

Medicines and Healthcare products Regulatory Agency

MINUTES OF THE MEETING

23 June 2017

Present:

The Board

Professor Sir Michael Rawlins GBE, Kt.	Chairman of MHRA
Mr Martin Hindle	Deputy Chairman
Dr Ian Hudson	Chief Executive
Mr Jon Fundrey	Chief Operating Officer
Dr Barbara Bannister MBE	Non-Executive Director
Dame Valerie Beral	Non-Executive Director
Professor Bruce Campbell	Non-Executive Director
Mr Stephen Lightfoot	Non-Executive Director
Ms Deborah Oakley	Non-Executive Director
Professor David Webb	Non-Executive Director

Others in attendance

MHRA executive and supporting officials

Ms Rachel Bosworth	Director of Communications
Mr Andy Gregory	Deputy Director – EU, International and Strategy
Dr Samantha Atkinson	Director, Business Transformation
{Redacted: Section 40 - personal data}	Stakeholder Communications Specialist
{Redacted: Section 40 - personal data}	Head of Science Strategy
Mr Aidan McIvor	Head of Directorate
{Redacted: Section 40 - personal data}	Executive Assistant to the Chairman
Mr Richard Humphreys	Deputy Director – Finance (for item 7 only)

Legal Services

Mr Paul Wright	Deputy Director, MHRA, Medicines and Information Team, DH Legal Advisers, Government Legal Department
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Special announcement by Martin Hindle, Deputy Chairman

Prior to the opening of the meeting, Mr Martin Hindle, Deputy Chairman, extended his and the Board's warmest congratulations to the Chairman on the award of the Knight Grand Cross of the Most Excellent Order of the British Empire (GBE). Sir Michael's GBE was announced as part of the Queen's Birthday Honours on 17 June 2017. The Chairman thanked Mr Hindle and the Board for their kind words.

Item 1: Introductions and Announcements

1.1 Apologies were received from Matthew Campbell-Hill, Non-Executive Director; Sir Alex Markham, Non-Executive Director; Jonathan Mogford, Director of Policy; Gerald Heddell, Director of Inspection, Enforcement and Standards; and John Quinn, Director of Information Management Division.

1.2 The Chairman went on to make the following announcement:

- Mrs Carly McGurry, Deputy Director - Medicines Regulation & Prescribing at the Department of Health (DH), has been appointed to succeed Libby Green as DH's representative at Board meetings. Ms Green returned to the Foreign Office from DH in April 2017.

Item 2: Declarations of interest

2.1 No declarations of interest were made.

Item 3: Minutes of the last meeting, 22 May 2017, and Matters Arising

3.1 The minutes of the Board meeting of 22 May 2017 were agreed and the actions listed were reviewed under Matters Arising.

DISCUSSION ITEMS

Item 4: Brexit - update

4.1 Andy Gregory gave an update on Brexit-related work since the last Board meeting on 22 May. While the Agency continues to focus on scenario-planning (including financial analytical work), the Purdah-related restrictions that had previously been in force have since been lifted.

4.2 Mr Gregory went on to update the Board on developments at the Department of Health, including plans for the Health Secretary, along with other Ministers (with an interest in Life Sciences) to publish a public letter. The letter is expected to set out the Government's position on the UK's future relationship with the EU on medicines regulation.

4.3 Mr Gregory also gave an update on recent discussions at the meeting of the International Coalition Medicines Regulatory Authorities (ICMRA) in Chicago, which was held alongside the Drug Information Association meeting, which Dr Hudson and other officials from MHRA attended. Dr Hudson added that during the course of the three-day DIA conference in Chicago, he held a series of bilateral meetings with counterparts from a range of countries, including Canada, Australia, USA, and Japan, where the prospect of future collaborative working was discussed.

4.4 An update was also given on discussions on ongoing work with the European Medicines Agency, including the appointment of UK officials in leadership roles to scientific expert committees.

4.5 A further update will be given at the Board / Corporate Executive Team (CET) away day on 25 July.

Item 5: Operational Transformation

5.1 Jon Fundrey introduced Dr Samantha Atkinson, the newly appointed Director of Operational Transformation (OT) Programme Board, who presented an update on the Operational Transformation (OT) project. Dr Atkinson gave an overview on recent work, which has taken place after an External Challenge review that was undertaken by PA Consulting. Dr Atkinson outlined the work that has been carried out with PA Consulting to start defining the structure and resourcing for the project. One of the

areas highlighted by PA Consulting was that the Agency has a high burn rate, therefore a prioritisation exercise of all the existing projects in the Agency will be carried out; the results of this will be brought back to the OT programme board and Corporate Executive Team (CET).

5.2 As an early input and to inform decision making, the OT board will seek customers' and stakeholders' views of our products and services. This will be a time constrained piece of work with focus on obtaining maximum insight, with activities such as one-to-ones with key individuals and obtaining feedback from key customer groups. To help inform these discussions, a list of the key questions will be drafted. Linked to this is another piece of work on market analysis, which is currently being drafted. Moreover, the Board heard that there is increasing interest from staff in this area, with which the OT programme board will engage and make full use. Dr Atkinson concluded by explaining the timeframe for this work: 5-6 months.

5.3 The Chairman thanked Dr Atkinson for her report and sought the Board's views, which centred on the following areas:

- *Opening comments* – The Board congratulated Dr Atkinson on her appointment and commended her on the work that had been done so far. The Board commented that the scale of the project was significant and the timeframe was very tight. The Board also expressed concern about the 'burn' rate.
- *Governance* – In reply to the Board's questions about the governance arrangements for the project, Jon Fundrey advised that Dr Atkinson, as Programme Director, would report to the Chief Operating Officer (Jon Fundrey), who chairs the OT Programme Board, which in turn will report to the CET. Mr Fundrey assured the Board that it would be kept regularly informed of progress. Mr Fundrey went on to mention that he and Dr Atkinson have had discussions with Stephen Lightfoot, Non-Executive Director, which have proved beneficial. The Board welcomed the update and asked that it be kept regularly informed of developments.
- *Approvals processes* – In order to answer the Board's questions about affordability, Mr Fundrey reported that he has already had discussions with Mr William, Director-General (Finance) at the Department of Health about drawing on our retained funds, and advised of the approvals process, which will include the need to use HM Treasury templates.

Item 6: Public and Patient Engagement Strategy

6.1 {Redacted: Section 40 - personal data} presented the refreshed Patient and Public Engagement (PPE) strategy. {Redacted: Section 40 - personal data} reported that significant progress has been made with patient and public engagement over the last five years. The refreshed strategy is in response to a number of external factors that, collectively, have increased both Government and public expectation for patient involvement, particularly in relation to innovative treatments and products. These include most recently the recommendations of the Accelerated Access Review. Six actions were proposed for an updated strategic approach to help MHRA to further increase engagement with patients and the public:

- i) Update the Agency engagement policy to ensure that it recognises the value and formalises the role of patient and public involvement in regulatory decision-making and policy development.

- ii) Strengthen the role of the Patient Group Consultative Forum.
- iii) Increase the role of patients in the licensing process building on work done to date.
- iv) Develop support materials to facilitate patient involvement with the Agency.
- v) Develop an evaluation process to assess the impact of greater patient engagement.
- vi) Expand our collaboration with domestic, EU and international peer organisations and the Devolved Administrations to support future development.

6.2 The Chairman thanked {Redacted: Section 40 - personal data} for his report and sought the Board's views. These centred on the following areas:

- *Working with patients* – The Board recommended that the Agency should liaise with NICE on their approach to helping patients to engage more effectively at patients forums and meetings. The Board thought that NICE had much useful and relevant experience from which the Agency could benefit and Mr Dykes said he would follow-up on this suggestion.
- *Academic Health Science Networks* – The Board also recommended that the Agency engage with the Academic Health Science Networks.
- *Partnership working* – The Board recommended closer working in this area between MHRA, and other regulators, including Public Health England and NICE.
- *Practical matters - size of patients' group meetings* – The Board advised that the Agency should consider what is the optimal size for a patients' meetings, as some patients' group meetings could be unwieldy because of the large number of attendees present.

6.3 {Redacted: Section 40 - personal data} thanked the Board for their comments, which he said he would take into account.

Item 7: Draft Annual Report and Accounts, 2016/17

7.1 Rachel Bosworth presented the draft Annual Report and Accounts for sign off. Ms Bosworth reported that the revised draft of the Annual Report reflected the Board's earlier comments, and is now in a near complete final stage.

7.2 As regards the Annual Accounts, Richard Humphreys advised that the National Audit Office was expected to issue an unqualified opinion, subject to the completion of final field work. Deborah Oakley agreed but expressed ARAC's disappointment at the level of errors found both by the auditors and by management. She observed that many of the issues raised in the report were the same as reported in the previous year's audit and that Dr Hudson and Mr Fundrey were to provide a report to the next ARAC meeting on the control environment.

7.3 The Board endorsed the draft Annual Report and Accounts for sign off, and thanked Ms Bosworth, Mr Fundrey, Mr Humphreys and their colleagues for all their hard work in preparing the Annual Report and Accounts.

Item 8: Revalidation Annual Report

8.1 {Redacted: Section 40 - personal data} presented the Revalidation Annual Report – A Framework of Quality Assurance for Responsible Officers and Revalidation. The Revalidation Framework was introduced in 2014 in order to provide a quality assurance required to demonstrate that the Responsible Officer and Designated Body are discharging their respective statutory responsibilities.

8.2 The Board considered the following documents:

- (i) The fourth Revalidation Annual Report covering the period April 2016 to March 2017 (Responsible Officers are required to present an annual report to their board or management team)
- (ii) The Annual Organisation Audit (AOA) (end of year questionnaire submitted to NHS England /Department of Health)
- (iii) A Statement of Compliance, which should be signed off by the Chairman before 29th September and submitted to the higher level responsible officer (the Chief Medical Officer).

8.3 The Board heard that the revalidation process for MHRA's clinical assessors in 2016/17 had gone well, despite there being issues with a small number of clinical assessors. Moreover, despite one of the appraisers being unavailable because of ill health, there was sufficient cross-cover in place for the revalidation process.

8.4 Dr Hudson thanked {Redacted: Section 40 - personal data} for coordinating the revalidation exercise and for producing the annual report, which the Board endorsed.

8.5 The Board welcomed the assurance provided by the report that the Agency's approach is robust, comprehensive and thorough

STANDING ITEMS**Item 9: CEO's report**

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

- *Quinolone* - An update was given on a meeting between Agency officials, members of the Pharmacovigilance Expert Advisory Group (PEAG) and representatives of a support group for those who have experienced adverse reactions to quinolone antibiotics.
- *Silimed* – An update was given on the work of the Independent Clinical Expert Advisory Group on Silimed implants and subsequent discussions at an EU level.
- *Heads of Medicines Agencies (HMA) meeting, 10-12 May* – An update was given on the HMA meeting that took place in Malta from 10-12 May. A broad range of topics were discussed at the HMA meeting. These included Brexit and its implications for the network, Clinical Trials, the review of the fees regulations, as well as updates on other aspects of the work of the HMA network.

- *UK Stem Cell Bank* – An update was given on an audit that was carried out by the Human Tissues Authority (HTA) on the UK Stem Cell Bank on 4 May 2017. Although only two minor non-compliance issues were reported, the HTA's feedback on the audit was very positive.

9.2 The Chairman thanked Dr Hudson for the update and sought the Board's views. These centred on the following areas:

- *U.S. Food and Drug Administration (FDA)* – The Board was interested to note that three MHRA inspectors had provided training to the U.S.FDA on Good Clinical Practice (GCP) compliance and clinical trials.
- *Daily Mail report* – In answer to a question from the Board, an update was given on the background to an article that was published in the *Daily Mail* about a former contractor in Accounts Payable who was subsequently prosecuted for fraud while being employed by the Agency. The contractor had a previous conviction, about which the Agency was unaware. Mr Fundrey explained that under the Rehabilitation of Offenders Act, applicants, whose convictions have been 'spent', are not obliged to disclose such convictions. The Board heard that the Agency is looking at what lessons can be learned from this case and what can be done to reduce the risk of a reoccurrence of a similar episode.

Item 10: Remuneration Committee - oral update

10.1 Professor David Webb gave an oral update on the meeting of the Remuneration Committee, which took place earlier in the morning. Professor Webb reported that the Remuneration Committee had a very a productive meeting, the recommendations of which were agreed unanimously.

Item 11: Audit and Risk Assurance Committee

11.1 Deborah Oakley, Chair of the Audit and Risk Assurance Committee (ARAC), gave an oral update on the meeting of the ARAC, which took place earlier in the day. The main business of the meeting was the draft Annual Accounts, the National Audit Office's Statutory Report, the internal audit reports and a review of the Corporate Risk Register.

11.2 Although final field work has to be completed by the auditors, Ms Oakley reported that the NAO has recommended a draft unqualified opinion. In view of the NAO's draft opinion and ARAC's detailed consideration of the draft Annual Accounts, the NAO's Statutory Report, etc., ARAC formally recommended that Dr Hudson as Accounting Officer could sign the Annual Accounts. Once Dr Hudson has signed off the Annual Accounts, they would be submitted to the Comptroller and Audit General for signature.

11.3 Ms Oakley drew the board's attention to the following:

- The surplus had reduced by £1.8m from that reported at the accounts workshop due to errors identified in the accounts both by the NAO and by management. Many of these related to the same issues as last year in respect of recording invoices in the correct accounting period.
- The NAO work was almost concluded and the opinion was "unqualified". The recommendation was to approve the accounts subject to nothing more than trivial arising as from the remainder of their work.

- NAO had also reviewed the annual report and the Annual Governance Statement. (AGS) They recommended that the recent WannaCry cyber attack which exposed a vulnerability at NIBSC be added as a risk in the AGS.
- The head of internal audit opinion is unchanged from that reported at the previous meeting. The overall opinion is “moderate” with moderate for governance but remains “limited” in respect of internal control.
- ARAC were also concerned about the control environment.as a result of the issues identified around the year end and two internal audit reviews of procurement and contracting both of which concluded in unsatisfactory ratings. ARAC had requested a paper be prepared for the next meeting by the Chief Operating Officer with a diagnosis of the issues and remedial actions. Mr Fundrey had given a verbal update at the private session immediately following the meeting.
- A new risk (cyber security at NIBSC) was added to the Corporate Risk Register. A report would come to the next meeting.
- ARAC received an update on health and safety following a number of issues which had arisen in the annual report. The ARAC had noted a positive BSI audit and the work achieved over the last year by the new Health and Safety team. However, ARAC were concerned by the reported low levels of training for laboratory workers at NIBSC (less than 50% for most modules). Occupational Health provision at NIBSC remains unsatisfactory. ARAC had requested that Dr Schneider attend the November meeting to report on progress in addressing these issues. It had previously been agreed that the board would receive the updated annual report on H&S.
- The committee noted that the executive were currently dealing with a significant number of major projects: Brexit; Operational Transformation & office move as well as the regular business, and asked the CET to consider whether “executive stretch” needed to be added to the risk register.
- ARAC requested the board’s permission that due to the number of agenda items and the issues identified in respect of internal control, it should meet five (rather than four) times a year at least for this year. The October meeting will be replaced by meetings in September and November. The Board approved this suggestion.

11.4 The Chairman thanked Ms Oakley for her oral update.

Item 12: Draft programme for Board / CET away day, 25 July

12.1 The Board considered a draft programme for the Board / Corporate Executive Team away day on 25 July, which will be held at the Royal Society. The Board endorsed the proposed programme, but asked that consideration be given to making the Awayday sessions more interactive and less like a standard Board meeting. Dr Hudson said that he would discuss the practical aspects of the away day with the Chairman after the meeting.

Item 13: Minutes of the Corporate Executive Team (CET) meetings

13.1 The minutes of the CET meetings of 11 April and 9 May 2017 were noted.

Item 14: Any Other Business (AOB):

Board meeting dates

14.1 The Board agreed the meeting dates for 2018. It was noted that one of the Board meetings (in February 2018) would take place at the Laboratory of the Government Chemist in Teddington, after which there would a tour of the MHRA's laboratory facilities in Teddington.

Legal update

14.2 Paul Wright gave an update on Brexit-related legal work, in particular, upcoming work on Statutory Instruments.

Review of Board members' Conflicts of Interest declarations

14.3 Deborah Oakley, Chair of ARAC, reminded the Board of a previous internal audit recommendation that Board and CET declarations of interest be reviewed annually at the time of the annual report.

Action: Annual review of Declarations of Interest to come to the next Board meeting

Date of next meeting (Board/CET away day): 25 July 2017