Medicines and Healthcare products Regulatory Agency

MINUTES OF THE MEETING

9 May 2016

Present:

The Board

Professor Sir Michael Rawlins	Chairman of MHRA
Mr Martin Hindle	Deputy Chairman
Dr Ian Hudson	Chief Executive
Dr Barbara Bannister MBE	Non-Executive Director
Professor Dame Valerie Beral	Non- Executive Director
Mr Matthew Campbell-Hill	Non-Executive Director
Professor Bruce Campbell	Non-Executive Director
Mr Stephen Lightfoot	Non-Executive Director
Professor Sir Alex Markham	Non-Executive Director
Ms Deborah Oakley	Non-Executive Director
Professor David Webb	Non-Executive Director – by telephone

Others in attendance

MHRA executive and supporting officials

Ms Rachel Bosworth	Director of Communications
Mr Jonathan Mogford	Director of Policy
Mr Gerald Heddell	Director of Inspections, Enforcement and Standards – item 5
Mr John Quinn	Director of Information Management Division – item 5
Mr Richard Humphreys	Deputy Director of Finance – deputising for the Chief Operating Officer and Director of Finance
Name redacted under s40(2) of the FOIA (personal data) -Head of Business Analysis – item 5	
Name redacted under s40(2) of the FOIA (personal data) - Chief Financial Accountant – item 5	
Name redacted under s40(2) of the FOIA (personal data) -Financial Accountant – item 5	
Name redacted under s40(2) of the FOIA (personal data) - Customer Services Manager, Communications Division, item 5	
Mr Mick Foy	Group Manager, Vigilance and Risk Management of Medicines (VRMM) Division - item 6
Name redacted under s40(2) of the FOIA (personal data) - Pharmacovigilance Information Scientist, VRMM - item 6	
Ms Patience Wilson	Head of Corporate Strategy, Accountability and Partnership, Policy Division – item 7
Name redacted under s40(2) of the FOIA (personal data) - Team leader, Business, Planning and Programme Management, Policy Division – item 7	
Name redacted under s40(2) of the FOIA (personal data) - Head of Science Strategy	
Mr Aidan McIvor	Head of Directorate
Name redacted under s40(2) of the FOIA (personal data) - Executive Assistant to the Chairman	

Department of Health (DH) and Legal Services

Mrs Claire Armstrong	Deputy Director (Medicines, Pharmacy and Industry Division)
Mr Mark Wilson	Deputy Director, MHRA Nutrition and EU Team, DH DH Legal Advisers, Government Legal Department

Item 1: Introductions and Announcements

1.1 Apologies were received from Mr Peter Commins, Chief Operating Officer and Director of Finance. Mr Commins was unable to attend the Annual Accounts Seminar and Board meeting because of a pressing personal commitment.

1.2 The Chairman announced that Mr Commins would retire in October 2016; Mr Commins had written to Board earlier about his planned retirement. Dr Hudson, Chief Executive, reported that arrangements for recruiting to replace the Chief Operating Officer were commencing.

1.3 The Chairman welcomed everyone to the meeting.

Item 2: Declarations of interest

2.1 Mr Stephen Lightfoot, Non-Executive Director, reported that since the last Board meeting he had signed a consulting agreement Blue Earth Diagnostics Limited; the agreement came into force on 13 April 2016.

Item 3: Minutes of the meeting of 14 March 2016 (final version)

3.1 The final version of the minutes of the Board meeting of 14 March 2016 was noted. Sir Alex Markham, Non-Executive Director (NED), sought clarification about the variation between the number of Full-time Equivalents (FTEs) mentioned in the Finance and Procurement Reports of March and April 2016 and what was mentioned in the draft Annual Report. The Chairman explained that variations occurred from month to month, but asked that Aidan McIvor, Head of Directorate, to check the accuracy of the figures for FTEs in the March and April minutes.

Action: Directorate to check with Finance about the accuracy of the FTE figures.

Item 4: Minutes of the last meeting, 12 February 2016, and matters arising

4.1 The draft minutes of the Board meetings (part 1 and part 2) of 11 April 2016 were agreed.

Matters arising

4.2 The Board reviewed the actions' list from previous meetings.

DISCUSSION ITEMS

Item 5: Annual Accounts Seminar

5.1 The seminar was presented by Richard Humphreys, Deputy Finance Director, supported by (names redacted under s40(2) of the FOIA (personal data)); (name redacted under s40(2) of the FOIA (personal data)) of Communications Division joined for the discussion of the draft Annual Report.

5. 2 Mr Humphreys explained that the purpose of the seminar was to allow the Board to review the draft Annual Accounts before they were submitted to the Agency's auditors and, in particular, the key statements, and to take questions on the draft annual accounts. Additionally, the Board would consider future reporting to the Board (an analysis of the key vulnerabilities and challenges facing the Agency in 2016-17), as well as a paper on benefits realisation management from John Quinn, Director of Information. Management Division.

5.3 Prior to opening the seminar to a wider discussion, Richard Humphreys and his colleagues provided the following updates:

- *Timetable:* The Board heard that the National Audit Office's (NAO) final audit fieldwork would begin on 23 May and should be completed by mid-June, which, together with the draft Annual Accounts, would be reviewed by the Audit and Risk Assurance Committee (ARAC) on 17 June. Sign-off of the accounts is due to take place by the w/c 4 July 2016, with the Annual Report and Accounts being tabled in Parliament by mid-July, prior to Parliamentary Recess on 21 July.

- *Draft Statutory Accounts 2015/16* – The Board heard there were no significant accounting changes; the period 9 accounts have been completed on time with no issues identified by the NAO. Although the final internal audit opinion is still awaited, the draft opinion gives the Agency "moderate assurance".

- The Board received an overview of the Agency's financial performance for 2015/16; an update was also given on the Agency's strategic finance and its budgets of the Agency's three centres (MHRA Regulator, NIBSC and CPRD) for 2016/17.

5.4 The Board, at the invitation of the Chairman, asked questions and offered comments. These centred on the following areas:

- *Governance Statement* – The Board asked that a number of factual errors in the Governance Statement be corrected, e.g. the HR sub-committee was stood down in 2015. The Board heard that the document was in draft form and was in the process of being updated.

- *Board effectiveness Terms of Reference (ToRs)* – The Board asked that the final version of the ToRs be sent to the Board. The Board was assured this would be done after the seminar.

Action: Directorate to circulate the final version of the Board Effectiveness ToRs.

- *NAO Audit Opinion* – Mr Humphreys informed the Board about the interim management letter on the implementation of the Cabinet Office controls on certain categories of expenditure. This included the comment that, should these not be complied with, it could result in qualification of the accounts. Mr Humphreys explained that this was a possibility on the grounds of regularity and would depend on how the Agency responded to the recommendations The Chairman and members of the Board expressed concern that this was a possibility. The Board heard that action has been taken by the owners of the various controls to ensure that the Agency is compliant with each of the controls.

- *Fraud* – Deborah Oakley, Chair of ARAC, highlighted an issue that ARAC had raised in relation to fraud, where concern had been raised by ARAC that there was not an overall Agency lead for non-regulatory fraud. Dr Hudson responded to say that this had been addressed, with Mr Mogford being appointed to the role of leading/coordinating all aspects of non-regulatory fraud. Ms Oakley asked that ARAC being informed in writing of the appointment, for a brief paper to the next ARAC explaining how Mr Mogford intended to fulfil this responsibility. The ARAC annual report would be amended accordingly. Dr Hudson advised that this would be done.

  Action: Fraud: (i) Policy Division to prepare a short paper on fraud in time for the ARAC meeting on 17 June; (ii) ARAC to be informed in writing by Dr Hudson of arrangements within the Agency to deal with non-regulatory fraud.

- *Information Risk* – The Board asked that the wording on cyber security on page 50 in the Annual Report be strengthened.

- *Information Technology expenditure* – The Board expressed concern about the lack of clarity of what was being spent on IT and the need for tracking and assurance of such expenditure. John Quinn explained the current processes in place, about which he would cover in his paper towards the end of the seminar.

- *Transaction / digital engagement with the Agency* – The Board commended the Finance team on progress in this area; in particular, there had been an 11% increase in the use of iRIS, the online account management system for Agency customers, during the year. The Board noted that a team from Finance and Procurement Division had been shortlisted for the Civil Services Awards in 2015, which the Board recognised was a major achievement

- The Board asked if the Agency could oblige customers to only use iRIS; the Board heard that the current regulations would not permit the Agency to make such a request.

- *Financial forecasting* - The Board queried if more could be done to improve the approach to and the process of financial forecasting. The Board heard that this was regularly considered and finance recognised the need to work closely with the teams that are spending the money. The Board also asked about business ownership of the operational transformation plans. Dr Hudson advised that the CET had recently discussed this topic and agreed a CET subgroup would be established, under the Chief Operating Officer to take this forward. In addition, the operational divisions were closely involved in development of specific business cases in the operational transformation project, for example John Wilkinson, Director of Devices, was responsible for presenting the device business case to CET recently.

  - *Business analysis section - layout and format* – The Board agreed that the format was good, although many NEDs would have appreciated being advised in advance that the figures quoted in the draft report were not final versions.

  Action: Should the NEDs have any additional comments, they should be sent to Richard Humphreys, Deputy Finance Director, via Directorate.

  - *Accounting rules* – The Board heard because of Government accounting rules, all capital money received from DH has to be recognised as income in the year I is received.

Draft Annual Report 2015/16

- The Board reviewed the draft report, which would be finalised over the coming weeks. Ben Scott, who gave an update on the draft Annual Report, asked that any comments about the text of the draft Annual Report be sent directly to him. Aidan McIvor of Directorate would circulate Mr Scott's email address after the seminar.

Benefits Realisation Management

- As part of the Annual Accounts Seminar, John Quinn presented a paper on Benefits Realisation Management. The paper provided an overview of the Benefits Realisation Management framework and associated processes which included an update on plans for operational transformation. Mr Quinn went on to explain the seven priorities of the strategy: the Information Management Division (IMD) Operating Model; Service Operation; Infrastructure; Enterprise Resource Planning; Information; Service Improvement; and Digital Services Transformation. The update also covered ongoing running of services, enterprise resource planning, which will be focussed on the HR, finance and procurement system, as well as an overview on business intelligence information and a digital workplace.

- Mr Quinn explained that the projections of costs were estimates at this stage and subject to change, and did not yet include cashable or cost avoidance benefits that would be derived, as these get produced as part of annual budget planning and with the formation of business cases. Mr Quinn highlighted that investments were not yet approved, and that control would be exerted on affordability through visibility at CET, that further apportionment of costs needed to be spread across NIBSC and CPRD budgets, and that the move to buying services rather than building technology would impact positively on deprecation costs. IMD are delivering change with an agile approach, this affords the ability to stop and change projects mid delivery allowing a further lever to address affordability concerns should the economic position change.

- A number of NEDs expressed concern about the clarity of the proposed IT spend and that the digital strategy had not yet been fully-costed to take account of operational efficiencies. The Board were also concerned that there seemed to be a lack of ownership at organisational level, with finance and IT having differing views about the level of expenditure; the Board emphasised that decisions on investment require a high level scrutiny given the risk of deficit due to affordably after the current 5 year period. A number of NEDs asked specific questions about IT expenditure, in particular, about the full costs' recovery against IT spend, as well as the need for assurance that the organisation has control over such expenditure. It was agreed that these questions would be addressed in greater detail at the Board meeting on 17 June. Dr Hudson said that a joint Finance / Information Management Division paper would be prepared in time for the June Board. Dr Hudson also advised that a sub-group of the CET had been set up to consider this and the wider issue of operational transformation.

Other comments

- A number of NEDs expressed dissatisfaction with the quality of the papers for the seminar and their very late circulation.

- The Board expressed some concern about apparent discrepancies between figures in different papers and asked that, in future, every attempt is made to ensure consistency in papers, with the executive presenting a single position. The Board requested that the table for IT expenditure in the new style finance report be completed with the agreed amounts for expenditure.

Related Party Transactions

- Members of the Board were asked to complete Related Party Transactions declaration forms, which were distributed at the end of the meeting.

Summary of actions from Annual Accounts Seminar:

(i) Directorate to circulate the final version of the Board Effectiveness ToRs
(ii) Business analysis section: Should they have additional comments, NEDs to send on additional comments.
(iii) Fraud: (i) Policy Division to prepare a short paper on fraud in time for the ARAC meeting on 17 June; (ii) ARAC to be informed in writing of arrangements within the Agency to deal with non-regulatory fraud.
(iv) Directorate to send Ben Scott's MHRA email address to the Board so to allow NEDs to send comments directly to Communications Division.
(v) Peter Commins and John Quinn to prepare a short paper on IT expenditure in time for the Board meeting on 17 June.

Item 6: Yellow Card reporting system

6.1 Mick Foy and (name redacted under s40(2) of the FOIA (personal data) presented a progress report on the reporting of suspected Adverse Drug Reactions (ADRs) to the Yellow Card (reporting) Scheme. The update covered (i) ADR trends (ADR reporting has increased by 56% over the past five years); (ii) patient reporting, which has increased by 43% over in 2015; (iii) electronic reporting; (iv) Medication Safety Officers' network; (v) the Yellow Card Roadmap; (vi) update on the five Yellow Card Centres; and (vii) signal detection.

6.2 The Chairman thanked Mr Foy and (name redacted under s40(2) of the FOIA (personal data) for the paper and sought the Board's views. These centred on the following areas.

- *Signal detection* – While commending the report, a number of Board members said they would have preferred that the report had included several specific examples and the effects they had. Mr Foy noted these comments for use in future reports to the Board.

- *Objective 2 (Extending the Scheme to capture reports of incidents of all types of harm with healthcare products)* - The Board commented that the Agency should consider collecting more data on poisoning / unwanted therapeutic effects. The Board heard that the Agency is in discussion with the National Poisons Information Service (NPIS) about establishing links between their respective reporting systems; moreover, a paper on the reporting of overdosing via the Yellow Card Scheme will come to the Board later in the year.

- *Roadmap* – The Board asked why the report was entitled a Roadmap; Mr Foy advised that the word is a commonly used term for such documents; an alternative term is 'delivery pathway'.

- *Apps* – A number of NEDs commented on the Yellow Card App, which one thought was overly complicated; another NED advised that healthcare professionals want an app that is easy and quick to use and suggested that the Agency could consider providing two apps: one to report an ADR, while the second would be for information about medicines. Mr Foy said that independent research had been conducted as part of the WebRADR project which had led to the development of the App, but the Agency could consider commissioning further independent research in this area; additionally, he would take into account the Board's other comments.

6.3 The Chairman and the Board congratulated Mr Foy and his team on their work to date. The Board confirmed they would welcome further periodic updates on the Yellow Card Scheme, which should reflect the Board's earlier comments, e.g. on the use of specific examples.

Item 7: Business Plan targets and strategic activities – Quarter 4

7.1 (name redacted under s40(2) of the FOIA (personal data) presented a progress report for Quarter 4 of the Business Plan 2015/16. The Board heard that the Agency had met 33 of its 36 targets for 2015-16. Two targets were not met – increasing CPRD coverage of primary care data to 20% by the end of the financial year; and to enable 280 CPRD research studies in 2015/16. The Board heard that the metrics for CPRD required re-base-lining during the course of the year, to ensure they were precise. Ms Bostock went on to report that one target, to assess 97% of Decentralised Procedure Reference Member State Marketing Authorisation applications within 70 days, was nearly met at 96.1%.The Board heard that the target had been missed because of understaffing in Licensing Division.

7.2 Of the 78 activities due to be completed, 70 were completed and 8 were postponed; 6 of these postponed were due to factors outside of the Agency's control.

7.3 The Chairman thanked (name redacted under s40(2) of the FOIA (personal data) for the report and then sought the Board's views. These centred on the following area:

- *CPRD targets* – The Board asked if it would be possible to meet the targets in 16/17, in particular, to increase CPRD coverage of primary care data to 20%. Dr Hudson noted the challenges involved in meeting next year's CPRD targets, but explained the range of work that the Agency will carry out to increase GP coverage and to support the new research studies. Also, it was clarified that, rather than maintaining this year's target of increasing CPRD coverage of primary care data to 20%, next year's target was to drive the increase of CPRD GP coverage from 600 to 1000 GP practices.

OPERATIONAL AGENDA

Item 8: Chief Executive Officer's (CEO) Report

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

- *TPP practice software* - An update was given on an emerging issue: concerns about the QRISK2 predictive algorithm for cardiovascular disease in TPP practice software. The Board heard that a cross-agency incident group has bene set and Agency officials are working closely with DH.

- *House of Commons Science and Technology Select Committee, 19 April* – An update was given on the evidence the Agency gave at the House of Commons Science and Technology Committee Inquiry into the impact of EU regulation on Life Sciences. The Board heard that the Parliamentary Committee was keen to understand how EU regulation impacts on the pharmaceutical and medical devices sectors in the UK, how we influence policy development and EU decision making, and whether there are any legislative changes we would like to see. Dr Hudson reported that at the hearing the Agency was able to underline the very influential role the MHRA holds in both the medicines and devices sectors. The Agency's role was supported by the representative of the Cancer Research UK and the Life Sciences Minister, George Freeman MP, both of whom addressed the Committee.

- *Medical kits in Life Rafts* – An update was given on advice that the MHRA and the Maritime & Coastguard Agency (MCA) issued on 27 April to suppliers of inflatable life rafts. The advice asked that suppliers check the origin of their life-rafts. This follows a GDP (Good Distribution Practice) inspection which found that some UK life raft service stations, manufacturers and distributors of life rafts had been importing and supplying inflatable life rafts with medical kits that contain medicines and medical devices which originated from China, and are not authorised for use in the UK.

- *Laboratory animal welfare and ethics standards in China* – An update was given on China's plans to publish national standards on laboratory animal welfare and ethics before the end of the year. The Board heard that the UK played a key role in influencing China's decision, which is likely to have a positive impact on global cosmetic and pharmaceutical markets. The new legislation, when it comes into force later this year, will be modelled on the UK's system for regulating animal welfare and ethics following the '3Rs' of Replacement, Reduction and Refinement. A toxicologist in MHRA's Clinical Trials Unit first became involved in the Chinese negotiations in around 2012 as the MHRA's representative to the National Centre for the replacement and Refinement & Reduction of Animals in Research (NC3Rs).

- *Priority Medicines (PRIME)* – An update was given on the European Medicines Agency's PRIME scheme, which aims to optimize the development and accelerated assessment of medicines of major public interest. The Board heard that the scheme has proved very popular with almost twenty applications reported, including a number from small and medium sized enterprises (SMEs).

- *Joint MHRA/ Bio-Industry Association (BIA) conference "Accelerated development and access to innovative medicines for patients"* – An update was given on the sixth joint BIA/MHRA regulatory conference that was held at the Royal Society of Medicine on 4 May.

- *Litigation* – An update was given on three cases, two of which were appeals against Judicial Reviews in favour of the MHRA.

Item 9: Minutes of the Corporate Executive Team (CET) of 10 March 2016

9.1 The minutes of the CET meetings of 10 March 2016 were noted.

Item 10: Any Other Business (AOB):

10.1 The Chairman reported that he would address a briefing session on EU drugs and devices regulation at the Scottish Medicines Consortium.

Date of next Board meeting: 17 June 2016