control (NIBSC) – update

8.1 Dr Christian Schneider presented a progress report on the work of NIBSC over the past six months. This covered the work of NIBSC's three programme boards (Standards, Research, and Control) which monitor progress and plan the strategic needs in their respective areas. Dr Schneider advised that the majority of NIBSC's objectives remain on track; these are reviewed on a quarterly basis by NIBSC's Senior Management Team. During the course of his report, Dr Schneider cited examples of NIBSC's work, which included the development of a significant number of new and replacement biological standards, including the first Ebola antigen standard. Additionally,

standards sales have continued to be strong across many areas, and control testing also continues to increase.

8.2 Looking ahead, Dr Schneider outlined the priorities for the next three months. Among these were the recruitment of staff into key scientific positions, for PhD studentships, as well as follow-up work on the recommendation from the Quinqennial Reviews of Advanced Therapies and Biotherapeutics.

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

- *Opening comments* – The Board welcomed the report, the contents of which they thought were impressive. The Board advised that science and disease does not stop at borders, which they thought was why international collaboration was so important. The Board welcomed the news of the signing of a MoU with NIBSC's counterpart in the Republic of Korea, and NIBSC'S decision to open up its PhD programme to international students.

- *Staff recruitment – In answer to questions about staff recruitment, Dr Schneider advised that he was hopeful that the horizon scanning post would be advertised soon.*

- *Gene therapy standards and batch release work* – Dr Schneider addressed questions that members of the Board had asked on these areas.

8.4 The Chairman then invited questions from members of the public and staff. None was asked.

Operational agenda

Item 9: Finance and Procurement report

9.1 Richard Humphreys outlined the financial performance of the Agency for the first seven months of the financial year 2016/17. Mr Humphreys reported that after allowing for dividends and financing, the Agency had a retained surplus of £2.2m, which was £2.5m above budget. Mr Humphreys went on to report that the Clinical Research Practice DataLink (CPRD) and NIBSC are ahead of their budgeted operating surplus positions, while the Regulator (Operating and Corporate divisions) was £0.5m below its budgeted position. As for the cash balance, the bank balance at the end of October 2016 stood at £128.8m., which was £1.3m higher than at the end of September 2016.

9.2 The Board welcomed the report and asked a number of questions about expenditure on Information Communications Technology (ICT), CPRD's income, and the income risk assessment at Schedule 8, all of which Mr Humphreys addressed. Jon Fundrey advised that the format of the monthly Finance and Procurement report would change, about which he had helpful discussions with Deborah Oakley, Chair of the Audit and Risk Assurance Committee, and Stephen Lightfoot, Non-Executive Director. Mr Fundrey said that the new version of the report would have a particular focus on ICT expenditure. To help inform the Agency's thinking, external challenge would be sought.

9.3 There were no questions from staff or public observers about the report

Item 10: Revised Terms of Reference for the Board

10.1 Aidan McIvor presented a revised set of terms of reference for the Board. Mr McIvor explained that the revised set of terms of reference reflected changes that had taken place over the past year, e.g., the introduction of periodic Board meetings in public session. The Board endorsed the proposed changes but asked that the proposed quorum of six should include one of the Board's two executive members. The Board also asked that at future public sessions, any vacant seats that had been allocated to public observers should be offered to additional staff observers.

10.2 In an answer to a question from a member of the Board about what would happen should any of the Board's objectives not be met, the Chairman advised that depending on the seriousness of the issue this would be for the Secretary of State to raise with the Chairman.

10.3 The Chairman then invited questions from members of the public and staff. None was asked.

Action: Directorate (Aidan McIvor) to revise the terms of reference and ensure that any vacant seats at future Board meetings in public session are made available for staff observers.

Item 11: Timetable for the Annual Report 2016/17

11.1 Rachel Bosworth presented the timetable for the Annual Report, 2016/17. While noting the timetable, the Board asked the text be made more reader-friendly and endorsed strongly the use of inforgraphics in the Annual Report.

11.2 The Chairman then invited questions from members of the public and staff. None was asked.

Item 12: Any Other Business (AOB):

12.1 The Chairman and the Board thanked members of the public and staff for attending the meeting.

12.2 The following item of AOB was presented.

NIBSC lunchtime scientific lecture programme for 2017

12.3 Dr Schneider invited members of the Board, along with members of NIBSC's Scientific Advisory Committee, to attend NIBSC' s programme of lunchtime scientific lectures, details of which Directorate (Aidan McIvor) would circulate.

12.4 While welcoming the open invitation to the lecture programme, the Chairman asked if the lectures could be recorded and shared via Webinar. Dr Schneider said he would liaise with colleagues in Communications Division about this.

Action: (i) Directorate (Aidan McIvor) to circulate details of the lecture programme.
(ii) NIBSC and Communications Division to liaise about the possibility of broadcasting the lectures via a Webinar. An update will be given at the next Board meeting under matters arising.

Date of next public meeting: 24 April 2016