MHRA Agency Board

MINUTES OF THE MEETING

19 February 2014

Present:

The Agency Board

Sir Gordon Duff	Chairman of MHRA
Dame Valerie Beral	Non-Executive Director
Professor Barry Furr	Non-Executive Director
Mr Martin Hindle	Non-Executive Director
Professor Vincent Lawton	Non-Executive Director
Sir Alex Markham	Non-Executive Director
Professor David Webb	Non-Executive Director - for items 1-6
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 National Institute of Biological Standards and Control – by telephone for items 1-5
Dr John Parkinson	Director of Clinical Practice Research Datalink – for item7
Mr John Wilkinson	Director of Devices – for item 6
Name redacted: Section 40 of FOI Act (personal data)	Head of Corporate Policy - for item 7
Name redacted: Section 40	Team leader, Business Planning and Corporate Management – for item 7
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

Guests – for items 1-4 (inclusive)

Professor Sir Patrick Sissons	Chair of NIBSC Science Review
Name redacted: Section 40	DH – assistant to Sir Patrick
Professor Terence Stephenson	Chair of the Review Panel on access by MHRA to clinical advice and engagement with the clinical community in relation to medical devices

Item 1: Apologies

1.1 Apologies were received from Deborah Oakley, Non-Executive Director, who was on leave; Jonathan Mogford, Director of Policy, who was attending the Heads of Medicines

Agencies' meeting in Athens, Greece; Rachel Bosworth, Director of Communications, who was on leave; and Mark Wilson, Legal Services.

Item 2: Announcements

2.1 The Chairman welcomed everyone to the meeting. The Chairman went on to announce that the draft terms of reference for the Audit and Risk Assurance Committee, which were due to come to the February Board, had been deferred to the next Board meeting.

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 meeting of 15 January 2014

4.1 The draft minutes of the Board meeting of 15 January were adopted.

DISCUSSION PAPERS

Item 5: Scientific Review of NIBSC: Report of the independent panel chaired by Professor Sir Patrick Sissons – submitted to the MHRA Board and the Chief Medical Officer of England

Overview and discussion

5.1The Chairman welcomed Sir Patrick Sissons and (Name redacted: Section 40) from the Department of Health to the Board and invited Sir Patrick to present his report.

5.2 Sir Patrick prefaced his remarks by thanking (Name redacted: Section 40) for his strong support throughout the process. Sir Patrick then went on to outline the context for the report, namely the request by Dame Sally Davies, Chief Medical Officer, in September 2013 for an independent panel, which Sir Patrick was appointed to chair, to consider and make recommendations about the current position and future direction of the scientific work of the institute and its geographic location. Sir Patrick explained the aims, composition and methodology of the independent review panel.

5.3 Sir Patrick said that he been able to form a strong panel of UK and European scientists at short notice, which had paid a site visit to NIBSC at South Mimms on 4 December. Sir Patrick said that he had been unable to recruit panel members who had worked in industry and that the panel's site visit had been confined to a single day. This was due to diary constraints on both counts. 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 (all of whom have previous experience in industry/commerce). Sir Patrick said that their perspective of the work of NIBSC was much appreciated.

5.4 Sir Patrick said he was very grateful to Dr Stephen Inglis, Director of NIBSC, and the staff at NIBSC for arranging the site visit and for the range of the documentary material that was provided in advance of the visit. Sir Patrick commended Dr Inglis for his strong leadership and went on to say that the excellent presentations and documentation, which had been put together at such short notice, said much about the NIBSC's strength and depth as a scientific organisation, and the performance of its management team.

5.5 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.

5.6 Sir Patrick said that the review panel thought that NIBSC's website was uninformative and needed attention. The panel also noted that only three-joint academic appointments had been made with partner universities; it was recommended that more should be done in this area. However, Sir Patrick did commend NIBSC on the appointment of Professor Mary Collins of University College London as head of the newly established Advanced Therapies Division. Sir Patrick also strongly recommended that the Scientific Advisory Committee should be reactivated.

5.7 The Chairman and the Board thanked Sir Patrick for his report, which collectively they thought was an excellent, insightful report that provided a blueprint for NIBSC to move forward. Dr Inglis also praised the report and advised that work on a number of the report's 19 recommendations, e.g. on NIBSC's website were already in hand. The Chairman and Board also endorsed Sir Patrick's recommendation about the need to reactivate the Scientific Advisory Committee, and that this was underway.

Next steps

5.8 Dr Hudson again thanked Sir Patrick for his report and advised the Board that the Agency would prepare a formal response to the report's findings within three months. The Chairman concluded by saying he would write to each of the members of the review panel to thank them for their contribution to the report.

Item 6: MHRA access to clinical advice and engagement with the clinical community in relation to medical devices – report by Professor Terence Stephenson

Overview and discussion

6.1The Chairman welcomed Professor Stephenson to the Board and invited him to present his report. Professor Stephenson said that he was keen to keep his presentation short, especially as he had already given a preliminary outline of the draft report to the Board on 15 January and he didn't want to repeat in detail what was set out in the report.

6.2 To set the report in context, Professor Stephenson explained why it had been commissioned; the composition of the expert group that he chaired, its aims, including its terms of reference; and its methodology. The latter helped inform the report's thinking and ultimately its findings. For the report's twelve recommendations fell under four distinct headings: (i) Organisation of clinical advice input, resources and leadership; (ii) Collecting and using device incident data; (iii) Communications and partnerships; and (iv) future and emerging challenges.

6.3 Professor Stephenson explained that for medical devices, patient safety is a multi-stakeholder activity that involves manufacturers, Notified Bodies, regulators, healthcare professionals and patients. Moreover, the medical devices landscape is one that is characterised by significant change, with a rapid expansion in both volume and complexity. Professor Stephenson referred the Board to examples in the report of the

scale and complexity of the devices sector. These included the development of hybrid products that combine medicine with a delivery device, e.g. a medicated stent.

6.4 Professor Stephenson commended MHRA for the prominent leadership it has given in the development and management of the regulatory system in the EU and beyond. Professor Stephenson noted that MHRA was the first regulatory authority in the world to identify problems with metal-on-metal hip replacements and to issue guidance on their management. The Board heard that much of the Agency's work on this, breast implants and other high profile device-related events has been valued and used by regulators around the world.

6.5 Professor Stephenson said that the report also covered some areas that were outside the remit of the group, but which nevertheless the group felt were too important to omit. The Board heard that the report's findings were deliberately distilled down to twelve recommendations, some of which fell within MHRA's remit, while some of the other recommendations were dependent on other stakeholders in the wider health community to take forward.

6.6 The Chairman, along with Dr Ian Hudson, and members of the Board thanked Professor Stephenson for his report, which they all thought was excellent. Mr John Williams said that the report highlighted many of the issues that had bedevilled the devices sector and would provide an excellent catalyst for change. Mr John Williams cautioned that the way regulation of devices is currently funded, was a restraining factor. Mr John Williams concluded his remarks by observing that the report was particularly timely as the Agency's new clinical director, Dr Neil McGuire, would join the Agency on 3 March.

6.7 During the subsequent discussion, several Board members recommended a number of relatively low cost measures, such as having additional sub-categories of codes for use in hospital records. These would be considered in the Agency's formal response to the report, including the possibility of having a pilot study to evaluate their merit.

Next steps

6.8 Dr Hudson again thanked Professor Stephenson for his report and advised the Board that the Agency would prepare a formal response to the report's findings within three months. Dr Hudson went on to report that the Agency planned to review progress one year on from the report's publication. Professor Stephenson welcomed Dr Hudson's announcement, adding that he would be willing to reconvene the review group in 2015 to assist with any such look back exercise. The Chairman concluded by saying he would write to each of the members of the review panel to thank them for their contribution to the report.

6.9 Before concluding the discussion, the Chairman and Board noted an article in *Clinical Medicine* (2014, Vol 14), hard copies of which were tabled at the meeting. The article ('Regulation of medicines and medical devices: contrasts and similarities') was authored by Sir Kent Woods, former Chief Executive of MHRA, and (Name redacted: Section 40), former Clinical Fellow at MHRA.

Item 7: Draft Business Plan, 2014/15

7.1(Name redacted: Section 40), Head of Corporate Policy, gave an update on business planning, in particular, the draft Agency Business Plan, 2014/15. The update was informed by a copy of the draft strategic narrative, the Agency planning grid and a copy of the draft Business Plan 2014/15.

7.2 (Name redacted: Section 40), explained that the green highlighted activities in the planning grid were those that would be tracked by Corporate Executive Team (CET) on a quarterly basis. Divisions and centres leading on the remaining activities would be responsible for tracking and reporting to CET as part of the established monthly reporting process. Key issues or decisions may be elevated to CET or Regulatory Group as necessary.

7.3 The Chairman and Board welcomed the update. Mr Martin Hindle, who is the Board's link to the executive on business planning, commended the Policy team for the high quality of their work to date. Mr Hindle said the draft business plan was a case of work in progress. Dame Valerie Beral recommended that, rather than relying solely on metrics, the draft Business Plan could benefit from examples, along the lines of those mentioned in the monthly CEO's report.

STANDING ITEMS

Item 8: Human Resources sub-committee - oral update

8.1 Professor Barry Furr, Chair of the Human Resources (HR) sub-committee, gave a summary of the highlights from the HR sub-committee meeting, which was held prior to the Board meeting. Professor Furr reported that the sub-committee's role was to challenge and advise and not to carry out any executive functions. Professor Furr went on to advise that the draft terms of reference for the sub-committee, which are currently being prepared, would come to the next Board for adoption.

8.2 Professor Furr advised that the membership of the sub-committee would need an additional member; it currently comprises two non-executive directors. This would be reflected in the terms of reference. Professor Furr went on to comment that, as he will leave the Board in July 2015, longer-term consideration would need to be given to planning for the membership of Board sub-committees. The Chairman advised that work is in hand with the Department of Health to recruit new board members in time for the summer of 2015.

Item 9: CEO's report for January 2014

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

- *New Corporate Executive Team appointment* – Mr John Quinn formally took up his appointment as Director of Information Management Division and Chief Information Officer on 1 February 2014.

- *Pension Statements (MyCSP)* – Work is in hand to identify why a large number of pension statements were sent to addresses that are no longer occupied by the intended recipients. This work will help inform the risk mitigation measures to ensure this error doesn't happen again. The Information Commissioner has been notified.

- *Herbals* – The first meeting of the independent Working Group on herbal practitioners, which is chaired by the deputy Chief Medical Officer, took place on 30 January.

- *Public Accounts Committee (PAC) report into the stockpiling of Tamiflu* – The PAC report into the decision to stockpile Tamiflu was published on 3 January

2014. MHRA will contribute to the Government's response, which is being prepared by the Department of Health.

- *Product issues: (i) Interferon beta (Rebif)* – The Pharmacovigilance Expert Advisory Group considered an assessment of thrombotic microangiopathy in advance of the February meeting of the Pharmacovigilance Risk Assessment Committee. (ii) Redacted: Section 43 (Commercial confidentiality).

- *Update on EU negotiations:* (i) Clinical Trials Regulation: Once legal and linguistic clarification of the draft text has been completed, the Regulation could be formally adopted by the European Parliament and Council in April or May 2014. (ii) Medical Devices (2 regulations): It now seems likely that securing an agreement in advance of the European Parliament elections in May is unlikely.

- *Early Access to Medicines* – Work continues across Government to agree a public document to announce the scheme.

- *Nicotine Containing Products* – MHRA's proposals on how it might take forward the provisions of the Tobacco Products Directive that relate to electronic cigarettes will be considered the European Parliament in February.

- *Devices Innovation Summit 2014* – Dr Hudson gave a presentation at the summit, which was held at the Royal College of Physicians.

- *Devices fees* – Dr Hudson and other officials from MHRA met with Health Minister Earl Howe in early February to discuss a proposed supplementary fee structure for medical devices.

- *CPRD and access to patient data* – Dr John Parkinson, Director of CPRD, joined Dr Hudson to give an update on the recent media interest in NHS England's leaflet and poster campaign about GPs collecting patient data.

- *Animal rights* – Around 50 demonstrators attended an animal rights' protest outside the Agency's offices on Buckingham Palace Road on 24 January. The protest went off without incident.

- *International Coalition of Medicines Regulatory Agencies (IMCRA)* – work has started on the Good Manufacturing Practice project, which MHRA is leading on.

Item 10: Operations and Finance report

10.1 Mr Peter Commins gave the highlights for the first three-quarters of the financial year 2013/14. They were:

- MHRA (Regulator) income: for the year to end of December 2013 was at £72.5m, which is in line with the budget.
- NIBSC operational income: for the year to end of December 2013 was at £13.8m, which was £2.9m (27%) above budget.
- CPRD income for the year to the end of December 2013 was at £5.7m, which was £2.3m (29%) below budget.
- Operating income for the Agency was £105.1m, which is £0.6m above budget.
- Total operating costs at £90.9m were £8.2m below budget.
- January 2014 cash report: the bank balance at the end of December was £167.0m.

- Capital expenditure was £9.7m out of the full year budget of £19.7m.
- Total Product Licensing deferred revenue at the end of December was £14.9m.
- The number of full-time equivalents at the end of December was 1,220, with 93 short-term contracts and 39 non-payroll employees.

Item 11: Minutes of the Corporate Executive Team (CET) meeting of 7 January 2014

11.1 The minutes of the CET meeting of 7 January 2014 were noted.

Item 12: NEDs' updates

12.1 Mr John Williams reported that he attended the last DH-hosted meeting for non-executive directors.

Item 13: Any Other Business (AOB)

13.1 *Joint Valedictory dinner for Professor Angus Mackay and Dr Shelley Dolan* – The Board heard that that Professor Mackay, who had retired from the Board in 2013 and had been suffered from an eye complaint during much of last year, was now able to attend a belated farewell dinner. The Chairman asked that arrangements be made to invite Professor Mackay and Dr Dolan, the latter of whom also retired from the Board in 2013, to a board dinner.

Action: Directorate to liaise with Professor Mackay and Dr Dolan about a mutually convenient date for a valedictory dinner.

13.2 *Civil Service Learning (CSL) training course for staff and Board members* – Peter Commins updated the Board on a Cabinet Office requirement for all staff and non-executive directors of Arms Lengths Bodies to receive training on data security and information awareness. The Board heard that the training course for non-executive directors would be rolled out shortly.

Date of next Board meeting: Wednesday, 19 March 2014 at 14.00 hours

Aidan McIvor
Head of Directorate