INTERNATIONAL SOCIETY OF PHARMACOVIGILANCE

Keeping the lights green - your risk management roadmap

Training Course, 26-27 March 2009, Verona, Italy
University of Verona (Via Paradiso 6 – 37100 Verona)

Day 1: Thursday 26 March 2009

Chairpersons: Deirdre McCarthy & Brian Edwards

8.30 to 9.00 am **Registration**

9.00 - 9.10 am
Introduction Course objectives
Deirdre McCarthy, Quintiles, Ireland

9.10 - 9.50 am
How to write a risk management plan and the link with PSURs
Carol Markwell, Drug Safety Solutions, UK

9.50 - 10.30 am
Risk management and the prevention of adverse drug reactions from a regulatory and public health perspective
John McEwen, Visiting Lecturer, Department of Pharmacy, University of Canberra, Australia

10.30 - 11.00 am
Coffee-break

11.00 - 11.45 am
Perspectives on Signal Detection
Marie Lindquist, WHO

11.45 - 12.20 pm
Monitoring the effectiveness of your risk minimization measures
Brian Edwards, NDA Regulatory Science Ltd, UK

12.20 - 1.00 pm
An example from real life: a risk management plan from Celgene Italy
Roberta di Menno, Celgene, Italy

Lunch

2.00 - 2.45 pm
Practical examples of risk minimization tools
Nicholas Moore, University of Bordeaux, France

2.45 - 3.30 pm
Risk communication such as the Direct Healthcare Professional Communication
Priya Bahri, EMEA

3.30 - 4.00 pm
Coffee-break

4.00 - 5.00 pm
Interactive Tutorial - Future developments in Risk Management
Ralph Edwards, WHO

Close of Day 1

Day 2: Friday 27 March 2009

Chairpersons: Deirdre McCarthy and Brian Edwards

Welcome to Day 2

9.00 - 9.45 am
Review of examples of recent post-marketing commitments (EU and US)
John McEwen, Visiting Lecturer, Department of Pharmacy, University of Canberra, Australia

9.45 am – 11.00 am
Risk Management Planning Workshop
John McEwen, Visiting Lecturer, Department of Pharmacy, University of Canberra, Australia,
Brian Edwards, NDA Regulatory Science Ltd, UK
Eugene van Puijenbroek, Netherlands Pharmacovigilance Centre (LAREB)

11.00 - 11.30 am
Coffee-break

11.30 am - 12.15 pm
Quality Management Systems as a way of identifying and managing risk
Maria Grazia Zurlo, Pfizer, Italy

12.15 - 1.00 pm
Quality Risk Management and the QPPV
Carol Markwell, Drug Safety Solutions, UK

Lunch

2.00 - 3.30 pm
Regulatory inspections – perspectives from MHRA
Calvin Johnson, Pharmacovigilance Inspector, Medicines & Healthcare products Regulatory Agency, UK

Regulatory inspections – preparing for an inspection
Deirdre McCarthy, Quintiles, Ireland

3.30 - 4.00 pm
Coffee-break

4.00 - 4.45 pm
'When the lights turn amber – how to create a Safe System'
Brian Edwards, NDA Regulatory Science Ltd, UK

4.45 - 5.00 pm
Closing remarks - *Panel*