

17 September 2014

Board Meeting Report

1 Declarations of Interest

There were no conflicts of interest declared.

2 Risk Management

There were no updates to report.

3 HPRA Updates (such as changes to legislation, competencies, terms of reference)

The recent publication of the Protected Disclosures Act 2014 was noted by the Board.

4 Chief Executive's Report

The Chief Executive provided an overview of the main highlights of his report:

- The Minister for Health, Mr Leo Varadkar TD, visited the HPRA in late July to meet the Chairman and the Chief Executive on an informal basis. Matters discussed included licensing and benefit/risk, product reclassification (switching), the interchangeable medicines list, parallel trade, medical devices fees and scientific animal protection. There were also discussions concerning the organisational rebrand, the HPRA building, quality systems, and staffing as well as Regulatory Science Ireland and the Health, Social Care and Regulatory Forum. It was a very productive introductory meeting and the Minister expressed his intention to meet regularly with the HPRA.
- The management team held a successful planning session in preparation for the development of the 2015 business plan. Preparatory work has also commenced on the strategic plan for 2016 – 2020. The HPRA, while currently working to the Department of Health approved staffing plan for 2014, is now seeking to have a staffing plan for the period 2015 to 2018 approved by the Department.
- The introduction of the Health Products Regulatory Authority (HPRA) name and brand, in addition to the associated launch event on 1 July, were considered very successful. The new name has been well received externally and there are a number of ongoing initiatives to raise further awareness of the new HPRA brand identity.
- Finally, it was noted that the contractors responsible for the addition of two additional floors to the HPRA building received a "best commercial project" award for the construction.

5 Regulatory Science Ireland (RSI)

The Board considered this newly founded organisation consisting of representatives from academia, state agencies (including the IDA, Enterprise Ireland and Science Foundation Ireland), the pharmaceutical industry, the medical devices industry and the HPRA. The main pillars of the

RSI will be to co-ordinate and possibly fund research, to promote education and training, and to provide outreach in respect of regulatory science. The HPRA is represented on the Board of this organisation by the Chief Executive while the Director of Scientific Affairs is his alternate.

6 Irish Blood Transfusion Service: 2013 Report to the Minister for Health

The 2013 Report on the Irish Blood Transfusion Service was reviewed and adopted by the Board for submission to the Minister for Health.

7 Committee Meetings

7.1 Audit Committee

The Chairperson provided a brief overview of the most recent meeting. This related primarily to a meeting with the Internal Auditors, BDO (appointed for the next 3 years). Discussions centred on the proposed Audit Plan which will focus initially on the Accounts area and also HR, IT and risk management.

8 Financial

The management accounts for May, June and July 2014 were noted by the members. The Supplemental Director Bank Mandate was signed at the meeting as required by the Chairman and the Chief Executive.

9 Licensing Activities

The tables of Licences from 30/05/14 to 05/09/14 approved by the Management Committee were noted.

10 Board Meeting Dates 2014 and 2015

The Board noted the meeting dates for 2014 and 2015.

11 Nomination of New Board Member to the Audit Committee

It was noted that Dr. Keane is to join the Audit Committee membership.

12 International Conference of Drug Regulatory Authorities (ICDRA)

The HPRA may be asked by the World Health Organization (WHO) to host this event in either two or four years' time. This potential development was viewed favourably by the members due to the importance of supporting the WHO and also given the significance of the conference for medicines regulation globally.