

**EFPIA/IFPMA/PhRMA Position Paper
Medicrime Convention
22 October 2012**

IFPMA, EFPIA, and PhRMA welcome the MEDICRIME Convention launched by the Council of Europe in December 2010 and opened for signature by all states on 28 October 2011.

The Convention brings a new approach and renewed focus to the fight against counterfeit medicines.

The threat of counterfeit medicines is substantive and growing. Counterfeit medicines have been documented in every therapeutic category and in every region of the world. Recent cases of e.g. counterfeit oncology treatments underline the urgent need for action and stringent measures to protect patients worldwide.

In order to combat this growing threat to public health and patient safety, the three associations share the position of the Council of Europe recognizing the eradication of counterfeiting as a **common responsibility for the global community** and support the following overarching aims of the Convention:

- Safeguarding of public health through penal measures against criminal behaviors,
- Protection of victims,
- Promotion of cooperation at national and international levels,
- Preventive measures.

The three associations support the Convention's definition of counterfeit medical products i.e. "*products where a false representation has been made as regards identity and/or source*". The definition allows for filling in gaps in certain national legislations in which criminal and administrative liability for manufacturing, distributing and selling of "falsified" medicines is not covered outside the scope of IP legislation.

The Convention criminalizes the manufacture and supply of counterfeits as well as similar offences and provides that sanctions and measures should be "*effective, proportionate and dissuasive*".

Key provisions to be highlighted amongst others include:

- Protective measures set out **must apply irrespective of whether certain medical products are protected by IP (patent, trademark, etc.) legislation or not** (Article 3);
- **Falsification of documents** (Customs documents, invoices, certificates, labeling etc.) are established as offences (Article 7);
- **Liability is established for intentional manufacturing, distributing and selling** of medicines that are without the authorization required under domestic law (article 8);
- **Proceedings may continue even if a victim withdraws his/her complaint.** If the defendant settles with the victim (such as by paying substantial compensation or by intimidation) that should not mean proceedings are automatically dropped given the risk to public health and safety (Article 15);
- Signatories to the Convention **must establish quality and safety requirements of medical products (medicines and devices), creating a "safety net"** to catch products that for example may be sold as herbal treatments (not requiring approval as medicines) but in fact include active pharmaceutical ingredients (Article 18);
- **Possibility for non-Member States of the Council of Europe to ratify** the Convention (Article 28).

Government regulatory and/or enforcement authorities must be fully vested with the proper power and resources to fight counterfeits. While the incidence of counterfeit medicines occurs in both developed and developing countries, the problem is more prevalent in countries where regulatory oversight and enforcement are weak.

The three associations welcome the signing of the Convention by twenty-one¹ countries and encourage other countries both from members of the Council of Europe and beyond to sign and ratify too.

In that respect, EFPIA, IFPMA and PhRMA and their members invite the Committee of Ministers to focus their efforts on mobilizing countries which are the most affected by counterfeit medicines and assisting them in deploying the measures necessary to comply with the Convention's requirements.

IFPMA, EFPIA, and PhRMA and their members stand ready to work in partnership with all signatories on implementation and enforcement.

¹ Armenia, Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Guinea, Iceland, Israel, Italy, Liechtenstein, Luxembourg, Moldova, Portugal, Russia, Spain, Switzerland, Turkey, Ukraine