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**MHRA Board
Laboratory of the Government Chemist
Teddington**

**MINUTES OF THE MEETING
26 February 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
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
Professor David Webb	Non-Executive Director

Others in attendance*MHRA executive and supporting officials*

Mr Jonathan Mogford	Director of Policy
Mr Paul Inglefield	Deputising for the Director of Communications
Dr Janet Valentine	Director of CPRD
Ms Patience Wilson	Deputy Director - Policy
Ms Vanessa Birchall-Scott	Director of Human Resources
Mrs Kerry McEyeson	Deputy Director of HR
Mr Richard Humphreys	Deputy Finance Director
{Name redacted: Section 40 – personal data	Head of Science Strategy
Mr Aidan Mclvor	Secretary to the Board and Head of Directorate

Legal Services

Ms Anne Paskin	Senior Lawyer, DHSC Legal Advisers, Government Legal Department.
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Department of Health and Social Care (DHSC)

Carly McGurly	Deputy Director, Medicines Regulation & Prescribing
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Item 1: Introductions and Announcements

1.1 Apologies were received from Rachel Bosworth, Director of Communications; Paul Wright, Department of Health and Social Care Legal Advisers.

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

- On behalf the Board, the Chairman thanked Mr Tim Robinson, Chief Executive of the Laboratory of the Government Chemist (LGC), and his colleagues for hosting the Board and for arranging a series of tours of the MHRA laboratory facilities within the LGC complex at Teddington . Mr Robinson had met privately with the Chairman and the Board before the meeting.

Item 2: Declarations of interest

2.1 Two declarations of interest were made:

- (i) Stephen Lightfoot, Non-Executive Director, reported that he had been appointed as a Non-Executive Director for Elite Hotels (Rotherwick) Limited.
- (ii) Dame Valerie Beral, Non-Executive Director, reported that she was a regular user of Clinical Practice Research DataLink (CPRD).

Item 3: Minutes of the Board meeting of 16 December 2017

3.1 The minutes of the Board meeting of 16 December 2017 were adopted.

Item 4: Minutes of the Board / CET away day of 29 January 2018

4.1 The minutes of the Board meetings (morning and afternoon sessions) of 29 January were adopted.

Item 5: Actions list / matters arising

5.1 The Actions list was reviewed.

DISCUSSION ITEMS**Item 6: Brexit**

6.1 Jonathan Mogford gave an update on Brexit-related work by the Agency. This covered the following areas: (i) UK/EU negotiations on Withdrawal Agreement; (ii) UK/EU negotiations on the implementation period; (iii) preparations for negotiations on the UK's future relationship with the EU (which includes advice to Ministers and next steps); (iv) and internal work to ensure readiness for Brexit, namely a cross-agency business continuity exercise. The latter would aim to test the how the Agency will maintain operations on Day 1 after EU Exit (whether on 1 April 2019) or 1 January 2021 – depending on the implementation period.

6.2 The Board was also updated on a planned inter-ministerial committee meeting on Brexit, which will be chaired by Steve Baker MP, Parliamentary Under-Secretary of State at the Department for Exiting the European Union, and which Health Minister Lord O'Shaughnessy will also attend.

6.3 The Chairman welcomed the update and advised that he, along with Dr Hudson and Jon Fundrey, had met with Lord O'Shaughnessy on 26 February to discuss the Agency's evolving preparatory work on Brexit, including an upcoming meeting of an EU Life Sciences Task Force (also on 1 March), which will consider the total cost of regulation in the UK. The Board also considered the Information Technology aspects of Brexit for the

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Agency, e.g. safety and signal detection systems, a submissions portal. A further update will come to the Board on 26 March.

Item 5: Corporate Plan 2018-2023

5.1 Jonathan Mogford and Patience Wilson presented a near final version of the draft Corporate Plan, 2018/2023. The outline of the Corporate Plan was set out in slide deck form drawing on the materials discussed at the Board/CET awayday of 29 January 2018. This comprised: (i) a narrative summary; (ii) the key actions and activities to underpin the strategic objectives; (iii) the challenges posed by Brexit, in particular; (iv) the practical substance of the plan setting out key actions and activities to deliver the five strategic objectives.

5.2 The Chairman thanked Mr Mogford and Ms Wilson for the presentation and sought comments from the Board. These centred on the following areas:

- *Opening comments* – The Chairman congratulated Mr Mogford and Ms Wilson for their work on the draft Corporate Plan, especially in view of the Brexit-related uncertainty.
- *CPRD* – The Chairman asked if the Corporate Plan and CPRD's five year Strategic Plan, which would be discussed later in the meeting, could be aligned, as they were operating to different timescales. Later in the meeting (item 7: CPRD Strategic Plan) Dr Valentine explained the background to CPRD's current Strategic Plan, which concerns a joint ten-year venture with the National Institute for Health Research (NIHR), the timeline for which CPRD has to adhere.
- *Monitoring* – The Board noted that the Corporate Plan included 88 individual actions, all of which would require monitoring on a regular basis, which the Board advised would be resource-intensive.
- *Aligning the Corporate Plan and Operational Transformation (OT)* - Dr Hudson assured the Board that two major strands of work (Corporate Plan and OT) would be properly aligned so that they were coherent and could ensure the efficient delivery of the Agency's strategic vision.
- *Governance* – In answer to a question about OT governance, Dr Hudson outlined the reporting lines of the newly established OT Change Board: it would report to the CET, which reports to the Board. It was noted that the Change Board oversees 'in-flight' delivery of the OT portfolio, oversees portfolio risks and benefits, maintains alignment with strategy, provides prioritisation for the business and final forecasting aligned to decision making.
- *Diverse sources of funding* - In answer to a question from the Board about funding, Dr Hudson explained that one source of non-statutory funding would be the Gates Foundation.
- *Eudravigilance* – In answer to a question about post-Brexit cooperation on vigilance, Dr Hudson advised that such cooperation was mutually beneficial and would most likely continue, e.g. Germany's Paul Ehrlich Institute and MHRA share data.

5.3 A final version of the Corporate Plan will come to the Board on 26 March.

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Item 6: Operational Transformation

6.1 Dr Samantha Atkinson presented a paper that outlined the development process for the Agency's Operational Transformation Programme Business Case. As part of the update, Dr Atkinson explained plans to engage with members of the Board over the coming weeks through a series of interview, either by telephone or by face to face meetings. Once this work has matured more fully, a further paper will come to the Board.

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

- *Opening comments* – The Board asked if the draft outline business case had been shared with anyone outside the Agency, e.g. the sponsor team at DHSC? Dr Atkinson advised that, so far, it had not gone outside the Agency.
- *Recruitment issues (economist)* – The Board asked why the Agency was having difficulties recruiting an economist to carry out an impact analysis of Operational Transformation on public health outcomes. Dr Atkinson explained there was significant competition from other Government agencies and departments of state for economists who were needed for Brexit-related economic modelling work. In response, Martin Hindle, Deputy Chairman, and other members of the Board, offered to help by drawing on various research networks and academic partners.

Action: Members of the Board to contact Dr Atkinson; Aidan McIvor (Directorate) will help coordinate the responses.

Item 7: CPRD Strategic Plan 2016-2021 Year 2 progress report

7.1 Janet Valentine presented an overview of progress during the first 2 years of the Strategic Plan. The report highlighted major achievements of the past 12 months; outlined planned developments for 2018; described CPRD market competitors; maps the anticipated growth of CPRD's business over the next decade; and updates the financial model.

7.2 Dr Valentine reported that the first two years of the Strategic Plan have been characterised by an organisational transformation to secure CPRD's future within a dynamic health data environment. Staff numbers have doubled (a GP engagement lead was appointed the previous week), bringing in the requisite skills and capacity to deliver CPRD's observational and interventional research services, and a 33% increase in GP practices signed up to CPRD has been achieved. Data can be extracted daily from *EMIS* software, opening the potential to reach out to 55% of GP practices across the UK. A new database product has been released, enabling CPRD to provide high quality near real time patient data on upwards of 10% of the UK population. The interventional research services platform developments have advanced and CPRD is now poised to pilot a range of real world clinical services. The past two years have also brought significant operational improvements and efficiency saving. During year 3 of the Plan, CPRD can look forward to realising the many developments currently in progress that will fundamentally shape the organisation's future services. Dr Valentine concluded by mentioning the upcoming review of the Independent Scientific Advisory Committee (ISAC).

7.3 The Chairman thanked Dr Valentine for her report and invited questions from the Board; these centred on the following areas:

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- *Opening remarks* - The Chairman and Board commended Dr Valentine on her report and what CPRD has achieved to date. The Board noted with satisfaction that thanks to EMIS, CPRD will have access to over 10 million people.
- *Aligning the CPRD Strategic Plan and the Corporate Plan* – In answer to an earlier question about synchronising the timelines of the CPRD Strategic Plan and the new Corporate Plan, Dr Valentine explained that CPRD has a joint ten-year venture with the National Institute for Health Research (NIHR), to whose timeline CPRD has to adhere.
- *Population coverage* – In answer to a question from the Board, Dr Valentine reported that once the backlog of data has been loaded into CPRD's database by the summer of 2018, the population coverage of patients currently registered at contributing GP practices will be around 14% of the UK's population.
- {Redacted: Section 35: policy in development}.
- *Conflicts of Interest* – In response to a question from the Board about managing conflicts of interest, Dr Hudson explained the Agency's approach. For example, Agency asked its Irish counterpart, the Health Products Regulatory Authority, to review the Decide study.
- *Push Doctor* – A member of the Board suggested that in future CPRD may also wish to approach Push Doctor, an online doctor consultation service in the UK. The service currently has over 7,000 GMC registered UK General Practitioners available and connects patients to these for secure online video consultations.

Item 8: People Survey 2017/2018

8.1 Kerry McEyeson presented an update on the People Survey results. Ms McEyeson reported that the Agency overall Engagement Index Score for the 2017 survey was 64%; the same as in 2016. This was 3% higher than the Civil Service average and 1% lower than the Civil Service High Performers Group (top 25% of most engaged organisations). Ms McEyeson went on to report that this year the Agency did not make it into the High Performers Group, having done so the previous two years. However, when compared to other Civil Service organisations of a similar size (1,000 to 2,499 employees), the Agency scored 2% higher than the benchmark on the engagement index. Ms McEyeson concluded by setting the survey results in the context of three current major change programmes: Brexit, Operational Transformation and the London site relocation .

8.2 The Chairman welcomed the report and asked if the data could be broken down by location, e.g. NIBSC. Ms McEyeson confirmed that each division has its own report on the survey results. Ms McEyeson went on to say that the Agency has a range of training and development programmes, e.g. coaching and mentoring for leaders, which is being rolled out, and which will help address some of the concerns that came out of the survey. Ms McEyeson also outlined the Agency's Action Plan in response to the survey results. Dr Hudson added that, in view of the challenges the Agency is facing, e.g. with the relocation to Canary Wharf, uncertainty over Brexit and the impact of the major OT programme, he was encouraged by the survey results.

Item 9: Gender Pay Gap – update

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9.1 Vanessa Birchall-Scott presented an interim report on gender pay gap, which the Chairman specifically requested when the Equality and Diversity Annual Report came to the Board in October 2017. Ms Birchall-Scott explained that gender pay gap reporting legislation for the public sector took effect from 31 March 2017, with the Department for Health and Social Care (DHSC) publishing its report on 18th December 2017, while the Agency published its own report on the same day. The Board also heard that the Agency will join a working group on gender pay gap being organised by the Department for Health and Social Care

9.2 Ms Birchall-Scott then outlined the Action Plan that was set out within the Agency report and progress achieved to date. Ms Birchall-Scott's update included the number of female staff who are being recruited into more senior roles and the allocation of special bonus awards by gender.

9.3 The Board welcomed the interim report and the work which Human Resources are leading on in this area. Several Board members mentioned the importance of mentoring opportunities for female staff, e.g. by way of the Board's own mentoring programme. Carly McGurry mentioned DHSC's approach to helping staff, in particular, female staff, who return to work after a career break or maternity leave. This included flexible working arrangements and training. Ms Birchall-Scott advised that the Agency operates similar flexible and very supportive policies, especially for female staff.

Item 10: Business Plan, 2017-2018 – Quarter 3 report

10.1 The Board reviewed the third quarterly report of the 2017-18 Agency business plan, which Patience Wilson presented. This covered Agency's Quarter 3 position against the commitments made in the 2017-18 business plan for: (i) Targets, (ii) Activities (iii) Metrics and (iv) further performance related work.

10.2 The Board welcomed the report and asked about the mitigation measures that have been put in place around the strands of work affected by the OT pause, which Ms Wilson and Dr Atkinson went on to address.

Item 11: Chief Executive's Report

11.1 Dr Hudson presented the highlights from the CEO's report, which covered a two-month period. These centred on the following areas:

- *Memorandum of Understanding with China* - an update was given on the Memorandum of Understanding between MHRA and the Chinese State Food and Drug Administration that was signed by Dr Hudson in Beijing in the presence of the Prime Minister, Rt Hon Theresa May, and Premier Xi at the end of January. The Prime Minister was in China with a UK trade delegation.
- *Food Standards Agency Memorandum of Understanding* – an update was given a Memorandum of Understanding that was signed between MHRA and the Food Standards Agency on 15 January 2018.
- *Memorandum of Understanding with Russia* – an update was given on a Memorandum of Understanding between MHRA and the Federal Service for Surveillance in Healthcare (Roszdravnadzor) of the Russian Federation on Regulatory Cooperation on Medicines, which will be signed in due course.

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- *Concordat* – An update was given on the Concordat on Openness with Understanding Animal Research which was signed on 31 January 2018.
- *Mesh implants* – An update was given on Urogynaecological mesh implants – an update was given on recent developments, including Lord O’Shaughnessy’s second meeting with an All Party Parliamentary Group on surgical mesh.
- *Valproate and risk of neurodevelopmental disorders* - an update was given on recent developments, including a meeting between the Minister, Lord O’Shaughnessy, and the All Party Parliamentary Group on antiepileptic drugs in pregnancy on 11 January 2018.
- *Algorithms in decision-making* – An update was given on The House of Commons Science and Technology Committee inquiry about algorithms in decision-making, before which Dr Hudson gave oral evidence on 16 January.
- *Hormone Pregnancy Tests* – An update was give on the report of the Expert Working Group on Hormone Pregnancy Tests (HPT) and the subsequent Parliamentary interest.
- *Gentamicin* – An update was given on Gentamicin use in medical devices and discussions which the Agency has had with the Human Fertilisation and Embryology Authority and the Association of Clinical Embryologists.
- *Fake medicines and devices campaign* – An update was given on the findings of a joint Fake Meds Survey, which the Agency arranged with the support of Slimming World.

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

- *Judicial Review* – In answer to a question from the Board, Dr Hudson gave an update on the case (Teva v MHRA (dimethyl fumarate), which was heard on 29-31 January, the judgement on which was handed down on 13 February in MHRA’s favour. Dr Hudson went on to report that the Government Legal Service will seek to recover the Agency’s legal costs.
- *Concordat* – In answer to a question from the Board, Dr Hudson advised that the Agency’s approach to publicity was to keep it low key.

Item 12: Finance and Procurement report

12.1 Richard Humphreys presented the Finance and Procurement report for the first nine months of the financial year. After allowing for Dividends and Financing, the Agency has a deficit of £7.1m, which is £2.6m worse than budgeted. Mr Humphreys reported that, after the costs of Operational and Digital transformation are considered, the Agency is budgeted to deliver a deficit in 2017/18 of £13.2m, and is currently forecast to deliver a deficit of £17.7m. Mr Humphreys then went on to comment on the downward trend in deferred income. For EMA applications work, income from which is 6% below budget, the MHRA has submitted several bids for work; an analysis will be carried out to understand any reductions due to the Brexit changes. Mr Humphreys said this will be reviewed in the Budget.

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

- *Relocation costs* – The Board asked if the Agency planned to negotiate with the Government Property Agency about the £9m cost. Mr Humphreys advised this was a matter of ‘accounting treatment’ as the Agency is a Trading Fund so has to fund these costs from its own resources, whereas a ‘normal’ department would reallocate the funding through the estimates process.
- *Finance reporting* – The Board expressed concerns about the overall trend, namely that its costs are increasing, while its income is decreasing. The Board thought the report came across as one where financial performance was “reported but not controlled” and suggested improvements to the reporting of steps being taken to manage its performance.

12.3 Dr Hudson thanked the Board for its comments and advised that the downward trend was partly due to reduced fees as planned as a result of the last triennial review. Dr Hudson went on to say that the focus now was on getting a balanced budget set for 2018/2019.

Item 13: Audit and Risk Assurance Committee

13.1 Minutes of the Audit and Risk Assurance Committee (ARAC) of 15 January 2018 – The draft minutes of the ARAC meeting of 15 January 2018 were noted.

13.2 Minutes of ARAC meeting of 14 November 2017 – The minutes (final version) of the ARAC meeting of 14 November 2017 were noted.

Item 14: Minutes of the Corporate Executive Team (CET) of 16 January 2018

14.1 The minutes of the CET meetings of 16 January 2018 were noted.

Item 15: Any Other Business (AOB):

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

Date of next meeting: 26 March 2018