MHRA Board

MINUTES OF THE MEETING

18 September 2015

Present:

The Board

Professor Sir Michael Rawlins	Chairman of MHRA
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 Peter Commins	Chief Operating Officer and Finance 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

Others in attendance

MHRA executive and supporting officials

Ms Vanessa Birchall-Scott	Director of Human Resources – items 1-4 inclusive
Ms Rachel Bosworth	Director of Communications
Dr Stephen Inglis	Director of National Institute for Biological Standards and Control (NIBSC)
Mr John Quinn	Director of Information Management Division
Dr June Raine	Director of Vigilance and Risk Management of Medicines Division (VRMM)
Ms Patience Wilson	Deputising for the Director of Policy
Mr Mick Foy	Group Manager, VRMM
Dr Phil Bryan	Unit Manager, Vaccines, anti-infectives and advanced therapies, VRMM
[Redacted Section 40 personal]	Head of Science Strategy
Mr Aidan McIvor	Head of Directorate
[Redacted Section 40 personal]	Executive Assistant to the Chairman

Department of Health (DH)

Mrs Claire Armstrong	Deputy Director (Medicines, Pharmacy and Industry Division)

Item 1: Introductions and Announcements

1.1 Apologies were received from Mr Martin Hindle, Non-Executive Director (NED), and Jonathan Mogford, Director of Policy.

1.2 For technical reasons, Mr Mark Wilson, Legal Services, and colleagues from Policy Division were unable to join the meeting by telephone.

1.3 Sir Michael thanked Dr Stephen Inglis, Director of NIBSC, and his staff for hosting the Board meeting. Sir Michael then welcomed everyone to the meeting, including Dr Barbara Bannister, Professor Bruce Campbell, Mr Matthew Campbell-Hill, Mr Stephen Lightfoot, who were attending the meeting first time as members of the Board. They had joined the Board on 1 September 2015.

1.4 Sir Michael advised that after lunch, there were would a number of induction sessions for the new Board members.

Board membership

1.5 Sir Michael reported that Board had met without Executives present, at the start of the meeting to discuss the Agency's move towards becoming a unitary board. Sir Michael went on to report that the Board had agreed that Dr Ian Hudson, Chief Executive, and Mr Peter Commins, Chief Operating Officer and Director of Finance, would join the Board as Executive Members with immediate effect.

Board sub-committees

1.6 Sir Michael reported that following a discussion he had with members of the Board, along with Dr Ian Hudson, Mr Peter Commins, and Ms. Vanessa Birchall-Scott (Director of Human Resources), it had been agreed that the Human Resources sub-committee would be discontinued, as it was no longer required.

1.7 Sir Michael went on to report that the Board had agreed the composition of the Board's two other sub-committees. Their membership from 18 September 2015 would be as follows:

- *Audit and Risk Assurance Committee*: Ms. Deborah Oakley (Chair), Mr. Martin Hindle (member), Mr. Stephen Lightfoot (member) Sir Alex Markham (member).

- *Remuneration Committee* – Professor David Webb (Chair), Dr. Barbara Bannister (member), Professor Bruce Campbell (member), Mr. Matthew Campbell-Hill (member).

Item 2: Declarations of interest

2.1 None was declared.

Item 3: Minutes of the last meeting, 20 July 2015, and matters arising

3.1 The draft minutes of the Board meeting of 20 July 2015 were agreed.

Matters arising

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

DISCUSSION ITEMS

Item 4: Five Year Talent Management Strategy – update

4.1 Vanessa Birchall-Scott presented a progress report on of the Agency's Talent Management Strategy. The update covered progress to date during current financial year, as well as details of work due to take place during the remainder of 2015/16 and in

the next financial year. The Board heard that a pan-agency career pathways group has been set up; a new Head of Talent Management & Development has been appointed; a 360 degree feedback programme has been piloted; succession planning as a critical business process has been launched; Agency staff at Senior Civil Service (SCS) level 2 and their direct reports at SCS1 level are being selected for Civil Service and DH talent management programmes; and training on career conversations and on the use of the 9 box grid for all SCS1 staff is being rolled out. Ms Birchall-Scott advised this approach will be piloted among members of staff at all grades in Policy Division and Inspection, Enforcement and Standards Division. The pilot will begin in October 2015. It was noted that HR will explore specific development support for those staff who are in senior roles and do not want to be nominated for the DH programmes or who were unsuccessful.

4.2 In reply NEDs' questions about the recruitment, Ms Birchall-Scott said the Agency highlights its flexible working arrangements, as well as the training and development packages which are on offer. The Board heard that it is increasing difficult to match NHS or private sector salary packages for specialist posts, e.g. medical assessors and in the inspectorate, hence the emphasis on the Agency's broader package of inducements, such as flexible working. Ms Birchall-Scott said there was more to be done in a range of areas, for example, raising the profile of the Agency as an attractive employment option with medical doctors via the Medical Royal Colleges. Moreover, the Agency will liaise with Public Health England, which faces similar challenges, to explore a possible joint solution.

Item 5: Triennial Review – update on implementation

5.1 Mr Peter Commins gave a progress report on the implementation of the recommendations of the triennial reviews into the Agency as a whole, the Commission on Human Medicines and the British Pharmacopeia Commission. The Board heard that good progress had been made in taking forward the recommendations, with some already having been completed. The Board welcomed the report and asked for an update on the recommendation on the funding of the Agency's devices' work. A number of NEDs questioned what incentive there would be and requested reassurance about the practicality of the scheme. Mr Commins addressed these questions and gave an update on discussions to introduce a levy to help fund the Agency's work in this area. A further update will come to the Board later in the year.

Item 6: Developing an MHRA integrated patient safety and surveillance strategy

6.1 Mick Foy presented a paper on the Agency's integrated patient safety and surveillance strategy. The Board heard that the strategy aims to directly support the agency's primary objective, namely to enhance and safeguard the health of the public ensuring that medicines and medical devices work and are acceptably safe. It builds on the work already completed to put in place a single reporting tool for adverse drug reactions, device adverse incidents, counterfeit products and defective medicines. The Board heard that that the strategy takes into account the recent and continuing changes to the UK healthcare system, including the replacement of the National Reporting and Learning System (NRLS) with a Patient Safety Incident Management System (PSIMS), as well as the findings of the reports by Francis (in particular, a duty of candour), Berwick, and Stephenson.

6.2 Mr Foy said the joined up approach across the agency will improve MHRA's signal detection capability; improve signal and risk assessment including acquiring access to wider vigilance data pools such as CPRD; improve MHRA's ability to deliver and target safety and learning messages; improve benefit/risk assessment; and ensure effective capture of information from incident reports and also the wider scientific evidence base,

including social media information and other technologies such as the Yellow Card App. To help this work an internal steering group has been set up to develop further the strategy and oversee implementation. The steering group will also look at vigilance best practices in Europe and beyond.

6.3 A number of NEDs commented on the variety of reporting mechanisms in the NHS and the need for them to be linked to PSIMS, thereby reducing the risk of double counting. Other Board members expressed concern about the incidents which go unreported, which the strategy aims to reduce. Dr Hudson advised that he had raised the issue of the reporting of incidents by general practitioners at his recent bilateral meeting with Mr Niall Dickson, Chief Executive of the General Medical Council. The Agency is trying to get the reporting of adverse incidents by doctors to become part of the revalidation and appraisal process.

6.4 Sir Michael and the Board thanked Mr Foy and his colleagues in Devices and VRMM Divisions for their work and endorsed the direction of travel of the vigilance strategy.

Item 7: Vaccines pharmacovigilance – key challenges for 2015/16

7.1 Dr Phil Bryan presented a paper outlining the key vaccines pharmacovigilance challenges for the current year and the Agency's strategy for strengthening vaccine risk management. This included an update on the work of the Vision Network (Vaccination and Immunisation Safety – Integrated Operations Network), as well as the 'Strengthening vaccine risk management project', which was launched in September 2013. The VISION Network provides a framework to explore how NIBSC-based research and expertise into VRMM-led risk benefit assessments for particular vaccines.

7.2 Dr Bryan went on to report that two major new immunisation campaigns to protect against meningococcal group B and W are about to commence across the UK. In addition there is some public concern about a possible safety signal in relation to human papillomavirus (HPV) vaccine and MHRA is now leading on an EU referral of the issue. The Board heard that these issues present an opportunity for the Agency to lead in evidence-based decision-making. Dr Bryan said that in each case the Agency will seek to strengthen and make best use of internal networks, particularly joint working across the agency's three centres (MHRA regulatory, NIBSC and CPRD). Dr Bryan went on to mention the Agency's collaborative work in this area with Public Health England and the Devolved Administrations.

7.3 The Board welcomed Dr Bryan's paper and went on to advise on the need to handle public relations and communications in this area most carefully in order to avoid any miscommunication. Several examples were given of high profile vaccine stories in the media. Mr Matthew Campbell-Hill, NED, said it is vital that schools featured significantly in any educational campaigns to highlight the importance of vaccines' programme. School children need to be made aware of benefits that flow from having a vaccine programme. In conclusion, the Board endorsed the direction of travel of the Agency's vaccine strategy.

Item 8: Cyber and information security

8.1 John Quinn presented a paper on cyber and information security. Sir Michael said he had asked Mr Quinn to present the paper following a seminar on cyber security he had attended at the DH for the chairs of arms-length bodies. Sir Michael said cyber security was an area about which he was very concerned.

8.2 Mr Quinn set the subject in context by explaining the journey the Agency has made over the past twelve months and the changes that need to be made over the next eighteen months. The Board heard about the infrastructural changes, in particular, those which will arise from the change of the main supplier. The Board heard that significant progress has been made in developing the Agency's digital and information technology capacity and awareness; this has been helped by a series of audits of processes and controls in place, which the Agency has acted on to remedy and make more robust. Mr Quinn, as the Agency's Senior Information Risk Owner, then went on to give his assessment of cyber and information security, and the strategy for addressing the range of threats which the Agency faces. Mr Quinn also advised the Board of technological developments (software and hardware), as well as current and emerging threats. For example, the Board heard that of approximately 2.5 million emails which the Agency receives every month, around a quarter are 'attacks'.

8.3 A number of non-executive directors asked what the Agency was doing to raise awareness of cyber security among new and current staff. Mr Quinn explained that all staff undergo IT security training, which is mandatory. New joiners are, in particular, made aware of IT security protocols, which are currently being updated, e.g. about the use of IT hardware while overseas. Mr Quinn said there was much that was being addressed quickly and that progress was being tracked in a systematic way.

Item 9: Business Plan – monitoring report for Quarter 1 (April - June 2015)

9.1 Ms Patience Wilson presented the Quarter 1 monitoring report for the Business Plan for 2015/16. The Board heard that the Agency is on track to meet all but two of its performance targets. The two targets which are not on track are: PM7(b) increasing population cover of primary care data within CPRD to 20% by year-end; and PM8(b) answering at least 80% of PQs within a set deadline. The Board heard that the CPRD team had redefined the way that the CPRD coverage is now calculated. Current coverage is 19 million people who had ever been included and 5.5 million actively contributing data, representing 8.5%of the UK population.). The Board heard that CPRD expects a major increase in population coverage by Quarter 3. As for target PQ target [PM8 (b)], the Board heard that measures had been put in place to lift the Agency's performance and that the target should be met by year end.

STANDING ITEMS

Item 10: CEO's report for July and August 2015

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

- *DEAC* – An update was given on the inaugural meeting of the Devices Expert Advisory Group (DEAC), which took place at 151 Buckingham Palace Road on 2 July under the chairmanship of Dr Peter Nightingale.

- *Yellow Card App launch* – An update was given on the launch of the Yellow Card App on 14 July 2015 by George Freeman, Minister for Life Sciences, in the Apple and Play Stores.

- *Valproate* – An update was given on a meeting between Ministers and a patient group about their concerns over the risks of Valproate in pregnancy.

- *Product-related cases*: [Redacted Section 35 Government policy]

- *Alteplase* - An update was given on the review by an ad hoc expert working group of the CHM on the risks and benefits of Alteplase. A press briefing about the review's findings was held on 23 July.

- *Choloroform* - [Redacted Section 35 Government policy]

- *Falisified Medicines Directive* – The distance-selling provisions of the FMD came into effect on 1 July 2015. it is now an offence for UK-based sellers to offer medical products for sale online without displaying the common logo or without being included on the MHRA's list of registered online sellers.

- *Safety of HPV vaccine* – [Redacted Section 35 Government policy]

- *Innovation case studies* - An update was given on the Agency's sixth and seventh innovation cases studies, which have been published recently.

- *Early access to medicines scheme (EAMS)* – An update was given on the eight promising innovative (PIM) designations that have been issued so far. The Board heard that Sir Michael and Dr Hudson had met recently with their counterparts at NICE: Professor Haslam and Sir Andrew Dillon, to ensure that a gap doesn't develop between a product being made available under the EAMS and subsequent funding decisions and adoption by the NHS.

- *Devolved administrations* – an update was given on the second quarterly cross-UK Forum that took place on 1 July 2015 in Edinburgh between MHRA and the devolved administrations. The next forum will take place in London on 7 October.

- *Care Quality Commission (CQC)* – an update was given on collaborative work that is taking place between the Agency's Good Clinical Practice (GCP) inspectorate and inspectors from the CQC.

- *British Pharmacopoeia (BP)* – a new BP website was launched on 10 August.

- Royal Colleges – an update was given on the a series of introductory meetings that have taken place between the Agency's chairman and chief executive and the presidents of a number of the Medical Royal Colleges.

- *ICMRA* – an update was given on preparatory work that is taking place for the next meeting of the International Coalition of Medicines Agencies (ICMRA), which will take place alongside the Global Regulators' Summit in Mexico in November.

- Litigation – Updates were given on two judicial review appeals.

Item 11: Finance and Procurement report

11.1 Mr Peter Commins gave the highlights for first four months of the financial year 2015/16. They were:

- MHRA (Regulator) income: year to date was £34.3m.

- NIBSC operational income: year to date was £15.0m.
- CPRD income: year to date was £3.1m.
- Operating income for the Agency was £52.5m, which is £3.2m above budget.
- Total operating costs were £42.5m, which was £1.6m below budget.
- The Agency's bank balance at the end of July 2015 was £214.7m.
- Capital expenditure for the year to end of July 2015 was £2.5m.
- Total Product Licensing deferred revenue at the end of July 2015 was £18.0m.
- The number of full-time equivalents in July 2015 was 1,206, with 137 short-term contracts and 38 non-payroll employees.

Item 12: Minutes of the Corporate Executive Team (CET) of 14 July 2015

12.1 The minutes of the CET meeting of 14 July 2015 were noted.

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

13.1 None was given.

Item 14: Any Other Business (AOB):

14.1 Tim Kelsey – It was noted that Tim Kelsey, Director for Patients and Information at NHS England, will leave the NHS to take up a new post in Australia.

Date of next Board meeting: 16 October 2015