DIA-TOPRA Workshop on Falsified Medicines

6 JUNE 2016

Pullman Hotel Midi , Brussels, Belgium

DIA DEVELOP INNOVATE ADVANCE

TOPRA

FINAL PROGRAMME

WORKING PARTY

TOPRA Representatives

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Director, European Directorate of Quality of Medicines & Healthcare, France

OVERVIEW

This conference will take stock of where we stand in the EU on falsified medicines and paint the landscape of the global issue. The speakers will present the approaches of the Member States on the implementation of the new legislation, and the impact and achievements of the concerned stakeholders such as industry, patients, pharmacies and distributors who have worked independently and together to find solutions.

The key messages of the meeting will be presented in a paper outlining the positive benefits until now and also the challenges yet to be addressed.

WHO WILL ATTEND

The meeting is intended for professionals working with the implementation of the new rules in various points of the supply chain. Regulators or policymakers involved in the endorsement of the rules at national level and professionals participating in the stakeholder groups of manufacturers, market authorisation holders, wholesalers, pharmacy owners and managers and patient representatives would find the meeting interesting as well.

BACKGROUND TO THE THEME

Falsified medicines are a major threat to public health (the term 'falsified' refers to all forms of falsification, while the term 'counterfeit' specifically refers to an infringement to intellectual property rights). As falsifications become more sophisticated, the risk that falsified medicines reach patients in the EU increases every year. To counteract this in the EU the European Council and European Parliament have taken certain legal measures such as the Falsified Medicines Directive (Directive 2011/62/EU) published on 1 July 2011 and coming into effect on 2 January 2013. This called for the introduction of the following measures:

> Obligatory safety features on the outer packaging of the medicines, to be detailed via a delegated act;

> A common, EU-wide logo to identify legal online pharmacies. This would make it easier to distinguish between legal and illegal online pharmacies throughout the European Union;

> Tougher rules on the controls and inspections of producers of active pharmaceutical ingredients; and

> Strengthened record-keeping requirements for wholesale distributors

Further delegated acts such as (Commission Delegated Regulation (EU) 2016/161 were published on 9th February 2016 and apply as of 9th February 2019.

The result of these initiatives has enabled a closer working together across not only Europe but also the wider global network to improve this threat to patient health. As a directive national implementation across the EU has taken on subtle differences and also all stakeholders have had to work closely together to meet the needs of this falsified legislation in the EU.

Workshop on Falsified Medicines

FINAL PROGRAMME

10:20 Opening Remarks
Lynda Wight, Executive Director, TOPRA, UK

10:30 Key Note: How the Issue of Falsified Medicines has Evolved and what are the Global Implications?
Hugo Bonar, Enforcement Manager, Health Products Regulatory Authority, Ireland

10:50 Session 1 – The Views from the European Commission and Member States
The session will start with a presentation from the Commission on the developments at the EU level and work the Commission is leading. Implementation of the legislative requirements at the Member State level are explored, discussing which direction different Member States are taking and how they are endorsing the legislation. The topics include serialization, data protection, national reimbursement systems and IT systems or unique identifiers linked to those.

Session Chair:
Hugo Bonar, Enforcement Manager, Health Products Regulatory Authority, Ireland

Updates from European Commission
Patrizia Tosetti, Policy Officer, European Commission

Views from Belgium
Philippe De Buck, Head of Division, Federal Agency for Health and Medicinal Products, Belgium

Views from Luxembourg
Marcin Wisniewski, Pharmacy Inspector, Ministry of Health, Luxembourg

Views from Spain
Belén Escribano, Head of Department, Pharmaceutical Inspection and Enforcement Department, AEMPS, Spain

Views from the UK
Jan MacDonald, Group Manager, Licensing Division, MHRA

EDQM-EMVO Conformity Assessment
François-Xavier Lery, Head of Section for Pharmaceutical Care, Consumer Health Protection and Anti-Counterfeiting, European Directorate of Quality of Medicines & Healthcare, France

12:45 Lunch

13:30 Session 2 – Panel discussion with various stakeholders
The session brings together the stakeholders in the supply chain to discuss the implementation on each part of the chain.

Session Chair:
Gerald Heddell, Director, Inspection Enforcement & Standards Division, MHRA, UK

Innovator Industry View
Francois Bouvy, Director Market Access, EFPIA, Belgium

Distributors' View
Martin FitzGerald, Deputy Director General, European Healthcare Distribution Association, Belgium

Generic and Biosimilar Medicine Industry View
Maarten Van Baelen, Director, Medicines for Europe, Belgium

Hospital Pharmacists' View
Robert Moss, Director of Professional Development, European Association of Hospital Pharmacists, Belgium

Patients' Perspective
Stephen McMahon, Irish Patients' Association, Ireland

Panel discussion

15:30 Coffee break

15:50 Session 2 continued – Examples the industry

Applicable Standards for the Technical System
Tania Snioch, Director, Healthcare, GS1, Belgium

An Example of a Technical System
Iris Liberloo, Sales and Content Manager, Aegate, Belgium

Panel discussion with all presenters

17:20 Closing Remarks
Holger Adelmann, Senior Vice President and Managing Director, DIA Europe, Middle East and Africa, Switzerland

DIA EUROPE MIDDLE EAST & AFRICA

DIA is a global volunteer and member community representing thousands of life science professionals working together to bring innovative, safe and effective medical products to patients. An association of more than 30,000 key stakeholders, DIA builds productive relationships by bringing together regulators, life sciences professionals, academics and researchers, patient advocates and other influencers to exchange knowledge and collaborate in a neutral setting.

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TOPRA

The Organisation for Professionals in Regulatory Affairs
TOPRA is the professional membership organisation for individuals working in healthcare regulatory affairs. We represent and promote the global healthcare regulatory profession, enabling legislators and other opinion leaders to access the best possible information and advice from among our diverse membership, which in turn strengthens healthcare regulation for everyone. We provide our members with top-quality, relevant support with a European focus. We support them throughout their careers to help them perform to the highest level and to help retain the brightest and the best within the profession.

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