**Agenda for the Irish Medicines Board (IMB) Information Day on the implementation of the new Pharmacovigilance legislation**

Date: 2nd December 2011

Location: The Crowne Plaza Hotel, Northwood Park, Santry

Time: Registration will take place from 8.30am to 9am.

**Session 1: Chairperson – Dr. Joan Gilvarry, IMB**

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09.00 – 09.10 Welcome and introduction

*Mr. Pat O’Mahony, CEO; IMB*

09.10 – 09.45 New Pharmacovigilance legislation to promote and protect public health.

*Dr. Peter Arlett, EMA*

09.45 – 10.15 Implementation of the new Pharmacovigilance legislation: IMB and Joint EMA–Member State Project Planning. (Good Vigilance Practice and EC Implementing Measures).

*Dr. Almath Spooner, IMB*

10.15 – 10.30 Q&A session

10.30 – 11.00 Tea/Coffee

11.00 – 11.15 Requirements for systems for the performance of pharmacovigilance activities by Marketing Authorisation Holders, including the content and maintenance of the pharmacovigilance system master file.

*Ms. Sinead Curran and Ms. Majella Quinn, IMB*

11.15 – 11.45 Changes to Adverse Reaction reporting requirements, including expanded scope of reporting, format and content of electronic transmission of adverse reaction reports, revised arrangements for report submission and monitoring of data quality in EudraVigilance

*Ms. Niamh Arthur, IMB*

11.45 – 12.15 Signal Detection Activities including Direct Patient Reporting.

*Mr. Mick Foy, MHRA*

12.15 – 12.30 Q&A session

12.30 – 13.30 Lunch break

**Session 2: Chairperson – Ms. Marita Kinsella, DoHC**

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13.30 – 14.15 Benefit-Risk Evaluation and Pharmacovigilance Planning - changes to Periodic Safety Update Reports, Risk Management Plans and Signal Management.

*Dr. Almath Spooner, IMB*

14.15 – 14.30 Post authorization safety studies (format and content of the protocol, abstract and study report)

*Dr. Yvonne Buggy, IMB*

14.30 – 14.45 Risk minimization/Educational Materials (IMB submission requirements)

*Dr. Eleanor Carey, IMB*

14.45 – 15.00 Q&A session

15.00 – 15.30 Key concepts on Communication/Transparency (i.e. Coordination of safety announcements, Public hearings, Transparency, Web-portal)

*Dr. Caitriona Fisher, IMB*

15.30 – 16.15 Information to Patients- Communication and Transparency

*Mr. Francois Houyez, Eurordis*

16.15 – 16.30 Q&A session, Key messages and Final Conclusions.

16.30 Close of meeting