MHRA Board (in public session) Part 1

MINUTES OF THE MEETING

12 September 2016

Present:

The Board

Professor Sir Michael Rawlins	Chairman of MHRA
Mr Martin Hindle	Deputy Chairman
Dr Ian Hudson	Chief Executive
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

Others in attendance

MHRA executive and supporting officials

Mr Jonathan Mogford	Director of Policy
Ms Rachel Bosworth	Director of Communications
Ms Vanessa Birchall-Scott	Director of Human Resources
Mr Andy Gregory	Deputy Director / Head of EU, International and Strategy, Policy Division
Mrs Jan MacDonald	Group Manager, Vigilance and Risk Management of Medicines (VRMM)
Mr Mick Foy	Group Manager, VRMM
Mr Richard Humphreys	Deputy Finance Director
Dr Christian Schneider	Director of the National Institute for Biological Standards and Control (NIBSC)
Ms Patience Wilson	Deputy Director / Head of Corporate Strategy, Accountability and Partnership, Policy Division
Mrs Louise Loughlin	Head of Science Strategy
Mr Aidan McIvor	Head of Directorate
Ms Jude Thompson	Executive Assistant to the Chairman

Department of Health (DH) and Legal Services

Ms Libby Green	Deputy Director Clinical and Cost Effectiveness, Medicines and Pharmacy Directorate, DH.
Ms Anne Paskin	Senior Lawyer, MHRA, Nutrition and EU Team, DH Legal Advisers, Government Legal Department.

Devolved Administrations

Wales: Mrs Janet Davies, Acting Deputy Director of Healthcare Quality Division.

Item 1: Introductions and Announcements

1.1 Apologies were received from Professor David Webb, Non-Executive Director, and Dr Sara Davies of the Scottish Executive.

1.2 The Chairman welcomed everyone to the meeting, in particular, the staff and public observers and then made the following announcements:

Chief Operating Officer

- Mr Jon Fundrey, currently Financial Controller at the Department for Work and Pensions, has been appointed to succeed Mr Peter Commins as MHRA's Chief Operating Officer. Mr Commins retired from the Agency on 9 September. Mr Fundrey's start date with MHRA had still to be confirmed.

- The Chairman asked that the minutes record the Board's deep gratitude to Mr Commins for his exemplary service to the Board and the MHRA, and his many achievements during his ten year tenure as Chief Operating Officer.

Senior legal adviser and DH sponsor representative

The Chairman went on to ask that the minutes record the Board's gratitude to Mark Wilson, formerly the Agency's senior legal advisor, and to Claire Armstrong of the Department of Health's sponsor team, for their past services to the Board. The meeting heard that Mr Wilson had moved on promotion to HMRC and Mrs Armstrong had moved to a new position within DH. Mrs Armstrong's successor, Ms Libby Green, was welcomed to the meeting. The Chairman concluded by advising that Mr Wilson's successor would be announced in due course.

Item 2: Declarations of interest

2.1 Declarations of interest were made by two Non-Executive Directors:

- Professor Bruce Campbell – is providing advice to a medical device company, as part of similar work with National Institute for Health and Care Excellence (NICE) Scientific Advice.

- Matthew Campbell-Hill – is working for MMPathIC (Manchester Molecule Pathology Innovation) as an external consultant providing advice on strategic planning and public engagement.

Item 3: Minutes of the public Board meeting of 11 April

3.1 The minutes of the last public Board meeting were agreed.

DISCUSSION ITEMS

Item 4: EU Referendum and MHRA

4.1 Dr Hudson and Jonathan Mogford gave an oral update on the work the Agency has been doing following the outcome of the EU referendum on 24 June 2016. The Board heard that much work is going on across government to determine what Brexit could mean for each department of state and its arm's length bodies. In the case of MHRA, the

Agency is 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. While negotiations continue, the UK remains a full and active member of the EU, with all the rights and obligations of EU membership firmly in place. The Board heard that the Agency has been in discussion with a range of stakeholders, such as the industry trade associations, and with European and international counterparts. In the shorter term, work is being done within the Agency on a number of scenarios for regulation outside the current EU arrangements.

4.2 Dr Hudson concluded by reaffirming that day to day business of the Agency continues; moreover, Agency's priority continues to be to protect and promote public health.

4.3 The Chairman thanked Dr Hudson and 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. Martin Hindle, Deputy Chairman, mentioned a note of thanks that the Bio-Industry Association had sent on about their appreciation for MHRA's input into discussions over the summer at a serious of workshops and discussions with industry stakeholders. In answer to questions from the Board about what reassurance the Agency has given international counterparts, Dr Hudson mentioned that he has had many discussions with counterparts from other European and international regulators.

4.4 The Board commented on the Agency's many strengths, which can be exploited to the full in a post-Brexit environment. It was noted that the Board would consider further the Agency's initial thinking on its strategic response to Brexit in the afternoon session of the Board.

4.5. The Board then invited questions from the staff and public observers.

- Aisling Burnand of the Association of Medical Research Charities (AMRC) said she would share AMRC's position on Brexit with MHRA. Ms Burnand went on to say that AMRC's priority is that, whatever happens following Brexit should not be to the detriment of patients.

4.6 The Chairman concluded by thanking Dr Hudson and Mr Mogford for the update.

Item 5: Chief Executive Officer's report

5.1 Dr Hudson presented the Chief Executive Officer's (CEO) report for July and August 2016. These centred on the following areas:

- *DECIDE* – an update was given on a key milestone for the Agency with the enrolment of the first patient into the Astra Zeneca (AZ) sponsored clinical trial, DECIDE. This will provide the first data on clinical effectiveness of an approved Type 2 Diabetes medicine. The novelty of the DECIDE trial is the use of electronic health records within the Clinical Practice Research DataLink.

- *E-cigarette notification scheme* – an update was given on the progress of this regulatory scheme

- *Northwick Park documentary* – an update was given on a BBC television documentary that is being made about the 10th anniversary of the TGN1412 clinical trial at Norwich Park NHS Hospital. The documentary will be aired in January 2017.

- *Falsified medicines and medical devices campaign* – an update was given on the falsified medicines and medical devices campaign that was launched in August 2016. As part of that campaign, the Agency worked with the makers of the television series Coronation Street on the development of a storyline that involves a character taking unlicensed slimming pills the episode in question was broadcast in late August and reached an audience of seven million viewers.

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

- The Board congratulated Communications Division on the success of using a popular television series to raise awareness of the dangers of buying unlicensed slimming pills. The Board thought this was an excellent way of raising awareness of important public health messages to a large segment of the national population. The Board recommended that the Agency should do more of the same – to work with the makers of popular television and radio programmes in helping to develop similar storylines.

- *National Data Guardian Review* – The Board congratulated the Agency on the excellent work it has done with the National Data Guardian Review (Caldicott 3), which was published in July 2016.

- *Guidance on Apps as medical devices* – The Board noted the reference in the CEO's report on the recently updated guidance on apps, and commented more widely on work the apps the NHS are introducing, as well as on work which NICE and the National Information Board are doing in this area.

5.3. The Board then invited questions from the staff and public observers.

- None was asked.

5.4 The Chairman concluded by thanking Dr Hudson for his report.

Item 6: The Strategic direction for Patient Information

6.1 Jan MacDonald presented a paper on the current position of statutory medicines information in the UK, along with an update on recent research. The Board heard that statutory medicines information is the public face of the marketing authorisation and is an essential part of risk minimisation to ensure medicines can be used safely and effectively. Research sponsored by the MHRA and data published by the European Commission point to the need for quality improvements in this area. The paper set out the following proposals:

I. The development of a UK strategy for the optimisation of medicines information at all stages of the product lifecycle aligning with the Agency Communications Strategy
II. Enable a state-of-art online offering and resource tool (to complement the written document) supported by the wider Agency Digital Transformation Strategy
III. To develop consistent information sets for generic medicines to improve patient confidence in MHRA-authorised information
IV. Working with healthcare and professional bodies as well as communications experts, explore the scenarios in which high risk products, including medical devices, can be provided with timely,

bespoke information which empowers patients to make informed decisions about medical interventions.

6.2 Mrs Macdonald advised that the proposals were aspirational and would need to be tested through engagement with stakeholders, followed by the development of business cases.

6.3 The Chairman thanked Mrs MacDonald for her paper, which he welcomed. Sir Michael then sought the views of the Board, which centred on the following areas:

- *Yellow Card* – The Board suggested that there was an opportunity to link this work to the Yellow Card, as way of getting information back.

- *Welsh Language Act* – Mrs Davies of the Welsh Assembly Government highlighted similar work that is being done in Wales, as well as the requirements of the Welsh Language Act. Mrs Davies said that she would gladly work with MHRA colleagues on this.

- *Community / hospital pharmacists* - The Board asked about liaison to date with the Royal Pharmaceutical Society and pharmacists. Mrs MacDonald advised that the Agency had worked closely with community pharmacists, less so with hospital pharmacists but considered pharmacists would be the gatekeepers of information for patients in future.

- *Kite-mark* – The Board suggested that there should a logo for websites that present information well.

- *Apps* – The Board advised that the use of apps allows patients to access a range of important information on their i-phones, including their patient records. A number of Board members, however, cautioned there is still a segment of the UK population who do not have access to the internet. This Board mentioned the work by Baroness Martha Lane Fox to close that gap.

6.4 The Board then invited questions from the staff and public observers.

- *Charities* - Kate Dunn of MIND recommended that the Agency should talk to relevant charities that provide drugs information, as there is much helpful experience and information that could be obtained from such dialogue.

- *Patients' needs* – Shirley Nurock of the Alzheimer's Society commented on the challenges faced by people living with Alzheimer's, and why community pharmacists could be a source of help in accessing drugs information.

6.5 Sir Michael concluded by thanking Mrs MacDonald for her paper and in endorsing the direction of travel set out in the paper, including its proposals.

Item 7: Yellow Card collaboration with the National Poisons Information Service

7.1 Mick Foy presented a paper on an opportunity for collaboration with the National Poisons Information Service (NPIS) for the collection of data on harms associated with overdose of medicinal products. The Board heard that reports of overdose have always been received via the Yellow Card Scheme (YCS), although in relatively low numbers. Mr Foy advised that it is important for the MHRA to do more to capture reports going into

other systems in the Health Service, e.g. the National Reporting and Learning Systems (NRLS). Mr Foy went on to explain the work that VRMM has done with Professor Simon Thomas to source reports from the NPIS, and, separately, outlined the practical difficulties associated with managing an influx of overdose reports.

7.2 The Board were asked to consider a proposed pilot project which would allow the Agency to review UK Poisons Information Database (UKPID) data outside of the usual signal environment. This would help find out how best to utilise the data in the Agency's pharmacovigilance system and to develop clear guidance and costs for moving forward with a fully integrated system.

7.3 The Board welcomed the paper and endorsed the proposed pilot, recognising that it would be important to evaluate whether there was any potential negative impact on signal detection.

7.4 The Chairman then invited questions from the staff and public observers. Shirley Nurock of the Alzheimer's Society mentioned the risk of poisoning as a result of polypharmacy.

7.5 The Chairman concluded the discussion by again welcoming the paper and endorsing the proposed pilot project, about which an update would return to the Board during the spring of 2017.

Item 8: Working with the Devolved Administrations

8.1 Patience Wilson presented a paper on working with the Devolved Administrations (DAs). The Board heard that the relationship between MHRA and the DAs has improved since the formation of the cross-UK group with quarterly meetings. There is a good strategic and operational level of communication; medicines colleagues hold quarterly teleconferences with their counterparts in the DAs and this is also being set up for Devices. However, there is room for improvement. The Board heard that the next meeting of the cross-UK group is on 26 October.

8.2 Janet Davies of the Welsh Assembly Government endorsed the thrust of the paper, and advised that the Welsh colleagues are keen to work closely with the MHRA, and to make the two-way flow of information and collaboration work better. Ms Davies cautioned that the DAs should not be seen as a collective unit, as each was different. In particular, Ms Davies highlighted the Welsh Language Act. Ms Wilson welcomed Ms Davies' comments and said that MHRA officials looked forward to working more closely with colleagues in the Welsh Assembly Government, as well as in the DAs in Scotland and Northern Ireland.

8.3 The Chairman and Board thanked Ms Wilson for the update and Ms Davies for her comments. There were no questions on this item from the staff and public observers.

Item 9: People Strategy 2014-2019 (refreshed 2016)

9.1 Vanessa Birchall-Scott presented the refreshed People Strategy which has been designed to provide medium to long term direction of travel for the people-related aspects of the Agency and to complement the recently refreshed Corporate Plan. Ms Birchall-Scott went on to outline the structure of the strategy document, which has been designed to reflect the potential employee's lifecycle and, in particular, drew the Board's attention to an infographic video, which was launched alongside the Strategy in July 2016 and has been well received by staff.

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

- *Opening comments* – The Board welcomed the refreshed strategy, which they thought was comprehensive and informative. In answer to a Board member's question about the issue of bullying and discrimination, Ms Birchall-Scott advised that this was being addressed through the Agency's response to the People (staff) Survey.

- *Operational transformation - The* Board asked about the connection between the refreshed People Strategy and the work of Operational Transformation Programme. Ms Birchall-Scott advised that there were clear links, e.g. recruitment, training, workforce planning, which, as a member of the Operational Transformation Programme Board, she would ensure are taken forward.

- *Secondments* – The Board asked about the possibility of having short-term secondments from the NHS or industry. The Board heard that the Agency has had clinical seconders from the NHS, e.g. under the Chief Medical Officer's Clinical Advisors' scheme; but these were for a minimum of a year, and not three months, the latter of which would be too short to prove worthwhile. As for secondments from industry, these would prove problematical because of the inevitable issues of conflict of interest.

- *Engaging medical colleges and universities* – Dr Hudson advised that over the past year he and the Chairman have met with nearly all of the Presidents of the Royal Medical Colleges, a process of engagement which has proved very successful. Dr Hudson advised there was scope to carry out similar programme of meetings with relevant parts of the university sector. Dr Hudson went on to advise that the Agency does operate training days for trainee clinical pharmacologists, which have proved successful. Martin Hindle, Deputy Chairman, offered to facilitate such engagement between the Agency and the East Midlands Academic Health Science Network at Nottingham and Leicester Universities, of which he is chair. The offer was gratefully accepted.

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

- *Apprenticeships* – Lynda Wight of The Organisation of Professions in Regulatory Affairs (TOPRA) expressed an interest in the Agency's work in this area, about which she is keen to talk to MHRA colleagues. One of the staff observers praised the Agency's apprenticeship scheme and raised the issue of training for non-scientific staff, which he thought was very important. Ms Birchall-Scott advised that the Agency plans to have 28 apprenticeships in place by the end of 2016 and training provision is intended to encompass all types of roles.

- *MHRA's profile at UK's universities* – A member of staff advised that from his perspective many students studying for science degrees at university were unaware of, or knew little about, the work of the MHRA. This was acknowledged as a continuing concern.

- *Career planning and development* – In answer to questions about training resources available to staff, the meeting heard that a range of training information

is available on the Agency's intranet site, including the Civil Service Learning (CSL) website. Ms Birchall-Scott advised that if CSL cannot provide the required training, the Agency's HR learning and development team will arrange bespoke training.

9.4 The Chairman concluded the discussion by thanking Ms Birchall-Scott for her report.

Operational agenda

Item 10: Finance and Procurement report

10.1 Richard Humphreys outlined the highlights for the first four months of the financial year 2016/17. The Board heard that the Agency has an operating surplus of £6.4m which is £1.9m above the budgeted surplus for the first four months of the financial year. The £100m super dividend was paid on the 20 July 2016 with the normal dividend to be paid in September 2016; as shown in the statement of financial position which showed the reduction in the cash balance to £127m on 31st July from £216m at the end of June. Mr Humphreys went on to report that the Income Risk Assessment had been reviewed following the outcome of the referendum and that the income streams most likely to be impacted by Brexit have been identified.

10.2 The Board thanked Mr Humphreys for the report, and expressed satisfaction with the scale of the retained surplus (£4.3m against the budgeted £2.6 m for the first four months of the financial year). In answer to a question from the Board about the NIBSC developing its income from standards work, Dr Schneider advised that there is a working group at NIBSC that is already considering this.

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

Item 11: Quarterly report – Business Plan monitoring report (Quarter 1, 2016/17)

11.1 Patience Wilson presented a progress report on the first quarter of the current financial year of the Agency's Business Plan. The report set out the Quarter 1 position against the commitments made in the 2016-17 business plan for: (i) targets, (ii) activities, (iii) metrics, (iv) further performance related work. Ms Wilson explained that the metric relating to the British Pharmacopoeia Chemical Reference Substances sales was not present in the report, as it is commercially sensitive information. Ms Wilson concluded by explaining that the quarterly reports are reviewed and examined rigorously by the Corporate Executive team.

11.2 The Board noted that the majority of targets have been met in Q1, while five targets have not been met; Ms Wilson explained the reasons for the missed targets. Additionally, in answer to a question from the Board, Ms Wilson and Dr Schneider clarified the wording of the commentary at Annex A about the turnover of staff in the standards supply area.

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

Item 12: Any Other Business (AOB):

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

Date of next public meeting: 12 December 2016