

## FIGHTING FALSIFIED MEDICAL PRODUCTS

### GRI Standards:

103: Management approach

416-1: Customer Health and Safety

### EXECUTIVE SUMMARY

Since its foundation, Sanofi has for ambition to fight against diseases and to improve populations' health everywhere in the world.

From prevention by vaccines to treatment with effective therapeutic solutions, Sanofi contributes to protect hundreds of millions of women, men and children. Ongoing launches of innovative medicines will change the living conditions of many additional patients who do not find answers today to their suffering.

Unfortunately, this vision can be seriously thwarted by the criminal acts of traffickers.

That is why Sanofi has set up a dedicated and tailored strategy, governance internal organization, tools and adopted a harmonized and holistic anti-counterfeiting approach to protect the patient, preserve trust in the supply chain, cooperate with national and international organizations, use advanced technologies to ensure product quality and operate our own dedicated anti-counterfeiting laboratory. Sanofi is also taking action to fight falsified medicines by raising awareness through promotion of access to safe medicines and educational programs to its third parties.

Sanofi's strategy in the fight against falsified medicines aims to protect patients' health by:

- securing Sanofi products;
- fostering awareness among public authorities, professionals and the public about the reality and the dangers of falsified medicines; and
- actively cooperating with official institutions.

However, to remain relevant, this strategy has to adapt to the following changes:

- new threats and trends in the crime of falsified medicines;
- Sanofi's growth strategy; and
- the commitment and efficacy in the fight against falsification of the stakeholders in the ecosystem.

Falsified medical products represent a crucial challenge in the field of public health.

As underlined by the European Commission: “Falsified medicines may contain ingredients of bad or toxic quality, or in the wrong dosage.”

But the concept of falsified medicines as used in this document refers to the definition expanded to the integrity of the product as commonly accepted thus far by the WHO:

“A fraudulent product whose real origin or identity is not stated whether or not it is compliant in terms of name, composition or packaging, whether or not it contains active ingredients.”

The WHO approved a new definition in May 2017 in its General Assembly. We now refer to “falsified” medical products, that is to say:

“Falsified” medical products deliberately or fraudulently misrepresent their identity, composition or source”. Any consideration related to intellectual property rights does not fall within this definition.

Thus, the difference between counterfeiting, related to intellectual property rights and falsification, presented as a public health issue, would need to now be made.

# TABLE OF CONTENTS

<b>1. BACKGROUND</b>	<b>4</b>
1.1. Definitions	4
1.2. A public health challenge	5
1.3. A global mobilization	5
<b>2. MORE STRINGENT LEGISLATION</b>	<b>5</b>
2.1. The European Union	6
2.2. The Council of Europe	6
<b>3. ORGANIZATION</b>	<b>7</b>
3.1. A dedicated internal Anti-counterfeiting Strategy & Coordination organization	7
3.2. Fighting falsified medical products and promoting access to safe medicines	7
<b>4. ACTIONS</b>	<b>8</b>
4.1. A unique asset: The Central Anti-Counterfeit Laboratory (LCAC)	8
4.2. Using innovative technologies to ensure the quality of our medicines	8
4.3. Implementing a global medicine protection strategy	9
4.4. Cooperating with national and international organizations	9
4.5. Developing awareness and educational programs	11
4.6. Sanofi anti-counterfeiting strategy	11

## 1. BACKGROUND

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### 1.1. Definitions

The term “falsified” is frequently used to distinguish such public health offences 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 mislabeled 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 previous terminology adopted more than 20 years ago and lacking common understanding to “Substandard and Falsified (SF) medical products”.

Falsified medical products are:

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 National or Regional Regulatory Authority.
- “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.

## 1.2. 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<sup>1</sup> estimated that 1 in 10 medical products in low- and middle-income countries is substandard or falsified.
- WHO Global Surveillance and Monitoring System (GSMS)<sup>2</sup> for substandard and falsified medicines, vaccines and in vitro diagnostic tests during its first four years of operation, up to 30 June 2017, contains more than 1,500 product reports. 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 of 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<sup>3</sup> 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).

## 1.3. 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.

<sup>1</sup> [Substandard and falsified medical products](#), 31 January 2018

<sup>2</sup> [WHO Global Surveillance and Monitoring System for substandard and falsified medical products](#), November 2017

<sup>3</sup> European Union intellectual Property Office (EUIPO), [The Economic Cost of IPR Infringement in the Pharmaceutical Sector](#), September 2016

## 2. MORE STRINGENT LEGISLATION

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Besides the WHO new definition, to date there is no international instrument that is universal in scope and would provide an 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.

### 2.1. 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 implemented in February 2019;
- A common EU-wide logo introduced in July 2015 to identify legal online pharmacies so that it is 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.

### 2.2. The Council of Europe<sup>4</sup>

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 15 countries: Austria, Cyprus, Denmark, Finland, Germany, Iceland, Israel, Italy, Ivory Coast, Liechtenstein, Luxembourg, Morocco, Niger, Serbia, Slovenia.

It was ratified by 18 countries, namely: Albania, Armenia, Belarus, Belgium, Benin, Bosnia and Herzegovina, Burkina-Faso, Croatia, France, Guinea, Hungary, Moldova, Portugal, Russia, Spain, Switzerland, Turkey, and Ukraine. The convention entered into force on January 1<sup>st</sup>, 2016 thanks to the 5<sup>th</sup> ratification.

The convention entered into force, in France, on January 1, 2017 - after a ratification act signed in September 2016<sup>5</sup>.

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<sup>4</sup> 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>

<sup>5</sup> <https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/211/signatures>

### 3. ORGANIZATION

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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.

#### 3.1. A dedicated, internal Anti-counterfeiting Strategy & Coordination organization

Sanofi's corporate Anti-counterfeiting Strategy & 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, communication, quality, external affairs, medical and regulatory are all involved. The Anti-counterfeiting Strategy & Coordination organization is active on all continents and ensures the strategic alignment of all our preventive actions worldwide.

#### 3.2. 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 several 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:

- Securing the supply chain and proactively implementing innovative packaging protection solutions for its products to better protect them from falsification;
- 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 suspect 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;
- Fostering a dedicated, structured organization involving experts from the security, legal, industrial affairs, quality, external affairs, medical and regulatory departments to coordinate all activities regarding the fight against falsified medical products at global, regional and local level.
- Raising internal and external awareness about the risks associated with falsified medicines and vaccines.

## 4. ACTIONS

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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 many 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.

### 4.1. A unique asset: 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 database designed for a large network of users everywhere in the world, was launched in November 2018. This unique tool gathers detailed information on all suspect cases and reinforces the global observatory for falsification and diversion on all Sanofi products 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.

### 4.2. Using innovative technologies 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 and eSASL). It allows visible verification (by distributors, health professional and patients) as well as invisible verification (known by Sanofi only).

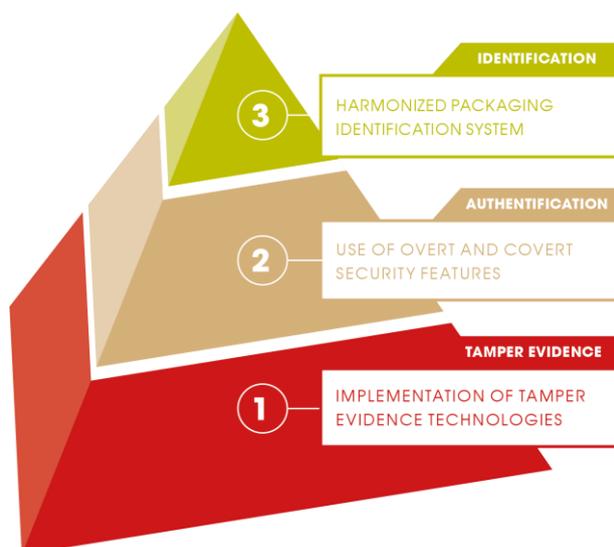
Sanofi continues the development of these technologies for all new drugs and addresses new worldwide regulations, in terms of identification and serialization to protect products and secure the supply chain. Moreover, Sanofi is working on the use of tamper-evident packaging to reduce risks of violation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

We have also implemented the use of Data Matrix technology for improved traceability, and proactively identify new digital technologies able to facilitate detection and verification.

Read more on "Serialization: Medicine Identification, Authentication & Traceability" in our [Document Center](#).

### 4.3. Implementing a global medicine protection strategy

Sanofi takes a three-level approach to pack protection, illustrated in this diagram:



As part of measures to ensure patient safety and uphold the company's responsibility, Sanofi has put in place an 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.

### 4.4. 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), Europol, the Organization for Economic Co-operation and Development (OECD);
- National and international health agencies; WHO (World Health Organization);
- 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 country 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);
- The G5 Santé with peers.

### **Combating networks responsible for illicit sales of medicines online: Operation Pangea<sup>1</sup>**

Pangea is an annual international operation coordinated by Interpol and targets the online sale of counterfeit and illicit medicines and medical devices.

“Since its launch in 2008, the Operation has removed more than 105 million units (pills, ampoules, sachets, bottles and so on) from circulation and made more than 3,000 arrests. This Operation reveals that at least 11 % of medical products sold online are counterfeit and all regions of the world are affected. Since 2015, the types of illicit medicines seized have become more diversified, including quantities of hypnotics, sedatives and anti-inflammatory medication.”

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.

### **Operation Shield<sup>2</sup>, to target trafficking of counterfeit and misused medicines, and protect patients' health**

Europol coordinated operation Shield, a global effort to target trafficking of counterfeit and misused medicines and doping substances. The operation was led by Finland, France, Greece and Italy and involved law enforcement authorities from 27 countries (19 EU Member States and 8 third-party countries), the European Anti-Fraud Office (OLAF), the Pharmaceutical Security Institute and the private sector. The operation took place between March and September 2020.

Points of interest include:

- Seizures worth nearly €73 million;
- More than 25 million units of medicines and doping substances seized;
- 25 organized crime groups dismantled;
- 10 clandestine laboratories seized;
- 453 websites shut down.

New Trends include:

- Most of the oncologic medicines are diverted from the legal supply chain through the massive use of falsified prescriptions.
- Asia remains the main source region for the supply of raw materials for medicines and anabolic substances.
- Illegal sale of medicines obtained with forged or stolen medical prescriptions.

Europol also launched other successful operations Mismed<sup>3</sup> and Viribus to tackle the trafficking of

<sup>1</sup> <https://www.interpol.int/en/News-and-Events/News/2019/Operation-Pangea-shining-a-light-on-pharmaceutical-crime>

<sup>2</sup> [MEDICINES AND DOPING SUBSTANCES WORTH €73 MILLION SEIZED IN EUROPE-WIDE OPERATION](#), Europol, December 2020

<sup>3</sup> [€7.9 MILLION OF ILLEGAL PRODUCTS SEIZED IN A HIT AGAINST MEDICINE TRAFFICKERS](#), Europol, March 2020

counterfeit medicines and doping substances.

#### 4.5. Developing awareness and educational programs

Sanofi has training programs 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 eLearning Modules for in-house training;
- Developing a dedicated press kit about fighting falsified medical products;
- Organizing regularly scheduled information meetings and conferences at Sanofi's LCAC site in Tours (France) and worldwide;
- Providing training specifically for customs officials, police officers and healthcare professionals;
- Promoting Sanofi global anti-counterfeit activity during Security week and involving all regions.
- Developing programs with peers and international organizations to raise awareness widely.

As a member of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), Sanofi supports the "Fight the Fakes" 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.

Read more on the "Fight the Fake" campaign: <http://fightthefakes.org/>

In 2020, the [Youth IGF movement](#) has teamed up with the [Alliance for Safe Online Pharmacy in the EU \(ASOP EU\)](#) supported by the global healthcare companies [Ipsen](#), [Servier](#) and Sanofi to educate the youth about buying fake medicines online in particular COVID-19 scams. The campaign was called "We rely on you. We rely on youth".

The campaign comprised 10 educational debates across the world to inform the youth about the rising tide of websites capitalizing on fear and misinformation regarding COVID-19. These illegal sites advertise and sell falsified medicines and vaccines. Ultimately, this places significant risks and opportunities for harm to citizens.

#### 4.6. Sanofi anti-counterfeiting strategy

A major internal initiative was conducted in 2017\*, involving all departments engaged in the fight against falsified medical products, leading to the definition and implementation of an anti-counterfeiting strategy taking into account the evolution of our environment.

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 healthcare professionals students.

\*Challenges 2021:

- > Sanofi transformation with focus on GBUs including innovative medicines “Specialty Care”, Vaccines and lifesaving creates strong expectations from patients and opportunities.
- > Anti-counterfeiting strategy is aligned with its new challenges to ensure complete risk mitigation and patient safety.