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Medicines and Healthcare products Regulatory Agency

Minutes of the Board meeting

Ground floor meeting room
National Institute for Biological Sciences and Control (NIBSC)

17 December 2018

Present:

The Board

Professor Sir Michael Rawlins GBE	Chair of MHRA
Professor David Webb	Deputy Chair
Dr Ian Hudson	Chief Executive
Mr Jon Fundrey	Chief Operating Officer
Dr Barbara Bannister MBE	Non-Executive Director
Ms Amanda Calvert	Non-Executive Director
Professor Bruce Campbell	Non-Executive Director
Mr Stephen Lightfoot	Non-Executive Director
Ms Anne-Toni Rodgers	Non-Executive Director
Mr Michael Whitehouse OBE	Non-Executive Director

Others in attendance

MHRA executive and supporting officials

Mr Jonathan Mogford	Director of Policy
Mrs Rachel Bosworth	Director of Communications
Dr Christian Schneider	Director of NIBSC
Ms Vanessa Birchall-Scott	Director of Human Resources
Dr June Raine CBE	Director of Vigilance and Risk Management of Medicines
Mr John Wilkinson OBE	Director of Devices
{Redacted: Section 40: Personal data}	Head of Learning and Development
{Redacted: Section 40: Personal data}	Science Communicator
{Redacted: Section 40: Personal data}	Head of Corporate Services
{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.

Department of Health and Social Care (DHSC)

Ms Carly McGurry (by telephone)	Deputy Director, Regulation and Prescribing, Medicines and Pharmacy Directorate, DHSC.

Item 1: Introductions and Announcements

1.1 Apologies were received from Professor Dame Valerie Beral, Non-Executive Director; Professor Sir Alex Markham, Non-Executive Director.

1.2 The Chair welcomed everyone to the Board meeting, including Mr Michael Whitehouse, who officially joined the Board on 1 December 2018.

Item 2: Declarations of interest

2.1 None was declared.

Item 3: Minutes of the Board meeting of 19 November 2018 / Actions list

3.1 The minutes of the last Board meeting (19 November 2018) were adopted.

3.2 The Board reviewed and noted the Actions list.

DISCUSSION ITEMS

Item 4: Exiting the EU – update

Exiting the EU - update

4.1 Jonathan Mogford presented a comprehensive update on the Agency's recent work to prepare the Agency for the UK's exit from the EU. This covered (i) Deal negotiations and (ii) the Agency's readiness for a 'No Deal' outcome, including legislation, IT systems, and Day 1 continuity; and other preparatory work, such as resourcing and finances.

4.2 The Chair thanked Mr Mogford for his update and asked the Board for its comments. The Board asked about the impact of various Exit scenarios and the particular challenges facing the medical devices sector. Dr Hudson and Mr Mogford addressed these queries.

World Class Medicine and Medical Devices Regulator Fit for the future

4.3 The Board considered a revised draft of the '*World Class Medicine and Medical Devices Regulator Fit for the future'* document. The document had been prepared at the Board's request at its meeting on 22 October and which was considered in draft form on 19 November.

4.4 The Board welcomed the document, which Dr Hudson said would not be published, but would be used as resource, e.g. for meetings with Ministers. As the document was tabled, Dr Hudson said he would welcome any subsequent comments members of the Board may wish to send on.

Item 5: Operational Transformation

5.1 Jon Fundrey presented the progress report. Since the Board reviewed the draft Operational Transformation Programme Business Case on the 24th September, it was submitted to DHSC at the end of September. Mr Fundrey reported that since October and November, the focus for the programme has been on: establishing governance and obtaining formal approval; beginning to progress change proposals through our revised governance; and continuing communications and enabling change activities. The

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Operational Transformation Programme Business Case was formally approved by the Department of Health and Social Care (DHSC) Investment Committee on 29th November 2018. The case was approved with a series of conditions the major two being that we return to DHSC with a more defined case showing our response following the Brexit outcome; and that we expand on the economic and financial analysis in the Economic Case. Mr Fundrey concluded by advising that in view of the cost of the OT Programme Business Case, that case would also be considered by HM Treasury, despite earlier indications to the contrary from DHSC.

5.2 The Chair thanked Mr Fundrey for his update and asked the Board for its comments. These centred on the following areas:

- *Opening comments* – The Board congratulated Mr Fundrey and the team on the getting the Business Case approved by the DHSC Investment Committee.

- *Government-wide* – The Board advised that for projects such as the OT, it is very important to understand the interdependences across government.

- *Commercialisation* – The Board asked about opportunities for commercialisation. This, Mr Fundrey, said was being considered.

- *Cultural aspects* – The Board asked about workplace cultural issues, which could be barriers to progress. Ms Birchall-Scott explained that the Corporate Executive Team (CET) is very aware of barriers to streamlined working, such as 'perceived silo working', and behaviours, which the CET have discussed at CET Mini Awayday sessions, and at the Senior Leaders Group meeting. Ms Birchall-Scott also said that consideration is being given to internal and external secondment opportunities. A member of the Board also mentioned that several staff from NIBSC had told her that the broad scope of the work of the Institute and its impact on chronic as well as acute diseases was not well understood by many across Government, and even within some parts of the Agency.

- *Sharing of expertise, data and equipment* – the Board asked if the Agency had explored greater sharing of expertise, data and equipment across the Agency, e.g. in secretariat work, pharmacovigilance or assessment. Dr Raine, said that she, along with Dr Janet Valentine (Director of the Clinical Research Practice DataLink), and Mr John Wilkinson, have been discussing the possibilities around greater collaboration. Dr Schneider said that the sharing of equipment, data and expertise is something that NIBSC has been progressing with colleagues across the Agency.

- *Board engagement and support* – The Board asked if there was anything individual NEDs could do to support this work. Mr Fundrey thanked the Board for the offer, which he welcomed, and which he and Mr John Quinn, Director of Business Transformation, would reflect on but he said that as the individual business cases were developed, there would be many requests to NEDS to assist in supporting taking this forward.

Item 6: Talent Management – update

6.1 {Redacted: Section 40: Personal data} presented an update to the Board on recent and planned talent management activity, against the Agency Talent Management Strategy 2015 – 2020. As part of the update, {Redacted: Section 40: Personal data} explained and elaborated on each of the objectives set out in the 2015 – 2020 Strategy:

1. Planning for succession into senior roles
2. Developing our future senior leaders, in technical and/or scientific areas to enable low risk internal appointments into some senior roles
3. Developing our future senior leaders, in commercial/ corporate areas to enable low risk internal appointments into some senior roles
4. Mapping of career pathways across the Agency to improve morale, enhance internal promotion and thus increase retention for all our staff
5. Demonstrating our commitment to talent management, which is likely to remain a Civil Service priority.

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

- *Opening comments* – The Board asked whether the discussions about performance, personal development, and the Nine-Box Grid took place at the same appraisal meetings between a line manager and the staff member. {Redacted: Section 40: Personal data} and Ms Birchall-Scott (Director of Human Resources) explained that because of the packed agenda for annual performance appraisals, in most instances line managers hold a separate conversation with their staff members, which focuses on personal and career development, including covering Nine-Box Grid placements. However, the talent and performance processes and tools are closely connected through information-sharing at a team, division/centre and pan-Agency level.

- *Feedback* – The Board asked if feedback had been sought from staff on the process. {Redacted: Section 40: Personal data} explained that, so far, only informal feedback had been sought, as many of the talent management processes and tools in place in 2018/19 are new to the Agency. She explained that a more formal approach to obtaining feedback will be sought on completion of the 2018/19 talent and performance cycle.

- *Nine-Box Grid* – During the discussion Dr Schneider advised that the Nine-Box Grid developed for technical experts at the Agency has been well received at NIBSC and meets their needs effectively.

- *Sharing experience* - The Board asked if there were opportunities for staff to share their experiences and insights from leadership development training within the Agency. {Redacted: Section 40: Personal data} confirmed that this was indeed the case. She cited one example of a colleague who participated in the 2017 cohort of the Civil Service Future Leaders Scheme, who has subsequently shared her experience of the scheme with colleagues, helped to promote the scheme within the Agency, and brought leadership insights back into her division. {Redacted: Section 40: Personal data} also cited the example of a member of staff who has participated in the Health and Care Leaders Scheme, specifically with the objective of bringing back leadership insights and capabilities into the regulator.

- *Alumni* – The Board suggested that the Agency build up a network among its staff alumni. This would allow former staff, who previously have benefited from career development within the Agency to return to share their experience and perspectives.

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Item 7: Moving towards greater transparency on using animals in research – update

7.1 {Redacted: Section 40: Personal data} and {Redacted: Section 40: Personal data} presented the update on the Concordat on Openness on Animal Research with Understanding Animal Research (UAR), which was signed in February 2018. The update covered the internal and external responses to signing up, NIBSC's requirements as a signatory of the Concordat, and progress which has been made in key areas.

7.2 The Chair thanked {Redacted: Section 40: Personal data} and {Redacted: Section 40: Personal data} for the update and asked the Board for its comments. The Board noted the examples of best practice from other organisations which use animals in research and recommended that the Agency adopt some of the good examples. The Board also advised that the work that was outlined in the update should tie in with the Operational Transformation Programme.

Item 8: The Independent Medicines and Medical Devices Review (Cumberlege Review) – update

8.1{Redacted: Section 40: Personal data}, supported by Dr June Raine and Mr John Wilkinson, presented the update on recent work by the Agency to respond to the Independent Medicines and Medical Devices Safety (IMMDS) Review led by Baroness Cumberlege. {Redacted: Section 40: Personal data}, reported that on 31 October 2018 the Agency response to the Call for Evidence was submitted. The response included answers to the series of specific questions posed. The Chair of the Commission on Human Medicines (CHM) and the Chair of the CHM's former Hormone Pregnancy Test (HPT) Expert Working Group also submitted a response to a separate call for evidence invitation, answering the specific questions regarding the establishment of the HPT Expert Working Group and its terms of reference. On 20 November a series of oral evidence gathering sessions began and will continue into Spring 2019 and the Agency has now received an invitation to send participants to participate in the Review's oral hearing sessions in January and February.

8.2 The Chair thanked {Redacted: Section 40: Personal data}, Dr Raine and Mr Wilkinson for the update and sought the Board's views. These centred on the following:

- *Opening comments*: The Board thought the IMMDS Review offered a good opportunity for the Agency to raise greater awareness of a safety culture and to highlight the importance of a regulatory regime for medicines and medical devices that is essential to patient safety.

- Reporting of adverse incidents - The Board discussed aspects of the Agency's signal detecting system, the Yellow Card Scheme, which provides a vital source of new information, including from patients. While accepting that under-reporting is an issue, the Board noted that mandatory reporting had not apparently improved signal detection in those countries where it had been introduced. The Board was supportive of maximising the use of the Agency's Clinical Practice Research DataLink for strengthening safety signals.

Item 9: Devices – oral update on recent media coverage and next steps

9.1 Mr John Wilkinson gave an update on recent media interest in devices issues, in particular, a BBC Panorama documentary which was broadcast in late November. Mr Wilkinson explained the background to recent media interest, how the Agency responded, including an interview on camera with a senior official from Devices

Division, which appeared in the Panorama documentary. Mr Wilkinson also gave an update on subsequent work the Agency is doing with stakeholders, including health care professionals and patient groups. Mr Wilkinson advised that, while EU medical devices legislation is still in a formative stage, the scale of recent change has been significant: the new Medical Devices Directive is over 500 pages long; its predecessor was only 50 pages in length. Mr Wilkinson went on to advise that notwithstanding Brexit, the UK will continue to play an important role in driving forward the new EU devices safety legislation.

9.2 The Chair and Board thanked Mr Wilkinson for his update and asked the Board for its comments. These centred on the following:

- *Post-Brexit* – In answer to questions from the Board, Mr Wilkinson advised that for a time-limited period, the UK would continue to recognise the CE Mark on medical devices, which demonstrates their conformity with EU regulatory requirements. During this period, devices would be accepted on the UK market if they meet all EU requirements, which for all but the lowest-risk devices would include certification by EU Notified Bodies. UK-based Notified Bodies would, in a 'no-deal' scenario, no longer be able to assess the conformity of medical devices for devices to receive the CE mark and enter the EU market.

- *Balanced risk* – The Board advised that 'balanced risk' needed to brought back into discussion around safe use of medical devices.

Item 10: Chief Executive's Report

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

- *GcMAF* – An update was given on the prosecution and sentencing (on 27 November 2018) of Guernsey-based David Noakes who had manufactured and promoted GcMAF, an unlicensed medicine, at the Southwark Crown Court. Mr Noakes was sentenced after pleading guilty to 4 charges relating to the manufacture and sale and supply of an unlicensed medicine, and one count of money laundering.

- *FakeMeds campaign* – An update was given on the Agency's success in winning the PR and Communication Association's 'Value for Money, In-House' campaign award for the Agency's FakeMeds Campaign.

- *Hormone Pregnancy Tests (HPTs) and new meta-analysis of observational studies* – An update was given on a new publication and the Agency's plans to convene another expert group to review the publication, as well as asking the EMA to look at it.

- *World Health Organisation* (*WHO) and MHRA* - An update was given on discussions at the Agency's offices in November between Dr Hudson and Ms Emer Cooke of the World Health Organisation about future collaboration.

- *Valproate and the implementation of the Pregnancy Prevention Programme (PPP)* – An update was given on a meeting between Agency officials and members of the Valproate Stakeholder Network on 19 November. The Board heard that a further communication about PPP would be published in the Drug Safety Update in December.

- *Chinese visit* - An update was given on discussions in Beijing from 19-23 November with senior officials from the Agency's Chinese counterpart. The Agency's delegation comprised Dr Samantha Atkinson, Director of inspection, Enforcement and Standards Division; Dr Siu Ping Lam, Director of Licensing Division; and Dr Martin O'Kane, Head of the Clinical Trials Unit.

10.2 The Chair and the Board thanked Dr Hudson for his report and commended Rachel Bosworth and her colleagues on securing yet another communications award for the Agency. In answer to a query about the Agency's Memorandum of Understanding (MOU) with the Agency's counterpart in Russia, Dr Hudson and Dr Atkinson explained the background to the MOU (which focussed around sharing information on inspections) and the likely benefits that will flow from the agreement.

Item 11: Finance items:

11.1 Boryana Stambolova presented an update on the Cash Forecast 2018-2023. Ms Stambolova reported on the Agency's liquidity position in the five-year period to March 2023 under various Brexit scenarios, including the impact of the Operational Transformation Programme. The paper also summarised the key assumptions underpinning the modelling of future cash inflows and outflows with the aim of bringing transparency to the risk factors intrinsic to the forecast and ultimately to the Agency's financial stability in the Brexit transition period and immediately thereafter.

NIBSC finances

11.2 Ms Stambolova then provided the Board with an overview of NIBSC's funding, the change in the composition over time and the implications for NIBSC as a centre of scientific excellence. Ms Stambolova explained NIBSC has had to increase its external funding significantly since 1990 due to the reduction in funding from the Department of Health and Social Care (DHSC). The paper highlighted one area that has contributed significantly to this - income from influenza standards sales has brought in £36.3m over the last 10 years. Standards sales in this area continue to perform strongly however there is always uncertainty as this field moves rapidly and could result in a downturn in income. This is not only important from an income generation perspective but also in NIBSC's contribution to public health.

11.3 The Chair and Board commended Ms Stambolova for the work that has been done in recent months, in particular, the new approach to finance reporting: quarterly financial and procurement reports, quarterly cash forecasts, and periodic updates on the budget. The Board welcomed the specific report on NIBSC.

Item 12: Timetable for the Annual Report 2018/2019

12.1 Ms Rachel Bosworth presented the timetable for the Annual Board 2018/2019, which the Board noted. Ms Bosworth advised that the narrative section would be shorter than in previous Annual Reports.

Item 13: Draft programme for the joint Board / CET meeting of 21 January 2019

13.1 The Board endorsed the proposed programme for the joint Board / CET meeting on 21 January 2019.

Item 14: Minutes of the Corporate Executive Team (CET) meetings

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14.1 The minutes of the CET meeting of 9 October and 6 November 2018 were noted.

Item 15: Any Other Business (AOB):

15.1 None was tabled.

Date and place of the next meeting: 21 January 2019 – Round Room at Canary Wharf.