MHRA Board (in public session) Part 1

MINUTES OF THE MEETING

24 April 2017

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
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
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	Director of Devices
Dr Samantha Atkinson	Deputy Director of Inspection, Enforcement and Standards Division
Mr Mick Foy	Group Manager, Vigilance and Risk Management of Medicines Division
Andy Gregory	Deputy Director – EU and International
Redacted – Section 40 of Freedom of Information Act (FOIA) – personal data	Sub-Standard, Spurious, Falsely labelled, Falsified Counterfeit medical products (SSFFC) project – Communications Lead.
Mr Aidan McIvor	Head of Directorate
Redacted – Section 40 of FOIA – 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.

Devolved Administrations

Dr Mark Timoney	Chief Pharmaceutical Officer of Northern Ireland
Mr Ian Thomas	Welsh Assembly Government

Item 1: Introductions and Announcements

1.1 Apologies were received from Mr Gerald Heddell, Director of Inspections, Enforcement and Standards Division, and Mrs Janet Davies of the Welsh Assembly Government.

1.2 The Chairman welcomed everyone to the meeting, in particular, the staff and public observers. The Chairman advised that a group photograph of the Board, which would appear in the Annual Report 2016/17, would be taken at lunchtime in the 5th floor reception area.

Item 2: Declarations of interest

2.1 None was made.

Item 3: Minutes of the public Board meeting of 12 December 2016

3.1 The minutes of the last public Board meeting, which the Board adopted on 17 February, were noted.

DISCUSSION ITEMS

Item 4: Brexit and MHRA

4.1 Jonathan Mogford gave an update on Brexit-related work by the Agency, especially since the triggering of Article of 50 on 29 March. Mr Mogford prefaced his update by mentioning the restrictions (Purdah) which are now in force since the General Election was called.

4.2 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.

4.3 The Chairman thanked Mr Mogford for the update and invited comments from the Board. The Board commended the Agency for the work that has been done so far, in particular, the engagement with stakeholders, including industry. The Board also recommended that the Agency develop its links with other international regulators.

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

- A member of the public asked if drug names would change following the UK's departure from the EU. Dr Hudson replied that he thought such a change was highly unlikely.

4.5 The Chairman concluded by thanking Mr Mogford for the update.

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:

- *Algorithms Data and Regulation meeting* – an update was given on a workshop on Algorithms Data and Regulation on 23 March, which was held at the British Academy on 23 March.

- *Drug Information Association (DIA) Euro-meeting in Glasgow* – an update was given on the DIA meeting in Glasgow (April), which Dr Hudson co-chaired, and which a number of other officials from the Agency presented at.

- *Partnership* – An update was given on new partnership agreements work with relevant bodies across Government, the health sector and industry. In particular, an update was given on a meeting of the Cross-UK Group on 5 April; the next meeting of the group will take place in Northern Ireland.

- *Japan* – An update was given on a visit by Dr Hudson and Mark Birse, Group Manager of the Inspectorate, to Japan in April. During the visit, Dr Hudson and Mr Birse had meetings with the Pharmaceutical and Medical Devices Agency of Japan, and the Japanese Ministry of Health, Labour and Welfare. They also attended the 9th Asian Regulatory Conference, which Dr Hudson addressed.

- *China's National Institute for Food and Drug Control (NIFDC)* – An update was given on a visit by Dr Christian Schneider, Director of the National Institute for Biological Standards and Control, to the NIFDC, during which Dr Schneider signed a revenue share agreement with the NIFDC.

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

- *Vaginal meshes and tapes* – In answer to questions from the Board and a staff observer, an update was given on vaginal meshes. John Wilkinson, Director of Devices, advised that the Agency is working closely with the Royal College of Surgeons and specialist clinical societies to ensure that there is a very high level of awareness of this issue and about what the Agency is doing. Professor Campbell mentioned a recent academic study involving 100,000 patients, the report of which he would share with Mr Wilkinson.

- *E-cigarettes* – The Board noted the volume of e-cigarette notifications that had been submitted (over 36,000) and asked if the Agency was sufficiently resourced to manage such a high volume. Dr Hudson said that, while the volume of notifications was indeed high, the Agency was able to manage the current volume.

- *International relations* – A member of the public asked if reports of adverse drug reaction in the UK are shared with other countries. The meeting heard that the World Health Organisation's Coordination Centre in Uppsala, Sweden coordinates ADR reports worldwide, to which MHRA contributes data.

- Yellow Card Scheme – a member of the public asked if more was being done to improve the use of the Yellow Card Scheme. Mr Foy, Group Manager, explained the Agency's approach to Yellow Card,

5.3. The Chairman then concluded by thanking Dr Hudson for his report.

Item 6: Vigilance projects

6.1 Mick Foy presented an update on a range of projects in the pharmacovigilance area. These included the Patient Safety and Vigilance Strategy (PSVS), which aims to better align the way vigilance is conducted on medicines and devices; PSVS is a key strategic

priority for the agency. Alongside this, the Board heard that Vigilance and Risk Management of Medicines Division are engaged in a broader set of activities to expand Yellow Card reporting from healthcare professionals and the public, and how the Agency reviews signals using new tools to visualize data.

6.2 Mr Foy's report also covered the following projects: (i) Adverse Drug Reaction reporting, (ii) Harms from overdose (Poisons data); (iii) New Psychoactive Substances; (iv) Integrating case reports with electronic health records; (v) Access for the public to information; (vi) Strengthening Collaborations to Operate Pharmacovigilance in Europe; and (vii) Innovative Medicines Initiative project. Mr Foy concluded by explaining that the overarching aim of all of the activities covered in the update is to protect public health through a strong pharmacovigilance system that is embedded within the NHS and has open access to all.

6.3 The Chairman thanked Mr Foy for his report and invited comments from the Board, which centred on the following:

- *WEB-RADR* – The Board queried whether the Innovative Medicines Initiative, WEB RADR, which will conclude in September 2017, has been a success. Mr Foy said that some areas of this project have proved useful, particularly in the area of informing policy on the reporting of adverse drug reactions from social media. Although the final recommendations have still to be to be determined, it is likely to advise that ADRs should not be reported from this data source as there was a risk of large scale reporting system of poor quality data.

- *Apps* - The Chairman asked if it would not be better to have two pharmacovigilance apps: one for information, with the other as a reporting tool. Mr Foy advised that, overall, it was better to have a single, multi-functioning app. One Board member advised that apps can be significant consumers of memory and battery power on mobile devices, such as i-phones. The Board advised that there was scope to make apps better and more user-friendly.

- *Hospital reporting* – The Board queried about hospital reporting, which Mr Foy said was something the Agency is working on with one IT provider.

- *New Psychoactive substances* – The Board welcomed the initiative on new psychoactive substances

6.4. The Board then invited questions from the staff and public observers. A member of the public asked several questions about the user-friendliness and efficiency of the Yellow Card Scheme, with particular reference to the antibiotic, Fluoroquinolones. Mr Foy addressed the questions and agreed to arrange a meeting with the questioner at a later date.

6.5 The Chairman concluded by thanking Mr Foy for his report.

Item 7: Sub-Standard, Spurious, Falsely labelled, Falsified and Counterfeit medical products (SSFFC) project with the World Health Organisation

7.1 (Name redacted – Section 40 of FOIA – personal data) presented a report on the communications and campaigns work stream of a World Health Organisation (WHO) initiative, which the Agency is leading on. The work stream is one of eight by the WHO that will address, reduce and ultimately eliminate SSFFC medical products.

(Name redacted – Section 40 of FOIA – personal data) explained that the focus of the work is to learn, share and develop global communications thinking and campaign development amongst all 194 member countries of the WHO, with a particular emphasis on the use of SSFFC medical products.

7.2 The report covered last year's programme of work, the Agency's engagement with the WHO Member State Mechanism, and key stakeholders, together with a summary of the communications work stream that will be developed further in 2017 and 2018. The Agency is supporting the project through a dedicated Programme Manager on a three-year fixed appointment, which coincides with the duration of the WHO project.

7.3 The Chairman thanked (Name redacted – Section 40 of FOIA – personal data) for the report and sought the views of the Board, which centred on the following areas:

- *Opening remarks* – The Board welcomed the report and congratulated (Name redacted – Section 40 of FOIA – personal data on what had been achieved so far. The Board said that it was very supportive of the project.

- *International partners* – In answer to a question about whether the work was too UK and EU-centred, (Name redacted – Section 40 of FOIA – personal data) explained that the project's partners were global. (Name redacted – Section 40 of FOIA – personal data) went on to say that he had spoken at a WHO conference in South Africa in 2016 about SSFFCs, while Gerald Heddell, Director of Inspection, Enforcement and Standards Division, was currently at a WHO workshop in Thailand, where he would speak about SSFFCs. .

- *Publication* – The Board asked if the report of the 2016 Work Programme would be published. (Name redacted – Section 40 of FOIA – personal data) advised that the Agency's role in this work would be published and, as recommended by the Board, in a user-friendly format.

- *Funding* – In answer to questions about funding, (Name redacted – Section 40 of FOIA – personal data) advised that he has been looking at other sources of funding for this work, the governance arrangements for which would be addressed and handled appropriately.

- *Raising awareness / useful links* – The Chairman advised that the SSFFC project would be of interest to the British Pharmacological Society (BPS). Professor David Webb, President of the BPS, concurred with the Chairman, and suggested that he meet with (Name redacted – Section 40 of FOIA – personal data) to discuss next steps, to which (Name redacted – Section 40 of FOIA – personal data) readily agreed.

7.4 The Board then invited questions from the staff and public observers; none was offered. The Chairman concluded by commending (Name redacted – Section 40 of FOIA – personal data) for his work so far on the project.

Item 8: International Strategy

8.1 Dr Samantha Atkinson presented a paper on the Agency's proposed International Strategy, which set out the scope of the Agency's current and planned international work. The paper focused in particular on work to strengthen the security of the supply

chains from key global source countries, as well as on work with other leading regulators (in both pharmaceuticals and medical devices).

8.2 Dr Atkinson advised that the Agency's International Strategy reflected a truly, joined-up approach across the organisation. Dr Atkinson went on to say that the strategy was one that is ambitious but has a clear purpose and objectives, and which makes effective use of resources.

8.3 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 report, which they commended.

- *Outputs v activities* – The Board asked whether the range of activities outlined in the strategy translate into public health benefits. Dr Atkinson assured the Board that they would, but more work was needed to make this clearer.

- *Wider international links* – The Chairman advised that he, along with Dr Hudson, would meet with Baroness Scotland, Secretary-General of the (British) Commonwealth of Nations, which has a membership of fifty-two states across the globe. The Chairman added that Government is keen that the Agency should develop closer links with the Commonwealth.

- *China* – In answer to questions about the Agency's links with China, Dr Hudson advised that he is planning to visit China later this year, and has met with visiting Chinese delegations (to the UK), as well as with Chinese counterparts at other international fora. The Agency's ties with China are close.

- *Coordination* – The Board asked who would have lead responsibility for coordinating the Agency's international work. Dr Hudson advised that lead responsibility would rest with the Corporate Executive Team, but day to day activities would be progressed by the cross-Agency group.

- *Legal framework* – The Board recommended that Dr Atkinson and her colleagues should liaise with the Agency's legal advisors to consider a range of legal aspects of the International Strategy. Dr Atkinson welcomed and agreed with the suggestion.

8.4 The Chairman then invited questions from members of the public and staff. One member of the public asked that, as part of its international work, the Agency should learn more about adverse drug reaction (ADRs) in other countries. The Chairman advised that the World Health Organisation's Coordination Centre in Uppsala, Sweden coordinates international ADR reporting.

Item 9: Audit and Risk Assurance Committee Agency Risk Appetite Statement

9.1 Jon Fundrey presented the Agency's Risk Appetite Statement, which sets out how the Agency balances risk and opportunity in pursuit of achieving its objectives of promoting and protecting public health. Mr Fundrey explained that the statement forms a key element of the Agency's governance and reporting framework and is set by the Corporate Executive Team and approved by the Audit and Risk Assurance Committee on behalf of the Board. Mr Fundrey went on to outline component parts of the Risk Appetite Statement.

9.2 The Chairman thanked Mr Fundrey for his report and invited questions from members of the public and staff. The Board asked that specific reference to cyber security should be mentioned in the statement, which Mr Fundrey agreed would be done.

9.3 There were no questions from staff or public observers about the report

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: 20 October 2017