MHRA Agency Board

MINUTES OF THE MEETING

18 February 2015

Present:

The Agency Board

Professor Sir Michael Rawlins	Chairman of MHRA
Professor Dame Valerie Beral	Non-Executive Director
Professor Barry Furr	Non-Executive Director – by telephone
Mr Martin Hindle	Non-Executive Director
Professor Vincent Lawton	Non-Executive Director
Professor Sir Alex Markham	Non-Executive Director
Professor David Webb	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
Mr Jonathan Mogford	Director of Policy
Ms Diane Leakey	Deputising for the Director of Communications
Dr Stephen Inglis	Director of the National Institute for Biological Standards and Control (NIBSC)
Mr Gerald Heddell	Director of Inspection, Enforcement and Standards – for item 6
[redacted]	Editor-in-Chief, British Pharmacopeia - for item 6
Dr Siu Ping Lam	Director of Licensing – for item 7
[redacted]	Biologicals Manager, Licensing Division - for item 7
[redacted]	Acting Head of Clinical Trials Unit – for item 7
[redacted]	Acting Head of Policy, Government & Governance - for item 8
[redacted]	Policy Manager, Policy Division – item 8
[redacted]	Head of Science Strategy
Mr Aidan McIvor	Secretary to the Agency Board

Department of Health (DH)

[redacted]	DH sponsor representative
[redacted]	Observer (DH)

Item 1: Introductions and Announcements

1.1 Apologies were received from Deborah Oakley, Non-Executive Director (NED), Rachel Bosworth, Director of Communications, as well as from Liz Woodeson and Claire Armstrong of DH. The Chairman welcomed [redacted] of DH to the meeting, who was attending as an observer.

1.2 The Chairman reported that he received feedback from Ms Oakley about a recent meeting at DH of non-executive directors from arms-length-bodies, which he would share with the Board.

Item 2: Declarations of interest

2.1 None was declared.

Item 3: Minutes of the last meeting, 16 December 2014, and matters arising

3.1 The draft minutes of the Board meeting of 16 December 2014 were agreed.

Matters arising

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

Item 4: Minutes of the AB/CET away day (23 January 2015)

4.1 Following a request for a minor change to be made to para. 5.2 of page 7, which the Board endorsed, the draft minutes were agreed

DISCUSSION ITEMS

Item 5: Triennial Review – oral update

5.1 Mr Jonathan Mogford and Mr Peter Commins 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 Triennial Review is now well advanced, with the programme of interviews of non-executive directors and senior officials having been completed. The Agency has been asked for further information on the governance and finance, which has been provided, which the Project Board will be able to consider at its meeting on 23 February. The Board heard that part of the focus of the review is to considering where the agency should sit in the spectrum of an arms-length, independent scientific body, or a much closer, more integrated function to its sponsor department (DH), given its functions. In conclusion, Mr Mogford reported that the Triennial Review's final report is not expected to be completed until after the General Election.

5.2 The Board welcomed the update. Professor Furr commented that in the interests of public health, the Agency's ability to take scientifically independent decisions was important and should be protected. Professor Furr went to say that since joining the Board in 2008, he had noticed a significant (positive) change in the way the Agency conducts its business, e.g. in making the UK a more attractive country in which to carry out clinical trials. Other Board members echoed this view. A further update would be given at the next Board meeting.

Item 6: British Pharmacopeia – NIBSC collaborative activities

6.1 Dr Stephen Inglis, Director of NIBSC, who introduced the paper, was joined by Gerald Heddell, Director of Inspection, Enforcement and Standards Division (IE&S), and [redacted], Editor-in-Chief of the British Pharmacoepia (BP). Dr Inglis advised that [redacted] of IE&S, and [redacted] and [redacted] of NIBSC respectively, all of whom contributed to the paper, were unable to attend because of annual leave or overseas business commitments.

6.2 When presenting the paper Dr Inglis commented that at the time of the MHRA/NIBSC merger in 2013, the potential synergies between MHRA and the BP were recognised. These included: (i) reference materials for biologicals, which form a major element of NIBSC's remit, and which the BP cite in relevant monographs; (ii) analytical

test methodologies for biologicals; and (iii) the biological nature of some of the complementary therapies covered by the BP. The work of (merger) Project 1: realising the benefits in 2013 highlighted these areas of common work. Dr Inglis went on to say that collaboration between the two parts of the merged agency has allowed NIBSC and the BP to tap into each other's expertise and to work together internationally. Another example cited was a three-year pilot project to explore the advantages of DNA-based identification methods in herbal medicine. The Board heard that from a scientific and technical perspective, good progress has been made in this area during 2014.

6.3 Gerald Heddell highlighted the success of the merger, as it now feels like one team in operation, rather than two separate entities collaborating. Gerald Heddell also mentioned work taking place to second expert staff to China and the paper on the future of herbals-based on work, which will soon be presented to the CET.

6.4 The Board congratulated Dr Inglis and Mr Heddell and their colleagues on the evident success of the joint-working between the BP and NICE.

Item 7: Innovation Office and Clinical Trial Activities

7.1 Dr Siu Ping Lam presented a paper on the work of the Innovation Office. The Board heard that the Innovation Office is a virtual office that was set up in 2013 to provide regulatory advice to those who develop innovative medicines and medical devices. So far, the Innovation Office has answered around 120 queries; and recently, it has been expanded to work with other regulators, such as the Human Tissue Authority/HFEA/HRA in the area of regenerative medicine. Dr Lam reported that the Agency has recently published three case studies about the work of the innovation office, which are now available on the website, and more are planned to follow.

7.2 A number of Board members advised that the published case studies are difficult to find on MHRA's website, which is unfortunate as their potential is not being exploited fully. Board members also advised that developments in smartphones should be taken into account when optimising search results. It was noted that the UK Innovation Office appears 2nd in an online search. Diane Leakey of Communications Division said that she would take these matters up with relevant colleagues.

7.3 Prior to thanking Dr Lam and his colleagues for the progress report, the Chairman suggested that an article be prepared for publication in the *British Medical Journal (BMJ) or Lancet, with* a link to the Innovation Office's case studies.

Action: Communications Division to liaise with Licensing Division about (i) making the Innovation Office's website page more accessible and (ii) the Chairman's suggestion about publishing an article in the BMJ or Lancet.

Clinical Trials activities

7.4 Dr Lam went on to give an update on clinical trials activity. The Board heard that the number of clinical trial applications (CTAs) received by MHRA fell from 1,208 in 2007 to 941 in 2010. Since then, the number of CTAs submitted to the UK stabilised and has increased in recent years. The UK currently handles 40% of CTAs in the European Union; the fall off in CTAs has been greater in other parts of the EU. The Board noted that there has not been a reduction in non-commercial clinical trials.

7.5 In discussion, the Board suggested that it might be helpful to have a target to attract more CTAs, in conjunction with other relevant organisations.

Action: Licensing Division to consider the Board's suggested target to attract more CTAs to the UK.

Item 8 (i) **Business Plan 2014/15 – progress against targets for Quarter 3**
(ii) draft Business Plan 2015/16 – oral update

8.1 [redacted] of Policy Division gave a quarterly monitoring report on the Business Plan for Quarter 3 (October-December 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. One target (PM6a: 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. The second target (PM7b: primary care data cover) should be met by the end of the financial year.

8.2 [redacted] of Policy Division then gave a progress report on the draft Business Plan for 2015/16, which will be presented to the Board for formal sign off at its meeting on 23 March. [redacted] advised that a further revised version of the draft Business Plan would be sent to the Board for further comments later in the month.

STANDING ITEMS

Item 9: Audit and Risk Assurance Committee – oral update

9.1 Professor Vincent Lawton, Chair of the Audit and Risk Assurance Committee (ARAC), gave an update on the ARAC meeting on 20 January 2015. As part of his oral report, Professor Lawton gave an update on ARAC's discussion of managing and countering fraud, including regulatory fraud. The Board also heard that the problems with payroll, which the Agency had experienced in 2014, have since been resolved. Professor Lawton went on to mention a self-assessment form, which Board members will be asked to complete. Finally, the Board heard that the draft Governance Statement is being prepared and will be presented to the ARAC on 23 March for sign off.

Item 10: CEO's report for December 2014 and January 2015

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

- *Single brand for government* – MHRA's transition to GOV.UK has prompted No. 10/Cabinet Office to request that the agency change its corporate identity to align with the single brand for government. Initial discussions with No.10 / Cabinet Office suggest that the existing branding for the Agency's three centres will not be affected.

- *Joint MHRA/NHS conference* - for Medical Device Safety Officers (MDSO) and Medication Safety Officers (MSO) take place in London on 19 January. Feedback on the event has been very positive.

- *Maintaining our quality* - ISO 9001:2008 - An update was given on the visit by British Standards Institution (BSI) assessors in January 2015. The BSI team reported that both parts of the assessment confirmed that the management system continued to support the Agency's aims and objectives.

- *Medical devices* - negotiations continue as there are issues which remain to be resolved.

- *Early Access to Medicines Scheme (EAMS)* **-** An application for an EAMS opinion is ongoing and its outcome will be known by March. The EAMS' opinion is likely to be issued in the near future.

- *Clinical Pharmacologists Training* – The Agency and the British Pharmacological Society jointly hosted a training event for clinical pharmacologists at 151 Buckingham Place Road on 28th and 29th January. So far, the feedback from the event has been very positive.

- *Accommodation update* – Work is progressing well with the relocation of staff within 151 Buckingham Palace Road. The move from three to two floors will be completed by the end of March.

- *CPRD Clinical trials* **-** CPRD has now been contracted to provide patient services to a large clinical trial in the area of diabetes. Services being provided include patient identification, recruitment and data recording. An eHealthcare Record will be administered.

Product issues

- *Sodium Valproate (Epilim and Depakote) and neurodevelopmental disorder* – The Commission on Human Medicines (CHM) endorsed the need for better information to be made available to patients on the risks of developmental disorders in children exposed to sodium valproate in utero. The Commission advised that a multi-stranded approach to communication was needed and endorsed collaboration between MHRA, NICE and DH. In general, communications have been handled very well.

- *Amlodipine* – Professor David Webb asked for an update on the safety of Amlodipine given that it has a banned status overseas. Dr Hudson agreed to clarify and provide Professor Webb with further information.

10.2 Dame Valerie Beral commended Dr Hudson on the value of the CEO's report and suggested that an abridged version could form the basis of a CEO's blog or update on MHRA's external website.

Action: Dr Hudson to consider whether to produce a CEO's blog for external use.

Item 11: Finance and Procurement report

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

- MHRA (Regulator) income: for end of December 2014 was at £80.3m.
- NIBSC operational income: for year to end of December 2014 was at £15.1m.
- CPRD income: for year to end of October 2014 was at £6.0m.
- Operating income for the Agency was £115.7m, which is £7.1m above budget.
- Total operating costs for the year to end of October 2014 were £93.3m, which is £6.9m below budget.
- The Agency's bank balance at the end of December 2014 was £197.3m.

- Capital expenditure was £6.4m out of the full year budget of £15.0m.
- Total Product Licensing deferred revenue at the end of December 2014 was £17.2m.
- The number of full-time equivalents at the end of December 2014 was 1,209, with 139 short-term contracts and 39 non-payroll employees.

Item 12: Minutes of the Corporate Executive Team (CET) of December 2014 and January 2015

12.1 The minutes of the CET meeting of December 2014 and January 2015 were noted.

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

- *ALBs' seminar* - A number of NEDs reported that they had attended the DH-hosted ALBs' seminar on 3 February, which they thought was informative, and interesting. The Chairman then shared with the Board Deborah Oakley's reflections on the ALBs' seminar, which she had sent on earlier.

- *Yellow Card event, 20 March* - Professor Webb reminded fellow Board members of the MHRA's Yellow Card Scheme 50th Anniversary scientific conference: 'A new era for the Yellow Card Scheme – a Road Map for the Future', which will take place at the Royal College of Physicians in Edinburgh on 20 March.

Item 14: Any Other Business (AOB):

14 (a) The CET has agreed the Talent Management Strategy (TMS), which will be rolled out across the Agency. A paper on TMS will come to the Board on 23 March.

(b) The report on the Breast Registry will be finalised in February. This follows feasibility work carried out on a Breast Registry pilot.

(c) The Chairman reported that he has to appraise all NEDs by the end of April 2015.

(d)The Chairman announced the planned retirement of Dr Stephen Inglis, who will step down in April 2016. Although search consultants will be engaged to identify possible suitable candidates to succeed Dr Inglis, the Chairman asked Board members to consider (and share with Human Resources) the names of possible candidates.

Date of next Board meeting: 23 March 2015.

Aidan McIvor
Head of Directorate