

MHRA Agency Board
MINUTES OF THE MEETING
15 May 2015

Present:

The Agency Board

Professor Sir Michael Rawlins	Chairman of MHRA
Professor Dame Valerie Beral	Non-Executive Director
Mr Martin Hindle	Non-Executive Director
Professor Vincent Lawton	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
Mr Jonathan Mogford	Director of Policy
Ms John Wilkinson	Director of Devices
[redacted]	Deputy Director of Inspection, Enforcement and Standards (IE&S)
Dr Siu Ping Lam	Director of Licensing
[redacted]	Deputising for the Director of the National Institute of Biological Standards and Control (NIBSC)
Dr June Raine	Director of Vigilance and Risk Management of Medicines Division
[redacted]	Financial Accountant – items 1-5
[redacted]	Deputy Finance Director – items 1-5
[redacted]	Head of Business Analysis – items 1-5
[redacted]	Head of Financial Accounting – items 1-5
[redacted]	Head of Science Strategy
[redacted]	Executive Assistant to the Chairman
Mr Aidan McIvor	Secretary to the Agency Board
Mr Mark Wilson	Legal Services

Item 1: Introductions and Announcements

- 1.1 Apologies were received from Professor Sir Alex Markham, Non-Executive Director (NED); [redacted], DH.
- 1.2 For the Annual Accounts seminar, which was also attended by members of the Corporate Executive Team, apologies were received from; Ms Vanessa Birchall-Scott, Director of Human Resources; Mr John Quinn, Director of Information Management Division; Dr Janet Valentine, Director of Clinical Research DataLink (CPRD); and Mr Bill Martin, Head of Procurement.
- 1.3 The Chairman advised that discussion of the Triennial Review reports on the Agency, which has still to be published, as well as on the Commission on Human

Medicines and the British Pharmacopoeia Commission would take place at the next Board meeting on 22 June 2015.

Item 2: Declarations of interest

2.1 None was declared.

Item 3: Minutes of the last meeting, 27 April 2015, and matters arising

3.1 The draft minutes of the Board meeting of 27 April 2015 were agreed.

Matters arising

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

DISCUSSION ITEMS

Item 4: General Election – oral update

4.1 Mr Jonathan Mogford, Director of Policy, gave an update on the Ministerial appointments at the Department of Health which had been made following the outcome of the General Election of 7 May. The Board heard that further announcements, especially about ministerial portfolio responsibilities were expected in the days ahead.

Item 5: Annual Accounts seminar

5.1 The seminar was presented by [redacted], Deputy Finance Director, supported by [redacted], [redacted] and [redacted]. The Board heard that the purpose of the seminar was to allow the Board to review the final draft Annual Accounts before they are submitted to the Agency's auditors and, in particular, the key statements; and to identify major changes from the previous year. The seminar also entailed an analysis of the key vulnerabilities and challenges the Agency faces in 2014-16.

5.2 Key points to arise from the presentation:

- National Audit Office's (NAO) final audit fieldwork will begin on 27 May and should be completed by mid-June, which, together with the draft Annual Accounts, will be reviewed by the Audit and Risk Assurance Committee on 22 June. Sign-off of the accounts is due to take place by the w/c 29 June 2015. The Annual Report will be tabled in Parliament by mid-July. Although Recess has yet to be announced, the Board heard that it is likely to take place in late July.
- The year 2014/15 was the second year of an enlarged agency. There are no significant accounting changes; the period 9 accounts have been completed on time with an unqualified audit opinion from the NAO. Although the final internal audit opinion is still awaited, the draft opinion gives the Agency "moderate assurance". In addition, the Board were reminded that NIBSC had been brought into the Agency's accounts by "modified absorption accounting" in 2013/14.
- In answer to a number of questions from the Chairman and Board members about the internal audit rating categories, [redacted] explained that a "satisfactory" rating is actually a good rating – second from the best ("strong"),

which auditors hardly ever award. It was confirmed that financial control had received two “substantial” assessments from PWC, the internal auditors, the first and only such assessments received by the Agency across all of its activities.

- Procurement – [redacted] outlined developments in procurement. The Board heard that there is increasing expansion in procurement needs, especially at the Agency’s London offices. The Agency is expected to run over 120 tender exercises in the new financial year. The Board heard that the new Oracle system will help greatly to simplify and automate processes.
- The Board received an overview of the Agency’s financial performance for 2014/15; an update was also given on the Agency’s strategic finance and its budgets of the Agency’s three centres (MHRA Regulator, NIBSC and CPRD) for 2015/16. The Board heard that no new statutory fees are expected in 2015/16.
- In response to Board members’ queries, [redacted] explained the meaning of some of the definitions and categories which appeared in the presentations, e.g. liabilities, cash and assets. [redacted] also explained the Agency’s position on insurance cover, namely as a government body it is obliged to self-insure. The board indicated that they would like more information about the amount and the methodology used to calculate this potential liability, including benchmarking with other ALBs. The board also queried why this was not an item in the accounts. In response to Board members’ questions about the possible use of the Agency’s cash surplus to fund devices work or other activities, the Board heard that a paper on Strategic Finance would come to the Board at its meeting on 22 June, which would cover fees and cash issues.
- Key vulnerabilities were considered, e.g. the predicted decline in Decentralised Procedure (DCP) submissions in 2016/17 and 2017/18. The Board heard that the UK remains competitive, as it attracts 45% of RMS work. As for National Periodic Fees (NPFs), the Board heard that income from NPFs is expected to decline as product licences age. The Board also considered the possible changes to government funding for devices work and NIBSC, as well as CPRD’s funding model. Year 4 of CPRD’s forecast income is below re-plan but there remains a surplus to cover additional investments.

5.3 The Chairman thanked [redacted] and his team for their presentations, and said the he and the Board looked forward to the discussion on Strategic Finance on 22 June.

draft Annual Report 2014/15

5.4 Ms Rachel Bosworth, Director of Communications, presented a revised draft of the Annual Report, which reflected earlier suggested amendments from members of the Board. Ms Bosworth advised that a final version of the draft of the Annual Report would return to the Board on 22 June.

STANDING ITEMS

Item 6: CEO's report for April 2015

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

- *Devices fees* – An update was given on the work the Agency is doing with industry, the Department of Health, legal services, and the Office of life Sciences, and other interested parts of Government, such as HM Treasury, to refine the Agency's proposals on a few fees' regime for medical devices.
- *Clinical Practice Research DataLink (CPRD) collaboration with the Royal College of General Practitioners (RCGPs)* – An update was given on a collaborative project with the RCGPs. The project, which covers four strands of work, has the potential to double GP practices signed up with CPRD over the next two years.
- *[Section 43 redaction – trade secrets and prejudice to commercial interests]*
- *Use of hydrogen peroxide during surgery and risk of gas embolism* – An update was given on the Commission of Human Medicines' (CHM) consideration of the risk of gas embolism with the use of hydrogen peroxide intra-operatively. The Board heard that CHM has asked that its formal advice be shared with the Royal College of Surgeons.
- *Natural & Organic Products' trade show* – The Board heard that members of staff from the Agency's Borderline Section within the Inspection, Enforcement and Standards Division had attended the annual Natural and Organic Products Show on 20 April 2015, which was held at Excel Exhibition Centre in London.
- *MHRA surveillance audit of SGS* – An update was given on a surveillance audit of SGS, which is one of the United Kingdom's notified bodies. The audit was carried out under the Medical Devices Directive and the In Vitro Diagnostic Medical Devices Directive.
- *Information security*- An update was given on work to review and update the Agency's policies and processes on information security. The Board heard that information security remains high on the Agency's agenda.
- *Chief Executive's visit to Australia* – An update was given on the Chief Executive's visit to Australia in early May 2015. The Board heard that Dr Hudson had given two keynote presentations at the annual conference of the Association of Regulatory and Clinical Scientists (ARCS) in Sydney. While in Australia, Dr Hudson held meetings with the Agency's counterpart, the Therapeutic Goods Administration, at its federal head offices in Canberra.
- *NIBSC relationship with the World Health Organisation* – An update was given on a review of the National Institute for Biological Standards and Control's (NIBSC) relations with the World Health Organisation.
- *International Medical Device Regulators Forum (IMDRF)* – An update was given on the first face-to-face meeting of the IMDRFT in Tokyo, Japan in April 2015 at which the Agency was represented.

- *International visits (inward)* – the Board heard that a delegation from the Korean Ministry of Health and Welfare visited the Agency on 15 April 2015. In addition, members of staff from the Agency attended a workshop at the Department of Health on 30 April with counterparts from South Africa. The discussions centred on medical devices and natural health products.

Item 7: Minutes of the Corporate Executive Team (CET) of April 2015

7.1 The minutes of the CET meeting of 3 April 2015 were noted.

Item 8: Non-Executive Directors' (NEDs) updates

- *Professor David Webb* - Professor Webb reported that he will attend a conference imminently in China on herbal medicines. An update on the conference would be shared with the Board under NEDs' update at the next meeting.
- *Professor Dame Valerie Beral* – Professor Beral gave an update on an academic seminar she attended recently in Oxford on data use.

Item 9: Any Other Business (AOB):

There were no items of AOB.

Date of next Board meeting: 22 June 2015.

Aidan McIvor