MHRA Agency Board Meeting

MINUTES OF THE MEETING
16 December 2013

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 – from 12.30 hours
Ms Deborah Oakley	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
Dr Stephen Inglis	Director of NIBSC - from 12.00 hours
Mr Jonathan Mogford	Director of Policy
Ms Rachel Bosworth	Director of Communications
Name redacted: Section 40 of FOI Act (personal data)	Policy Division – item 8
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 and Legal Services

Dr Dorian Kennedy	DH sponsor representative
Mr Mark Wilson	Legal Services

Guests – for items 1-5 (inclusive)

Sir Patrick Sissons	Chair of NIBSC Science Review
Name redacted: Section 40	DH – assistant to Professor Sissons

Item 1: Apologies

1.1 Dame Valerie Beral	Non-Executive Director

Item 2: Announcements

2.1 After welcoming everyone, the following announcements were made.

- The joint Agency Board / Corporate Executive Team subscription lunch would take place after the board meeting at the nearby La Poule Au Pot restaurant.

Recent and upcoming meetings – to note

- The Chairman and Chief Executive attended the G8 Dementia Summit at Lancaster House in London on 11 December.

- The Chairman has been invited to attend a meeting on Early Access to Medicines at the House of Commons on 18 December. The invitation came from Sir Jeremy Heywood, Cabinet Secretary. Among those who will also attend the meeting are: Andrew Dillon of NICE, Oliver Letwin MP, George Freeman MP, Sir John Bell, Regius Professor of Medicine at Oxford.

- The Chairman, along with Gerald Heddell, Director of Inspection, Enforcement and Standards Division, and Jonathan Mogford, Director of Policy Division, will meet with Sir David Cooksey at MHRA's London offices on 19 December. Sir David has asked to discuss the digitisation of the pharmaceutical supply chain and CASMI (the Centre for the Advancement of Sustainable Medical Innovation).

Item 3: Conflicts of interest

3.1 The Chairman asked for any interests to be declared at the beginning of the meeting. Mr Martin Hindle asked that the minutes record his membership of Public Health England's Advisory Board.

Item 4: Minutes of the Agency Board extraordinary meeting of 16 October 2013

4.1 The draft minutes of the Board meeting of 16 October were adopted.

Item 5: Note of the Agency Board and CET away day of 12 November 2013

5.1 The Chairman and Board agreed to two suggested amendments from John Williams and Deborah Oakley, after which the note of the away day was adopted.

5.2 Dr Hudson reported that following the away day members of staff have been informed of the away day discussions and of the Board's endorsement of the need to rebalance the organisation over the coming three years. The communication to staff was done through divisional and unit meetings, as well as by a message to all staff from Dr Hudson on INsite.

DISCUSSION PAPERS

Item 6: NIBSC Science Review – update by Sir Patrick Sissons

6.1The Chairman welcomed Sir Patrick Sissons, Chair of the NIBSC Science Review, as well as Name redacted: Section 40 of the Department of Health (DH), to the Board meeting. The Chairman then invited Sir Patrick to provide an oral update on the work of the NIBSC Science Review to date.

6.2 Sir Patrick thanked the Chairman and the Board for the opportunity to provide the update, which was interim at this stage. Sir Patrick prefaced the update by expressing his gratitude to (Name redacted: Section 40) for helping to set up the review group and for all his support throughout the process.

6.3 Despite having been convened at short notice, and taking into account the diary constraints of the review panel's members, Sir Patrick said he had been pleasantly surprised by what the panel had been able to do so far. Indeed, despite the short notice, Sir Patrick said that he been able to form a strong panel of UK and European scientists who were able to have their first meeting (by telephone conference) on 25 November; this was followed by a site visit to NIBSC at South Mimms on 4 December. Sir Patrick said it was regrettable that, because of time constraints, he had not been able to recruit panel members with an industry background. Sir Patrick also referred to the three MHRA non-executive directors who served as observers on the review panel: Sir Alex Markham, Mr Martin Hindle and Ms Deborah Oakley. Sir Patrick said that their perspective of the work of NIBSC was much appreciated.

6.4 Sir Patrick said he was very grateful to Dr Stephen Inglis, Director of NIBSC, and the staff at NIBSC for arranging a the site visit which was of high quality and had impressed the panel members. Sir Patrick also thanked Dr Inglis for the range of the documentary material that was provided in advance of the visit. Sir Patrick commended Dr Inglis for his strong leadership, which he said was vital for maintaining the morale of NIBSC staff. Sir Patrick went on to say that the excellent visit programme, which was put together at such short notice, said much about the NIBSC's strength and depth as a scientific organisation. Sir Patrick said he would have preferred a two-day site visit, but that had not been possible because of diary constraints on the members of the review panel.

6.5 As a result of having to confine the review panel's visit to a single day, it had not been possible to visit the entire site at South Mimms or to examine and ask NIBSC staff about every aspect of NIBSC's work.

6.6 Sir Patrick reported that the review panel's overall impressions of NIBSC had been most definitely positive. In particular, the panel had been greatly impressed by what NIBSC has been able to do with a limited budget; for NIBSC's funding from DH has been static in real terms for over a decade. Sir Patrick went on to comment that the panel could not see any compelling reason for NIBSC to relocate from its present location. NIBSC's physical condition was good and its geographic location was strategically good, as it straddled the academic/research corridors from London, in particular, Imperial College, University College and the Crick Centre to Oxford and Cambridge.

6.7 During the update, Sir Patrick highlighted the need for succession planning for senior staff, many of whom were now in their late 50s or older. Sir Patrick also mentioned his surprise that the Scientific Advisory Committee had fallen into abeyance, something which should be rectified soon. Sir Patrick also commented on NIBSC's academic links, which will be clearly strengthened by the appointment of Dr Mary Collins on a two-year secondment as head of the new Advanced Therapies Unit.

6.8 Sir Patrick said his intention was for the review panel's report to be completed by the end of January 2014. This would allow for the report to be presented by Sir Patrick to the Agency Board at its meeting on 16 February 2014.

6.9 The Chairman, along with Dr Ian Hudson, and members of the Board thanked Sir Patrick for the interim report, and confirmed that the re-instatement of the NIBSC's Scientific Advisory Committee was seen as a priority, as was rigorous succession planning for staff. The Chairman also thanked Dr Inglis and his staff for their hard work in preparing for the review panel's visit.

Item 7: Progress against business targets

7.1 Jonathan Mogford, Director of Policy, presented the quarterly monitoring report on the Business Plan for the second quarter of the year 2013/14. The Board heard that the Agency is currently on track to meet 17 of its 23 targets, with a further two targets at amber/green status.

7.2 The remaining four targets have been given a red performance rating. Three of these were PM1a, PM1b and PM1d, which concern the validation of Type 1A, Type IB/II variations and granting of change of ownership applications. The Board heard that performance on these is expected to improve in quarters 3 and 4. The remaining red-rated target, PM7a, which sets a target for the number of NIBSC papers and scientific review articles in 2013, is unlikely to be met by year end. The Board looked forward to substantial and near-time progress towards achieving these targets.

Item 8: Timetable for the Annual Report 2013/2014

8.1 At the request of the Chairman, Richard Humphreys, deputy Finance Director, gave a verbal update on the timetable for the Annual Report, 2013/2014. The Board heard that a first draft of the Annual Report would be sent to the Corporate Executive Team and the Agency Board at the end of March 2014 on which the Board could comment further at the Annual Accounts seminar in May. As for the draft Annual Accounts, the National Audit Office's (NAO) final audit would begin on 27 May, with the NAO providing the Audit and Risk Assurance Committee with an audit opinion on 25 June. Richard Humphreys concluded his update by advising that the Agency's Annual Report and Accounts should be ready to put before Parliament on 11 July, a week before the Parliamentary recess.

STANDING ITEMS

Item 13: CEO's report for October and November 2013

10.1 Dr Hudson gave the update, which centred on the following areas:

- *SCOPE (Strengthening Collaboration for Operating Pharmacovigilance in Europe)* – Joint action on pharmacoviglance) – The European Agency for Health and Consumers has awarded MHRA 3.3 million Euros towards 70% of the costs of improving pharmacovigilance operations in Europe. The remaining 30% of the costs will be provided by participating regulators.

- *Visit by from the Irish Medicines Board* – a delegation from the Irish Medicines Board, led by its chief executive, Dr Pat O'Mahony, held a series of bilateral meetings with their counterparts at the Agency's London office on 22 November.

- *International Coalition of Medicines Regulatory Authorities (ICMRA)* – At the global regulators' summit in early December, it was agreed to establish a new network of regulatory authorities: ICMRA. This will be chaired by Canada. Among ICMRA's projects will be one on inspections, on which the UK will lead.

- *MHRA visit to India* – Gerald Heddell, Director of Inspection, Enforcement and Standards Division, met with senior officials from federal and state regulatory authorities in India, including the Drug Controller General of India.

- *Product issues* – An update was given on a number of product issues, including safety, quality issues, and where applicable, product recalls.

- *Hydroxyethyl Starch (HES)* – At its meeting in October, the Pharmacovigilance Risk Assessment Committee agreed that HES solutions for infusion should remain available for use in restricted patient populations for elective surgery.

- *EU negotiations* – Updates were given on the following: the Clinical Trials Regulations, the two Medical Devices negotiations; the Commission's proposal for a fees-regime for pharmacovigilance; and Tobacco Products Directive.

- *Animal rights demonstrations* – A small scale demonstration about the use of primates in the testing of vaccines for human use took place outside MHRA's London offices on 8 November. The demonstration, which involved ten protesters, passed off without incident. Dr Inglis, Director of NIBSC, reported that a larger scale demonstration involving approximately 60 protesters took place outside NIBSC on 14 December. This too passed off without incident.

- *Performance Management* – a new 'Managing Poor Performance' policy was launched on 1 October.

Item 15: Operations and Finance report

15.1 Peter Commins, Chief Operating Officer and Director of Finance, gave the highlights for the first seven months of the financial year 2013/14. They were:

- MHRA (Regulator) income: for the year to end of October 2013 was at £56.2m.
- NIBSC operational income: for the year to end of October 2013 was at £8.3m.
- CPRD income for the year to the end of October 2013 was at £4.3m.
- Operating income for the Agency was £79.0m, which was £2.1m below budget.
- Total operating costs at £70.8m were £6.6m below budget.
- November Cash report: the bank balance at the end of October was £177.9m.
- Capital expenditure was £7.7m out of the full year budget of £19.7m.
- Total Product Licensing deferred revenue at the end of October was £19.7m.
- The number of full-time equivalents at the end of October was 1,221, with 85 short-term contracts and 382 non-payroll employees.

Item 16: Minutes of the Corporate Executive Team (CET) meeting,

16.1 The minutes of the CET meeting of 1 October 2013 was noted.

Item 17: NEDs' updates

17.1 Professor Webb reported that he had been elected to the position of President Elect of the British Pharmacological Society from 1st January 2014 for 2 years, followed by a 2-year term as President. The Chairman congratulated Professor Webb on his appointment.

Item 18: Any Other Business (AOB)

18.1 There were no items of AOB.

Date of next Board meeting: Wednesday, 15 January 2014 at 14.00 hours

Aidan McIvor, Head of Directorate