19 October 2011
EMA/779345/2011
Patient Health Protection

Agenda - Third Stakeholders forum on the implementation of the new Pharmacovigilance legislation

Thursday, 20 October 2011 - 09:30hrs – 16:30hrs, room 2A.

European Medicines Agency (EMA) - 7 Westferry Circus, Canary Wharf, London E14 4HB

The objectives of this third meeting are to:

- Present an update on the implementation process.
- Share the orientations related to the EMA/ Member States planning and prioritization for the implementation.
- Continue to obtain relevant feedback from a range of topics particularly relevant to stakeholders.

Co-chairpersons: **Peter Arlett/ Jytte Lyngvig**

Time	Agenda item	Speaker
09:30	Registration and reimbursement arrangements	
09:45	Welcome and introduction	**Jytte Lyngvig** *Head of the Danish Medicines Agency* **Noël Wathion** *Head of Patient Health Protection Unit (EMA)*

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Time	Agenda item	Speaker
10:00	Update on progress of implementation: • Update from EMA on planning and prioritisation. • Feedback from Informal Heads of Medicines Agencies Meeting on the implementation of the new Pharmacovigilance legislation (5th October 2011).	**Noël Wathion** *Head of Patient Health Protection Unit (EMA)* **Jytte Lyngvig** *Head of the Danish Medicines Agency*
10:30	Consultation on the implementing measures for the performance of Pharmacovigilance activities	**Dagmar Stará** *DG Health & Consumers (European Commission)*
10:45	Planning for guidance on transitional measures	**Christelle Bouygues** *Regulatory Affairs Adviser (EMA)*
11:15	*Coffee break*	
11:30	Pharmacovigilance system master file – an approach towards system simplification	**Joanna Harper** *Inspection, Enforcement and Standards Division - GPvP (MHRA)* **Fergus Sweeney** *Head of Sector Compliance and Inspections (EMA)*
12:00	Good Vigilance Practice - structure, scope and planning	**Patricia Moore** *Inspection, Enforcement and Standards Division - GCP/GPvP (MHRA)* **Priya Bahri** *Pharmacovigilance and Risk Management (EMA)*
12:30	*Lunch break*	
13:30	Commission appointments to the Pharmacovigilance Risk Assessment Committee (PRAC)	**Dagmar Stará** *DG Health & Consumers (European Commission)*
13:45	Periodic Safety Update Reports – update on Union Reference Dates list	***Almath Spooner*** *Human Products Monitoring Department (Irish Medicines Board)*

Time	Agenda item	Speaker
14:15	Access to EudraVigilance data – demonstration	**Steven Le Meur** *Pharmacovigilance and Risk Management (EMA)*
15:00	*Coffee break*	
15:15	Urgent Union procedure (including the concept of public hearings).	**Anthony Humphreys** *Head of Sector Regulatory, Procedural and Committee Support (EMA)*
15:45	Conclusions • Stakeholder forums 2012	**Jytte Lyngvig** *Head of the Danish Medicines Agency* **Peter Arlett** *Head of Sector, Pharmacovigilance and Risk Management (EMA)*
16:15	*Close of meeting*	