EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 February 2012
EMA/53186/2012

# Agenda – Stakeholders forum on the implementation of the new Pharmacovigilance legislation

27 February 2012, 9.00-17.00pm, room 3A

**Co-Chairpersons: June Raine and Peter Arlett**

| Time | Agenda item | Speaker |
|---|---|---|
| 08:00 – 09:00 | Registration and reimbursement arrangements | |
| 09:00 - 09:15 | Welcome and introduction | **June Raine** *Medicines and Healthcare products Regulatory Agency, UK* |
| 09:15 – 09:45 | Implementation of pharmacovigilance legislation: prioritisation of activities | **Peter Arlett** *Pharmacovigilance and Risk Management (EMA)* |
| 09:45 – 09:55 | EudraVigilance Access Policy - update | **Sarah Weatherley** *Communications and Media (EMA)* |
| 09:55 – 10:15 | PRAC nomination – update on status | **Sheila Kennedy** *Regulatory, Procedural and Committee Support (EMA)* |
| 10:15 – 11:00 | Transitional arrangements | **Florian Schmidt** *European Commission* |
| 11:00 – 11:30 | *Coffee break* | |
| 11:30 – 12:15 | Implementation of Regulation 1235/2010, Article 57(2) | **Sabine Brosch** *Pharmacovigilance and Risk Management (EMA)* |

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
**Telephone** +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
**E-mail** info@ema.europa.eu **Website** www.ema.europa.eu

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|---|---|---|
| | First wave of Good Vigilance Practice modules Discussion and feedback on: | |
| 12:15 – 12:45 | Module I: Pharmacovigilance Systems and their Quality Discussion | **Suvi Loikkanen**<br>*Finnish Medicines Agency, FI* |
| 12:45 - 13:45 | *Lunch break* | |
| 13:45 – 15:00 | First wave of Good Vigilance Practice modules Discussion and feedback on: | |
| | Module II: Pharmacovigilance System Master File Discussion | **Joanna Harper**<br>*Medicines and Healthcare products Regulatory Agency UK* |
| | Module V: Risk Management Systems Discussion | **Stella Blackburn**<br>*Pharmacovigilance and Risk Management (EMA)* |
| 15:00 - 15:15 | *Coffee break* | |
| 15:15 – 16:30 | Module VI: Individual Case Safety Reports Discussion | **Gilles Touraille**<br>*Pharmacovigilance and Risk Management (EMA)* |
| | Module VII: Periodic Safety Update Reports Discussion | **Almath Spooner**<br>*Irish Medicines Board, IE* |
| | Module VIII: Post-Authorisation Safety Studies Discussion | **Xavier Kurz**<br>*Pharmacovigilance and Risk Management (EMA)* |
| | Module IX: Signal Management Discussion | **Agnieszka Szmigiel**<br>*Pharmacovigilance and Risk Management (EMA)* |
| 16:30 – 17:00 | Conclusions | **June Raine**<br>*Medicines and Healthcare products Regulatory Agency, UK*<br><br>**Peter Arlett**<br>*Pharmacovigilance and Risk Management Sector (EMA)* |
| 17:00 | *Close of meeting* | |