Medicines and Healthcare products Regulatory Agency

Minutes of the Board meeting 23 March 2020

(1.30pm – 3.30 p.m.)

By conference call

Present:

The Board

Professor Sir Michael Rawlins GBE Kt	Chair
Professor David Webb	Deputy Chair and Non-Executive Director
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
Ms Anne-Toni Rodgers	Non-Executive Director
Mr Michael Whitehouse OBE	Non-Executive Director

Others in attendance

MHRA executive

Dr Samantha Atkinson	Director of Inspection, Standards and Enforcement
Ms Vanessa Birchall-Scott	Director of Human Resources
Ms Rachel Bosworth	Director of Communications
Mr Jonathan Mogford	Director of Policy
Dr Christian Schneider	Director of National Institute for Biological Sciences and Control
Dr Janet Valentine	Director of Clinical Practice Research DataLink
{Name redacted: Section 40 – Personal data}	Deputising for the Business Transformation Director

Supporting officials – in order of attendance for specific items

Ms Boryana Stambolova	Deputy Director of Finance and Procurement
Ms Patience Wilson	Deputy Director, Corporate Strategy, Policy Division
{Name redacted: Section 40 – Personal data}	Head of Analytical Science
{Name redacted: Section 40 – Personal data}	Head of Science Strategy
{Name redacted: Section 40 – Personal data}	Executive Assistant to the Chairman
Mr Aidan McIvor	Secretary to the Board and Head of Directorate

Legal Services

Ms Elizabeth O'Neill	Deputy Director, MHRA, Medicines and Pharmacy Team, DHSC Legal Advisers, Government Legal Department

Department of Health and Social Care (DHSC)

Ms Carly McGurry	Deputy Director - Medicines and Devices Regulation and Prescribing, Medicines and Pharmacy Directorate, DHSC.
Ms Helen Gibson	Head of Medicines Regulation and EU Exit, 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 all to the meeting which was being held as a conference call because of the extraordinary circumstances around COVID-19.

Apologies and announcements

1.2 Apologies were received from John Quinn, Business Transformation Director.

1.3 The Chair made the following announcements:

- *Chief Executive* - The DHSC has extended Dr June Raine's appointment as interim Chief Executive until April 2021. The Chair said that in the months ahead Dr Raine would need the full support of the Board and Executive as she leads the Agency through a pandemic.

- *Public Board meetings* – Because of COVID-19, the Agency's programme of public board meetings will be on hold until further notice.

- *NEDs' recruitment* – In February 2020, interviews were held for two Board vacancies. The decision on who to appoint is now with Ministers.

- *Other announcements* - Carly McGurry will join the Agency on secondment from DHSC on 30 March. Ms McGurry will support the delivery of the Agency Change Strategy.

Item 2: Declarations of interest

2.1 None.

Item 3: Minutes of the Board meeting of 20 January 2020 and Board / Corporate Executive Team (CET) Strategy Day of 24 February 2020.

3.1 The minutes of the Board meeting of 20 January and the Strategy Day of 24 February were adopted. The Board also reviewed and noted the Actions list.

DISCUSSION ITEMS

Item 4: Coronavirus (COVID-19) – update

4.1 The Board received an update on the Agency's response to the COVID-19 pandemic from Dr Sam Atkinson, who chairs the Agency's COVID-19 task force, with Vanessa Birchall-Scott providing an update on staff, business, and health and safety aspects. As part of the update, Dr Atkinson explained the role of the COVID-19 incident management team; expert scientific advice from the Commission on Human Medicines; the Agency's procedures for rapid scientific advice, which has been built on the Agency's role in the fight against Ebola; and the Agency's input into DHSC, e.g. on supply issues, such as ventilators and key medicines. As for staff, the Board was updated on measures to ensure staff can work effectively from home and have a range of support in place during the pandemic. This is being provided via emails, INsite (the Agency's intranet), regular internal communications, and by video-enabled team and larger meetings.

4.2 The Chair said he was very impressed by how quickly the Agency has acted and responded to the pandemic, about clinical trials, and asked Dr Raine to pass on the Board's thanks to staff. The Chair noted the welcome decision by several UK companies to manufacture ventilators on a short-term basis but noted that this was not new; during a polio epidemic in 1952, Lord Nuffield arranged for the Morris automobile plant to manufacture 'iron lungs'.

4.3 The Board noted the Agency's approach to external messaging about COVID-19 and how that ties in with messaging from DHSC and wider Government.

4.4 The Board considered licensing arrangements for vaccines during the transition period following the UK's exit from the EU and asked that relevant officials liaise with Elizabeth O'Neill about the legal aspects. A further update will be given to the Board on 27 April.

Item 5: Exiting the EU – update

5.1 The Board received an update on the Agency's work with DHSC and wider Government on the future relationship with the EU, trade negotiations (free trade agreement) and the Northern Ireland Protocol: the latter entails a major block of work. The Board noted that the Government's timetable for taking forward this work remains unchanged, with discussions /meetings being conducted 'remotely' (by conference/video-calls) in line with Public Health England's guidance on COVID-19. A further update will come to the Board on 27 April.

Item 6: Future Agency Change Strategy

6.1 Dr Raine updated the Board on the Agency's evolving Change Strategy. The Board noted that following the joint Board/CET Strategy Day on 24 February, the vision for the future Agency was set out at an all staff meeting on 25 February, which Michael Whitehouse, Non-Executive Director, also addressed in person. The focus now is on three priority areas: (a) Patients, Public and Health Service), (b) Innovation and Regulatory Science, (c) and Lifecycle Safety Management. The Board were updated on work to develop the Agency's Regulatory Science capability, which Professor Sir Kent Woods is advising on; and work with the Accelerated Access Collaborative and the Office of Life Sciences, along with informal discussions with industry. Carly McGurry of DHSC, who will join the Agency on 30 March on secondment, will play a key role in coordinating this work.

Together, the aim is to roll out an integrated strategy during the first quarter of 2021 that will be aligned with the budget and workforce plan. Dr Raine concluded by mentioning the new Customer Service centre, which was launched 'remotely' earlier in the day, and which CET directors have committed to spending half a day each working in.

Item 7: Business Plan for 2020/21

7.1 Patience Wilson presented a final draft of the Business Plan for review and sign off. The Business Plan built on the discussion of a skeleton plan at the Board meeting on 20 January 2020, and further work on a Change Strategy following the Board/CET awayday on 24 February. There will be two versions of the plan this year:

- a short, very high-level plan for external publication, with the core operational heart of the plan focused around the top deliverables to drive forward the Agency's agreed 5 strategic goals, and
- a more detailed plan showing leads for strategic objectives, milestones etc for internal use (including for accounting to the Board and DHSC for delivery against plan).

7.2 The plan ensures that the Agency will grip key work in 2020/21 to make sure that the Agency is robustly contributing to cross-sector action to combat COVID-19, is delivering agreed strategic change, and will be ready to operate as a fully Third Country to the EU from 1 January 2021. There is significant work to be done in Q1 of the new business year on aligning funding/resourcing and delivery proposals for the plan.

7.3 After detailed consideration, the Board endorsed the Plan and the proposed approach, though asking that the intent to engage with the health service as well as with patients be made clear. The Board noted the upcoming launch of Customer Service Centre and asked about the savings to flow from this. The Board was particularly interested in plans to align workforce to the future strategic model and to the response to/effects of COVID-19, which were likely to have a major impact on the immediate work of the Agency.

Item 8: Business Plan 2019/20 – Quarter 3 report

8.1 Patience Wilson presented a progress report on Quarter 3 of the Business Plan 2019/20. The Board heard that most objectives are on track, with the paper highlighting on an 'exception basis' objectives where delivery is at risk of delay. The Board queried the amber rating given to OT, given earlier reports on overall delivery.

Item 9: Operational Transformation – Highlights Report

9.1 Jon Fundrey presented an update from the Operational Transformation (OT) portfolio. Mr Fundrey reported that a six-week impact assessment was underway against the new business strategy and business plan targets, along with an assessment of programme performance and of a review the Enterprise Architecture. Mr Fundrey explained that the previously forecasted shortfall in benefits for the current financial year remains and will not be resolved until another version of the transformation programme business case is published. Consequently, the OT portfolio status therefore remains at red.

9.2 Mr Fundrey went on to report that the reorganisation of the Finance function was launched in February and is under way, while a similar transformation of Human Resources Division is in progress. Moreover, the Board heard that the first phase of a new Customer Services Centre, which should realise staff savings, had been launched, with a newly appointed manager to lead its work. While noting these developments, the Board

asked how many posts will be saved as a result of the new Customer Services Centre. The Board heard there will be savings in posts after the second phase has been rolled out in the summer. Moreover, work is underway to shrink the Agency's footprint at 10 South Colonnade, which will produce further savings. Mr Fundrey said that future restructuring must be aligned with the Agency's future business model and therein the business planning process.

9.3 The Board concluded by emphasising the need for a new structure and business model for the Agency and added that the fees structure should be considered as well in 2020/21.

Item 10: Independent Medicines and Medical Devices Review – update

10.1 The Board received an update on the Agency's response to the likely recommendations of the Independent Medicines and Medical Devices Safety Review (IMMDSR). The Board heard that the IMMDSR, which was due to be published on 24 March, has been postponed (date to be confirmed) because of the COVID-19 pandemic.

10.2 The Board was supportive of the broad approach and noted that the proposed Agency response consists of Agency-wide and intervention-specific items. This includes action that has been taken to strengthen the way it engages with patients and the public. The proposed approach and actions set out in the paper will form the basis of a longer-term Patient and Public Engagement / Involvement Strategy and will support the Agency's transformation into a more public-facing organisation. It was noted that DHSC is taking the lead on the overarching response to the report, and the Agency needs to be prepared to respond to the specific regulatory issues raised.

10.3 It was commented that the Agency's response came across as rational, rather than sympathetic and would benefit from some finessing. One Board member had submitted some comments, and another would share their comments in writing on Annex A after the meeting.

10.4 The Board commented that the Agency's proposed response was focussed mainly on patients and not clinicians and that the importance of engaging with healthcare professionals should be emphasised, and the role of other regulators and how they work effectively together was also highlighted; the Board recommended that engagement with clinicians should feature in the Business Plan. One Board member advised that of over 300,000 adverse incident reports submitted through the Yellow Card Scheme, only 3,000 came from clinicians. It was suggested that this aspect could be addressed through the appraisals process (revalidation of medical doctors). Moreover, the Agency has been in discussion with the Royal Medical Colleges and the General Medical Council, which is something that will be built on. The Board also cautioned against introducing mandatory reporting of adverse incidents by healthcare professionals.

Item 11: MHRA Laboratories

11.1 {Name redacted: Section 40 – Personal data} presented a paper that outlined the work of the MHRA and British Pharmacopoeia laboratories, and how the Agency's laboratory capability supports public health and helps manage public health incidents. {Name redacted: Section 40 – Personal data} outlined several case studies that demonstrated the importance of collaboration and systems-wide engagement and coordination and the extra impact this can bring. {Name redacted: Section 40 – Personal data} went on to report that having access to our its own expert laboratory capability supports the Agency's mission to enhance and safeguard the health of the public. {Name redacted: Section 40 – Personal data} explained that the Agency is currently considering how its laboratories can be best used for the national good during the COVID-19

pandemic. In conclusion, {Name redacted: Section 40 – Personal data} said that maintaining and adapting the Agency's capabilities will ensure that the MHRA remains an effective and enabling regulator, in line with the future vision of the Agency.

11.2 The Board commended the work of laboratories noting that income from the Agency's laboratories was £3.3m against expenditure of £2.8m. Moreover, in answer to a question from the Board about income derived through the Proceeds of Crime Act 2002, Dr Atkinson advised that so far, the Agency has been able to obtain around £400,000 from criminal assets that have been seized by the Agency. {Name redacted: Section 40 – Personal data} advised that in the past some proceeds of crime income had been used to invest in new laboratory equipment.

Item 12: Chief Executive's Report

12.1 Dr Raine presented highlights from the Chief Executive's report for January and February 2020. These included the following:

(i) Prescribed medicines dependency.
(ii) Valproate and implementation of the pregnancy prevention plan.
(iii) Safety and anti-epileptic drugs in pregnancy.
(iv) E-cigarettes and vaping associated lung injury (EVALI).
(v) New guidance concerning Cannabidiol–containing products.
(vi) Partnership working with NICE and Public Health England.
(vii) An update on recent work of the Innovation Office, including the launch of the Innovation Office marketing campaign on 24 February.
(viii) An update on the work of the Regulatory Information Service.
(ix) Yellow Card Scheme and the Adverse Drug Reaction week (w/c 17 February)
(x) Medical devices issues, including reports of adverse incidents.
(xi) An update was given on the improved homepage of NIBSC's website.
(xii) An update was given on operational performance (new marketing authorisations) and about the trend in the sale of biological standards, which has been downward.
(xiii) An update on litigation.

12.2 While noting the update on partnership working with NICE, the Board asked for a paper on this work for the meeting on 27 April.

The Chair noted the very positive tone of Dr Rasi's letter which emphasised the Agency's important contribution by MHRA staff and experts to the EMA's scientific and regulatory activities since its creation 25 years ago.

Action: Policy Division to provide an update on work with NICE for the April Board.

Item 13: Update on Audit and Risk Assurance Committee meeting of 23 March

13.1 Michael Whitehouse, Chair of the Audit and Risk Assurance Committee (ARAC), gave an oral update on the ARAC meeting, which was held earlier in the day. He mentioned the following highlights from the meeting:

- *External Audit* – interim work has been completed and there is nothing apparent at this time that might impact negatively on the Audit opinion or the timetable. The Department and HM Treasury are considering how 2019-20 reporting might be streamlined in view of COVID-19.

- *Internal audit* – ARAC reviewed two reports. The first, Devices- handling of incidents, which received a substantial assurance. The Committee considered that the substantial assurance was premature and decided not to accept the report until after publication of the Independent Medicines and Medical Devices Safety Review. The second report was Contract Management and Procurement, which received moderate assurance. The Agency has made good progress; the aim is to have a revised commercial operating model in place by December 2020 and in light of the importance of this and the need to implement a number of outstanding recommendations ARAC will review progress further in the Autumn.

- *Internal audit review of workforce planning*. ARAC received an oral update of this review which has received limited assurance. Mr. Whitehouse reported that to put into operational use the Agency's enhanced strategic objectives requires a capability to model different scenarios in terms of size of work force, the implications for skills, how best to sustain them and the funding requirements. This now needs to be prioritised.

- Overall assurance- Work to date suggested positive annual governance to the Accounting Officer by Internal Audit for 2019-20. This will be confirmed by the time of ARAC's June meeting once Internal Audit has completed its remaining work and determined that there are no wider systemic issues.

- *Report of Fraud and Whistleblowing* – this was reviewed and discussed, along with an Annual Assurance of Non-Regulatory Fraud, and the biannual review of Regulatory Fraud
- *Corporate Risk Register* (CRR) – A revised CRR with a risk heat map and risk actions log was approved, a copy of which was shared with the Board.

13.2 As regards the impact of COVID-19 on audit work, Mr Whitehouse said work was continuing as planned, although it was noted that KPMG's audit staff, as are Agency staff, are now working from home. Mr Whitehouse concluded that the Annual Report is still on target to be laid before Parliament in July.

Item 14: Forward programme of Board business for 2020

14.1 The Board noted the forward programme of Board business

Item 15: Minutes of the Corporate Executive Team (CET) meetings

15.1. The Board noted the final minutes of the CET meetings of December 2019 and January 2020.

Item 16: AOB

None was tabled.

Date of the next meeting: 27 April 2020 – by Zoom video link