10 June 2013
EMA/254698/2013
Patient Health Protection

Workshop on Patient Support Programmes and Market Research Programmes – Understanding the diversity of such programmes and the management of safety information

1. Introduction

The Good Vigilance Practices (GVP)-Module VI addresses the legal requirements applicable to stakeholders regarding the collection, data management and reporting of suspected adverse reactions associated with medicinal products for human use authorised in the European Union (EU).

This module also contains requirements applicable to Marketing Authorisation Holders (MAHs) for the management and reporting of safety data arising in Patient Support Programmes (PSPs) and Market Research Programmes (MRPs), whereby cases of adverse reactions occurring in those programmes should be considered as solicited reports.

Since the release of GVP-Module VI, pharmaceutical industries have raised concerns about the difficulty of implementation of those requirements. They have suggested simplifying and harmonising the reporting to competent authorities in the EU and to the USA.

There is a need to have a common understanding of the diversity of such programmes to allow informed decision making on the reporting of suspected adverse reactions.

2. Objective to be achieved

This workshop will bring together stakeholders responsible for the protection of public health and the conduct of PSPs and MRPs with the following objectives:

- Understand the spectrum of programmes that fall under the terms of PSPs and MRPs and the type of safety information which is collected in those programmes.
- Assess the optimum way of collecting safety data from PSPs and MRPs while ensuring compliance with
  - The obligations applicable to competent authorities and marketing authorisation holders set out in Directive 2001/83/EC and Regulation (EC) No 726/2004, and
  - The principles defined in ICH E2A and E2D guidelines.

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3. Meeting date

- Friday 7 June 2013, from 10:00 to 16:30, Room 3A, European Medicines Agency, London UK;

4. Invited stakeholders

- PRAC chair and Vice Chair
- EU Competent authorities members of PRAC or representatives of Project Team 1 (collection of key information on medicines) for Project 00305 – Implementation of pharmacovigilance legislation.
- EU PhV IWG representatives
- International Regulators
  - FDA (via teleconference);
  - International liaison officers at EMA from Canada and Japan.
- Pharmaceutical industry associations
- Market research organisations associations;
- Patients and Healthcare Professionals associations

5. Agenda

Co-chairs: Peter Arlett, Almath Spooner

Time	Agenda item	Speakers
09:45 – 10:00	Registration and reimbursement arrangements	
10:00 – 10:15	Welcome and introduction	• EMA, Peter Arlett
Session 1	**Management of safety data originating in Patient Support Programmes and Market Research Programmes**	
10:15 – 10:30	Overview of EU legal requirements	• EMA, Gilles Touraille
10:30 – 11:20	Current experience for safety monitoring from an EU Regulators' perspective	• PhV IWG, Anya Sookoo • PRAC, Qun-Ying Yue
Session 2	**Common understanding of Patient Support Programmes and Market Research Programmes**	
11:20 – 12:30	Spectrum of programmes falling under the terms of PSPs and MRPs and type of safety data collected	• Pharmaceutical industry associations • Market research associations
12:30– 13:30	*Lunch*	
13:30 – 14:00	Experiences from patients and healthcare professionals participating in PSPs and MRPs; involvement in collecting and reporting safety data from those programmes.	• Patients associations • Healthcare Professionals associations
14:00 – 14:45	International Regulators' perspectives in handling PSRs and MRPs	• FDA, Gerald Dal Pan • Health Canada, Chris Turner • Pharmaceuticals and Medical Devices Agency, Junko Sato
14:45– 15:00	*Coffee break*	
Session3	**Management of safety data originating in Patient Support Programmes and Market Research Programmes – Options to move forward**	
15:00 – 15:40	Current challenges from pharmaceutical industry and proposals to move forward	• Pharmaceutical industry associations • Market research associations
15:40 – 16:20	General discussion	• All
16:20 – 16:30	Conclusions	• Co-chairs
16:30	*Close of meeting*	

List of Participants

Organisation	Participants
Pharmacovigilance Risk Assessment Committee vice chair (PRAC)	Almath Spooner
Members of PRAC	Sabine Straus
	Qun-Ying Yue
Representatives from Project Team 1 (collection of key information on medicines) for Project 00305 – Implementation of pharmacovigilance legislation	Majella Quinn
	Carmela Santuccio
	María del Naranco Marcos Fernández
	Nobert Paeschke
Representatives from Pharmacovigilance Inspection Working Group (PhV IWG)	Krzysztof Szczesny
	Anya Sookoo
	Nele Matthijs
	Sinead Curran
Food and Drug Administration - Center for Drug Evaluation and Research	Gerald Dal Pan
International liaison officers at EMA from Canada	Chris Turner
International liaison officers at EMA from Japan	Junko Sato
European Generic medicines Association (EGA)	Michel Mikhail
	Veronika Bayew-Felber
	Maarten van Baelen
	Patrick Caubel
Association of the European Self-Medication Industry (AESGP)	Helmut Oberender
	Agnieszka Majcher-Dann
	Claire Allman
European biopharmaceutical enterprises (EBE)	Gro Laier
	Peter De Veene
	Birgitt Gellert
	Janet Hormbrey
European Federation of Pharmaceutical Industries and Associations (EFPIA)	Val Simmons
	Esteban Herrerro-Martinez
	Kristina Lawler

Organisation	Participants
	Andy Cochrane
	Liz Swain
Vaccines Europe (EVM)	Elodie Garric
European Association for Bio-industries (EuropaBio)	Merete Schmiegelow
	Guy Murray
	Johan Hellmer
European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)	Alexander Natz
	Dirk Lenz
British Healthcare Business Intelligence Association (BHBIA)	Paula Walker
European Pharmaceutical Market Research Association (EphMrA)	Catherine Ayland
	Bernadette Rogers
	Bob Douglas
European AIDS Treatment Group (EATG)	David Haerry
Pain Alliance Europe (PAE)	Joop Van Griensven
Global Alliance for Mental Illness Advocacy Networks (GAMIAN)	Paul Arteel
European Institute of Women's Health (EIWH)	Hildrun Sundseth
European League Against Rheumatism (EULAR)	Neil Betteridge
Pharmaceutical Group of the European Union (PGEU)	Suzete Costa
European Medicines Agency (EMA)	Peter Arlett
	Fergus Sweeney
	Sabine Brosch
	Xavier Kurz
	Ana Rodriguez Sanchez Beato
	Gilles Touraille
	Priya Bahri