FINAL

Medicines and Healthcare products Regulatory Agency

Minutes of the Board meeting (in public session: 10.30 a.m. – 12.30 p.m.)
Round Room
10 South Colonnade, Canary Wharf
London
22 October 2018

Present:

The Board

Professor Sir Michael Rawlins GBE	Chair of MHRA
Dr Ian Hudson	Chief Executive
Mr Jon Fundrey	Chief Operating Officer
Dr Barbara Bannister MBE	Non-Executive Director
Professor Dame Valerie Beral	Non-Executive Director
Ms Amanda Calvert	Non-Executive Director
Ms Anne-Toni Rodgers	Non-Executive Director
Mr Stephen Lightfoot	Non-Executive Director
Professor Sir Alex Markham	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 OBE	Director of Devices
Mr Patrick Carey	Deputy Director – EU & International
{Redacted: Section 40: Personal data}	Senior Stem Cell Biologist
{Redacted: Section 40: Personal data}	Head of NIBSC Corporate Affairs
{Redacted: Section 40: Personal data}	Communications Campaign Lead
{Redacted: Section 40: Personal data}	Diversity and Wellbeing Lead
{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 Joanna Greenidge	Deputy Director, MHRA, Medicines and Information Team, DHSC Legal Advisers, Government Legal Department.
Ms Carly McGurry	Deputy Director – Medicines Regulation and Prescribing, Medicines and Pharmacy Directorate, Department for Health and Social Care

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Item 1: Introductions and Announcements

1.1 Apologies were received from Professor David Webb, Non-Executive Director; Professor Bruce Campbell, Non-Executive Director; Dr Christian Schneider, Director of NIBSC.

1.2 The Chair welcomed everyone to the meeting, including staff observers and members of the public. The Chair advised that among the public observers were Ms Ann Horan, Chairman of the Healthcare Products Regulatory Authority of Ireland, along with officials from UK Anti-Doping, all of whom had come to the meeting to learn about the Agency's approach to opening some of its Board meetings to external observers.

Item 2: Declarations of interest

2.1 None was declared.

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

3.1 The minutes of the last Board meeting in public session (23 April 2018), which were adopted by the Board in May 2018, were noted.

DISCUSSION ITEMS

Item 4: Exiting the EU – update

4.1 Jonathan Mogford and Patrick Carey presented an update on work that is taking place to prepare the Agency for several outcomes that could arise flowing the EU's departure from the EU. This included work on the Agency is doing on 'No deal' contingency planning, as well as on the future shape of the Agency. As part of his update, Mr Mogford also mentioned the planned audit of the Agency by the Cabinet Office's Infrastructure and Projects Authority to assess the Agency's readiness for the UK's exit from the EU after March 2019.

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

- *Infrastructure and Projects Authority (IPA) review* – In answer to questions from the Board about the Agency's readiness for the UK's exit from the EU, Mr Mogford advised that the Agency is well advanced in its preparatory work for all eventualities.

- *Technical Notices* – The Board asked what feedback the Agency had received following the publication on 6 August 2018 of the Technical Notices. The Notices set out what companies would need to do in the event of a no deal. Mr Mogford replied that the feedback had been positive, echoing the Agency's approach which is to be pragmatic and focussed on public health.

4.3 The Chair went on to invite questions from staff and public observers; none was offered.

Item 5: Chief Executive's Report

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

- *Rescheduling of cannabis-based medicines* – An update was given on the Agency's work with the DHSC and the Home Office on the Rescheduling of cannabis-based medicines.

- *Cumberlege Review* – An update was given on the Government's Independent Medicines and Medical Devices Safety (IMMDS) Review Group, the terms of reference for which were published on 6 September 2018. The Review's Call for Evidence is now open, and the Agency has been invited to submit comments.

- *Paraffin containing products* – An update was given on the Commission of Human Medicines Expert Advisory Group's (EAG) consideration of the risk of severe burns associated with paraffin containing healthcare products, such as skins creams. The EAG had its firsts meeting on 7 September 2018.

- *ICMRA* – An update was given on the International Coalition of Medicines Regulatory Authorities (ICMRA) meeting, which took place over three days in Washington DC in September 2018, which Dr Hudson and Jonathan Mogford attended.

- *GCMAF (Gc protein-derived macrophage activating factor)* - An update was given the outcome of a trial following a long-standing investigation by the Agency's Enforcement Group. The trial ended with the Agency successfully prosecuting two members of the public who were engaged in criminal activity.

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

- *GCMAF – The Board commended the Agency on the outcome of the trial.*

- *'Transformation LIVE'* – The Board noted the 'Transformation LIVE' event and commended the way technology has enabled staff to engage at what was a highly successful event.

- *Cannabis-based medicines* – In answer to questions from the Board, Dr Hudson explained the role of the Home Office in this area and the Agency's current role and position.

- *Blood Inquiry* – In answer to a question from the Board, John Quinn explained how the Agency is assisting with the Inquiry and the challenges posed by trying to access records which are held on microfiche and in paper form, some dating from the 1980s and earlier.

5.3 The Chair went on to invite questions from staff and public observers. These centred on the following areas.

- *Cannabis-based medicines* – A member of Cure Parkinson's Trust asked if MHRA planned to give advice to GPs on this subject on areas where cannabis based

medicines might be useful. Dr Hudson explained that NICE (and not MHRA) is planning to develop guidelines.

- A member of the public highlighted the risks associated with weaning patients off medication for epilepsy and cited examples of where patients have overdosed on their medication. Dr Hudson thanked the member of the public for sharing their knowledge of such incidents and asked that such experiences should be shared with the Agency, e.g., via the Yellow Card Scheme. Dr Hudson went on to advise that a legal framework is being prepared for the use of cannabis-based medicines.

- *Medicines pricing* - A member of the public asked if the price of medicines would be affected by the UK's decision to leave the EU. Dr Hudson explained that DHSC and not the MHRA has policy responsibility for medicines pricing.

Item 6: Operational Transformation - update

6.1 John Quinn presented a progress report on the Agency's Operational Transformation Programme (OTP) and an update since the OTP Business Case went to the Board on 24 September. For the benefit of public observers, Mr Quinn explained the background to the Agency's OTP, the reasons why the Agency had to embark on an OTP and the challenges and opportunities which lie ahead. Mr Quinn then went on to explain the work that has taken place since the OTP was submitted to DHSC at the end of September, the meetings Jon Fundrey, Chief Operating Officer, and Mr Quinn have had with senior officials at DHSC, and how he and members of the Corporate Executive Team are actively engaging with staff, e.g. the recent 'The Transformation LIVE' staff event. Mr Quinn concluded by advising that the Agency's OTP business case will be considered by DHSC's Investment Committee on 15 November 2018.

6.2 The Chair thanked Mr Quinn for his report and sought the Board's views. These centred on the following areas:

- *Staff engagement* – The Board commended the level of Corporate Executive Team's engagement with staff, but asked if this was equalled by the commitment of operational / middle level managers? Mr Quinn said that Pulse Survey returns show that most staff, including operational managers, recognise the need for change and that the key is to empower staff to take ownership of the OTP. This is something that the CET firmly supports.

- *The cost of the first tranche of work* – In answer to a question from the Board, Mr Quinn confirmed that the cost of the firsts tranche of work of the OTP is estimated to be £5-7M, which will be for the Investment Committee at DHSC to approve. Mr Quinn went on to advise that unlike major projects in the previous decade, the aim of OTP will be to deliver changes in 'bite-size' parts, which is easier to manager and deliver.

- *Internal communications* – The Board advised that the internal communications came across as rather 'dry' and went on to offer its practical support, e.g. providing advice, which Mr Quinn welcomed.

- *NIBSC* – The Board asked if during this programme of change NIBSC might need additional support? Mr Quinn said that NIBSC is closely involved with the OTP, e.g. Dr Schneider, Director of NIBSC, chairs one of the seven OT workstreams (Science and Research).

9.3 The Chairman invited questions from members of the public and staff. A member of the Alzheimer's Society asked if because of the UK's decision to leave the EU the Agency has had to recruit hundreds of more staff. Dr Hudson confirmed that the Agency has not recruited hundreds of new staff; instead, many staff are having to spend more time on Brexit-related work. However, that effort has not lessened the Agency's vital public health role.

Item 7: MHRA's role in the development and use of Artificial Intelligence (A.I.) for safety reporting

7.1 John Wilkinson presented a paper on the development and use of A.I. for safety reporting. The paper considered the regulation of software that applies to A.I., an analysis of data lakes to identify / validate safety issues associated with the use of A.I.; the use of A.I. to prompt and facilitate incident reporting; and the automation aspects of internal incident processing using A.I.

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

- *Unique Device Indicators (UDIs) - The* Board thought that while rolling out UDIs was to be welcomed, it requires hospitals to have electronic health records, which may not be case. Moreover, the Board advised that there must be a link between primary and secondary care.

- *Leeds exemplar* – The Board advised that hospitals in Leeds are an exemplar in the UK with 'scan for safety'. Mr Wilkinson said that the pilot programmes in Leeds and the other sites had highlighted practical issues around collection and use of medical device information captured in e-patient records.

- *Incentivisation* – The Board asked that consideration be given to the Government /DHSC giving hospitals a financial incentive to collect additional information, e.g. not only what type of operation was carried out, but what type of medical device was used / implanted.

7.3 The Chairman invited questions from members of the public and staff. These centred on the following areas:

- *Yellow Card Scheme* - A member of the Organisation of Anti-Convulsant Syndrome (O.A.C.S) spoke highly of the Yellow Card Scheme and advised that greater care needs to be taken of the management of patients who take long-term medications and whether they developed ADR's. Dr Hudson noted he was grateful for the comment and recognised that diagnosing Adverse Drug Reactions was sometimes difficult; and is something that requires more collaborative work across the healthcare system.

- *Deep Brain stimulation* - A member of the Cure Parkinson's Trust said that more research was needed and asked if there was scope within this work for Deep Brain stimulation. Mr Wilkinson replied that the potential for research would depend on whether there was enough data recorded in electronic patient records.

Item 8: The Sustainability of the UK Stem Cell Bank

8.1 {Redacted: Section 40: Personal data} presented a paper on the Sustainability of the UK Stem Cell Bank (UKSCB). {Redacted: Section 40: Personal data} reported that

the UK Stem Cell Bank (UKSCB) was established in 2003 on the recommendation of the House of Lords Select Committee on Stem Cell Research. It has been housed at NIBSC since its inception with funding via the Medical Research Council (MRC). The UKSCB collects, banks, and supplies all human embryonic stem cell (hES cell) lines generated in the UK (and some from overseas). {Redacted: Section 40: Personal data} went on to advise that the UKSCB is seen as a considerable strategic asset for the UK in the field of regenerative medicine, being able to provide both research-grade and, currently underway, clinical grade hESC lines. The latter can be obtained from the UKSCB as "starting material" for generation of cell-based medicinal products for clinical trials.

8.2 {Redacted: Section 40: Personal data} went on to report that the current financial support from the MRC for the UKSCB ceases in 2020. Beyond that, no funding source has been identified. Moreover, there are structural constraints that limit the capacity of NIBSC to make the Bank financially self-sustaining.

8.3 The Chair thanked {Redacted: Section 40: Personal data} for her paper and sought the Board's views. These centred on the following areas:

- *Opening comments* – The Board commended the work that the UKSCB does, advising it is highly regarded internationally.
- *Funding* – The Board asked why the MRC discontinued its funding; {Redacted: Section 40: Personal data} said that no specific reason was given. The Chair then asked how much does the UKSCB receive? {Redacted: Section 40: Personal data} said it was approximately £500K per year.
- *Volume of activity* – The Board asked how many clinical applications does the UKSCB receive? {Redacted: Section 40: Personal data} advised that it was between 2-3 per year; it's a very small niche market however there were around 700 research applications.
- *Possible next steps* – The Board suggested that NIBSC contact Keith Thompson, Chief Executive of Catapult – Cell and Gene Therapy, as well as Innovate UK (the Government's innovation agency), to discuss possible alternative sources of funding.

8.4 The Chairman invited questions from members of the public and staff. One member of the public declared an interest as having been a lay representative on the MRC between 2003-2010. The member of the public in question went on to advise that the MRC's costings were similar to NIBSC.

Item 9: National Institute for Biological Standards and Control – highlights

9.1 {Redacted: Section 40: Personal data} presented the report on 'Highlights from the Director of NIBSC'. The report, which covered the first quarter of 2018/19, provided a summary of key achievements by NIBSC as well as other areas where work will continue through the financial year. Among the highlights cited were: (a) work on developing new standards and reference materials, (b) work on promoting the role of biological standards in the biosimilars regulatory framework; (c) work to support the timely supply of influenza vaccines; (d) work on support for the eradication of Polio; (e) work on the development of materials for emerging infections; (f) work on medicines control testing; (g) work on Advanced Therapies (the Board noted the award of £2.1m grant to fund continued support of the development of the EU Tissue and Cells Directive grade cell line programme); and (h) NIBSC's work on supporting innovation.

9.2 The Chair thanked {Redacted: Section 40: Personal data} for her report and sought the Board's views. The Board commended {Redacted: Section 40: Personal data} on the impressive spectrum of work that NIBSC carries out. The Board went on ask if NIBSC had enough funding to carry out its work; {Redacted: Section 40: Personal data} confirmed that, while funding streams were in place and NIBSC operates within a ringfenced budget, there is currently financial pressure, as for the rest of the agency, and a need to provide its share of corporate costs. There was also concern about retaining staff and recruiting new staff, especially with the uncertainty around Brexit. Dr Hudson added that the NIBSC site was also old and in need of investment and was currently subject to an accommodation review to plan. The Board cautioned that NIBSC was a national scientific asset of great importance and great care was needed to ensure that it would not wither in the years to come. The Board also advised that NIBSC's global counterpart, the Paul Ehrlich Institute of Germany, was planning to expand, especially after the UK leaves the EU.

9.3 The Chairman invited questions from members of the public and staff; none was offered.

Item 10: Falsified Medicines and Medical Devices campaign

10.1 {Redacted: Section 40: Personal data} presented a progress report on the Agency's Falsified Medicines and Medical Devices campaign and plans for future activity. {Redacted: Section 40: Personal data} reported that since the last update to the Board, the focus on slimming pills has continued, with additional activity focused on sports supplements sold as medicines, dental equipment and erectile dysfunction medication.

10.2 The Board heard that all the campaign's objectives have been achieved and exceeded which means that the campaign has succeeded in creating behaviour change in our target audience and reduced the prevalence of consumers purchasing fake slimming pills sold online, thus having a positive impact on public health. {Redacted: Section 40: Personal data} reported that work on creating relevant case studies and meaningful partnerships with organisations that have helped to develop further engaging content; generating significant media coverage in a broad range of outlets and through social media marketing of to maximise audience engagement with campaign messages.

10.3 {Redacted: Section 40: Personal data} went on to report that the campaign has received industry recognition through the award of Best Healthcare campaign in 2018 and a Mark of Excellence in the Public Sector campaign category from the Chartered Institute of Public Relations. It has also been shortlisted for three additional awards from PRCA and the Government Communications Service, which recognises excellence in public sector communications campaigns. {Redacted: Section 40: Personal data}concluded by reporting that the next stage (phase 2) of the campaign, which focuses on Sexually Transmitted Infection self-test kits, has now launched (October 2018) and will run until May 2019. Initial coverage of campaign messages has been secured in The Sun; Daily Mail and on ITV Tonight.

10.4 The Chair thanked {Redacted: Section 40: Personal data} for her report and sought the Board's views. These centred on the following areas:

- *Opening comments* – The Chair and Board commended {Redacted: Section 40: Personal data} and her colleagues on the success they had achieved so far, in particular, the Best Healthcare campaign award (2018). The Chair also congratulated the Agency in working with popular national television series

such as Coronation Street and Casualty to help raise awareness using stories around falsified medicines and medical devices of this threat to public health to millions of people across the UK and beyond.

- *Value for money* – The Board congratulated {Redacted: Section 40: Personal data} and her colleagues on managing to reach out to so many with such a very small amount of financial outlay: around £7,500. The Board advised that in the private sector, to reach out to millions of people in the way the Agency has achieved, e.g. through the Fake Meds themed storylines in television series, would require a significantly higher rate of investment.

10.5 The Chairman invited questions from members of the public and staff. A member of the Organisation for Anti-Convulsant Syndrome (OCAS) asked about the Agency's work to reach out to the younger generation, especially to those who are at risk of self-harm or worse. The OCAS member suggested that the Agency should work with schools and through social media to reach out to younger people.

10.6 {Redacted: Section 40: Personal data} thanked the OCAS member for her very helpful comments and explained the Agency's approach to reaching out to 18-25-year olds, as well as to children and young people outside this age bracket. The Chair, too, thanked the OCAS member for her very helpful comments and advised that the Government has recently appointed the first ever Health Minister with responsibility for preventing suicide: Jackie Price Doyle MP. {Redacted: Section 40: Personal data} said she would reflect on and act on the very helpful comments that were made about working with schools and children and young people.

Item 11: Equality and Diversity Annual Report

11.1 Ms Vanessa Birchall-Scott introduced {Redacted: Section 40: Personal data}, Diversity and Wellbeing Lead, who presented the Equality and Diversity annual report to the Board. The report covered (i) the work of the Agency's Equality and Diversity Group; (ii) a summary of key progress to date; (iii) an update on the work of the Equality and Diversity Group's Statistics Sub-Group; (iv) and work on the Gender Pay Gap. {Redacted: Section 40: Personal data} advised that the gender pay data for this year's report is currently being analysed and that the Agency's report on Gender Pay will be published in December 2018. {Redacted: Section 40: Personal data} also highlighted the Agency's work on health and well-being the setting up a network of Mental Health Champions, as well as the Agency's confidential listening service and coaches.

11.2 The Chair thanked {Redacted: Section 40: Personal data},for her report and sought the Board's views. These centred on the following areas:

- *Benchmarking* – The Board asked if the Agency plans to benchmark itself against other organisations? Ms Birchall-Scott said this was something the Agency is very keen to do.

- *Mental Health Champions* – The Board commended the Agency on its work in setting up a network of Mental Health Champions. {Redacted: Section 40: Personal data} explained the background to the scheme and recent developments, e.g. establishing a network of eighteen mental health champions. {Redacted: Section 40: Personal data}, went on to say that the Agency is working closely with the Department of Health and Social Care and Public Health England to share experience and best practice in this area.

- *Parents' network* – The Board commended the Agency on establishing a Parents' network, which comprises male and female staff, and which {Redacted: Section 40: Personal data} advised would be formally launched on 24 October. The Board advised that, if staff leave because of work/life balance issues related to having become a parent, this is something that warranted investigation – why are staff leaving and what can the Agency can do to reverse the trend.

11.3 The Chair invited questions from the public and staff; none was offered.

Item 12: Any Other Business (AOB):

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