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Medicines and Healthcare products Regulatory Agency

Minutes of the Board meeting (1.30 p.m. – 3.30 p.m.)
Rooms 5.09 & 5.10
10 South Colonnade, Canary Wharf
London
19 November 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
Professor Dame Valerie Beral	Non-Executive Director
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
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
Mr John Quinn	Director of Transformation
Dr Janet Valentine	Director of Clinical Practice Research DataLink
Ms Boryana Stambolova	Deputy Finance Director
Mr Patrick Carey	Deputy Director – EU & International
{Redacted: Section 40: Personal data}	Head of International Office
{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 Rebecca Diment	MHRA Sponsorship and EU Exit Team, Medicines Regulation and Prescribing, Medicines and Pharmacy Directorate, DHSC.

Observers

Mr Michael Whitehouse OBE

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Item 1: Introductions and Announcements

1.1 Apologies were received from Ms Anne-Toni Rodgers, Non-Executive Director; and Ms Carly McGurry, Deputy Director, Medicines Regulation and Prescribing, Medicines and Pharmacy Directorate, DHSC.

- The Chair welcomed everyone to the Board meeting, including Mr Michael Whitehouse, who will join the Board on 1 December 2018, and who was attending the Board meeting as an observer.

- The Chair reported that, in view of the financial challenges facing the Agency, he had decided not to go ahead with the Board dinner at which Dame Sally Davies, the Chief Medical Officer (England), was to have been the guest of honour. The Chair advised that Dame Sally fully appreciated the reason between cancelling the dinner.

Item 2: Declarations of interest

2.1 Professor Dame Valerie Beral asked that the minutes record that she is a user of CPRD data, which would be discussed under item 7.

Item 3: Minutes of the Board meeting of 22 October 2018 / Actions list

3.1 The minutes of the last Board meeting (22 October 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) ongoing negotiations around the draft Withdrawal Agreement; (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.

World Class Medicine and Medical Devices Regulator Fit for the future

4.2 The Board then considered a draft document entitled '*World Class Medicine and Medical Devices Regulator Fit for the future',* which had been prepared at the Board's request at its meeting on 22 October. The document, which was intentionally short (4 pages) at the Board's request, gave a high-level overview of the Agency's role. This included the Agency's support for innovation and the life science industry; NIBSC's world-leading role in biological standards; CPRD's unique clinical database through its provision of healthcare data for research; the Agency's extensive links and influence internationally; and the Agency's broader contribution to the HM Government's Public Health priorities. The high-level document also covered the impact of Brexit, the financial aspect and the Agency's efficiency programme.

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4.3 The Chair thanked Dr Hudson and Mr Mogford and sought the Board's views. These centred on the following areas:

- *Technical Notices consultation* - The Board asked for an update on the feedback that had been received following the Agency's consultation at the end of August 2018 on 25 technical notices. The technical notices provided information to allow businesses and citizens to understand the implications of and prepare for a Brexit 'No deal' scenario. Mr Mogford said the feedback that had been received had been very helpful, he updated the Board about this. Mr Mogford also mentioned the 'No deal' public consultation which was launched in October 2018 on the Agency's Statutory Instruments (SIs) which have been drafted for a no deal scenario.

- *Legislative workload* – The Chair asked about scale of the Agency's Brexit-related legislative workload. Joanna Greenidge explained the Agency has to prepare three Statutory Instruments (SIs), which is much fewer than those required by other public bodies. However, the three SIs were unusually long and complex documents.

4.4 The Board welcomed the draft document and made several recommendations about how it could be improved. These included (i) explain the Agency's 'three centres' in the introduction to the paper; (ii) provide a much stronger emphasis on the Agency's contribution to public health and the unique role that NIBSC plays.

4.5 Dr Hudson thanked the Board for its comments, which he said would be reflected in the revised version which would come to the next Board meeting.

4.6 The Chair concluded by asking that a copy of a recent submission to Ministers on the 'MHRA Brexit No Deal' be shared in confidence with members of the Board.

Action: (i) A revised version of the paper to come to the Board at its meeting on 17 December; (ii) a copy of the 'MHRA Brexit No-Deal' submission be shared with members of the Board.

Item 5: International Strategy – update

5.1 Patrick Carey presented an update on the work of the Agency's International Strategy and priorities and opportunities over the remainder of the financial year. This included partnership work-sharing with other countries; the Agency's role in providing chairmanship, secretariat and strategic leadership of the International Coalition of Medicines Regulatory Authorities; our current and future engagement with a spectrum of international organisations, and a new focus on commercialisation opportunities.

5.2 The Chair thanked Mr Carey for his update and sought the views of the Board. These centred on the following areas:

- *International organisations* – In answer to questions from the Board, Mr Mogford clarified the Agency's current engagement with the following international forums for a: (i) International Pharmaceutical Regulators Programme (IPRP), (ii) International Committee on Harmonisation (iii) and International Medical Device Regulators Forum.
- *Commercialisation:* In answer to a question from a member of the Board, Mr Mogford elaborated further on the possibility of commercial opportunities for the Agency through its international strategy.

- Department for International Development (DFID) funding – In answer to a question from the Chair about the possibility of the Agency obtaining funding from DFID, Dr Hudson advised that DFID funding could not be used to fund the Agency directly

Item 6: Operational Transformation

6.1 John Quinn gave a progress report on the Operational Transformation Programme Business Case that was submitted to DHSC following the Board's own consideration on 24 September. Mr Quinn reported that since the Business Case was submitted to DHSC, the Agency had received over one hundred comments and requests for information, all of which have been answered or are being addressed. Mr Quinn reported that the review date for the Business Case by DHCS's Investment Committee will now take place on 23 November 2018.

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

- *Cyber security* – The Chair asked if the Board should have any concerns about the cyber security. Mr Quinn replied that cyber security is formally reported to the Audit and Risk Assurance Committee, which regularly reviews measures to protect the Agency from breaches in IT security. He went on to report that, although the Agency is still subject to cyber security attacks, it is among the world's top 10% of organisations in terms of cyber security protective measures. Mr Quinn went on to report on the cyber / IT security training that staff receive and what the Agency is doing to raise awareness on the importance of IT security across the organisation. Mr Quinn said that more work had still to be done on governance, capacity and security measures, training and general wider awareness among staff.

- *Security classification* – The Board also sought clarification of the security classification of the Agency systems, which Mr Quinn addressed.

- *Costs of OT* – In response to a question about providing the Board with explicit information about the trajectory of the OT project towards its target savings for the Agency, in the context of the progressive expenditure on OT. Mr Quinn responded that he would provide details in a clear format, on a regular basis.

- *Cultural change* – The Board discussed the cultural change that will be required across the organisation to make OT successful in addition to the financial and process changes.

6.3 Mr Quinn concluded by advising that a further update on OT will come to the Board at its meeting on 17 December 2018.

Item 7: Clinical Practice Research DataLink Progress Report

7.1 Dr Janet Valentine presented an update on progress during the third year of the CPRD five-year Strategic Plan. The paper provided an update on key achievements since the CPRD Strategic Plan update to the Agency Board in February 2018, and explained the new pricing model for delivering CPRD observational research data and outlines activities for rest of the current financial year.

7.2 The key highlights were:

- More than 1 in 10 GP practices across the UK now contribute data to CPRD.
- The number of currently registered patients has doubled since February 2018, and quadrupled in one year to reach 10 million, representing 15% UK population coverage.
- The total number of patients in the database has increased by 60% since February 2018 from 22 million to 35 million patient lives.
- The number of patients available for routine linkage has more than doubled from 10.5 million in February to 25 million in October.
- 4 new linked datasets routinely to primary have been added, bring the total to 14 linkages.
- CPRD has celebrated its 30th anniversary, with 20 of the 43 original GP practices still contributing data to CPRD.
- Peer-reviewed publications using CPRD data have surpassed 2000.
- Sponsorship of the type 2 Diabetes real-world pragmatic trial has been successful transferred.
- CPRD has developed a new simplified pricing model for observational research data services.
- CPRD partnered with Devices to win funding from the Regulators' Pioneer Fund to develop a benchmarking primary care dataset to enable testing AI algorithms for regulatory purposes.
- TPP has publicly committed to carry out developments to allow data to flow from TPP practices to CPRD.

7.3 Dr Valentine then updated the Board on the progress on the DECIDE clinical trial, where sponsorship has been transferred from Astra Zeneca (AZ) to the University of Liverpool, and where a tripartite agreement between AZ, the University of Liverpool, and CPRD was signed in July 2018. It was noted that patient recruitment had not been proactively promoted while the transfer of sponsorship was taking place.

7.4 Dr Valentine concluded by explaining the new pricing model for the provision of observational research data. The Board heard that observational research services had until recently been based on access to Vision data only which is only a third of data now available. The costs and models of providing observational research data have not changed for nine years. Dr Valentine went on to outline the features of the proposed pricing model and the benefits it would bring.

7.5 The Chair thanked Dr Valentine for her report and sought the Board's views. These centred on the following:

- *Opening comments*: the Board congratulated Dr Valentine on the tremendous success she and her colleagues have achieved over the past nine months, in particular, CPRD's doubling of the UK population coverage.

- *Patients' status* – The Board asked about the status of 25 million patients on the database who were not "currently registered". Dr Valentine advised that a significant proportion of these patients were registered at practices that had moved from Vision to TPP, which highlighted the importance of being able to receive data from these practices.

- *Population coverage* – The Board asked what level of population coverage would CPRD have once TPP's data becomes accessible? Dr Valentine said

the figure should increase to around 20% of the UK population very quickly but could rise to 30% in the near future.

- *CPRD's visibility* – in response to Board members' comments, the DHSC representative advised that it would help if the excellent work which CPRD carries out was to have a higher visibility, especially in Whitehall. Such messaging should explain what CPRD's work means for patients and wider public health.

- *Pricing*—The Board endorsed CPRD's new pricing model for observational research data noting that the newly introduced pricing tier for SMEs should attract new CPRD customers.

- *NHS Digital* – Dr Hudson advised that the Agency is in discussion with NHS Digital, and that Dr Valentine and himself had recently met with Sarah Wilkinson, CEO of NHS Digital.

Item 8: Business Plan 2018/19 – Quarter 2

8.1 Ms Patience Wilson gave a progress report that summarised the delivery of the 2018/19 Business Plan in Quarter 2 (July – September 2018). This included an integrated monitoring spreadsheet which tracked progress against targets, metrics and further performance-related work. Ms Wilson reported that the Agency is on track to meet most of its objectives and targets. Ms Wilson explained the mitigation actions that are in place to try to ensure the targets can be met.

8.2 Ms Wilson then summarised cross-Agency work to identify areas where the Agency could scale back activity to free up resources for Brexit Day 1 preparedness. Directors had identified cross-cutting areas to scale back (e.g. stopping EU work other than that needed to meet legal obligations). The Q2 business plan report further set out specific objectives and targets which it was proposed the Agency should de-prioritise in the second part of the business year.

8.3 The Chair thanked Ms Wilson for her report and asked the Board for its comments. The Board noted the update on the Business Plan (Quarter 2) and fully endorsed the proposed re-prioritisation of the Agency's work for the remainder of the financial year. Ms Wilson thanked the Board for the endorsement and advised that after DHSC had endorsed the re-prioritisation plan, the Agency would inform the Devolved Administrations in writing and industry stakeholders via a next formal meeting.

Item 9: Chief Executive's Report

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

- *Operation Pangea (OP) XI* – An update was given on INTERPOL's Operation Pangea XI, to which the Agency made a significant contribution. During the week of action (9-16 October 2018) police, customs and health regulatory authorities from 119 countries. OP targeted criminal networks which operated illegal online pharmacies selling falsified and unlicensed medicines and medical devices. Globally, over 10 million doses of medical products were seized of which the UK seized 1,037,960 doses.

- *Cumberlege Review* – A further update was given on work the Agency's response to the Government's Independent Medicines and Medical Devices Safety (IMMDS) Review Group, which was submitted on 31 October 2018.

- *Valproate and the implementation of the Pregnancy Prevention Programme (PPP)* – An update was given on Valproate and the PPP. A letter, which was signed by the Chief Pharmaceutical Officers of England, Northern Ireland, Scotland, and Wales, as well as MHRA's CEO, was sent to UK pharmacists on 22 October. The letter reminded pharmacists of the need to provide a Patient Information Leaflet (PIL) and to dispense original packs of Valproate where possible. Moreover, the Minister has called a meeting of the General Pharmaceutical Council, the General Medical Council, the Care Quality Commission, and MHRA to discuss any further action which may be required.

- *WHO Expert Committee for Biological Standardisation* – An update was given on the WHO Expert Committee on Biological Standardisation meeting, which took place from 30 October – 2 November in Geneva.

- *Communications award* – An update was given on the Agency's success in winning the Best Public Sector Low-Cost Campaign.

9.2 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.

Item 10: Finance and Procurement Report

10.1 Boryana Stambolova presented the monthly Finance and Procurement Report for the first six months of 2018/19. The report included (i) a performance summary of the Agency and its three centres (NIBSC, CPRD and the MHRA Regulator) for the first six months of 2018/19; and the financial forecast for 2018/19 that has been developed in collaboration with the Agency's three centres. Ms Stambolova went on to report that the year-end forecast, inclusive of change costs, is a deficit of £8.4m compared to a budgeted surplus of £12.9m, while the Full Year forecast includes £26.2m change costs. Ms Stambolova stated, and the Board noted, that the forecast deficit for 2018/19 will be funded from reserves.

10.2 Ms Stambolova then asked the Board to consider a prototype of an updated version of the Finance and Procurement Report, which reflected comments which had been shared earlier by Mr Stephen Lightfoot, Dame Valerie Beral and Ms Amanda Calvert. Ms Stambolova confirmed that future reporting of financial performance to the Board would be in the new report format. She then went on to propose that in-year financial performance would be reported to the Board quarterly together with an updated Full year reforecast, with other Finance topics tabled at Board in the intervening months. The Board supported the proposal.

Item 11: Audit and Risk Assurance Committee meetings – feedback

11.1 Stephen Lightfoot, interim Chair of the Audit and Risk Assurance Committee, gave an oral update on the last two ARAC meetings: 26 October and 19 November.

11.2 The following highlights were mentioned:

- *ARAC membership*: Following the departure of two of ARAC's four members from the Board on 31 August 2018, the Committee's will have a full complement of non-executive directors from 1 December 2018. Mr Lightfoot reported that Amanda Calvert, who joined the Board on 1 September became a member of ARAC on 26 October, while Michael Whitehouse, who will join the Board on 1 December, will also become Chair of ARAC with effect of 1 December.

- The main topics of discussion at the last two ARAC meetings were:

  - *External Audit* – The National Audit Office (NAO) has appointed KPMG to carry out the external audit of the Agency's financial accounts, although the NAO will still retain overall accountability for the audit.
  - *Annual Accounts Seminar* – this will be held on 17 June 2019, rather than on 20 May 2019, based on the lessons learned from the last financial year end.
  - *Internal Audit* – an annual assurance mapping exercise will be added to the programme of work to replace an audit on e-cigarettes, which was no longer needed for this year's internal audit programme.
  - *Three internal audit reports* were reviewed at the ARAC meeting in November: (i) Quality Assurance of CPRD's data (substantial assurance), (ii) Financial Forecasting and Planning (moderate assurance), and (iii) Regulatory variations and safety notices (substantial assurance).
  - *Corporate Risk Register* (CRR) – was reviewed by ARAC in October.

Item 12: Corporate Risk Register

12.1 The Board reviewed and noted the Corporate Risk Register.

Item 13: Draft agenda for the Board meeting of 17 December 2018

13.1 The Board noted the draft agenda for the next Board meeting on 17 December.

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

14.1 The minutes of the CET meeting of 18 September and 9 October 2018 were noted.

Item 15: Any Other Business (AOB):

15.1 The following items were raised under AOB.

(a) Non-Executive Directors' sponsor roles

15.2 The Board reviewed and endorsed the sponsor roles for each of the Board's Non-Executive Directors.

Dr Barbara Bannister	• Broader Public Health role / vaccines • Conflict of Interest
Professor Dame Valerie Beral	• Medicines vigilance and observational research
Ms Amanda Calvert	• Corporate and Business Planning
Professor Bruce Campbell	• Medical devices
Mr Stephen Lightfoot	• Operational Transformation (OT) • Board champion for OT and Whistleblowing

Professor Sir Alex Markham	• CPRD • Leads on NHS Annual Appraisals for clinicians employed by MHRA
Ms Anne-Toni Rodgers	• Human Resources / Equality, Diversity and Inclusion. • Communications
Professor David Webb	• Chair of NIBSC Scientific Advisory Committee • Brexit policy • Devolved Administrations
Mr Michael Whitehouse OBE	• Finance and Procurement

(b) Board committees' membership

15.3 The Board reviewed and endorsed the updated the membership of the Board's two committees.

Audit and Risk Assurance Committee

- Mr Michael Whitehouse OBE – Chair - from 1 December 2018
- Mr Stephen Lighthouse – interim chair until 30 November 2018
- Professor Sir Alex Markham
- Ms Amanda Calvert – with effect from 26 October 2018

Remuneration Committee

- Professor David Webb (Chair)
- Professor Bruce Campbell
- Dr Barbara Bannister
- Ms Anne-Toni Rodgers – with effect from 19 November 2018

(c) Chief Executive

15.4 The Chair reported with regret that Dr Ian Hudson will step down as Chief Executive (CEO) in September 2019. Dr Hudson explained his reasons were personal and professional. Dr Hudson went on to say that, having worked for MHRA since 2001 and having been CEO since 2013, it was time for someone new to take on the role as the Agency's CEO. The Chair advised that a recruitment campaign will be led by DHSC and will begin in the New Year.

Date and place of the next meeting: 17 December 2018 – at NIBSC.