FIGHTING FALSIFIED MEDICAL PRODUCTS

GRI Standards: 103: Management approach
416-1: Customer Health and Safety

I. BACKGROUND

Falsified medical products represent a crucial challenge in the field of public health in this early part of the 21st century.

As underlined by European Commission, "Falsified medicines may contain ingredients of bad or toxic quality, or in the wrong dosage. As they have not been properly checked for quality, safety and efficacy, as required by strict EU authorisation, they can pose a real risk to your health. As falsified medicines become more sophisticated, the risk of them reaching patients in the EU increases. They represent a serious threat to global health and call for a comprehensive strategy both at European and international level."

1. Definition

The term "falsified" is frequently used to distinguish such breaches from pure intellectual property rights infringement.

The Falsified Medicines directive of the European Parliament and the Council of the European Union amending directive 2001/83/EC is aimed at preventing the introduction of falsified medicines into the legal supply chain. Falsified medicines are those that are mislabelled from the viewpoint of their identity, their history, or their source. Published in July 2011, the amended directive defines falsified medical products as follows:

"Any medicinal product with a false representation of:

> (a) its identity, including its packaging and labelling, its name or its composition in respect of any of its components including excipients and strength; and/or
>
> (b) its source, including the manufacturer, country of manufacturing, country of origin, marketing authorization holder and/or
>
> (c) 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 legislation on intellectual property rights."

Sanofi welcomes this definition, although it is enforceable only in European Union countries.

Also, in May 2017, to strengthen international coordination and collaboration, and obtain greater stakeholders engagement on this issue, the World Health Organization (WHO) decided to simplify its old terminology adopted more than 20 years ago and lacking common understanding to "Substandard and Falsified (SF) medical products"
Falsified medical products :
Medical products that deliberately/fraudulently misrepresent their identity, composition or source.
Such deliberate/fraudulent misrepresentation refers to any substitution, adulteration, reproduction of an authorized medical product or the manufacture of a medical product that is not an authorized product.
"Identity" shall refer to the name, labelling or packaging or to documents that support the authenticity of an authorized medical product.
"Composition" shall refer to any ingredient or component of the medical product in accordance with applicable specifications authorized/recognized by NRRA.

“Source” shall refer to the identification, including name and address, of the marketing authorization holder, manufacturer, importer, exporter, distributor or retailer, as applicable.

Moreover, WHO applies its global surveillance and monitoring system and the Member State mechanism to three categories of products:

- Substandard also called "out of specification", these are authorized medical products that fail to meet either their quality standards or specifications, or both.
- Unregistered/unlicensed medical products that have not undergone evaluation and/or approval by the National or Regional Regulatory Authority for the market in which they are marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation.”
- Falsified medical products that deliberately/fraudulently misrepresent their identity, composition or source.

2. A public health challenge

Fighting falsified medical products represents a major public health challenge. The extent of this pharmaceutical crime is impossible to quantify. However, the WHO estimates that falsified medical products account for 10% of the worldwide market and for more than 30% in some countries. In markets with powerful and effective regulatory systems (such as Australia, Canada, most EU countries, etc.), falsified medical products are estimated to represent less than 1% of the market value. Internet is a perfect hiding place for counterfeiters. It provides an international channel for sales, as well as anonymity and ease of concealment.

- Last WHO fact sheets of January 2018 estimated that 1 in 10 medical products in low- and middle-income countries is substandard or falsified.
- (WHO) Global Surveillance and Monitoring System for substandard and falsified medicines, vaccines and in vitro diagnostic tests (GSMS) during its first four years of operation, up to 30 June 2017, contains more than 1,500 product reports.
- Ex: The Indonesian Ministry of Health believes that around 5,000 children received falsified vaccines in 2016 alone.

Falsified medical products give rise to multiple risks because they:

- Endanger patients’ health (according to the WHO, falsified medical products may be responsible for a large number of deaths worldwide), it is estimated to hundreds of thousands deaths a year.
- Feed a parallel and freeloading economy, which is contrary to sustainable development and may present risks to safety, hygiene, the environment, ethics, human rights, *etc*.

We can also note the economic cost of counterfeit medicines for industry, government and society as a whole. Each year in the European Union alone it causes[1] the:

- Loss of 4.4% of legitimate sales;
- Loss of €10.2 billion in revenue for the sector;
- Destruction of 90,900 direct and indirect jobs;
- Loss of €1.7 billion in government revenue (taxes and social contributions).

3. A global mobilization

The fight against falsified medical products mobilizes an increasing number of stakeholders, governments and healthcare authorities as well as police organizations and customs officials.

[1] European Union intellectual Property Office (EUIPO),
The Economic Cost of IPR Infringement in the Pharmaceutical Sector, 2016

II. MORE STRINGENT LEGISLATION

Besides the WHO new definition, to date there is no international instrument that is universal in scope and would provide a unanimously accepted basis for preventive measures and for efficiently fighting against falsified medical products. Nevertheless, such threat to public health has given rise to political mobilization in recent years.

1. The European Union

Directive 2011/62/EU introduced tougher rules to protect public health with new harmonized measures to prevent the entry of falsified medicines in the legal supply chain. It includes provisions ensuring easier identification of falsified medicines as well as improved verifications and controls including:

- A tamperproof system on the outer packaging as well as safety features for identification by serialization/aggregation by February 2019;
- A common EU-wide logo to identify legal online pharmacies so that it will be easier to distinguish between legal and illegal online pharmacies throughout the EU;
- Tougher rules on the controls and inspections of producers of active pharmaceutical ingredients;
- More stringent record-keeping requirements for wholesale distributors.

2. The Council of Europe[2]

Medicrime is the Council of Europe's Convention on the counterfeiting of medical products and similar crimes involving threats to public health. For the first time, it constitutes an international instrument in the criminal law field on counterfeiting of medical products and similar crimes involving threats to public health. Adopted in December 2010, the Medicrime Convention has been signed by 29 countries: Albania, Armenia, Austria, Belgium, Benin, Bosnia and Herzegovina, Burkina-Faso, Croatia, Cyprus, Denmark, Finland, France, Germany, Guinea, Hungary, Iceland, Israel, Italy, Liechtenstein, Luxembourg, Moldova, Morocco, Portugal, Russia, Slovenia, Spain, Switzerland, Turkey and Ukraine. It was ratified by 15 countries, namely: Albania, Armenia, Belgium, Benin, Burkina-Faso, France, Guinea, Hungary, Moldova, Portugal, Russia, Spain, Switzerland, Turkey and Ukraine.. The convention entered into force on January 1st, 2016 thanks to the 5th ratification.

The convention entered into force, in France, on January 1, 2017 - after a ratification act signed in September 2016[3].

III. POLICY

The fight against falsified medical products is part of the company's commitment to social responsibility in order to meet the needs of all patients, especially those in emerging and developing countries who are seeking access to medicines in the various disease areas in which the company has developed specific expertise. It is also part of our commitment to ensure patient safety worldwide.

1. A dedicated, internal anti-counterfeiting coordination organization

Sanofi's corporate anti-counterfeiting coordination organization takes a harmonized and holistic approach to tackling the issues related to falsified medical products, implemented through various initiatives. Experts from departments such as security, legal, industrial affairs, quality, communication, medical and regulatory are all

[2] The Council of Europe is an international organization comprising 47 member States in Europe whose aim is to promote democracy and protect human rights in Europe. For more information about Medicrime: http://conventions.coe.int/Treaty/EN/Treaties/Html/211.htm
[3] https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/211/signatures

involved. The anti-counterfeiting coordination organization is active on all continents and ensures the strategic alignment of all our preventive actions worldwide.

2. Fighting falsified medical products and promoting access to safe medicines

Falsified medical products are a major concern for Sanofi. The company coordinates international efforts to fight against falsification of its medicines in cooperation with many different health and enforcement authorities, and has developed a number of programs to promote access to safe medicines.
Sanofi actively supports efforts by the public authorities to maintain the highest standards of drug quality and safety and fight counterfeit drugs by:

- Working closely with local authorities and professional organizations to deliver information and design educational programs to create awareness and fight against falsified medical products and their potential damage to patients' health;
- Reinforcing cooperation with official bodies (international agencies, customs, police, *etc.*) to support their work in the fight against falsification;
- Centralizing all suspected products that correspond to products manufactured by Sanofi and samples from the market in our specialized laboratory, the Central Anti-Counterfeiting Laboratory (LCAC) based in Tours, France;
- Securing the supply chain and proactively implementing innovative solutions for its products to better protect them from falsification;
- Fostering a dedicated, structured organization involving experts from the security, legal, industrial affairs, quality, quality, communication, medical and regulatory departments to coordinate all activities regarding the fight against falsified medical products at global, regional and local level.

IV. ACTIONS

Sanofi organizes a wide range of initiatives in support of a single, critical goal: contributing to the fight against falsified medical products and, whenever possible, preventing the phenomenon. Our approach simultaneously pursues a large number of different objectives: protecting the patient, preserving trust in the supply chain, cooperating with national and international organizations, using cutting-edge technology to ensure product quality and operating our own dedicated Anti-Counterfeit Laboratory.

1. An essential tool: The Central Anti-Counterfeit Laboratory (LCAC)

Sanofi's LCAC is located at the company's pharmaceutical site in Tours, France. The laboratory started with 5 employees when it opened in 2008, and now operates with 15 employees. It represents an integral part of the program set up by Sanofi to combat falsified medical products.

NewCassys, a global Sanofi application designed for a large network of users everywhere in the world, was successfully launched on the 27th of November 2018. This unique tool gathers detailed information on all suspect cases, and reinforce the global observatory for falsification on all Sanofi product to ensure better communication to stakeholders.

With a dedicated team of specialists and state-of-the-art technologies, the LCAC pursues a three-fold mission:

- Perform direct technical examination of suspected samples with the most sophisticated analytical techniques;
- Design new analytical methods, in part with the aim of sharing them globally, to allow each industrial site worldwide to apply the same criteria when examining and performing analyses on all suspected products that correspond to products manufactured by Sanofi;
- Centralize so-called "identity cards" containing information about counterfeit products in a single, centralized database—the only database that enables wide-scale group cross-referencing of products identified as counterfeiting the company's drugs.

2. Using innovative technology to ensure the quality of our medicines

Counterfeiters increasingly use sophisticated means to produce fake medicines. Consequently, the pharmaceutical industry must continuously update innovative technological solutions to ensure the protection and traceability of products, to identify fake products and to secure the supply and distribution chain.

To reduce risks of falsification and rapidly authenticate our products, Sanofi has developed a specific label known as the Sanofi Security Label (SASL). It allows visible verification (by distributors and patients) as well as invisible verification (known by Sanofi only).

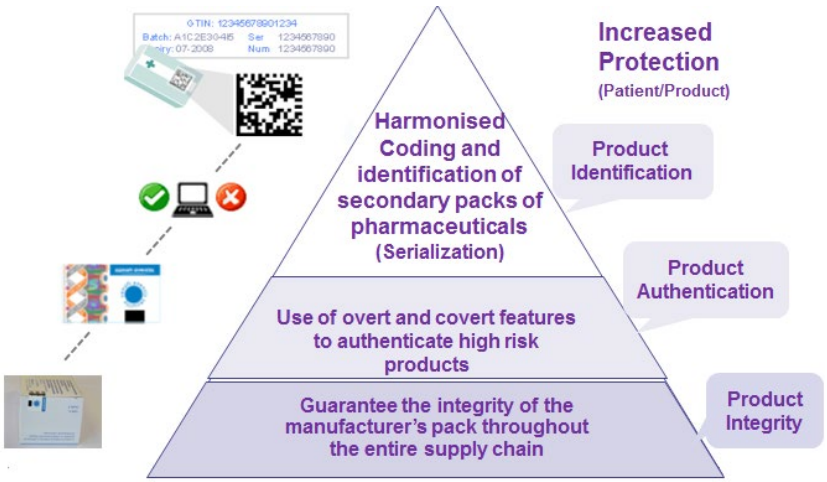
In 2017 Sanofi continued the development of these technologies for all new drugs and addressed new worldwide regulations, in terms of identification and serialization to protect products and secure the supply chain. Moreover, Sanofi is working on the use of tamper-evident packaging to reduce risks of violation of the integrity of the original manufacturer's packaging.

We have also implemented the use of Data Matrix technology for improved traceability.

For more information, see the factsheet "Serialization: Medicine Identification, Authentication & Traceability" in our Documents Center.

3. Implementing a global medicine protection strategy

Sanofi takes a layered approach to pack protection, illustrated in this pyramid diagram:



As part of measures to ensure patient safety and uphold the company's responsibility, Sanofi has put in place a new end-to-end product security program. Led by corporate security in close collaboration with supply chain, quality and insurance, it aims to:

- Identify threats and vulnerabilities from R&D, manufacturing, distribution to destruction and establish a cross-risk assessment;
- Define procedures, monitor and audit third parties to mitigate malicious acts all along the supply chain and to avoid attempts to falsify Sanofi products;
- Ensure secure delivery of our products to patients everywhere, particularly in emerging countries and regions that are vulnerable to this phenomenon.

4. Cooperating with national and international organizations

Convinced that public/private cooperation is essential to effectively fight counterfeit drugs, Sanofi participates actively in international and local organizations. Internationally, Sanofi collaborates with:

- Organizations such as the World Customs Organization (WCO), the International Criminal Police Organization (Interpol), Europol, the Organization for Economic Co-operation and Development (OECD);
- National and international health agencies;
- Professional federations, such as the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the Pharmaceutical Security Institute (PSI).

At the local level, the company cooperates with:

- The National Anti-counterfeit Committee (CNAC) and Union des fabricants (Unifab), a French organization of manufacturers that seeks to protect intellectual property and fight against counterfeit drugs;
- The Pharmaceutical Research and Manufacturers of America (PhRMA) in the United States;
- National federations such as LEEM (the French pharmaceutical companies association).

These collaborative ties have made it possible for Sanofi to:

- Sign charters supported by the French Ministry of Industry to facilitate prevention and contribute to the fight against counterfeit drugs sold on the Internet. These charters were signed with key players of e-commerce (2009) and classified ads and postal operators (2012).

For more information, see the following document available in our Documents Center.

- *Charte de lutte contre la contrefaçon (in French)*

Combating networks responsible for illicit sales of medicines online: Operation Pangea[4]

Pangea XI took place in October 2018:

- 116 countries participated;
- 500 tons of illicit potentially harmful medicines seized, worth approximately USD$14 million;
- 3,671 websites shut down;
- More than 859 arrests worldwide
- More than 110,000 medical devices were also seized

This global initiative, which also relies on support from Internet service providers, postal services and financial intermediaries, is aimed at educating Internet users about the dangers of buying medicines online.

Operation Pangea clearly demonstrates the importance of cooperation between public authorities and private companies to identify and dismantle these networks.

Each year, experts from Sanofi Corporate Security collect and analyze information on illicit networks. They share with Interpol information about dedicated cases that are ready to be handed over for action.

Source, consulted on March 20, 2019: https://www.interpol.int/News-and-Events/News/2018/Illicit-online-pharmaceuticals-500-tonnes-seized-in-global-operation

[4] https://www.interpol.int/News-and-media/News/2017/N2017-119

5. Developing awareness and educational programs

In 2017 Sanofi continued its training program for employees, public health agents, customs officials and police officers from around the world. There has been a focus on internal awareness among sales forces as well as quality and supply chain representatives to better detect malicious acts (theft, falsification, illicit diversion) involving Sanofi products, and to put in place mitigation measures within the framework of an end-to-end product security program.

Raising awareness among Sanofi employees, healthcare professionals and the health authorities is an important part of anti-counterfeit actions led by Sanofi.

The company pursues a policy to actively promote information and education across the globe, based on:

- Developing e-learning programs for in-house training;
- Creating a press kit about fighting falsified medical products (updated October 2018);
- Organizing regularly-scheduled information meetings and conferences at Sanofi's LCAC site in Tours (France) and worldwide;
- Providing training specifically for customs officials and police officers;
- Promoting the annual internal Sanofi global anti-counterfeit day, and involving all regions;

At the same time, we launched a mobile application called "Travel Tips," delivering advice and information to travellers.

As a member of the International Federation of Pharmaceutical Manufacturers and Associations, Sanofi supports the "Fight the Fake" campaign. Launched in November 2013, this campaign gathers several health organizations in a worldwide campaign to protect patients from fake medicines. The campaign gives a voice to those who have been personally impacted and shares the stories of those working to put a stop to this threat to public health.

For more on the "Fight the Fake" campaign, see: http://fightthefakes.org/

6. Update of the Sanofi AC strategy

A major internal initiative has been conducted in 2017, involving all departments engaged in the fight against falsified medical products, leading to the definition and implementation of an updated AC strategy taking into account the evolution of our environnment.

Highlights include:

- An improved governance model at global, regional and local levels;
- The creation of an Intelligence risk unit to better capture and manage solutions;
- An improved organization of the Central Anti-counterfeit Laboratory (LCAC);
- The enforcement of an "End-to-End" program: industrial securing of all supply-chain's steps;
- A more active presence in round tables and colloquium to further healthcare professional and large public alertness, as well as university conferences to train HCP students

Indicator	2016	2017	2018
Improvement of sampling, analysis and data collection of falsified Sanofi products	Since it was opened in 2008, more than 30,000 entries have been recorded by the Central Anti-Counterfeit Laboratory for the analysis of potential falsified medical products.	2,248 suspect samples have been analysed by the Central Anti-Counterfeit Laboratory, and by local teams, according to cases.	2,143 suspect samples have been analysed by the Central Anti-Counterfeit Laboratory, and by local teams, according to cases.
Greater visibility of Sanofi's commitment to combat falsified medical products worldwide	The fifth Sanofi global anti-counterfeit day involved more than 50 Sanofi sites/affiliates.	Inclusion of the anti-counterfeit day in a Sanofi worldwide Security day	Participation into diverse anticounterfeit conferences in different countries
Development of partnerships to strengthen collaboration with enforcement authorities (police, customs, etc.).		- Organization of a major local symposium with local authorities in Colombia, as a part of the Franco-Colombian year. - Mapping of key NGOs and patients associations. - Awareness sessions to various publics, notably French magistrates.	Awareness session to healthcare professional students (universities)
Contribution and involvement in international operations	Sanofi's contribution to major operations: **Pangea IX:** - 103 countries participated; - 12.2 million fake and illicit potentially harmful medicines seized, worth approximately US$53 million; - 4,932 websites shut down; - 393 arrests made.	Sanofi's contribution to major operations: **Pangea X:** - 123 countries involved; - 25 million fake and illicit, potentially harmful medicines seized (worth approximately US$51 million); - 3,548 websites shut down; - More than 400 arrests made.	Sanofi's contribution to major operations: **Pangea XI:** - 116 countries participated; - 500 tons of illicit potentially harmful medicines seized, (worth approximately USD$14 million); - 3,671 websites shut down; - More than 859 arrests worldwide