HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Agenda for the Health Products Regulatory Authority (HPRA) Information Day

The Pharmacovigilance legislation: two years on

Date: 21st November 2014
Location: The Crowne Plaza Hotel, Northwood Park, Santry
Time: Registration will take place from 8am to 9am.

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

09.00 Welcome and introduction

Dr. Joan Gilvarry, HPRA

09.00 – 09.30 Pharmacovigilance Risk Assessment Committee Perspective – two years of enhanced public health protection.

Dr. Almath Spooner, HPRA

09.30 – 10.00 European Medicines Agency Update on Implementation – focus on EudraVigilance, article 57 database and operation of the new tools.

Dr. Sabine Brosch, EMA

10.00 – 10.30 HPRA perspective on practical implementation of the legislation – focus on signals, RMPs, PSURs, timetables, and product labelling updates.

Dr. Yvonne Looney, HPRA

10.30 – 11.00 Panel discussion

11.00 – 11.30 Tea/Coffee

11.30 – 11.50 Pharmacovigilance for biologics – focus on traceability

Dr. Emma Lawless, HPRA

11.50 – 12.15 RMPs for generics and established medicinal products

Dr. Ria Mahon, HPRA

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12.15–12.40 PSUR submission requirements for nationally authorized products

Dr. Eleanor Carey, HPRA

12.40-13.00 Pharmacovigilance referrals – national implementation processes

Ms. Anna Marie Coleman, HPRA

13.00 – 14.15 Lunch break

Session 2: **Chairperson – Dr. Caitríona Fisher, HPRA**

14.15 – 14.45 The Impact of Legislative Changes on National Adverse Reaction Reporting

Ms. Niamh Arthur, HPRA

14.45 – 15.00 Achieving compliance – lessons learned from Inspection

Ms. Sinead Curran, HPRA

15.00 – 15.15 Notification of withdrawn products

Dr. Jayne Crowe, HPRA

15.15 – 16.00 How have the benefits of strengthened pharmacovigilance impacted on the patient?

Mr. François Houÿez, EURORDIS

16.00 **Meeting close**