

**Position Paper**  
**on a common logo for legally-operating online pharmacies/retailers offering medicinal products for human use for sale at a distance to the public (Directive 2011/62/EU and Implementing Regulation No 699/2014)**

Brussels, 17<sup>th</sup> February 2015

**Illegal Online Sellers of Medicines Threaten Patient Safety in the EU and Globally**

The Internet is the largest unregulated market place for medicines in the world. There are approximately 30,000 websites at any one time selling medicines targeting European citizens. According to the European Alliance for Access to Safe Medicines (EAASM)<sup>1</sup> 62% of medicines purchased online are fake or substandard. Moreover, 95.6% of online sellers of medicines globally are operating illegally.<sup>2</sup> Of these, 94% of online sellers of medicines do not have a named, verifiable pharmacist, and more than 90% supply prescription-only medicines without a prescription.<sup>3</sup>

**Key Messages**

- ASOP EU strongly supports the effective implementation of the FMD requirements pertaining to selling of medicines at a distance.
- Ensuring the Common Logo is secure and that the public is aware of the Common Logo must be a top priority for implementation and post-implementation.
- ASOP EU stands ready to serve as a partner to the appropriate European Institutions and Member States as they refine their implementation plans and strategies for public education.

**New EU Law Seeks to Protect Patients Online**

In January 2013, the European Commission introduced the Falsified Medicines Directive (FMD), part of which mandates the establishment of a 'Common Logo' that must be clearly displayed on websites offering medicinal products for sale at a distance. The Common Logo is intended to allow patients to identify legally operating online sellers of medicines. Many of these websites will be licensed pharmacy premises but the Directive includes all types of medicines and as such supermarkets and other non-

<sup>1</sup> European Alliance for Access to Safe Medicines (EAASM), *The Counterfeit Superhighway* (2008)

<sup>2</sup> *Id.* See also LegitScript, LLC

<sup>3</sup> *Id.*

pharmacy outlets will be included. Registered online sellers of medicines in the European Union (EU) must link to the national competent authority's website where all legally operating online sellers of medicines in their respective countries will be listed (the National Registry). National competent authorities have until July 1st 2015 to apply the [Commission Implementing Regulation \(EU\) No 699/2014](#).

This Implementing Regulation establishes the design of the Common Logo, the functioning of the system and the Member States obligations on security of the system. However, it did not include cryptographic or technical requirements of the common logo.

**Position of ASOP EU:** ASOP EU supports the implementation of the Common Logo, National Registries and public awareness about their existence, as a means to improve patient safety in the EU.

**Security:** ASOP EU supports the implementation of the Common Logo but recognises the need for it to be as secure as possible from criminals who may wish to use it to feign legitimacy. ASOP EU therefore believes that to create a reliable and secure system in the EU, a clear technical guideline has to be put in place to ensure security of the logo and the database it connects to. ASOP EU stresses the importance that the same security standards should be applied in all EU Member States. This can be achieved by a clear implementing guideline for Member States which comply with national and European legislation. ASOP EU recognises the challenge for EU Member States to maintain the required database, ensure an active monitoring, and secure the Common Logo. ASOP EU is therefore, committed to share best practices and lessons learned during the implementation, with the hope of advancing patient safety and the public interest.

**Consistency with laws:** ASOP EU recognises that Member States will, as entirely appropriate, be implementing the Common Logo in accordance with their national pharmacy and medicine laws. This is an example of the unique strength of the European Union. Of course, when dealing with the Internet and sales at a distance, the laws of other countries are also relevant. ASOP EU supports implementation of the Common Logo that is consistent with both the laws where the retailer is established and where the patient is located, in accordance with EU and Member State laws.

**Public Awareness:** The FMD establishes that implementing Member States will run awareness campaigns on the risks related to medicinal products illegally supplied to the public via the internet and explaining the purpose of the Common Logo as a secure place to buy medicines online. ASOP EU recognises the need for effective campaigns that signal the legal and secure channels where medicines can be purchased. ASOP EU is committed to support EU Member States in educational campaigns on safe online purchase and promoting the new Common Logo.

Internet commerce companies, including e.g. Google, provide grants to enable advertisements to appear next to search engine results following search terms added by the consumer (e.g. "buy



medicines online”). Google is an active Member of ASOP EU and “and has indicated willingness to help advance public education through advertisements of this nature and other potential partnerships. The advertisement can be linked to each Member State’s Common logo public awareness campaigns and therefore highly tailored to each Member State. This is just one example of how Internet commerce companies and NGOs may be able to support the pertinent regulatory authorities to help advance public education and enhance patient access to legitimate and secure websites that sell medicines online.

*The [Alliance for Safe Online Pharmacy EU \(ASOP EU\)](#) is a multi-stakeholder organisation with the specific objective of making the internet a safe place to buy medicines (where it is allowed within the EU).*