SAFER EUROPE WITHOUT FALSIFIED MEDICINES

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„SAFER EUROPE WITHOUT FALSIFIED MEDICINES" – conference during the Estonian Presidency of the EU Council

November 8–9, 2017 at Kultuurikatel, Tallinn, Estonia

PRELIMINARY AGENDA October 16th

	Theme	Organization	Discussion topics	Chair and speakers
DAY 1				
12.00	Registration and coffee			
13.00–13.30	**Opening session** Setting the Scene	Estonian Ministry of Social Affairs EU Commission	– Welcome – Situation with the falsified medicines in the world and in Europe – Overview of the requirements in EU – Benefits for the patients	Estonian Ministry of Social Affairs Keynote address: Mr **Andrzej Rys**, Director of Health Systems and Products DG SANTE, European Commission
13.30–15.00	**I session** European and National Medicines Verification Organizations – state of play	EMVO NMVOs	– EMVO – what is the status – Overview of NMVOs, Estonian experience – Repositories – central HUB, national repositories, what is ready, what is under development, what data is available to whom	Chair: Mr **Andreas Walter**, General Manager, EMVO Speakers: Mr **Mart Levo**, Chief Executive, REKS Ms **Maija Gohlke-Kokkonen**, Executive Director, FiMVO Ms **Leonie Clarke**, Project Manager, IMVO Ms **Illiana Paunova**, Executive Director, BgMVO
15.00	Coffee break			

15.30–17.00	**II session** Developers of the new system – their challenges in setting up data repositories	EU stakeholders and EMVO	– View of stakeholders: Manufacturers (EFPIA, Medicines for Europe, EAEPC) Wholesalers (GIRP) Pharmacies (PGEU)	Chair: Mr **Per Troein**, VP Strategic Partners QuintilesIMS Speakers: Ms **Monika Derecque-Pois**, Director General, GIRP Mr **Richard Freudenberg**, Chief Executive, EAEPC Mr **Michael Rose**, Vice President, Supply Chain Visibility, Johnson & Johnson and Chair of EFPIA's Supply Chain Ms **Jurate Svarcaite**, Secretary General, PGEU Mr **Adrian van den Hoven,** Director General, Medicines for Europe *5 minutes each presenter, panel discussion*
17.00–17.30	Coffee break			
17.30–18.30	**III session** Challenges of implementing hospitals within NMVS	FAMHP, HOPE, EAHP, EMVO	Panel discussion	Chair: Mr **Philippe De Buck**, FAMHP Mr **Pascal Garel**, Chief Executive, HOPE Ms **Stephanie Kohl**, Policy Officer, EAHP Mr **Hugh Pullen,** Chariman, EMVO
18.30–21.00	Reception followed by the dinner			

DAY 2				
9.00– 10.30	**IV session** Implementing by the Member States – timetable and challenges How to get more value – future developments – additional applications – is it possible?	HMA – Heads of Medicine Agencies EMVO stakeholders	– National requirements – ATD (Anti-tampering Device) on OTC products, extension of the requirement of safety features, multi-market packs vs potential inclusion of national reimbursement numbers in data matrix codes, update of marketing authorization files – Supervision of repositories – who is responsible for what – National Competent Authorities' (NCA) access to data contained in repositories	Chair: Ms **Belén Crespo Sánchez-Eznarriaga**, Director General, Spanish Agency of Medicines and Medical Devices Panel: with participation of representatives from National Competent Authorities, Commission and EMVO stakeholders Speakers: Mr **Michael Rose**, Vice President, Supply Chain Visibility, Johnson & Johnson and Chair of EFPIA's Supply Chain Ms **Jurate Svarcaite**, Secretary General, PGEU Ms **Monika Derecque-Pois**, Director General, GIRP Ms **Jan MacDonald**, Head Patient Information Quality, MHRA Ms **Agnès Mathieu-Mendes**, Deputy Head, DG SANTE, European Commission
10.30	Coffee break			
11.00–12.00	**V session** Availability of medicinal products after Feb 2019	Estonian State Agency of Medicines (SAM) EMVO stakeholders	– How do Member States intend to use the data contained in repositories? – To what extent the setting up of EMVS (European Medicines Verification System) would impact availability? – Will the situation with the availability of medicines worsen or improve?	Chair: Ms **Kristin Raudsepp**, Director General, Estonian State Agency of Medicines Speakers: Mr **Adrian van den Hoven**, Director General, Medicines for Europe Mr **Richard Freudenberg**, Chief Executive, EAEPC Ms **Stephanie Kohl**, Policy Officer, EAHP

12.00–13.00	**Panel session** Is Europe ready?		– Identification of key priority issues for progressing implementation and recommendations for action – Conclusions of the conference	Moderator: Ms **Agnès Mathieu-Mendes**, B4, Deputy Head, DG SANTE, European Commission Panellist: Mr **Andreas Walter**, General Manager, EMVO Ms **Anci Kvarnström**, CEO, PhQConsulting AB, NMVO Sweden
13.00–14.00	Lunch			