

**COMMENTS: FEDERAL REGISTER NOTICE USTR-2013-0019**  
**Regarding the Transatlantic Trade and Investment Partnership**  
**May 9, 2013**

Thank you for your consideration of these comments submitted in response to Federal Register Docket Number USTR-2013-0019, Section 2(f) regarding public health and safety by US and EU organizations: Alliance for Safe Online Pharmacies, the Center for Safe Internet Pharmacies, and the Alliance for Safe Online Pharmacy - European Union.

**BACKGROUND**

While the Internet is a valuable, positive force for information and convenience, patients globally are increasingly put at risk by illegal online drug sellers peddling spurious/falsely-labeled/falsified/counterfeit (SFFC) medicines:

- 97% of entities offering to sell drugs are illegitimate and operating in violation of U.S. law (National Association of Boards of Pharmacy);
- 50% of the prescription medicines sold online by websites that hide their physical address are counterfeit (World Health Organization);
- 23% of adult Internet consumers surveyed have bought prescription medicine online (U.S. Food and Drug Administration);
- Illegal online drug sellers can generate \$1 - \$2.5 million in sales each month (MIT Technology Review).
- A website designed to look like illegal online pharmacy generated in excess of 360,500 hits in nine weeks, making it the third most popular “online pharmacy” in Germany. Taking conservative estimates for the orders had the consumer been able to buy from the website the study revealed a potential €35million of sales. (European Alliance for Access to Safe Medicines);
- At any one time there are in excess of 30,000 fake pharmacy websites are accessible by the European population (LegitScript)
- A conservative estimate of between €1-3bn for total European counterfeiting medicines sales is projected, with this figure rising to over €10bn by 2020 (Falsified Medicines – Costing the Earth” Alliance for Safe Online Pharmacy - EU and European Alliance for Access to Safe Medicines, March 2013);
- FY2011 U.S. seizures of counterfeit pharmaceuticals increased by 200% and seizures occurring at express consignment and mail facilities have risen by 84% since 2007 due to the continued growth of websites selling counterfeit products and a marked shift towards using international mail and express courier services to transport the illegal merchandise (Report from U.S. Customs and Border Protection, January 2012)
- The number of shipments stopped by EU Customs has doubled compared to 2010, with an 82% increase in detentions of postal traffic largely due to the increase in online purchases and 69% of articles detained in postal traffic are medicines, and quotes Algirdas Šemeta, Commissioner for Taxation, Customs, Anti-fraud and Audit as saying: “We have experienced a spectacular increase of detentions in the postal traffic since last year: the number of cases tripled and many of the seized goods included medicines...This upward trend reflects a growing number of online purchases.” (European Commission's annual report on European Union Customs enforcement, July 2011)

Given the transnational and trans-border nature of the criminal networks that perpetrate illegal online drug sales, the Alliance for Safe Online Pharmacies (ASOP), the Center for Safe Internet Pharmacies (CSIP) and the Alliance for Safe Online Pharmacy - European Union (ASOP-EU) believe it is critical to pursue opportunities for improved international cooperation, including among major trading partners. Cooperation exists between the United States and Europe at the working and law enforcement level. However, future cooperation formalized through TTIP would help to advance existing objectives at the national and international level, develop shared best practices, and harmonize regulations and policies as appropriate.

Resulting outcomes such as expanded and formalized transatlantic collaboration would also advance efforts to establish models or best practices for use multilaterally or globally. Several regional forums and countries are also working to harmonize regulations and develop national and international strategies to enhance drug safety and reduce sales in illegal channels. As an example, the Asia-Pacific Economic Cooperation (APEC) Regulatory Harmonization Steering Committee recently adopted a Road Map for Global Medical Product Quality and Supply Chain Integrity, under which it established an "Internet Sales" working group to conduct a gap analysis and tool-kit to assist governments and other stakeholders in efforts to ensure drug safety in the age of the Internet and combat the global growth of illegal online drug sellers. We applaud APEC's recognition of this growing international public health threat and the leadership of the United States in driving the effort. Additionally, the May 2012 G-8 Commitments included an agreement to collaborate and share information regarding illegal online pharmacies, illustrating further the existing consensus among major trading partners that we need to work together to address this growing public health threat.

Collaboration between the U.S. and the EU as an element of TTIP can help to produce outcomes on these commitments as well as developing best practices and lessons-learned that can feed into the APEC Road Map. Such collaboration would also serve to advance the specific policies of the United States and the European Union. The serialization and traceability of pharmaceutical products has been required in Europe as part of the Falsified Medicines Directive at individual pack level. Similar requirements have been adopted in the United States (California e-pedigree law) and legislation is pending at the federal level. As significant investments are made to prepare for and implement these systems, it is ever more important for the U.S. and EU to collaborate on these emerging regulations and the ability of illegal Internet pharmacies to circumvent them. Together, the U.S. and the EU can develop more unified policies to enhance further our common objectives for drug distribution security and public health and safety.

## **RECOMMENDATION**

ASOP, CSIP, and ASOP EU encourages USTR to seize the opportunity afforded by TTIP to advance and inspire further collaboration between the U.S. and EU governments on this important public health and safety issue. Specifically, in response to Federal Register Docket Number USTR-2013-0019, Section 2(f) regarding public health and safety, we recommend the following be considered for the TTIP negotiations and the proposed TTIP agreement:

### *Transatlantic Collaboration to Protect the Integrity of the Supply Chain and Prevent Illegal Internet Drug Sales*

- *Establishment of a working group or mechanism, consisting of representatives of relevant expert agencies, to engage in coordination and information sharing to prevent infiltration of the regulated supply chain by illegal internet drug sales, including:*
- *Information sharing about respective legislative, policy and enforcement strategies, as well as the role*

*of voluntary protocols from private sector stakeholders;*

- *Collaboration to improve regulation/enforcement and interdiction operations designed to prevent and deter infiltration of legitimate channels by illegal online drug sellers;*
- *Finalization of Memorandum of Understanding to improve intelligence cooperation targeting organized criminal networks involved in illegal Internet drug sales, as well as associated enforcement operations;*
- *Information sharing of best practices as they relate to third party verification, national registry requirements, and awareness/education programs for health care professionals and the general public;*
- *Harmonization, where appropriate, of regulatory/legal framework to deter illegal Internet drug sales; and*
- *Establishment of lessons-learned and best practices to advise regional/global forums.*

## **CONCLUSION**

The Alliance for Safe Online Pharmacies, the Center for Safe Internet Pharmacies, and the Alliance for Safe Online Pharmacy - European Union appreciate your consideration of these comments. We welcome the opportunity to meet with U.S. and EU government officials to answer questions and further explore ways to protect patients globally through TTIP commitments addressing illegal online drug sellers.

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