EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 April 2012
EMA/49479/2012

Agenda – SME Workshop "*Focus on Pharmacovigilance*"

19 April 2012, 9.00-16.00

7, Westferry Circus, Canary Wharf, London E14 4HB

Room 2A

~ Registration and Coffee ~

8.00 - 9.00

Co-Chairpersons: June Raine and Peter Arlett

1.	Introduction	9.00 – 9.45
1.1	**Opening address and goals of the workshop** June Raine, MHRA and Chair of Pharmacovigilance Working Party, EMA	10'
1.2	**Overview of the new pharmacovigilance legislation** (including transitional arrangements) Peter Arlett, Head of Pharmacovigilance and Risk Management, EMA	35'

2.	Quality systems for pharmacovigilance, pharmacovigilance master files	9.45 – 11.05
2.1	**Quality systems for pharmacovigilance** Suvi Loikkanen, Finnish Medicines Agency	20'
2.2	**Pharmacovigilance master files** Joanna Harper, MHRA	20'

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2.	Quality systems for pharmacovigilance, pharmacovigilance master files	9.45 – 11.05
2.3	**A SME perspective on the implementation of a pharmacovigilance system** Ahmed Bouzidi, Vaxeal (representing EBE)	20’
2.4	**Questions and discussion moderated by:** Fergus Sweeney, EMA Additional panellist: Priya Bahri, EMA	20’

~ Coffee Break ~

11.05 - 11.25

3.	Reporting and signal management	11.25-12.25
3.1	**Reporting of adverse reactions** Gilles Touraille, EMA	20’
3.2	**Signal management** Agnieszka Szmigiel, EMA	20’
3.3	**Questions and discussion moderated by:** Peter Arlett, Head of Pharmacovigilance and Risk Management, EMA Additional panellist: Mick Foy, MHRA	20’

~ Lunch ~

12.30-13.30

4.	**Periodic safety update reports, risk management plans and post-authorisation safety studies**	13.30 – 15.00
4.1	**Periodic safety update reports and interface with development safety update reports and risk management plans** Almath Spooner, IMB	30’
4.2	**Risk management plans and post-authorisation safety studies** 4.2.1 Madalena Arriegas, EMA (20’) 4.2.2 Xavier Kurz, EMA (20’)	40’
4.3	**Questions and discussion moderated by SME stakeholder:** Marc Czarka (representing Europharm SMC)	20’

5.	Formats and standards for pharmacovigilance activities and electronic adverse events reporting; 'Art. 57'	15.00 – 16.00
5.1	**Formats and standards** Nick Halsey, EMA	20'
5.2	**'Article 57' and ISO standards** Paolo Alcini, EMA	20'
5.3	**Questions and discussion moderated by SME representative:** Vicki Page-Clark, ProStrakan (representing Eucope)	20'

~ Closing remarks by Co-Chairpersons ~