FIGHTING COUNTERFEIT MEDICINES

G4 indicators: G4-DMA, G4-PR3

I. BACKGROUND

1. Definition

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

The term "falsified" is frequently used to distinguish such infringements from breaches of intellectual property rights, so-called "counterfeits." The directive of the European Parliament and the Council of the European Union amending directive 2001/83/EC is aimed at preventing the introduction of counterfeit medicines into the legal supply chain. Counterfeit 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 labeling, 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 will be enforceable only in European Union countries.

The World Health Organization (WHO), at an international meeting held in Geneva in April 1992, adopted the following definition: "A counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to its identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient (inadequate quantities of) active ingredient(s) or with fake packaging."

2. A public health challenge

Fighting counterfeit drugs represents a substantial public health challenge. The extent of the counterfeiting problem is impossible to quantify. However, the WHO estimates that counterfeit products account for 10% of the market worldwide, and for more than 30% in some countries. In markets with powerful and effective regulatory systems (such as Australia, Canada, most EU countries, etc.), counterfeit drugs 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. According to WHO, approximately 50% of drugs sold on illegal websites that conceal their physical address have been found to be counterfeit.

Counterfeit medicines give rise to multiple risks because they:

- Endanger patients' health (according to the WHO, counterfeit medicines may be responsible for a large number of deaths worldwide)
- 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 counterfeit drugs 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

To date there is no international instrument that is universal in scope and would provide a unanimously accepted definition of the falsification of medical products. Such a definition would provide a basis for preventive measures and the fight against counterfeit medicines. Counterfeiting, which is indeed a 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
- 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 26 countries: Albania, Armenia, Austria, Belgium, Bosnia and Herzegovina, Croatia, Cyprus, Denmark, Finland, France, Germany, Guinea, Hungary, Iceland, Israel, Italy, Liechtenstein, Luxembourg, Moldova, Morocco, Portugal, Russia, Spain, Switzerland, Turkey and Ukraine. It was ratified by Albania, Armenia, Belgium, France, Guinea, Hungary, Moldova, Spain and Ukraine; eight are Council of Europe members. After the fifth ratification by Guinea in 2015, the Convention entered into force on January 1, 2016.

[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

III. POLICY

The fight against counterfeit medicines 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 the counterfeit of medical products, implemented through various initiatives. Experts from departments such as security, legal, industrial affairs, cybercrime, communication, medical and regulatory all take part. The anti-counterfeiting coordination organization is active on all continents and ensures the strategic alignment of all our preventive actions worldwide.

2. Fighting counterfeit medicines and promoting access to safe medicines

Counterfeit drugs are a major concern for Sanofi. The company coordinates international efforts to fight against the counterfeiting 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 counterfeiting drugs 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 counterfeiting
- 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 and counterfeiting
- Fostering a dedicated, structured organization involving experts from the security, legal, industrial affairs, quality, cybercrime, communication, medical and regulatory departments to coordinate all activities regarding the fight against counterfeit medicines 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 counterfeit drugs 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, where 17 people work, was opened in 2008 and represents an integral part of the program set up by Sanofi to combat counterfeit drugs. Since 2008, more than 30,000 entries have been recorded by the LCAC for the analysis of potential counterfeit products.

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 contains the means for visible verification (by distributors and patients) as well as invisible verification (known by Sanofi only).

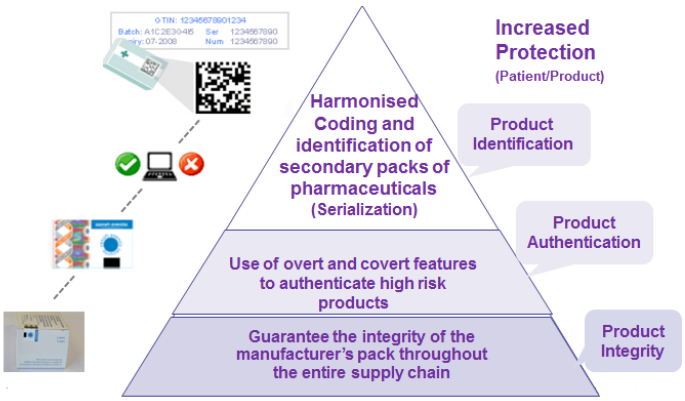
In 2016 Sanofi continued the development of these technologies for all new drugs and addressed new worldwide regulations, in terms of identification and serialization to protect products and secure the supply chain. Moreover, Sanofi is working on the use of tamper-evident packaging to reduce risks of 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 Download 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 Download Center.

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

Combating networks responsible for illicit sales of medicines online: Operation Pangea[3]

Pangea IX took place in May-June 2016:

- 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
- More than 270,000 medical devices worth an estimated US$1.1 million recovered

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 January 18, 2017: https://www.interpol.int/en/News-and-media/News/2016/N2016-076

5. Developing awareness and education programs

In 2016 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, counterfeit, 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 counterfeit drugs
- Organizing regularly-scheduled information meetings and conferences at Sanofi's LCAC site in Tours (France) and worldwide (142 people visited the LCAC in 2016)
- Providing training specifically for customs officials and police officers
- Promoting the fourth Sanofi global anti-counterfeit day, held in June and involving more than 50 Sanofi sites/affiliates
- Launching a website dedicated to counterfeit medicines in December 2013; the site is designed to meet information needs, provide guidance and highlight Sanofi's commitment to addressing this public health challenge. For more information, see the website at *http://fakemedicinesrealdanger.com/web/*

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

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 together 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/

[3] http://www.interpol.int/fr/Crime-areas/Pharmaceutical-crime/Operations/Operation-Pangea

V. INDICATORS

Indicator	2014	2015	2016
Improvement of sampling, analysis and data collection of counterfeit Sanofi products	Due to better targeting and strong collaboration with authorities around the world, the percentage of suspect products received from seizures (police, customs, etc.) grew from 6% in 2013 to 16% in 2014. The product range analyzed in 2014 is much larger and includes veterinary products and vaccines. Since the LCAC was opened in 2008, around 30,000 entries were recorded by the Central Anti-Counterfeit Laboratory in order to analyze potential counterfeit 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 counterfeit 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 counterfeit products.
Greater visibility of Sanofi's commitment to combat counterfeit medicines worldwide	In 2014 Sanofi trained around 20,000 people including employees and non-employees. The third Sanofi global anti-counterfeit day involved 50 Sanofi sites/affiliates. The website and travel application are now in place.	Sanofi trained around 15,000 people including employees and non-employees. The fourth Sanofi global anti-counterfeit day involved more than 60 Sanofi sites/affiliates.	The fifth Sanofi global anti-counterfeit day involved more than 50 Sanofi sites/affiliates.
Development of partnerships to strengthen collaboration with enforcement authorities (police, customs, etc.).	More than 7,300 public agents (ministries of health, customs, police, judges) were trained on Sanofi product recognition and/or alerted to the danger of pharmaceutical counterfeiting worldwide.	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, counterfeit, diversion) involving Sanofi products, and to put in place mitigation measures within the framework of an end-to-end product security program.	
Contribution and involvement in international operations	Sanofi's contribution to major operations: **Pangea VII:** - participation of 113 countries - the seizure of 9.6 million potentially harmful medicines, worth approximately US$32 million - 11,800 websites shut down - 434 individuals under investigation or arrest Through OMD Sanofi took part in Operation Biyela II in April 2014: - 14 customs administrations - 10 days - 290 containers inspected - 118 million of fake/illicit products intercepted, including 113 pharma products The operation was conducted in several African countries, resulting in the seizure of illicit medicines. No Sanofi products were seized.	Sanofi's contribution to major operations: **Pangea VIII:** - 115 countries took part - seizure of 20.7 million fake and illicit potentially harmful medicines, worth approximately US$81 million - more than 2,410 websites shut down - 156 people arrested - 550 advertisements for illicit pharmaceuticals removed from the Internet	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