

FRANCE & THE FIGHT AGAINST FALSIFIED MEDICINAL PRODUCTS

WHAT IS A FALSIFIED MEDICINAL PRODUCT?

The European Union has adopted a common definition for falsified medicinal products which prioritizes a public health approach and moves beyond the notion of counterfeiting (which is the infringement of an intellectual property right).

A falsified medicinal product is regarded as “any medicinal product with a false representation of:

- its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients;
- its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder;
- its history, including the records and documents relating to the distribution channels used.

This definition does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights.” (EU, 2011)



The falsification of medicinal products has become a true global scourge and affects the most disadvantaged people in the world's poorest countries. Data and studies on such trafficking around the world remain obscure and incomplete, and only offer a very limited insight into the situation. Falsified medicinal products could account for as much as 10% of all medicinal products throughout the world. The World Health Organization (WHO) has stated that these products are linked with several hundreds of thousands of deaths per year.

The fight against falsified medicinal products is not only essential from a public health perspective, but also to reduce the scope of organized crime.



Information campaign on the dangers of falsified medicinal products in Mali and throughout French-speaking Africa, 2008.

France's commitment

- France, which has a reputation for expertise in the area of public health, is fully committed to the fight against trafficking by increasing international cooperation between the different administrations and organizations concerned.
- In addition to medicinal products, trafficking of all health products must be addressed, including active ingredients and medical devices.
- This must be achieved via multisectoral action, bringing together healthcare professionals, customs, police and justice services, as well as private companies. France has a three-pronged strategy based on advocacy, prevention and enforcement.

Establishing France's position internationally

- It is essential to raise awareness among the Heads of State, Ministers and Members of Parliament responsible for these issues in the countries affected by this scourge.
- Since the Cotonou Declaration made by Fondation Chirac in 2009, awareness of this issue has increased.
- The International Organisation of La Francophonie (IOF) addressed this issue in October 2010 by adopting a resolution on the initiative of Benin and Burkina Faso.
- The World Health Organization (WHO) put in place a working group of Member States responsible for the prevention and monitoring of substandard, spurious, falsely-labelled, falsified and counterfeit medical products (SSFFC).
- Within international bodies, France promotes a public health-centred approach in order to avoid the opposition linked to intellectual property issues which can exist between developed and emerging countries.

THE MEDICRIME CONVENTION

Adopted by the Committee of Ministers of the Council of Europe in December 2010, this is the first legally binding instrument in the field of criminal law. It criminalizes the counterfeiting, production and distribution of medical products placed on the market without authorization or which are not in line with safety standards. To allow better inter-State cooperation and appeal for the creation of a large common judicial area, France intends to mobilize as many States as possible within the Council of Europe, but also among non-member countries, especially those from Africa.

By the end of 2012, 22 States had already expressed their support for this project.

Preventive action

Recognizing the importance of access to quality and affordable medical products

The best barrier against the increased trafficking in falsified medicinal products is the availability of high-quality products to all.

- France is a strong supporter of the policies on access to treatment for people in developing countries. It is the second largest contributor to the Global Fund to Fight AIDS, Tuberculosis and Malaria and the largest contributor to UNITAID, the international drug purchase facility. France also contributes by supporting insurance and health coverage programmes in developing countries.

The increased monitoring of production, distribution and traceability channels for medicinal products

■ The fight against falsified medicinal products requires efficient monitoring structures across all production, supply and distribution channels: central procurement systems, quality control laboratories, regulations governing distribution, pharmaceutical inspections, professional associations, etc. France provides technical expertise and trains foreign professionals in all these fields. The Agence française de développement (AFD) supports several projects to strengthen central procurement agencies and harmonize pharmaceutical regulations. Finally, the French pharmaceutical industry is also combating falsified medicinal products.

Direct and concrete action funded in the world's hardest-hit regions

■ France is running a project on the Priority Solidarity Fund (PSF) in the countries of the Mekong region worth 3.5 million euros for the 2010-2013 period. Following a round table organized in Ouagadougou (Burkina Faso) in September 2011, France intends to step up its collaboration with West Africa by mobilizing all regional technical and financial partners. In 2011, France also undertook action aimed at better identifying the scale of trafficking in the Balkans region and the bordering countries.

Enforcement action

Complementary actors on a national scale

- The customs services and the Ministry of the Interior are two key actors in the fight against falsified medicinal products. They provide technical expertise on the ground, customs officers and internal security attachés.
- In 2004, the Ministry of the Interior created the Office central de lutte contre les atteintes à l'environnement et à la santé publique (OCLAESP, a national agency for the fight against environmental and public health crime).

■ The customs services also ensure that intellectual property rights are protected and work alongside rights holders to combat the counterfeiting of medicinal products. Following the conclusions of the CSIS (a strategic council for healthcare industries) in October 2009, the French Directorate-General for Customs and Indirect Taxes (DGDDI) drew up an enhanced action plan against the counterfeiting of medicinal products. This action plan is based around the creation of an observatory of counterfeit goods under the Customs Intelligence Directorate, a Medifraude network, run by this Directorate and enhanced intervention and investigation capacities of the National Judicial Customs Department (SNDJ).



Hawkers selling medicinal products which are falsified are a common sight in West Africa.

Collaborating with international organizations

■ The enforcement component is implemented via discussion and collaboration between the French authorities and international organizations such as the World Customs Organization (WCO), the United Nations Office on Drugs and Crime (UNODC) and Interpol. Interpol in particular provides cooperation to help countries affected by the trafficking of medicinal products (production, transit and distribution areas).

An assertive French position

- France supports implementing strong and effective enforcement legislation, similar to that which applies to drug trafficking. It thus regards the following tools as important:
 - the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health, known as the Medicrime Convention opened for signature in 2011;
 - the United Nations Convention Against Corruption, known as the Merida Convention, adopted in 2003;
 - the United Nations Convention Against Transnational Organized Crime, known as the Palermo Convention, adopted in 2000.

FOR FURTHER INFORMATION

WHO

www.who.int

Fondation Chirac – Cotonou Declaration

www.fondationchirac.eu/en/programs/access-to-medicine/international-mobilization-against-the-traffic-of-falsified-medicines/

Interpol

www.interpol.int

OIF – Montreux Declaration

www.francophonie.org/Cloture-du-XIIIe-Sommet-de-la.html

Council of Europe – Medicrime Convention

www.coe.int/t/dghl/standardsetting/medicrime/default_en.asp