FINAL

MHRA Board (in public session)

MINUTES OF THE MEETING
15 December 2017

Present:

The Board

Professor Sir Michael Rawlins GBE Kt	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
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
Mr John Wilkinson OBE	Director of Devices
Dr Samantha Atkinson	Director, Business Transformation
{Redacted Section 40 – personal data}	Senior Regulatory Affairs Manager, Devices
{Redacted Section 40 – personal data}	Head of Science Strategy
Mr Aidan McIvor	Head of Directorate
{Redacted Section 40 – personal data}	Executive Assistant to the Chairman

Legal Services

Mr Paul Wright	Deputy Director, MHRA, Nutrition and EU Team, DH Legal Advisers, Government Legal Department.

Department of Health

Mrs Carly McGurry	Deputy Director, Medicines Regulation & Prescribing

Item 1: Introductions and Announcements

1.1 Apologies were received from Dame Valerie Beral, Non-Executive Director, and Janet Davies and Ian Thomas of the Welsh Assembly Government

1.2 The Chairman welcomed everyone to the meeting.

Item 2: Declarations of interest

2.1 Two declarations were made:

(i) *Professor Bruce Campbell:* Professor Campbell advised that he has been asked by NICE Scientific Advice to join them in providing advice to Roche Diagnostics about a test used in the management of atrial fibrillation. This is as part of a package, for which companies pay NICE Scientific

Advice. Professor Campbell went on to advise that he would receive a consultancy fee from NICE Scientific Advice for this work.

(ii) *Matthew Campbell-Hill*: Mr Campbell-Hill advised that he has become a member of a governance and strategy advisory board for the remote medical services provider 'Push Doctor', which provide medical appointments by video conference, e.g. Skype.

Item 3: Minutes of the public Board meeting of 20 October 2017

3.1 The minutes of the last public Board meeting, which the Board adopted on 20 November, were noted.

DISCUSSION ITEMS

Item 4: Brexit

4.1 Jonathan Mogford gave an update on Brexit-related work to analyse the best options and opportunities available for the safe and effective regulation of medicines and medical devices in the UK. To inform this work, the Agency has also been working closely with a range of stakeholders, such as the industry trade associations, and with European and international counterparts. Two scenarios are being considered: (a) one where the Agency would continue to work in close regulatory partnership with its EU counterparts and (b) a 'no deal' / 'stand alone' scenario. As part of his update, Mr Mogford also reported on the decision by the European Medicines Agency to relocate to Amsterdam, which was announced on 20 November 2017.

4.2 The Chairman thanked Mr Mogford for the update and invited comments from the Board. These centre on the following areas:

- *Medical devices / Notified Bodies* – The Board asked about the position of the UK's five Notified Bodies post-Brexit. Dr Hudson advised that it was too early to give a view as it would depend on the outcome of the UK's negotiations. Dr Hudson added that UK medical device companies and Notified Bodies are making contingency plans for a possible 'no deal' outcome.

4.3 The Chairman then invited questions from the staff and public observers.

- A member of the Alzheimer's Society expressed concern that post-Brexit could entail delay and additional expense to new treatments due to different regulatory frameworks being in place between the UK and the EU. Dr Hudson advised that the Government's preferred option is for the UK to continue to work closely with European partners and to avoid regulatory hurdles.
- A member of the public asked if medicines would be more expensive after Brexit. Dr Hudson advised that medicines pricing falls outside the Agency's remit, which rests with the Department of Health.

Item 5: Chief Executive Officer's report

5.1 Dr Hudson presented highlights from the Chief Executive Officer's (CEO) report. These centred on the following areas:

- *Reclassification* - An update was given on the reclassification of Viagra Connect (sildenafil 50 mg) in November 2017 as a non-prescription Pharmacy (P) Medicine in the UK.

- *Hormone Pregnancy Tests (HPT)* - An update was given on the report of the Expert Working Group on Hormone Pregnancy Tests, which the Commission on Human Medicines considered in November 2017.

- *Gentamicin* - An update was given on concerns about higher levels of histamine in some batches of gentamicin.

- *Breast implants* – An update was given on recent information that has been provided on Breast implant associated Anaplastic large cell lymphoma (ALCL) via the Agency's webpage on ALCL.

- *Working groups* – An update was given on a new strategic working group that has been set up to further cooperation between the Heads of Medicines Agencies (HMA) and the Competent Authorities for Medical Devices networks at a strategic level. The group met following the recent HMA meeting in Estonia.

5.2 The Chairman then invited questions from the Board, which centred on:

- *Internal Communications awards* – The Chairman noted that Communications Division had won two national awards from the Institute of Internal Communications for best storytelling initiative and as public sector internal communications team of the year. The Chairman congratulated the team concerned.

- *SCOPE* – The Board noted the success of the recent Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) Adverse Drug Reaction (ADR) campaign. This involved 19 EU member states, Brazil, New Zealand, as well as various European organisations.

Questions from staff and public observers

5.3. The Chairman then invited questions from the staff and public observers, which centred on:

- Several members of the public shared their own experience of and reflections on their perceptions of the low awareness of the Yellow Card Scheme among healthcare professionals. Dr Hudson explained that the Agency has a programme of engagement with a range of healthcare bodies, including the Royal College of Nursing (RCN) and the Royal College of GPs. Dr Hudson advised that the need to incorporate awareness of the importance of Yellow Card reporting in the curricula for pharmacists and nursing staff is something that is being considered.

- Dr Hudson also mentioned how the Agency has successfully raised awareness of the dangers of buying healthcare products over the internet through television, e.g. Britain's longest-running drama series, Coronation Street.

Item 6: The next Corporate Plan

6.1 Jonathan Mogford presented an update on work to develop the next Corporate Plan. Mr Mogford explained that in view of the large degree of uncertainty that stems from Brexit 2017 was far from an ideal time to prepare a five-year strategic Corporate Plan. That said,

the work on preparing the Corporate Plan is very well advanced, and is closely aligned with that on Operational Transformation. Mr Mogford then outlined the strategic challenges for the Agency that were reflected in the draft Corporate Plan and which will be considered more fully at the Board / CET away day on 29 January.

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

- *Affordability* – The Board advised that a point in time will come when decisions on resources will need to be made, namely what the Agency can afford to do, and what it should stop doing or do less of.

- *Review process* – The Board asked if there were plans to review the Corporate Plan during its life cycle. Mr Mogford advised that this was a feature of the current Corporate Plan and would be applied to the next Corporate Plan. Mr Mogford went on to explain the process for reviewing annual business plans and the mid-life review for the Corporate Plan.

6.3 The Chairman then invited questions from the staff and public observers. These centred on the following areas:

- *Food supplements* – A member of Cure Parkinson's Trust asked if as part of its work on the next Corporate Plan the Agency planned to regulate food supplements. Dr Hudson explained that the Agency does not regulate products that are not medicines or medical devices; food supplements fall within the remit of the Food Standards Agency (FSA). Dr Hudson went on to advise that where something falls on the borderline, the Agency liaises closely with the FSA.

Item 7: Operational Transformation

7.1 Dr Atkinson presented an update on the Operational Transformation (OT) Programme. This included work that has taken place since the Board's consideration of the draft Outline Business Case on 20 November, and further consideration by the Corporate Executive Team at its meeting on 5 December. Dr Atkinson went on to explain that work on OT would be closely aligned with the next Corporate Plan.

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

- *Opening comments* – The Board welcomed the update and commended Dr Atkinson and colleagues across the Agency for their work so far on Operational Transformation for work on external research and customer insight.

- *Costs* – The Board asked that further work be done on estimating the likely costs and benefits associated with the preferred option (Option 4). Dr Atkinson advised that the Board would receive a costed plan for Option 4, which would include elements from Options 3 and 5.

- *Market research* – The Board asked how the market research would be fed into the model. Dr Atkinson advised that the Agency will carry out further consultation to the test a range of ideas, e.g. IT systems and processes, to ensure that the Agency will make the right choices.

7.3 The Chairman then invited questions from the staff and public observers; none was offered.

7.4 In conclusion, the Board endorsed the overall direction of travel set out in the update.

Item 8: Implementation of EU devices legislation – update

8.1 {Redacted Section 40 – personal data} presented an update on progress with implementing of new EU Regulations for medical devices (MDR) and *in vitro* diagnostic devices (IVDR), which entered into force on 25 May 2017. As part of her update, {Redacted Section 40 – personal data} outlined progress made with UK and EU implementation, as well as highlighting the need for additional resources within the Agency to meet the range of additional obligations placed on competent authorities by the Regulations. {Redacted Section 40 – personal data} went on to advise that the Agency will continue to engage with industry and work closely with other Member States to ensure that the MHRA and its stakeholders are prepared for the new Regulations.

8.2 The Chairman thanked {Redacted Section 40 – personal data} for her report and sought the views of the Board, which centred on the following areas:

- *Opening remarks* – While noting the wide range of current and planned activity, the Board thought the report could benefit from specific examples on the key changes that the new Regulations will introduce. {Redacted Section 40 – personal data} acknowledged this point and agreed that specific examples would be cited in future updates to the Board.

- *Resourcing aspects* – The Board noted the need for significant additional resources (at para 11) in the paper and asked if this was reflected in the Operational Transformation Programme and the next Corporate Plan? John Wilkinson advised that the resources aspect of the future work has been factored into the Agency's future planning for the next Corporate Plan.

Questions from staff and public observers

8.3 The Chairman invited questions from the staff and public observers; none was offered.

Item 9: Patient Safety and Vigilance Strategy – update

9.1 {Redacted Section 40 – personal data} presented an update on the three-project work-streams which underpin the Patient Safety and Vigilance Strategy (PSVS): Project Team 1: incident reporting and signal detection, Project Team 2: risk benefit assessment, and Project Team 3 – safety messaging and risk communication. Among the highlights cited in 1 {Redacted Section 40 – personal data} 's report were:

- Plans are progressing well with other key partners for the Improving the Impact of Safety Messages Health Summit on 18 January 2018.
- A report regarding the development of methodologies for device signal generation was considered at a workshop in early September 2017. A plan to prioritise and take forward the recommendations and next steps has been drafted and will be discussed at the next PSVS Steering Group meeting.

- The proposed study protocol in relation to use of CPRD data for devices vigilance had been submitted to the Independent Scientific Advisory Committee (ISAC) in December 2017 and the study should begin early in 2018.
- A strategy document for uses of CPRD in relation to devices vigilance is being further developed and will be brought to the next PSVS Steering Group.
- The joint assessment of paraffin-based topical products and fire risk is in progress and will be used as a case-study/opportunity to learn and build from.

9.2 The Chairman thanked {Redacted Section 40 – personal data} for her report and sought the Board's views. These centred on the following areas:

- *Electronic reporting* – The Board asked what the Agency was doing to encourage greater uptake in hospital reporting of Adverse Drug Reaction (ADR) reports and linking the ability to report through existing GP and hospital systems. {Redacted Section 40 – personal data} advised that this is being considered in conjunction with the Operational Transformation work.

- *Dear Doctor letters* - The Board suggested that these should be sent with a recognisable 'stamp/logo' or be clear that it is from GOV.UK

- *Health Summit* – The Board asked if there was an app and/or website for the Health Summit, and if there are plans to record the summit's discussions. {Redacted Section 40 – personal data} advised that a dedicated weblink had been developed and that the summit would be recorded.

Questions from staff and public observers

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

- A member of public recommended that flat screens in the waiting / public areas of GP surgeries and health centres should be used to promote the use of Yellow Card, and that Yellow Cards should be available for completion at the reception desks in local health centres and GP surgeries. The Chairman thanked the questioner and advised that the Agency would consider her suggestion.

- Another member of the public said that, from her experience, some GPs were reluctant to listen to patients' concerns about possible adverse reactions to medicines. Dr Hudson advised that the Agency is working with a range of healthcare stakeholders, including the Royal College of GPs and the Royal College of Nursing, on this matter. Dr Hudson went on to say that the Agency is very keen to make the reporting of ADRs via Yellow Card as straightforward as possible.

Item 10: Board / Executive interaction - update

10.1 Aidan McIvor presented an update on a range of work that has taken place during 2017 to enhance interaction between the executive and the Board; the update also covered opportunities for Board members to provide advice to the Agency and therein raise the profile of the Board among staff.

10.2 Mr Martin Hindle and Dr Ian Hudson referred to the Board/CET awayday on 29 January, where what improvements could be made to Board/Executive interaction would

be considered. Dr Hudson concluded by saying that the Awayday discussion would be informed by a programme of interviews which would take place over the next three weeks with Mr James Humphreys of the Woodnewton Associates Limited.

10.3 The Chairman thanked Mr McIvor for the update and sought the Board's views, which centred on the following areas:

- *Opening remarks* - While welcoming the update, the Board noted that two areas of Board member sponsorship were missing from the update: Dr Bannister's advice to the Agency on vaccines work and Professor Webb's role on relations with the Devolved Administrations. Mr McIvor said he would update the progress report accordingly.

- *Mentoring* – Professor Webb advised that he would like to participate in the mentoring programme for staff. Mr McIvor said he would inform HR.

Questions from staff and public observers

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

Item 11: Timetable for the draft Annual Report – to note

11.1 Rachel Bosworth presented the draft timetable for the Annual Report 2017-2018, which the Board noted.

Item 12 Board and Corporate Executive Team awayday – draft programme

12.1 Dr Hudson presented the draft programme for the next Board / Corporate Executive Team awayday, which would be held at the Academy of Medical Sciences on 29 January 2018. The Board endorsed the draft programme, but asked that the item on Artificial Intelligence could be taken in the morning (time to be confirmed) so as to allow one of the Board members to attend a Ministerial meeting. The other items for the awayday: Brexit, the Corporate Plan / Operational Transformation, and Board / Executive interaction would remain unchanged.

Action: Aidan McIvor to circulate a final version of the awayday programme in January.

Item 13: Any Other Business (AOB):

13.1 The Chairman and the Board thanked members of the public and staff for attending the meeting.

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

Date of next public meeting: 23 April 2018