FINAL

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

16 December 2019

Present:

The Board

Professor Sir Michael Rawlins GBE Kt	Chair of MHRA
Dr June Raine CBE	Interim Chief Executive
Mr Jon Fundrey	Chief Operating Officer
Dr Barbara Bannister MBE	Non-Executive Director
Ms Amanda Calvert	Non-Executive Director
Professor Bruce Campbell	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
Dr Sarah Branch	Interim Director, Vigilance and Risk Management of Medicines (VRMM)
Dr Julian Bonnerjea	Group Manager, Licensing Division
{Redacted: Section 40: personal data}	Head of Patient, Public and Stakeholder Engagement, Communications Division
Mr Phil Tregunno	Group Manager, Vigilance, Intelligence and Research, VRMM
{Redacted: Section 40: personal data}	Pharmacovigilance Information Unit Manager, VRMM
{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 Mabinthy Kanu	Senior Legal Adviser, DHSC Legal Advisers, Government Legal Department.

Lay representatives from Expert Committees

Ms Susan Bradford	Lay representative from the Commission on Human Medicines

Ms Sara Payne	Lay representative from the Devices Expert Advisory Committee

Item 1: Introductions and Announcements

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

1.2 Apologies were received from Professor David Webb, Deputy Chair and Non-Executive Director; Ms Anne-Toni Rodgers, Non-Executive Director; Ms Joanna Greenidge OBE, Deputy Director, MHRA, Medicines and Information Team, DHSC Legal Advisers, Government Legal Department; and Ms Carly McGurry, Deputy Director, Medicines and Medical Devices Regulation and Prescribing Policy, Department of Health and Social Care (DHSC).

1.3 The Chair welcomed all to the meeting.

Item 2: Declarations of interest

2.1 None was made.

Item 3: Minutes of the Board meeting of 21 October 2019

3.1 The minutes of the last Board meeting in public session (21 October 2019) were adopted.

DISCUSSION ITEMS

Item 4: Exiting the EU – oral update

4.1 Jonathan Mogford updated the Board on developments following the outcome of the general election of 12 December. The Board heard that the Agency, as with other public bodies across Government, expected to hear in the coming days the Government's plans for the future, including the introduction of legislation that will allow the UK to leave the European Union (EU) on 31 January 2020. It was noted that the Government's legislative programme would be set out in the Queen's Speech on 19 December.

4.2 In answer to a question from a Non-Executive Director, the Board heard that the Government has no intention of extending the post-EU Exit implementation period beyond 31 December 2020. The Board went on to ask if supplies of medicines and medical devices in the UK were assured. The Board heard that thanks to extensive preparatory work for a possible 'No deal' outcome during 2019, issues around the supply of medicines and medical devices in the UK had been addressed as far as possible.

4.3 The Chair invited questions from the public; none was offered.

Item 5: Chief Executive's Report

5.1 Dr June Raine presented the highlights from the CEO's report for June 2019. These included the following:

(i) *MHRA Annual Lecture 2019* – an update was given on the Agency's 2019 Annual Lecture which was given in October by Sir John Bell, Regius Professor of Medicine at the University of Oxford. The title of Sir John's lecture was "The future of life sciences: keeping the UK at the forefront of medical and scientific excellence".

(ii) *Awards*: an update was given on awards which the Agency's Communications Division had recently received: the 'Shaping our future' campaign won the Staff Engagement category at the 2019 Public Relations and Communications Association awards ceremony in London; and the Bronze Award for the Agency's #fakemeds campaign in the Public Service Communications Excellence Awards 2019'.

(iii) *Yellow Fever Vaccine* – An update was given on the third and final meeting of the Expert Working Group (EAG) on Yellow Fever Vaccine. The EAG concluded that the balance of benefits and risks of Yellow Fever vaccine remains favourable for most travellers when used in accordance with the current indications, but that additional measures should be put in place to minimise the risk of two rare but potentially fatal adverse effects: viscerotropic disease (YEL-AVD) and neurotropic disease (YEL-AND). The recommendations of the EAG were endorsed by the Commission on Human Medicines and have been sent to Yellow Fever vaccine clinics through a letter co-signed by the Agency, Public Health England, National Travel Health Network and Centre, and Health Protection Scotland.

(iv) *E-cigarettes and reports of lung adverse reactions* – An update was given on the Agency's investigation of reports of lung adverse effects linked to vaping.

(v) *Emerade Adrenaline Autoinjectors* – An update was given on a wholesaler and pharmacy level recall of Emerade adrenaline autoinjectors due to a defect possibly affecting performance, which was shared with DHSC and patient groups.

(vi) *International Coalition of Medicines Regulatory Authorities (ICMRA)* – an update was given on the ICMRA summit meeting in Rome in October, which was attended by the CEO and Policy Director and focussed on a range of relevant issues including mutual reliance between regulators.

(vii) *Clinical Practice Research Datalink (CPRD)* – An update was given on CPRD's population coverage, which has reached 20% of the population, with 13 million registered patients.

(viii) *National Institute for Biological Standards and Control (NIBSC)* – An update was given on activities and recent developments at NIBSC. This included the appointment of a Service Coordinator for NIBSC's website.

(ix) *Licensing* – an update was given on the number of new UK Marketing Authorisations which were assessed in October and November.

(x) *Black History Month* – An update was given on the Agency's programme of events to celebrate Black History Month in October. These included a lecture for staff by John James OBE, Chief Executive of the Sickle Cell Society.

5.2 The Board asked for an update about the apprenticeship scheme in Devices Division. The Board heard that three apprentices are undertaking a master's degree level apprenticeship standard in regulatory affairs, which is being provided by The Organisation for Professionals in Regulatory Affairs (TOPRA). The Board went on to note the success of the Good Manufacturing Practice Inspectorate annual symposium in November, which was held back to back with a Good Distribution Practice symposium.

5.3 The Chair invited comments and questions from public and staff observers; none was offered.

Item 6: The Innovation Office

6.1 Dr Julian Bonnerjea presented a progress report on the work of the Innovation Office; this followed an update that had come to the Board in April 2019. The Board noted the progress that has taken placed since the earlier update, e.g. two workshops / events which were each attended by 40-50 academics. The Board asked whether larger companies use the Innovation Office; Dr Bonnerjea explained that larger companies use the Scientific Advice Service. Dr Bonnerjea also explained the relationship between the Innovation Office and the Scientific Advice Service. The Board noted that the update paper contained abbreviations and acronyms, which required explanation and asked that in future a glossary is provided.

6.2 The Chair invited questions from staff and public observers. A member of the public asked if patients can attend any of the advice meetings. Dr Bonnerjea explained companies have brought patients along to meetings, however, because of the highly confidential nature of the discussions, patients or patient representatives cannot attend 'company meetings' unless at the invitation of the company concerned.

Action: A glossary of abbreviations and acronyms to be produced and to accompany all future Board papers

Item 7: Update on the Patient and Public Consultation

7.1 The Board received an update on the initial analysis of response to the Patient and Public Engagement consultation on how the Agency engages with patients and the public in its work. {Redacted: Section 40: personal data} reported that a total of 808 responses had been received and 64 people attended five consultation events across the UK, including representatives from each of the Devolved Administrations. The Board noted that a more detailed qualitative analysis of the responses is being carried out, which will form the basis of a report that will be published on GOV.UK.

7.2 The Board asked if there would be follow-up with individual respondents. {Redacted: Section 40: personal data} explained that where people provided their contact details, the Agency would follow up directly with respondents. The Board advised it was important not to allow a situation where a response is submitted with little or no acknowledgement or follow-up. The Board advised that the Agency's web pages should be easily accessible and user-friendly, and that we should put ourselves in the position of a member of the public. The Board heard that the Agency is looking at a range of issues, including the following key emerging themes: responsiveness, transparency/accessibility, communicating through partners, patient involvement and the Agency's public profile.

7.3 The Chair invited questions from staff and public observers. One member of the public said it would be helpful if the Agency's website had a two-way communication facility, which would "allow people to respond organically, which would help build trust". Another member of the public asked what can be done to encourage people to use the Yellow Card Scheme? A brief update was given on what work is being done by the Agency in this area.

Item 8: Adverse Drug Reaction reporting by patients

8.1 {Redacted: Section 40: personal data} presented a progress report on suspected Adverse Drug Reaction (ADR) reporting by patients to the Yellow Card Scheme. The

Board noted that patients now account for the largest reporting group and make a significant contribution to the scheme, generating a number of important signals. In fact, in 2019 20% of all suspected ADR reports came from patients. The Board noted that patients' knowledge of the Yellow Card Scheme is still low and so a range of sustained engagement activities is needed to increase awareness and reporting. {Redacted: Section 40: personal data} explained what the Agency is doing to increase patient awareness and reporting through its Yellow Card Strategy. As part of the Yellow Card Strategy a Yellow Card mobile app was launched 2015. To date, over 15,000 patients and healthcare professionals have download the app. {Redacted: Section 40: personal data} concluded by advising that responses to the Patient and Public Engagement consultation are currently being analysed and will provide valuable information that will inform the Agency's Yellow Card Strategy.

8.2 The Chair asked that more is done to raise awareness and increase patient reporting, especially as the number of ADR reports submitted via the Yellow Card app over the past three years was still relatively modest (1,000). However, members of the public informed the Board that they found the news features in the app very useful. The Board also advised that further work should be done on the website to make it more visible, and easy to use. The Board advised that the process should be 'two-way', with feedback given to patients, which together will build patient trust in the ADR system. The Board heard that work is in hand to address these points, many of which featured in the recent patient and public consultation exercise.

8.3 The Chair invited questions from the public and staff observers. One public observer highlighted the importance of keeping of the Agency's stakeholders' list up to date and of ensuring 'search optimisation' to help patients and members of the public access the Yellow Card web page quickly and effectively. Another public observer highlighted the importance of engaging with General Practitioners and suggested it going into the BNF publication updates all doctors use.

Item 9: Timetable for the Annual Report

9.1 The Board considered and noted the timetable for the Annual Report 2019/20. The Board recommended that in view of the size of the Annual Report document (the 2018/2019 Annual Report was around 129 pages in length) it would be useful to produce a short executive summary as a standalone document. Rachel Bosworth said she would be happy to consider the proposal. The Board also asked if paper copies were still required. The Board heard that paper copies of the Annual Report had to be laid before Parliament, but a minimal number were printed to satisfy this requirement, with the main circulation being digital.

Action: Communications Division to consider preparing an Executive Summary handout for the Annual Report.

Item 10: Pre-submitted questions from public observers:

10.1 None was submitted.

Item 11: Any Other Business (AOB)

Chief Executive appointment

11.1 A member of the public asked for an update on the appointment of the Agency's future Chief Executive. The Chair advised that an announcement will be made during the first quarter of 2020.

Drug safety issues

11.2 Several members of the public asked about drug safety issues, including the chemical difference between generic and brand name medicines. Dr Raine said she and her colleagues would address such specific questions outside the meeting. Dr Raine went on to say that if any member of the public wanted to speak to her or her colleagues about specific issues relating to today's meeting, they would make themselves available after the meeting.

11.3 The Chair invited questions from members of the public and staff; none was offered.