



IRISH MEDICINES BOARD

BOARD MEETING REPORT – 27 MARCH 2013

1. Declarations of Interest

There were no conflicts of interest declared.

2. Chief Executive's Report

The Chief Executive highlighted a number of points from his report including an overview of the proposed changes under Croke Park II pay proposals to be finalised later in the year.

It was noted that the meetings chaired by the IMB as part of the European Presidency are proceeding well, that the IMB is due to meet with Minister White to provide an overview of its role and that the judicial review in relation to the Irish language has been resolved satisfactorily. The CESP project, the centralised European IT portal developed by the IMB, is progressing well and the new disaster recovery site using Revenue systems is underway at St. John's Road. With regard to the generic substitution project, it was noted that legislation is almost finalised. The Board noted the successful conclusion of an archive tender and the future commencement of a large scanning project to reduce the amount of IMB files in storage. It was also noted that the Chairman of the Consultative Panel on the Legal Classification of Medicines, Colm Gaynor, has written an outcome paper and circulated it to the panel members for comment. The responses are currently being collated by the IMB.

In relation to the Pharmacovigilance Risk Assessment Committee (PRAC) at the European Medicines Agency, fees have not yet been agreed for the significant work required by the rapporteur and the co-rapporteur on any referred product and the matter is under review at Commission level. This issue will affect IMB income in the short term as the earliest date for the introduction of these fees is likely to be 2014.

The Board was briefed on an issue with certain Hospira pumps which are used in two Irish hospitals.

3. Update on Scientific Animal Protection Project

A brief overview of the 'protection of animals used for scientific purposes' project was provided. It was noted that the Statutory Instrument appointing the IMB as the Competent Authority in this area was implemented on 1 January 2013. The specific staff numbers approved for the project by the Department of Health have been recruited and licences are being granted since early 2013. It was noted that it is anticipated that there will be a 40 day or less approval process for the majority of project applications. Relevant documents, including application forms, are available on the IMB website. The appeals procedure is to be published in due course.

The Board complimented the Veterinary Sciences Director and his staff on the work to date.

4. Corporate Communications Strategy 2013-2015

An overview of the Corporate Communications Strategy 2013-2015 was presented to the Board under the headings: communications objectives, target audiences, core communications pillars/channels and communications activities over the time period.

The IMB is to focus on an incremental approach to building on existing stakeholder communications activity across the organisation.

It was noted that the work on rebranding the IMB to the new approved name, the Health Products Regulatory Authority (HPRA), is well underway. The new website is planned to go live with the new name during 2014.

Having considered the above, the Board approved the adoption of the Corporate Communications Strategy 2013-2015 which is intended to deliver clear, relevant and timely communications to IMB core audiences.

5. Advisory Committee Medical Devices (ACDM) – 25 January 2013

The Chairperson of the ACMD provided a brief update to the Board on matters discussed at the meeting including:

- Surgical mesh products.
- An update on the PIP breast implant situation.
- The Commissioner Dallí Action Plan.
- An update to the European medical devices regulatory framework.
- An update in relation to the Irish Presidency of the European Council.
- IMB statistics in the medical devices area for 2012.

6. Advisory Committee Human Medicines (ACHM) – 6 February 2013

The Chairperson of the ACHM provided a brief update to the Board on matters discussed at the meeting including:

- The appointment of 2 new Committee members, Professor Tom Fahey, Professor of General Practice at the RCSI and Dr. Brian O'Connell, Clinical Microbiologist at St James Hospital, Dublin.
- Information in relation to the recommendation by PRAC to suspend the marketing authorisation for Tredaptive.
- Information about the requested Combined Oral Contraceptives referral by France although no new safety data is available.
- A new initiative on use of the IMB online adverse reaction report form.
- The IMB Drug Safety Newsletter for Continuing Professional Development purposes.
- An initiative to facilitate AR and quality defect reporting through a national incident management system for pharmacists.

7. Advisory Committee for Veterinary Medicines (ACVM) – 20 February 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 spot-on solutions for dogs and cats, and a request from an applicant company for a change in the approved method of supply of a spot-on-product from Prescription Only Medicine Exempt (POM (E)) to Licensed Merchant (LM). It was agreed that a working group be established to review the application under the current IMB policy to determine if there are grounds to update the policy based on the evidence provided. A request was also considered to strengthen the warning in relation to the adverse reactions associated with a product when used following treatment with a footrot vaccine. The matter was considered and while the number of adverse events reported is extremely

low it was agreed to approach the company to discuss the matter in relation to a labelling or an educational solution.

8. Accommodation

A brief update on the work to date was provided. It was noted that the building work is progressing as planned. While there have been a number of unexpected issues to deal with, all have been resolved. Regular communications are issuing to staff and neighbours.

It was also noted that intruders had entered the premises on the third floor via the scaffolding on the night of 30 January. The IMB intruder alarm had worked as programmed, the IMB security firm and the Gardaí responded extremely promptly and only a small sum of money and a number of mobile phone devices were removed from the premises. Onsite security has subsequently been upgraded and physical deterrent measures increased on the building works as a result.

9. Financial

The management accounts for December 2012, January and February 2013 were noted by the members.

10. Licensing Activities

Tables of Licences from 18/01/13 to the 15/03/13

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

11. Proposed Board Meeting Dates 2013

The Board noted the proposed meeting dates for 2013.

It was agreed to reschedule the 27 June meeting to 4 July 2013.

12. AOB - Corporate Governance

It was noted that the Department of Health is organising a second symposium on governance for 11 April 2013 to be attended by the chairs and CEOs of bodies under the aegis of the department with a view to establishing a Standing Committee.