IRISH MEDICINES BOARD

BOARD MEETING REPORT – 28 MARCH 2012

1. Declarations of Interest

There were no conflicts of interest declared.

2. Publication of Board Declaration of Interest Forms

It was noted that the document compiling all the Board members declarations of interest would, in line with best practice, be published on the IMB website in May 2012.

3. Annual Report

It was agreed that a report including draft accounts be sent to the Minister, on the understanding that final accounts would follow once approved by the Comptroller and Auditor General.

4. Risk Management

The Board received an update on the quarterly risk management review. The Chair of the audit committee complimented the risk review process.

5. Chief Executive's Report

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

- The IMB continues to monitor the Poly Implant Prosthese (PIP) breast implant issue, and has attended meetings with the Department of Health (DoH) and the clinics involved. The IMB and the DoH also met with the PIP Action Group to discuss the matter.

- The Board was informed that the Chief Executive and the Director of Human Products Monitoring are to attend an Oireachtas Joint Committee on Health and Children hearing in relation to the PIP breast implants on Thursday 29 March. An information pack has been prepared for the Oireachtas Joint Committee. The Chief Executive's opening statement to the Joint Committee was circulated to the members.

- It was noted that the IMB is to attend a meeting organised by the DoH on the Organs Directive for which the IMB has been named the competent authority.

- The Chief Executive also drew the Board's attention to a new report format from the Human Products Authorisation and Registration Department.

6. Meeting with Minister Shortall

It was noted that the IMB had a productive briefing meeting with Minister Róisín Shortall which, it is hoped, to follow up with biannual meetings. Among other matters, the Minister is particularly interested in the legal supply classification of medicines and enforcement activities in relation to illegal supply of prescription and counterfeit medicines via the internet.

7. Update from Consultative Panel on the Legal Classification of Medicines

The DoH made a presentation at the last meeting of the panel which it is hoped will be presented to the Board at a future meeting. The terms of reference of the panel were approved.

8. Committees

8.1 Audit Committee – 27/3/12

The Chairperson of the Audit Committee provided a brief overview of the matters discussed at the meeting. She outlined that the IMB document on The System of Internal Controls had been reviewed by the Audit Committee, and the Committee was now recommending its approval to the Board which was agreed. The internal auditor from Crowley's DFK attended the meeting with the Audit Committee and stated that he was very satisfied with the IMB systems and the assistance provided by the staff in the Finance & Corporate Affairs Dept. The Board noted the satisfactory outcome from the various internal audits.

8.2 Advisory Committee for Medical Devices (ACMD) –20/3/12

The Chairperson provided an overview of the main issues discussed at the ACMD meeting of 20 March last including: a PIP update, metal on metal implants and implantable cardiac defibrillator leads. He referred to Commissioner Dalli's plan of immediate action arising from the PIP breast implants issue, the revision of the medical devices directives, an update on the notified body and a presentation from IMDA.

8.3 Advisory Committee for Veterinary Medicines (ACVM) – 7/3/12

The Chairperson of the ACVM, provided an overview of the main issues discussed at the meeting including: a peer review of the assessment of the efficacy of an antibiotic product for dogs which was found to be robust; the submission of an application for a product to relieve sweet itch in horses, which it was determined met the requirements for an exceptional authorisation for a non-food producing horse as defined by Article 6(3) of Council Directive 2001/82/EC as amended and a letter from the IPU in relation to the classification of a product.

9. IMB Patient Engagement

The IMB is seeking to establish a mechanism that will allow for structured and two-way interaction with Irish patients resulting in meaningful and ongoing engagement.

10. BT Young Scientist Exhibition Report

A report on the IMB involvement with the BT Young Scientist Exhibition 2010, 2011 and 2012 was noted by the Board. It was noted that approximately 10,000 visitors attend the stand each year over the three days and the Board considered that the benefits to the IMB well justified the expenditure involved. The Board also noted the contribution of IMB staff to the success of the IMB involvement and the good will generated among staff who attend. The Board agreed that the IMB continue its involvement with the event for another three year period.

11. IMB Strategic Plan 2011-2015 – First Year Review

The results of the first year review of the IMB Strategic Plan 2011-2015 were noted by the Board. The organisation is meeting its objectives in a phased process. It was agreed that the review would be sent to the Secretary General of the DoH for information.

12. Report of the Research Prioritisation Group

The Forfás report was noted by the members.

13. Financial

The management accounts for January and February 2012 were noted by the members.

14. Licensing Activities

The Board noted the Tables of Licenses (from 20 January 2012 to 16 March 2012) specifying the licences approved by the Management Committee.

15. IMB Change of Name

It was noted that the Minister had approved the principle of a name change for the IMB to reflect that the remit of the organisation extended far beyond medicines. It is anticipated that the change of name might be included in the upcoming legislation providing for generic substitution.

16. Office Accommodation

The Board noted that the building work to extend Kevin O'Malley House upwards by two floors is to commence in early June. It was noted that the top floor may be uninhabitable for a period of approximately six months and the Board approved the proposal for the decant of the affected staff for that period.