FAKE MEDICINES
A REAL DANGER FOR HEALTH

COUNTERFEIT MEDICINES
INFORMING YOU TO RAISE PATIENT AWARENESS

SANOFI
FOR HEALTH

A DANGER

WHAT IS A FALSIFIED MEDICINE?
A falsified medicinal product is any medicinal product with a false representation of its identity, its source or its history. (1)

It is a product that does not comply with the safety, quality and efficacy standards that apply to authentic drugs.

Counterfeit drugs may be products containing the correct active ingredients, no active ingredient, insufficient or excessively-dosed active ingredient, or having a fake packaging.

WHAT TYPES OF DRUGS ARE SUBJECT TO COUNTERFEITING?

- All health products can be subject to counterfeiting: innovative drugs, generics, non prescription drugs or treatments for life-threatening pathologies.
- Cosmetics, reactants and medical devices (contact lenses, condoms, blood glucose strips, etc.), are also exposed to counterfeiting. (2)

WHAT ARE THE RISKS FOR PATIENTS?

- Patients may fail to receive the treatment which they need,
- If toxic substances are used, intake can result in death,
- Certain strains resistant may develop to treatments for infectious diseases (antibiotics, anti-malaria drugs, etc.).
- Patients exposure to viral or bacterial infections (sterile products, vaccines),
- Public confidence may be lost in medical products and the healthcare system.

(1) Directive 2011/62/UE
(2) ANSM, (National Agency for Medicinal and Health Product Safety), guidebook for pharmacists

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Counterfeit medicines come from international trafficking networks, which generates profits exceeding those of narcotics trafficking.\(^{(1)}\)

In many countries, counterfeiting is not a criminal offence and the sanctions are limited.

WHERE DO FAKE MEDICATIONS ORIGINATE?

China remains the country from which the vast majority of counterfeit medications come.\(^{(2)}\)

However, the roads of counterfeiting have no borders.

A falsified product can be produced in Asia, exported to Europe and infiltrate the legal distribution chain in this manner, via a wholesaler.

WHICH COUNTRIES ARE MOST EXPOSED?

In industrialised countries with regulatory systems and effective market control mechanisms, the occurrence level is low.

However, in many countries in Africa, Asia, Latin America and in emerging economies, where the pharmaceutical control system is less regulated, the percentage of counterfeit drugs is higher.\(^{(3)}\)

WHAT IS THE INCIDENCE IN EUROPE?

In 2011, medicines topped the list of counterfeit products retained by the European Customs Authorities (24% of the total), toppling counterfeited cigarettes.

27 460 538 counterfeit medicines were retained amounting to a total value of approximately €28 million.\(^{(4)}\)

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\(^{(2)}\) Pharmaceutical Security Institute, “2011 situation report”


\(^{(4)}\) Report on UE customs enforcement of intellectual property rights 2011
OVERVIEW OF THE ONLINE DRUG MARKET

WHERE DO ONLINE DRUG SALES STAND TODAY?

The sale of drugs on the Internet has surged in recent years. While some online pharmacies are legally-established in certain countries, 96% of the websites offering drugs are believed to be operating in blatant defiance of the law\(^{(1)}\). These sites offer prescription drugs without requiring a prescription and sell unapproved or falsified products. Run by illegal organisations, such structures operate as a network, hiding their true identity or misrepresenting their actual location.

WHAT ARE THE RISKS INCURRED BY THOSE BUYING DRUGS ONLINE?

In 50% of cases, medicines purchased over the Internet from illegal sites that conceal their physical address have been found to be counterfeit\(^{(2)}\).

When on-line pharmacy does not comply with the conditions set out by the local legislation, neither the drug quality, origin nor storage and transport conditions can be guaranteed.

WHAT IS THE LEGAL FRAMEWORK GOVERNING ONLINE DRUG SALES?

- Some countries allow and regulate the sale of drugs online (Germany, United States, Netherlands, Portugal, United Kingdom, etc.), but in others, the legislation does not allow it yet.
- However, the legislation is changing and it is possible that online drug sales will develop. The European Directive on “Falsified Drugs” sets out provisions intended as a means of better fighting against falsified drugs online (e.g., Community logo).

\(^{(1)}\) Survey published in 2011 by the National Association of Boards of Pharmacy (NABP)
SANOFI’S INVOLVEMENT IN THE FIGHT AGAINST FAKE MEDICINES

WHICH ARE THE DIFFERENT EXPERTISES INVOLVED IN THE FIGHT AGAINST COUNTERFEITING?

In 2007, Sanofi set up its own central coordination team combining a variety of expertise:

- Industrial affairs
- Medical/Regulatory affairs
- Legal
- Safety
- Public affairs
- Communication

By inter-connecting its operational teams in this manner, it also became more responsive and was able to instigate concrete actions, such as:

- detection of suspicious drugs
- Sanofi product protection
- cooperation with the public sector to trace clandestine supply channels

WHAT IS THE ROLE OF THE CENTRAL ANTI-COUNTERFEIT LABORATORY (LCAC)?

In 2008, Sanofi created its own laboratory dedicated to analysing counterfeit Sanofi products in Tours, France. With its own dedicated team of experts and cutting-edge technologies, the LCAC is in charge of:

- running technical examinations of packaging and chemical analyses of suspicious samples,
- centralising the “ID cards” established whenever counterfeiting is identified, in a single, central database,
- and producing reports that later serve as a solid foundation for mobilising the local authorities and initiating legal proceedings.

WHAT IS THE SOURCE OF SUSPICIOUS DRUGS?

All Sanofi medicines suspected of being counterfeited are sent to the Central Anti-Counterfeit Laboratory (LCAC) to be analysed.

ORIGIN OF PRODUCTS RECEIVED BY THE LCAC

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<thead>
<tr>
<th>Seizures by authorities</th>
<th>Investigations</th>
<th>Quality</th>
<th>Pharmacovigilance</th>
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<td><strong>SUSPICIOUS PRODUCTS</strong></td>
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PROTECTING MEDICINES

THE DRUG SUPPLY CHAIN

It is a high priority to secure the flows of products from end to end in order to avoid the penetration of falsified medicines.

WHAT IS THE DATA MATRIX?

Since 1 January 2011, in compliance with the legislation in force, all Sanofi products marketed in France have been equipped with a "Data Matrix", a two-dimensional bar code printed on each box, containing traceability elements: product code (CIP code), batch number and expiration date.

Under European Directive 2011/62/EC, this safety requirement is to be extended to all of Europe with a unique serial number for each box that will strengthen distribution safety and delivery of medication requiring prescription and ensure it is appropriately identified at the point of dispensation.

WHAT IS THE SECURITY LABEL?

In order to prevent its own products from being falsified and in order to quickly authenticate its drugs on the market, Sanofi developed a specific highly secured label (SASL: the Sanofi Aventis Security Label). The label contains both visible (for distributors and patients) and invisible (known only to Sanofi) authentication elements.

Sanofi has extended the use of the SASL security label to all of its new prescription drugs across the world.

Sanofi makes a point of using packaging equipped with tamper evidence devices, so that the integrity of the original packaging is guaranteed.
TOP TIPS

WHAT IS THE ROLE OF HEALTHCARE PROFESSIONALS?

• Raise awareness in patients about the risks of counterfeiting, in particular during their travels abroad
• Be attentive to possible reports of incidents from patients
• Discourage the consumer public from using illegal (other than pharmacies) sources of supply
• Alert to the dangers connected with online drug sales (drug quality, risks for personal and bank details)
• Remind that only pharmacists operating as part of a secured distribution system are allowed to provide drugs to patients
• Report suspected cases of counterfeiting to the relevant Healthcare Authority.

HOW TO IDENTIFY SUSPICIOUS PRODUCTS?

Drug counterfeiting is becoming increasingly difficult to detect. Certain details must, however, awaken attention:

• Secondary conditioning or non-matching expiration dates
• A disparity in colour or consistency, or the emergence of unexpected side effects: these are often the triggers for reports of counterfeiting.

WEBSITES OFFERING MORE INFORMATION

• Your country’s Healthcare Authority
• Physicians or pharmacists associations in your country
• The manufacturer’s website
• The WHO (World Health Organisation) website: http://www.who.int/

Extensive information can be found at sanofi.com
Should you have any additional questions, feel free to write to us at: anticounterfeit.coordination@sanofi.com

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