

BOARD MEETING REPORT – 25 SEPTEMBER 2013

1. **Declarations of Interest**

There were no conflicts of interest declared.

2. **Risk Management**

The Risk Register was noted by the members.

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

The updated Terms of Reference for the Board were approved.

4. **Chief Executive's Report**

The Chief Executive highlighted a number of points from his report including that fact that August outputs were high, the finances were satisfactory and the IMB has begun publishing interchangeable lists of medicines on the IMB website. It was noted that the new Director of Human Products Authorisation and Registration has been appointed and her former role as Pharmaceutical Assessment Manager has also been filled.

It was noted that the Chief Executive and other IMB representatives had attended the Oireachtas Joint Committee on Health and Children meeting on 24 September. The IMB had provided an update on its main activities which was well received. The Committee had been particularly interested in the update on medicines being sourced illegally from websites, metal on metal hip implants and the withdrawal of the DePuy ASR hip implant. An update on interchangeable products was also provided. The Committee Chairman requested that the IMB consumer information leaflets be sent to all TDs to display in their clinics.

With regard to the Hospira pumps issue, it was noted that Hospira is managing the supply of consumables to the wholesale distribution network.

It was noted that the Chief Executive and the Director of Finance and Corporate Affairs had attended a Committee on Foreign Relations meeting in Washington DC, hosted by the FDA. The IMB has a joint lead role in the development of greater co-operation between international Medicines authorities which will be examined further at the Summit of Medicines Regulators in Amsterdam in December 2013.

It was also noted that a staff information session was held in early September in relation to the European Presidency, the extending of Kevin O'Malley House upwards by two floors and the rebranding of the organisation in 2014.

5. **Consultative Panel Report**

The Board was provided with a background document by the Chief Executive and an overview of the final deliberations of the Consultative Panel following its inception in

December 2011 under the Chairmanship of Dr. Colm Gaynor, a veterinary surgeon and barrister, and former Director in the European Commission.

The Panel recognised that the “self care agenda” is part of Department of Health policy which promotes making medicines available in a safe environment at the lowest cost point in health care system. The Panel was in agreement that low risk medicines which can be switched safely from prescription only medicines (POM) to over the counter (OTC) in the pharmacy should be switched. The Panel also agreed that products can be switched from OTC to POM should pharmacovigilance evidence deem this necessary for patient safety.

The two main initiatives approved for the IMB are the publication of an initial indicative active ingredient list for consideration for switching and a change in the IMB processes. The latter will allow applicants greater up front access to IMB assessors so as to fully understand the clinical and quality criteria required. This will facilitate the application being assessed in the shortest possible timeframe once it is received by the IMB.

The Board complimented Dr. Gaynor on the work of the Panel to date and adopted the background document presented by the Chief Executive, the Chairman’s Report and the recommendations therein.

6. Audit Committee

The Chairperson of the Audit Committee provided a brief update of the meeting held on 25 September 2013. IMB pensions were discussed while it was noted that the Audit Committee had agreed to evaluate the tender applications for the Internal Auditor role from 2014 to 2016 inclusive at its next meeting. There had also been a visit from the external audit company representing the Comptroller and Auditor General who was satisfied with the systems and controls in place in the IMB.

7. Building Report

A report following the completion of the building work to extend Kevin O’Malley House upwards by two floors while keeping the building live was provided. It was noted that the construction work was completed on time and under budget. The Board members had taken the opportunity to view the two new floors earlier in the day and were very pleased with the outcome and complimented the staff involved in the project.

8. Medical Devices

In line with the European Commission Joint Action Plan for medical devices, it was noted that the IMB has agreed additional headcount and funding with the Department of Health in 2013 to carry out additional activities. While a European fee model is still some time away, it is anticipated that the IMB will have a national fee model for medical devices in place for 2015, in line with other Member States of the EU.

9. European Presidency Feedback

It was noted that the IMB hosted, organised and administered 22 meetings in total during Ireland’s Presidency of the Council of the European Union. Feedback received showed that participants were highly satisfied with the standard of organisation, the level of progress achieved at the meetings and the welcome received from staff. A letter from the President of the Polish regulatory agency to this effect was noted by the Board.

10. Financial

The management accounts for June and July 2013 were noted by the members.

11. Licensing Activities

Tables of Licenses from 28/6/13 to 13/9/13

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

12. Board Appointments

It was noted that there will be a requirement for the Department of Health to progress IMB Board appointments as four Board members' terms of office expire at the end of 2013.

13. Ms. Nuala Harman - RIP

A tribute was paid to Ms. Harman, former PA to the Chief Executive, who passed away after a short illness on 8 August. May she rest in peace.