Medicines and Healthcare products Regulatory Agency

MINUTES OF THE MEETING

14 November 2016

Present:

The Board

Professor Sir Michael Rawlins	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 - by video link
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
Ms Rachel Bosworth	Director of Communications
Dr Christian Schneider	Director of the National Institute for Biological Sciences and Control (NIBSC)
Dr Siu Ping Lam	Director of Licensing
Mr John Quinn	Director of Information Management Division
Mr John Wilkinson	Director of Devices
Mr Richard Humphreys	Deputy Finance Director
Mr Graham Crossland	Head of Biological Services Division
Redacted - Section 40 of Freedom of Information Act (FOIA) - (personal data)	Head of Corporate Services, NIBSC
Redacted - Section 40 of FOIA (personal data)	Head of Science Strategy
Mr Aidan McIvor	Head of Directorate
Redacted - Section 40 of FOIA (personal data)	Executive Assistant to the Chairman

Legal Services

Mr Paul Wight	Deputy Director, MHRA, Medicines and Information Team, DH Legal Advisers, Government Legal Department

Item 1: Introductions and Announcements

1.1 Apologies were received from Dame Valerie Beral, Non-Executive Director, and Ms Libby Green, Deputy Director (Medicines, Pharmacy and Industry Division), DH

1.2 The Chairman welcomed Jon Fundrey, Chief Operating Officer, and Paul Wright, the Board's legal advisor, to their first meeting of the Board.

1.3 Prior to welcoming everyone to the meeting, including staff observers from NIBSC, the Chairman thanked Dr Schneider, Director of NIBSC, for making the Board so welcome during their visit to NIBSC and for arranging a tour of the facilities before lunch.

Item 2: Declarations of interest

2.1 Two declarations of interest were made: (i) by Professor Bruce Campbell concerning a training course, together with one night's accommodation, that was provided by Medtronic in relation to his professional practice and (ii) by Matthew Campbell-Hill concerning consultancy work with Microsoft.

Item 3: Minutes of the last meeting, 14 October 2016, and matters arising

3.1 The minutes of the Board meeting of 14 October were agreed.

Matters arising

3.2 The Board reviewed the actions list from previous meetings. The Board noted an annex to the actions list. The annex provided details, which were requested by the Board at its meeting on 14 October, about income derived from the European Medicines Agency over the past six months.

DISCUSSION ITEMS

Item 4: EU Referendum - update

4.1 Jonathan Mogford presented an update on Brexit-related work. The update covered the Agency's discussions with industry, particularly through the regulatory and devices sub-groups of the EU/UK Life Science Steering Committee ahead of a key ministerial meeting on 23 November.

4.2 Mr Mogford went on to update the Board on key developments since the last Board meeting (14 October). These included parallel work with the Department of Health (DH) on a follow-up submission to Ministers on medicines regulation; the Accelerated Access Review, which was published on 24 October; the Health Select Committee's inquiry into Brexit, to which the Agency is contributing evidence; the Chief Executive's visit to the U.S. Food and Drug Administration in late October (this followed MHRA's election as chair of the International Coalition of Medicines Regulatory Authorities in October 2016); and the Secretary of State for Health's interest in developing a broader Life Science Strategy by March 2017, to which the Agency would contribute.

4.3 The Board heard that the volume and pace of the Brexit work continues to be high, with increasing interest from DH and Department for Exiting the European Union, who are focusing on the broader UK negotiating strategy.

4.4 The Chairman thanked Mr Mogford for the update and sought the Board's views. The Board was firmly of the view that whatever path the UK opts to take as it leaves the EU, for the MHRA, the option of adopting the 'simple recognition' model was unattractive. The Board agreed that the best options were for the MHRA to continue

to operate in the EU regulatory process, or to operate as a sovereign regulator. {Redacted Section 35 – Government policy in formulation}.

4.5 The Board suggested there would be merit in working up real life examples of what the Agency does, including any risks to public health that could arise from a particular post-Brexit regulatory regime. The Board also advised that the Agency's thinking on how to respond strategically to the challenges and opportunities posed on by Brexit were closely linked in part with the important work on Operational Transformation.

4.6 A further update will come to the Board on 12 December.

Item 5: Horizon scanning

5.1 Dr Christian Schneider presented a paper on the status and a proposed strategic direction of horizon scanning work at the Agency. The Board heard that there is a horizon scanning working group that reports to the CET; this group is developing closer contacts with others in the Agency, such as the Innovation Office, the Advanced Therapies Forum, the Vision Group, and the Research Programme Board.

5.2 Dr Schneider reported that when the CET previously discussed horizon scanning, they had highlighted the need to develop a more active identification and analysis of emerging trends in drug discovery and development, and of medical devices and associated technologies. The CET also recommended that a Horizon Scanning Strategic Lead be recruited to coordinate and develop the Agency's work in this area. The Board heard that recruitment for the post is about to begin.

5.3 Dr Schneider went on to report that the focus of the work will be on developments in science, such as deep sequencing; developments in pharmacology; developments in genomics and emerging pathogens; and regulatory and legislative developments. The scope of the work is very wide and its success will partly depend on the successful candidate being able to develop closer links across the European scientific and regulatory network, so that they can become a point of scientific and regulatory intelligence.

5.4 The Chairman thanked Dr Schneider for his report and then sought the Board's views. These centred on the following areas:

- *Opening comments* – The Board warmly welcomed the paper, which it thought was timely and very informative.

- *Accelerated Access Review (AAR)* – The Board advised that the Agency will need expertise in a number of areas, as they develop. The Board asked that consideration being given on how the horizon-scanning work will feed into the AAR and the work of National Institute for Health and Care Excellence. Dr Schneider replied that the project was still at an early stage and its focus will be on science.

- *Horizon-scanning lead* – The Board highlighted the importance of gathering intelligence, and of becoming aware of the 'unknown knowns'. To help with this, the Board recommended that once the Strategic Lead has settled in, she / he should meet with counterparts from the Medical Research Council, National Institute for Health Research, Medicines Discovery Catapult, and the Wellcome Trust.

- *Artificial Intelligence (A.I.)* – The Board advised that consideration be given to A.I. and cognitive developments, and how these systems could work together.

5.3 The Chairman and the Board thanked Dr Schneider for the update.

Item 6: Transparency around animal research

6.1 Graham Crossland and {redacted under Section 40 (personal data)} presented a paper on the Agency's move towards greater transparency on the use of animals in research. The paper also covered the Agency's approach to internal communications, with improved information now being made available to staff on the Agency's intranet site, alongside presentations to staff. The Board heard that the Agency plans to include more structured information on the external website, with impact stories, such as the meningitis B vaccine and polio vaccine. Additionally, there will be more information on the 3Rs: 'refining, reducing and replacing', the principles underpinning humane animal research work.

6.2 Mr Crossland advised that making more information public will allow the Agency to better control any adverse attention and demonstrate that the Agency has nothing to hide. Mr Crossland went on to report that a risk register has been prepared, although more work needs to be carried out to reduce risks and provide information externally. Mr Crossland concluded by saying that the Agency has a ' very good story to tell' about the contribution NIBSC's research work (with animals) to the safeguarding of public health in the UK and beyond, which would be best told in a measured, step by step approach.

6.3 The Chairman thanked Mr Crossland and {redacted under Section 40 (personal data)} for the report and sought the Board's views. These centred on the following areas:

- *Opening remarks* - The Board welcomed the paper and commended Mr Crossland and his colleagues on the very valuable work they carry out for the wider benefit of public health. The Board thought NIBSC's track record on upholding the principles and practices of '3Rs' was exemplary. The Board also recognised the sensitivities around research facilities, such as NIBSC's, and for the need to promote the excellent work that NIBSC does for public health.

- *Security issues / contingency planning* – One of the Board's members, who has relevant experience, offered to provide advice on contingency planning.

- *Pace of change* – The Board agreed that the pace of change should be incremental, and endorsed the proposed 'step by step' approach as set out in the paper.

- *Cyber security aspects* – The Board highlighted the need to strengthen cyber security protection.

- *Staff security* – The Board welcomed Jon Fundrey's proposal to liaise with the relevant government security agencies about how to mitigate the threats posed to NIBSC and its staff.

- *Positive engagement with the broadcast media* – The Board suggested there were opportunities to explain confidently through, for example, television documentaries, the vital work that NIBSC's animal research facilities play in the protection of public health, e.g. on vaccines. One of the Board members offered to work with Mr Crossland and Ms Hull on this.

- *Concordat* – The Board endorsed signing the animal concordat.

Item 7: Academic relationships

7.1 Dr Christian Schneider presented an paper on progress in building and maintaining academic relationships across the Agency. The paper outlined the history of recent partnerships with academic institutions, the benefits to the Agency of academic partnerships, the benefits to the academic partners, and how academic links should be maintained after they have been set up. The paper also considered how the success of academic relationships should be measured.

7.2 Dr Schneider explained that academic relationships are an agreed and important strategic component of the Agency's current and future work. Academic links have to be maintained after their formal establishment. Currently, the Agency has Memorandums of Understanding with Imperial College London and University College London (UCL); however, continuing engagement is needed to maintain these relationships. The Board heard that colleagues have been seconded between UCL and NIBSC, which has proved successful. Dr Schneider also reported that there are strong links between the Clinical Practice Research DataLink and the London School of Hygiene and Tropical Medicine.

7.3 The paper also considered the possibility of a research retreat for scientists, as well as to how the success of academic relationships could be measured, for example, measuring scientific papers, conferences abstracts and teaching courses. The Board heard that some deliverables are, however, more difficult to measure.

7.4 The Chairman thanked Dr Schneider sought the Board's views; these centred on the following areas:

- *Opening comments* – The Board welcomed the paper, the direction of travel of which was supported. The Board advised that collaborative working with academic partners would undoubtedly benefit patients, whom the Agency is there to serve.

- *Link between horizon scanning and academic ambassador* – The Board suggested that the role of an academic ambassador, as suggested by NIBSC, and of the Strategic Lead for horizon-scanning, could be linked.

- *Table structure* - The Board asked that the table that accompanied the paper include a 'current status' column. Dr Schneider said he would add a new column to the table.

- *Data protection* – The Board advised that the linking of multiple academic databases could pose data protection challenges.

7.4 The Chairman concluded by thanking Dr Schneider for the update and asked for a progress report in 2017.

Action: NIBSC to bring a progress report to the Board in May or June 2017.

Item 8: Operational Transformation - Digital, Data and Technology update

8.1 John Quinn presented an update on the Operational Transformation Programme. As part of the update, Mr Quinn outlined the CET's Innovation Day at the Accenture Innovation Centre on 4 November, where the CET explored how changing political and global developments created uncertainty on direction, and how data and digital disruption might affect the Agency's business landscape and workforce. Mr Quinn then updated the Board on the governance arrangements for the Operation Transformation Programme Board, which is chaired by Jon Fundrey, Chief Operating Officer, as well as on project delivery and next steps. Mr Quinn said that a further report would come to the Board at its meeting on 12 December 2016.

8.2 The Chairman then sought the Board's views. These centred on the following areas:

- *Success criteria* – the Board asked for more information about the costs of the IT programme, details of cashable benefits, savings, and the baseline costs of the IT spend. Mr Quinn advised that project costs would be included in the update in December and that benefits profiles will be updated as part of the annual budget and planning cycle and will be presented to Jon Fundrey and the Operational Transformation Programme Board.

- *External / internal challenge* – The Board welcomed the move to have external challenge; the recent CET Innovation Day was a good example of the value to be derived from such challenge. Mr Quinn said that the programme would also benefit from internal challenge that the CET would provide as part of the internal review. The Board/CET strategic away day on 27 January 2017 would also provide an excellent opportunity for such challenge.

8.3 The Chairman thanked Mr Quinn for his report.

Item 9: Cyber Security

9.1 John Quinn presented an update to the Board on Cyber Security and Information Security. Mr Quinn advised that prior to the last meeting (in October 2016) of the Audit and Risk Assurance Committee (ARAC), the Chair of ARAC had asked for a report on the Agency's response to the 10 Caldicott data security recommendations. Mr Quinn said that the requested report would be ready in time for the ARAC meeting in January 2017. Mr Quinn also reported that ARAC has been provided with the Agency's response to the Communications Electronics Security Group's (CESG) 10 Steps to Cyber Security. The CESG is the information security arm of the Government Communications Headquarters. Mr Quinn went on to outline the Department of Health's cross-cutting cyber security review for itself and its arms-length bodies, including MHRA. The overview went on to cover the Agency's information management and information security policies, the cyber security threats and risks to the Agency, and the measures the Agency currently has in place to manage these risks. Mr Quinn concluded by updating the Board on a current recruitment exercise to find a full-time, permanent IT security officer.

9.2 The Chairman and Board welcomed the update, which they said was very timely and important. For the Chairman, and along with three of the Agency's non-executive

directors, had recently attended a seminar on cyber security, which DH had arranged for the chairs and board members of DH's ALBs.

9.3 The Chairman sought the Board's views; these centred on the following areas:

- *Risk appetite / risk assessment* – In reply to Board members' questions on risk assessment, Mr Quinn outlined work to assess a range of IT security risks to the operation of the Agency's business. Redacted: Section 31 – law enforcement – information likely to be of benefit to criminals. The Board expressed concern about the risks of unauthorised entry to the databases of the Clinical Research DataLink (CPRD) and regulatory systems. Mr Quinn said he was discussing cyber security with CPRD, and would jointly present at the next Audit and Risk Assurance Committee

- *Office security* – The Board asked about security protocols and practices for staff. Mr Quinn assured the Board that all staff receive IT security training, which is mandatory. The protocols also cover IT security 'good practice' for staff when they are away from the office on business, e.g. when travelling. Moreover, a 'clear desk' policy is maintained, which Mr Quinn as Senior Information Responsible Officer (SIRO) actively promotes in the Agency's offices.

- *Recruitment* – While expressing concern that the Agency was still without a permanent, full-time IT security officer, Mr Quinn assured the Board that a recruitment exercise was in motion. The challenge the Agency faced was trying to match the salary packages for similar posts on offer by the private sector.

9.4 The Chairman thanked Mr Quinn for the update and asked that, once work on the risk assessment form / metrics has been developed, a report on this work should come to the Board.

Action: IMD (John Quinn) to update the Board at a suitable time in 2017 on the Agency's IT risk assessment work.

STANDING ITEMS

Item 10: CEO's report

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

- *Accelerated Access Review (AAR)* - An update was given on the AAR, which was published on 24 October 2016. The Government will respond to the consultation later in the year.

- *Cannobidiol* – As part of the update that was given, the Board heard that the Borderline Section has written to a number of companies advising them of the Agency's position concerning the regulatory status of products containing Cannabidiol.

- *Benchmarking of European Medicines Agencies (BEMA)* – An update was given on the audit of MHRA that was carried out from 17-19 October 2016 by a team of assessors from Denmark, Greece and the European Medicines Agency. The initial findings of the assessment of the Agency's systems and processes against a set of indicators were very positive.

- *Regenerative medicines* – An update was given on the House of Commons Science and Technology Committee inquiry into regenerative medicines. Dr Hudson gave evidence at the hearing on 19 October.

- *TGN1412* –An update was given on a television documentary that is being made on the tenth anniversary of the TGN1412 clinical trial, which will feature MHRA officials. The programme is expected to be broadcast between January and March 2017.

- *U.S. visit* – an update was given on the meetings held between Dr Hudson and Jonathan Mogford and the U.S. Food and Drug Administration, and separately with industry representatives in Washington D.C. from 27-28 October 2016.

- *Annual Accountability meeting* – An update was given on the Annual Accountability meeting that was held with Lord Prior, Parliamentary Under Secretary of State for Health on 16 October. The Chairman asked that the published minutes of the Annual Accountability meeting be sent to the Board.

Action: Directorate to send the published minutes to the Board.

Item 11: Finance and Procurement report

11.1 Richard Humphreys presented the finance and procurement report at the half year point. After the first half of the year, in-year performance shows that all three centres Regulator (operating divisions & corporate), CPRD and NIBSC are ahead of their budgeted surplus positions. Overall, after six months, the agency has a retained surplus of £2.0m, £0.3m above budget. The year-end forecast is positive, with assumptions that the regulator performance continues and recognises that the regulator share of the dividend payment has been reduced by £3.5m due to the super-dividend payment. The regulator income is higher than the previous year; this is primarily EMA income.

11.2 The Chairman invited questions from the Board; these centred on the following areas.

- *DECIDE clinical trials* – The Board asked why the income stream was lower than originally expected. The Board heard that the clinical trials were proving challenging, with patients numbers lower than expected. The Agency is working to address these challenges.

- *IT expenditure* – The Board asked that the tables for IT expenditure be made clearer.

- *Schedule 4 (Management accounts)* – expenditure to end September 2016 – The Board asked for clearer budget comparisons, e.g. original costs. Jon Fundrey said he would review the format of the current monthly Financial Report, taking into account Board members' suggestions and comments. Mr Fundrey to produce an updated format for the financial report in early 2017.

Action: Jon Fundrey to revise the format of the financial report in early 2017.

Item 12: Quarter 2 report, Business Plan 2016/17

12.1 Jonathan Mogford presented a progress report for the second quarter (July – September 2016) of the current Business Plan. The report provided an update on the Agency's Quarter 2 position against the targets, activities, metrics and further performance related work.

12.2 The Board heard that the Agency is on track for the majority of targets for Quarter 2. There were two targets – PM2(b) - Medicines licensing - assessment of applications, specifically - % of Decentralised Procedure Reference Member State in 70 days; and PM6 (a) - Standards and control - Biologics standards supply - 93% of all materials supplied within six working days – which are at risk of delay. This is an improvement from Q1 when five targets were missed. Mr Mogford went on to report that of the 14 activities due for completion in Quarter 2, the respective divisions reported 12 of these as having been 'completed' by the end of Quarter 2. Two of these activities were reported as 'risk of delay'.

12.3 In answer from a question from the Board about CPRD, Dr Hudson advised that Dr Janet Valentine, Director of CPRD, would present a strategic progress report to the Board at its meeting on 17 February 2017.

Item 13: Audit and Risk Assurance *Committee* – report of last meeting

13.1 The Board noted the report of the last meeting the Audit and Risk Assurance Committee, which was held on 14 October 2016. Attached to the report were revised terms of reference for ARAC, which had been agreed at the ARCA meeting on 14 October, and which the Board noted. .

Item 14: Minutes of the Corporate Executive Team (CET) of October 2016

14.1 The minutes of the CET meetings of 31 August 2016 were noted.

Item 15: Any Other Business (AOB):

Board lecture programme

15.1 The Chairman enquired if the Board would be interested in re-introducing the programme of Board lectures that ran from 2012-2013. The Board thought that the lecture programme, which had proved popular with staff, in particular, clinical and pharmaceutical assessors, should be reintroduced on a quarterly basis. Subject to a suitable room being available, the first lecture of the new programme of lunchtime talks / lectures by members of the Board would be given on 17 February 2017 by Dr Barbara Bannister.

Board/ CET away day programme, 27 January 2017

15.2 The endorsed the proposed outline programme for the Board / CET away day on 27 January 2017. The away day would consider the following topics: Brexit, Operational Transformation, Stakeholder engagement strategy, and Board/Executive interaction.

Date of next Board meeting: 12 December 2016