

Medicines and Healthcare products Regulatory Agency

Minutes of the Board meeting 27 April 2020

(10.30 am – 12.30 a.m.)

By Zoom / 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 John Quinn	Business Transformation Director
Mr Jonathan Mogford	Director of Policy
Dr Christian Schneider	Director of National Institute for Biological Sciences and Control (NIBSC)
Dr Siu Ping Lam	Director of Licensing
Dr Janet Valentine	Director of Clinical Practice Research DataLink

Supporting officials for specific items

Ms Boryana Stambolova	Deputy Director of Finance and Procurement
Ms Patience Wilson	Deputy Director, Corporate Strategy, Policy Division
(Redacted: Section 40: personal data)	Head of Capabilities, Talent & Transformation Academy
Ms Liz Baker	Group Manager, Licensing Division
(Redacted: Section 40: personal data)	Senior Pharmaceutical Regulatory Advisor, Inspection Enforcement and Standards (IE&S)
(Redacted: Section 40: personal data)	Borderline Section Manager, IE&S
(Redacted: Section 40: personal data)	Corporate Affairs Manager, NIBSC
Ms Carly McGurry	Deputy Director, Change Strategy
(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 Elizabeth O'Neill Deputy Director, MHRA, Medicines and Pharmacy Team, DHSC Legal Advisers,

Department of Health and Social Care (DHSC)

Ms Helen Gibson Head of Medicines Regulation and EU Exit, Medicines and Devices Regulation and Prescribing, Medicines and Pharmacy Directorate, DHSC.
Dr Alastair Hardisty Head of MHRA Sponsorship, DHSC (Leeds)

Devolved Administrations

Mr Chris Garland Principal Pharmaceutical Officer, Northern Ireland
Dr Sara Davies Consultant in Public Health Medicine Planning and Quality, Scotland

Lay representatives from Expert Committees

Ms Susan Bradford Lay representative from the Commission on Human Medicines
Ms Sarah 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 Zoom-enabled and telephone conference call because of the extraordinary circumstances around COVID-19.

Apologies and announcements

1.2 Apologies were received from: Mr Andrew Evans, Chief Pharmaceutical Officer (Wales); Mrs Cathy Harrison, Chief Pharmaceutical Officer (Northern Ireland); Professor Rose-Marie Parr, Chief Pharmaceutical Officer (Scotland); and Dr Keith Ridge, Chief Pharmaceutical Officer (England)

1.3 The Chair made the following announcements:

- *Helen Gibson* - The Chair welcomed Helen Gibson, Head of the MHRA Sponsorship Team at DHSC, to her new role.
- *August meeting* - The Board endorsed the Chair's recommendation that in view of the Coronavirus pandemic the Board should meet in August. Previously, the Board did not meet during August.
- *Jon Fundrey* - The Chair reported that Jon Fundrey, Chief Operating Officer, had been seconded to DHSC to support the DHSC during the Coronavirus pandemic, although he would continue to attend Board meetings.

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- *Patience Wilson* - The Chair asked that the minutes record the Board's gratitude to Patience Wilson who will leave the Agency on early retirement on 30 April 2020.

Action: Directorate to trawl for a suitable date for a Board meeting in August.

Item 2: Declarations of interest

2.1 None.

Item 3: Minutes of the Board meeting of 23 March 2020.

3.1 The minutes of the Board meeting of 23 March 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 ongoing 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; and Jonathan Mogford providing an update on work on regulatory flexibilities. Dr Atkinson went on to outline work across the Agency, focussing on access to key medical devices and medicines, rapid approval of clinical trials, and agreement of regulatory flexibilities to expedite availability of key medicines and medical devices. As part of the update, Ms Birchall-Scott reported on work to support managers and staff in general, especially those working at the laboratories at NIBSC during the pandemic.

4.2 The Chair asked what measures the Agency was taking to combat efforts by criminals to exploit the pandemic, e.g. by selling fake personal protective equipment online. Dr Atkinson replied by explaining work currently being undertaken by the Agency's Enforcement Group, working in parallel with Communications Division (on messaging) and UK law enforcement agencies. The Board asked about the approval mechanism for the new flexibilities, which Dr Atkinson explained was carefully calibrated to match the task in question with appropriate levels of senior management sign off. The Board went on to ask how the Agency can keep pace with such a rapidly changing environment. Dr Atkinson explained that in addition to the Covid-19 Task Force and Work Stream meetings, and regular daily conference calls with DHSC and health partners across government, the Corporate Executive Team, chaired by Dr June Raine, has one hour long daily meetings about Covid-19 at 9.00 a.m.

Item 5: Exiting the EU – update

5.1 Jonathan Mogford updated the Board 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 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. The Board considered how the Northern Ireland Protocol would work in practice, which was informed by advice from Mr Mogford.

5.2 A further update will come to the Board on 20 May.

Item 6: Future Agency Change Strategy

6.1 Carly McGurry presented a paper that explained work underway to progress the implementation of the November 2019 Change Strategy. The paper sought the Board's agreement to a set of proposals listed under three headings. They were: (a) to commission external consultants to carry out a short and focussed governance review of the Agency; (b) to seek the Board's agreement to a prioritised list of Agency-wide priority activity for the current business year; and (c) to seek the Board's agreement to improve focus and accountability for implementing the new strategy through the creation of new programme boards which will align with the critical business priorities. In addition, the paper provided an update on recent developments around the Operational Transformation Programme.

6.2 The Board was supportive of the direction of travel set out in paper and specifically the need to reshape the governance structure. Some Board members, however, did challenge the use of external consultants and asked whether there was relevant expertise within the Agency. The Board went on to observe that the 'clock is ticking', as 1 January 2021 (the day after the end of the post-Brexit transition period) is looming ever closer and that the Agency must be ready for 2021. The Board appreciated that at the core of the paper's thinking was the need to have a new governance structure that will enable the future Agency Strategy to be delivered in an agile and efficient way. During the discussion, the Board suggested several new ways of working, e.g. locating staff outside the London office. Dr Davies of the Scottish Executive Government asked that the Devolved Administrations be kept informed of developments as the future Agency's Strategy is rolled out.

Operational Transformation Programme

6.3 John Quinn reported that the CET had agreed that now was the time to close the Operational Transformation Programme; a closure report will be submitted to the Corporate Executive Team in May 2020. Mr Quinn advised that the closure report will include total cost, benefits, achievement and lessons learned. Mr Quinn went on to report that an impact assessment is underway against the future strategy and business plan targets. This includes an assessment of projects outlined and a review the technical and data architecture roadmaps.

6.4 In conclusion, the Board endorsed the paper's overall direction of travel and its specific recommendations, namely for an external governance review, to have a 'critical' list of priorities for 2020/21, and for the creation of new programme boards.

Item 7: Partnership working with National Institute for Health and Care Excellence (NICE)

7.1 The Board received an update on joint working with National Institute for Health and Care Excellence (NICE). Early in 2020, MHRA and NICE had established a core strategic group to take forward the joint strategic priorities to develop and deliver a compelling national 'offer' across regulation and health technology assessment. The Board heard that given the pressures on the system caused by COVID-19, a need has also been identified to develop an integrated approach across MHRA and NICE, and other partner organisations, to 'pull' medicines potentially useful in treating COVID-19 infections from research into clinical practice as efficiently as possible. The Board was advised that this approach is consistent with the compelling national offer the Agency set out to develop through the MHRA/NICE core strategic group. Accordingly, the Agency proposed to reprioritise and apply the MHRA and NICE core strategy group to first develop this 'super-charged' approach for COVID-19 medicines.

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7.2 The Board welcomed the initiative and offered comments, including the need to provide joint advice to the NHS. The Board also suggested that when the next MHRA/NICE Memorandum of Understanding is prepared, it should emphasize opportunities for working together for the benefit of patients. In conclusion, the Board noted the Terms of Reference, membership, proposed priorities for the group's work.

Item 8: Talent and Learning Report

8.1 (Redacted: Section 40: personal data) presented an update on Talent and Learning. The Board noted the coaching programme for high potential SCS1 staff, which had received positive evaluation feedback, as well as an internal leadership development programme which was launched for the top 120 Grade 6 and Grade 7 staff. (Redacted: Section 40: personal data) went on to outline the talent workshops which were run for 168 members staff (from Administrative Officer to Senior Executive Officer grade) and reported a 50% rise in the number of applications for the Future Leaders Scheme. (Redacted: Section 40: personal data) concluded by reporting that staff had attended over 2,000 days of technical training during 2019/20.

8.2 The Board commended (Redacted: Section 40: personal data) and her team on the success of the T&L programme but asked that, in future, outcome measurements should also be provided, rather than the number of staff who had attended courses or workshops and evaluation feedback. (Redacted: Section 40: personal data) advised there was more that can and would be done to measure the organisational and personal impact of the training. The Board also asked if Non-Executive Directors (NEDs) could provide mentoring? (Redacted: Section 40: personal data) welcomed the offer and asked that any NEDs who would like to become mentors contact her by email.

Action: HR to coordinate offers of mentoring from Non-Executive Directors.

Item 9: Cannabis Products report – update

9.1 The Board received an update on the regulation of Cannabis Based Products. The Board noted that Cannabis-based products for medicinal use were rescheduled in November 2018 to permit their prescription (by specialist doctors) for the first time. MHRA, DHSC and the Home Office have continued to collaborate to facilitate the supply of products to meet public health demands within the relevant regulatory frameworks and to provide regulatory and scientific advice to companies and researchers. The Board noted that so far there have only been two licenced cannabis-based products, while 106 adverse incidents have been reported through the Yellow Card Scheme, half of which have been related to licensed products and sixteen to food supplements.

9.2 There was a shared view by the Board about the very complicated nature of regulating Cannabis-based products. The Board asked about Cannabidiol (CBD), which is one of many chemicals called cannabinoids found within hemp and cannabis. The Board heard that CBD is not psychoactive and available both as a licensed medicine for the treatment of epileptic conditions and as a food supplement. It is regarded by the Food Standards Agency to be a novel food and subject to additional regulatory controls. MHRA's Borderline Medicines Section works closely with the FSA in this regard and although CBD is also touted as a treatment for other conditions there is insufficient evidence that it is effective for these conditions.

Item 10: Animal Transparency

10.1 (Redacted: Section 40: personal data) updated the Board on NIBSC's approach to openness around animal research since the Agency signed the Concordat on Openness on Animal Research in February 2018. (Redacted: Section 40: personal data) explained the range of activities NIBSC have in place to ensure the Agency is not only compliant with the requirements of the Concordat, but goes beyond what is required, in order to raise awareness of the Agency's animal research work. The Board noted that NIBSC is following the 3Rs principles, namely reducing the number of animals needed in any given study, replacing animals with other models whenever possible and refining procedures to involve the fewest number of animals while still giving valid results. The improved methods for animal handling was also noted.

10.2 The Board commended NIBSC on progress to date and recommended that greater visibility be given to the importance of this work. The Board heard that the Covid-19 pandemic has highlighted the importance of animal research to the safeguarding of public health, and recommended that this be given greater visibility, e.g. through the Science Media Centre. The Board also advised that the paper should include reference to alternatives to animal research work. The Board accepted all the recommendations in the paper except one.

Item 11: Annual Report 2019/20

11.1 Rachel Bosworth presented a draft outline of the Annual Report. An updated version of the Annual Report would come to the Board at its next meeting on 20 May. Meanwhile, the Board were asked to review the outline of the Annual Report and to send on their comments to Ms Bosworth.

Item 12: Chief Executive's Report

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

- (i) Launch of the Customer Services Centre on 23 March.
- (ii) Polio – NIBSC's re-designation as a World Health Organisation (WHO) Collaborating Centre for Reference and Research on Poliomyelitis with effect from February 2020 to February 2024.
- (iii) CPRD (Clinical Practice Research Datalink) – update was given on a further milestone achieved by CPRD as the volume of primary care data it now receives represents 21% of the UK's population.
- (iv) Valproate and implementation of the pregnancy prevention plan.
- (v) Update on the Isotretinoin Expert Working Group on reports of psychiatric and sexual disorders, which held its first meeting on 12 March.
- (vi) An update on the recent volume of enquiries received by the Innovation Office in March.
- (vii) Operation Pangea - an update on collaborative work with Royal Mail, the Home Office and Interpol to disrupt the online sale of counterfeit and illicit health products.
- (viii) Convalescent Plasma Therapy – an update on the use of convalescent whole blood and convalescent plasma in the treatment of infectious diseases.
- (ix) NIBSC – an update on biological standards' sales.
- (x) Organisational / staff developments, including an update on the 'Let's Stay Together's' Yammer platform during the pandemic.
- (xi) Medical devices issues, including reports of adverse incidents.

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12.2 The Board commended Rachel Bosworth and her team on the success of the launch of the Customer Services Centre. The Board asked if a summary of the Q&As on COVID-19 used by for staff working in the Customer Services Centre could be shared with the Board. Ms Bosworth said this would be arranged.

Action: Communications Division to send a summary of the COVID-19 related Q&As used by staff in the Customer Services Centre to members of the Board.

Item 13: Forward programme of Board business for 2020

13.1 The Board noted the forward programme of Board business

Item 14: Minutes of the Corporate Executive Team (CET) meetings

14.1. The Board noted the final minutes of the CET meetings of February 2020 and March 2020.

Item 15: AOB

15.1 None was tabled.

Date of the next meeting: 20 May 2020 – by Zoom video link