29 November 2012
EMA/483816/2012
Patient Health Protection

Agenda - Training session on the new pharmaceutical legislation

Thursday, 29 November 2012 - 09:00hrs – 16:30hrs, room 4B

Chair: Juan García Burgos (EMA)

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

Time	Agenda item	Speaker
09:00	Welcome and registration / Health and safety information	
1. Overview of the new legislation		
09:15	1.1 Introduction, setting the scene	Peter Arlett
	1.2 Where we are and where we are going	Franck Diafouka
	1.3 What is Good Pharmacovigilance Practice (GVP)	Priya Bahri
	1.4 The life cycle of a medicinal product	Nathalie Bere
2. Pharmacovigilance Risk Assessment Committee (PRAC)		
10:15	2.1 Mandate, composition and tasks	Roberto de Lisa
	2.2 Outcome communication following PRAC, CMDh & CHMP	Monika Benstetter
11:00	***Coffee break***	
3. Risk Management Plans (RMPs) / Post Authorisation Safety Studies (PASSs)		
11:15	3.1 RMPs; new requirements, RMP summary	Stella Blackburn
	3.2 Measuring the effectiveness of RMPs	Annalisa Rubino
	3.3 What is a PASS; format and evaluation	

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4. Adverse Drug Reaction (ADR) reporting and Signal Detection		
12:15	4.1 ADR Reporting ; requirements 4.2 Public database 4.3 Signal detection; principles and process 4.4 Medicinal products subject to additional monitoring	Victoria Newbould Georgy Genov Madalena Arriegas
13:00	***Lunch***	
5. Periodic Safety Update Reports (PSURs)		
14:00	5.1 What is a PSUR procedure & concept of benefit-risk evaluation	Rodrigo Postigo
6. Safety Referral procedures		
14:30	6.1 What is a Referral; framework & types of safety referrals 6.2 Article 107i - 'New' Urgent Union Procedure 6.3 Article 31 - Quality, safety or efficacy issues 6.4 Article 20 - Manufacturing or safety issues	Anabela Marcal Helena Matos Vanessa Seguin
15:30	***Coffee break***	
7. Impact on product information and EPAR summaries		
15:45	7.1 Package leaflet / SmPC 7.2 EPAR summaries	Claire Espinasse Daniel Glanville
16:30	***Close of meeting***	