Just Announced!

DIA-TOPRA Workshop on Falsified Medicines

6 JUNE 2016

DIA DEVELOP INNOVATE ADVANCE

TOPRA

WORKING PARTY

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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.

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.

OBJECTIVES

› Understand nature of the issue at the EU and global level comprehensively

› Hear from the Member States on their approaches on the endorsement and implementation

› Discuss how to navigate the various systems and exchange experiences on challenges and solutions

› Address the challenges linked to the whole supply chain by bringing the stakeholders to the same table and understand the challenges each stakeholder group is addressing

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.

Visit the meeting website for regular programme updates at www.DIAGlobal.org and www.topra.org

This programme is in development. For more information contact: Inka Heikkinen at inka.heikkinen@diaglobal.org or Christopher Bailey at Christopher@topra.org

Registration

Participation fees (inc. VAT):

Industry	GBP 665.50
Government	GBP 332.75
Academic	GBP 332.75
Student	GBP 114.95

To book go to **www.topra.org/fm16**

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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