4th ISoP-UMC Training Course
4th – 6th of September 2017, Panama City – Panama

Pharmacovigilance concepts and tools in Latin America

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Preliminary Programme

Introduction

The International Society of Pharmacovigilance (ISoP) and the Uppsala Monitoring Centre (UMC) have a common aim to explore the benefits and risks of medicinal products and to promote and enhance the safe and effective use of medicines. It is one of the primary objectives of ISoP and UMC to offer appropriate education and training in pharmacovigilance and to collaboratively intensify their activities in Latin America.

Aim

This three day-course is conducted with expertise from WHO-UMC and ISoP and is designed to address the practical and theoretical aspects of pharmacovigilance. Part of the training will address the safety monitoring of biotherapeutics and vaccines, and the problem of antibiotic resistance.
Target audience include regulatory agencies, hospitals, universities as well as industry professionals in all areas of pharmacovigilance and those staff members in related functions, such as clinical trials, technical product complaints, medical information, sales and marketing, regulatory affairs, legal affairs and audits.
At the end of the course, the participants are expected to understand the complexities of pharmacovigilance and to use various sources of information about risks and appropriate tools to advance better detection, monitoring, reporting and prevention to promote product safety.
Lectures, working groups and panel discussions between regulators and industry will be the main training method.

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Day 1 Monday 4th, September 2017	
08:30	*Registration*
	Chairpersons: Mario Torrero (Ministry of Health of Panama) and Sten Olsson (ISoP)
09:00-09:15 09:15-09:30	**Opening words and introduction** Introduction of ISoP: History, vision and mission and programmes *Sten Olsson (President of ISoP)* Introduction of the UMC: history, vision and mission and activities *By: Elki Sollenbring (UMC)*
Session	**Individual case safety reports (ICSR) – a basic source in pharmacovigilance - & spontaneous reporting systems (SRS) – Part I** *Chairpersons: Mario Torrero (Ministry of Health of Panama) and Sten Olsson (ISoP)*
09:30-09:50	**The WHO Programme for International Drug Monitoring** *By: Heloisa Conesa (UMC)*
09:50-10:30	**Improving reporting – developing a positive ADR reporting culture and ways to collect safety information** *By: Elki Sollenbring (UMC)*
10:30-11:00	*Coffee Break*
Session	**Individual case safety reports (ICSR) – sources of safety data & spontaneous reporting systems (SRSs) – Part II** *Chairpersons: Monica Tarapués (UMC) and Sten Olsson (ISoP)*
11:00-11:30	**Individual case safety reports (ICSR): quality of ICSR** *By: Heloisa Conesa (UMC)*
11:30-12:30	**Managing ICSRs and safety data exchange in a global PV environment** *By: Elki Sollenbring and Heloisa Conesa (UMC)*
12:30-13:30	*Lunch*
Session	**Signal detection & management – Part I** *Chairpersons: Elki Sollenbring (UMC) and Martina Vlkova (ISoP)*
13:30-15:00	**Case assessment: certainty of diagnosis, seriousness and severity, causality, expectedness** *By Monica Tarapués (UMC)*
15:00-15:30	**Signals: definition and sources** *By Monica Tarapués (UMC)*
15:30-15:45	Coffee Break
15:45-18:00	**Signal detection – small databases - workshop** *By Monica Tarapués (UMC) and Mariano Madurga (Pharmacovigilance Expert)*

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Day 2 Tuesday 5th, September 2017	
	Opening Day 2
Session	**Signal detection & management – Part 2** *Chairpersons: Elki Sollenbring (UMC) and Martina Vlkova (ISoP)*
08:30-10:00	**Experiences with signal management – did signal contribute to early detection of risks and to early decision making?** Panel discussion (regulators and industry)
10:00-10:30	**Disproportionality and statistics (overview)** *By: Mariano Madurga (Pharmacovigilance Expert)*
10:30-11:00	*Coffee Break*
Session	**Assessment of risks and benefits** *Chairpersons: Veronica Vergara (Instituto de Salud Pública de Chile) and Bruce Hugman (UMC)*
11:00- 11:30	**Pharmacovigilance systems and Risk Management Systems** *By: Martina Vlkova (ISoP)*
11:30-12:00	**Comparative benefit-to-harm assessment** *By: Mariano Madurga (Pharmacovigilance Expert)*
12:00-12:30	**Organizational management in pharmacovigilance and decision making** *By: Martina Vlkova (ISoP)*
12:30-13:30	*Lunch*
13:30-14:30	**Antibiotic resistance –Updates from REACT** *By: Arturo Quizhpe Peralta (REACT)*
Session	**Risk communication** *Chairpersons: Monica Tarapués (UMC) and Mariano Madurga (Pharmacovigilance Expert)*
14:30-15:30	**Effective communication in pharmacovigilance** *By: Paula Alvarado and Bruce Hugman (UMC)*
15:30-15:45	*Coffee Break*
15:45-17:00	**Risk communication** *By: Paula Alvarado and Bruce Hugman (UMC)*

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Day 3 Wednesday 6th, September 2017	
Session	**The broader scope of PV: vaccines, biotherapeutics** *Chairpersons: Veronica Vergara (Instituto de Salud Pública de Chile) and Heloisa Conesa (UMC)*
08:30-09:30	**Pharmacovigilance on vaccines** *By: Rebecca Chandler (UMC)*
09:30-10:30	**Safety monitoring of biotherapeutics - challenges and options** *By: Mariano Madurga (Pharmacovigilance Expert)*
10:30-11:00	*Coffee Break*
Session	**Harmonization of pharmacovigilance concepts and tools in Latin America** *Chairperson: Sten Olsson (ISoP) and Elki Sollenbring (UMC)*
11: 00–11:45	**Pharmacovigilance in Public Health Programs** *By: Sten Olsson (ISoP)*
11:45-12:30	**Pharmacovigilance indicators (PAHO)** *By: Veronica Vergara (Instituto de Salud Pública de Chile)*
12:30-13:30	*Lunch*
13:30-14:15	**Harmonization of pharmacovigilance concepts and tools in Latin America – how far are we?** *By Veronica Vergara (Instituto de Salud Pública de Chile)*
14:15-16:15	**Regulators meet industry:** Roundtable discussion about common problems and solutions
16:15-16:30	*Coffee Break*
16:30-17:00	**Concluding remarks. Joint-statement from UMC and ISoP**. *By the Chairpersons and Presenters* *Distribution of course evaluation forms* *Collection of course evaluation* *Training Certificates collection*
17:00	*End of the meeting*

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