FINAL

MHRA Board
Rooms 501-502
151 Buckingham Palace Road

MINUTES OF THE MEETING
26 March 2018

Present:

The Board

Professor Sir Michael Rawlins GBE	Chairman of MHRA
Mr Martin Hindle	Deputy Chairman
Dr Ian Hudson	Chief Executive
Mr Jon Fundrey	Chief Operating Officer
Dr Barbara Bannister MBE	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
Professor David Webb	Non-Executive Director

Others in attendance

MHRA executive and supporting officials

Mr Jonathan Mogford	Director of Policy
Mr Rachel Bosworth	Director of Communications
Mr Gerald Heddell	Director of Inspection, Enforcement and Standards Division
Mr John Quinn	Director of Information Management Division
Ms Patience Wilson	Deputy Director - Policy
Dr Julian Bonnerjea	Manager, Biological Medicines, Licensing Division
{Name redacted: Section 40 – personal data}	Resourcing Manager, Human Resources
{Name redacted: Section 40 – personal data}	Head of NIBSC Corporate Affairs
Mr Richard Humphreys	Deputy Finance Director
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.

Department of Health and Social Care (DHSC)

Carly McGurry	Deputy Director, Medicines Regulation & Prescribing

Item 1: Introductions and Announcements

1.1 Apologies were received from Dame Valerie Beral, Non-Executive Director.

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

- *Brexit NED* - The Chairman reported that Professor David Webb, Non-Executive Director (NED), had agreed to take on the role as Board member with specific responsibility on MHRA's Board for EU Exit. The appointment followed a request from Health Minister Lord O'Shaughnessy that MHRA should follow the example of the Department of Health and Social Care and appoint a Brexit NED. The Chairman thanked Professor Webb for agreeing to take on the role. Professor Webb in turn advised that he had already met with Jonathan Mogford to discuss Brexit and that he looked forward to meeting with other officials across the Agency to have similar discussions.

- *Gerald Heddell's retirement* - The Chairman asked that the minutes record the Board's deep gratitude to Mr Gerald Heddell, Director of Inspection, Enforcement and Standards Division (IE&S), who would retire from the Agency later in the week. The Chairman thanked Mr Heddell for his exemplary service to MHRA, and his many achievements during his fourteen year tenure as Director of IE&S, and on behalf of the Board, wished him a pleasant retirement.

Item 2: Declarations of interest

2.1 Although no declarations of interest were made, Matthew Campbell-Hill, Non-Executive Director, reported that he had been appointed chair of the National Public Strategy Group for the digital healthcare provider, PushDr.

Item 3: Minutes of the Board meeting of 26 February 2018

3.1 The minutes of the Board meeting of 26 February 2018 were adopted.

Item 4: Actions list / matters arising

4.1 The Actions list was reviewed.

DISCUSSION ITEMS

Item 5: Brexit

5.1 Jonathan Mogford presented an update that covered the following: (i) update on the overall negotiation, (ii) implications for the Agency of the implementation period agreement; (iii) the Agency's immediate response to recent developments; and (iv) and wider positioning and considerations.

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

- The Agency's status during the implementation period;
- Fees structure;
- Staff retention and morale; and
- Brexit task force.

Action: (i) paper on future medicines fees structure to come to the Board (date to be confirmed); (ii) Aidan McIvor (also Secretary to the Brexit Task Force) to arrange for Professor Webb to attend a Brexit Task Force meeting.

Item 6: Corporate Plan 2018-2023

6.1 Jonathan Mogford and Patience Wilson presented a near-final version of the draft Corporate Plan, 2018/2023. Ms Wilson advised that the paper reflected the Board's comments on an earlier version of the draft Corporate Plan which was discussed at the Board meeting of 26 February 2018; it was also informed by the subsequent discussion at and following the 13 March CET meeting. Ms Wilson asked if the Board was content with the revised draft and if it would agree to its publication.

6.2 The Chairman thanked Mr Mogford and Ms Wilson and sought the Board's views. The Board thought the Corporate Plan was now 'fit for purpose' and commended Mr Mogford and Ms Wilson and their colleagues for their efforts over the past six months, especially in view of the Brexit-related uncertainty.. Ms Wilson thanked the Board for its comments, which she would reflect on. The Board concluded by formally endorsing the Corporate Plan.

Item 7: Draft Business Plan, 2018-2019

7.1 Patience Wilson presented the draft Agency Business Plan for 2018-19, which was discussed by the Corprate Executive Team at its meeting on 13 March 2018. Ms Wilson explained that the draft Business Plan sets out in more detail what the Agency will do in the new business year to deliver the Corporate Plan. Ms Wilson then invited the Board to review and comment on the draft and agree that – subject to further very minor changes following the Board meeting, for it to be signed off by the Executive, thereby allowing it to come into operation at the beginning of April.

7.2 The Chairman thanked Ms Wilson and then sought the Board's views. They endorsed the Buiness Plan subject to some text being included in the final version about staff retention and morale, which the the Board was surprised had been omitted from the text. Ms Wilson said that she would reflect the Board's comments about staff morale and retention in the final draft before it was sent to the Executive for final sign off.

Item 8: Operational Transformation

8.1 Dr Samantha Atkinson gave an update on the Agency's Operational Transformation Programme (OT); this included recent one-to-one discussions which Jon Fundrey and Dr Atkinson have had with members of the Board. Dr Atkinson advised that the next iteration of the Programme Business Case is being prepared, which, as part of this process, would take into account the Agency's current financial position and costs of operational transformation.

8.2 The Chairman thanked Dr Atkinson for the update and sought the Board's views. These centred on the following areas:

- *Funding aspects* – The Board advised that, rather than ask how much the OT programme will cost, the question that needs to be addressed is how much does the Agency have to spend; on that basis, decisions can be made on what is necessary and affordable. Dr Atkinson advised that affordability would be addressed in the next iteration.

- *Timeframe* – The Board asked what the next steps were. Dr Atkinson advised that the next iteration of the business case would hopefully return to the Board at its meeting on 25 June. The business case would include updated costs.

Item 9: Securing Cyber Resilience in Health Care - update

9.1 John Quinn presented an update on the Agency's position in response to the requirements necessary for securing cyber resilience in health and care. The requirements were set out in a letter dated 1 March 2018 from Sir Ian Andrews, Non-Executive Director at NHS Digital, and Gerry Murphy, Non-Executive Director and Chair of the Audit and Risk Committee at the Department of Health and Social Care. Mr Quinn went on to explain that the letter set out a series of questions that Boards need to consider to assess how they meet the ten data security standards and the DH 2017/18 Data Security and Protection Requirements. Mr Quinn went on to outline the Agency's response to the fourteen questions and the Agency's performance against the National Data Guardian's ten data security standards.

9.2. With regard to IT security training for members of the Board, it was agreed that such training would be provided and, as with members of staff, members of the Board would receive certificates recording that they had completed the required training. John Quinn said he would look into the practical aspects of arranging this (liasing with Aidan McIvor of Directorate).

Action: Mandatory IT security training to be arranged for members of the Board, with certificates being issued once the training has been completed.

Item 10: MHRA Innovation Office – the first five years of operation

10.1 Dr Julian Bonnerjea presented a progress report on the work of the Agency's Innovation Office, which marked its fifth anniversary. Since its establishment, the Innovation Office has answered over 500 regulatory queries about medicines or medical devices, and has held over 100 meetings with companies and other enquirers. During this time, the service has expanded to include collaborative work with other UK regulators, specifically in the field of advanced therapies. To mark the Innovation Office's fifth anniversary, the Agency arranged a meeting at its offices in London on 23 March 2018 with key funders of UK medical research to discuss future collaboration. Among the attendees at the meeting were the Medical Research Council, the Wellcome Foundation and medical charities.

10.2 The Chairman thanked Dr Bonnerjea for his report and then invited questions from the Board; these centred on the following areas:

- *Opening comments* - The Chairman and Board commended Dr Bonnjerea on the success of the Innovation Office and on how it has evolved over the past five years. .

- *Charging* – In answer to a question from the Board, Dr Bonnerjea explained that the Innovation Office does not charge for advice, unlike the Agency's Scientific Advice service, where fees are applied. When asked if other regulators charge for advice, Dr Bonnerjea advised that he was not sure what fee regimes other regulators may apply. Dr Bonnerjea went on to say it depends on how one defines 'innovation'.

- *Quantifying advice* – The Board asked about how one quantifies the work of the Innovation Office and its wider impact on UK plc. Dr Bonnerjea explained that it was difficult to quantify the impact of the Innovation Office as new medicines often take many years or even decades to develop. The Innovation

Office could potentially reduce this time, which would benefit the UK, but it would take many years to collect these data.

Item 11: Apprenticeships and resourcing – update

11.1 {Name redacted: Section 40 – personal data} presented a progress report which covered apprenticeships and strategic resourcing. With regard to apprenticeships, {Name redacted: Section 40 – personal data} advised that, at present, there are only ten members of staff in apprenticeship roles, and that meeting the apprenticeship target is proving to be a challenge. {Name redacted: Section 40 – personal data} said he and colleagues in Human Resources will look at new roles that could be re-designated as apprenticeships and identify entry level roles that would benefit from a technical qualification.

11.2 As regards resourcing, {Name redacted: Section 40 – personal data} reported that 65% of new recruits have LinkedIn profiles, which have proved to be a useful method of attracting candidates. {Name redacted: Section 40 – personal data} advised that this approach will reduce the time needed to recruit new staff, which is an important consideration for the needs of the business. In the past, good candidates have been lost because a failure to provide a prompt offer of employment.

11.3 The Chairman and Board welcomed the update. In answer to a question about apprenticeships programme, {Name redacted: Section 40 – personal data} that he and other colleagues in MHRA's Human Resources Division do liaise with counterparts at the Department of Health and Social Care, e.g. about sharing 'lessons learned'. It was agreed that this was a discussion (between HR and DHSC) that should continue outside 'offline'.

Item 12: Health and Safety Annual Report 2017/2018

12.1 {Name redacted: Section 40 – personal data} presented the health and safety annual report, which the Audit and Risk Assurance Committee had asked be brought to the Board. As part of her report, {Name redacted: Section 40 – personal data} outlined a number of achievements over the past year, including: introduction of Safety Advocates at BPR; support for the Move Group to identify any significant health and safety issues; fully compliant reports from planned intervention inspections by the Health and Safety Executive (HSE) at NIBSC for work in high containment areas; and successful assessment by the Environment Agency for compliance for Ionising Radiation work. {Name redacted: Section 40 – personal data} then outlined a number of risk areas which need to be managed, e.g. the Occupational Health (OH) service provision, was a key issue. A contract monitoring group is in place to address these issues. {Name redacted: Section 40 – personal data} went on to report the statistics of completion of mandatory training courses showing a significant improvement over the last six months.

12.2 The Chairman thanked {Name redacted: Section 40 – personal data} for her report and then invited questions from the Board; these centred on the following areas:

- *Home working aspects* – The Board asked if staff would receive monitor screens similar in size to those in place at the Agency's offices in London and at South Mimms (NIBSC); the Board was particularly concerned about the possible risk posed by such monitors in the home environment, especially if there were young children nearby. {Name redacted: Section 40 – personal data} advised that staff who receive Display Screen Equipment (DSE) for use

at home, as defined by the Home Working Policy, would be expected to carry out a DSE assessment at home to ensure appropriate safety.

- Monitor size – Jon Fundrey advised that a range of screen sizes are available for use at home; not all will have the same dimensions of the monitor screens in place at the Agency's offices.

- *Benchmarking* – The Board asked if the Agency benchmarks its health and safety arrangements against other relevant organisations. {Name redacted: Section 40 – personal data} advised that the Agency works closely in this area, with Public Health England, and the Pirbright Institute, which is part of the UK Government's Biotechnology and Biological Sciences Research Council.

- *KPIs on training* – The Board noted that of CL3 (Containment Laboratory level 3) staff, only 40% had completed modules 1-6 of their training. Mrs Donatantonio explained this was due to the course being currently updated before making the next dates available.

Item 13: Chief Executive's Report

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

- *Cumberlege Review* – An update was given on the Medicines and Medical Devices Safety Review into vaginal mesh, Primodos and sodium valprorate, which was formally announced by the Secretary of State on 21 February.

- *Valproate and risk of neurodevelopmental disorders* – An update was given on an announcement by the Pharmacovigilance Risk Assessment Committee's (PRAC) recommendation for a strengthened regulatory position for Valproate at its meeting in February.

- *Daclizumab (Zinbryta) and immune mediated encephalitis* – An update was given on consideration by the Pharmacovigilance Expert Advisory Group's (PEAG) on Zinbryta at its meeting of 28 Februray 2018.

- *Visits to USA and Canada* – An update was given on a visit by Dr Hudson and Jonathan Mogford to the US Food and Drug Administration and Health Canada for a series of bilateral discussions.

- *Medical cannabis* – An update was given on the use of medical cannabis by a patient; the Agency has been in discussion about this with the Home Office.

- *KRAS Mutuation International Standards* – An update was given on the first international standards for 'KRAS' mutations, which have been produced. This will underpin the harmonization of cancer genomic dagnostics.

13.2 The Chairman thanked Dr Hudson for his report and invited questions from the Board. The Board asked if the Agency has been in discussion with Genomics England about the KRAS standard. Dr Hudson advised that he did not know and that he would find out and inform the Board accordingly.

Action: Dr Hudson to find out if the Agency has been in discussion with Genomics England about KRAS Standard.

Item 14: Finance and Procurement report

14.1 Richard Humphreys presented two reports on the Agency's financial position: (i) Strategic Finance, 2018-2023 and (ii) the monthly Finance and Procurement Report. Mr Humphreys explained that the Strategic Finance paper was considered by the CET at its meeting on 13 March and provided an update on the Agency's financial strategy in preparation for the new five-year financial objective period, which will begin on 1 April 2018. The paper also covered consideration of the Operational Transformation Programme Business Case and the Agency's Budget for 2018/2019.

14.2 As regards the second report (the monthly Finance and Procurement report), Mr Humphreys said that, after allowing for Dividends and Financing, after the first ten months of the year the Agency has a deficit of £4.7m which is £0.9m worse than budget. The Agency is budgeted, after the costs of Operational and Digital transformation are considered, to deliver a deficit in 2017/18 of £13.2m and is currently forecast to deliver a deficit of £18.7m.

14.3 The Chairman thanked Mr Humphreys for his report and invited questions from the Board; these centred on the following areas:

- *Opening comments* – The Board thought the Strategic Finance report made for sober reading, especially in relation NIBSC and the Regulator.

- *Cost savings* – The Board advised that the Agency will soon face some stark choices, which may include a pay freeze or staff cuts; the cost base had to be reduced. Some thought it better that the headcount is cut thereby allowing the remaining staff, especially those who are high performers, to be paid more.

- *Devices fees* – The Board asked for an update on Devices fees. Dr Hudson explained there is unlikely to be any movement on this, as it would require primary legislation, which is unlikely to happen in view of the very heavy legislative programme already in the pipeline.

- *May Annual Accounts Seminar* – In answer to a question from the Board, Mr Humphreys advised that the 'new accounting standards' would be addressed at the Annual Accounts Seminar on 21 May.

Item 15: Audit and Risk Assurance Committee meeting of 26 March 2018 – oral update

15.1 Deborah Oakley, Chair of the Audit and Risk Assurance Committee (ARAC), gave an oral update on the ARAC meeting which took place earlier on the morning of 26 March. The update included ARAC's consideration of the Internal Audit Plan; the ARAC work plan for the next financial year, which ARAC adopted; reports on procurement, fraud, including regulatory fraud; and the establishment of a new cross-agency group to assess risks.

Item 16: Minutes of the Corporate Executive Team (CET) of 13 February 2018

16.1 The minutes of the CET meetings of 13 February 2018 were noted.

Item 17: Forward programme for 2018/2019

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

Item 18: Any Other Business (AOB):

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

Date of next meeting: 23 April 2018