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Medicines and Healthcare products Regulatory Agency

Minutes of the Board meeting
Marcus Beck Library,
Royal Society of Medicine,
London
16 July 2018

Present:

The Board

Professor Sir Michael Rawlins GBE	Chair of MHRA
Mr Martin Hindle	Deputy Chair
Dr Ian Hudson	Chief Executive
Mr Jon Fundrey	Chief Operating Officer
Dr Barbara Bannister	Non-Executive Director
Professor Dame Valerie Beral	Non-Executive Director
Mr Matthew Campbell-Hill	Non-Executive Director
Professor Bruce Campbell	Non-Executive Director
Mr Stephen Lightfoot	Non-Executive Director
Professor Sir Alex Markham	Non-Executive Director
Ms Deborah Oakley	Non-Executive Director

Others in attendance

MHRA executive and supporting officials

Mr Jonathan Mogford,	Director of Policy
Mrs Rachel Bosworth,	Director of Communications
Dr Samantha Atkinson	Director of Inspection, Enforcement and Standards
Mr John Wilkinson	Director of Devices
Ms Patience Wilson	Deputy Director, Corporate Strategy and Planning
Ms Boryana Stambolova,	Deputy Finance Director
{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 Katie Foster	Senior Lawyer, MHRA, Medicines and Information Team, DHSC Legal Advisers, Government Legal Department.
{Redacted: Section 40: Personal data}	MHRA and NICE Sponsorship Branch, Department for Health and Social Care

Item 1: Introductions and Announcements

1.1 Apologies were received from Professor David Webb, Non-Executive Director, and Mrs Carly McGurry of the Department of Health and Social Care (DHSC).

1.2 The Chair welcomed everyone to the meeting and made the following announcements:

- That the minutes formally record the Board's gratitude to Martin Hindle, Deputy Chair, and Deborah Oakley, Chair of the Audit and Risk Assurance Committee, who would leave the Board in August having served two three-year terms of appointment. The Chair said he would express his thanks more fully at the Board dinner in honour of Ms Oakley and Mr Hindle which would be held later that evening.

Item 2: Declarations of interest

2.1 None was declared.

Item 3: Minutes of the Board meeting of 25 June 2018

3.1 Subject to a minor typographical error being corrected, the minutes of the Board meeting of 25 June 2018 were adopted.

Item 4: Actions list / matters arising

4.1 The Actions list was reviewed.

DISCUSSION ITEMS

Item 5: Exiting the EU – update

5.1 Jonathan Mogford presented an update on the UK's negotiations to leave the EU. This covered (i) the White Paper on the UK's future relationship with the EU, which was published on 12 July; (ii) the Withdrawal Agreement, including the Implementation Period; (iii) future regulatory system; and (iv) work the Agency is doing on 'No deal' contingency planning, as well as on the future shape of the Agency, which Dr Hudson would discuss with Health Minister Lord O'Shaughnessy on 24 July. {Redacted: Section 35: Government policy in development}.

5.2 The Chair thanked Mr Mogford for the update and sought the Board's views. These centred on the following areas:

- *The White Paper* – The Board made several observations and comments on the White Paper. {Redacted: Section 35: Government policy in development}

- *Stockpiling* – In answer to questions from the Board, the DHSC representative gave an update on a range of precautionary work, e.g. on the stockpiling of medicines and healthcare products, which is taking place in the event of a 'No deal' scenario. {Redacted: Section 35: Government policy in development}.

- *UK Notified Bodies* - In answer to a question from the Board, Mr Mogford confirmed his understanding was that UK Notified Bodies would continue to be recognised in the EU during an implementation period

Item 6: Budget 2018/19 update and Finance Report

6.1 Jon Fundrey presented a paper on the 2018/2019 Budget and financial performance to date. Mr Fundrey reported that the Agency had balanced its budget for 2018/2019 with

some risks remaining, the latter of which were set out in the Board paper. Mr Fundrey reported that the Agency is broadly on target to meet the budget challenge,. Mr Fundrey referred to the next monthly Brexit meeting with Lord O'Shaughnessy - on 24 July - where the financial implications of the worse-case scenarios for the Agency would be considered. {Redacted: Section 35: Government policy in development}.

6.2 Boryana Stambolova joined Mr Fundrey to give a fuller update on the outcome of the Budget Challenge exercise, which began in April 2018 when the CET agreed a target of £13m of savings. The Board heard that a total of £10m of savings has been identified, while the shortfall of £3m has been allocated to Divisional budgets, but not yet specifically identified by directors. Ms Stambolova went on to report that as the available figures for the current financial year only cover April and May, it was too early to draw conclusions.

6.3 The Chair thanked Mr Fundrey and Ms Stambolova for their updates and sought the Board's views; these centred on the following.

- *Opening comments* – The Board welcomed the update: they thought that the figures were encouraging.

- *Income and Expenditure Account* – The Board asked how many of the figures set out in the Annex were extrapolated. Ms Stambolova advised none was extrapolated; the figures were actual numbers.

- *Budget challenge / income generation* - In answer to a question from the Board, Dr Atkinson gave an update on income related to British Pharmacopoeia chemical reference substances.

Item 7: Operational Transformation - update

7.1 On behalf of John Quinn, Director of Transformation, who was unable to attend the Board, Jon Fundrey gave an update on progress to date. Mr Fundrey reported that work on Operational Transformation (OT) continues apace. Since the last Board meeting, the review and challenge process for each of the seven work streams has taken place, alongside drop-in sessions for all members of staff and an extraordinary meeting of the CET on 17 July to discuss OT. Together, these strands of work and meetings will help inform the business case for OT, which is expected to be ready by late July. Mr Fundrey went on to mention that further progress is required to identify savings in some areas of the Agency's work.

7.2 Mr Fundrey concluded by reporting that the Agency's approach to the business case will take the form of a programme business case that will be subject to more frequent review and update, given the various scenarios the Agency faces. This approach is in line with HM Treasury's 'Green Book' on business cases and value for money and "Managing Successful Programmes" guidelines.

7.3 The Chair and Board thanked Mr Fundrey for his update.

Item 8: Brexit No deal Statutory Instrument (fees element)

8.1 Patience Wilson presented a paper that set out proposals for specific changes to fees Statutory Instruments (SIs) to enable statutory fees to be charged for new regulatory processes post-Brexit (e.g. targeted assessment) in the event of a no deal outcome.

{Redacted: Section 35: Government policy in development}.

8.2 The Chair thanked Ms Wilson for her paper and sought the Board's views. These centred on the following.

- *Opening comments* – The Board welcomed the paper. {Redacted: Section 35: Government policy in development}.

- *Consultation* – In answer to questions from the Board, Ms Wilson explained any new fees or changes to existing fees will need to be addressed in the Brexit SI exercise, which means reaching a clear decision with DHSC Ministers within the next four weeks. MHRA will consult the Devolved Administrations. Ahead of this, Brexit and the SIs will form a core element of a meeting with officials from the devolved administrations in Cardiff on 18 July. Ms Wilson also mentioned plans to consult industry in September.

- *Orphan drugs* – The Board asked if DHSC would cover the cost of the waiver for orphan medicinal products, noting that the overall cost would be relatively modest. The Board heard that this is being discussed with DHSC.

- *Current software packages* – In answer to questions from Matthew Campbell-Hill, Non-Executive Director, it was agreed that Mr Campbell-Hill and {Name reda of DSHC would discuss this matter outside the meeting.

- *Other UK regulators' approaches to fees* – The Board asked what other regulators were doing about inflation-related fees increases, e.g. veterinary medicines, and pesticides. Mr Fundrey welcomed the question, which he said he would investigate.

Conclusion

8.3 The Chairman concluded by thanking Ms Wilson for her paper. The Board agreed that the Agency should also consult on the Brexit fees SIs making clear the intent to retain all medicines statutory fees at their current level for the immediate post-Brexit period.

Item 9: The strategic challenge of software, algorithms and A.I.
(taken together with item 10)

Item 10: Managing safe introduction and monitoring of software

10.1 John Wilkinson presented two papers which were taken together. The first paper explained the need to have a strategic discussion about the Agency's approach to artificial intelligence (A.I.), while the second paper outlined a proposal to develop a strategy to monitor and manage rapid developments in A.I. and software. The proposal was based on the development of a collaborative relationship with NHS Digital to develop a 'one stop shop' approach to the safe introduction and monitoring of software in the UK. {Redacted: Section 35: Government policy in development}

10.2 The Chair thanked Mr Wilkinson for his papers and sought the Board's views. These centred on the following areas:

- *Histology* - The Chair said he was surprised that the first paper did not mention histology. Mr Wilkinson said he would address this. {Redacted: Section 35: policy in development}.

- *Other regulators' experiences* – In answer to several questions from the Board, Mr Wilkinson advised that the U.S. Food and Drug Administration has not approved anything that is based on a dynamic algorithm. One non-executive director, who is also a member of the Advisory Board of the Department of Digital, Culture, Media and Sport (DCMS), advised that the Agency should work closely with DCMS.

- *Working with other health partners* – The Board recommended that the Agency continues to develop ties with relevant health partners, such as Public Health England and NHS Digital, especially in view of common links and areas of work, e.g. clinical trials. Mr Wilkinson said that such discussions have already taken place. The Board asked that consideration be given to having joint NHS Digital / MHRA teams, which Mr Wilkinson said he would follow-up.

- *UK Biobank* – The Board recommended developing links with UK Biobank. {Redacted: Section 40: personal data}.

Action:

(i) The Chair to raise the subject of closer cooperation, such as having joint teams, with the Chair and CEO of NHS Digital at the next bilateral meeting in September 2018

(ii) The Chair to discuss scope for closer cooperation between MHRA and UK Biobank with {Redacted: Section 40: personal data}.

Item 11: Revalidation Annual Report

11.1 Louise Loughlin presented the Revalidation Annual Report – A Framework of Quality Assurance for Responsible Officers and Revalidation. The Revalidation Framework was introduced in 2014 to provide a quality assurance to demonstrate that the Responsible Officer and Designated Body are discharging their respective statutory responsibilities.

11.2 The Board considered the following documents:

(i) The fifth Revalidation Annual Report covering the period April 2017 to March 2018 (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 Chairman before 28th September and submitted to the higher level responsible officer (the Chief Medical Officer).

11.3 The Board heard that the revalidation process for MHRA's clinical assessors in 2017/18 had gone well. Dr Hudson thanked Louise Loughlin for coordinating the revalidation exercise and for producing the annual report, which the Board endorsed.

Item 12: Accommodation Strategy – Redacted: Section 5: Commercial confidentiality

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Item 13: Travel policy for Board members

13.1 Jon Fundrey presented a paper that sought the Board's agreement to bring the Agency's travel policy on first class travel by non-executive directors into line with the travel policy for civil servants. Mr Fundrey explained that since 2010 it has been Government policy that Ministers and civil servants should no longer travel first class by train. So far, this policy has not applied to the Agency's non-executive directors or members of its statutory committees and expert working groups. {Redacted: Section 35: Policy in development}.

13.2 The Chair thanked Mr Fundrey and sought the Board's views. The Board asked what the policy was on first class rail travel by other public bodies. The Board heard that Public Health England's staff and Board members, when travelling by rail on official business, must travel by standard class. The Board also heard that NICE permits members of its expert committees and Board to travel by first class, so long as the ticket is booked well in advance. One Board member explained that, as he worked on the train, and as his rail journey lasted over three hours (each way), he preferred to travel first class. He went on to advise that it was difficult to work when travelling by train in a standard class seat.

13.3 Having considered the paper and the comments offered by several non-executive directors, the Board agreed to the proposal that the Agency's non-executive directors who use rail travel should in future travel by standard class. For those who wish to continue to travel by first class they could claim the cost for a standard class ticket and cover the cost of an upgrade to first class at their own expense.

(Late discussion item (paper no. 22): Independent Medicines and Medical Devices Safety Review

22.1 Dr Hudson presented a paper on the Independent Medicines and Medical Devices Safety Review Group led by Baroness Cumberlege. Dr Hudson reported that the draft Terms of Reference (ToR) have now been published and the Agency has been invited to provide observations on the ToR and to raise any other important questions relating to the production, distribution, regulation, prescription of, and practice around, each of the three interventions, as well as the exchange of information between the manufacturers, suppliers, regulators, clinicians, healthcare providers and patients and the oversight of the whole by the Department of Health and Social Care. Dr Hudson commented that the ToR were very broad and concluded by advising that Agency's Regulatory Group would discuss the same paper at its meeting on 17 July.

11.2 The Chair thanked Dr Hudson for the update. These centred on the following.

- *Draft Terms of Reference* - The Board thought the scope of the Terms of Reference were very broad and were noted some of the wording was very open, covering far wider aspects that perhaps recognised before.

- *Ensuring a balanced perspective* – The Board noted the reference in the Terms of Reference under 'Approach' to 'we will listen to those who have suffered harm'. The Board thought the review would benefit from receiving a range of feedback, including positive experiences of patients.

- *Concluding remarks:* The Board expressed the hope that the review would take into account the importance of balancing risk and benefit.

- The Board noted the importance of obtaining input from a broad range of stakeholders including researchers

Item 14: Chief Executive's Report

14.1 Dr Hudson presented the highlights from the CEO's report for June 2018. These centred on the following areas:

- *Fake meds campaign* – An update was given on the Chartered Institute of Public Relations annual wards (2018) for the 'best healthcare campaign' award, which the Agency won for its 'Fake meds campaign'.

- *Blackcurrant cough syrup recall - An* update was given on a recall of some own-brand children's blackcurrant cough syrup, which was taken as a precautionary measure.

- *Recall of Tourniquets* ‑ An update was given on the recall of tourniquets following the discovery of an error in the manual sewing operation of the tourniquets.

- *Valsartan* – An update was given on an alert that as issued by the European Medicines Agency via a rapid alert about contamination of the Valsartan active pharmaceutical substance.

- *Cannabis oil products* – An update was given on discussions the Agency has had with the Home Office on the use of cannabis oil products.

- *Heads of Medicines Agencies (HMA) meeting, 11-13 July* – An update was given on the HMA meeting in Vienna, which Dr Hudson and Jonathan Mogford attended.

- *Public Accounts Committee (PAC)* – an update was hearing on the PAC hearing on 4th July on 'price increase for generic medications', at which Dr Hudson gave evidence.

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

- *Counterfeit Condoms* – The Board noted work the Agency's Media Centre has been doing with a journalist from the Global news network about counterfeit and non-compliant condoms which the Agency has seized. In answer to a question from the Board, Rachel Bosworth confirmed that the Agency has been working with family planning centres about the risks posed by counterfeit condoms.

- *Clinical Trials Authorisations (CTAs)* – The Board noted that 65 CTAs had been processed in June 2018, which the Board thought was a positive development. Dr Hudson confirmed that the number of CTAs, especially first-in-human, have increased.

Item 15: Corporate Risk Register – oral update

15.1 Boryana Stambolova gave an overview of the Corporate Risk Register which was reviewed by the Audit and Risk Assurance Committee at its meeting on 25 June 2018.

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Item 16: Audit and Risk Assurance Committee (ARAC) Annual Report & update from the ARAC meeting of 16 July – Redacted: Section 33: Audit functions}

Item 17: Minutes of the Corporate Executive Team (CET) of 5 June 2018

17.1 The minutes of the CET meeting of 5 June 2018 were noted. A member of the Board asked about the reference in the CET minutes to staff morale. In reply, Dr Hudson said he was conscious of the many pressures the organisation continues to face and how the weight of many of these challenges bears down on a relatively small number of staff, but that support is being provided to alleviate the pressure. Dr Hudson concluded by saying that the recent relocation has been a major success, and the feedback he had received from colleagues on the 'move' had been positive.

Item 18: Draft agenda for the Board meeting of 22 October 2018

18.1 The Board noted the draft agenda for the next Board meeting on 24 September.

Item 19: Forward Programme of Board Business, 2018-2019

19.1 The Board noted the Forward Programme of Board Business for 2018/2019.

Item 20: Any Other Business (AOB):

20.1 The Chairman then asked if there were any items of AOB; none was tabled.

Date of next meeting: 24 September 2018