IRISH MEDICINES BOARD

BOARD MEETING REPORT – 23 APRIL 2014

1. Declarations of Interest

There were no conflicts of interest declared.

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

The Board reviewed and approved the terms of reference for the Committee for Scientific Animal Protection (SAP) Appeals and the SAP Guide to Refusals and Appeals under S.I. no. 543 of 2012.

3. Chief Executive's Report

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

The Board was informed that the new name and brand – the Health Products Regulatory Authority (HPRA) – would be a launched in early July.

It was noted that the new multi-functional HR IT system is currently being tested and will be integrated fully throughout the organisation in May 2014.

The Board noted that the EU Food and Veterinary Office (FVO) findings in relation to the IMB audit of the NSAI in December 2013 had been complimentary of IMB processes. The Commission is now using the IMB run Central European Submission Portal (CESP) system to facilitate the work of the FVO which the IMB is providing free of charge.

The Board noted that the interchangeable products lists project is progressing well and that without any additional funding or resource the IMB is managing to surpass Department of Health expectations in this area which was complimented by the Board.

The IMB continues to be an active participant in the International Coalition of Medicinal Regulatory Authorities (IMCRA) and is leading discussions in a number of areas such as terms of reference for the IMCRA and its Management Committee. It was also noted that the IMB is now represented at Board level on the IMDRF – the International Medical Devices Regulatory Forum.

4. IMB BEMA III Assessment Outcome

The Quality Manager provided an overview of the outcome of the IMB's Benchmarking of European Medicines Agencies (BEMA) peer assessment held in October 2013. Three European assessors reviewed the IMB based on a 36 page questionnaire. Overall, the IMB achieved a score of 4.1 out of 5 which is an excellent result and demonstrates continued improvement since the last assessment in 2010 when the organisation scored 3.5 out of 5. The IMB nominated three best practices in

relation to the establishment of the Project Management Office, the success of the Leadership and Development Programme which has been certified by the Irish Further Education and Training body, and the ongoing contribution of the organisation to the European network. The European assessors accepted these three and also nominated a fourth best practice; the link between the individual performance management plans, department plans and the IMB Strategic Plan. Some opportunities for improvement were also identified.

The Board commended the Quality Manager and her team for the considerable work to date in this area.

5. Board Appointments in 2014

It was noted that since the expiration of the terms of a number of Board members on 31 December 2013 that five Board members only remained. The Minister for Health is currently reviewing a list of names for the unfilled four positions.

6. Financial

The Management Accounts were noted and approved and the Board agreed to continue to support the education and outreach projects of the National Concert Hall. The *Surrounding Sounds* project is run for autistic children and the *Kids Classics* Programme brings interactive music workshops to each of the three main children's hospitals.

7. Licensing Activities

Tables of licenses from 21/02/14 to the 11/03/14

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

8. Board Meeting Dates 2014

The Board noted the meeting dates for 2014.

9. Centre for Regulatory Excellence

An overview was provided of the proposal to set up a virtual centre of scientific/regulatory excellence with collaboration from all stakeholders including academia, the pharmaceutical industry, the IMB, Science Foundation Ireland, the Health Research Board, the IDA and Enterprise Ireland. A similar initiative is already underway in the US with the FDA collaborating. A meeting to garner the initial views of stakeholders is to take place in May.