FINAL

PHARMACOVIGILANCE WORKSHOP IN ZAGREB

Dialogue, explanation, clarification

Date: 1-2 October 2018
Venue: THE WESTIN ZAGREB
Kršnjavoga 1, 10 000, Zagreb, Croatia

Facilitators: Željka Škunca, AstraZeneca, Croatia
Janne Malene Kampmann, H. Lundbeck A/S, Denmark
Betina Østergaard Eriksen, Novo Nordisk A/S, Denmark

In collaboration with: HALMED & HFD

Programme

Day 1 – Monday, 1 October 2018

8.00 – 9.00	**REGISTRATION**
9.00 - 9.30	**WELCOME & SETTING THE SCENE** *Siniša Tomić, PhD, Assoc. Prof., Head of Agency* *Maja Jakševac Mikša, Doc. dr. sc., mag. pharm. Executive Director, Croatian Pharmaceutical Society* *Facilitators* *Atrium*
9.30 – 10.00	**REGULATORY UPDATE** New/upcoming EU legislation, including recent changes to EU GVP modules *Darko Krnić, HALMED*
10.00 - 10.15	**SHORT BIO-BREAK**
10.15 – 10.45	**GDPR -** influence of GDPR in PV • Implementation perspective *Wim Nauwelaerts SIDLEY AUSTIN LLP, Belgium*
10.45 – 11.00	**Regulatory Q & A** *Darko Krnić, & Wim Nauwelaerts*
11.00 - 11.30	**BREAK**

11.30 - 12.00	**RISK MANAGEMENT PLANS (RMP)** Short intro to regulatory requirements including new template and practical example of development of an RMP *Samuel Ramsden, Boehringer Ingelheim International GmbH, Germany*
12.00-12.30	**RMP FLOW** Implementation locally and the end-to-end process *Samuel Ramsden, Boehringer Ingelheim International GmbH, Germany*
12.30 - 13.30	**LUNCH**
13.30 - 13.50	**RMP CHALLENGES FOR GENERIC COMPANIES** *Tatjana Ajhler Đuretek, MD., MSc., Belupo, Croatia*
13.50-14.10	**RMP** HALMED expectations *Željana Margan Koletić, HALMED*
14.10 -14.40	**COFFEE BREAK**
14.40 – 16.10	**RMP WORKSHOP** *Facilitators (Betina, Janne & Željka)* *Darko Krnić, HALMED* *Dunja Vukić, HALMED* *Iva Galić, HALMED* *Velimir Šimičević, Servier* *Anja Kos Petrak, Marti Farm*
16.10- 17.00	**WRAP UP from workshop and highlights of the day** *Facilitators*
17.00	**GOODBYE & SEE YOU AGAIN TOMORROW**

Day 2 – Tuesday, 2 October 2018

9.00 – 9.15	**WELCOME BACK & SETTING THE SCENE** *Facilitators*
9.15 – 10.30	**RISK MINIMISATION ACTIVITIES** • Introduction to different risk minimisation activities *Anja Kos Petrak, Regulatory affairs Director, Marti Farm, Croatia* • How are risk minimisation activities effectively implemented locally? *Ivana Franić, MD, Merck Sharp & Dohme d.o.o., Croatia* • Effectiveness measurements incl. case stories with examples of how effectiveness can be measured – Industry perspective *Emanuel Lohrmann, Boehringer Ingelheim International GmbH, Germany* • Effectiveness measurements including case stories with examples of how effectiveness can be measured – Regulators perspective *Inge Zomerdijk, Medicines Evaluation Board, Netherlands*
10.30 – 11.00	**COFFEE BREAK**
11.00 – 12.00	**ORGANISED SAFETY DATA COLLECTION** PV requirements within organised safety data collection activities: • Clinical trials including pragmatic trials/ low-interventions trials *Mette Stie Kallesøe, Ferring, Denmark* • Non-interventional studies including post-authorisation safety studies *Henny Bang Jakobsen, LEO A/S, Denmark*
12.00 – 12.30	**ORGANISED SAFETY DATA COLLECTION** • Market Research Programs & Patient Support Programs *Martino Grizelj, Pliva, Croatia*
12.30 – 13.30	**LUNCH**
13.30 – 14.00	**GVP INSPECTION** *Dunja Vukić & Iva Galić, HALMED*
14.00 – 14.30	**DIGITAL HEALTH ACTIVITIES & SOCIAL MEDIA** • WEB-RADR outcome and PV requirements for social media and apps *Petar Mas, HALMED*
14.30 – 15.00	**COFFEE BREAK**

15.00 – 15.30	**DIGITAL HEALTH ACTIVITIES & SOCIAL MEDIA (CONT.)** • Challenges in PV collection, evaluation and reporting in these activities *Birgitte Sharling, Novo Nordisk A/S, Denmark* • ADR campaign in Croatia (experience) *Anita Galić, HFD, Croatia*
15.30 - 16.15	**WHAT HAVE WE LEARNED?** *Facilitators*
16.15 – 16.30	**WRAP-UP** *Facilitators, Planning committee & Atrium*
16.30	**GOOD-BYE**