



Combating Falsified and Other Illegal Medicines - 4th Symposium for OMCLs: New Trends, New Frontiers

Date: 11-13 May 2022

Location: ISS, Rome, Italy

Plenary Room: Aula Pocchiari

Scope of the symposium

New trends, new frontiers: focus on the need for closer collaboration and better communication between OMCLs and their partners; new trends in falsifications and illegal trading of medicines; advanced techniques for the detection of falsifications

POSTER SESSION: space for max. 20 posters; poster session is open to all participants for the entire duration of the symposium; authors will be invited to provide a short oral presentation of their poster on the first day of the symposium (poster pitch session); a specific time slot for discussion with the authors at the stands is planned on Day 2

Duration of Symposium: 2 ½ days / Working language: English

PROGRAMME

Wednesday, 11 May 2022

Registration: 8:30-9:00

1. GENERAL INTRODUCTION: 9:00-9:40

Welcome addresses and opening

- 1.1. **Welcome address:** *Pierpaolo Sileri, Italian Ministry of Health – 10 min*
- 1.2. **Welcome address:** *Silvio Brusaferrò, ISS – 10 min*
- 1.3. **Welcome address:** *Michael Wierer, EDQM – 10 min*

Introduction to the topic

- 1.4. **How the GEON contributes to the fight against falsified medicines;** *Richard Wanko, EDQM – 10 min*

2. LEGAL SUPPORT OF LABORATORY WORK: FALSIFIED MEDICINES LEGISLATION / MEDICRIME CONVENTION: 9:40-10:30

- 2.1. **Introduction and Moderation:** *Richard Wanko, EDQM – 5 min*
- 2.2. **EU legislation against falsified medicines;** *Gudrun Gallhoff, EC – 20 min*
- 2.3. **The MEDICRIME Convention and OMCL contributions,** *Ines Du-Plessis (remotely), EDQM – 20 min*

Coffee break: 10:30 – 11:00 (Group photo)



2. LEGAL SUPPORT OF LABORATORY WORK: FALSIFIED MEDICINES LEGISLATION / MEDICRIME CONVENTION (cont.): 11:00-12:00

- 2.4. **Medicrime at work; Roman Leist, OMCL, CH – 20 min**
- 2.5. **Illegal import of medicines as observed by Dutch Customs – Seizures and enforcement issues; Mariël Zwaagstra, Customs laboratory, NL – 20 min**
- 2.6. **General discussion – 10 min**

Lunch break: 12:00-13:15

3. FALSIFIED APIs: 13:15-14:15

- 3.1. **Introduction and Moderation: Yvan Grange, OMCL, FR – 5 min**
- 3.2. **Falsifications of APIs: challenges and pitfalls, Jelena Acevska, OMCL, MK – 20 min**
- 3.3. **OMCL testing and the API Working Group: part of the solution?, Eric Deconinck, OMCL, BE – 20 min**
- 3.4. **General discussion – 10 min**

4. FALSIFIED MEDICINES TRENDS / INTELLIGENCE GATHERING: 14:15-15:15

- 4.1. **Introduction and Moderation: Graziella Li-Ship, MHRA, UK – 5 min**
- 4.2. **Information management of the German police (in particular pharmacrime) - Project PIAV, Matthias Lob, BKA, DE – 20 min**
- 4.3. **Falsified medicines: trends & intelligence gathering, Solveig De Rancourt De Mimerand, French Customs Mediwatch, FR – 20 min**
- 4.4. **General discussion – 10 min**

Coffee break: 15:15 – 15:45

4. FALSIFIED MEDICINES TRENDS / INTELLIGENCE GATHERING (cont.): 15:45-16:45

- 4.5. **Health Authority Perspective: COVID-related borderline products and other new challenges, Domenico Di Giorgio, AIFA, IT – 20 min**
- 4.6. **Fora fueling the finding of fortified food supplements, Peter Keizers, OMCL, NL – 10 min**
- 4.7. **Illegal websites selling of "COVID-19 medicines", Maria Cristina Gaudiano, IT – 20 min**
- 4.8. **General discussion – 10 min**



5. POSTER PITCH SESSION: 16:45-17:30

5.1. Oral presentation of posters by the authors – 3 min each

Eric Deconinck, OMCL, BE: Use of NIR spectroscopy and chemometrics for the classification of different Cannabis spp. samples found in Belgium

Bart Desmedt, OMCL, BE: Development of a discovery strategy for extractables and leachables from feminine intimate products

Josée Trudel, OMCL, CA: Falsified Sleep aid

Jing Chiu Chong Cheung, ES: Illegal Products Laboratory - Spanish OMCL (AEMPS-C). Activity Overview 2010-2022

Hervé Rebiere, OMCL, FR: Benefits of chemometrics for OMCLs

Mariangela Raimondo, OMCL, IT: Chemometric analysis of the NIR, ¹H-NMR and LC-MS Q-TOF data for discovering falsification of the origin of active substances: A study on Carvedilol APIs

Agata Blazewicz, OMCL, PL: Falsified oxycodone medicinal product from the legal supply chain – case report

Magdalena Poplawska, OMCL, PL: Strategy for tentative structure identification of non-pharmaceutical fentanyl and their metabolites

Hui-Chun LEE, TW: Application of a quantitative NMR method for borneolum quality control

Evening Programme: 17:30 Visit of ISS Museum

Thursday, 12 May 2022

6. SUMMARY OF THE FIRST DAY: 9:00-9:15

6.1. Claude Marson, OMCL, LU – 15 min

7. NEEDS FOR COLLABORATION BETWEEN GEON AND OTHER ANTI-FALSIFIED MEDICINES INITIATIVES: 9:15-10:50

7.1. Introduction and Moderation: Maria João Portela, OMCL, PT – 5 min

7.2. Activities of the CLEN and the JRC including a summary of CLEN2SAND III achievements and presentation of the actions planned in CLEN2SAND IV, Claude Guillou, EC-JRC, IT – 20 min

7.3. The European Network of Forensic Science Institutes (ENFSI) and the Challenge of Analysing New NPS, Irene Breum Müller, SUND, DK – 20 min

7.4. Activities of the CMED, Bastiaan Venhuis, RIVM, NL – 20 min

7.5. Activities of the WGEO, Marcus Wittstock, BfArM, DE – 20 min

7.6. General discussion – 10 min

Coffee break: 10:50 – 11:20

8. FALSIFIED BIOLOGICALS: 11:20-12:20

8.1. Introduction and Moderation: Peter Keizers, OMCL, NL – 5 min

8.2. Falsification cases of Monoclonal Antibodies, Zoe Waibler (remotely), OMCL, DE – 15 min

8.3. Starting to test biological activity of biosimilars and gene therapy products using bioassays to detect falsified products, Roman Leist and Jenifer Sen (remotely), OMCL, CH – 15 min



8.4. General discussion – 10 min

Lunch break: 12:20-13:30

9. POSTER SESSION: 13:30-14:30

- Use of NIR spectroscopy and chemometrics for the classification of different Cannabis spp. samples found in Belgium, *Céline Duchateau, ULB, Jean-Michel Kauffmann, ULB, Kris De Braekeleer ULB, Michaël Canfyn, OMCL, BE, Eric Deconinck, OMCL, BE*
- Development of a discovery strategy for extractables and leachables from feminine intimate products, *Quinten Marcellis, Bart Desmedt, OMCL, BE*
- Falsified Sleep aid, *Josée Trudel, OMCL, CA*
- Illegal Products Laboratory - Spanish OMCL (AEMPS-C). Activity Overview 2010-2022, *Jing Chiu Chong Cheung, ES*
- Chemometric analysis of the NIR, ¹H-NMR and LC-MS Q-TOF data for discovering falsification of the origin of active substances: A study on Carvedilol APIs, *Anna Borioni, Maria Cristina Gaudiano, Francesca Prestinaci, Isabella Sestili, Mariangela Raimondo, OMCL, IT*
- Benefits of chemometrics for OMCLs, *Jelena Acevska, OMCL, MK, Eric Deconinck, OMCL, BE, Hervé Rebiere, OMCL, FR, Mariangela Raimondo, OMCL, IT*
- Falsified oxycodone medicinal product from the legal supply chain – case report, *Agata Blazewicz, OMCL, PL*
- Strategy for tentative structure identification of non-pharmaceutical fentanyl and their metabolites, *Magdalena Poplawska, OMCL, PL*
- Application of a quantitative NMR method for borneolum quality control, *Hui-Chun Lee, FDA, TW*

10. BREAK-OUT SESSIONS: 14:30-17:00

Focus of the break-out sessions should be information exchange in smaller groups. The short presentations during these sessions are understood as "teasers" to animate discussion.

Coffee break: 15:30 – 16:00

10.1. Falsified cosmetics and medical devices (Aula Bovet); Moderators: *Maria Cristina Gaudiano and Andrea Luca Rodomonte, OMCL, IT; EDQM support by Silvia Muñoz-Botella*

- Falsified cosmetics and medical devices. Introduction, *Maria Cristina Gaudiano, OMCL, IT*
- Anti-motion sickness patches with "CE" marking containing APIs, *Monica Bartolomei, OMCL, IT*
- Cosmetics safer than Medical Devices?, *Bart Desmedt, OMCL, BE*
- Condoms, *Monica Miranda, OMCL, PT*

10.2. Examination of packaging (Aula Marotta); Moderator: *Yvan Grange, OMCL, FR, EDQM support by Marie Bertrand*

- Examination of packaging. Introduction, *Yvan Grange, OMCL, IT*
- Photographic documentation of illegal medicines, *Roman Leist, OMCL, CH*
- Examination of packaging and photo documentation for detection of falsified medicinal products, *Katerina Brezovska, OMCL, MK*



10.3. Analysis of herbals including cannabis and Traditional Chinese Medicines (Aula Pocchiari); Moderator: Eric Deconinck, OMCL, BE, EDQM support by Richard Wanko

- **Detection of regulated and prohibited plants in plant food supplements, Eric Deconinck, OMCL, BE**
- **Non-conforming medicinal products of herbal origin (discussion about products which do not comply with their specification and how to detect falsifications), Thomas Lang, OMCL, AT**
- **Cannabis testing and Cannabis legislation in Luxembourg, Claude Marson, OMCL, LU**

Evening Programme: 17:00 Visit of ISS Museum

Friday, 13 May 2022

11. SUMMARY OF THE SECOND DAY: 9:00-9:10

11.1. Claude Marson, OMCL, LU – 10 min

12. FEEDBACK FROM BREAK-OUT SESSIONS: 9:10-10:20

12.1. Introduction and Moderation: Katerina Brezovska, OMCL, MK – 5 min

12.2. Falsified cosmetics and medical devices; Maria Cristina Gaudiano and Andrea Luca Rodomonte, OMCL, IT – 15 min

12.3. Examination of packaging; Yvan Grange, OMCL, FR – 15 min

12.4. Falsification of herbals; Eric Deconinck, OMCL, BE – 15 min

12.5. General discussion – 15 min

Coffee break: 10:20 – 10:50

13. ADVANCED TECHNOLOGIES FOR DETECTING FALSIFIED MEDICINES / NEW PHENOMENA IN FALSIFICATION OF MEDICINES: 10:50-12:15

13.1. Introduction and Moderation: Andreas Hackl, OMCL, AT – 5 min

13.2. Benchtop NMR spectroscopy, Peter Keizers, OMCL, NL – 20 min

13.3. Low-dose active substances: evaluation of chemical imaging and surface-enhanced Raman spectroscopy (SERS), Herve Rebiere, OMCL, FR – 20 min

13.4. A special case of medicine in disguise: Tattoo inks containing anaesthetics, Maria Cristina Gaudiano, OMCL, IT – 20 min

13.5. General discussion – 15 min

14. PLENARY DISCUSSION: 12:15-13:00

14.1. Moderator: Michael Wierer, EDQM – 45 min

What are the next steps: take home messages from symposium?

15. CLOSING SESSION: 13:00 - 13:20

15.1. Closing Remarks: Patrizia Caprari, Director of the National Centre for the Control and Evaluation of Medicines, ISS and Michael Wierer, EDQM – 20 min

Lunch: 13:30 - 14:30