Medicines and Healthcare products Regulatory Agency

Minutes of the Board meeting of 21st September 2020

(13:00 – 15.50)

By MS Teams conference call

Present:

The Board

Mr Stephen Lightfoot	Chair
Professor David Webb	Deputy Chair
Dr June Raine CBE	Interim Chief Executive
Dr Samantha Atkinson	Interim Chief Quality Officer
Dr Barbara Bannister MBE	Non-Executive Director
Ms Amanda Calvert	Non-Executive Director
Professor Bruce Campbell	Non-Executive Director
Mr Jon Fundrey	Chief Operating Officer
Ms Mercy Jeyasingham MBE	Non-Executive Director
Mr John Quinn	Interim Chief Technology Officer
Ms Anne-Toni Rodgers	Non-Executive Director
Dr Christian Schneider	Interim Chief Scientific Officer
Professor Liam Smeeth	Non-Executive Director
Mr Michael Whitehouse OBE	Non-Executive Director

Others in attendance

Mr Aidan McIvor	Secretary to the Board and Head of Directorate
{Section 40: name redacted - personal data}	Executive Assistant to the Chair

Department of Health and Social Care (DHSC)

Dr Alistair Hardisty	Head of MHRA Sponsorship and EU Exit Medicines and Pharmacy Directorate, DHSC

Devolved Administrations

Mrs Cathy Harrison	Chief Pharmaceutical Officer, Northern Ireland

Item 1: Introduction

What are the priorities for this meeting?

1.1 The Chair introduced his expectations and priorities for the meeting, which was his first since being appointed as Chair of the Agency on 1st September 2020. He was keen to change the format of Board meetings to ensure the business of the agenda was strategically focussed with sufficient quality time for discussion. Information items and updates could be addressed separately as part of a monthly information pack of papers. The Board seminar, which had preceded the meeting, was an example of a new way of working. The Board supported the new approach.

1.2 The Chair welcomed all to the meeting, including Dr Samantha Atkinson, Mr John Quinn and Dr Christian Schneider, who were appointed to the Unitary Board as interim Chief Officers.

Apologies

1.3 No apologies were received from members of the Board.

Declarations of interest

1.4 Professor Campbell announced that he had agreed to consider joining a group being formed by a commercial company to focus on a treatment for varicose veins which has benefits for patients over other methods in common use.

Item 2: External environment

What can the Agency do to support the health system this winter?

2.1 Dr Alastair Hardisty outlined what the Agency can do to support the health system during the coming winter. Among the challenges set out were:

(a) the end of the transition period on 31st December 2020;
(b) preparing for winter seasonal flu, alongside the ongoing challenges around COVID-19, including preparing for a roll-out of a vaccine programme of work; and
(c) preparing for Government's response to the Independent Medicines and Medical Devices Safety Review.

2.2 The Board considered issues around the Northern Ireland Protocol and other challenges facing the UK such as the issues surrounding COVID-19 vaccines.

Item 3: Internal context

What are the current issues from the Chief Executive's point of view?

3.1 Dr June Raine presented the Chief Executive's monthly report which was divided into the four strategic priorities of the Agency:

(a) Dynamic Organisation – including updates on the return to work sites and the Change Programme;
(b) Market Access – COVID-19 diagnostics, vaccines and therapeutics, and international collaboration;
(c) Patient Safety - Review of UK Plasma, Patient Safety Day (17th September), Opioids; and
(d) Financial Sustainability – Spending Review and Day 1 Readiness (1st January 2021).

3.2 The Board noted the report and discussed the Agency's preparedness for a second wave of COVID-19, the redeployment of staff to support work on multiple vaccines at the same time, and Day 1 Readiness and, in particular, its impact on Northern Ireland.

3.3 Concerning vaccine development, the Board asked Dr Samantha Atkinson to give assurance at the next Board meeting that the Agency will be able to assess and determine multiple licence applications for COVID-19 vaccines in parallel with speed, rigour and independence.

3.4 As regards Day 1 readiness, the Board noted that the Agency will be subject to an audit by the Infrastructure and Projects Authority (IPA) about whether the Agency's systems are ready.

How is the Agency performing against its Balanced Scorecard?

3.5 As regards the Performance Scorecard, the Board noted this will be considered by the Audit and Risk Assurance Committee at its meeting on 2nd November.

- **Action:** Dr Samantha Atkinson to give assurance at the next Board meeting that the Agency will be able to assess and determine multiple licence applications for COVID-19 vaccines in parallel with speed, rigour and independence.

- **Action:** Jon Fundrey to give the Board assurance at its next meeting on 26th October that the Agency will be ready to operate on Day 1 of EU transition with actions on how gaps will be mitigated

Item 4: Market access

How is the Agency going to regulate COVID-19 In-Vitro Diagnostics (IVD) tests quickly and effectively?

4.1 The Board considered a paper on how the Agency has worked to address the regulatory challenges seen during the pandemic for COVID-19 diagnostics. The paper gave an overview of the Agency's work to address the challenges with COVID-19 diagnostics, and that it is meeting the objectives of both being an 'enabler' of new diagnostics reaching the market and as a protector of patient safety.

4.2 The Board noted how the pandemic has caused a major shift for Devices Division into pre-market activity. This has enabled high-quality diagnostics to enter the supply chain, thereby meeting Government objectives. Examples cited of such work were: derogations for exceptional use, and Target Product Profiles (TPPs), the latter of which the Agency established to support industry in their development of new IVDs to respond to the pandemic.

4.3 The Board discussed the complexity of this area and how the Agency can become an enabling regulator in this new and evolving area. The Board advised that NHS Procurement was a partner with which the Agency should engage. The Board also mentioned new genetic tests, known as polygenic risk scores. These have increased access to genetic risk information for a wide range of conditions.

4.4 The Chair reported that he had recently had an introductory meeting with Doris-Ann Williams MBE, Chief Executive of the British In Vitro Diagnostics Association (BIVDA), during which he had received very positive feedback on the work of MHRA's Devices Division, led by Graeme Tunbridge. The Chair asked that this positive feedback be shared with Mr Tunbridge.

4.5 The Board concluded by asking that the following actions be carried out:

- **Action:** John Quinn to present an overview of how Device Registries, Unique Device Identifiers and Device Databases are being developed in the health system and the MHRA role in their development to strengthen device regulation.

Item 5: Patient safety

What are the Agency's priorities on the implementation of the Cumberlege Review?

5.1 The Board considered a paper on work by the Agency following the publication of the Independent Medicines and Medical Devices Safety Review (IMMDSR) Report, 'First Do No Harm'. The paper set out priority areas being addressed and outlined work being done with others in the healthcare system.

5.2 The Board noted that, while the Government's response to the IMMDSR is not due until the autumn, the Agency started work on next steps immediately after the IMMDSR's publication on 8th July 2020. The Agency has made a public commitment to act quickly where it can and to deliver IMMDSR's recommendation no. 6 ('MHRA needs substantial revision particularly in relation to adverse event reporting, medical device regulation, and the need to engage more with patients and their outcomes'.

5.3 The following examples were cited as actions that have been taken:

(i) *The Medicines and Medical Devices Bill (MMD*), which is currently before Parliament, will provide the Agency with the powers to update the current regulations for medicines, medical devices and clinical trials in the best interests of patient safety.

(ii) *Patient engagement* – The Agency is working to embed learnings from the IMMDSR into all planned communications, incorporating opportunities to consult with relevant patients' groups where possible ahead of publication.

(iii) *Overhauling safety systems* – the Yellow Card Scheme is being overhauled as part of a large-scale programme of technology improvements for the MHRA vigilance systems.

(iv) *Valproate* – The Agency is working across the healthcare system to reduce the number of women of childbearing potential exposed to valproate and to support compliance with the valproate Pregnancy Prevention Programme.

(v) *Mesh and registries* – While NHS Digital continue to work on the development of a mesh registry, DHSC have amended the MMD Bill to include a clause on Information Systems for all medical device implants.

(vi) *Chief Safety Officer* – work on recruiting for this new role has begun.

5.4 The Board noted the programme of work but added that a required shift in the culture and attitude of staff to patients was also needed. The Board went on to endorse a proposal by the Chair to hold a Board seminar in November on patient engagement. The Board also asked John Quinn to share information on the new patient safety IT systems.

5.5 The Board concluded by agreeing the following actions:

- **Action:** John Quinn to share information on the new patient safety IT systems that are being introduced in the next Board Information Pack.

- **Action:** The Chair to arrange a Board Seminar to discuss how the MHRA could engage patients more widely, building on existing engagement activities by other organisations. The seminar will take place on 23rd November 2020.

Item 6: Financial sustainability

How is the Agency building a strategy to secure its financial sustainability?

6.1 The Board considered a paper on delivering financial sustainability following the Agency's formal exit from the European system on 1st January 2021. The paper considered the changes to the Agency's income from that date, including the implications of significant investments required to replace legacy systems and the impact of the Northern Ireland Protocol.

6.2 The Board discussed what needed to be done during the remainder of the calendar year, as well as to prepare for the next business plan and to consider what can be funded through existing fees. The Board noted the importance of having the correct sequence of activities to be reflected in an action plan that will come to the Board. As part of the Board's consideration, the Board discussed the current level of corporate overheads, future investments in digital and organisational design. The Board also highlighted the importance of the new skills required for the new Agency in 2021 and beyond.

6.3 The Board asked that the following actions be carried out:

- **Action**: Jon Fundrey to present a high-level action plan and deadlines of key activities to achieve MHRA financial sustainability for the next Board Information Pack.

Item 7. Dynamic organisation

What were the key issues discussed at the last Remuneration Committee?

7.1 Professor David Webb, Chair of the Remuneration Committee (REMCO), presented a report on the Committee's meeting of 25th June 2020. Professor Webb said the Committee's task was a difficult one, as the number of awards is limited, and many of the senior staff are doing extremely impressive work, particularly at this challenging time. Nevertheless, after receiving advice from the Director of Human Resources and reports from the Chief Executive, the Committee was able to come to a unanimous decision on the awards following an extensive discussion.

Item 8. Meeting administration

8.1 The Board adopted the minutes of the meeting of 24th August 2020 and asked that in future, the actions list be considered at the beginning of the meeting. The Board went on to have an initial discussion about agenda-setting for the next meeting.

Item 9. Any Other Business (AOB)

9.1 None was tabled.

SUMMARY OF ACTIONS FROM MHRA BOARD MEETING – 21 September 2020

	ACTION	Who	When
1.	Present assurance at the next Board that MHRA will be able to assess and determine multiple licence applications for COVID-19 vaccines in parallel with speed, rigour and independence	Sam Atkinson	26/10/20
2.	Present assurance at the next Board that the MHRA will be ready to operate on Day 1 of EU transition with detailed actions on how any gaps will be mitigated	Jon Fundrey	26/10/20
3.	Present an overview of how Device Registries, Unique Device Identifiers and Device Databases are being developed in the health system and the MHRA role in their development to strengthen device regulation	John Quinn	23/11/20
4.	Share information on the new patient safety IT systems that are being introduced in the next Board Information Pack	John Quinn	09/10/20
5.	Set up a Board Seminar to discuss how the MHRA could engage patients more widely, building on existing engagement activities by other organisations	Stephen Lightfoot	23/11/20
6.	Present a high-level action plan and deadlines of key activities to achieve MHRA financial sustainability in the next Board Information Pack	Jon Fundrey	09/10/20