

## Conference

"Intervention Strategy of Health Products Agencies:  
Strengthening of co-operation and  
information and work sharing"

12 December 2008, Paris

## Agenda

9.15-10.15

### PLENARY SESSION :

Opening remarks  
Introduction

- Coordination of clinical trials assessment  
Jean Marimbert, Afssaps
- Evaluation - Inspection - Laboratory control  
Johannes Loewer, PEI

10.30-14.45

### **WORKSHOP 1 :**

Coordination of clinical trials assessment

*Moderator:*  
Xavier De Cuyper, AFMPS

### **WORKSHOP 2 :**

Evaluation - Inspection - Laboratory control

*Moderator:*  
Philippe Lechat, Afssaps  
Marie-Hélène Tissier, Afssaps  
Marc Stoltz, Afssaps

12.30 *Lunch break*

### PLENARY SESSION :

15.00-15.45

Summary Report on Workshop 1  
Chantal Bélorgey, Afssaps

15.45-16.30

Summary Report on Workshop 2  
Susanne Keitel, EDQM

16.30-16.45

**Closing remarks**  
Jean Marimbert, Afssaps

## Conference

"Intervention Strategy of Health Products Agencies:  
Strengthening of co-operation and  
information and work sharing"

12 December 2008, Paris

### WORKSHOP 1 :

#### COORDINATION OF CLINICAL TRIALS ASSESSMENT

<b>10.30-14.45</b>	<b>WORKSHOP 1 : COORDINATION OF CLINICAL TRIALS ASSESSMENT</b>	<b>MODERATOR: Xavier De Cuyper, AFMPS</b>
<b>10.30</b>	<b>Shared assessment of multinational clinical trials authorizations</b>	
10.30	1- The importance of clinical trials shared assessment. The national competent authorities' point of view	<b>Hartmut Krafft, PEI</b>
10.45	2- The clinical trials sponsors' point of view	<b>Mats Ericson, EFPIA Jacques Demotes, ECRIN</b>
11.05	3- Experience of shared assessment of Marketing Authorization Applications processes	<b>Arielle North, EMEA</b>
11.20	4- The CTFG coordination of multinational clinical trials assessment	<b>Chantal Bélorgey, Afssaps</b>
11.40	5- Progress of the work of the Clinical Evaluation Task Force (CETF) : cooperation between Competent Authorities for Clinical Evaluation of Medical Devices	<b>Wolfgang Ecker, Federal Ministry of Health, Family &amp; Youth of Austria</b>
12.00	6- Debate	<b>CO-MODERATOR: Hartmut Krafft, PEI</b>
12.30	<i>Lunch break</i>	
<b>13.45</b>	<b>Shared Assessment of safety data from clinical trials</b>	
13.45	1- Eudravigilance, what for ?	<b>Gaby Danan, EFPIA</b>
14.00	2- PSUR work-sharing experience	<b>Pim Van Der Giesen, MEB</b>
14.15	3- CFTG coordination of the assessment of safety data from clinical trials	<b>Brian Davis, MHRA</b>
14.40	4- Debate	<b>CO-MODERATOR: Brian Davis, MHRA</b>
14.50	<i>Coffee break</i>	

## Conference

"Intervention Strategy of Health Products Agencies:  
Strengthening of co-operation and  
information and work sharing"

12 December 2008, Paris

### WORKSHOP 2 :

#### EVALUATION - INSPECTION - LABORATORY CONTROL

<b>10.30-14.45</b>	<b>WORKSHOP 2 :</b> <b>EVALUATION – INSPECTION – LABORATORY CONTROL</b>	
<b>10.30-11.30</b>	<b>Evaluation</b>	<b>MODERATOR: Philippe Lechat, Afssaps</b> <b>Susanne Keitel, EDQM</b>
10.30	1- CEP certification procedure: risk management and cooperation in the evaluation between EU Member States	
10.45	2- Medical devices: a case of cooperation between EU Member States in a risk-based approach	<b>Ann O'Connor, Chair of Group COEN</b>
11.00	3- Debate	
<b>11.30</b>	<b>Laboratory Control</b>	<b>MODERATOR: Marie-Hélène Tissier, Afssaps</b>
11.30	1- Which medicines to test? Test sharing among Member States	<b>Jean-Marc Spieser, EDQM</b>
11.45	2- Cooperation in market surveillance: example of tooth-pastes contaminated with Diethylene Glycol (DEG)	<b>Catherine Desmares, Afssaps</b>
12.00	3- Debate	
<i>12.30</i>	<i>Lunch break</i>	
<b>13.45</b>	<b>Inspection</b>	<b>MODERATOR: Marc Stoltz, Afssaps</b>
13.45	1- Inspections planning at European level: strategies, criteria of choice, organisation, cooperation between Member States	<b>Emer Cooke, EMEA</b>
14.00	2- World public health alert regarding heparin: use of control and evaluation data for an effective cooperation in the inspection domain	<b>Jacques Morenas, Afssaps</b>
14.15	3- Debate	
<i>14.45</i>	<i>Coffee break</i>	