MHRA Agency Board

MINUTES OF THE MEETING

15 January 2014

Present:

The Agency Board

Sir Gordon Duff	Chairman of MHRA
Dame Valerie Beral	Non-Executive Director – by telephone until 3.40 pm
Professor Barry Furr	Non-Executive Director
Mr Martin Hindle	Non-Executive Director
Professor Vincent Lawton	Non-Executive Director
Sir Alex Markham	Non-Executive Director – by telephone
Ms Deborah Oakley	Non-Executive Director
Professor David Webb	Non-Executive Director – by telephone
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
Mr Jonathan Mogford	Director of Policy
Ms Rachel Bosworth	Director of Communications
Name redacted: Section 40 of FOI Act (personal data)	Vigilance and Risk Management of Medicines
Name redacted: Section 40	Head of Science Strategy – for items 1-4
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 1-4 (inclusive)

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 All members of the Board were able to join the meeting.

Item 2: Announcements

2.1 The Chairman welcomed everyone to the meeting, including Professor Terence Stephenson, who had come to the Board at very short notice. The Chairman thanked Professor Stephenson for his attendance, as well as for ensuring that he could attend the Board meeting on 19 February.

2.2 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 January 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. No conflicts of interest were announced.

Item 4: Minutes of the Agency Board meeting of 16 December 2013

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

DISCUSSION PAPERS

Item 5: MHRA access to clinical advice and engagement with the clinical community in relation to medical devices - oral update by Professor Terence Stephenson

5.1 The Chairman welcomed Professor Stephenson to the Board and invited him to give an update on the draft report he was preparing for MHRA. Professor Stephenson thanked the Chairman and the Board for the opportunity to provide the update, which was at an interim stage.

5.2 Professor Stephenson prefaced his update by expressing his gratitude to Mr John Wilkinson, Director of Devices Division, and (name redacted: Section 40), Head of Science Strategy, for their help and support throughout the process. Professor Stephenson also expressed his thanks for the discussions he had with Sir Gordon Duff and Dr Ian Hudson, which had proved to be very informative and helpful.

5.3 Professor Stephenson explained the aims, composition and methodology of the Independent Review Group, which he had been invited to chair. Professor Stephenson then set the draft report in context by giving a brief historical overview of the devices sector in the UK and beyond, in particular, by explaining how that sector had changed significantly over the past decade. Professor Stephenson outlined the difference between the regulation of medicines and medical devices in the UK, and went on to mention several recent high-profile events. These included the fraudulent use of industrial grade silicon in the PIP breast implants and the issues with metal on metal hip implants. Professor Stephenson said that these events had raised many questions about the regulatory system and the role of the MHRA in managing that system. Professor Stephenson also referred to the recent government reviews by Sir Bruce Keogh, NHS Medical Director on cosmetic surgery, and by Health Minister Earl Howe into the PIP breast implants.

5.4 After setting out the likely direction of travel of the review group's report, including an overview of the likely recommendations, there was a discussion with members of the Board. In conclusion, Professor Stephenson said the report should be ready by the end of January, which would be in time for the Board's meeting on 19 February.

5.5 The Chairman, along with Dr Ian Hudson, and members of the Board thanked Professor Stephenson for the interim verbal report.

Item 6: Nicotine-Containing Products – update

6.1, Name redacted: Section 40 – of Vigilance and Risk Management of Medicines Division, gave a short verbal update on the outcome of the negotiations on the Tobacco Products Directive (TPD) as they relate to Nicotine Containing Products, including electronic cigarettes.

6.2 The Board heard that on 18 December 2013, a compromise between Member States and the European Parliament (EP) was reached on the regulation of e-cigarettes. Other nicotine-containing products will not be regulated under the Directive. Under the compromise text, e-cigarettes which are not required to be authorised as medicines or which do not fall under the medical devices regime, will be regulated as consumer products with specific additional regulatory requirements. These regulatory requirements include a limitation on the nicotine content of e-cigarettes, a requirement for manufacturers and importers to report on ingredients in and emissions resulting from the use of e-cigarettes and provide toxicological data, a requirement for the provision of information to consumers including a health warning on packaging and restrictions on advertising and promotion.

6.3 Name redacted: Section 40 went on to report that the initial view of the Corporate Executive Team, was that, subject to further analysis, there are significant risks for the Agency in acting as the competent authority for the new regime for e-cigarettes with doubtful benefit to the Agency's core public health delivery function.

6.4 The Board welcomed the update and asked that Dr Hudson and the Corporate Executive Team consider in-depth the Agency's approach to NCPs. The Chairman asked that following such careful consideration a paper should be prepared for the Board's deliberations.

STANDING ITEMS

Item 7: Audit and Risk Assurance Committee (ARAC), 15 January 2014 – oral update

7.1 Professor Vincent Lawton gave a summary of the highlights from the Audit and Risk Assurance Committee meeting, which was held prior to the Board meeting. They were:

- *ARAC Terms of Reference (ToRs)* – The ARAC considered and made further suggested revisions to the draft ToRs. The final draft of the ToRs would come to the Board in February for sign off.

- *Update on the National Audit Office's (NAO) audit plan work* - The NAO has been on site in December 2013 and is due to commence the interim audit on 20 January 2014. So far, good progress is being made.

- *Internal audit* - PwC presented an interim report on the internal audit. Only one audit has been completed, about which ARAC expressed concerns. ARAC has been assured that the executive summaries and recommendations of the other audit reports will be sent to ARAC as soon as they are finalised and well before the March meeting.

- *Audit Tracker and Corporate Risk Register (CRR)* – Both documents were reviewed. Concerns were expressed about the risk associated with CPRD's KPIs, as well as the quality of the written KPIs. It was noted that the Board would

have an in-depth discussion of CPRD in April 2014. Also, the ARAC recommended that the CRR be shared with the Board at least once a year.

- *NIBSC* - Professor Mary Collins of University College London will begin her appointment as head of the new Advanced Therapies Division on 17 January 2014. ARAC warmly welcomed this news.

- *NIBSC - animal rights demonstrations* – ARAC commended the detailed planning and preparation that went into managing the animal rights demonstrations at NIBSC on 13 December 2013. The demonstration went off peacefully.

- *NIBSC Staff succession planning* – ARAC expressed concern about the need to address successful planning among senior staff, particularly at NIBSC. It was noted that the Board's new HR sub-committee would consider this matter at an early date.

- Audit workshops - PwC has invited ARAC members to attend an assurance and governance workshop on 30 January, also, DH will organise another Audit Chairs' meeting in the spring.

7.2 The Chairman welcomed the update, and the Board agreed that the CRR should come to the Board, although due care would have to be observed with such a sensitive document. The Board also commended staff for the way the animal rights demonstration had been handled at NIBSC on 14 December 2013. It was noted that the demonstrators too had made their point with a strong, yet peaceful, representation of their views, as is their entitlement.

Item 8: CEO's report for October and November 2013

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

- EU Clinical Trials – Political agreement had been reached in December 2013 on the Clinical Trials Regulation, although the UK's preferred (and shorter) assessment timescales were not included in the package.

- *Regulating e-cigarettes* – a compromise between Member States and the European Parliament was reached in December 2013 on the regulation of e-cigarettes.

- *Other EU negotiations* – Updates were given on the following: the two Medical Devices negotiations and the EU Commission's proposal for a fees-regime for pharmacovigilance.

- *Herbals* – Ministers have approved the Agency's approach and the terms of reference for the working group, which will hold its first meeting on 30 January 2014.

- *India visit*– 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, in early December 2013. The Agency will provide Good Manufacturing Practice training (9 days) to Indian inspectors in 2014. The Board also heard that Dr Hudson plans to visit India in May 2014, possibly accompanied by the Chairman.

- *Rebif (recombinant interferon beta) and thrombotic microangiopathy* – an article was published in the December 2013 edition of Drug Safety Update about Rebif. The article concerned an issue with Rebif's use in the treatment of multiple sclerosis and thrombotic microangiopathy. The Pharmacovigilance Expert Advisory Group of CHM will consider the matter at its meeting in January 2014.

- *Drug alerts* – An update was given on a number of products in December 2013, including safety and quality issues, and where applicable, product recalls.

- *Innovative Medicines Project* – Following a public consultation in 2012, policy development in this area is well advanced. Cross-government discussions are continuing, including a meeting that was held at the Houses of Parliament on 18 December, which was hosted by Sir Jeremy Heywood, Cabinet Secretary, and which Sir Gordon Duff attended.

- *Earlier access to medicines scheme* – An update was given on the progress of negotiations in Council. They are progressing more slowly than those on Clinical Trials.

- *Adaptive licensing* – Discussions between the European Medicines Agency (EMA) and the European Commission continue. MHRA is part of an EMA discussion group on adaptive licensing that has developed case studies and guidance.

- *Information Commission cases* – An update was given on the Freedom of Information Act (FOIA) requests that the Agency had received in December. Professor Barry Furr requested further information, which Dr Hudson said he would provide.

- *Litigation* – Two wholesale companies that sought to prevent MHRA from inspecting their premises had lost their cases at the High Court on 19 December.

ACTION: Dr Hudson to provide the Board with a fuller account of the FOIA requests for the month of December 2013.

Item 9: Operations and Finance report

9.1 Mr Peter Commins gave the highlights for the first two-thirds of the financial year 2013/14. They were:

- MHRA (Regulator) income: for the year to end of November 2013 was at £64.3m, which is £1.6m (2%) below budget.
- NIBSC operational income: for the year to end of November 2013 was at £10.9m, which was £1.5m (14%) below budget.
- CPRD income for the year to the end of November 2013 was at £5.1m, which was £1.6m (26%) below budget.
- Operating income for the Agency was £91.9m, which was £2.0m below budget.
- Total operating costs at £80.5m were £7.9m below budget.
- December Cash report: the bank balance at the end of November was £171.5m.
- Capital expenditure was £8.8m out of the full year budget of £19.7m.
- Total Product Licensing deferred revenue at the end of November was £14.6m.
- The number of full-time equivalents at the end of November was 1,217, with 72 short-term contracts and 37 non-payroll *employees*.

9.2 Mr Peter Commins also gave an update on work toward rebalancing the Agency over the next three years, which was commended by the Chairman.

Item 10: Minutes of the Corporate Executive Team (CET) meetings of November and December 2013

10.1 The minutes of the CET meetings of 5 November 2013 and 10 December 2013 were noted. In answer to a number of Board members' questions about the November 2013 minutes, Dr Hudson explained the type of business the Corporate Executive Team and Regulatory Group handle. Dr Hudson also reported on a recent innovation: the Monday morning hot topics meeting, which he chairs, and which is attended by all CET directors or their designated representatives. The Chairman noted this development with high approval.

Item 11: NEDs' updates

11.1 Mr Martin Hindle reported that he attended an in-house meeting earlier in the morning about Conflicts of Interest. The meeting was chaired by Mr Jonathan Mogford, Director of Policy.

Item 12: Any Other Business (AOB)

12.1 There were no items.

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

Aidan McIvor, Head of Directorate