IRISH MEDICINES BOARD

BOARD MEETING REPORT – 6 DECEMBER 2012

1. Declarations of Interest

There were no conflicts of interest declared.

2. Welcome New Board Member

The Chairman welcomed Dr. Elizabeth Keane to the meeting as a new Board member.

3. Risk Management

The Risk Register was reviewed by the Audit Committee at the most recent meeting and was brought to the Board for information. The Board noted that the updates to the risk register are in the areas of the ongoing construction works, pensions and fee income. It was noted that the IMB employs a robust system of risk management.

4. Chief Executive's Report

The Chief Executive highlighted a number of points from his report including the fact that the IMB staffing proposal for 2013-2014 has been submitted to the Department of Health, the significant progress made with the Scientific Animal Protection project to date, the IMB role with regard to the Dallí medical devices action plan. A brief overview was provided on the possible role the Food and Veterinary Office (FVO) in relation to the action plan.

The Board was updated on the Health (Pricing and Supply of Medical Goods) Bill 2012 and the importance of agreeing a priority list of products. It was noted that the IMB would be providing support to the DoH during the Irish Presidency of the EU.

The Board noted the issues in relation to the implementation of the Falsified Medicines Directive and the potential impact right across Europe on the availability of active pharmaceutical ingredients (APIs) required for manufacturing medicinal products. The implications for product supply and potential shortages were highlighted.

5. Service Plan

The IMB Service Plan 2013 was noted by the Board.

6. Department of Health Medicines Policy

The Department of Health's Chief Pharmacist presented an overview of the *Future Health* policy which aims to support an integrated care model from prevention, to self-care, to primary care, to acute care and better management of chronic diseases through self-care and primary care.

With regard to the reclassification of medicines a number of matters were considered such as: expanding the prescribing rights of health professionals, expanding the role of the pharmacist and reclassifying medicines from prescription control to over the counter (OTC).

Some comments were made about responsibility for adverse event reporting as the prescribing model is expanded, and it was emphasised that Ireland should continue to maintain its independence where possible in making classification decisions.

With regard to the work of the IMB Consultative Panel on the Legal Supply Classification of Medicines on which the Department of Health is represented, it was noted that the IMB is in the process of gathering all national stakeholder views on the subject. It was also noted that the IMB in collaboration with RCSI has commissioned a research project on medicines deregulation to identify, appraise, select and synthesise all high quality research evidence that exists in the literature and elsewhere.

7. Committees

7.1 Audit Committee

The Chairperson of the Audit Committee provided a brief overview of the matters discussed at the most recent meeting including: the risk register as outlined above and the 2013 Budgets.

It was noted that the Audit Committee had reviewed the process for determining the budgets for the following year and the budgets themselves in detail. It was noted that fee income is projected as being lower in 2013 than in 2012 primarily due to a predicted decrease in human medicines applications.

The budgets reflect the additional legislative requirements arising from new competencies for which there is as yet no funding such as falsified medicines and pharmacovigilance. Based on their review, the Audit Committee had professed itself satisfied with the budgets.

7.2 Advisory Committee Human Medicines

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

It was noted that the ACHM had been informed about a national action that had been taken recently by the public health authorities in Finland not to recommend the flu vaccine Fluarix to those under 65. This data had been reviewed in the EU under a referral procedure to the CHMP (the scientific body of the EMA) which concluded that the data was hypothesis generating only and that no regulatory action was deemed necessary.

The ACHM was also updated on a recent referral commenced at EMA in relation to cardiovascular risks associated with diclofenac. This review should be complete in April 2013.

A further EMA review of codeine-containing medicines for the treatment of pain in children was noted. The review will be completed in April 2013 and the committee thought it important that healthcare professionals are informed of the outcome of both reviews.

7.3 Advisory Committee Medical Devices (ACVM) – 23/10/12

The Chairman of the ACMD provided an update on the key items discussed at the meeting including: the PIP breast implants and metal on metal implants in relation to which IMB representatives attended the Joint Oireachtas Committee on Health and Children to discuss the Depuy recall in July 2012.

It was noted that the ACMD had been provided with an update on the IMB's progress with the implementation of the Dallí Joint Plan for immediate action.

7.4 Advisory Committee for Veterinary Medicines (ACVM) – 17/10/12

The Chairman of the ACVM provided an update on the main items discussed at the meeting: including a Committee peer review of an assessment of a variation to the withdrawal period for a flukicidal product containing triclabendazole in cattle.

The ACVM was also provided with an update on the availability of fluke treatments for dairy cows intended to produce milk for human consumption.

8. Accommodation

A brief update on the work to date was provided. It was noted that the building work is progressing as planned. Regular communications are issuing to staff and neighbours.

9. IMB Annual Report on IBTS 2011

The Board noted the contents of the report.

10. Financial

As outlined above, the Audit Committee recommended that the Budgets for 2013 be adopted and the Board adopted the budgets.

The management accounts for September and October 2012 were noted by the Board.

11. Licensing Activities

Tables of Licenses from the 21/9/12 to the 23/11/12

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