MHRA Agency Board

MINUTES OF THE MEETING

18 June 2014

Present:

The Agency Board

Sir Gordon Duff	Chairman of MHRA
Professor Barry Furr	Non-Executive Director
Mr Martin Hindle	Non-Executive Director
Professor Vincent Lawton	Non-Executive Director
Sir Alex Markham	Non-Executive Director
Ms Deborah Oakley	Non-Executive Director
Professor David Webb	Non-Executive Director
Mr John Williams	Non-Executive Director

Others in attendance

MHRA executive and supporting officials

Dr Ian Hudson	Chief Executive
Mr Peter Commins	Chief Operating Officer and Finance Director
Ms Rachel Bosworth	Director of Communications
Dr Stephen Inglis	Director of National Institute of Biological Standards and Control – from item 8
Name redacted: Section 40 of FOI Act (personal data)	Deputising for the Director of Policy
Mr John Wilkinson	Director of Devices
Name redacted: Section 40	Team leader, Business Planning & Corporate Management, Policy Division – for item 7
Name redacted: Section 40	Policy Manager, Policy Division – for item 7
Name redacted: Section 40	Head of Science Strategy
Mr Aidan McIvor	Secretary to the Agency Board
Name redacted: Section 40	Executive Assistant to the Chairman

Department of Health and Legal Services

Mr Mark Wilson	Legal Services
Name redacted: Section 40	DH sponsor representative

Item 1: Apologies

1.1 Apologies were received from Dame Valerie Beral, Non-Executive Director, Mr Jonathan Mogford, Director of Policy, and Mr Dorian Kennedy of the Department of Health.

Item 2: Announcements

2.1 After welcoming everyone to the meeting, the Chairman made the following announcements.

- *Board lecture programme:* The Chairman congratulated Professor Webb for giving the inaugural Board lecture earlier in the day. Professor Webb's lecture was on "The UK Prescribing Safety Assessment: underpinning patient safety"

- *Dr Dorian Kennedy* - The Chairman reported that because of changes in the sponsorship arrangements at the Department of Health, Dr Kennedy will no longer attend MHRA board meetings. Name redacted: Section 40 of the Sponsor Branch at DH would continue to represent DH at Agency Board meetings until Dr Kennedy's successor was named. The Chairman asked that the minutes record the Board's gratitude to Dr Kennedy for his services to MHRA in recent years.

Item 3: Conflicts of interest

3.1 The Chairman asked for any interests to be declared at the beginning of the meeting; none were declared.

Item 4: Minutes of the Agency Board meeting of 16 April 2014

4.1 The draft minutes of the Board meeting of 16 April 2014 were adopted.

Item 5: Minutes of the Agency Board / CET away day of 21 May 2014

5.1 As the draft minutes were only circulated for comment on 11 June, it was agreed to defer consideration of the minutes until the next Board meeting.

DISCUSSION PAPERS (in the order in which the items were taken)

Item 6: The Agency's draft response to the Stephenson Review

6.1 Mr John Wilkinson was welcomed to the meeting. He then presented the draft agency response to the review led by Professor Terence Stephenson on MHRA access to expert clinical advice and engagement with the clinical community.

6.2 The Board was informed that the independent review panel members had been given the opportunity to comment on the draft response and that these had been incorporated. The Committee on Safety of Devices (CSD) had also been invited to comment and the response received was tabled for the Board's information.

6.3 The report gave a good framework for going forward and the draft agency response provided a detailed response to the twelve recommendations in the report, all of which were accepted.

6.4 The following comments were made in discussions:

- The importance of appointing the right chair of the new Devices Expert Advisory Committee was emphasised.

- It was discussed whether there are sufficient resources to take forward the associated work and whether the capacity within the clinical team was sufficient. In response, Mr Wilkinson indicated that there had already been a review of processes and areas that need to be invested in for the future, and that resources would be kept closely under review in relation to the expectations on the team. Furthermore the balance of expertise within the devices team needed to be considered. There is Ministerial and DH support

to establish fee-based funding, but this will take time to deliver and industry and other stakeholders are being kept closely involved with these developments. Other European countries are also looking into this funding avenue.

- It will be important to involve the medical directors of NHS organisations and specialist organisations and societies through which some activities could hopefully be devolved. The work force required to take forward this work would need to be agreed.

- Prioritisation and timing of the activities within the restrained environment should be established carefully.

6.5 John Wilkinson informed the Board that a cross-agency group had been formed to take forward prioritisation and implementation of the various strands of work. A progress update would be published one year after publication of the Stephenson report.

6.6 The draft response would be updated to reflect the Board's comments before being submitted to Ministers and published on the website.

Item 7: Progress against Business Targets, Quarter 3

7.1 (Name redacted: Section 40) presented the quarterly monitoring report on the Business Plan for the third quarter of the year 2013/14. The Board heard that the Agency has met 18 of its 23 targets, while five targets have not been met this year and were given a red rating.Three of these were PM1a, PM1b and PM1d, which concern the validation of Type 1A, Type IB/II variations and granting of change of ownership applications. The Board heard that performance on these is expected to improve in quarter 4. As for the remaining red-rated targets, PM6b, the Board heard that this had only been narrowly missed. The meeting heard that the overall performance on batch release being issued with ten days for blood products was just over 99%. (Name redacted: Section 40) went to report that the other part of this target (certificates being issues with 60 days for vaccines) stood at 100%. As for PM7a, which sets a target for the number of NIBSC papers and scientific review articles, the Board heard that 72 articles had been authored up to quarter three.

7.2 The Chairman commended (name redacted: Section 40) for presenting a very clear report. One Board member asked about arrangements for planning annual leave for staff for operational units, such as the Information Processing Unit (where some targets had not been met). Clarification was also sought about whether the business targets were appropriately demanding and how the emerging IT Strategy could assist with business planning. In response, Dr Hudson assured the Board that the Agency's business targets were set as stringent and somewhat stretching targets. Dr Hudson advised that the IT Strategy would be considered by the Corporate Executive Team on 1 July. As to long-term leave planning for staff, Dr Hudson advised that this is something that all parts of MHRA do, so as to ensure minimum disruption to the delivery of business during the year, especially over Christmas and New Year.

Item 8: MHRA / NIBSC integration – one year on

8.1 Dr Stephen Inglis presented a progress report on the National Institute for Biological Standards and Control's (NIBSC) integration following its merger with MHRA in April 2013. The Board heard that two overarching projects had guided the integration: Project 1: 'Realising the benefits' and Project 2: 'Creating the new organisation'. Dr Inglis' report

focussed mainly on the work of Project 1, which as the Board heard was more strategic and long-term in its focus. Its aim was to ensure that the new organisation identifies and takes full advantage of the opportunities that the merger would bring.

8.2 Dr Inglis reported that since NIBSC joined MHRA in April 2013, much progress has been achieved. A strong culture of integrated, collaborative working developed prior to and since the merger, and this has been fostered by a number of initiatives, for example, the VISION Network for Vaccines. Other examples of work cited were the cross-agency groups on Biosimilars and the Advanced Therapies Forum.

8.3 The Chairman and Board congratulated Dr Inglis on the report and the success of the merger, which had benefited from strong strategic leadership. Dr Inglis said that the success of the MHRA/ NIBSC union was due to the hard work and commitment of staff in both organisations and the excellent organisational fit that arose from the merger.

8.4 The Board commended Dr Inglis on what NIBSC had achieved within current resource constraints and asked if NIBSC could apply for grants from research councils and philanthropic bodies, such as the Wellcome Trust. Dr Inglis advised that this was possible in specific cases, although for general 'response mode' research funding NIBSC was ineligible as it already received government funding. The Board asked about NIBSC's work with the British Pharmacopeia, and requested that a paper be brought to the Board about the NIBSC/ British Pharmacopeia joint strategy. Dr Inglis said he would liaise with Directorate about when to bring such a paper to the Board. On a point of detail, Dr Inglis reported that on the previous day, 17 June, Health Minister Earl Howe signed a Memorandum of Understanding (MoU) on the Agency's behalf with the China Food and Drug Administration. Part of the MoU covered the British Pharmacopeia's relations with its counterpart in China and this could bring benefits, for example, to the joint project between NIBSC and the British Pharmacopeia on DNA-based analysis of herbal medicines. In conclusion, Dr Inglis asked that the minutes record his thanks to Louise Loughlin of Directorate who prepared the report and supported the Project 1 team.

STANDING ITEMS

Item 9: CEO's report for May and June 2014

9.1 Dr Hudson's updates centred on the following areas:

- *Adaptive licensing* – Following the European Medicines Agency's (EMA) launch of an adaptive licensing pilot project in March 2014, Earl Howe chaired a workshop with UK industry trade associations in April. This was followed by a series of cross-government meetings and other initiatives to promote the scheme in May. The EMA has so far received at least 20 expressions of interest, of which MHRA staff have been asked to assess four as to their suitability.

- *Earlier Access to Medicines Scheme* – The Secretary of State announced the new scheme on 14 March, which was then launched on 7 April. The scheme aims to address unmet need on an unlicensed or off-label basis for patients with life-threatening or seriously debilitating conditions without adequate treatment options. The Agency has been actively engaging with industry and others, in many fora, promoting awareness of the scheme, including the recent visit by the Chairman to the USA where he met with 26 companies.

- *Vaginal mesh implants* A teleconference was held with Alex Neil, Scottish Health Secretary, about concerns raised in Scotland about the safety of vaginal mesh and tape implants for pelvic organ prolapse and stress urinary incontinence. The agency has been reviewing the safety of such products since 2011, working closely with the clinical community, and commissioning an external review of the evidence, and remains of the view that the benefits outweigh the risks, provided the devices are used in appropriate circumstances by suitably trained surgeons. NHS England is in the process of establishing a working group (including the Scottish Government, and MHRA) to consider the use of such products. Subsequently, the Scottish Government has decided to ask trusts to stop using such products until a report is issued by a new independent group to be set up by the Scottish Government. The Chairman and Dr Neil McGuire, Clinical Director Devices, were due to visit the Scottish Health Secretary on 25 June.

- *Bacillus cereus incident* – The agency has been working closely with Public Health England to investigate the tragic outbreak of Bacillus cereus septicaemia associated with the use of total parenteral nutrition among newborn babies in neonatal intensive care units at hospitals in the South East of England. Sadly, two of the babies have died; however, the second death does not appear to be related to the Bacillus cereus infection. An investigation, involving MHRA inspectors, is continuing as to how the parenteral nutrition supplies became contaminated.

- *Product issues* – up-dates were given on: (i) the use of sodium valproate in pregnancy and the risk of neurodevelopmental delay, (ii) Alteplase (Actilyse) balance of risks and benefits, and (iii) Statins and overall benefit risk.

- *Nicotine Containing Products (NCPs)* – The revised Tobacco Products Directive was published on 29 April 2014 and Member States have until May 2016 to transpose it into national law. DH is in the lead on how the Directive will be transposed. A cross-agency working group has been set up to consider developments in relation to the wider DH policy on smoking cessation.

- *Yellow Card 50th anniversary* – the MHRA is contributing to the DH work on dementia and has attended various meetings. These included the inaugural meeting of the international steering group on dementia and the research funders meeting.

- *Re-designation audit of a UK Notified Body* – MHRA assessors, along with representatives from the European Commission, and other EU Members States participated in the first re-designation joint assessment of a UK Notified Body. This took place from 28 April to 2 May.

- *Paediatric Pharmacovigilance* – Agency officials attended the Chief Medical Officer's Children and Young People's Health Outcomes Board meeting on 13 May. This followed written feedback that was provided on the MHRA's Paediatric Medicines Expert Advisory Group.

- *Operation Pangea VII* – MHRA enforcement staff participated in Operation Pangea VII from 11-21 May 2014. This was a global operation against the illegal internet trade in medicines. As a result, approximately £18.6 million

worth of illegal medicines were seized, with 237 people being arrested worldwide, and with over 10,000 websites being closed down.

Item 10: Operations and Finance report

10.1 Mr Peter Commins gave the highlights for the first month of the financial year 2014/15. They were:

- MHRA (Regulator) income: for April 2014 was at £8.3m.
- NIBSC operational income: for April 2014 was at £1.4m.
- CPRD income for April 2014 was at £0.5m.
- Operating income for the Agency for April 2014 was £11.9m, which is £0.1m above budget.
- Total operating costs for April 2014 were £9.8m, which is £1.2m below budget.
- The Agency's bank balance at the end of April 2014 was £166.9m.
- Capital expenditure was £1.0m out of the full year budget of £11.0m.
- Total Product Licensing deferred revenue at the end of April 2014 was £14.6m.
- The number of full-time equivalents at the end of February 2014 was 1,216, with 96 short-term contracts and 30 non-payroll employees.

10.2 Peter Commins reported that short-listing for the post of Director of Human Resources had taken place earlier in the morning. Peter Commins thanked Professor Furr for taking part in the short-listing as well as Professor Lawton for agreeing to sit on the interview panel. Peter Commins went on to report that Ms Belinda Quinn has been appointed as interim Director of the Clinical Practice Research DataLink. The Board heard that arrangements are in place to recruit a permanent successor to Dr John Parkinson, who stood down as Director of CPRD on 8 June 2014.

10.3 The Chairman thanked Peter Commins for the update. The Chairman went on to say that it was very important for the Agency that a high calibre candidate is selected to lead Human Resources Division.

Item 11: Minutes of the Corporate Executive Team (CET) meetings of 1 April and 13 May 2014

11.1 The minutes of the CET meetings of 1 April and 13 May 2014 were noted.

Item 12: Non-Executive Directors' (NEDs) updates

12.1 Mr John Williams reported that he had visited the Chemistry Department of the University of Cambridge.

Item 13: Any Other Business (AOB)

13.1 The Chairman reported that he had spent the previous week in Boston and New York attending a series of meetings, which UK Trade and Investment had arranged. The visit programme, which included meetings with 26 companies, centred on the Earlier Access to Medicines Scheme, Adaptive Licensing, and the work of CPRD.

Date of next Board meeting: 16 July 2014.

Aidan McIvor
Head of Directorate