

## BOARD MEETING REPORT – 23 MAY 2012

### 1. **Declarations of Interest**

There were no conflicts of interest declared.

### 2. **New Board Member**

In line with the new Government system for the appointment of Board members, the IMB Board vacancy is being advertised on the Public Appointments Service website with a closing date of 1 June. The vacancy details have also been published on the front page of the IMB website.

### 3. **Publication of Board Declaration of Interest Forms**

It was noted that the document compiling all the Board members declarations of interest was published on the IMB website in May 2012.

### 4. **Chief Executive's Report**

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

- IMB resources for 2012 have been approved by the Department of Health.
- A number of IMB representatives attended a briefing session at Dublin Castle in relation to the Organs Directive, for which the IMB will be the Competent Authority.
- It is anticipated that a proposed IMB name change will be included in the generic substitution legislation (with effect from 1 January 2014).
- The Chief Executive and the Director of Human Products Monitoring attended an Oireachtas Joint Committee on Health and Children hearing in relation to Poly Implant Prothese (PIP) breast implants on Thursday 29 March 2012.
- It was noted that Ms. Paola Testori of DG Sanco had written to the Department of Health asking the Secretary General to attend a meeting in Brussels in relation to Commissioner Dallí's proposed action plan with regard to medical devices. The action plan may have certain resource implications for the IMB which will be reviewed.
- The Board was informed of the appointment of a new Secretary General to the Department of Health, Dr. Ambrose McLoughlin, former Registrar of the Pharmaceutical Society of Ireland. The Chief Executive has sent a letter of congratulations on behalf of the Board.

### 5. **IMB Seal**

Pursuant to section 8(10) of the Irish Medicines Board Act 1995, as amended, the Board members authorised to authenticate by signature the seal of the Irish Medicines Board shall be Mr. Patrick Brangan and Ms. Ann Horan and the officers authorised to authenticate by signature the seal of the Irish Medicines Board shall be the Chief

Executive, Mr. Pat O'Mahony, the Director of Finance and Corporate Affairs, Ms. Rita Purcell and the Secretary, Ms. Amhairgín Ní Laoi.

## **6. Committees**

### **6.1 Advisory Committee Human Medicines**

The Chairperson of the Advisory Committee for Human Medicines provided a brief overview of the matters discussed in the meeting held earlier in the day (23 May 2012).

An update was provided in respect of Pandemrix and the publication of recent studies.

The issue of cannabis containing medicinal products was discussed and it was noted that the matter was currently under review by the Department of Health.

In relation to Domperidone, it was noted that the IMB is working with the MAH to update the product information. In the interim, the PSI is working with the IMB to ensure that only suitable patients are receiving the product.

With regard to the recall in the UK earlier that day of Anapen (adrenaline injection for emergency use) due to a potential dose delivery issue, it was noted that Anapen is the main product on the Irish market and, at this time, there is no alternative product that could provide sufficient replacement stock. Anapen will continue to be available in Ireland until such time as there is an alternative. Patients would be at greater risk if no product was available. Accordingly the IMB has issued an advisory notice to healthcare professionals and patient groups relating to this issue.

It was noted that an upcoming Clinical Trials seminar for hospital investigators is to be hosted by the IMB in June.

### **6.2 Audit Committee**

The Chairperson of the Audit Committee provided a verbal update of the meeting held earlier that day. Firstly she welcomed Mr. Brendan McLaughlin to the Audit Committee. It was noted that the Audit Committee had reviewed the Financial Statements for 2011 in detail and was satisfied to recommend their adoption to the Board.

With regard to the recent external audit, it was noted that the Auditors did not plan to issue a Management Letter; a testament to the good accounting and corporate governance practices in the IMB.

## **7. CEO Performance Evaluation Committee**

In line with good corporate governance it was agreed that a sub-committee of the Board be established to evaluate the performance of the Chief Executive.

## **8. Accommodation**

The Chief Executive informed members of developments in relation to the Board agreement to extend Kevin O'Malley House upwards by two floors. The tenders have been received and evaluated. However, prior to appointing the builders the IMB are reviewing their property requirements in the context of future resource needs and the market place.

## **9. Financial**

The management accounts for March and April 2012 were noted by the members.

The Board adopted the Financial Statements for 2011, as recommended by the Audit Committee (see item 6.2) pending final sign off by the Comptroller and Auditor General.

**10. Licensing Activities**

The Board noted the Tables of Licenses (from the 23 March 2012 to 11 May 2012) specifying the licences approved by the Management Committee.

**11. Electronic Papers**

It was agreed that the Board papers would be sent electronically except to those members who preferred to receive them in hard copy.

**12. June Board Meeting**

It was agreed that the Secretary would circulate details of the venue for the June Board meeting in due course.

**13. AOB**

13.1 Board Performance Evaluation Committee

In line with good corporate governance it was agreed that a sub-committee of the Board be established to evaluate Board performance. The first meeting will be prior to the September Board meeting.

13.2 Meeting of Chairpersons of Scientific Advisory Committees

It was noted that a future meeting between the Chairpersons of the committees is to be organised to discuss the operation and interaction between those committees.

13.3 Mortgage

In light of current Euro volatility it was agreed that the Finance Department would seek to fix the interest rate of the mortgage for its remaining term.

**14. Schedule of Board Meetings**

The Board noted the schedule of Board meetings for the remainder of 2012.