

Irish Medicines Board
Pharmacovigilance Information Day

National Transposition of new EU Pharmacovigilance Legislation

Marita Kinsella
Chief Pharmacist

*Medicines, Controlled Drugs &
Pharmacy Legislation Unit*
Dec 2nd 2011



An Roinn Sláinte
DEPARTMENT OF HEALTH

Negotiation of Pharmacovigilance Legislation



- Negotiation of EU Pharmacovigilance Legislation
 - Pharmacovigilance EU legislation negotiated over 2 years
 - Pharmaceutical legislation & pharmacovigilance priority for Irl
 - DoH with experts from IMB actively participated in negotiations
 - Part of suite of new EU legislation with Falsified Medicines Directive

National Transposition of Pharmacovigilance Legislation

- National Transposition
 - Deadline for national transposition July 2012
 - Work ongoing between DoH & IMB for a number of months
 - Consultation on proposed text of national transposition legislation in Spring 2012
 - Purpose of consultation: to engage on how legislation will be transposed into Irish law (cannot amend EU policy / legislation)