IRISH MEDICINES BOARD

BOARD MEETING REPORT – 18 DECEMBER 2013

1. Declarations of Interest

There were no conflicts of interest declared.

2. Risk Management

The Risk Register was adopted by the members.

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

The updated Terms of Reference for the Management Committee were approved.

4. Chief Executive's Report

The Chief Executive highlighted a number of points from his report beginning with the fact that the Chairman and he had had their annual meeting with the Secretary General of the Department of Health on 16 December. Matters discussed included imminent Board appointments, medical devices and the rebranding of the organisation to the Health Products Regulatory Authority (HPRA) in 2014.

It was noted that the IMB had met with the Oireachtas Joint Committee on Health and Children three times in 2013 including a meeting in early December to update on the De Puy hip implant and the PIP breast implant issues and to provide further updates on the implementation of the Dallí joint action plan for medical devices. In line with the joint action plan, the European Commission's Food and Veterinary Office recently assessed the IMB's audit of the National Standards Authority of Ireland (NSAI), the national notified body. Following the assessment of the audit, the IMB received very positive feedback on its role.

It was also noted that IMB senior staff recently met with their peers in the UK's MHRA for a strategic day and that the IMB Chief Executive is to meet with the Chief Executive of the HSE in early 2014 to discuss matters of mutual interest.

The Board heard that a second externally accredited leadership development programme is to commence in early 2014. The Chairman presented the certificates to the graduates of the first course earlier in 2013.

It was noted that the Chief Executive was elected at the International Summit of Heads of Medicines Regulatory Agencies to serve as Vice Chair with Japan for a two year term on the International Coalition of Medicines Regulatory Authorities. The group is to be chaired by Canada.

5. IMB Workflow and IT Systems Development

It was noted that in line with the Board approval of a comprehensive IT Strategy in 2011, the IMB has been consistently upgrading and improving its systems to align with this

vision. In order to maintain performance the IMB now needs to upgrade its workflow system. To this end PwC was appointed to manage the first phase of the project.

The benefits include:
(1) a comprehensive workflow management solution to centralise and expand upon services currently provided by existing workflow applications; and
(2) integration with the document management solution to address the IMB's current and future document management requirements.

Having considered the facts the Board agreed the proposal in respect of a workflow system. The next steps will include systems procurement and implementation organisation wide on a phased basis beginning in 2014.

6. One Year Overview of the EMA's Pharmacovigilance Risk Assessment Committee (PRAC)

As Vice Chair of the PRAC Committee, the IMB's Dr. Almath Spooner provided an overview of the role of the PRAC Committee to date. The Board was updated on the establishment and composition of the PRAC as a public health focused committee, how the committee is using the new public health protection tools and the future challenges for the PRAC.

The PRAC was founded on the premise, in line with Directive 2010/84/EU, that pharmacovigilance rules are necessary for the protection of public health in order to prevent, detect and assess adverse reactions to medicines placed on the European market. It was noted that 5% of hospital admissions are as a result of adverse reactions and 5% of hospital patients suffer adverse reactions. The committee is made up of representatives from each Member State and six EU expert appointees as well as a clinical expert patient representative and a clinical expert healthcare professional.

The main functions of the PRAC can be classified into three areas:
(1) Proactive safety monitoring and planning.
(2) Prompt benefit/risk action.
(3) Transparency and communication.

Proactive safety monitoring and planning means that the PRAC analyses the signals coming from the monthly adverse drug reactions (ADRs) being fed into the pan-European Eudravigilance ADR database and consider national recommendations and other data sources. In the first year, 92 signals have been identified, all of which have been assessed: 12 of these required no further action; 44 have led to labelling changes; eight have moved to referral evaluation with restriction of use for codeine and suspension for MA (HES); there was one update to Risk Management Plan (RMP) while 27 assessments are ongoing. The PRAC has also been involved in 374 assessments which included a number of Post Authorisation Safety Studies (PASS).

In respect of prompt responses and benefit risk recommendations, firstly the PRAC recognises the enormous importance of binding outcomes on referrals ensuring a harmonised approach EU wide. The second aspect is the adherence to timeframes. Thirdly, the Patient Safety Update Report (PSUR) is recognised as a benefit-risk decision making tool.

With regard to PRAC transparency, there are very clear timelines as to when the PRAC meeting highlights and the PRAC minutes will be published which allows all stakeholders access to meeting information the same week of the meeting.

It was noted that while referrals can take between 2 to 8 months to complete, fees are still to be agreed with the EU which means that Member States are currently doing the work free of charge which is not sustainable.

The PRAC has had a very challenging first year and will continue to focus on rigorous science, risk being proportionate to decision-making and relevance to public health. Dr. Spooner was thanked for her overview and complimented for her contribution to date on the PRAC.

7. Committees

7.1 Audit Committee – 18/12/13

The Chairperson of the Audit Committee provided a brief update of the meeting held on 18 December 2013. The budgets for 2014 were reviewed in detail including IT maintenance and capital spend, revenue, rebranding costs, and medical devices costs. It was noted that the Audit Committee had reviewed the tender applications for the Internal Auditor role from 2014 to 2016 inclusive and recommended to the Board that BDO be the selected candidate as it achieved the highest scoring following the tender process. The Audit Committee had also considered the IMB investment strategy for 2014 and recommended to the Board that the IMB as a government organisation continue to invest with Irish Institutions.

7.2 Advisory Committee Human Medicines (ACHM) – 5/12/13

The Chairperson of the ACHM provided an overview of the meeting held on 5 December 2013. The main matters discussed included: Access to unauthorised medicines, the successful implementation of the interchangeable medicines procedure and the review of product information changes for an emergency contraceptive product. The quarterly updates from the Herbal Medicines Subcommittee and the Clinical Trials Subcommittee were presented and an update provided on European referrals and Direct Healthcare Professional Communications (DHPCs).

7.3 Advisory Committee for Medical Devices (ACMD) – 23/10/13

The Chairperson of the ACMD provided an overview of the meeting held on 23 October 2013. The main matters discussed included: Hospira, the NSAI surveillance audit update, the IMB contribution to the European Presidency and developments at a European level in the medical devices arena. An update was provided on the number of safety notices and medical device alerts issued.

7.4 Advisory Committee Veterinary Medicines ACVM) - 9/10/13

The Chairperson of the ACVM provided an overview of the meeting held on 9 October 2013. The main matters discussed included: Reconsideration of the IMB policy on the supply of certain veterinary vaccines for cattle which is to remain as is and the draft Pharmacovigilance Report for 2012 including all serious adverse events (SAEs). A peer review was assessed and an update was provided on European referrals.

8. IBTS Report 2012

The Board approved the above report for submission to the Minister for Health.

9. Board Appointments

It was noted that the Department of Health and the Department of Agriculture, Food and the Marine are in discussion on the matter of future IMB Board appointments as the terms of office of a number of Board members will expire at the end of 2013.

10. Financial

10.1 Budgets 2014

Having made a thorough review of the Budgets for 2014 at the Audit Committee meeting, the budgets were recommended to the Board for approval and adopted.

10.2 Management Accounts

The management accounts for August, September and October 2013 were noted by the members.

11. Licensing Activities

Tables of Licenses from 20/9/13 to 9/12/13

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

12. Proposed Board Meeting Dates 2014

The Board noted the proposed meeting dates for 2014. It was agreed that another date be proposed for the June 2014 meeting.

13. AOB

There was nothing to report.