



**Twinning CARDS 2005 SR 05 SO 01:
Capacity Building of the National Medical Products Agency**

**EU Clinical Evaluation of Medicinal Products:
Main fields, Methodology, Pitfalls**

**Best Western Hotel M
Belgrade, 2nd February 2009**

Preliminary Programme of the Seminar

8.00 – 8.45 REGISTRATION

8.45 – 9.00 OPENING OF THE SEMINAR

Ministry of Health representative, ALIMS representative

9.00 – 9.15 INTRODUCTION TO THE SEMINAR

Dr Ljiljana Milosevic-Kapetanovic, former RTA, Clinical Assessor, AFSSAPS

9.15 – 9.30 SERBIAN REALITY AND EUROPEAN PERSPECTIVES

Prof Goran Jankovic, gastroenterologist, Clinical Centre of Serbia, President of the Committee for Human Medicines

9.30 – 9.50 THE CHMP ROLE AND FUNCTIONING, BENEFIT-RISK ASSESSMENT OF MEDICINAL PRODUCTS

Dr Eric Abadie, Chairman of the Committee for Medicinal Products for Human Use (CHMP), EMEA, AFSSAPS

9.50 – 10.10 EVALUATION OF BIOLOGICAL MEDICINAL PRODUCTS

Prof Jean-Hugues Trouvin, Chairman of the Biotechnological Working Party, EMEA, AFSSAPS

10.10 – 10.30 PRE-CLINICAL DOSSIER, PHARMACOKINETICS AND BIOAVAILABILITY

Dr Dominique Tremblay, Chairman of Non-Clinical Working Group, AFSSAPS/ EMEA Expert

10.30 – 10.50 CT METHODOLOGY: DESIGN, THERAPEUTIC EQUIVALENCE, NON INFERIORITY...

Prof Michel Lièvre, Chairman of the Cardiovascular Advisory Group, AFSSAPS



10.50 – 11.00 DISCUSSION

11.00 – 11.15 *Coffee Break*

11.15 – 11.35 CLINICAL EVALUATION, MAIN POINTS AND DIFFICULTIES

Dr Pierre Démolis, Head of the Pharmaco-Toxicological and Clinical Assessment Unit, AFSSAPS, Representative to CHMP, EMEA

11.35 – 11.55 INTERNAL / EXTERNAL EXPERTISE

Dr Mira Pavlovic, Scientific advice coordination at AFSSAPS, SAWP, EWP, BMWP, Vice-Chair of SAWP at the EMEA

11.55 – 12.15 SmPC and PIL

Prof Georges Hazebroucq, Professor of Clinical Pharmacy, Member of the Académie Nationale de Pharmacie

12.15 – 12.30 DISCUSSION

12.30 – 13.45 *Lunch Break*

13.45 – 14.00 INTRODUCTIONS TO THE WORKSHOPS

14.00 – 16.00 INTRODUCTIONS TO THE WORKSHOPS

WS 1 ONCOLOGY - Dr Pierre Démolis

WS 2 INFECTIOLOGY – Dr Nathalie Morgenstzejn

WS 3 DIABETES – Dr Catherine Rey-Quinio, Dr Ljiljana Milosevic-Kapetanovic

WS 4 NEUROLOGY – PSYCHIATRY- Dr Catherine Deguines

WS 5 CARDIOLOGY – Prof Michel Lièvre, Dr Mira Pavlovic

WS 6 BIOEQUIVALENCE - GENERICS – Prof Georges Hazebroucq, Dr Ridha Belaiba

16.00 – 16.30 *Coffee Break*

16.30 – 17.00 SUMMARY FROM EACH WORKSHOPS AND CONCLUSIONS

17.00 DELIVERY OF THE ATTENDANCE CERTIFICATES

