IRISH MEDICINES BOARD

BOARD MEETING REPORT – 22 MAY 2013

1. Declarations of Interest

There were no conflicts of interest declared.

2. Risk Management

The Risk Register was approved by the members.

3. Chief Executive's Report

The Chief Executive highlighted a number of points from his report including an overview of the IMB Management Review Day held in April.

It was noted that the European Presidency has taken up considerable resources organisation-wide particularly in the area of medical devices. With regard to the Health Pricing Supply Bill, it was noted that the IMB is preparing the relevant lists.

In relation to the Hygeia sheep dip legal case which has been ongoing for a number of years, it was noted that the Supreme Court had ruled in favour of the company and the matter had been the subject of successful mediation.

4. Hospira

The Board was updated in relation to quality issues with Hospira pumps which first came to light in February 2013. The IMB is taking a lead role in Europe on the matter as the authorised representative is based in Sligo. It has been agreed with the company that the pumps in Irish hospitals will be removed free of charge and replaced with an alternative approved pump.

5. TSE Verification Report

It was noted that European Council Regulation 722/2012 concerning devices containing tissues of animal origin (posing a risk of transmissible spongiform encephalothopy) will replace Directive 2003/32/EC. Under the Regulation, Member States must verify the competence of notified bodies they have designated to conformity assess devices containing tissues of animal origin.

Following a comprehensive review of the relevant National Standards Authority of Ireland (NSAI) documentation in December 2012 by the IMB and IMB assessors subsequently attending the NSAI site, it was agreed that the IMB verify NSAI as a notified body for medical and active implantable devices utilising tissues of animal origin under Regulation 722/2012 with certain conditions.

6. Addendum to Board Policy on Antiparasitic Products for Companion Animals

The Board approved the contents of the addendum.

7. Advisory Committees Updates

7.1 Advisory Committee for Human Medicines – 22 May 2013

The Chairperson of the ACHM provided a brief update to the Board on matters discussed at the meeting including products reviewed at the EMA Pharmacovigilance Risk Assessment Committee (PRAC): Protelos, Diane, codeine containing medicines for children under 12, diclofenac and starch containing medicines for critically ill patients. It was noted that omeprazole and esomeprazole were recommended for switching to supply 'over-the-counter' (without prescription). The work of the Clinical Trials and the Herbal Medicines Subcommittees for Q2 was reviewed.

7.2 Audit Committee – 22 May 2013

The Chairperson of the Audit Committee provided a brief update of the meeting held on 22 May including the report from the Internal Auditor DFK for 2012 which stated that there were satisfactory systems and controls in place in the organisation. The Director of Finance and Corporate Affairs and her staff were complimented on the results.

7.3 Advisory Committee for Veterinary Medicines – 15 May 2013

The Chairperson of the ACVM provided a brief update to the Board on matters discussed at the meeting including a peer review of the assessment of a pour-on solution for horses and an update on the request from an applicant company for a change in the approved method of supply of a spot on product. It was also noted that following the request to strengthen the warning in relation to the adverse reactions associated with Cydectin when used following treatment with a footrot vaccine, the company had agreed to amend the labelling and communicate the information to users.

7.4 Advisory Committee Medical Devices – 30 March 2013

The Chairperson of the ACMD provided a brief update to the Board on matters discussed at the meeting including: Hospira, upcoming medical devices legislation including the Dallí requirements, an overview of the European Council Working Party meetings on pharmaceuticals and medical devices held under the Irish Presidency, an update on the recent Competent Authority for Medical Devices meetings held in Dublin, and vigilance activities.

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. It is anticipated that the handover date will take place in July when the Veterinary Sciences Department and the Human Products Monitoring Department will relocate to their new accommodation.

9. Financial

The management accounts for March and April 2013 were noted by the members.

On the advice of the Audit Committee, it was recommended that the Board adopt the Internal Controls 2012 document and the audited Financial Statements for the year ended 31 December 2012. The Board approved both these proposals.

10. Licensing Activities

Tables of Licences from 22/03/13 to 10/05/13

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