FINAL

MHRA Board

MINUTES OF THE MEETING
16 October 2015

Present:

The Board

Professor Sir Michael Rawlins	Chairman of MHRA
Dr Ian Hudson	Chief Executive
Dr Barbara Bannister MBE	Non-Executive Director
Professor Dame Valerie Beral	Non- Executive Director
Professor Bruce Campbell	Non-Executive Director
Mr Matthew Campbell-Hill	Non-Executive Director
Mr Peter Commins	Chief Operating Officer and Finance Director
Mr Martin Hindle	Non-Executive Director
Mr Stephen Lightfoot	Non-Executive Director
Professor Sir Alex Markham	Non-Executive Director
Professor David Webb	Non-Executive Director

Others in attendance

MHRA executive and supporting officials

Ms Vanessa Birchall-Scott	Director of Human Resources
Ms Rachel Bosworth	Director of Communications
Mr Jonathan Mogford	Director of Policy
[Redacted Section 40 – personal data]	Policy Division –item 4
[Redacted Section 40 – personal data]	Deputising for the Director of Inspection, Enforcement
[Redacted Section 40 – personal data]	Standards Division – item 5
[Redacted Section 40 – personal data]	Head of Intelligence, Enforcement Group – item 5
[Redacted Section 40 – personal data]	Head of Directorate
[Redacted Section 40 – personal data]	Executive Assistant to the Chairman

Legal Services and Department of Health (DH)

Mr Mark Wilson	Legal Services
[Redacted Section 40 – personal data]	Sponsorship Branch

Item 1: Introductions and Announcements

1 Apologies were received from Ms Deborah Oakley, Non-Executive Director (NED), and Mrs Claire Armstrong, Deputy Director (Medicines, Pharmacy and Industry Division).

1.1 Sir Michael gave an update on his recent official visit to India where he signed the first Memorandum of Understanding between the Agency and the Central Drugs Standards Control Organisation of India.

1.2 Sir Michael advised that after lunch, there were would a number of induction sessions for the new Board members.

Item 2: Declarations of interest

2.1 None was declared.

Item 3: Minutes of the last meeting, 18 September 2015, and matters arising

3.1 The draft minutes of the Board meeting of 18 September 2015 were agreed.

Matters arising

3.2 The Board then reviewed the actions list from previous meetings.

DISCUSSION ITEMS

Item 4: Review of the Corporate Strategy

4.1 [*Name redacted*] of Policy Division outlined recent work to review and refresh if necessary the Corporate Plan, 2013-2018, which is now at a mid-life point. The paper that [*Name redacted*] presented reflected recent discussions by the Corporate Executive Team (CET), including an all-day session in September, which resulted in a 'SWOT' analysis and identification of key areas of strategic focus. [Name redacted] explained the nine key areas of strategic focus. They were: Supporting innovation; Leading patient safety and surveillance systems; Confidence in global supply chain to ensure safe supply of medicines/devices; People strategy; Customer service strategy; Digital strategy; Partnership in the health and care system; Optimising the Unique Selling Points (USP) of our three centres; and Business development.

4.2 *[Name redacted]* advised that the CET had concluded that the Corporate Plan continues to provide a coherent strategic focus for the Agency's annual business planning, staff engagement and external communication; moreover, its relevance to the Agency's operating environment and the organisation's capabilities are broadly valid. But as the Corporate Plan was at its mid-life stage, the Agency has to consider what has changed since it was published in 2013 and what changes need to be made to ensure that it continues to be 'fit for purpose'.

4.3 The Chairman and Board welcomed the paper, which they thought was most timely. For the Board's four new non-executive directors, who joined the Board in September 2015, the discussion presented an opportunity for an additional fresh analysis, which *[Name redacted]* said the organisation welcomed. The Board considered the SWOT analysis and agreed that the regulatory, political, financial and technological environment in which the Agency operates had developed since 2013. Accordingly, the Agency's Corporate Plan had to evolve and be recalibrated to reflect these changes. The Board thought that, in addition to responding to the aforementioned changes, the Agency should also be seeking new ways to influence its stakeholders, in order to deliver its strategic goals, as well as to help shape the regulatory environment in which it operates. As part of this wider discussion, the Board considered a range of developments, such as the NHS's move away from keeping paper records, global supply issues, developments in innovation, as well as scope for the Agency to consider whether there were business development opportunities. There was also a need to define the unique selling point (USP) of the Agency as a whole and its three centres: MHRA Regulatory, Clinical Practice Research DataLink (CPRD) and the National Institute for Biological Standards and Control (NIBSC).

4.4 The Board agreed that the Corporate Plan remains a strong document and broadly still provides an appropriate strategic framework for the organisation. Furthermore, it endorsed the direction of travel set out in the paper for the ongoing review at the mid-life point of the Agency's Corporate Strategy, which will feature as the centre-piece of the Board/CET strategic away day on 15 January 2016.

4.5 Having been informed that *[Name redacted*] would leave the Agency on 23 October to take up a new post at the Department of Health, Sir Michael and the Board asked that the minutes record their gratitude to Mr Markson for his work on the Corporate Plan in this and preceding years.

Item 5: Strategic Threat Assessment for Enforcement

5.1 Mark Jackson, Head of Intelligence, Inspection, Enforcement and Standards Division, presented the Agency's Strategic Threat Assessment (STA) for Enforcement. The report set out prioritised risk areas, key trends and recommendations proposed for each risk area. Each of the risks was identified through internal consultation within MHRA and with key partners. At the end of the process, each of the risks was subject to assessment and the professional judgement of those developing this crucial piece of work. The Board heard that the model used to produce the report is in line with those used by other UK law enforcement agencies. The Board heard that the next phase will be to develop a control strategy, which prioritises the identified enforcement work into an action plan. [Redacted Section 35 Formulation of Government policy]

Item 6: Open Board meetings

6.1 Aidan McIvor, Head of Directorate, presented an options paper on the opening of Board meetings to members of the public. Mr McIvor outlined the current approach by other arms-length bodies within the Department of Health family and beyond to allowing members of the public to attend Board meetings as observers. The paper considered a range of practical matters, including advance registration, accommodation, and agenda management, e.g. having Part 1(open) and Part 2 (closed) agendas, the latter of which other public bodies and NHS Foundation Trust Hospitals use. Finally, the paper set out a number of options and sought the Board's views.

6.2 Having considered the options set out in the paper, the Board decided to pilot two 'open' Board meetings in 2016. The first meeting would take place in February 2016, which would be evaluated afterwards; a second open board meeting would provisionally take place in May 2016.

Action: Aidan McIvor to lead work on planning for the Board's first open meeting.

Item 7: Equality and Diversity Report

7.1 Ms Vanessa Birchall-Scott, Director of Human Resources, presented a paper that outlined progress on equality and diversity within the Agency; the report also set out a range of assurances in terms of the current position and future plans. Ms Birchall-Scott explained that the approach to equality and diversity was intended to be holistic going forward, as it included the Agency's roles as employer, service provider and site occupier. The Board heard that key leadership roles and a pan-agency Equality and Diversity Group have been established; an outline plan for action has been prepared.

7.2 Ms Birchall-Scott went on to say that the Agency has legal and moral obligations in respect of equality and diversity. These responsibilities are taken very seriously by the Agency, and there is recognition that in all aspects of the Agency's role there is a need to

ensure that it is both meeting these obligations and moving beyond them towards an overarching aim of such issues being part of normal business and no longer requiring a heightened level of focus.

7.3 In terms of services, the Board noted the two examples of services and related equality and diversity issues provided in the report. In particular, the Board heard that disability access audits were carried out in August 2015 at the Agency's sites in central London and South Mimms, Hertfordshire (NIBSC), and related actions were being progressed. In terms of staff, Ms Birchall-Scott referred to the staff profile report provided and noted that these would be used to identify areas for further investigation and action.

7.4 The Board welcomed the report and asked a range questions including questions about staff training, such as 'unconscious bias awareness', which Ms Birchall-Scott advised was compulsory for all staff. Additionally, the Board asked if the Agency, through NIBSC, could participate in the Athena Programme; which is run by the King's Fund and designed to support women realise their true potential as senior leaders in the public sector. Ms Birchall-Scott said she would look into this and report back to the Board.

Action: Ms Birchall-Scott to find out if the Agency is eligible to participate in the King's Fund's Athena Programme and report back to the Board on equality & diversity progress next year.

Item 8: Audit and Risk Assurance Committee – revised terms of reference

8.1 As Deborah Oakley, Chair of the Audit and Risk Assurance Committee (ARAC), was unable to attend the Board meeting, Mr. Martin Hindle, Non-Executive Director, and a member of ARAC, presented the revised terms of reference for adoption. As part of the changes to the terms of reference, the Board agreed to the proposal that ARAC's membership should be fixed at four, while its quorum should continue to be two. As regards to whom the ARAC reports formally, it was proposed that a dual accountability line should exist: to the Board and the Accounting Officer (subject to further clarification from the NAO). According, the revised terms of reference were endorsed by the Board, subject to clarification of above.

Action: Colleagues in Finance Division to seek further clarification from the NAO about the dual accountability line.

Item 9: Audit and Risk Assurance Committee – oral update

9.1 On behalf of Deborah Oakley, Chair of ARAC, Mr. Martin Hindle, Non-Executive Director, gave an oral report on the committee's meeting that was held in the morning. The Board heard that the meeting was attended by all four members of ARAC, for three of whom it was their first ARAC meeting. They were: Martin Hindle, Stephen Lightfoot and Sir Alex Markham. The Board heard that ARAC considered a range of business. This included the accounting treatment of CPRD; Conflicts of Interest; the external audit plan; licensing fraud; the Corporate Risk Register; and ARAC's revised terms of reference. ARAC will meet again in January 2016.

STANDING ITEMS

Item 10: CEO's report for September 2015

10.1 Dr Hudson presented the highlights from the CEO's monthly report. These centred on the following areas:

- *Seasonal flu vaccine* – [Section 43 - commercial interest]

- *Medical devices* – An update was given on the suspension of the CE certificate of all implantable medical devices manufactured by Silimed, a Brazilian company. The Agency issued a press statement about the suspension on 23 September, with a medical device alert being issued on 25 September.

- *MHRA Annual Lecture* – Dr Margaret Chan, Director-General of the World Health Organisation, has agreed to give the next MHRA Annual Lecture, which will take place at the Royal College of Physicians on 1 March 2016.

- *Tysabri – An update was* given on Natalizumab (Tysabri) [Section 43 - commercial interest]

- *SGLT inhibitors* - An update was given on SGLT inhibitors (canagliflozin, dapagliflozin and empagliflozin) and diabetic ketoacidosis. [Redacted: Section 43 - commercial interest]

- *GCMAF* - An update was given on the ongoing investigation in the unlawful manufacture of an unauthorised medical product known as GcMAF (Globulin component Macrophage Activing factor).

- *Human Papillomavirus (HPV) vaccine* - [Redacted Section 35 Formulation of Government policy]

- *Falsified Medicines Directive* – An update was given on the distance-selling provisions of the Falsified Medicines Directive which came into effect on 1 July 2015. It is now an offence for UK-based sellers to offer medical products for sale online without displaying the common logo or without being included on the MHRA's list of registered online sellers. During the first eight weeks of its operation, 288 companies have applied for the logo.

- *Early access to medicines scheme (EAMS)* – An update was given on the eight promising innovative (PIM) designations that have been issued so far. The Board heard that Office for Life Sciences is chairing a stakeholder group, which includes the devolved administrations, to ensure a joined-up approach across the UK on access to EAMS medicines in the UK.

- *The Accelerated Access Review (AAR)* – an update was given on AAR. An interim report will published around mid-October, with the final report is expected to be published in March 2016.

- *Metal-on-metal hips – an update was* given on a study, which is being conducted outside the UK, on possible associations between metal-on-metal hips and heart failure. The results of the study are expected to be published in the New England Journal of Medicine.

- *Type 2 Diabetes clinical trial DECIDE study* – an update was given on progress with CPRD's pragmatic Type 2 Diabetes clinical trial DECIDE. The Board heard about the Agency's decision to ask the Irish regulator to audit the regulatory decision process, so as to ensure there would not be a risk of a perceived conflict of interest during the process.

- Data linkages – An update was given on the three new datasets which will be lined to CPRD.

Item 11: Finance and Procurement report

11.1 Mr Peter Commins gave the highlights for first five months of the financial year 2015/16. They were:

- MHRA (Regulator) income: year to date was £42.9m.
- NIBSC operational income: year to date was £17.6m.
- CPRD income: year to date was £3.8m.
- Operating income for the Agency was £53.6m, which is £3.6m above budget.
- Total operating costs were £53.6m, which was £2.2m below budget.
- The Agency's bank balance at the end of August 2015 was £209.5m.
- Capital expenditure for the year to end of August 2015 was £3.5m.
- Total Product Licensing deferred revenue at the end of August 2015 was £18.2m.
- The number of full-time equivalents in August 2015 was 1,208, with 136 short-term contracts and 42 non-payroll employees.

Item 12: Minutes of the Corporate Executive Team (CET) of 11 August 2015

12.1 The minutes of the CET meeting of 11 August 2015 were noted.

Item 13: Non-Executive Directors' (NEDs) updates

13.1 The following updates were given:

- *Matthew Campbell-Hill* – Attended meetings recently with Vivienne Parry of Genomics England and with colleagues from Information Management Division with Accenture.
- *Martin Hindle* – Attended a meeting with a bio-medical group on 15 October, at which George Freeman MP, Life Sciences Minister, addressed.

Item 14: Any Other Business (AOB):

14.1 None was tabled.

Date of next Board meeting: 20 November 2015