

IMB Pharmacovigilance Meeting
7th November 2008
Crowne Plaza Hotel, Northwood Park, Santry, Dublin 9

Agenda

- 09.00** Registration
- 09.30** Opening Address
Dr. Joan Gilvarry (Chair)
Director of Human Medicines, IMB
- 09.40** Risk Management in the EU - Concept and Components
Dr. Xavier Kurz,
Principal Scientific Administrator, EMEA
- 10.20** Risk Management in Practice
Dr. Kevin Blake,
Medical Assessor, IMB
- 10.45** Discussion/Q&A
- 11.00** Tea/Coffee
- 11.30** PSUR Assessment – Practical Issues
Dr. Elaine Breslin,
Medical Assessment Manager, IMB
- 12.00** Periodic Safety Update Reports - Synchronisation and Work-Sharing
Dr. Pim van der Giesen,
Pharmacovigilance, MEB and ND PhVWP Delegate
- 12.30** Discussion/Q&A
- 12.45** Lunch
- 14.00** Opening
Ms. Niamh Arthur (Chair),
Pharmacovigilance Manager, IMB
- Surveillance-related Activities in Pharmacovigilance
Ms. Almath Spooner,
Market Surveillance Executive, IMB
- 14.15** Overview of Experience with Pharmacovigilance Inspections
Ms. Carrie Scott,
Pharmacovigilance Operations Manager, MHRA
- 14.45** Compliance Monitoring by IMB
Ms. Deirdre O'Regan,
GCP/Pharmacovigilance Inspection Manager, IMB

- 15.00** Discussion/Q&A
- 15.15** EudraVigilance/Electronic Reporting – Update on Requirements and Experience
Ms. Leigh-Anne Carney, Market Surveillance Assessor, IMB
- 15.45** Discussion/Q&A
- 16:00** Close of Meeting