14 April 2011
EMA/280084/2011

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

15 April 2011 – 08:45hrs to 17:00hrs - Conference room: 3A, European Medicines Agency – 7, Westferry Circus, Canary Wharf, London E14 4HB

Chair: Noël Wathion (NW)

European Commission: Dagmar Stara (DS);

Patient Organisation Representative: Lise Murphy (LM);

Healthcare Professionals: Birgit Beger (BB), Giovanna Giocamuzzi (GG);

Industry Representatives: Barry Arnold (BA), Wendy Huisman (WH), Christelle Anquez-Traxler (CAT).

European Medicines Agency (EMA): Franck Diafouka (FD), Isabelle Moulon (IM), Fergus Sweeney (FS), Sabine Brosch (SB), Xavier Kurz (XK), Stella Blackburn (STB) Peter Arlett (PA);

Member State Representatives: Jane Ahlgvist-Rastad (JAR), Anna Toth (AT), Sarah Morgan (SM), Almath Spooner (AS), Sabine Straus (SS), June Raine (JR);

Invited experts: see the List of participants.

Item	Preliminary draft agenda	Initials	Mins
08:00 – 8:45	**Registration**		
08:45– 08:55	Welcome and introduction: objectives of the new legislation and objectives of a dialogue with stakeholders	NW	10
08:55– 09:10	Opening address: 'New pharmacovigilance legislation to promote and protect public health'	DS	15
09:10– 10:10	Stakeholders perspective: patients, healthcare		

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	professionals and industry representatives		
	1. Patient representatives	LM	20
	2. Healthcare professional representatives	BB, GG	20
	3. Industry representatives (EFPIA/EBE/EuropaBio, EGA, AESGP and Europharm SMC)	BA, WH, CAT	20
10.10 – 10.25	Discussion and feedback		15
10:25 – 10.30	Preparation for the implementation of the new legislation on pharmacovigilance	FD	5
10:30 – 10:45	Key concepts on Communication/Transparency (i.e. Coordination of safety announcements, Public hearings, Transparency, Web-portal)	IM, JAR	15
10:45– 11:15	Discussion and feedback		30
11:15– 11:30	*Coffee break*		15
11:30 – 11:40	Good Vigilance Practice: structure and principles	FS	10
11:40 – 12:05	Discussion and feedback		25
12:05 – 12:15	Minimum requirements for the quality system for the performance of pharmacovigilance activities by the Agency, Member States and Marketing Authorisation Holders and content and maintenance of the pharmacovigilance system master file kept by the marketing authorization holder (Technical contribution to EC implementing measures)	AT	10
12:15 – 12:30	Discussion and feedback		15
12:30 – 12:40	Use of internationally agreed terminology, formats and standards for the performance of pharmacovigilance activities and format and content of electronic transmission of suspected adverse reactions by Member States and Marketing Authorisation Holders (Technical contribution to EC implementing measures)	SM, SB	10
12:40 – 13:15	Discussion and feedback		35
13:15 – 14:15	*Lunch break*		60

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14:15 – 14:25	Minimum requirements for the monitoring of data included in the Eudravigilance database to determine whether there are new risks or whether risks have changed (Technical contribution to EC implementing measures)	XK, SM	10
14:25 – 15:00	Discussion and feedback		35
15:00 – 15:10	Format and content of electronic periodic safety update reports and risk management plans (Technical contribution to EC implementing measures)	AS	10
15:10 – 15:40	Discussion and feedback		30
15:40 – 15:55	*Coffee Break*		15
15:55 – 16:05	Format and content of risk management plans (Technical contribution to EC implementing measures)	STB	10
16:05 – 16:15	Format of protocols, abstracts and final study reports of the post-authorisation safety studies (Technical contribution to EC implementing measures)	SS	10
16:15 – 16:45	Discussion and feedback		30
16:45 – 17:00	Key messages and issues for future meetings by Project Coordination co-chairs	JR, PA	15
17:00	**End of the meeting**		