WORKSHOP AGENDA

Workshop on New Directions in Postmarket Surveillance of Pharmaceuticals & other Health Products: Improving Patient & Product Safety

University of Ottawa, Fauteux Hall, 57 Louis Pasteur St.
Room 147

May 28-29, 2009

Background:

Globally, there is growing awareness of the need for augmented monitoring of drug and health products' safety and efficacy, but at the same time, it is acknowledged that undue caution can significantly delay or entirely prevent patients from accessing life-saving medications. The challenge facing drug manufacturers, regulatory agencies, and prescribing professionals alike is to achieve balance between providing beneficial medications to patients who need them, and protecting patients from the serious adverse health effects sometimes caused by those medications. The emerging discipline of pharmacovigilance offers a good approach to solving problems of expediting new product approval, while maintaining rigorous safety and efficacy standards. The workshop will examine available data mining methods in pharmacovigilance and a few examples where pharmacovigilance has helped to identify safety issues of particular drugs. It will also look at new initiatives at Health Canada for health products vigilance including pharmaceuticals, biological drugs, natural health products, and medical devices.

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Day 1 – May 28, 2009 University of Ottawa, Fauteux Hall, Room 147	
Applications of Pharmacovigilance	
2:00 pm to 2:10 pm	Welcome and Opening Remarks **Nicholas Birkett, University of Ottawa**
2:10 pm to 2:45 pm	Comparison of Signal Detection Methods for Passive Pharmacovigilance **Chris Gravel, Carleton University**
2:45 pm to 3:20 pm	Mining Pharmacovigilance Data using Bayesian Logistic Regression with James-Stein Type Shrinkage Estimation **Lihua An, University of Windsor**
3:20 pm to 3:30 pm	Break
3:30 pm to 4:05 pm	Cardiovascular risks associated with anti-diabetic drugs, rosiglitazone and pioglitazone **Lorraine Lipscombe, ICES, Women's College Hospital, and University of Toronto**
4:05 pm to 4:40 pm	High Risk Pregnancy Drugs **Mark Walker/Shi Wu Wen, Ottawa Health Research Institutes (OHRI)**
4:40 pm to 4:50 pm	Summary and Agenda day 2 **Nicholas Birkett, University of Ottawa**

Day 2 – May 29, 2009 University of Ottawa, Fauteux Hall, Room 147	
Product Vigilance Transformation	
8:30 am to 9:00 am	Continental breakfast
9:00 am to 9:10 am	Welcome and Opening Remarks **Nicholas Birkett, University of Ottawa**
9:10 am to 9:40 am	Modernization of Legislation and Regulations: How Does it Support Product Vigilance? **Maurica Maher, Health Canada**
9:40 am to 10:10 am	Overview of the Health Product Vigilance Transformation Initiative **Annic Grondin, Health Canada**
10:10 am to 10:20 am	Break
10:20 am to 10:50 am	Canada Vigilance **Heather Sutcliffe, Health Canada**
10:50 am to 11:20 am	Canadian Medical Devices Sentinel Network **Lynda Laforest, Health Canada**
11:20 am to 11:50 am	Drug Safety and Effectiveness Network – What is it and Why is it Important to Pharmacovigilance in Canada? **Diane Forbes, Canadian Institutes of Health Research (CIHR)**
11:50 am to 1:05 pm	Lunch
1:05 pm to 1:10 pm	Overview of the afternoon agenda **Nicholas Birkett, University of Ottawa**
1:10 pm to 1:40 pm	US FDA Sentinel Initiative **Judy Racoosin, US FDA via videoconference**
1:40 pm to 2:10 pm	Risk Management Planning in Canada **Nashwa Irfan**, **Health Canada**
2:10 pm to 2:20 pm	Break
2:20 pm to 2:50 pm	Periodic Safety Update Reporting (PSUR) **Vicky Hogan**, **Health Canada**
2:50 pm to 3:20 pm	Medication Incidents **Margaret Zimmerman**, **Health Canada**
3:20 pm to 3:50 pm	Question Period and Discussion **Vicky Hogan**, **Health Canada (Chair)**
3:50 pm to 4:00 pm	Summary – The Future of Pharmacovigilance **Daniel Krewski, University of Ottawa**
4:00 pm	Adjournment