FINAL

Medicines and Healthcare products Regulatory Agency

Minutes of the Board meeting (in public session: 1.00 p.m. – 3.00 p.m.)
Round Room
10 South Colonnade, Canary Wharf
London

16 September 2019

Present:

The Board

Professor Sir Michael Rawlins GBE Kt	Chair of MHRA
Professor David Webb	Deputy Chair
Dr Ian Hudson	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
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
Dr Christian Schneider	Director of National Institute for Biological Standards and Control (NIBSC)
Mr Mark Jackson	Head of Enforcement Group
Mr Kyle Christie	Digital and Strategic Content Manager
Mr Mick Foy	Group Manager, Vigilance and Risk Management of Medicines (VRMM)
Dr Kirsty Wydenbach	Senior Medical Assessor, Clinical Trials Unit
Ms Louise Loughlin	Head of Science Strategy
Ms Jude Thompson	Executive Assistant to the Chairman
Mr Aidan McIvor	Secretary to the Board and Head of Directorate

Legal Services

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

Department of Health and Social Care (DHSC)

Ms Elizabeth Woodeson CBE	Director, Prescribing, Medicines and Pharmacy Directorate, Department of Health and Social Care.

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 Mr Stephen Lightfoot, Non-Executive Director; 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 made the following announcements:

(i) The Chair asked that the minutes record the Board's gratitude to Dr Hudson, who will retire on 20 September, for his distinguished service to the Agency as Chief Executive since 2013 and as Director of Licensing since 2001.
(ii) The Chair thanked Dr June Raine, Director of Vigilance and Risk Management of Medicines Division, for agreeing to take on the role of interim Chief Executive. The Chair advised that an announcement about Dr Hudson's permanent successor will be made in due course.
(iii) A recruitment campaign is underway to find two new Non-Executive Directors for the Board. The closing date for applications is 30 September.

Item 2: Declarations of interest

2.1 None was made.

Item 3: Minutes of the Board meeting of 22 July 2019

3.1 The minutes of the last Board meeting in public session (22 July 2019) were adopted.

DISCUSSION ITEMS

Item 4: Exiting the EU – oral update

4.1 Jonathan Mogford updated the Board on work to ensure the Agency is ready for a negotiated or a 'no deal' exit from the EU on 31 October 2019. As part of the update, Mr Mogford advised that work on 'no deal' has heightened considerably in recent weeks and that the Agency is working very closely with the Department of Health and Social Care (DHSC) and other partners across government, as well as with other stakeholder groups.

4.2 The Chair and Board thanked Mr Mogford for the update. The Chair went on to invite questions from staff and public observers; the following questions were asked:

Possible shortage of healthcare products

4.3 A member of the public asked what measures were being taken to ensure the UK would not suffer from shortages of medicines after 31 October.

4.4 Dr Hudson explained that responsibility for medicines supply rests with DHSC and not the Agency, Dr Hudson invited Ms Woodeson of DHSC to address the question. Ms Woodeson explained that DHSC has been working very closely with partners across government, e.g. the Department for Transport, as well the NHS, trade associations, wholesalers, pharmaceutical companies, suppliers of medical devices and many others, to help to ensure medicines and medical products continue to be available if there is a 'no deal' EU Exit.

4.5 Ms Woodeson went on to advise that the Government has put in place contingency measures to help ensure medicines continue to be available. These include: (a) improving trader readiness for new border arrangements; (b) building up buffer stocks of prescription-only and pharmacy medicines (these stocks will continue to be replenished as used); and (c) securing additional ferry capacity for all medicines, not just those included in the stockpiling.

4.6 Another member of the public thanked Ms Woodeson for her reply, which she thought was very reassuring and asked that greater public awareness be made of DHSC's preparedness work.

Item 5: Chief Executive's Report

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

(i) Update on what the Agency is doing following the suspension of manufacture of Total Parenteral Nutrition (TPN) at a site in England following the discovery of irregularities.
(ii) September's edition of the Agency's Drug Safety Update will include an article about Hormone Replacement Therapy (HRT) and breast cancer.
(iii) Preparatory work ahead of a meeting of the International Coalition of Medicines Regulatory Authorities (ICMRA) in Rome in late October.
(iv) Update on the signing of a Memorandum of Understanding with Iceland.
(v) Mesh for urinary incontinence – an update was given on future work.
(vi) Patient and Public Engagement consultation - the Agency is grateful for the feedback to date and is reviewing all the responses carefully.
(vii) Fake Meds Campaign – the Agency is working with partners to help develop the campaign.
(viii) Update on UK GP practices participating in the Clinical Practice DataLink (CPRD) - more than 1,600 are now contributing.

5.2 The Chair thanked Dr Hudson for his report and invited questions from the Board. These centred on the following areas:

- *Adverse Drug Reactions (ADRs) reports* - The Board noted that 20% of Yellow Card ADRs now come from members of the public, which the Board thought was a significant achievement and requested further details. Dr Raine said that a paper on ADRs from patients would come to the Board in due course.

- *Innovation* – A member of the Board advised that she had recently attended a conference at the London School of Economics where there was much interest in how the UK can best position itself to support innovation post-Brexit. The Board

noted that the Agency plays an important role in enabling the UK Life Sciences Strategy.

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

Action: VRMM to prepare a progress report on ADR reporting by patients for a future Board meeting.

Item 6: Criminal Enforcement within MHRA

6.1 Mark Jackson gave a progress report on key achievements within the MHRA criminal enforcement area over the past twelve months, the development of innovative practices, and the implementation of new approaches to increase efficiency and effectiveness.

6.2 The Chair thanked Mr Jackson for his report and sought the Board's views; these centred on the following areas:

- *'The dark web' v the 'open web'* - The Chair asked if a site located on the 'dark web' could be taken down. Mr Jackson advised that the Agency's focus is on the 'open web' where the greatest threat is posed by the sale of illicit healthcare products.

- *Funding* – A member of the Board asked how the work of the Enforcement Group was funded. Mr Jackson replied that it was funded through the Agency's budget. Mr Jackson also advised that the Agency is eligible to receive monies in accordance with the provisions of the Proceeds of Crime Act.

- *Legislative aspect* – The Board asked if the current legal sanction was a sufficient deterrent. Mr Jackson explained the difference between the prison tariffs for those who traffic in counterfeit healthcare products and class A drugs, the latter of which are covered by different legislation.

6.3 The Chair invited questions from staff and public observers. One member of the public asked about the illegal sale of food supplements, which Mr Jackson advised fell within the remit of the Food Standards Agency.

6.4 Rachel Bosworth gave a short update on the work carried out by Communications Division to publicise the work of the Enforcement Group, including the risks of fake medical products, especially those bought over the internet. She explained that Communications Division and the Enforcement Group work closely together to ensure media and social media coverage of enforcement operations and prosecutions.

6.5 The Chair concluded by thanking Mr Jackson for his excellent report.

Item 7: National Institute for Biological Standards and Control (NIBSC) - The Director's Report

7.1 Dr Christian Schneider presented 'Highlights from the Director of NIBSC'. The report provided a summary of the full year's activities against NIBCS's 2018/19 objectives, as well as highlighting some areas that will continue into 2019/20. The focus of the report was the scientific work of the Institute rather than corporate functions, such as finance, governance and risk. The reported scientific work and developments were on (a) Standards, (b) Biosimilars, (c) Advanced therapies, (d) Influenza, (e) Polio (f) Emerging infections, (g) Medicine Control Testing, (h) Research, (i) Refresh of the NIBSC Science

Strategy, (j) Antimicrobial resistance, (k) Microbiome, (l) Biological therapeutics, (m) NIBSC's work to support the Agency, (n) Financial sustainability, (o) new systems and initiatives, and (p) organisation developments.

7.2 The Chair thanked Dr Schneider for his comprehensive report and sought the Board's views. The Board was very appreciative of NIBSC's impact on public health both in the UK and globally and considered it important that this continues. The Board asked about future funding arrangements for the UK Stem Cell Bank, which is located at NIBSC. Dr Schneider explained that the Corporate Executive Team will consider this very important matter in October 2019.

7.3 The Chair invited questions from members of the public and staff. A representative of Cure Parkinson asked if NIBSC's work included gene therapy. Dr Schneider confirmed that NIBSC's work does include gene therapy and that NIBSC has an Advanced Therapies Division.

Item 8: Report of Quarter 1 – delivery against the Agency's Business Plan 2019/20

8.1 Jonathan Mogford presented Quarter 1 report on progress against the Business Plan, 2019/20. The Board noted that almost all objectives are on track. The report highlighted on 'an exception basis' the few objectives where delivery against the Business Plan is at risk.

8.2 The Chair thanked Mr Mogford for his report and sought the Board's views. The Board asked for further information about the small number of objectives that are at risk of not being fully met. Mr Mogford outlined these and explained the measures being taken to mitigate the risk.

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

Item 9: A Framework of Quality Assurance for Responsible Officers and Revalidation

9.1 Louise Loughlin presented the Revalidation Annual Report – A Framework of Quality Assurance for Responsible Officers and Revalidation. Ms Loughlin reported that, with the imminent retirement of Dr Ian Hudson, Dr June Raine will take on the role of Responsible Officer with effect from 23 September. Ms Loughlin also reported that Dr Barbara Bannister, Non-Executive Director, succeeded Sir Alex Markham, who left the Board in August 2019, as the medical appraiser for some of the more senior medical doctors. Moreover, Dr Bannister will act as the Board's 'Revalidation Champion'. The Board thanked Dr Bannister for taking on this role.

9.2 The Board went on to consider the following documents:

(i) The sixth Revalidation Annual Report covering the period April 2018 to March 2019 (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 Chair of the Agency before 27 September and submitted to the higher-level responsible officer (the Chief Medical Officer).

9.3 The Board heard that the revalidation process for MHRA's clinical assessors in 2018/19 had gone well. Dr Hudson thanked Louise Loughlin for coordinating the revalidation exercise and for producing the annual report, which the Board endorsed. The Chair said he would sign the Statement of Compliance.

9.4 The Chair invited questions from members of the public and staff. A member of the public sought clarification about the scope of the Agency's Revalidation process. Dr Hudson explained that the Agency's regulatory remit concerns products and does not extend to healthcare professionals; the General Medical Council is the responsible authority for medical doctors. Dr Hudson went on to explain that his role as Responsible Officer concerns those medical doctors who are employed by the Agency.

Item 10: Digital and social media trends – update

10.1 Kyle Christie presented a progress report on the trend of audiences moving from traditional to digital communication channels, and where the public now obtain their information about healthcare products. As part of his report, Mr Christie explained how UK citizens obtain information about healthcare products, e.g. through the widening use of multiple channels. Mr Christie also updated the Board on how healthcare professionals use digital channels; and on what the Agency is doing in this area via a variety of digital platforms, such as Facebook, Twitter, YouTube and LinkedIn. Mr Christie said that the Agency uses a range of digital and traditional communications channels to ensure the Agency can reach relevant audiences.

10.2 The Chair thanked Mr Christie for his report and sought the Board's views. The Board commended Mr Christie on the brevity and clarity of his presentation and on what had been achieved so far. The Board noted that 50% of visits (or more) to the GOV.UK website are made via a mobile or tablet and observed that a high percentage of people now obtain information via smartphones. The Board asked if the use of multimedia helps to raise the Agency's profile and whether a strapline should be used to enhance brand recognition?

10.3 As regards re-branding the Agency, Rachel Bosworth advised that Ministers considered this five years ago and decided against it. Ms Bosworth went on to advise that building a brand takes time and that to start again would pose many challenges. Ms Bosworth said she would consider the matter and return to the Board with further thoughts later.

10.4 The Chair invited questions from members of the public and staff. A member of the public asked if the Agency regulates herbal medicines, which Dr Hudson confirmed that it does and that the Agency's web pages set out which herbal products are licensed. Another member of the public observed that when she was seeking information about a particular medicine, she often sought the advice of a community pharmacist, whom she found to be most helpful and knowledgeable.

Item 11: Pre-submitted questions from public observers:

11.1 Two sets of questions were submitted ahead of the meeting.

Question no. 1

11.2 The first concerned research by a member of the public, a PhD student, into autologous platelet concentrates (APCs) in wound healing of the dental extraction socket in dentistry and the classification and use of APCs in clinical trials in the UK.

11.3 The Chair thanked the member of the public for his question, which, in view of its specialised and technical nature, would be addressed outside the meeting. The Chair invited Dr Wydenbach, a senior medical assessor from the Clinical Trials Unit, to have an initial discussion with the questioner, after which a detailed written reply to the question would be sent in due course.

Question no. 2

11.4 The second re-submitted question concerned how the Agency can educate and encourage patients to look at the Yellow Card data before they make a decision to take a drug that has been prescribed for them so that they can be more informed?"

11.5 Mick Foy of VRMM thanked the member of the public for her question and went on to explain the work the Agency is doing. This includes awareness raising campaigns, the work of the five Yellow Card Centres, of access to helpdesk professionals, and work on updating the Agency's IT systems so that they have greater outreach, working closely with others with the Agency, e.g. communications teams, and with stakeholders, the NHS, healthcare professionals, and partners across government, including the Devolved Administrations. Mr Foy explained that the Agency works closely with the NHS and healthcare professionals, but it must balance the desire for close collaborative working with the need to treat information provided by the Yellow Card Scheme as confidential.

11.6 In answer to the member of the public who asked about the Yellow Card Scheme, Dr June Raine advised that in regard to Isotretinoin, a prescription only medicine, about which the member of the public had asked previously, the Commission on Human Medicines has set up an expert group to consider concerns about side-effects.

Item 12: Any Other Business (AOB):

(a) *Chinese Pharmacological Society*

12. 1 Professor David Webb reported that earlier in the summer he attended a series of meetings with the Chinese Pharmacological Society in Beijing. Professor Webb thanked Agency staff for providing helpful background information.

12.2 The Chair concluded the meeting and advised that the next public session of the Board will take place on 16 December.