

MHRA Agency Board Meeting

MINUTES OF THE MEETING

16 October 2013

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 - for items 1-10
Professor Vincent Lawton	Non-Executive Director
Sir Alex Markham	Non-Executive Director
Ms Deborah Oakley	Non-Executive Director
Professor David Webb	Non-Executive Director
Mr John Williams	Non-Executive Director – for item 1-9

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
Mr Jonathan Mogford	Director of Policy
Ms Rachel Bosworth	Director of Communications
Dr John Parkinson	Director of Clinical Practice Research DataLink – for items 1-6 only
Name redacted: Section 40 of FOI Act (personal data)	Head of Corporate Policy, Policy Division – items 7&8
Mr Aidan McIvor	Head of Science Strategy
Name redacted: Section 40	Secretary to the Agency Board
	Executive Assistant to the Chairman

Department of Health and Legal Services

Dr Dorian Kennedy	DH sponsor representative
Name redacted: Section 40	'Fast stream' recruit - observer
Mr Mark Wilson	Legal Services

Item 1: Apologies

1.1 None was received.

Item 2: Announcements

2.1 After welcoming everyone, the Chairman made the following announcements.

- *Dr Hudson* – The Chairman welcomed Dr Hudson to the Board in his capacity as chief executive. Dr Hudson took up his appointment on 21 September.
- *Sir Alan Langlands* – The Chairman reported that Sir Alan Langlands had resigned from the Agency Board with effect from 20 September 2013. Sir

Alan's decision was dictated by the very heavy demands on his time since becoming Vice Chancellor of the University of Leeds in September 2013. Sir Gordon asked that the minutes record the Board's gratitude to Sir Alan for his previous service to MHRA.

- *Order of business* - Sir Gordon advised that the order of the business would be subject to change as Dr John Parkinson, Director of CPRD, had to leave for Heathrow by 2.30 pm and John Williams, Non-Executive Director, had to attend a meeting with Professor Terence Stephenson at 4.00 pm.

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. Later on, Professor Dame Valerie Beral declared an interest (as a professional user) of the Clinical Practice Research DataLink.

Item 4: Minutes of the Agency Board extraordinary meeting of 4 September 2013

4.1 The revised draft minutes of the extraordinary Board meeting of 4 September were adopted without further amendment.

Item 5: Minutes of the Agency Board meeting of 18 September 2013

5.1 The draft minutes of the Board meeting of 18 September were adopted.

DISCUSSION PAPERS (in the order the papers were taken)

Item 6: Clinical Practice Research DataLink's Key Performance Indicators

6.1 Dr John Parkinson, Director of the Clinical Practice Research DataLink (CPRD), presented a half-year report on CPRD's key performance indicators (KPIs) for 2013/2014. The report covered CPRD's data and clinical trials income, its operating costs, its sales and marketing KPIs. The report also outlined KPIs for CPRD's governance arrangements and impact on public health.

6.2 During the opening presentation, Dr Parkinson reported on CPRD's achievements during the year. These included the development of CPRD's broad range of commercial activities, and the progress achieved in signing up NHS general practitioners – a 50% increase since CPRD was established in April 2012. Dr Parkinson acknowledged that much had changed in the environment in which CPRD operates since the original business case for CPRD was prepared over three years ago. Dr Parkinson went on to say that he recognised that CPRD was not meeting some of its targets in the immediate term as it bedded in and developed its portfolio of activities.

6.3 The Chairman and Board thanked Dr Parkinson for his paper. Professor Furr wanted the KPIs to be further strengthened and offered to provide some comments on the KPI's outside the meeting. Many Board members acknowledged the challenges and noted what had been achieved as CPRD bedded in and began to operate in an environment different from the one that was envisaged when the original business for CPRD was prepared. The Chairman and many Board members advised that what needed to be done now was to manage expectations about the rate of achievement of CPRD's objectives in the changed climate in which it was operating. Accordingly, it was agreed that the original business case for CPRD may need a 'refresh'; that a detailed review

should be done immediately after the end of the current financial year. It was agreed that a substantive part of the Board's meeting in April 2014 should be given over to CPRD.

6.4 Meanwhile, Martin Hindle invited Dr Parkinson to give a presentation on the work of CPRD to the Academic Health Science Network in Leicester, which Martin Hindle said should prove highly beneficial in developing links with a wide range of relevant networks.

Item 7: Update on Public Science Hub

7.1 The Chairman reported that following the Board's discussions on 4 September and 18 September, he had written to Dr Felicity Harvey, MHRA's senior sponsor at DH, setting out the Board's position on the Public Science Hub proposal. Copies of the letter were tabled at the meeting. Now that the Board's position had been communicated to DH, the Agency awaited the outcome of an analysis by DH of the business case for a possible public science health hub at Harlow, Essex.

7.2 The Chairman thanked members of the Board for their comments on the draft terms of reference of the NIBSC Science Review. Again, copies of the terms of reference were tabled at the meeting. The Chairman advised that Professor Sir Patrick Sissons, formerly Regius Professor of Physic at the University of Cambridge, would chair the review panel. The meeting heard that Dr Tom Barlow at DH would co-ordinate the work of the review panel, whose members were in the final stages of being appointed. The Chairman reported that three members of MHRA's Board would act as observers on the review panel. They were: Martin Hindle, Sir Alex Markham and Deborah Oakley. It was noted that Mr Hindle is also a member of Public Health England's Advisory Board.

7.3 The Chairman asked that copies of Sir Alex Markham's report on NIBSC from 2008 be sent to members of the Board for their information only.

Action: Directorate to send copies of Sir Alex Markham's report on NIBSC to the Board.

Item 8: Update on Strategy and Business planning – 12 November away day

8.1 Jonathan Mogford, Director of Policy Division, and Dan Markson, Head of Corporate Policy outlined the draft programme for the Agency Board / Corporate Executive Team away day on 12 November 2013. The away day would be centred on the strategic direction of the Agency as set out under the five themes of the Corporate Plan and in particular how these could be achieved in a changing financial environment. The Board welcomed the update and endorsed the proposed programme, which had been discussed previously with the Chairman and the Chief Executive.

Item 9: Devices update

9.1 Dr Ian Hudson gave an update on recent developments in Devices Division. The update covered the revision of the EU Regulations for Medical Devices, progress in recruiting clinical specialists and discussions about securing sustainable funding for MHRA's devices work.

9.2 As regards clinical input into device work, the Board heard that an independent review on the Agency's access to clinical advice in the devices field is underway under the chairmanship of Professor Terence Stephenson. The update paper included the draft terms of reference of the Stephenson Review. The Board also heard that a junior clinical specialist had been appointed on 14 October, while discussions are well advanced on securing the appointment of a senior clinical specialist.

9.3 As regards devices funding, the Board heard that the DH has asked MHRA to prepare an options paper which will go to Ministers, possibly in November.

Item 10: Strategic finance

10.1 Peter Commins, Chief Operating Officer and Director of Finance, presented a paper on Strategic Finance. The paper identified the strategic position of MHRA's three centres: the Regulator, NIBSC, and CPRD and set out proposed financial principles to manage each centre. The paper also provided updates on the Regulatory Centre's vulnerability around National Periodic Fees and the trading imbalance work with the EU; the latter being informed by a time-recording exercise that was carried out in July 2013 across MHRA's operating divisions.

10.2 Peter Commins advised that the paper and the subsequent Board discussion would help inform a Budget Paper that would be discussed at the joint Board / Corporate Executive Team away day on 12 November. The Chairman and Board commended Peter Commins on his paper, which they thought would help focus the Board's thinking on the discussions that would take place on 12 November.

10.3 A number of Board members asked that the away day on 12 November must address the issue of prioritisation of the broad spectrum of MHRA's work. There was a strong feeling that the organisation must decide on what it must do and what work or activities it should disengage from, especially if others in Europe or beyond are able and willing to carry out such work. Many Board members said they appreciated fully that, since the merger with NIBSC in April 2013, MHRA was a larger and much more complex organisation, especially in the ways it was funded. Indeed, the Board asked that the discussion on 12 November should also focus on the financial and organisational challenges and opportunities that lie ahead over the next three to five years.

Item 11: Human Resources sub-committee of the Board

11.1 The Chairman welcomed Rebecca Starling, Director of Human Resources (HR) to her first meeting of the Agency Board. The Board then considered Rebecca Starling's paper on a sub-committee on HR. The paper was informed partly by earlier discussions by the Board about setting up a sub-committee that could address a range of strategic HR-related issues, including manpower planning. The paper recommended that a sub-committee be set up that would comprise two Non-Executive Directors and be attended by the Chief Operating Officer, the Director and Deputy Director of HR.

11.2 The Chairman and Board welcomed Ms Starling's paper. Professor Barry Furr, Non-Executive Director, was invited to chair the new sub-committee, while Mr John Williams, Non-Executive Director, was invited to serve as the sub-committee's second Board member. The Chairman sought and received the Board's endorsement of the new sub-committee and of its membership. Ms Starling said she would arrange a preliminary meeting with Professor Furr and Mr Williams to discuss meeting dates and the drafting of the terms of reference of the new sub-committee, the latter of which would come to Board for formal endorsement.

Action: HR Division to draft terms of reference for the new sub-committee.

STANDING ITEMS

Item 12: Audit and Risk Assurance Committee (ARAC), 16 October 2013 – oral update

12.1 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:

- It was the first formal meeting of the Audit and Risk Assurance Committee (ARAC) meeting, and the first such meeting to be attended by MHRA's new Chief Executive, Dr Hudson. The ARAC meeting was also attended by new representatives from the National Audit Office (NAO) and PwC.
- *NAO Factsheet & HM Treasury Audit Committee Handbook* – The Committee considered these documents, which were thought to be very useful.
- 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 December for sign off.
- *HR report* – Rebecca Starling and (name redacted: Section 40) (deputy HR director) presented a report on the work of HR Division for the last financial year.
- *Audit Planning Report 2013-2014* – ARAC received a progress report from the NAO on its audit of MHRA. Professor Lawton reported that ARAC impressed upon the NAO the need to complete as much of their audit field work in time to get the accounts signed off in early July.
- *Internal Audit plan 2013/14 (PwC)* – ARAC considered the first draft of the audit plan for the current financial year, which PwC acknowledged was much delayed. PwC agreed to ARAC's request to defer work on an audit on MHRA's work with the Laboratory of the Government Chemist to 2014/15.
- *Audit Tracker and Corporate Risk Register* – Both documents were reviewed.
- *Assurance mapping* – ARAC was updated on the assurance mapping project.

Item 13: CEO's report for September 2013

10.1 Before Dr Hudson presented Chief Executive's report for September 2013, he asked that minutes record his gratitude to his predecessor, Sir Kent Woods, for his all his support over the past ten years. Dr Hudson also thanked the Chairman and members of the Board, and officials in MHRA and at DH for all the support he had received in the weeks before and immediately after taking up his appointment as chief executive on 21 September. Dr Hudson said he was looking forward to working with Chairman and the Board.

Dr Hudson went on to present the update, which centred on the following areas:

- *Quality of generic medicines* – An update was given on recent inspection issues and the steps that the MHRA is taking to deal with the findings.
- *EU negotiations* – Updates were given on the following: the Clinical Trials Regulations, the two Medical Devices negotiations; the EU Commission's proposal for a fees-regime for pharmacovigilance; and Tobacco Products Directive.,

- *Paracetamol* – MHRA held a meeting with representatives of National Institute for Health and Care Excellence (NICE) to discuss key data which formed the basis of the recommendation that paracetamol should not routinely be used for the treatment of osteoarthritis. The Commission on Human Medicines' ad hoc Working Group on Analgesics would discuss this at its meeting on 18 October. Dr Hudson also reported that he, along with the Chairman, would have an introductory meeting with Professor Haslam, Chairman of NICE, on 29 October.

Item 15: Operations and Finance report

11.1 Peter Commins gave the highlights for the first five months of the financial year 2013/14. They were:

- MHRA (Regulator) income: for the year to end of August 2013 was at £40.0m, which is £0.4m (1%) below budget.
- NIBSC operational income: for the year to end of August 2013 was at £5.1m, which is £0.8m (18%) above budget.
- CPRD income for the year to the end of August 2013 was at £3.0, which was £0.5m (68%) below budget.
- Operating income for the Agency was £56.2m, which was £0.7m below budget.
- Total operating costs at £50.2m were £4.7m below budget. The overall operating costs included staff costs at £28.9m and other operating costs at £21.3m.
- September Cash report: the bank balance at the end of August was £160.5m.
- Capital expenditure was £5.4m out of the full year budget of £19.6m.
- Total Product Licensing deferred revenue at the end of August was £12.9m.
- The number of full-time equivalents at the end of July was 1,215, with 59 short-term contracts and 32 non-payroll employees.

Item 16: Minutes of the Corporate Executive Team (CET) meeting, 13 September'13

12.1 The minutes of the CET meeting of 13 September 2013 was noted.

Item 17: NEDs' updates

14.1 Professor Dame Valerie Beral reported that, because of long-standing diary commitments, which were made before she had been appointed to the Board in September 2013, she would be unable to attend any Board events until February 2014.

Item 18: Any Other Business (AOB)

There were no items of AOB.

Date of next Board meeting: Monday, 16 December 2013 at 10.30 hours

Aidan McIvor,
Head of Directorate