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

22 July 2019

Present:

The Board

Professor Sir Michael Rawlins GBE	Chair of MHRA
Dr Ian Hudson	Chief Executive
Mr Jon Fundrey	Chief Operating Officer
Dr Barbara Bannister MBE	Non-Executive Director
Dame Valerie Beral	Non-Executive Director
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
Ms Bernadette Sinclair-Jenkins	Deputising for the Director of Inspection, Enforcement and Standards
Ms Vanessa Birchall-Scott	Director of Human Resources
Dr Chris Jones	Senior Pharmaceutical Regulatory Advisor
Ms Sarah Morgan	Pharmacovigilance Risk Management Group Manager
Mr Colin Attrill	Head of Patient, Public and Stakeholder Engagement
Mrs 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 Dunia Alamaddine	MHRA Sponsorship and EU Exit Team, Medicines and Devices Regulation and Prescribing, Medicines and Pharmacy Directorate, DHSC.

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, Non-Executive Director and Deputy Chair of the Board; 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) A recruitment campaign took place earlier in the year to find a successor to Dr Hudson, who will step down as Chief Executive on 20 September. An announcement about Dr Hudson's successor is expected in the near future.

(ii) Sir Alex Markham and Dame Valerie Beral will leave the Board on 31 August, having served two three-year terms. The Chair asked that the minutes record the Board's deep gratitude for their outstanding service to the Board and the Agency over the past six years.

Item 2: Declarations of interest

2.1 None was made.

Item 3: Minutes of the Board meeting of 15 April 2019

3.1 The minutes of the last Board meeting in public session (15 April 2019), which were adopted by the Board on 20 May 2019, were noted.

DISCUSSION ITEMS

Item 4: Exiting the EU – oral update

4.1 Jonathan Mogford presented an update 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 his update, Mr Mogford reported on the considerable level of stakeholder engagement with industry and the third sector which has taken place.

4.2 The Chair and Board thanked Mr Mogford for the update. The Chair went on to invite questions from staff and public observers; none were offered.

Item 5: Chief Executive's Report

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

- *Public relations award* – The Board heard that the Agency won the 'in-house Public Relations team of the year', which was recently presented at the Chartered Institute of Public Relations. The Chair and the Board congratulated Rachel Bosworth and asked that Ms Bosworth pass on the Board's congratulations to members of the team for this outstanding achievement.

- *Channel 4 Dispatches programme* – An update was given on a review of internal process that the Agency has set up following the broadcast of a report entitled "How safe are our medicines?" on Channel 4 on 17 June 2919. The review will look at current internal processes, how effective they are across the Agency, along with wider areas of governance, decision-making, the regulatory regime, communications and information management. An update on the review will come to the Board in September.

- *Biosimilars* – An update was given on a recent publication of a Med Regs blog on 'What is a biosimilar medicine'? The guide provides an update for stakeholders about the role of biosimilar medicines in the NHS in England. An update was also given on the ICMRA statement on Biosimilars that had been agreed and now published.

- *Emerade* – an update was given on an alert in June 2019 that was issued about a potential defect affecting Emerade auto injectors (adrenaline). The Board heard that the Agency has liaised closely with manufacturer and kept stakeholders, especially patient groups informed.

- *ICMRA* – An update was given on the International Coalition of Medicines Regulatory Authorities (ICMRA) all-members meetings which was held in San Diego on 23 June. At the meeting, Dr Guido Rasi, Executive Director of the European Medicines Agency, was elected as the future Chair of ICMRA after the UK term of office comes to an end on 30th September 2019.

- *Memorandum of Understanding (MoU)* – an update was given on an MoU that was signed between MHRA and Ireland on 24 June 2019. The MoU concerns further cooperation and information sharing.

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

- *Emerade* – The Board asked, how in the case of the aforementioned auto injectors, the Agency reaches out to patients and the public. Rachel Bosworth explained the process of contacting healthcare professionals and patients. Ms Bosworth went on to explain the Agency's approach to communicating with the media, patient groups, charities, and campaigning groups. During this discussion, the Chair referred to an article in *The Times* newspaper (27 May 2019) about the Yellow Card app. The Chair commended the article, which was written by Dr Mark Porter, a General Practitioner (GP).

- *Yellow Card app* - Anne-Toni Rodgers vouched for how important the Agency's Yellow Card app is, and how easy it is to use. Ms Rodgers said the app is an

important tool for patients and the public to report side-effects and to obtain safety information on their medicines. Ms Rodgers urged all present, who do not already have the app, to download it, which she said is very easy to do.

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

- *Valproate* – A member of the public commented that there have been some issues around getting information about Valproate out to patients. It was noted that an update on Valproate would be given later in the agenda.
- Another member of the public said that, from her perspective, GPs and specialists, e.g. dermatologists, have a low awareness of the Agency's safety alerts and the Yellow Card Scheme. It was noted that the MHRA regulates products while others are responsible for regulating healthcare professionals, who themselves carry a professional responsibility to keep up to date.

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 and the cost of the programme. Mr Fundrey said that while £80m will be invested in the OTP, around £130m of returns, including cost savings, are expected over the programme's seven years lifespan. 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. The Board noted the report and asked when a further update on the overall business case, as distinct from the individual workstreams, was expected. Mr Fundrey advised that such a report will come to the Board at the end of the calendar year.

6.3 The Chair went on to invite questions from staff and public observers; none was offered.

Item 7: The work of the Medicines Borderline Section

7.1 Dr Chris Jones presented a paper on the work of the Medicines Borderline Section. The paper outlined how products which fall on the borderline between medicines and other regulatory frameworks are classified by MHRA's Medicines Borderline Section. The paper also set out the high volume of borderline cases which the Agency has had to deal with in recent years: 3,549 cases between 2015-2018.

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

- *Interaction with other regulators* – The Board asked about the Agency's work with other similar public bodies. Dr Jones advised that the Agency works closely with other regulators, such as the Food Standards Agency (FSA).

- *Definitions* – The Chair asked if a dermal filler is a medicine or a medical device? Dr Jones advised that, when used for a medical purpose, it is a medical device as it has a physical mode of action.

- *Funding* – In answer to a question from the Board, Dr Jones advised that the work of the Medicines Borderline Unit is financed through the Trading Fund.

- *Proactive work* – The Board asked how much proactive work the Agency does. Dr Jones explained that there are limitations on what the unit can do because of its size: five members of staff and the majority of work is responding to complaints or requests for advice, but on occasions they will carry out some proactive reviews of the market. Dr Jones went on to advise that despite the unit's size and busy workload, it has developed very good collaborative working relations with the FSA (Dr Jones explained that he joined MHRA from the FSA) and the Section also has a close working relationship with many trade bodies, with whom they will communicate advice and collaborate with the drafting of guidance. Moreover, the Agency has good liaison with internet auction and marketplace websites who can very quickly 'take down' a product if MHRA advises they are unlicensed medicines.

- *Overlap* – The Board asked how the Agency manages the overlap between borderline and herbal medicines. Dr Hudson explained that the first consideration is the determination of whether the product is a medicine, if not to refer on to another relevant body, such as the Food Standards Agency.

7.3 The Chair invited questions from members of the public and staff. A member of the public asked what action can be taken against deficient borderline medicines. Dr Jones advised that the Agency can only take action when the products are classed as a medicine; moreover, if the Agency believes there is a safety issue, e.g. with a food supplement, the Agency will notify the Food Standards Agency.

Item 8: Implementing the strengthened risk management measures for Valproate

8.1 Ms Sarah Morgan presented a progress report on implementing regulatory measures to prevent harm from exposure to valproate in pregnancy. Ms Morgan said that since April 2018 MHRA has been working to implement strengthened regulatory measures for valproate to prevent harm from exposure in pregnancy. Despite these measures, including a pregnancy prevention programme, monitoring of valproate prescribing using various data sources shows that implementation of the new measures across the healthcare system remains variable. The Board heard that concerted action across the healthcare system is needed to urgently embed the regulatory changes. She went on to advise that the Agency is collaborating with NHS England, NHS Improvement and the Devolved Administrations to take forward next steps.

8.2 The Chair thanked Ms Morgan for her report and sought the Board's views. The Board noted the progress report and in particular the Agency's efforts to monitor impact and compliance using bespoke research studies and healthcare data. The Board considered why some GPs prescribe medicines that could prove to be of a heightened risk in certain patient categories. The Board also considered the barriers that may prevent GPs from becoming fully conversant with the safety issues.

8.3 As part of their considerations, the Board noted that if more patients were referred to specialists, e.g. neurologists, this would place an additional heavy burden on an already stretched neurological service. Dr Hudson advised that GPs' awareness of safety alerts and safety measures are tested as part of a GP's revalidation process.

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

- *Roaccutane* and *Isostretinion* – A member of the public said that, as she understood it, many GPs are not aware of side-effects caused by certain medicines. She added that such side-effects are not mentioned in the medicine's Patient Information Leaflet. The member of the public mentioned two medicines (*Roaccutane* and *Isostretinion)* which she said can cause chemical castration in young males and/or suicide as side effects.

- Dr Hudson thanked the member of the public for her comments and said the Agency would follow-up on her concerns after the meeting. Dr Hudson explained that MHRA's role is to regulate healthcare products, e.g. medicines, to issue safety alerts and to communicate with patients and the public and other stakeholders. Dr Hudson went on to explain that the Agency's remit does not cover the regulation of Doctors; that is the responsibility of the General Medical Council.

Item 9: Patient and Public Engagement Delivery Plan – update

9.1 Colin Attrill presented a progress report on the implementation of the Patient and Public Engagement (PPE) Delivery Plan, 2019-21. As part of his report, Mr Attrill outlined recent highlights. These included (i) the launch of a 12-week consultation seeking views on how best to engage and involve patients in the Agency's work; (ii) the involvement of members of the Patient Group Consultative Forum in the review of the Early access to Medicines Scheme at an Office for Life Sciences task force workshop; (iii) progress of the cross-agency PPE champions network; (iv) PPE as a key feature of the Agency's Managers' Conference in May 2019; and (v) the appointment of two lay representatives from the expert committees to the Board.

9.2 The Chair thanked Mr Attrill for his report and sought the Board's views. The Board welcomed the report and noted the progress that had been achieved. The Board commented on the range of cultures, age groups and other demographic characteristics represented by wider networks of the participants in the Patient Group Consultative Forum (PGCF), which it said was beneficial in helping to promote the consultation to a diverse audience. The Board asked about how one manages the inevitable challenge of being more transparent while also acknowledging the need to respect the confidential nature of certain discussion items. Dr Hudson advised that in the USA, part of the U.S. Food and Drug Administration's advisory committee meetings are held in public and broadcast via the web, yet the assessment reports which are published are heavily redacted. The Board concluded by saying how they looked forward to seeing the outcome of the public consultation; an update on the consultation's findings will come to the Board later in the year.

9.3 The Chair invited questions from members of the public and staff. A member of the public said that the Agency should learn from the good practice of charities in this area, especially the medical charities. Another member of the public, who had recently attended a health conference commended the Agency on what it has done.

Item 10: Any Other Business (AOB):

10.1 The Chair then asked if there were any items of AOB; none was tabled.
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