

# International regulatory and pharmacovigilance conference “Croatian Mark in the EU”

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## 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 **Presentation of PhV modules**, 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

09:30 – 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 – 13:30 **PSUSA**, TBC (EMA)

13:30 – 15:00 Close and lunch