Medicines and Healthcare products Regulatory Agency

Minutes of the Board meeting (in public session: 10.30 a.m. – 12.30 p.m.)
Round Room
10 South Colonnade, Canary Wharf
London

15 April 2019

Present:

The Board

Professor Sir Michael Rawlins GBE	Chair of MHRA
Professor David Webb	Deputy Chair of MHRA
Dr Ian Hudson	Chief Executive
Mr Jon Fundrey	Chief Operating Officer
Ms Amanda Calvert	Non-Executive Director
Professor Bruce Campbell	Non-Executive Director
Mr Stephen Lightfoot	Non-Executive Director
Ms Anne-Toni Rodgers	Non-Executive Director
Mr Stephen Lightfoot	Non-Executive Director
Mr Michael Whitehouse OBE	Non-Executive Director

Others in attendance

MHRA executive and supporting officials

Mr Jonathan Mogford	Director of Policy
Ms Rachel Bosworth	Director of Communications
Dr Samantha Atkinson	Director of Inspection, Enforcement and Standards
Ms Vanessa Birchall-Scott	Director of Human Resources
Dr Dan O'Connor	Medical Assessor
Dr Julian Bonnerjea	Head of Biological Medicines Unit
{Redacted: Section 40: Personal data}	Head of Signal Detection Unit Vigilance and Risk Management of Medicines Division
{Redacted: Section 40: Personal data}	Head of Science Strategy
{Redacted: Section 40: Personal data}	Executive Assistant to the Chairman
Mr Aidan McIvor	Secretary to the Board and Head of Directorate

Legal Services

Ms Joanna Greenidge	Deputy Director, MHRA, Medicines and Information Team, DHSC Legal Advisers, Government Legal Department.

Item 1: Introductions and Announcements

1 Apologies were received from Dr Barbara Bannister, Non-Executive Director; Professor Dame Valerie Beral, Non-Executive Director, Professor Sir Alex Markham, Non-Executive Director; Ms Carly McGurry, Deputy Director, Medicines

and Medical Devices Regulation and Prescribing Policy, Department of Health and Social Care (DHSC).

- The Chair welcomed everyone to the meeting, including staff observers and members of the public.

Item 2: Declarations of interest

2.1 Professor Bruce Campbell reported his appointment as Associate Editor of a new publication: *British Medical Journal - Surgery, Interventions and Health Technologies (BMJ-SIT).*

Item 3: Minutes of the Board meeting of 22 October 2018

3.1 The minutes of the last Board meeting in public session (22 October 2018), which were adopted by the Board on 19 November 2018, were noted.

DISCUSSION ITEMS

Item 4: Exiting the EU – oral update

4.1 Jonathan Mogford presented an update on the recent agreement between the UK and the European Union (EU) on the flexible extension of Article 50. Mr Mogford explained that in practice the UK will remain a member of the EU until 31 October 2019, that is, unless one of the optional flexibilities, such as Parliament endorsing the Withdrawal Agreement, be used between now and 31 October. Mr Mogford went on to explain what the recent agreement between the UK and the EU would mean for the Agency and the work the Agency will continue to carry out to ensure that it is ready for a No Deal outcome, as well as for a Withdrawal Agreement. Mr Mogford's update also covered work the Agency is doing regarding preparing for post-Brexit relations with the EU and globally.

4.2 The Chair thanked Mr Mogford for the update and sought the Board's views. These centred on the following areas:

- *Transitional period* – The Board asked if the end date of the UK's transitional period, which had been December 2020, would change because of the recent extension granted to the UK. Mr Mogford advised that the end date would remain unchanged.

- *Impact on grant applications* – The Board asked if there was any discernible impact on obtaining research grants from the EU, e.g. in relation to NIBSC. Mr Mogford advised this was being monitored and there is a downward trend in grants being offered from the EU. This is something that this Agency will raise with DHSC.

- In answer to questions from the Board about the Agency's readiness for the UK's exit from the EU, Mr Mogford advised that the Agency is ready for all eventualities. Moreover, the Agency's state of readiness has been recognised and applauded by Ministers.

4.3 The Chair went on to invite questions from staff and public observers; the following questions were asked:

- *Stockpiling of medicines* – A representative of the Alzheimer's Society asked if patients should stockpile medicines. Dr Hudson advised that stockpiling was not

necessary and would be counterproductive. Dr Hudson explained that DHSC has asked companies to stockpile and also put in place arrangements, e.g. ships, aircraft, and with transport routes, to ensure that medicines and healthcare products would be supplied in an orderly fashion, in the event of a No Deal Brexit.

- *Clinical trials* – A member of the public asked if clinical trials would be impacted by Brexit-related medicines shortages. Again, Dr Hudson reassured the public observers that DHSC has taken precautionary measures to minimise the risk of any such shortages.

Item 5: Chief Executive's Report

5.1 Dr Hudson presented the highlights from the CEO's report for March 2019. These centred on the following areas:

- *Opioids* – An update was given on a recent meeting of an Expert Working Group on opioids. A stakeholder network has been set up to support this work, which held its first meeting on 27 March. The meeting was attended by 28 different stakeholder organisations representing relevant healthcare professionals, health system agencies and, regulators and patient groups.

- *Cumberlege Review* – An update was given on the public hearing of the Government's Independent Medicines and Medical Devices Safety (IMMDS) Review Group, which was held on 27 February, before which Dr Hudson and other officials from MHRA gave evidence. The Agency is providing additional information to supplementary questions from the Review Team.

- *Hormone Pregnancy Tests (HPTs)* – An update was given on a meeting of an Expert Working Group of the Commission on Human Medicines which met on 18 March to consider the re-analysis of studies by Professor Carl Heneghen on HPTs and congenital anomalies.

- *Sartans* - An update was given on the recent recall of batches of Losartan-containing products.

- *ICMRA* – An update was given on the International Coalition of Medicines Regulatory Authorities (ICMRA) all-members telephone conference which was held on 14 March.

- *Partnership working* – An update was given on CEO-level bilateral meetings with Healthcare Inspectorate Wales on 26 February and Healthcare Improvement Scotland on 1 March, as well as other meetings with Healthcare Improvement Scotland on 14 March and NICE on 27 March.

- *Gates Foundation* - An update was given on a visit by Dr Hudson; Dr June Raine, Director of Vigilance and Risk Management of Medicines Division; and Mick Foy, Group Manager, to the Bill and Melinda Gates Foundation in Seattle, USA in early April. The visit was arranged to discuss the Agency's ongoing project supporting pharmacovigilance in developing countries.

5.2 The Chair thanked Dr Hudson for his report and invited questions from the Board. The Board commended Dr Hudson for ensuring that, despite the many pressures posed by Brexit-related work, the Agency is still able to discharge its 'day job' responsibilities. The Chair mentioned that he, along with Professor Webb, Deputy Chair, had written to

staff to thank them for all their hard in ensuring that the Agency was ready for whatever outcome occurred by 29 March 2019. The Board also asked what would happen to marketing authorisations that were being processed in April 2019, should we leave the EU. Dr Hudson addressed this question.

5.3 The Chair went on to invite questions from staff and public observers. None was offered.

Item 6: Operational Transformation - update

6.1 Jon Fundrey presented a progress report on the Agency's Operational Transformation Programme (OTP). For the benefit of public observers, Mr Fundrey explained the background to the Agency's OTP, the reasons why the Agency had to embark on an OTP and the challenges and opportunities which lie ahead with the need to replace ageing IT systems. Mr Fundrey went on to explain the seven workstreams, each of which is led by a Corporate Executive Team (CET) director.

6.2 The Chair thanked Mr Fundrey for his report and sought the Board's views. These centred on the following areas:

- *Customer engagement* – The Board asked about the Agency's approach to this aspect of the OTP. Mr Fundrey explained the analysis the Agency carried out on its customer base.

- *Medical devices work* – The Board asked about the Agency's approach to meeting the requirements of new devices legislation. Mr Fundrey said the Agency would ensure that resources would be in place to respond to the new regulations. Dr Hudson added that, while the Agency awaited the findings of the Government's Independent Medicines and Medical Devices Safety (IMMDS) Review Group under the chairpersonship of Baroness Cumberlege later in the year, it had to act now on things that could and should be done.

- *Staff engagement* – The Board asked about the Agency's approach to engaging staff more effectively about the OTP. Mr Fundrey explained what has been done so far: workshops, open forum sessions, updates and discussion sessions at all staff and managers' meetings, as well as updates on the staff intranet site, Insite. The Agency is also tracking staff comments and concerns that have been expressed in staff survey returns. Mr Fundrey said that although much has been done, further staff engagement actions are planned.

6.3 The Chair invited questions from members of the public and staff. A member of the Alzheimer's Society asked about the international implications of Brexit for signal detection, e.g. through the UK's Yellow Card Scheme. Dr Hudson advised that the Agency will continue to work with European partners and the World Health Organisation in this vital area.

Item 7: Early Access to Medicines Scheme (EAMS)

7.1 Dr Dan O'Connor presented an update on the Early Access to Medicines Scheme (EAMS) as it reached its 5th year milestone. Dr O'Connor explained that EAMS provides patients who have life-threatening or seriously debilitating conditions access to medicines that do not yet have a marketing authorisation when there is an unmet medical need. Unmet medical need means a condition for which there exists no satisfactory method of

treatment. Dr O'Connor explained that MHRA is responsible for the scientific aspects of the scheme which involves a benefit/risk scientific opinion that is issued after a two-step evaluation process: Step I, the Promising Innovative Medicine (PIM) designation; and Step II, the EAMS scientific opinion. Dr O'Connor concluded his update by reporting that since the launch of EAMS in April 2014, over 1500 patients have been treated with EAMS medicines, for a variety of conditions.

7.2 The Chair thanked Dr O'Connor for his report and sought the Board's views. These centred on the following areas:

- *Adverse incidents* – The Board asked if any patients had been harmed since the EAMS was rolled out. Dr O'Connor said that while no medicine was risk-free, no unexpected adverse reaction had been reported by a medicine delivered through EAMS, nor has a PIM had to be withdrawn.

- *Patient engagement - The* Board asked about EAMS' approach to patient engagement. Dr O'Connor said that patient input is greatly valued and explained the role of the patients and public forum.

7.3 The Chair invited questions from members of the public and staff. These centred on the following areas:

- *Repurposing* - A member of the public asked if it would be possible to 'tweak' a repurposed medicine. Dr Hudson explained the implications of changing, evenly slightly, the molecular structure of a medicine.

- *Post code lottery* – A member of the public highlighted perceived concerns about different approaches by healthcare professionals in the UK to EAMS, depending on where you live. Dr O'Connor asked that examples of any such divergence from UK-wide practice be shared with him.

Item 8: The Innovation Office

8.1 Dr Julian Bonnerjea presented a progress report on the work of the MHRA's Innovation Office. During his report, Dr Bonnerjea explained that the Innovation Office is now established as a key source of regulatory advice on novel medicines, medical devices and methods. The focus over the past year has been to raise awareness of the Office with academics and Small and Medium Enterprises (SMEs) who are less likely to be familiar with regulatory affairs than large companies. To date, the Office has answered over 700 queries and held over 100 meetings. This service is run in tandem with the MHRA's more formal Scientific Advice service. Dr Bonnerjea also mentioned that the Innovation Office operates on a 'virtual 'basis, as it does not have a physical structure or dedicated staff.

8.2 The Chair thanked Dr Bonnerjea for his report and sought the Board's views. The Board commended Dr Bonnerjea on the continuing success of the Innovation Office, noting that approximately 22% of enquiries were software / IT-related, which the Board thought was an interesting trend. Dr Bonnerjea went on to mention that the Innovation Office also contributes to the MHRA's work on horizon-scanning, which prompted the Board to ask if the Innovation Office has enough resource to carry out its work. Dr Bonnerjea said that, at present, the Innovation Office is able to function well, although the matter of resourcing is kept under review.

8.3 The Chair invited questions from members of the public and staff. One member of the public said she was would like to learn more about the work of the Innovation Office and planned to contact Dr Bonnerjea by email.

Item 9: WEB-RADR update

9.1 {Redacted: Section 40: Personal data} presented an update on the WEB-RADR (Recognising Adverse Drug Reactions) project and outlined the future possibilities of the programme. {Redacted: Section 40: Personal data} explained that MHRA is leading an innovative programme of work funded by the European Commission's Innovative Medicines Initiative. That programme is providing enhanced tools for safety and surveillance of medicinal products. This will enable the integration of incident reporting into third party services including the recently announced NHS App.

9.2 The Chair thanked for his report and sought the Board's views. These centred on the following areas:

- *Opening comments:* The Board commended {Redacted: Section 40: Personal data} on the WEB-RADR project and its future potential. A member of the Board said that she had used the Yellow Card App to report adverse incidents and had demonstrated its use at other events / meetings.

- *Taxonomy* – The Board recommended that, where possible, plain English be used in new Yellow Card App, in order to make it easier to use. {Redacted: Section 40: Personal data} welcomed the feedback and asked those present who had other feedback should send it on.

- *Falsified Medicine Directive (FMD)* – The Board commented that there was scope to bring the FMD and WEB-RADR schemes together using bar-coding.

9.3 The Chairman invited questions from members of the public and staff; the following comments were offered.

- *Yellow Card app* – A member of the public said that she preferred using the Yellow Card App to the online system.

- *Awareness aspect* - Another member of the public said that awareness of the Yellow Card Scheme seemed to be low and that greater efforts should be made to raise its awareness. Rachel Bosworth said the Agency is working with healthcare professionals to raise awareness of the Yellow Card Scheme, e.g. using posters in GP surgeries / health centres, through social media, and with wider communications with healthcare professionals.

- *Raising awareness through television dramas* - When asked by the Chair if the Agency plans to raise awareness of the Yellow Card Scheme through popular television dramas, Ms Bosworth confirmed that consideration is being given to the use of appropriate of storylines. Ms Bosworth said the risks associated with buying healthcare products online had been highlighted, for example, in an episode of *Coronation Street.*

Item 10: Attendance of a lay representative from an expert committee at future Board meetings

10.1 The Board considered a proposal to invite a lay representative from one of the expert advisory committees to attend the Board as an observer, until a lay representative is appointed to the Board. The Chair explained that it had not been possible to recruit a lay representative to the Board in 2018 during the last recruitment exercise but that a further attempt to recruit a lay representative may take place in the autumn of 2019 (to be confirmed). The Chair also mentioned that the number of Board meetings in public session will increase from four (in 2019) to six (in 2020).

10.2 The Chair sought the Board's views on the proposal. The Board endorsed the proposal but suggested that rather than have one, two lay representatives be invited to attend the Board – one each from the Devices Expert Advisory Committee (DEAC) and the Commission on Human Medicines (CHM).

10.3 The Chair invited questions from members of the public and staff. A member of the public shared her family's experience of receiving excessive amounts of contraindicated medicines. Dr Hudson thanked the member of the public for sharing her family experience's and went on to explain the Agency's remit in relation to the licensing of medicines. Dr Hudson asked that if members of the public present experience adverse drug reactions they should report such incidences via the Yellow Card Scheme.

Action: Directorate (Aidan McIvor) to invite lay representatives' members of the DEAC and CHM to attend future Board meetings.

Item 11: Any Other Business (AOB):

11.1 The Chairman then asked if there were any items of AOB; none was tabled.