

MHRA Agency Board

MINUTES OF THE MEETING

19 March 2014

Present:

The Agency Board

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| 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 - by telephone link |
| 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

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| Dr Ian Hudson | Chief Executive |
| Mr Peter Commins | Chief Operating Officer and Finance Director |
| Ms Rachel Bosworth | Director of Communications |
| Ms Rebecca Starling | Director of Human Resources |
| 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

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| Dr Dorian Kennedy | DH sponsor representative |
| Name redacted: Section 40 | Legal Services |

Item 1: Apologies

1.1 Apologies were received from Dame Valerie Beral, Non-Executive Director; Mr Jonathan Mogford, Director of Policy; and Mr Mark Wilson, Legal Services.

Item 2: Announcements

2.1 The Chairman welcomed everyone to the meeting.

Item 3: Conflicts of interest

3.1 The Chairman asked for any interests to be declared at the beginning of the meeting; none were declared.

Item 4: Minutes of the Agency Board meeting of 15 February 2014

4.1 The draft minutes of the Board meeting of 19 February were adopted.

DISCUSSION PAPERS (in the order in which the items were taken)**Item 5: Draft Budget 2014/15**

5.1 Mr Peter Commins, Chief Operating Officer, presented the Agency's budget for 2014/15. This set out the recommended budgets for each of the Agency's three centres: the Regulator, the National Institute for Biological Standards and Control (NIBSC) and the Clinical Research Practice Datalink (CPRD). The paper set out the reasons for the proposed changes in the divisional budgets, as well as where reductions in the Agency's headcount would be made across the Agency. The Board also received an update on work to sub-let one of the Agency's floors; so far, the level of interest shown by possible tenants has been encouraging. The Board also heard that there would be more opportunities for staff to work at NIBSC, where 50 new work stations have been installed.

5.2 The Chairman and the Board thanked Mr Peter Commins for the budget paper. A number of Board members highlighted the funding of different parts of the agency, where, for example, CPRD had not yet spent all its allocated funds from DH, whereas Devices had received a cut in funding over recent years. Peter Commins explained that CPRD funds could not cross-subsidise Devices work; CPRD's funding model was separate and the money that DH had earmarked for CPRD, as agreed in CPRD's original business case, could not be diverted to other areas of the agency, such as the Devices Division. Peter Commins went on to explain that the Board would receive an update on CPRD on 16 April; moreover, much of the Agency Board / Corporate Executive Team away day on 21 May would be given over to a discussion of CPRD's future.

5.3 The Chairman thanked Mr Peter Commins for the update on CPRD, as well as the budget paper, which the Board endorsed.

Item 6: Revised draft Business Plan, 2014/15

6.1 (Name redacted: Section 40), Head of Corporate Policy, gave an update on the changes that had been made to the draft Business Plan since it was first presented to the Board at its meeting on 19 February 2014. This followed feedback from the Board on the draft Business Plan, the Agency's strategic narrative as well as on an internal planning grid. In particular, (Name redacted: Section 40) cited changes to Chapter 1 of the Business Plan, which addressed a request for less reliance on metrics to illustrate what the Agency planned to do.

6.2 The Chairman and Board welcomed the update. Mr John Williams advised that the wording on page 4 of the draft Business Plan about the new Advanced Therapies Division at NIBSC needed consideration in light of the work done in the NIBSC integration project. Professor Furr advised that reference to the need for human resources planning should be made in the draft Business Plan.

6.3 (Name redacted: Section 40) thanked the Board for its comments, which he said would be reflected in the final version of the Business Plan. Subject to these modifications, the Board then agreed the Business Plan, which would be published at the end of March.

Item 7: Progress against Business Targets, Quarter 3

7.1 (Name redacted: Section 40), then presented the quarterly monitoring report on the Business Plan for the third quarter of the year 2013/14. The Board heard that the Agency is currently on track to meet 18 of its 23 targets, with one target at amber/green status.

7.2 As for the remaining four targets, they 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 quarter 4. As for the remaining red-rated target, PM7a, which sets a target for the number of NIBSC papers and scientific review articles in 2013, this is likewise unlikely to be met by year end. The Chairman and Board welcomed the update, but noted the four red signals and recommended an exploration of ways to turn them to green in the near future.

Item 8: The People Strategy

8.1 Ms Rebecca Starling, Director of Human Resources, presented the Agency's People Strategy, which sets out the people and human resources elements of the Corporate Plan and their successful delivery at Centre and divisional level. The Board heard that the People Strategy was informed by the discussion at the Corporate Executive Team and at the Board's HR sub-committee, which is chaired by Professor Barry Furr.

8.2 The Chairman and Board welcomed the People Strategy, which Professor Furr said was the first HR Strategy that the Agency had produced since he had joined the Board. Professor Furr commended Ms Starling for her work on the People Strategy, which he said marked a good beginning for the Agency's HR work. Professor Furr asked that mentoring be included in the Strategy. Ms Oakley commented that there was a lot to do. The priorities for the first year had been listed but resources would inevitably focus at first on remedial work in respect of the staff data issue. Ms Oakley suggested that a "roadmap" indicating order of priorities and timescale would be helpful. Prof Furr considered that this was not part of the "strategy".

8.3 The Chairman thanked Ms Starling for the People Strategy, which the Board endorsed. The Chairman then asked that the minutes record the Board's best wishes to Ms Starling who would leave MHRA on 21 March to take up a post in Switzerland.

Item 9: Human Resources sub-committee terms of reference

9.1 Professor Barry Furr, Chair of the HR sub-committee, presented a set of draft terms of reference to the Board for adoption, which the Board endorsed. Professor Furr asked that another Board member serve on the sub-committee, which currently only has two non-executive directors. It was agreed that expression of interest would be sought in the weeks ahead.

Item 10: Audit and Risk Assurance Committee terms of reference

10.1 Professor Vincent Lawton, Chair of the Audit and Risk Assurance Committee, presented updated draft terms of reference to the Board for adoption, which were duly adopted after discussion.

STANDING ITEMS

Item 11: Audit and Risk Assurance Committee meeting, 19 March - oral update

11.1 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 a busy meeting, which Bronwyn Baker, Head of Internal Audit at DH, attended as an observer.
- *ARAC Terms of Reference (ToRs)* – The ARAC noted the revised draft ToRs, which would go to the Board for adoption.
- *Update on the pensions* - Rebecca Starling, Director of HR, briefed the ARAC on a significant loss of staff data when annual benefit pension statements were sent out in December 2013. The ARAC heard that the system was complex, involving MHRA, DH payroll and MyCSP, that once the data loss had been brought to the Agency's attention a major investigation was launched into why the loss had occurred across the system involving all parties, why the data contained errors, why this had been the case and what remedial action has been taken to ensure this would not happen again. While expressing grave concern about the data loss, the ARAC was reassured by the recent action taken by the Agency, including the involvement of John Quinn, Chief Information Officer, in the follow-up work. A progress report will be given at the next ARAC meeting in June.
- *Update on the National Audit Office's (NAO) audit plan work* - The ARAC reviewed the audit progress report on the 2013/14 financial statement. So far, good progress is being made with the programme of final audit work.
- *Internal audit* – ARAC reviewed the progress of the internal audit work as an outline of the internal audit plan for the next two financial years.
- *Audit Tracker and Corporate Risk Register (CRR)* – Both documents were reviewed, the latter of which was set out in a much more reader-friendly format. Copies of the CRR were tabled at the Board meeting for information only.
- *Any other Business (AOB)*: Two items were considered under AOB: (i) e-cigarettes, on which Dr Ian Hudson gave an updates and (ii) ARAC membership. As to the latter, an additional (fourth) member of ARAC is being sought.

Item 12: CEO's report for February 2014

12.1 Dr Hudson gave the following updates:

- *Pension Statements (MyCSP)* – The Information Commissioner, who was informed of the data loss, has advised that he will take no further action following the reporting of the incident. Meanwhile, work continues to ensure such a data loss will not happen again.
- *Visit to U.S. FDA and Health Canada* – Dr Hudson, Chief Executive, and Mr Jonathan Mogford, Director of Policy, paid an official visit to the U.S. FDA and Health Canada from 5-7 February 2014.
- *Stephenson Review* – The report by Professor Terence Stephenson on the provision of clinical advice to the agency in relation to medical devices was

submitted to Health Minister Earl Howe. The agency's response to the report's findings will be ready by June 2014.

- *Customer First* - The agency's customer services team, which is located within Communications Division, has achieved national accreditation with Customer First.
- The All Staff Meetings – Five all staff meetings took place between 14-18 March. One was held at NIBSC, while the other four were held at 151 Buckingham Palace Road.
- Product issues: updates were given on Sodium valproate and Alteplase.
- Clinical Trials Regulation: The plenary vote by the European Parliament is expected to take place on 3 April.
- The revised Tobacco Products Directive (TPD) was formally agreed by the European Parliament on 26 February. Member States are expected to adopt the revised Directive in March 2014. The agency is working with the Department of Health Tobacco Team to consider what role, if any, the agency will play following the transposition of the TPD.
- *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 by the European Parliament in February.
- *Devices* – Dr Neil McGuire, senior clinical specialist (Devices), started work with the agency on 2 March. The Chairman and Board welcomed the appointment of a permanent senior medical doctor within Devices Division, a role that had been filled on an interim locum basis by Board member Mr John Williams.
- Legal issues: updates were given on two judicial reviews.

Item 13: Operations and Finance report

13.1 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 January 2014 was at £82.5m, which was 1% above budget.
- NIBSC operational income: for the year to end of January 2014 was at £15.1m, which was £2.9m (24%) above budget.
- CPRD income for the year to the end of January 2014 was at £6.3m, which was £3.0m (32%) below budget.
- Operating income for the Agency was £105.1m, which is £0.6m above budget.
- Total operating costs at £100.9m were £9.0m below budget.
- January 2014 cash report: the bank balance at the end of December was £168.1m.
- Capital expenditure was £11.0m out of the full year budget of £19.7m.
- Total Product Licensing deferred revenue at the end of January was £14.1m.
- The number of full-time equivalents at the end of January 2014 was 1,224, with 97 short-term contracts and 44 non-payroll employees.

Item 14: Minutes of the Corporate Executive Team (CET) meeting of 11 February 2014

14.1 The minutes of the CET meeting of 11 February 2014 were noted.

Item 15: NEDs' updates

15.1 Mr Martin Hindle, Non-Executive Director, said that he, along with other members of the Board who attended the MHRA Annual Lecture on 6 March, thought that the lecture and subsequent reception was a great success. The Chairman asked Rachel Bosworth, Director of Communications, to convey the Board's thanks to those involved with the planning and preparation of the Annual Lecture.

Item 16: Any Other Business (AOB)

16.1 *Lunchtime lectures* – There was full support for a suggestion from the Chairman for a lunchtime lecture programme for staff by members of the Board. The Chairman said it was as a very good way to raise the profile of the board as well as enabling staff to get to know the Agency's our non-executive directors, and learn about their area of expertise. Each lecture would most likely take place on a board meeting day and would run from 12.00pm to 12.30pm and would be followed by a short Q&A session. A rota will be set up to include all NEDs and titles of talks relevant to MHRA staff that they could offer. Once all the necessary practical considerations have been addressed, details of the first lecture will appear on INsite.

Date of next Board meeting: Wednesday, 16 April 2014 at 14.00 hours

Aidan McIvor
Head of Directorate