International regulatory and pharmacovigilance conference "Croatian Mark in the EU"

Tuesday, 11 November 2014

08:00 – 09:00 Registration
09:00 – 09:15 Opening
09:15 – 10:45 **HALMED one year after the EU accession:**

- ***HALMED in the EU***, Viola Macolić Šarinić (HALMED)
- ***Medicines authorisation***, Maja Lovrek (HALMED)
- ***Distribution of medicines***, Anela Kraljević (HALMED)
- ***Medical devices***, Suzana Oštarčević (HALMED)
- ***Medicines quality control***, Rajka Truban Žulj (HALMED)
- ***Pharmacovigilance***, Darko Krnić (HALMED)
- ***Meeting the needs of HALMED's users***, Jasminka Tadin (HALMED)

10:45 – 11:15 Coffee break
11:15 – 11:45 **GMP inspection**, Ana Boban (HALMED), Ljubica Hodak (HALMED)
11:45 – 12:15 **GVP inspection: HALMED's experience**, Dunja Vukić (HALMED)
12:15 – 12:45 **Novelties in GVP modules after EU accession**, Adriana Andrić (HALMED)
12:45 – 13:15 **Educational materials**, Katarina Gvozdanović (HALMED)
13:15 – 14:45 Lunch break
14:45 – 16:45 **Round table "Falsified medicines and safety features"**

19:30 – 23:00 Conference dinner

Wednesday, 12 November 2014

09:00 – 09:30 **PSUSA**, Irene Rager (EMA)
09:30 – 10:00 **SCOPE and WEB-RADR**, Mick Foy (MHRA)
10:00 – 10:30 **Pharmacovigilance: Industry perspective**, David J. Lewis (Novartis)
10:30 – 11:00 Coffee break
11:00 – 11:45 **Biosimilars: Regulatory frame**, Viola Macolić Šarinić (HALMED)
11:45 – 12:30 **Biosimilars: Pharmacovigilance and principles of extrapolation**, Ana Hidalgo-Simon (EMA)
12:30 – 13:00 **Referrals**, María Luisa García-Vaquero (AEMPS)
13:00 – Close and lunch