

## BOARD MEETING REPORT – 28 JUNE 2012

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

There were no conflicts of interest declared.

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

It was noted that fifteen responses have been received in response to the advertisement for a new Board member on the Public Appointments Service (PAS) website and they are now being considered by the Department of Health.

### 3. **CEO Performance Evaluation Committee**

It was noted that a meeting of the CEO Performance Evaluation Committee has been scheduled.

### 4. **Board Performance Evaluation**

It was noted that following a discussion between the Chairman and an IPA Corporate Governance Expert, that it was suggested that a questionnaire on the performance of the Board as a whole be completed by all Board members individually.

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

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

The Chief Executive informed the meeting that some additional posts have recently been approved by the Department of Public Expenditure and Reform for new activities to be carried out by the IMB.

It was noted that at a recent meeting between the Minister for Health, the Secretary General and the Chief Executives of all agencies under the aegis of the Department of Health, the international reputation of the IMB was highlighted.

It was noted that the web domain name HPRA has been purchased in advance of the upcoming IMB name change to the Healthcare Products Regulatory Authority on 1 January 2014.

In line with government requirements for shared services opportunities, it was noted that the IMB has engaged with the Revenue Commissioners to investigate the potential locating of IMB disaster recovery solutions within the Revenue data centre.

Two significant outcomes were achieved in prosecutions taken by the DPP. Firstly there was the conviction on 2 May of James Bellamy, Director of Harmony Products Ltd, who received a three-year prison sentence with the final year suspended and a fine of €100,000 at the Dublin Circuit Criminal Court. He was convicted of the illegal importation and wholesale of unauthorised prescription only medicinal products which were later sold as 'herbal Viagra'. The company Harmony Products Ltd was also fined €150,000 with one year to pay or distress in default. The case was brought by the DPP following an investigation carried out by the IMB and An Garda

Síochána. On 1 May, Darren Pidgeon pleaded guilty to a charge of manufacturing medicinal products containing the active substance Zopiclone. Mr. Pidgeon was sentenced to four years in prison which was suspended pending good behaviour. This case followed an investigation by An Garda Síochána with technical assistance from the IMB.

The Chief Executive provided a brief overview of the role the Food and Veterinary Office (FVO) might play in relation to Commissioner Dallí's Joint Action Plan for medical devices in relation to medical device manufacturing facilities and notified bodies designation audits.

**6. Letter from Secretary General**

The Board noted the contents of the letter from the Secretary General of the Department of Health to all health agencies requesting that the salaries and expenses of Board members be published. It was agreed that the Chairman and Chief Executive's salaries continue to be disclosed as usual in the Annual Report, that the combined salaries of the Board members be registered as a nil value and the combined travel and subsistence expenses of all Board members be disclosed in the Annual Report.

**7. Key Priorities and Objectives 2012**

The Board reviewed the key priorities and objectives for 2012 which included the adoption of new competencies by the organisation under the Scientific Animal Protection and Organs Directives, new pharmacovigilance legislation, and implementation of the actions from the 2011 review of the ICT strategy.

**8. Committees**

8.1 Audit Committee – 28/06/12

The Chairperson of the Audit Committee provided a verbal update of the meeting held earlier that day.

It was noted that the Audit Committee had proposed that the IMB write to the Revenue in relation to the tax status of any future commercial activities. The Audit Committee had also reviewed the IMB Procurement Report 2012-2014 which was satisfactory. It was also noted that the 2011 Financial Statements had been signed off by the C&AG.

The Audit Committee had fully reviewed the Chairman's Report to the Minister for 2011 and was satisfied to recommend it to the Chairman of the Board for signature.

8.2 Advisory Committee for Medical Devices (ACMD) – 13/06/12

The Chairperson of the ACMD provided a verbal update of the meeting held earlier in the month. The main items discussed included the latest update with regard to the PIP breast implants, the latest update with regard to metal on metal implants, Commissioner Dallí's Joint Action Plan, an update in relation to inspection and audit activities including upcoming inspections of the NSAI, revision of the medical devices regulatory framework and the recent resignation of a Committee member. It was noted that a replacement Committee member would be sought via the national Public Appointments Service website.

8.3 Advisory Committee for Veterinary Medicines (ACVM) – 06/06/12

The Chairperson of the ACVM provided a verbal update of the meeting held earlier in the month. The committee discussed the classification of a flea collar, an increase in

the reporting of Suspected Adverse Events (SAEs) as a result of increased communication on the matter from the IMB to the Veterinary Council and veterinary medicines colleges and a risk assessment carried out on specific flea collars in France.

**9. Accommodation**

The Board held a detailed discussion on the future accommodation needs of the IMB. Having considered all the possible options and the financial, resource, space requirements, business needs and the economic climate, it was agreed that building upwards was the preferred option for the Board and the Executive was empowered to proceed in this regard.

**10. Financial**

The management accounts for May 2012 were noted by the members. The Board adopted the Financial Statements for 2011, as recommended by the Audit Committee.

**11. Licensing Activities**

The Board noted the tables of licenses from the 18/05/12 to the 15/06/12 which had been approved by the management committee.