IRISH MEDICINES BOARD

BOARD MEETING REPORT – 5 JUNE 2014

1. Welcome

The Chairman welcomed the reappointed Board members and the new Board member appointed by the Minister on 22 May 2014.

2. Declarations of Interest

There were no conflicts of interest declared.

3. Remuneration of CEO's of Non-Commercial State Agencies

The Board agreed that following the recent Department of Public Expenditure and Reform decision to review the grading of agency chief executives that the chief executive role should be evaluated in the light of other comparable organisations.

4. Centre for Regulatory Excellence

It was noted that the initial meeting took place in Dublin the week beginning 23 May was attended by 40 representatives from academia, the pharmaceutical industry, the IMB, Science Foundation Ireland, the Health Research Board, the IDA and Enterprise Ireland. It was agreed that a Board be established for the new organisation. The mandate of the new organisation is to be developed in line with government thinking and the Forfás Report.

5. Risk Management

The Risk Register was recommended to the Board for approval by the Chairman of the Audit Committee and approved.

6. IMB Updates (such as changes to legislation, competencies, terms of reference)

The Board reviewed and approved the amended Terms of Reference and the updated Declaration of Interest Policy.

7. Chief Executive's Report

The Chief Executive highlighted a number of points from his report.

It was noted that the Statutory Instrument authorising the name change of the organisation to the Health Products Regulatory Authority (HPRA) was signed on 14 May 2014.

The success of Operation Pangea was noted.

The Board heard that a Clinical Trials Seminar for those working in the sector was held in the IMB canteen space/lecture theatre with over 100 attendees.

The Chief Executive spoke about the progress made in interchangeable medicines at the Irish Pharmacy Union (IPU) AGM attended by Minister Alex White.

An overview was provided of the role of the IMB at an international level in relation to meetings with the FDA and the International Coalition of Medicines Regulatory Authorities (ICMRA). Also at a European level the IMB is attending meetings in relation to fee funding for Pharmacovigilance Risk Assessment Committee (PRAC) rapporteurships.

With regard to funding in the medical devices area in Ireland, the IMB has prepared a proposal and consulted with the Irish Medical Devices Association (IMDA) and the Irish Medical and Surgical Trade Association (IMSTA) on the matter. A submission will be made to government shortly.

8. PwC Presentation on Future Board Activities

PWC provided a presentation and an assessment of future business opportunities for the IMB. It was recognised that the IMB has a sterling reputation both at a national and international level and could use this as a springboard to generate future business opportunities.

PwC concluded that there were opportunities for IMB but these are dependent on a suitable resource model would need to be put in place and an appropriate governance and fee structures.

9. Audit Committee

The Chairperson of the Audit Committee provided a brief overview of the meeting held on 5 June. It was noted that the Financial Statements for 2013 had been reviewed and recommended to the Board for approval. The Risk Register and the *Systems of Internal Control* document were both reviewed and the latter was recommended to the Board for approval. The Corporate Procurement Plan and the document *Briefing for Resignations* in relation to the Senior Management Team were also reviewed. The engagement letter to the Internal Auditor was noted as was the IMB submission to the Department of Health in relation to pensions.

10. Advisory Committee Human Medicines – 22 May 2014

The Chairperson of the Committee provided a brief overview of the meeting held on 22 May including: Pharmacovigilance and product related reviews, access to unauthorised medicines/exempt medicinal products, interchangeable medicines, the proposal for a proactive approach to reclassification (switching) applications, the Clinical Trials Subcommittee Report and the Herbal Medicines Subcommittee Report. The Committee received presentations on medicinal products activities IMB wide for 2013 and the HPRA rebrand.

11. Financial

The management accounts for March and April 2014 were noted. On the recommendation of the Audit Committee, the Board approved the *Systems of Internal Control* document and the Financial Statements for the year ended 31 December 2013.

12. Licensing Activities

Tables of Licenses from the 14/3/14 to the 23/5/14

The Board noted the above tables specifying the licences approved by the Management Committee.

13. Board Meeting Dates 2014

The Board noted the meeting dates for 2014.