FINAL

MHRA Board (in public session) Part 1

MINUTES OF THE MEETING 20 October 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
Dame Valerie Beral	Non-Executive Director
Mr Matthew Campbell-Hill	Non-Executive Director
Professor Bruce Campbell	Non-Executive Director
Mr Stephen Lightfoot	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 Siu Ping Lam	Director of Licensing Division
Dr June Raine CBE	Director of Vigilance and Risk Management of Medicines Division
Ms Vanessa Birchall-Scott	Director of Human Resources
Dr Janet Valentine	Director of Clinical Practice Research DataLink
Dr Samantha Atkinson	Director, Business Transformation
Dr Dan O'Connor	Medical Assessor, Licensing Division
Dr Julian Bonnerjea	Manager, Biological Medicines Unit
Mr Alastair Jeffrey	Group Manager, Enforcement
{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 and Prescribing

Item 1: Introductions and Announcements

1.1 Apologies were received from Sir Alex Markham, Non-Executive Director.

FINAL

1.2 The Chairman welcomed everyone to the meeting, in particular, the staff and public observers. The Chairman also welcomed Mrs Carly McGurry of the Department of Health (DH), who was attending her first Board meeting at MHRA. Mrs McGurry succeeded Ms Libby Green, the previous sponsor representative.

Item 2: Declarations of interest

2.1 None was made.

Item 3: Minutes of the public Board meeting of 24 April 2017

3.1 The minutes of the last public Board meeting, which the Board adopted on 22 May, were noted.

DISCUSSION ITEMS

Item 4: Brexit

4.1 Jonathan Mogford gave an update on Brexit-related work by the Agency. Mr Mogford explained that the Agency has been working closely with Government 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 been working closely with a range of stakeholders, such as the industry trade associations, and with European and international counterparts. Mr Mogford concluded by explaining the Agency's work on preparing for two scenarios: (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.

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

- *Stakeholder engagement* – The Board thanked Mr Mogford for the progress report and asked about the planning for a 'no deal' scenario and, in particular, the Agency's engagement with DH, NICE, NHS, etc. Mr Mogford advised that the Agency is workly very closely with DH, other partners across Government (the Department for Exiting the European Union), the Office of Life Sciences, as well as with other stakeholders. Mr Mogford said that the Agency's approach to scenario planning was 'classic' government policy work. Mrs Carly McGurry (DH) echoed Mr Mogford's comments, adding that DH is also working closely with a wide range of partners.

- *The European Medicines Agency's (EMA) relocation* – In answer to a question about the EMA's relocation, Mr Mogford advised that the decision would be announced at the EU's General Affairs Ministerial Council in November.

- *Legal update* - In answer to a question from the Board, Paul Wright (Legal Services) gave an update on work on Brexit-related legal work, including Statutory Instruments.

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

- A member of the public asked if 'any good could come Brexit', e.g. with medicines coming more quickly to market. Dr Hudson said that Brexit offered a range of opportunities, which the Agency is considering in great detail, e.g. to think afresh about the Agency's risk-based approach.

4.4 A further update will come to the next public Board (on 15 December).

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:

- *Care Quality Commission (CQC)* - An update was given on a Memorandum of Understanding (MoU) that was signed in September 2017 between MHRA and CQC. Dr Hudson explained the new MoU sets a framework to support a joint working relationship.

- *ICMRA* - An update was given on preparatory work for the meeting of the International Coalition of Medicines Regulatory Authorities (ICMRA) in Japan, which would take place during the week beginning 23 October.

- *Human Factors* - An update was given on the guidance that has been published on the human factors' aspect of the design for medical devices, including those for drug-devices combination products.

- *Fake medicines campaign* – An update was given on the new campaign webpage which went live on 12 September 2017.

- *House of Lords Select Committee* – Dr Hudson gave an update on the House of Lords Science and Technology Select Committee's enquiry on Life Sciences and the Industrial Strategy. Dr Hudson appeared before the Select Committee on 16 October.

- *Valproate* – An update was given on Valproate and the risk of neurodevelopmental disorders. As part of the update, Dr June Raine, outlined recent developments and, in particular, progress in the European review and the first public hearing on Valproate, which was held at the European Medicines Agency's (EMA) offices in London on 26 September 2017. Dr Raine explained that the information gained in the public hearing would help inform the ongoing review of the effectiveness of risk minimisation measures that were introduced in 2014. Dr Raine went on to report that, following the recent Backbench debate, the All-Party Parliamentary Group on Epilepsy will meet soon with the Minister.

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

- *International Conference on Pharmacoepidemiology (ICPE) and CPRD group meeting* – The Chairman commended Dr Valentine and her colleagues in CPRD that a total of 70 abstracts using CPRD data were presented at the ICPE conference which was held in Montreal, Canada in August 2017.

- *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 public sector internal communications team of the year. The Chairman congratulated the team concerned.

- *Valproate* – In answer to a question about how CPRD data could help with this work, Dr Valentine and Dr Raine advised that CPRD is working with VRMM, the Royal College of GPs and NICE. The Board went on to note that, for Valproate, warnings about the risks in pregnancy have been present in the licence since the time of authorisation and in Patient Information Leaflets (PILs) since 2001. The Board advised that it was the Agency's role to provide up to date information to support joint decisions between prescribers and patients and not to affect the GP/patient relationship. Dr Raine went on to advise that the Agency is in close liaison with a number of the Royal Colleges.

Questions from staff and public observers

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

- *Valproate* – Deborah Mann, Secretary of the Organisation for Anti-Convulsant Syndrome (OACS), advised that she too had attended the public hearing at the EMA. Ms Mann asked that patient groups continue to be consulted, expressing concern that at the recent EMA Stakeholder meeting the topics of a contraindication in pregnancy and a pregnancy prevention plan had not been discussed despite being on the agenda. Ms Mann stressed that she and her fellow members of OACS are keen to work with the MHRA. Dr Raine welcomed Ms Mann's offer and assured her that patient groups would be kept informed of developments and would be consulted.

- Another member of OCAS, who suffered from epilepsy and whose daughter was seriously ill, shared her own experience of and reflections on her perception of the low awareness of the Yellow Card Scheme among healthcare professionals. The OACS member asked that MHRA do more to raise awareness of the Yellow Card Scheme, especially among healthcare professionals.

- Dr Raine thanked the OACS representatives for their feedback and assured the public and staff observers present, as well as the Board, of the Agency's determination to address this matter. Dr Raine went on explain the measures that the Agency is implementing, e.g. with a new Yellow Card app, to make the reporting system more widely available and user-friendly. Rachel Bosworth, Director of Communications, offered to meet the OACS representatives after the meeting to discuss their engagement with MHRA.

- **Item 6: Operational Transformation and Corporate Plan**

6.1 Dr Atkinson updated the Board on work that has taken place over and since the summer, in particular, with the development of the seven strategic imperatives and the findings which came out of the Market and Customer Insight Report. The Board was also updated on the other information-gathering and discussion / feedback sessions, e.g. Corporate Executive Team (CET) mini away days and the series of interviews with individual members of the Board. Together, this has helped inform the thinking of the

Operational Development Programme Board and the draft business case which the CET will consider on 7 November.

6.2 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, at a time when the Agency is faced with other significant challenges.

- Stephen Lightfoot, Non-Executive Director, commended Dr Atkinson and her colleagues for her work and urged those Board members who have not had an opportunity to discuss the work of Operational Transformation with Mr Fundrey and Dr Atkinson, to do so.

- *Next Corporate Plan* – In answer to a question from the Board about the alignment of the work on Operational Transformation and the next Coprporate Plan, Mr Mogford said that current discussions and engagement exercises were proving very helpful and would help ensure that the Agency's emerging new Corporate Plan would meet the challenges ahead.

- *Artifical Intelligence (A.I.)* – One Board member asked if consideration could be given to the regulation of robotics; the Chairman advised that A.I. would be considered again by the Board in the New Year.

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

Item 7: Early Access to Medicines Scheme (EAMS) and Innovation Office

7.1 Dr Siu Ping Lam introduced Dr Dan O'Connor and Dr Julian Bonnerjea, who presented a progress report on the Early Access to Medicines Scheme (EAMS) and the Innovation Office. The EAMS was launched in April 2014 following a public consultation and the recommendations of a working group on regulation and innovation in healthcare. Dr O'Connor reported that, to date, 42 Promising Innovative Medicine (PIM) designations have been awarded out of 52 applications, and 16 EAMS have then received scientific opinions. These scientific opinions support the prescriber and patient in making a decision to use a medicine before the licence is formally approved. There are three separate EAMS protocols: for patients, for healthcare professionals and regarding pharmacovigilance, and a document for NHS medical directors.

7.2 Dr Bonnerjea then presented a progress report on the work of the Innovation Office, which was set up four years ago. Its aim was to help developers of innovative medicines and medical devices, and to address regulatory questions from companies and individuals. While the MHRA's scientific advice procedure was already in existence, the Innovation Office was set up to answer regulatory queries in an informal setting. Dr Bonnerjea reported that, to date, over 500 queries have been received. Dr Bonnerjea also reported that MHRA has joined with a number of other UK regulators, including the Human Tissue Authority and Human Fertilisation and Embryology Authority, to answer questions related to advanced therapy medicinal products or

'regenerative medicines'. This approach was developed further to include DEFRA and HSE in the area of genetically engineered medicines.

7.3 The Chairman thanked Dr O'Connor and Dr Bonnerjea for their report and sought the views of the Board, which centred on the following areas:

- *Opening remarks* – The Board warmly welcomed the report and commended Dr O'Connor, Dr Bonnerjea and their colleagues on their achievements. Professor Webb, Non-Executive Director, said that his clinical colleagues in Edinburgh highly rate the work of MHRA's Innovation Office.

- *Practical aspects* – The Board asked how the Innovation Office operates in practice. Dr Bonnerjea explained that the main users of the Innovation Office are academics and Small to Medium-Sized Enterprises, and that the Office has been operating as a 'virtual' office, although a member of staff has recently been recruited to support its work. The Office has not replaced any existing advice channels, e.g. the Board heard that the Clinical Trials Advice Line continues to be heavily subscribed and receives on average 3,000 telephone calls and emails each year.

- *Working with NICE* – The Board asked if the Innovation Office worked with NICE. Dr Bonnerjea advised that the Agency does indeed work with NICE, e.g. on joint scientific advice procedures, of which there have been eight.

- *EAMS - feedback to applicants* – The Board asked if the feedback is offered to unsuccessful applicants and if there were common themes to why certain applications were unsuccessful? Dr O'Connor advised that feedback is provided and an analysis of all applications is carried out.

- *NHS network* – Martin Hindle, Deputy Chairman of MHRA, said he was keen to see greater collaboration with health academic centres and networks, and offered to assist the Agency in this regard. Dr Bonnerjea welcomed this offer, about which he said he would follow-up with Mr Hindle after the meeting.

Questions from staff and public observers

7.4 The Board then invited questions from the staff and public observers. A member of the Alzheimer's Society asked about the 're-purposing' of existing medicines to treat conditions, such as Alzheimer's Disease. Dr O'Connor explained the Agency's approach to this matter and also advised that the European Commission is looking at 're-purposing' through the STAMP group.

7.5 The Chairman concluded by thanking Dr O'Connor and Dr Bonnerjea for their reports, which he commended.

Action: Dr Bonnerjea to follow-up with Martin Hindle about exploring opportunities for scientific cooperation between MHRA and academic networks.

Item 8: Operation Pangea

FINAL

8.1 Mr Alastair Jeffrey presented an update on Operation Pangea X, which was a coordinated week of action in October 2017 that targeted the illicit sale of medical products via the internet. This year marks the tenth such annual week of action.

8.2 Operation Pangea X, as with earlier such operations, was coordinated by Interpol, and during the course of the past decade has evolved into one of Interpol's largest global operations. Mr Jeffrey's report covered the results of the operation from a UK and global perspective; in addition, an update was given on other collaborative work which the Agency's Enforcement Group has been involved with, such as Operation Arca (with the UK's National Crime Agency and the Home Office's Border Force) and Operation Lascar (with the Border Force and the U.S. Food and Drug Administration).

8.3 Mr Jeffrey also referred to Operation Daniel, which spanned a number of years, and concluded in 2016. This particular operation concluded with the conviction of twelve individuals at the Central Criminal Court in London '(the Old Bailey'), six of whom were sentenced to twenty-five years imprisonment collectively.

8.4 During the course of Operation Pangea X, which took place in October, 715,000 packages were inspected, with 470,000 seized. This led to 25m illicit falsified medicines(with a value of £38 million) being seized. Medical devices were also seized, including dental devices, surgical equipment and condoms. One hundred and twenty-three countries participated in Operation Pangea X, including countries, such as the Democratic Republic of Congo (DRC), that had previously not been involved. In DRC, 650kgs of illicit anti-malarial pills were confiscated. In the UK, 1.3m units of medicine were seized, valued at £4m, varying from lifestyle to lifesaving types of drugs, including for erectile dysfunction, narcolepsy, and breast cancer. The primary sources were India, China (including Hong Kong) and Singapore. During the week of action twenty-three investigations were raised and five search warrants were conducted. Of the 3584 websites that were taken down, over 3,400 were closed by the MHRA

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

- *Opening comments* – The Board welcomed the report and congratulated Mr Jeffrey and his colleagues on their work, which they said was making an important contribution to the protection of public health in the UK and beyond.

- *Scale of the problem* – While strongly welcoming the closure of 3,400 websites by MHRA, the Board asked if such work was being offset by criminals setting up new websites. Mr Jeffrey advised that this is an issue: however, the strategy for disrupting websites includes removing the domain name, the host and most importantly the payment facility which prevents the criminal from making a financial gain.To do that, the Agency and Interpol are working with the banking sector. The Board went on to ask if the Agency is working with major internet providers, such as Google. Mr Jeffrey replied that Interpol and partners, such as MHRA, are doing that.

- *Funding* – In answer to questions from the Board about how the Pangea operations are financed, Mr Jeffrey explained the funding arrangements, e.g. there is funding from Interpol for a further four years' work.

- *Dark web* – The Board asked if criminal websites can be removed from the 'dark web'. Mr Jeffrey explained that this is an area that more appropriately falls within the remit of the civil police and specialist agencies, such as the National Crime Agency.

Questions from staff and public observers

8.6 The Chairman then invited questions from members of the public and staff. One member of the public asked if counterfeit medicines were sold in the UK. Mr Jeffrey advised that since 2009 no falsified medicines have been found in the legitimate supply chain at pharmacy level. Mr Jeffrey went on to say that if you obtain medicines through the legitimate supply chain, you have should not have any concerns, but if one buys medicines or medical devices from an unregulated internet site, you face many risks.

8.7 The Chairman concluded by thanking Mr Jeffrey for his report; a further update will come to the Board in late 2018.

Item 9: Equality and Diversity Report

9.1 Ms Vanessa Birchall-Scott presented the annual report on Equality and Diversity. The report covered the work of the Agency's Equality and Diversity Group, a summary of key progress to date, an update on Equality Staff Data, and a report on Gender Pay Gap. The Board heard that because of the transition to the new Oracle Fusion system the report didn't contain all the data that was intended for this year's Equality and Diversity report. The Board heard that once Oracle Fusion is fully operational, it will be able to provide a fuller range of data and statistical analysis.

9.2 The Chairman thanked Ms Birchall-Scott for her report and sought the Board's views. These centred on the following areas:

- *Gender Pay Gap* – The Board considered the gender pay gap statistics and noted that for ordinary pay, male employees earn 10% more than their female colleagues, as an average figure. As a top line result, this was clearly of concern, however further information was necessary to understand what was behind the figures. Dr Hudson and Ms Birchall-Scott said that they too were very surprised by the 10% figure; they went on to say that further analyses were necessary to understand the reasons, indeed anaylyes presented by grade partially explianed this figure and it was quite possible this was a legacy issue, which will diminish over time. Ms Birchall-Scott advised that further work had to be done to analyse the statistics, which can then be refined and expanded, before definitive conclusions could be reached as to the underlying cause, and hence what action may need to be taken.

- *Disability* – The Board noted that, although 20% of the UK's population live with some form of disability, only 3% of the Agency's staff are registered disabled. Ms Birchall-Scott advised that the Agency did try to set up a cross-agency group for disabled staff, but there was no uptake. Ms Birchall-Scott went on to say that work is in place to set up a new "all minorities" diversity sub-group. Matthew CampbellHill, Non-Executive Director, who has attended one of the Agency's Equality and Diversity Group meetings and has provided advice to the Agency on

disability access, said that he would be glad to assist HR in this matter, e.g. speak at meetings or training events. Ms Birchall-Scott welcomed the offer, about which HR would follow-up.

- *Equality and Diversity and the next Corporate Plan (2018-2023)* – A number of Board members asked whether the next Corporate Plan should include goals for gender and Black Minority Ethnic (BME), and not wait for legacy issues to work their way out of the system. Dr Hudson advised that the Agency would consider this, but that any targets would have to be meaningful and deliverable, and the additional analyses planned on salaries would be necessary to help inform actionplans.

- *Bonuses* – The Board noted that the average size of bonuses for male members of staff was higher than for their female counterparts. Dr Hudson said this is something that the Agency was looking at. Ms Birchall-Scott concluded by advising that special bonuses are analysed on a quarterly basis.

- *Follow-up work* – The Chairman and the Board thanked Ms Birchall-Scott for the report and asked that further work be done to provide data on the breakdown by gender and BME of bonus awards, pay, etc. The Board asked that an update on gender pay be brought back to a future Board meeting.

Questions from staff and public observers

9.3 The Chairman invited questions from members of the public and staff. One member of the public asked if the Agency had arrangements to support staff who had carer responsibilities. Ms Birchall-Scott said that this was a very good and relevant question, as the UK's demographics meant that increasing numbers of people of working age now had caring responsibilities for elderly parents as well as for children. Ms BirchallScott explained that the Agency had very supportive and flexible working arrangements for its staff, e.g. part-time working, flexible hours at work and homeworking, which proved beneficial to staff with childcare responsibilities, as well as for those who care for older parents.

Action: HR to bring an update to the Board – date to be confirmed.

Item 10: Any Other Business (AOB):

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

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

Date of next public meeting: 15 December 2017