

**MHRA Agency Board**  
**MINUTES OF THE MEETING**  
 23 March 2015

**Present:***The Agency Board*

Professor Sir Michael Rawlins	Chairman of MHRA
Professor Dame Valerie Beral	Non-Executive Director
Mr Martin Hindle	Non-Executive Director
Professor Vincent Lawton	Non-Executive Director
Professor Sir Alex Markham	Non-Executive Director – by telephone
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 (in the order of the business taken)*

Dr Ian Hudson	Chief Executive
Mrs Rachel Bosworth	Director of Communications
Mr John Quinn	Director of Information Management Division
Mr Jonathan Mogford	Director of Policy
Dr Janet Valentine	Director, Clinical Practice Research DataLink – item 4
[redacted]	Acting Head, Policy, Government & Corporate, Policy Division – items 5-7
[redacted]	Team leader, Business Planning and Programme Management, Policy Division – items 5-7
Mrs Vanessa Birchall-Scott	Director of Human Resources – item 8
[redacted]	Chief Financial Accountant –item 9
[redacted]	National Audit Office –item 9
[redacted]	Head of Business Analysis – item 15
[redacted]	Head of Science Strategy
Mr Aidan Mclvor	Secretary to the Agency Board
[redacted]	Directorate

*Department of Health (DH) and Legal Services*

Mrs Claire Armstrong	DH sponsor representative
Mr Mark Wilson	Legal Services

**Item 1: Introductions and Announcements***Professor Barry Furr OBE, Non-Executive Director*

- 1.1 Prior to the start of the meeting, the Chairman, along with members of the Board and officials stood in silent memory of Professor Barry Furr who died on 27 February. The Chairman went on to report that he, along with Dr Ian Hudson, Chief Executive, and Aidan Mclvor, Board Secretary, had attended Professor Furr's funeral at St. Michael's Church in Macclesfield on 12 March.

*Announcements*

1.2 Apologies were received from Peter Commins, Chief Operating Officer and Director of Finance. The Chairman welcomed Claire Armstrong of DH to her first meeting of MHRA's Board.

**Item 2: Declarations of interest**

2.1 None was declared.

**Item 3: Minutes of the last meeting, 18 February 2015, and matters arising**

3.1 The draft minutes of the Board meeting of 18 February 2015 were agreed.

*Matters arising*

3.2 The Board then reviewed the actions list from previous meetings.

**DISCUSSION ITEMS (in the order of the business)****Item 4: Clinical Practice Research DataLink (CPRD) progress update**

4.1 Dr Janet Valentine presented a progress update on CPRD. The report centred on current and future population coverage of CPRD's work; the development of linkages services and interventional studies; the role and impact of CPRD within the wider UK research landscape, partnerships, information governance and assurances. The Board heard about one of CPRD's priorities, namely to focus on using real-world data in intervention studies, including ability to review feasibility, site identification, recruitment, randomisation at point of care, and use of electronic healthcare records to follow patients. The studies will be carried out, either in collaboration with the National Institute for Health Research (NIHR) Clinical Research Network (CRN), or directly with academic or commercial research organisations. The report also covered progress against Key Performance Indicators (KPIs), including income targets, new activities in 2015, as well as future priorities for the coming year, and activities, risks, and mitigations in place.

4.2 The Board asked about the level of funding required for this work. Dr Valentine informed the Board that progress had been made engaging with TTP and EMIS. The contractual, technical and methodological steps required to make this data research ready were explained. The proposed software development that will be required for this data extraction will use up some of the CPRD's cash reserves. During the discussion, the Board referred to the performance of CPRD against the targets which were set in the 2014/15 Agency Business Plan, one of which was to enable 280 research studies – in Q1-3; of these, 191 studies were enabled. The Board suggested that this target should be further developed for subsequent years. In the CPRD financial re-plan in May 2014, CPRD income for 14/15 was re-profiled to remain at a similar level to that of 2013/14. However, from 2015/16 onwards, the projected income is due to rise sharply, taking into account the increased level of clinical trials set to be carried out. Dr Valentine explained based on progress to date that it was unlikely that CPRD would reach its projected income targets for 2015/16. The Board noted this concern.

4.3 The Board noted that the most important target is to increase the population coverage. This is to ensure there can be more intervention studies, faster patient recruitment, enhanced epidemiological, drug safety, pharmacoepidemiology studies, and

the ability to investigate rare diseases, as well as to follow up outcomes in pregnancy. The Board heard that CPRD aims to expand its capability to link to a wider range of data sets than is currently available. This should help build up the intervention portfolio through innovative methodologies in trial design, recruitment, data capture, and follow up, using real world data. Finally, the Board heard that CPRD should cement and build new partnerships, in particular, but not exclusively, with the CRN, the Royal College of General Practitioners, NHS England, and the Farr Institute.

4.4 The Board commended Dr Valentine on her report, which was described as excellent.

#### **Item 5: Triennial Review – oral update**

5.1 Mr Jonathan Mogford, Director of Policy, gave an oral update on 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 Triennial Review reports on the British Pharmacopoeia Commission (BPP) and the Commission on Human Medicines (CHM) had received clearance from DH and Ministers and were with Cabinet Office. Although the BPC and CHM reports may be published prior to the election, the report on the Agency will not. The Board also heard that the 'end-to-end' (Med Tech) Review will be taken forward on a cross-party basis and can proceed without delay. A further update on the Triennial Review would be given at the next Board meeting.

#### **Item 6: Preparing for the General Election**

6.1 [redacted] of Policy Division presented a short paper on the preparations the Agency is making for the General Election. The Board heard that prior to the dissolution of Parliament on 30 March it will be 'business as usual'; in the meantime the Agency is in discussions with DH about what briefing / information may be required for a new administration. This will include: (i) a description of the role of the Agency, (ii) briefing on major themes for the next five years, (iii) the topics on which we may wish to consult on/publish during April – June 2015, and (iv) policy areas which may entail possible legislative change.

6.2 [redacted] also reported two-three members of staff have been invited to attend a training session at DH on preparing for the General Election, the contents of which would be shared with other members of staff.

#### **Item 7: Business Plan 2015-16**

7.1 [redacted] of Policy Division presented the revised draft Business Plan for 2015/16 for the Board's further consideration and sign off. The package of papers that the Board received included an assessment of current performance targets, which following the Board and Corporate Executive Team (CET) away day on 23 January 2015, each CET director had reviewed. At the away day, CET directors were asked to review their current performance targets again and to re-assess whether they thought each of their targets were (a) achievable, (b) achievable but stretching, or (c) very stretching / potentially unachievable. [redacted] outlined the changes that had been made to the draft Business Plan since the Board's meeting on 18 February 2015.

7.2 The Board commended [redacted] and her colleagues for their work on preparing the draft Business Plan over the previous four months, during which they consulted closely with the Board and a range of internal and external stakeholders. The Board formally signed off the Business Plan, which would now be submitted to DH.

## Item 8: Talent Management Strategy

8.1 Vanessa Birchall-Scott, Director of Human Resources, presented an overview of the organisation's Talent Management Strategy. The strategy is based on getting suitable candidates into business-critical roles, with a focus on the context in which the organisation operates. This is executed against a range of inputs - sourcing, development, deployment, reward and performance management - and outputs such as attracting and retaining talent, improving expertise and performance, and forming career pathways/a succession plan.

8.2 The management of talent in the Licencing and Devices Divisions has proven more difficult than in other areas of the business. The Board suggested creating partnerships with organisations, such as the NHS and academic institutions, in order to broaden the agency's pool of talent. Further, there should be focus placed on the long-term path of each role, for instance, gauging the potential for opening certain stages of each role to development opportunities. It is also important to identify the needs of more senior people, as this will act as an indicator of the work-streams that should be implemented throughout the organisation.

8.3 The Board asked for a further update to be provided in six months' time.

**Action:** HR to provide the Board with a further update in September 2015.

## Item 9: Board effectiveness self-evaluation questionnaire

9.1 [redacted] of the National Audit Office (NAO) presented a short paper on the Board effectiveness self-evaluation, about which [redacted] had spoken to the Audit and Risk Assurance Committee earlier in the morning. [redacted] outlined the thinking behind such questionnaires and their potential value. [redacted] went on to introduce the questionnaire: *Unlocking your Board's full potential*, which contained 47 questions, to which a respondent could reply: (i) strongly disagree, (ii) partly disagree, (iii) partly agree, (iv) strongly agree. Members of the Board were invited to complete the questionnaire, which would need to be sent to [redacted] of Finance Division, who would analyse all responses.

9.2 The Board agreed to complete the questionnaire, having sought clarification on the purpose of this self-assessment tool, its anonymity, its design, who would be performing the analysis and the handling of the results. The Board was informed by Mr Master that anonymity was guaranteed to all respondents.

## STANDING ITEMS

### Item 12: Audit and Risk Assurance Committee – oral update

12.1 Professor Vincent Lawton, Chair of the Audit and Risk Assurance Committee (ARAC), gave an update on the ARAC meeting that had been held earlier in the day. As part of his oral report, Professor Lawton reported that following the death of Professor Furr, the Committee's terms of reference had to be amended. This was to allow for the Committee's numerical membership and quorum to be reduced from four to three members at present. Also, at Professor Lawton's request, hard copies of the Agency's Corporate Risk Register were tabled for information.

### Item 13: Information and Technology (IT) Strategy update

13.1 Mr John Quinn, Director of Information Management Division (IMD), presented an update on the implementation of the IT Strategy. The update set out progress made since the IT Strategy was considered by the Board in November 2014. The Board heard that the scale of change that has taken place since November 2014 has been significant. Mr Quinn reported on the following developments:

- Detailed plans have been developed for the first wave of projects within each priority area;
- The first tranche of business cases have been submitted to the Information Management Governance Board (IMGB);
- Sentinel has been moved onto a new supported infrastructure; the IT team has been structured into a new operating model;
- IMD has successfully delivered accommodation moves;
- IMD has supported the internal audits of the IT Strategy and a Cyber Security review;
- IMD has undertaken the next level of analysis on business applications with internal teams; commenced engagement with Trade Associations on the IT strategy;
- IMD has tested the disaster recovery process and has updated the mobile management service;
- A pilot of tablet devices has begun; and
- IMD is developing detailed delivery plans for review by IMGB for 2015-16.

13.2 The Board queried the cost of the IT investment programme; Mr Quinn reported that there was significant demand from across the Agency for IT investment. A prioritisation exercise would be completed in May 2015 with the Information Management Governance Board (IMGB) to understand what the total delivery cost for 2015-16 will be. The Board asked that Mr Peter Commins, Chief Operating Officer and Director of Finance, to give an update at the next Board meeting on the financial aspect of the IT Strategy, in particular, the possible use of the Agency's cash reserves to pay for some of the IT investment programme.

*Gov.UK website*

13.3 During the discussion of the IT Strategy a number of Board members expressed concern about the quality and user-friendliness of the Agency's website, which is provided via the wider Gov.UK website. In particular, the Board disagreed strongly with the prohibition on Frequently Asked Questions (FAQs), which had been available previously on the former MHRA website. Rachel Bosworth, Director of Communications, explained that the Agency was obliged to follow a Government-wide position on FAQs, although FAQs-like pages were being developed. Mrs Claire Armstrong of DH agreed to pass on MHRA's concerns to the DH digital team.

**Actions:**

- (a) Mr Peter Commins to give an update on the financial aspect of the IT strategy at the next Board meeting (27 April), in particular, the possible use of the Agency's cash reserves to pay for some of the IT investment programme.
- (b) Mrs Claire Armstrong to convey the Board's view on the prohibition on FAQs to the digital team at DH.

**Item 14: CEO's report for February 2015**

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

- *GcMAF* (Gc protein-derived macrophage activating factor) – The Board heard that the Agency's enforcement group has carried out inspections at five separation locations. This has resulted in the seizure of over 10,000 of GcMAF in its various guises.
- *Faecal Microbiota Transplant (FMT)* - The Agency is currently in discussion with the Human Tissue Authority about the regulatory status of encapsulated products that are based on and may be used instead of FMT.
- *Adaptive pathways* – The European Medicines Agency (EMA) has received over 50 applications and the EMA, through the Scientific Advice Working Party (SWP) is assessing these submissions.
- *Relationships with vaccine manufacturers – GSK* – an update was given on a meeting between the Agency and GSK Vaccines.
- *Herbal practitioners* – An update was given on the draft report, which is now with Ministers. The Board heard it was not clear if the report will be published before or after the General Election.
- *Yellow Card 50<sup>th</sup> anniversary*– The Board heard that the Yellow Card forum event that was held at the Royal College of Physicians in Edinburgh on 20 March had been a significant success.
- *Foreign (inwards) visits* – An update was given on visits to the Agency from Dr Kondo, Chief Executive of the Japanese Pharmaceutical and Medical Devices Agency and Mikel Arriola, Commissioner of the Mexican Federal Commission for the Protection against Sanitary Risk (COFEPRIS). During the latter's visit, a confidentiality agreement was signed between the MHRA and COFEPRIS.
- *Glucosamine* – An update was given on the Glucosamine Judicial Review Appeal.
- *Court of Appeal* – Chemistree Homecare Limited and Blackbay Ventures Limited – The Board heard that the Court of Appeal have upheld the High Court's earlier decision to refuse a judicial review.

### Item 15: Finance and Procurement report

15.1 [redacted] of Finance Division gave the highlights for the first ten months of the financial year 2014/15. They were:

- MHRA (Regulator) income: for end of January 2015 was at £89.9m.
- NIBSC operational income: for year to end of January 2015 was at £16.5m.
- CPRD income: for year to end of January 2015 was at £6.7m.
- Operating income for the Agency was £129.0m, which is £8.2m above budget.
- Total operating costs were £103.2m, which is £7.4m below budget.
- The Agency's bank balance at the end of December 2014 was £197.3m.
- Capital expenditure was £7.6m out of the full year budget of £15.0m.
- Total Product Licensing deferred revenue at the end of January 2015 was £16.7m.

- The number of full-time equivalents at the end of January 2015 was 1,213, with 139 short-term contracts and 42 non-payroll employees.

15.2 [redacted] then went on to present the agency's draft budget 2015/16 for agreement. The budget for 2015/16 had been set in the context of the agency's medium-term financial strategy, which was last reviewed by the CET at its December 2014 meeting and endorsed by the joint Agency Board/CET Away day on 23 January 2015.

15.3 [redacted] advised that the aim was to achieve a 'soft landing' in 2016/17. Mr Jones went to report that, although the final 2015/16 Grant In Aid funding for devices and NIBSC has not yet been signed off by DH, the figures provided in the budget were thought to be secure. The Board agreed the proposed agency budget for 2015/16 and the specific budgets for the regulator, CPRD and NIBSC. Although there were some concerns about the size of the agency's cumulative surplus, it was accepted that the 2015/16 budget was designed in a way that would enable targeted, non-recurrent spending in the next business year – for example by supporting the new IT strategy, the ongoing data audit and implementing new transparency policies.

#### **Item 16: Minutes of the Corporate Executive Team (CET) meeting of February 2015**

16.1 The minutes of the CET meeting of 3 February 2015 were noted.

#### **Item 17: Non-Executive Directors' (NEDs) updates**

17.1 *Funders' event* - Professor Webb reported that he had chaired a one-day funders' event at the Wellcome Collection. The event was organised by Cancer Research UK on behalf of funders, including the British Heart Foundation, the Department of Health, the Economic and Social Research Council, and Medical Research Council, with delegates from MHRA, to explore the pharmacology, toxicology and addictive potential of e-cigarettes, and their relative harms and benefits when compared with standard cigarettes.

#### **Item 18: Any Other Business (AOB):**

18.1 No items of AOB were raised.

**Date of next Board meeting:** 27 April 2015

**Aidan McIvor**  
**Head of Directorate**