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Medicines and Healthcare products Regulatory Agency

MINUTES OF THE BOARD MEETING

21 May 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 MBE	Non-Executive Director
Professor Dame Valerie Beral	Non-Director of 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
Professor David Webb	Non-Executive Director

Others in attendance

MHRA executive and supporting officials

Mr Jonathan Mogford	Director of Policy
Mrs Vanessa Birchall-Scott	Director of Human Resources
Mrs Rachel Bosworth	Director of Communications
Dr Christian Schneider	Director of National Institute for Biological Standards and Control (NIBSC)
Mr John Quinn	Director of Transformation Division
Mr Richard Humphreys	Deputy Finance Director
{Redacted: Section 40: Personal data}	Chief Financial Accountant
{Redacted: Section 40: Personal data}	Financial Accountant
{Redacted: Section 40: Personal data}	Mrs Samantha Brookman, Change Communications and Engagement Specialist
{Redacted: Section 40: Personal data}	Head of Customer Services and Information Services
{Redacted: Section 40: Personal data}	Head of Science Strategy
{Redacted: Section 40: Personal data}	Ms Jude Thompson Executive Assistant to the Chairman
Mr Aidan McIvor	Secretary to the Board and Head of Directorate

Legal Services

Mr Paul Wright	Deputy Director, MHRA, Medicines and Information Team, DHSC Legal Advisers, Government Legal Department.
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Department of Health and Social Care (DHSC)

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Ms Liz Woodeson CBE

Director of Medicines and Pharmacy

Item 1: Introductions and Announcements

1.1 Apologies were received from Mrs Carly McGurruy of the Department of Health and Social Care (DHSC).

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

- *Guided tour of the new building (10 South Colonnade)* – Sir Michael asked the Board for its initial reflections on the Agency's new offices and work areas following a guided tour that was led by Dr David Guest of Licensing Division immediately prior to the Board meeting. The Board were unanimous in their praise of the Agency's new home, which the Agency would move into over three weekends in June.
- *Paul Wright* - The Chair asked that the minutes record the Board's gratitude to Paul Wright who would leave DHSC Legal Advisers on 25 May 2018 to take up a new appointment within the Government Legal Department. The Chair thanked Mr Wright for his excellent service to MHRA over the past twenty months. Mr Wright advised that his successor, Nicola Greenridge, who is currently with the Department of Exiting the EU, would join DHSC Legal Advisers in later in the summer.

Item 2: Declarations of interest

2.1 None was made.

Item 3: Minutes of the Board meeting of 23 April 2018

3.1 Subject to a minor factual correction, which the Board agreed, the minutes of the Board meeting of 23 April 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, namely the Withdrawal Agreement, including the Implementation Period. As part of his update, Mr Mogford explained that work on Exiting the EU continues at pace in several different areas. {Redacted: Section 35: Government policy in development}. Mr Mogford then outlined work the Agency is doing on 'No deal' contingency planning, on the future relationship between the EU and the UK, as well as on the future shape of the Agency.

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

- *The Implementation period* – The Board expressed concern about the possible implications for the Agency of the implementation period, e.g. the Agency not being able to lead on or influence scientific assessment work. It was thought such an outcome posed a risk of staff, who had joined MHRA to carry out cutting edge work, leaving.
- One member of the Board cautioned that the implementation period could last much longer than currently expected. {Redacted: Section 35: Government policy in development}.
- *Joined-up working* – Ms Woodeson outlined the breadth and depth of the very close working relations between DHSC and the Agency, e.g. Health Minister Lord O'Shaughnessy has regular meetings with Sir Michael, Dr Hudson and other senior officials from MHRA – that is in addition to the close working relations at all official levels.
- Professor David Webb, who was recently invited by Lord O'Shaughnessy to be the Board's lead member on Brexit-related discussions and developments, advised that he would meet with the Minister on 22 May.
- {Redacted: Section 27: International Relations}
- *Devices aspect* – In answer to a number of questions from the Board, Dr Hudson gave an update on the status of UK Notified Bodies after the UK leaves the EU; Dr Hudson also outlined the role of the recently established medicines and devices strategic coordination group.
- *Orphan and paediatric medicines* - The Board asked about the implications of the UK leaving the EU for special categories of medicines, such as 'orphans', which Dr Hudson addressed. At present, no fees are applied to many orphan medicines.
- *Scenario planning* – The Board noted that a paper will come to the June Board about three different scenarios for the future of the Agency.

Item 6: Annual Accounts seminar

6.1 The seminar was presented by Jon Fundrey, Chief Operating Officer; Richard Humphreys, Deputy Finance Director; Redacted: Section 40: Personal data}, Chief Financial Accountant; and {Redacted: Section 40: Personal data}, Financial Accountant. Mr Humphreys explained that the purpose of the seminar was to allow the Board to review the draft Annual Accounts before they are submitted to the Agency's auditors and, in particular, the key statements; and, to identify major changes from the previous year.

6.2 The seminar considered the timetable for the Annual Report and Annual Accounts, and the three main components of the accounts. They were (i) the Performance Report; (ii) the Accountability Report (particularly the Governance Statement and Internal Audit sections); and (iii) Financial Statements (Statement of Comprehensive Income, Statement of Financial Position and Statement of Cash Flows). The Board

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also considered the Five-year Financial Objective, Income Recognition (IFRS15), a paper that set out the 'value for money' case for the Agency's forthcoming relocation from Victoria to Canary Wharf.

6.3 Key points to arise from the presentation:

- Internal Audit – Twelve reviews have been carried out, nine of which have been discussed at the Audit and Risk Assurance Committee. Of the twelve reviews, seven were given a 'moderate' assurance rating, two were rated 'substantial', one was rated 'limited', and for the final review (Annual Follow-up of Recommendations), an assurance rating was not required. None of the reviews was rated 'unsatisfactory'.
- National Audit Office's (NAO) final audit report should be completed by 18 June, which, together with the draft Annual Accounts, will be reviewed by the Audit and Risk Assurance Committee on 25 June. Sign-off of the accounts is due to take place during the week commencing 2 July 2018, after which a submission will go to Ministers. The Annual Report will be tabled in Parliament by the week commencing 16 July. Recess is due to begin on 24 July.
- The following developments were outlined (i) trading outcome was down by £0.6m to £156.7m; (ii) staff costs had increased by £3.8m to £80.4m; and (iii) operating costs were increased by £19.0m to £96.3m (accommodation costs have increased by £12.3m, including a one-off cost of £10.0m to the Government Property Agency). Turning to the Statement of Financial Position, Mr Humphreys reported that current assets had fallen by £22.3m to £117.0m, while total liabilities had fallen by £8.0m to £72.1m. Redacted: Section 40: Personal data} reported that the NIBSC estate had been revalued upwards £30.4m. The Statement of Cash Flows showed that the Agency's cash balance had decreased by £30.4m.
- The draft internal audit opinion gives the Agency an overall "moderate" level assurance.

6.4 The Chairman thanked Richard Humphreys and his colleagues for their presentations and sought the Board's views. These centred on the following areas:

- *Cash flow* – The Board observed the £30m reduction in the Agency's cash reserves. If it were to continue at this rate of expenditure the Agency would run out of cash within three years. The Board asked for an assurance that the Agency had a plan in place to manage future cash flow.
- *Staff / operating costs* – Some Board members were surprised that the Agency's other Operating Costs now exceeded its staff costs. Redacted: Section 40: Personal data} explained this was partly due to the aforementioned payment of £10m to the Government Property Agency, as well as IT costs. Board members emphasised that it is essential the agency reduces its running costs in response to the forecast reduction in income as a result of Brexit.
- *Computing costs* – these have risen to £39 million this year from £33 million last year. The ARAC recognises that the organisation is currently in an investment phase but has requested high level information about the breakdown of this

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expenditure. In particular how much is one-off, how much is on-going running cost and how much is double-running cost which will be eliminated.

- *Relocation* – board members noted the paper but pointed out that the cost per square metre of space is higher at 10SC than at BPR. The paper will be discussed at ARAC.
- *NIBSC estate* – The ARAC has asked for further information about the re-valuation of the NIBSC estate including a reconciliation with previously reported values.
- *HM Treasury Minute* – The Agency noted that the Agency had achieved the target set out in the HM Treasury Minute of 24 February 2014 to ‘achieve a return, averaged over the period 1 April 2013 to 31 March 2018 of at least 3.5% expressed as a percentage of average capital employed’ The Chairman went on to ask if the Agency could ask the HM Treasury to decrease the percentage. Mr Humphreys said that we could ask, but when we do we would need to explain the reasons and what public health benefits would accrue from the requested change.
- *Government Digital Service (GDS) refund* – The Board asked for an update on the Agency’s plans to obtain a refund from the GDS, especially as GDS is due to merge soon with the Department of Digital, Culture, Media and Sport. Mr Humphreys advised that the Agency is currently in discussion with GDS about this.

Draft Annual Report 2017/18

6.5 Ms Rachel Bosworth presented a revised draft of the Annual Report for 2017/18, which as Ms Bosworth pointed out was still in draft form. Ms Bosworth advised that further work was still required on the infographics, as well as the front cover of the draft Annual Report. Mrs Bosworth explained that the current set of photographs were placeholders. Ms Bosworth asked that members of the Board send on comments to herself and members of the Annual Report team, details of which were circulated after the meeting

6.6 Ms Bosworth advised that when the revised version of the Annual Report returned to the Board on 25 June, it will have been comprehensively proof-read.

6.7 The Chairman concluded by thanking all concerned for their presentations.

Item 7: Operational Transformation

7.1 John Quinn gave an update on the Operational Transformation Programme (OT), including the establishment of the Transformation Division, which was created in April/May from the merger of Information Management Division and Operational Transformation Division.

7.2 Mr Quinn explained that in the weeks ahead, the priority will be to produce a business case that will set out the Vision, Design, Plan, Accountabilities and Resource requirements. The business case will be underpinned by a roadmap with key milestones, targets, benefits and costs. Mr Quinn went on to advise that an analysis has highlighted the opportunities open to the Agency to improve services for our customers; it has reinforced the need to address technology debt; it has also confirmed

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the digital platform approach to reduce the cost of change and operations, and identified the need for efficiencies.

7.3 Mr Quinn went on to report that seven work streams have been established that align to the Agency Service Model, with CET directors providing sponsorship for each work stream. Mr Quinn advised that this work will run in parallel with a CET budget challenge process across divisions, and within the context of Brexit discussions. The Board also heard that DHSC have commissioned scenario planning on the size and shape of the Agency that will be informed by the development of the business case and supporting plans.

7.4 The Chairman thanked Mr Quinn for the update and sought the Board's views. These centred on the following areas:

- *Opening comments* – The Board thanked Mr Quinn for his report on what they saw as a “huge and complex task”. A number of Board members asked how the Board could help with this work. Mr Quinn said that any support, in addition to that already being provided by members of the Board, would be much appreciated.
- *Practical challenges and timeframe* – In answer to questions about resourcing, Mr Quinn explained that the new division faced a range of practical challenges: shortage of staff with a background in project management and digital skills, and a very tight timeframe. Mr Quinn advised that he and his colleagues are working across the Agency to draw upon the widest possible pool of talent and skills to take forward this work. Mr Quinn went to say that OT is an exciting project by virtue of its scale and importance which will inspire much interest across the Agency. In particular, the Agency is keen to attract new staff on short-term contracts who will be very keen to be part of such an exciting project.
- *Affordability* – In answer to questions about affordability, Mr Quinn said OT was tied closely to ongoing work on budget challenge discussions with individual divisions. Stephen Lightfoot, Non-Executive Director, who, among others of the Board has been providing advice on OT and the Agency's business planning, said he had recently met with Jon Fundrey and John Quinn for a briefing session, which he said had been most helpful.

Item 8: Chief Executive's Report

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

- *House of Commons Science and Technology Select Committee inquiry into e-cigarettes* – An update was given on the evidence Dr Hudson gave at the Science and Technology Select Committee inquiry into e-cigarettes's on 24 April.
- *Valproate and risk of neurodevelopmental disorders* – An update was given on letters from the Chief Medical Officers of England, Northern Ireland, Scotland and Wales which were sent to healthcare professionals via the Central alerting System about the new strengthened regulatory system for Valproate. The letters were accompanied by an article in Drug Safety Update that gave details of the new restrictions, including the Pregnancy Prevention Programme. The Board was also

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updated on the Agency's engagement with the Valproate Stakeholders' Network, as well as with other stakeholders.

- *International meetings* – An update was given on a trilateral meeting the Agency held with Health Canada and the Australian Therapeutic Goods Administration (TGA), as well as on separate meetings with visiting delegations from the Japanese Pharmaceutical and Medical Devices Agency and the Australian TGA.
- *Judicial review*– An update was given on Judicial Review request: Mylan v MHRA (dimethylfumarate) .

8.2 The Chairman thanked Dr Hudson for his report and invited questions from the Board. The Board asked if ICMRA (International Coalition of Medicines Regulatory Authorities) would be affected by Brexit; Dr Hudson advised that Brexit would have no impact on ICMRA. The Board also asked about the post-Brexit proposals on the Agency's fees structure, which Dr Hudson answered. Dr Hudson went on to advise that a discussion paper on fees policy would come to the next Board meeting.

Item 9: Board Operating Framework

9.1 Aidan Mclvor presented a draft Board Operating Framework (BOF) for the Board's consideration. The request for a draft BOF arose as one of the actions that came out of the Board /Corporate Executive Team awayday on 29 January 2018.

9.2 Mr Mclvor explained that when preparing the draft BOF he looked at the BOFs of other organisations, as well as the terms of reference of the Board and its two sub-committees: (i) Audit and Risk Assurance Committee and (ii) Remuneration Committee, as well as the Framework Agreement between the Agency and its sponsor department (DHSC). Together, they helped inform the draft BOF which was circulated in late April for comment. The Board's comments were subsequently reflected in the draft BOF which the Board considered on 21 May.

9.3 Mr Mclvor went on to advise that, in view of the comments submitted, similar changes would need to be made to the terms of reference of the Board and its sub-committees, e.g. the need to ensure a consistent approach to the use of the non-gender term 'Chair'.

9.4 Sir Michael thanked Mr Mclvor for his presentation and sought the Board's views. The Board welcomed the BOF and endorsed the proposed BOF, along with the suggested minor changes to the terms of reference of the Board and its two sub-committees.

Item 10: Business Plan, 2017/2018 – Quarter 4 report

10.1 Jonathan Mogford presented the end of year position for the Agency's targets, activities and metrics. The Board noted that the Agency had met 36 of its 40 targets for 2017-18; Mr Mogford went on to report that of the 77 activities due to be completed by the end of Quarter 4, 59 had been completed, of which one was one was completed ahead of schedule. Of the remaining 18, two were postponed, while 16 were 'closed', that is, where activities have been overtaken by events and /or the Agency has an equivalent commitment in the 2018/19 Business Plan.

Item 11: Minutes of the Corporate Executive Team (CET) of 3 April 2018

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11.1 The minutes of the CET meeting of 3 April 2018 were noted.

Item 12: Draft agenda for the Board meeting of 25 June 2018

12.1 The Board noted the draft agenda for the next Board meeting on 25 June.

Item 13: Forward Programme of Board Business, 2018-2019

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

Item 14: Any Other Business (AOB):

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

(a) Occupational Health (OH) provision

{Redacted: Section 2 (43) Commercial in confidence.}

Date of next meeting: 25 June 2018