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Fight Against Falsified Medicines and Illicit Trafficking

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GRI Standards:

103: Management approach

416: Customer Health and Safety

EXECUTIVE SUMMARY

We chase the miracles of science to improve people's lives

Since its foundation, our Company 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, we contribute to protect hundreds of millions of women, men and children. Ongoing launches of innovative medicine solutions will change the living conditions of many additional patients who do not find answers today to their suffering.

Unfortunately, this ambition can be seriously thwarted by the criminal acts of traffickers. That is why we have established a transversal and centralized organization to design a dedicated strategy, coordinate action plans, and respond quickly to incidents or crises.

Falsified medical products⁽¹⁾ 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."

Conscious and serious about the role that health plays at the heart of society, a new strategy to fight against falsified medicines and illicit trafficking has been designed to consider new threats and challenges to ensure the protection of the patients of today and the patients of tomorrow. This is our responsibility.

This strategy includes the following actions:

- our Global Security network supports the implementation of actions to combat falsified medicine and illicit trafficking in conjunction with the industry, law enforcement, and health authorities. This provides a capacity to detect medicine trafficking globally and to deploy a consistent level of security measures to prevent risks to products and patient;
- monitoring online sales offers (marketplaces, social media, online pharmacies) to request the takedown of illicit offers and investigate sellers;
- our dedicated Central Anti-Counterfeiting Laboratory (LCAC) based in Tours (France) analyzes suspicious samples and provides scientific information useful for the public health authorities and for potential prosecutions;
- securing the supply chain to ensure integrity and avoid infiltration;
- authenticating products via labels and an innovative digital solution (eSASL);
- conducting awareness programs for the forty most underprivileged countries in the world;
- working within and partnering a wide variety of institutions, professional organizations, and international, regional, and national associations, both public and private (e.g. World Health Organisation - WHO, Europol, Pharmaceutical Security Institute - PSI, the European Federation of Pharmaceutical Industries and Associations - EFPIA, *G5 Santé*, OCLAESP, Unifab, LEEM) to help design and implement joint programs and initiatives to:
 - > comply with WHO recommendations by reporting all confirmed cases to national health authorities;
 - > support the implementation of specific legislation on the danger of falsified medicines for public health, and support law enforcement bodies and customs in their effort to dismantle criminal networks.

This comprehensive strategy shows our strong commitment from the market to remove dangerous medical products and thus protect the patients.

¹ WHO definition: "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."

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1. Global Overview

1.1. CONSCIOUS AND SERIOUS ABOUT ISSUES TO HEAD ON

1.1.1. To protect patients

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% for areas such as Southeast Asia, and Sub-Saharan Africa.

1.1.2. To ensure safe access to medication

One sub-branch of e-commerce is the online trade of medicines. This type of trade has not been impervious to the phenomenon of falsification. On the contrary, e-commerce has indirectly provided new possibilities for traffickers to deliver falsified goods and boost sales. Falsification activities on the Internet have rapidly become both professionalized and globalized. Moreover, falsified medicines are offered for sale on thousands of websites, almost all of which are registered in an opaque manner, making the work of the judicial authorities increasingly difficult.

The impact of the lockdowns on the use of online sales has been such that e-commerce has increased of over 36% in only two years.

Falsified medicines sold online because of hazardous effects can undermine consumers' trust regarding our Company and potentially result in a reputational risk for us.

As a manufacturer, all these elements inherent to e-commerce structure and specificities, we implement new measures to fulfill our missions against falsification and illicit trafficking.

1.1.3. To provide an inclusive and non-discriminating protection for all countries

Regarding the mature markets endowed with powerful and effective regulatory systems (Australia, Canada, most EU countries), 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.

1.1.4. Falsified medical products give rise to multiple risks because they endanger patients' health and feed a parallel economy contrary to sustainable development

We also note the economic cost of falsified medicines for industry, government, and society as a whole. Each year, in the European Union alone, it causes loss of €10.2 billion in revenue for the sector and destruction of 90,900 direct and indirect jobs.

These threats on public health could be aggravated by the outbreaking of e-commerce. Therefore, the situation is such that the total amount of Internet users has been increasing from 2.2 billion in 2014 up to 4.2 billion in 2021. In other words, the number of internet users doubled in less than ten years.

1.2. CONNECTED AND AWARE ABOUT LEGAL INITIATIVES

Taking into consideration new threats and challenges, some countries unveiled drafts and decrees to crack down on falsification by highlighting threats posed by e-commerce sales. In December 2020, the European Commission disclosed its intention to amend the 2001 e-commerce directive through the Digital Services Act (DSA).

The DSA is the result of recent legal trends observed all around the world. Therefore, the jurisdiction's will to prevent distribution of falsified medicines sold online thanks to a strong legal basis adapted to the weight of platforms, digitalization of economy and hazardousness of products has been observed in several countries such as the United States of America (SHOP SAFE Act - March 2020, INFORM Consumers Act - March 2021), Republic of China - the e-commerce law is currently under revision - or countries of Latin American area as Chile (decree no.466, May 2020).

2. Our organization

To tackle falsified medicines and illicit trafficking, we set up both global and local governance detailed hereinafter.

2.1. OUR DEDICATED INTERNAL ORGANIZATION

Our anti-falsification and illicit trafficking strategy is implemented and coordinated through a dedicated governance body. This organization takes a harmonized and holistic approach to tackling this main concern, implemented through various targeted and tailored actions. The effectiveness is also based on a dedicated decentralized network in charge of this mission with an in-depth knowledge of each large geographic region.

Since 2007, we have designed our organization with a global and local governance entity with a range of departments (e.g. Legal, Business Units, Quality, Regulatory, Pharmacovigilance, Medical, Corporate Affairs and Security representatives). We are determined to tackle issues thanks to this global vision of the challenges.

Our Company is endowed with a strong Security and anti-counterfeiting coordinator network at country level for suspicious case management. Moreover, we benefit from a specialized laboratory (LCAC) in Tours (France), to analyze suspicious products and provide scientific confirmation ready to use for public health authorities.

2.2. AN UNDISPUTABLE ASSET: THE CENTRAL ANTI-COUNTERFEIT LABORATORY (LCAC)

The laboratory is part of the strategy we set up to fight against falsified medicines. Thanks to a dedicated tool (NewCassys launched in November 2018), this database based on management tools details information about suspect cases and reinforces the global observatory for falsification and diversion on all our products to ensure better communication to stakeholders.

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

Since 2008, what missions has the LCAC been pursuing?

- 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 our manufactured products; and

- centralize so-called “identity cards” containing information about falsified products in a single, centralized database — the only database that enables wide-scale group cross-referencing of products identified as falsified.

3. Our responses

We are running a wide range of initiatives in support of a single critical goal: contributing to the fight against falsified medicines and illicit trafficking. Our approach is to simultaneously protect the patient, to preserve trust in the supply chain, to cooperate with national and international organizations, to use cutting-edge technology to ensure product quality and to operate our own dedicated Central Anti-Counterfeit Laboratory (LCAC).

3.1. OUR STRATEGY FULLY ALIGNED WITH NEW CHALLENGES

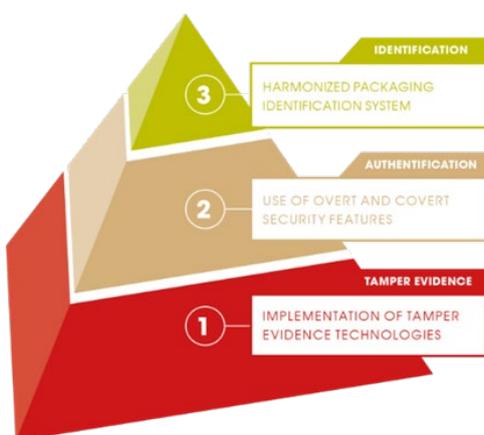
Our Company has developed a strategy highlighting priority actions accordingly to current challenges in terms of societal responsibility and geographical footprint.

In terms of business priority, our new strategy is based on three main directions guiding every action to be more humankind. Concretely, an effective protection of the product from the pipeline to deliverance to the patient warrants our products and business security. The protection of patients of today and tomorrow is ensured by involvement of all stakeholders with a tailored approach. Lastly, our engagement for people and planet is to multiply social and environmental impact by actions whose aim shall be to create a movement for a global and coordinated response.

3.2. DEDICATED PROGRAMS TO TACKLE THIS SCOURGE

3.2.1. Secure the product

As part of measures to ensure patient safety and uphold our responsibility, we put in place various programs hereinafter.



How industrial protection guides our actions?

The increasing distribution of falsified medicines has forced the pharmaceutical industry to conceive several ways to protect medical products by: identifying threats and vulnerabilities from R&D, manufacturing, distribution to destruction and establishing a cross-risk assessment; defining procedures, monitoring and auditing third parties to mitigate malicious acts all along the supply chain and to avoid attempts to falsify Sanofi products; ensuring secure delivery of our products to patients everywhere, particularly in emerging countries and regions that are vulnerable to this phenomenon.

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.

We launched in July 2021 in Hangzhou (China), an eco-friendly packaging thanks to which we protect the planet and reaffirm our values. To push the authentication of our products even further in a digitalized world, e-SASL label, a non-visible labelling technology using e-finger technology reduces production time and cost by removing physical labelling step. Patients can download our dedicated app on smartphones and this easy-to-use solution helps us to promptly tackle any issue we could face on. Once again, we try to do everything possible to chase miracles.

Convinced that innovation does increase protection, a consortium named PharmaLedger tends to develop a program based on blockchain technology to ensure the security of the supply chain.

What are our dedicated committees to secure our supply chain?

Two committees have been set up to secure our products such as: Protect the Pipeline Committee (critical assets) and an End-to-end product security committee. Led by the Security in close collaboration with Supply Chain, Quality and Insurance Departments.

What are our actions based on detection and investigation to ensure product's security? With web monitoring process, we verify the medical products distributed online are genuine. If necessary, we can set up operations of web cleaning to close fraudulent offers on platforms unauthorized to sell products. Under some circumstances, web monitoring can also result in test purchase.

Thanks to sampling exercise, physical samples are sent to the LCAC to verify products are falsified or not.

How are we involved in legal issues?

From the phase of detection until the court decision, the Legal Department works closely with several entities and supports security team for investigations to allow filing of a criminal complaint. In some cases, we can also be an actor in court proceedings and act in Court as a civil party.

How do we collaborate with operational partnerships?

Legal with/and Security Departments carry out several actions implemented by local and national authorities (police, customs) to maximize actions to stop distribution of falsified medicines. These actions are based on sharing of actionable information related to investigation to relevant law enforcement authorities; providing training specifically for customs officials, police officers and healthcare professionals to make identification of unnormal flows regarding the supply chain more efficient.

3.3. HOW TO BECOME AN INSPIRATIONAL AND RELIABLE ENTITY?

How can we develop awareness thanks to educational programs?

Raising awareness among our colleagues, healthcare professionals and the health authorities is a significant part of the anti-falsification actions led by our Company worldwide.

We pursue a policy to actively promote information and education across the globe, based on: eLearning modules for in-house training; a dedicated press kit about fighting falsified medical products; a regular basis scheduled information meetings and conferences at Sanofi's LCAC site and worldwide; several programs with peers and international organizations to raise awareness widely.

How can we build strong cooperation with trustworthy strategic partners?

Convinced that public/private cooperation is essential to effectively fight against falsified medicine and illicit trafficking in an uncoordinated ecosystem, we are determined to take actively part in international and local organizations.

At national level, our Company cooperates with the National Anti-Counterfeit Committee (CNAC), Union des fabricants (Unifab), G5 Santé.

At international level, we collaborate with a wide range of organizations: World Customs Organization (WCO), several national and international health agencies; some professional federations such as the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), EFPIA and PSI.

Regarding e-commerce, how can we reaffirm our commitment towards public actors and leaders?

We try to do everything possible to prevent hazardousness of fake medicines sold online and our actions resulted in advocacy actions such as report Blanchet-Bournazel (October 2021, about anti-falsification fight in France with Unifab); DSA amendments to crack down on falsified medicines’ distribution online (along 2021 year with national strategic partners).

4. Our achievements

Since the first quarter of 2020, the COVID-19 pandemic and the successive lockdowns imposed in countries have led to a drastic decrease in field investigations and law enforcement operations. These factors explain the reduction in the number of seizures and dismantling of illicit manufacturing sites since 2020, compared to 2019 - a phenomenon faced by all pharmaceutical companies.

Fight falsified medical products and illicit trafficking as of December 31, 2021	2021	2020	2019
Number of seizures (doses)	706,477	2,859,054	5,278,814
Number of illicit falsified medicine manufacturing facilities	1	3	23
Number of suspected products analysis conducted by LCAC since 2008	45,955	44,022	41,885
Sanofi legal actions against falsified medicines (including pre-litigation)	42	46	37
Web monitoring ⁽²⁾:			
Number of fraudulent offers detected	2,207	1,230	
Number of takedowns (offer removed)	1,610	ND	
Number of illicit online pharmacies detected	1,795	ND	
Number of takedowns (offline sites)	1,042	ND	ND

² Reduce illicit offers and mitigate risks on patient’s health, a proactive web monitoring and takedown process (since 2021) on life savings products in key markets (North America, Europe, Asia) have been accelerated. All actionable evidence is systematically shared with local authorities to leverage results against pharmaceutical fraud networks.