

BOARD MEETING REPORT - 25 JANUARY 2012

1. **Declarations of Interest**

There were no conflicts of interest declared.

2. **New Board Member**

In relation to the appointment of a new Board member to replace the recently vacated position, it was noted that a new system has been instituted, whereby membership of the IMB Board is to be open for public application on the Public Appointments Service website in due course; for selection by the Dept. of Health.

3. **Protection of Animals Directive – letter from Minister**

The letter from the Minister for Health designating the IMB as the National Competent Authority (NCA) for the Protection of Animals Directive 2010/63/EU was noted by the Board.

4. **Declaration of Interest**

With regard to the publication of Board Declaration of Interest (DoI) forms as agreed at the Board meeting of 24 November 2011, it was approved that a line listing for each member based on their 2012 DoI form submission would be prepared, reviewed by each member and then collated for publication on the internet.

5. **Risk Management**

It was noted that risk management is to be reviewed on a quarterly basis. The Risk Register has been reviewed and updated by Management, is to be reviewed at the upcoming Audit Committee meeting in March 2012 and will subsequently be submitted to the Board for approval.

6. **Chief Executive's Report**

The Chief Executive highlighted a number of points from his report among them the findings from the internal audit completed in November 2011 in relation to Corporate Governance which was very complimentary to the IMB.

With regard to the staffing strategy submitted by the IMB to the Dept. of Health it was noted that it has the full imprimatur of the Dept. The Assistant Secretary with responsibility for HR in the Dept. of Health is to meet with the Dept. of Public Expenditure and Reform to progress the matter.

Regarding the IMB pension which was raised at the recent annual meeting with the Secretary General of the Dept. of Health, it was noted that a follow up meeting with the Assistant Secretary with responsibility for HR in the Dept. of Health has been arranged for Friday 27 January.

In relation to the IMB policy circulated to wholesalers and retailers on the 28 December last with regard to traditional herbal medicinal products, it was noted that it is taking considerable time throughout Europe for applicants to submit applications for registration. It was noted that the IMB figures are in line with the rest of Europe. The majority of products have been on the market for the last 30 or 40 years and any health risk that arise with individual products are always dealt with immediately.

With regard to the first meeting of the Consultative Panel on the Legal Supply Classification in December, the members gained an understanding of the requirements and the terms of reference of the Panel. The meetings will be very useful in informing the IMB position. The Dept. of Health and the Pharmaceutical Society of Ireland are to make presentations at the next meeting.

Regarding the judicial review in relation to the Irish language, it was noted that the Dept. of Health has signed a Statutory Instrument interpreting EU Directive 2001/83/EC (as amended), which requires that medicines packaging and labelling and leaflets can be in the language or languages of the country, which in Ireland means English or English and Irish.

In relation to the Enforcement Review, it was noted that the main objective of the project is to devise an updated Enforcement Strategy for 2012/2015. Consultation is taking place with all relevant stakeholders from staff to industry and other relevant bodies in Ireland and internationally including Denmark, the UK, Canada and Australia who have a similar public health remit.

With regard to the BT Young Scientists' Exhibition, which the Chairman had attended, it was noted that over 40 staff had participated in the event and feedback had been excellent from the more than 8,000 visitors to the stand.

The Chief Executive highlighted ongoing consideration in relation to future patient engagement initiatives, and a paper will be presented to a future Board meeting.

7. Publication of Board Minutes

Having reviewed the reports of the Board meetings of 24 November and 9 December 2011, the members were in agreement that the format was suitable for publication.

8. Committees

8.1 Advisory Committee for Human Medicines (ACHM) – 24/01/12

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

It was noted that the ACHM currently has two vacant positions which will be filled by nominations from the Minister for Health through the Public Appointments Service in due course.

In relation to Clinical Trials, a reduction in the overall number of trials ongoing in Ireland has been noted. There is however a high level of cancer trials ongoing due in part to the effectiveness of the ICORG network. The IMB is to discuss with the National Director Clinical Strategy and Programmes in the HSE, to explore if a similar network model can be rolled out in other medical fields.

9. Financial

The management accounts for October, November and December 2011 were noted by the members.

10. Licensing Activities

Tables of Licenses from 18/11/11 to 13/01/12.

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

11. Regulatory work outside of Europe.

It was noted that there may be opportunities for fee paying work outside of Europe e.g. China and the Middle East. In respect of such opportunities the IMB signed an Agreement relating to inspections of pharmaceutical manufacturers with the Egyptian Ministry of Health, although due to the political situation have not yet carried out any such inspections.

12. Contract for the Chief Executive

Following a detailed review and assessment process, the Board agreed that the Chief Executive's contract due to end on 8 December 2012 be renewed for a further five year period to 8 December 2017.