IRISH MEDICINES BOARD

BOARD MEETING REPORT – 26 SEPTEMBER 2012

1. Declarations of Interest

There were no conflicts of interest declared.

2. New Board Member

It was noted that Dr. Elizabeth Keane, Director of Public Health, HSE South has been appointed to the Board to fill the position vacated by Ms. Windle.

3. Chief Executive – Board Evaluation Committee

It was noted that a meeting of the Board Evaluation Committee with regard to the performance of the Chief Executive had taken place.

4. Risk Management

It was noted that the Risk Register is reviewed regularly by the Management Committee. It will be brought to the next meeting of the Audit Committee prior to submission at Board.

5. IMB Updates (such as changes to legislation, Competencies, Code of Conduct)

The publication of the Statutory Instruments (S.I.s) named below was noted by the Board:

- S.I. No 272 of 2012 Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2012
- S.I. No 273 of 2012 Medicinal Products (Control of Manufacture) (Amendment) Regulations 2012
- S.I. No 274 of 2012 Medicinal Products (Control of Wholesale Distribution) (Amendment) Regulations 2012
- S.I. No. 262 of 2012 European Communities (Animal Remedies (Amendment) Regulations 2012
- S.I. No. 263 of 2012 European Communities (Control Of Animal Remedies And Their Residues) (Amendment) Regulations 2012

6. Chief Executive's Report

The Chief Executive highlighted a number of points from his report including the fact that the revised IMB staffing proposal will be submitted to the DoH in due course. An overview was provided of the recent meeting between the newly appointed Secretary General of the Dept. of Health, the Chairman and the Chief Executive. The Board was informed that the Secretary General was made aware of the IMB submission with regard to the Dallí medical devices action plan, the stated departmental support for future medical devices fees and the Health (Pricing and Supply of Medical Goods) Bill 2012. It was noted that the IMB would be providing senior scientific and some administrative staff support to the DoH during the Irish Presidency of the EU.

The Board was informed of the recent briefing meeting in Strasbourg between representatives of the IMB and Irish MEPs.

With regard to the Irish language judicial review, it was noted that preparation of a supplemental affidavit is ongoing.

It was noted that no appointments had been made to date for the vacancies on the Scientific Advisory Committees. The Board was informed of the IT & Change Management Director's recent visit to China as part of Minister Reilly's delegation. It was noted that Dr. Almath Spooner had been appointed as Vice-Chair of the Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicines Agency (EMA) for a three year period which is a great personal honour and an honour for the organisation.

The Board was updated on a briefing meeting requested by the IMB with the Oireachtas Joint Committee on Health and Children, to be attended by the Chief Executive and the Director for Human Products Authorisation and Registration on Thursday 27 September, to provide an outline of the activities of the organisation.

7. Falsified Medicines Directive

Ms. Anne Hayes, Inspection Manager, provided an overview of the Falsified Medicines Directive 2011/62/EU, focussing on the IMB remit in relation to the four Directive pillars of: safety features, supply chain actors, active substances and internet sales. A concern was raised in relation to the Active Pharmaceutical Ingredient (API) certifications required of third countries for sale of their products in Europe by July 2013, as it appears that very few third countries or manufacturing sites will be in compliance by then.

8. Proposed Revision to Declaration of Interest Form

The proposed revisions to the Declaration of Interest Form signed on an annual basis by all Board and Committee members and external experts were noted and approved.

9. Committees

9.1 Advisory Committee Human Medicines – 26/09/12

The Chairperson of the ACHM provided a brief overview of the matters discussed in the meeting held earlier that day.

In relation to Domperidone it was noted that the current status has been maintained.

It was noted that the ACHM was informed that new recommendations for the management of acute paracetamol overdose, with acetylcysteine were implemented by the UK MHRA in early September. These recommendations have resulted in substantial changes to the product information including the indications and posology sections. The IMB is to meet with concerned stakeholders in Ireland to discuss the matter further.

The issue of alcohol in herbal and conventional medicines for children under 12 and adolescents was discussed.

The ACHM was also updated on the recommendation from the Subcommittee in relation to the restriction of the use of Echinacea in children under 12 based on a lack of scientific data to support its use and the rare but potentially serious adverse reactions. It was noted that the EMA's Committee on Herbal Medicinal Products (HMPC) also supports this position.

10. Accommodation

Following on from the decision at the Board meeting of 28 June it was noted that the building work was proceeding as agreed. A timeline of the proposed building works had been circulated to all neighbours, following consultation. The work is due to start on 8 October with the establishment of the works site office in the interim.

11. Financial

The management accounts for June, July and August 2012 were noted by the members.

12. Licensing Activities

Tables of Licenses from the 22/06/12 to the 14/09/12

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

13. Board Performance Evaluation

The Chairman circulated a questionnaire in relation to the evaluation of Board performance requesting that each member complete it and returns to him in confidence.