MHRA Agency Board

MINUTES OF THE MEETING

16 December 2014

Present:

The Agency Board

Professor Sir Michael Rawlins	Chairman of MHRA
Professor Barry Furr OBE	Non-Executive Director – by telephone
Mr Martin Hindle	Non-Executive Director
Ms Deborah Oakley	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
Ms Rachel Bosworth	Director of Communications
Dr Siu Ping Lam	Director of Licensing –for items 1-5
Dr June Raine	Director of Vigilance and Risk Management of Medicines Division (VRMM) – for items 1-7
[redacted]	VRMM – for items 1-7
[redacted]	Policy – items 8-9
[redacted]	Policy Manager, Policy – items 8-9
[redacted]	Head of Science Strategy
Mr Aidan McIvor	Secretary to the Agency Board

Department of Health

Ms Liz Woodeson	DH sponsor representative

Item 1: Apologies

1.1 Apologies were received from Professor Dame Valerie Beral, Non-Executive Director (NED); Professor Vincent Lawton, NED; Sir Alex Markham, NED; Professor David Webb, NED. The Chairman reported that Professor Webb had sent on some comments about the away day on 23 January 2015, which he would share with the Board.

Item 2: Announcements

2.1 After welcoming everyone to the meeting, Sir Michael said it had been a huge privilege to take on the role as Chairman since his appointment on 1 December 2014. Sir Michael thanked his predecessor Sir Gordon Duff, Dr Hudson, the Chief Executive, and staff at MHRA for ensuring a smooth transition in late November and early December.

Item 3: Conflicts of interest

3.1 The Chairman asked for any interests to be declared at the beginning of the meeting. Martin Hindle asked that the minutes note his membership of the Advisory Board of Public Health England (for the item on Ebola) while Deborah Oakley asked that the

minutes note she is a Non-Executive Director at the Royal Free Hospital in London. The latter is an Ebola treatment centre.

Item 4: Minutes of the Agency Board meeting of 7 November 2014

4.1 The draft minutes of the Board meeting of 7 November 2014 were adopted.

Matters arising

4.2 The Board then reviewed the actions list from previous meetings. It was noted that a paper on the NIBSC / British Pharmacopeia Strategy would come to the Board in February 2015, while the Board would also continue to receive its next updates on the IT Strategy in February.

4.3 John Williams reported that for a number of weeks he had not received any electronic communication from the Agency that had been sent to other Board members. Sir Michael asked that Directorate contact the IT help desk team immediately after the Board meeting to look into the matter.

4.4 Professor Furr referred to the succession planning arrangements for the post of Director of NIBSC and felt that because of the critical importance of the post and the likely difficulty in identifying top grade candidates, we should appoint a search committee. Dr Hudson advised that he had started to address this and would be taking this forward in early 2015.

DISCUSSION ITEMS

Item 5: Ebola – oral update

5.1 Dr Siu Ping Lam, Director of Licensing, gave a progress report on the various strands of Agency work related to the current Ebola crisis. The Board heard that the cross-agency working group, which is led by Policy Division, and which involves representatives from Licensing, IE&S, VRMM, NIBSC, Devices, and Legal Services, continues to meet on a weekly basis and now feeds directly into the work headed by DH on the cross-Government programme. DH is co-ordinating the contribution on scientific, regulatory and clinical trial advice and UK government and international action on an Ebola vaccine and other treatments. Dr Lam went on to give an update on the current state of development of the Ebola trial vaccines, and the work of the aforementioned divisions in Ebola-related work.

5.2 Sir Michael thanked Dr Lam for the update and commended the Agency for its proactive approach in supporting those involved in developing vaccines and treatments. A number of Board members asked whether the Agency was sufficiently resourced to carry out Ebola-related work in addition to its other roles. Dr Hudson assured the Board that, at present, the Agency was managing the additional heavy workload. Sir Michael concluded the discussion by congratulating those staff involved with Ebola-related work.

Item 6: Triennial Review – oral update

6.1 Mr Peter Commins, Chief Operating Officer, gave an update on the course of the Triennial Review, which is considering the Agency's function and form, as well as performance, capability, efficiency and governance. The Board heard that the Review's timetable was tight, especially in view of the imminent Christmas and New Year holiday. Mr Commins explained that a first draft of the Review's report is expected in late February, with a final version of the report being submitted to Ministers in mid-March. Liz

Woodeson of DH said that, while such reviews are often seen as a bureaucratic process, they should be seen as an opportunity for the subject of the review to make the most of such a process. Ms Woodeson also mentioned DH's 'end to end' review of innovative medicines, which has a longer timescale (it will conclude in late 2015). Sir Michael said that the Minister, George Freeman, spoke about the end to end review and how the Agency could assist in its work during his meeting with the Corporate Executive Team on 15 December. Sir Michael concluded by thanking Mr Commins for the update.

Item 7: Strengthening vaccines risk management

7.1 Dr June Raine and [redacted] of VRMM gave an update on the Agency's strategy to strengthen vaccine risk management. The Agency's Corporate Plan 2013-2018 contains a specific objective to 'Explore how best to link NIBSC's laboratory-based research and analysis, Yellow Card data, and Clinical Practice Research DataBank (CPRD) records into a routine model of vigilance and surveillance for vaccines and other biologicals'. The Board heard that much of this work was being driven forward by the very successful cross-agency 'VISION' Network, which was established in the period leading to the merger with NIBSC in 2013. In addition a specific VRMM project has also been working to refine and further develop the agency's methods for integrating analysis of CPRD data, alongside Yellow Card data, into routine, proactive pharmacovigilance of vaccines.

7.2 The Board heard that this work has yielded several important outcomes during 2014, most notably publication in the British Medical Journal of VRMM's study, using CPRD data, of the safety of the pertussis vaccine in pregnancy. This had a major public health outcome in providing support for the Government's decision to continue the immunisation campaign for a further five years to reduce neonatal mortality from pertussis. The vaccine strategy has also supported enhanced pharmacovigilance of three other major new vaccines introduced in the UK during 2013/14.

7.3 Sir Michael thanked Dr Raine and [redacted] for the progress update, and congratulated everyone involved with the work.

Item 8: Business planning 2015/16 and the away day – update

8.1 [redacted] of Policy Division gave a progress report on the development of the draft Business Plan, 2015-16, which will be discussed at the Board/CET away day on 23 January 2015. [redacted] explained the work that had taken place since the last update to the Board on 7 November and went on to outline the proposed structure of the business plan. The Board heard that the draft business plan would comprise four main chapters: introduction, financial context, key strategic activities for 2015/16, and core business. This would be followed by three annexes: performance targets, performance metrics, along with collated strategic activities for 2015/16.

8.2 Sir Michael mentioned that, Professor Webb, who could not attend the Board meeting, sent on some comments about the away day on 23 January. The Board heard that Professor Webb thought it was important to discuss the Agency's lines of communications with healthcare professionals. Professor Webb also commented that it would be welcome if the away day could allow for an update on the work of CPRD. The Board heard that Professor Webb's comments would be taken into account when preparing the programme for the away day.

8.3 In answer to Deborah Oakley's query about the need to consider the wider financial context, Dr Hudson said that the away day programme would include a paper on Strategic Financial Choices, which Peter Commins would present on the day. Martin Hindle asked that the draft Business Plan include some consideration of the 'how, why

and when' for the Agency. Dr Hudson said that the away day would provide an opportunity to discuss a range of important questions, especially about the Agency's relationships with other stakeholders.

Item 9: Monitoring Report for the Agency's 2014-15, Business Plan activities, targets for Quarter 2

9.1 [redacted] of Policy Division gave a quarterly monitoring report on the Business Plan for Quarter 2 (July – September 2014). The Board heard that the Agency is currently on track to meet 20 of the 22 targets by 31 March 2015. Of the two that are not on track, the Board heard that the corrective actions put in place by Licensing Division would ensure that the target - of publishing 98% of UK Public Assessment Reports within 60 days - is met by year end. However, the target of providing biological standards materials within 6 working days would not be met by year-end. Although performance has improved considerably, the performance in quarter 1 was compromised, due largely to a major surge in demand for influenza standards.

9.2 The Board thanked [redacted] for the update, which was followed by discussion on whether the targets were sufficiently stretching. Deborah Oakley asked that future presentations should focus on the exceptions, that is, where targets are not being met. Dr Hudson assured the Board that the targets were demanding.

STANDING ITEMS

Item 10: CEO's report for November 2014

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

- *Yellow Card 50th anniversary celebrations* – The Agency hosted a forum discussion with stakeholders on 25 November, where George Freeman, Minister for Life Sciences, announced the roll out of a new adverse incident reporting portal. That portal will now cover medical devices and counterfeit products. A second event took place on 4 December at Church House in Westminster, at which the Chief Medical Officer, Dame Sally Davies, spoke. A further event (in Edinburgh) will take place in March 2015, details of which have already been sent to the Board.

    - *Products issues* – Updates were given on: Sodium Valporate (Epilim and Depakote), hydroxyethyl starch and Alteplase.

    - *Heads of Medicines Agencies (HMA) meeting* – The second HMA meeting of the Italian Presidency of the EU took place in Rome from 26-28 November 2014.

    - *European Medicines Agency (EMA)* – An update was given on temporary changes to the senior management arrangements at the EMA. Andreas Pott, Deputy Executive Director of the EMA, is now the Acting Executive Director.

    - *Global Regulators Summit* – Dr Hudson and Jonathan Mogford, Director of Policy, attended the summit of international medicines regulators in Beijing from 18-20 November 2014.

- *Update on CET appointments*: After a competitive selection process, Ms Vanessa Birchall-Scott has been appointed to the post of director of Human Resources. Ms Birchall-Scott will join the Agency on 19 January 2015.

Item 11: Finance and Procurement report

11.1 Mr Peter Commins gave the highlights for the first seven months of the financial year 2014/15. They were:

- MHRA (Regulator) income: for October 2014 was at £9.7m.
- NIBSC operational income: for year to end of October 2014 was at £10.1m.
- CPRD income: for year to end of October 2014 was at £4.7m.
- Operating income for the Agency was £89.0m, which is £0.5m above budget.
- Total operating costs for the year to end of October 2014 were £72.2m, which is £5.0m below budget.
- The Agency's bank balance at the end of October 2014 was £203.4m.
- Capital expenditure was £5.1m out of the full year budget of £13.9m.
- Total Product Licensing deferred revenue at the end of October 2014 was £17.4m.
- The number of full-time equivalents at the end of October 2014 was 1,209, with 127 short-term contracts and 49 non-payroll employees.

Item 12: Minutes of the Corporate Executive Team (CET) of November 2014

12.1 The minutes of the CET meeting of 11 November 2014 were noted.

Item 13: Non-Executive Directors' (NEDs) updates

13.1 Deborah Oakley reported that she had seen a presentation and discussion of the Civil Service's talent management programme, which DH had arranged for NEDs from arms- length bodies.

Item 14: Any Other Business (AOB):

14 (a) Timetable for 2014/15 Annual Report

The Board noted the timetable for the production annual report.

14 (b) Board meeting dates for 2015

[redacted – personal information re staff member's health]

Date of next Board meeting: 23 January 2015.

Aidan McIvor
Head of Directorate