

PRESS BOOK



THE FIGHT AGAINST
COUNTERFEIT
MEDICINES

MAY 2017



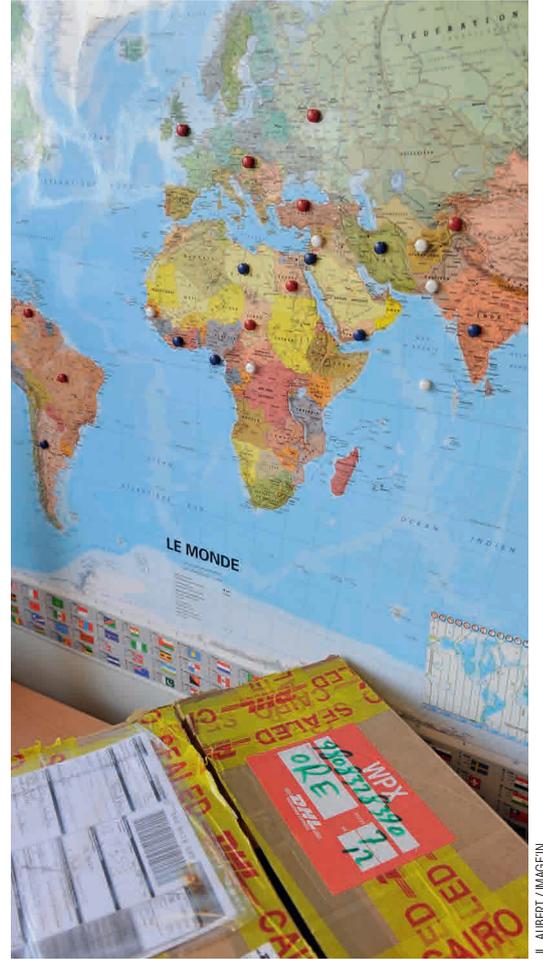
CONTENTS

- 2 Key Figures
- 3 Three questions for Geoffroy Bessaud,
Associate Vice-President, Anti-Counterfeit Coordination
- 4 What is the scale of counterfeiting worldwide?
 - » How do we define counterfeit medicines?
 - » The counterfeit market: a devastating public health menace
 - » Counterfeiting and the legal framework
- 5 Study results: perceptions of counterfeit medicines in Latin America, Asia,
the United States and Europe (full results of the international study are available
upon request)
- 12 How is the fight against counterfeiting being organized?
 - » How do we fight counterfeiting?
 - » Which levels of international cooperation?
 - » How do we protect our drugs from the counterfeiters?
 - » Increasing awareness of all stakeholders
- 16 The Central Anti-Counterfeiting Laboratory: a high-tech unit
 - » Who sends in the products?
 - » For which assignments?
 - » How to detect a fake drug in four stages
 - » What do we do with collected data?
 - » How do we deal with the diversification of counterfeit products?
- 19 Advice for patients: online and when traveling
 - » What are the risks online?
 - » Travelers: be on your guard
- 21 The facility in Tours
- 22 Sanofi a life science company
- 23 Useful links

KEY FIGURES

Counterfeit medicines around the world

- » **1 out of every 10 medicines sold** in the world is a counterfeit. This figure can reach 7 out of 10 in some countries¹.
- » **In 2015**, and among 40 million products intercepted by European Customs, 25.8% of health products in circulation seized were counterfeit medicines. A total of 895,324 medicines were seized².
- » **\$US 200 billion in 2014** versus 75 billion in 2010 reflect the scale of the profits pocketed from counterfeit medicines... The figure is higher than that from drug trafficking³.
- » **For every \$US 1,000** invested in the trafficking of counterfeit medicines, criminal organizations pick up a likely return of **\$US 500 000**⁴.
- » In 2016, 103 countries collaborated in Operation **Pangea IX** to fight illicit online pharmacies. It led to the **closure of 4,932 websites** and the **seizure of more than 12.2 million fake and illicit drugs**, valued at approximately **\$ 53 million**⁵.



JL. AUBERT / IMAGE'N



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The Central Anti-Counterfeiting Laboratory of Sanofi

- » In **2008**: the new laboratory opened in the city of Tours.
- » The laboratory has analyzed over **35,000 suspect** products to date.
- » With a policy based on tighter targeting and constructive collaboration with the international authorities, the percentage of detained products (police, customs...) has risen significantly: 6 to 16%. The majority of the classes of products analyzed by the Laboratory concern veterinary products and vaccines.
- » The Laboratory's headcount and centers of expertise have grown incessantly in order to **fight this threat** to public health.

¹ WHO. Counterfeit medicines, December 2011 - ² European Customs, 2016 - ³ Counterfeit medicines are estimated at around \$US 200 billion, i.e. the N°1 sector for illegal trafficking ahead of prostitution and marijuana. Source: World Economic Forum, Global Risks, Sixth edition, An Initiative of the Risk Response Network, 2011, p. 23. IRACM 2015 - ⁴ For every \$1,000 dollars invested, a criminal can make profits of \$US 20,000 trafficking heroine and counterfeit currency, and from \$US 200,000 to 500,000 trafficking fake medicines. Source: IRACM. - ⁵ Interpol 2016.

COUNTERFEIT MEDICINES: A GLOBAL CRIMINAL ACTIVITY, A THREAT TO PUBLIC HEALTH. WE ALL HAVE A ROLE TO PLAY



CREDIT PHOTO : SANOFI

Three questions for Geoffrey Bessaud
Director for Anti-Counterfeiting Coordination, Sanofi

» What is the scale of counterfeit medicines today around the world? Which countries and which populations are the worst affected?

The National Institute of Health (NIH) has recently issued a warning about this global pandemic.* Counterfeit medicines are a universal phenomenon: all countries, all patients (all age brackets) and all therapeutic sectors are concerned: medication for people, vaccines and veterinary drugs. Each year, the number of deaths due to the taking of counterfeit products is estimated in the hundreds of thousands.** According to the WHO, revenues from counterfeiting is estimated, at the very least, at between 10 and 15% of the pharmaceutical market worldwide, i.e. \$US 200 billion or the equivalent to the GNP of a country like Vietnam. Asia, but also the United States, Africa, the Middle East and Latin America are exposed to this worldwide scourge for public healthcare. In France, given that retail channels are very tightly controlled, the risk of exposure to counterfeit drugs is extremely low. By contrast, vigilance is essential when buying online.

» Which measures have been implemented internationally to fight this menace?

The phenomenon is spreading: the financial appeal is compelling and criminal organizations of all sizes are involved in this trafficking. An outlay of \$US 1,000 can lead to returns of up to \$US 500,000, while for the same investment, heroine and counterfeit currency would bring in \$US 20,000... Additionally, the Internet is significantly promoting the development of fake pharmacies online. The derisory level of penalties imposed upon counterfeiters is an additional factor in the development of this criminal activity. At the international level things tend to be on the move: the MEDICRIME Convention, adopted by the Council of Europe in December 2010 and finally ratified by 5

countries*** will come into force on January 1, 2016. This is the first international legal instrument that will criminalize all activities related to counterfeiting, production and distribution. But there is still a lot left to be done.

» Sanofi in the fight against counterfeiting? What is the role of the Central Anti-Counterfeiting Laboratory?

Firstly, Sanofi has a central coordination facility based in Paris, made up of experts in the fields concerned (pharmacovigilance, regulatory, industrial, medical and legal affairs, safety and communication) and of representatives from the group's entities (human health and vaccines). Its role is to identify and document occurrences of counterfeiting then to participate in the compiling of files case which, thanks to close work with the law-enforcement authorities, will make it possible to identify and take down networks. The same structure is also in place for regions and countries so that they can act locally. We attach a great deal of importance to prevention with the physical protection of our drug boxes and packs. We are working on strengthening the legislative aspect with, for instance, the promotion of the Medicrime Convention or the signing of agreement protocols with the customs authorities. Lastly, we are focusing on training and on information for both the public at large and healthcare professionals. Sanofi's Central Anti-Counterfeiting Laboratory (LCAC) is a one-of-a-kind facility. Based in the city of Tours, it was opened in 2008 and the experts who work there used the most highly advanced technologies to analyze suspect samples that reach us from all over the world. 30 000 products have been analyzed in the space of seven years and the lab has doubled in size since the day it was created. The LCAC has become a key tool in the war on counterfeit medicines.

* Global pandemic of fake medicines poses urgent risk, scientists say May / June 2015 | Volume 14, Issue 3 - ** Source = WHO; International Policy Network, 2009; J Res Pharm Pract. 2014 Oct-Dec; National Institutes of Health, April 2015. - *** Ukraine, Spain, Moldova, Hungary, Guinea, Albania, Armenia, Belgium and France. Council of Europe, April 2017.

WHAT IS THE SCALE OF COUNTERFEITING ACROSS THE WORLD?

» How do we define counterfeit medicines?

According to the World Health Organization (WHO), counterfeit medicine is medicine that has been deliberately and deceitfully labeled in order to mislead users over its identity and/or origins.

For its part, **the directive 2011 /62/UE from the European Parliament and Council***, published in the Official Journal on July 1, 2011, defines a fake drug as medicine that features a fake presentation of:

- » The identity, including the packaging and labeling, name or composition of any one of the ingredients, including excipients, and the dosage of the said components;
- » The source, including the manufacturer, the country of manufacture, the country of origin or the name of the marking authorization body;
- » The past history, including registrations and documents relative to the retail distribution channels used.

Fake drugs and medicines may concern both branded and generic products.

A falsified medicine is:

- » A product in which there is no trace of the active ingredient;
- » A product containing the proper active ingredient(s) but with the wrong dosage;
- » A product containing impurities or toxic substances;
- » A product containing active ingredients other than those contained in the genuine product;
- » A product with fake packing.



The risks produced by fake medicines:

- » detrimental to the safety and health of patients;
- » detrimental to hygiene;
- » detrimental to the environment;
- » detrimental to ethics.

Counterfeit medicines jeopardize the lives of patients.

* The WHO Executive Board adopted a new resolution replacing the former SSFFC terminology (sub-standard / false / falsely labeled / falsified / counterfeit) by «sub-standard» (inferior quality drugs) and «falsified» (products that are not medicines). The word counterfeiting will now be used for the infringement of industrial property rights. The new definition will be adopted in mid-2017.

» The Counterfeit Market: a devastating public health menace

Counterfeiting creates a deadly risk for patients: according to WHO, 100,000 to 1,000,000 people die each year because of it. In the majority of industrialized countries imposing effective market regulation and control systems (Australia, Canada, Japan, New Zealand, the United States and the greater part of the EU, counterfeit medicines are a very rare occurrence and represent less than 1% of total market value.*

The same cannot be said for many African countries, certain regions of Asia and Latin America, and emerging countries: the proportion of counterfeit medicines is much higher here and may reach 20 to 30% of the market, even more depending on the therapeutic classes concerned.* In these regions, retail channels are less tightly controlled and it is harder to prevent counterfeiters from worming their way in.



Counterfeit channels know no boundaries. A fake product may be manufactured in China, exported to the UK and then be slipped inside legal retail channels via a wholesaler, or else be purchased online anywhere in the world.

The Internet has become one of the preferred vehicles for the circulation of fake medicines. According to the WHO, in over half the cases medicines purchased online from websites that conceal their physical address are most likely counterfeit.

» Counterfeiting: the legislative framework



The action taken by Sanofi

On a legal level, the approach taken by Sanofi consists primarily in instigating any action that may lead to networks being taken down, in calling for penalties at law aimed at neutralizing counterfeiters, and in obtaining the destruction of merchandise.

Counterfeiting is a criminal offense in many countries. However, disparities are seen in terms of both legal system and the application of the said criminal laws.

Applicable penalties, which vary from country to country, may comprise the imposing of fines, imprisonment, the confiscation and destruction of counterfeit merchandise or the right to exercise certain professions. Counterfeiters may also be ordered to pay legal damages.

Usually, these penalties are not specific to the faking of medicines but are common to all acts of counterfeiting, more particularly the violation of intellectual property rights.

Sanofi would like to see more account taken of the specifics of counterfeit medicines and the faking of these products, and fully supports international measures that move in this direction.

*WHO

Internationally

The MEDICRIME Convention

The Council of Europe produced the first international legal instrument in criminal matters applicable specifically to counterfeit medicines: the MEDICRIME convention, adopted December 8, 2010.



This international convention designates the manufacture and the marketing of counterfeit medicines as criminal offenses. The text is open to the signatures of the 47 Member States of the Council of Europe and all States who wish to work with the Council of Europe in the fight against counterfeit medicines.

Of the 27 current signatory nations, 9 have ratified it.

For France, the Upper House (Sénat) is due to examine the draft bill for ratification on December 17, 2015.

It is up to the States that have signed and ratified the convention to make acts such as the intentional

The Cotonou Appeal

Instigated by President Jacques Chirac on October 12, 2009. Sanofi has supported the so-called Cotonou appeal, intended to spur the international community into drawing up a global legal response and into strengthening cooperation between civil society and national public services against the trafficking of fake medicines.

manufacture, provision or supply and trafficking of counterfeit medicines, and the intentional falsification of related documentation a criminal offense, and to take every measure to ensure that these offenses are met with penalties, including criminal or non-criminal fines and/or imprisonment.

In this respect, article 12 the Medicrime Convention ("Penalties and Measures") states, most notably, that physical persons found guilty of such offenses may be the subject of penalties leading to imprisonment and the eventuality of extradition.

As for convicted legal entities, the text provides for penalties such as measures of temporary or definitive exclusion from the right to conduct business, placing under judicial supervision and a judicial winding-up order.

France - Bamako Africa Summit

African Heads of State meeting for the 27th France-Africa summit in Bamako committed to further uniting their efforts to combat terrorism and illicit trafficking. African Heads of State are particularly engaged in combating counterfeit medicines and developing a comprehensive and coherent strategy.

The European Directive for Fake Medicines

Adopted on June 8, 2011, it aims to secure the legal supply chain for medicines.

It raises the issue of fake medicines and not the violation of intellectual property. Sanofi is an active contributor to the task forces that led to the adoption of this directive.



<http://conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=211&CM=8&DF=&CL=FRE>

STUDY RESULTS¹ : PERCEPTIONS OF COUNTERFEIT MEDICINES IN LATIN AMERICA, ASIA, THE UNITED STATES AND EUROPE

» LATIN AMERICA²



High awareness of the existence of counterfeit medicines

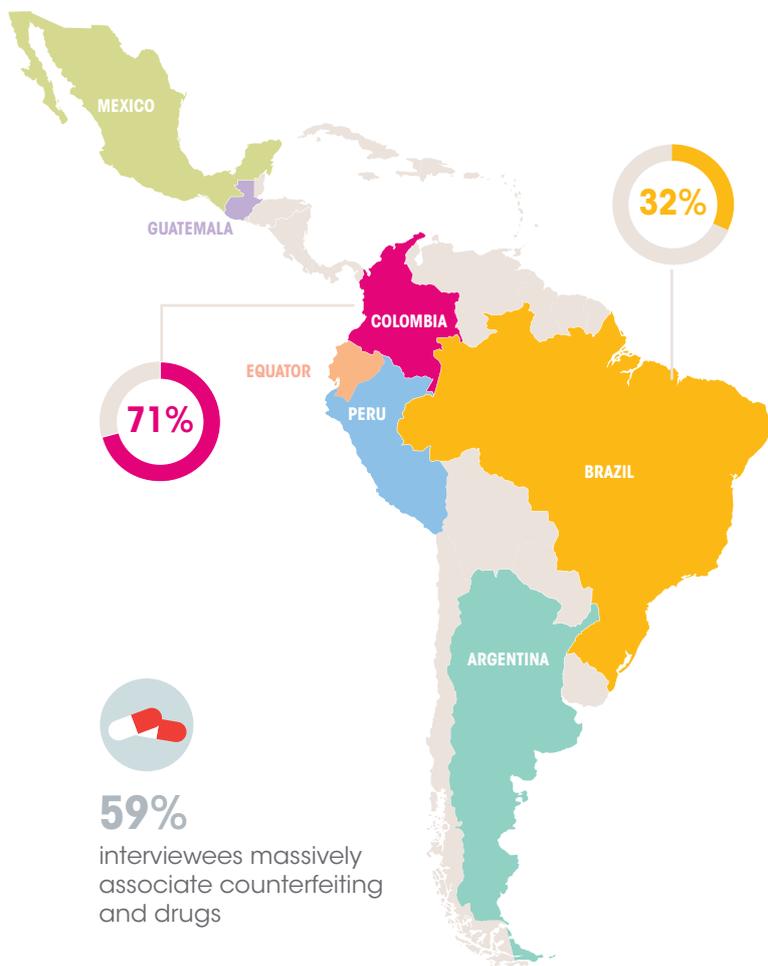
Interviewees massively associate (59%) counterfeiting and drugs, far ahead of fashion brands electronic products. On the other hand, there are significant disparities, notably Brazilians, who are only 32% to spontaneously make this association, and cite more easily fashion brands, luxury products and electronics counterfeiting.

A situation to follow, since Brazil shares borders with countries where drug counterfeiting is very active.

Conversely, Colombia has a very high spontaneous association, with 71% of respondents.

In response to the question «Have you ever heard of it», «Have you ever seen some» and «Do you think you have enough information not to be exposed to counterfeit medicines», trends emerge/are confirmed: Brazilians seem to be the least exposed and informed respondents, whereas Peruvians are the most savvy: 98% have already heard about it (91% on average of the 7 countries), 60% have already seen counterfeit drugs (35% on average) and 19% say they have enough information on the subject (13% on average).

Only 13% say they have enough information on the subject



A very disparate danger awareness

62% of respondents consider that counterfeit medicines are definitely dangerous and 36% that they can be dangerous.

Argentines seem the least cautious: they are only 44% to be affirmative on the dangerousness of counterfeit medicines. And they are also 3% to declare that they are harmless.

The Peruvians on the other hand confirm that they are among the best informed of the panel. Indeed, 75% say that counterfeit medicines are unquestionably dangerous.

¹ The full findings from the study are available on request.

² Study conducted from December 12-22, 2016 - Self-administered online questionnaire based on a representative sample of 7,044 Latin Americans (from Argentina, Brazil, Guatemala, Ecuador, Peru, Mexico, Colombia) aged 18 and up.

Internet, the main media of exposure, but also a mistrust of official distribution channels

For 72% of the respondents, one exposes themselves to the counterfeiting of drugs by buying them on the Internet.

For **72%** of the respondents, one exposes themselves to the counterfeiting of drugs by buying them **on the Internet**.



It is interesting to note a very high level of defiance with regard to the official distribution channels: more than 1 in 4 people (28%) declare that they sell counterfeits. This very high figure reaches 37% in Colombia.

On the other hand, Peruvians are rather confident in these official distribution channels: 23% say they are certain that they can not find counterfeit medicines (18% every country combined), confidence to analyze in the yardstick of their level of information and knowledge of the subject, very high.

Buying online, a very contrasted practice and feeling

In all countries, it is the possibility of saving time that is placed at the top of the probable motivations of online shopping, in the face of being able to make savings.

Only Argentines place access to drugs not available on their territory as motivation number 1.

Meanwhile, an average of **27% of respondents have already purchased drugs online**. The Argentinians are at the bottom of the rankings, with only 11%, while Brazilians declare a much more widespread practice, since they are 48% to have already bought online.



27% of respondents **have already purchased drugs online**.

Moreover, Brazilians who have already bought online have made it mostly in confidence (73% of them) and fairly regularly (40% at least once a month) whereas, in all countries, a buyer on 2 had the feeling of taking a risk and 26% did so at least once a month. Peruvians are the most suspicious: they are average in terms of the percentage of online shoppers, but are far ahead in terms of risk-taking: 68%, followed shortly Argentines and The Ecuadorians.

The purchase of medicines while traveling, a widespread and considered safe practice

41% of respondents have already bought drugs abroad. They did so mostly in pharmacies (86%) and with a sense of security (80%).

41%
of respondents
have already bought drugs abroad.

Slight disparities appear for some countries:

For example, 46% of Guatemalans report having purchased medicines from supermarkets (31% from all countries).

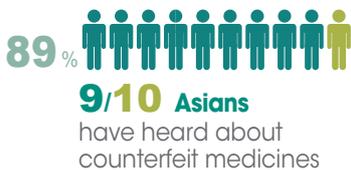
Peruvians also express a sentiment similar to what they declare for online purchases: they felt more than average that they took a risk (25% vs. 20%). The same trend as for Brazilians: more carefree than the average for online shopping, they are also for shopping on the road (16% of them only felt that they were taking a risk, vs 20% in all countries).

» ASIA³



A marked but contrasting shortfall of information

The study, conducted in May 2015 has helped cast light on the perceptions of nationals from several Asian countries with regard to counterfeit medicines. The countries concerned are China, Indonesia, Malaysia, the Philippines, Thailand and Vietnam. Overall, almost nine people out of every ten have heard about counterfeit medicines (89 %).



Vietnam, China and the Philippines appear to be the three countries that most clearly associate counterfeiting with medicines, virtually on a par with apparel and luxury products. Vietnam is the country that makes the clearest connection (53%) and has the highest level of awareness of the issue (98%). At the opposite end, Malaysia is the country that least associates counterfeiting with medicines (29 %).

All countries combined, just over one third of respondents made the connection between counterfeiting and medicines (36%), while more than one-half (53%) spontaneously associated counterfeiting with clothes).



53% associate counterfeiting with apparel



36% associate counterfeiting with medicines

Two thirds of Asians consider counterfeit medicines to be dangerous (67 %), less than one third see them as potentially dangerous (31%).



For instance, 86% of Indonesians consider these products to be potentially dangerous. Malaysians and Filipinos are rather more divided: the danger aspect is accepted but is only potential for 45% and 41% of them respectively. More than one in two Indonesians feel they are not given enough information about the subject (55%) while three-quarters of Thais (76%) and two-thirds of Chinese make the same observation. China is also where we find the highest level of unawareness of situations where people might be exposed to counterfeit medicines.

Purchasing medicines online: not the same everywhere you go

When looking at all countries combined, most respondents feel that buying online is where the risk of ending up with counterfeit medicines is the greatest (64 %). Thailand and Malaysia show the highest scores with over 70% of respondents. But buying online is not the only situation with a risk involved, as physical sales outlets and traditional retail channels are also mentioned. Vietnam is where we find the highest level of respondents (82%) who feel that traditional retail channels also entail the risk of counterfeit products, ahead of China and Thailand. By contrast, the Philippines and Malaysia are countries where the confidence in traditional channels is higher.

³ Results from the Happycurious opinion poll for Sanofi conducted in May 2015. An online questionnaire with a sample of 4,005 persons.

All countries combined, 67% of respondents feel that you could well come across counterfeit medicines in traditional retail channels. Buying medicines online shows a contrasting picture. In China, Vietnam and Indonesia, the practice is rather widespread, as opposed to the other 3 countries under study. In China and Vietnam, over 30% of respondents say they buy medicines online at least once a month. 50% of Chinese respondents have done so at least once. By contrast, 77% of Filipinos and 69% of Malaysians say they have never purchased their medicines on the Internet. On average, in the 6 countries under study, 39% of respondents had already purchased their medicines online, and of these 29% did so at least once a month and 42% felt confident about doing it.

Purchasing medicines when traveling

More than one in two respondents had traveled abroad over the past five years. On average, 78% of people travel with their own medicines, but the figure varies sharply between Vietnam (94%) and China (59%). Almost one-third had already purchased medicines abroad (31%), of whom 63% feeling safe and confident about doing so. This sentiment is higher outside of Asia (71% for buyers in Europe and the United States, versus 61% in Asia). The feeling of no-confidence when buying abroad is particularly high with the Vietnamese (50%).

» UNITED STATES⁴

A flagrant shortfall of information

Only 15% of American respondents made the connection between counterfeiting and medicines, while 54% of them associated the practice with apparel and 43% with luxury products. More than one in two persons said they had never heard about counterfeit medicines (53%).



54% felt that counterfeit medicines were definitely dangerous, 40% felt the danger was potential. A huge majority (82%) feel they have never been exposed to counterfeit medicines. 41% of respondents say they have no information about counterfeit medicines, 12% feel they are sufficiently well informed, 24% say they are relatively well informed.

Exposure to counterfeit medicines: the Internet first and foremost

79% of American respondents feel that purchasing medicines online constitutes the greatest risk to exposure to counterfeit medicines.



For **79%** buying medicines online is a vehicle for exposure to counterfeit medicines

62% also feel there is a risk when traveling abroad, while almost the same number feel that counterfeit medicines might also be found in traditional retail channels in the United States (59%). Only 18% of Americans had already purchased medicines online and of these three-quarters (74%) were not aware of the fact that they might be taking a risk.

⁴ Results from the Happycurious opinion poll conducted for Sanofi in July 2015. An online questionnaire with a sample of 1500 persons.

Taking medicines when traveling

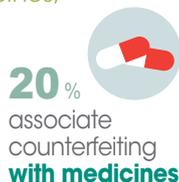
With foresight, 77% of Americans travel with their own medicines and almost 50% of them keep these products in their cabin baggage whenever they fly (47%). As most of them feel that buying medicines abroad is a risky business, only 16% actually do so, of whom 78% buy only from

pharmacies. Under these conditions, 70% feel confident about buying. However, this feeling of confidence varies according to destination: 83% when buying in Europe, but only 50% when purchases are made in Asia.

» EUROPE⁵

Three out of four Europeans lack information

It emerges that more than three out of every four Europeans feel under-informed about the topic of counterfeiting (77%). 20% of European respondents associate counterfeiting with medicines,



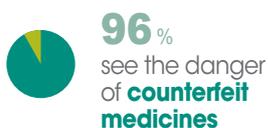
whereas the vast majority see a more, spontaneous connection with the worlds of luxury and clothes. The French and the Germans show the greatest awareness with this issue, while the Spanish are the least aware.

Two thirds of Europeans have already heard about counterfeit medicines (66%) but only 47% think that a counterfeit drug presents a definite danger.



A danger primarily associated with buying online

The perception of the danger of counterfeit medicines is high in Europe (96%)



and the danger arises primarily from online buying for nine people out of ten.

Only 18% of Europeans have ever purchased medicines online of whom 78% felt perfectly confident about doing so.



Germany has a place of its own, where economic arguments motivate the current practice of online shopping. The UK also seems to be more inclined to this type of buying albeit with considerable caution. The Latin threesome of France, Spain and Italy are much more loath to this practice.

The risk of buying medicines abroad

One half of the European sample (51%) consider that we may be exposed to fake medicines when traveling. As such, most Europeans say that they travel with their own pharmacy case (81%), although half of them sometimes purchase medicines on their travels (52%).

HOW THE FIGHT AGAINST COUNTERFEITING IS ORGANIZED: A MAJOR COMMITMENT FOR SANOFI



» How do we fight counterfeiting?

In 2007, Sanofi set up **an operational coordination unit** assembling the internal centers of expertise affected by fake drugs: Industrial Business, Safety, Medical and Regulatory Affairs, Legal, Public Affairs and Communication. This operational grid is conducive to greater responsiveness and allows the implementation of concrete actions in the fight against counterfeit medicines. In 2008, the Group created the Central Anti-Counterfeiting Laboratory (LCAC), located at the pharmaceutical site in the city of Tours to analyze suspected fake products.

What do we do when a product proves to be counterfeit?

Teams of the **Security Department** run verifications from the data we receive. They proceed with cross-check operations to prepare a report that is then submitted to the police or customs authorities of the competent countries. This network is driven by drug security managers operating around the world.

It collects items of information and evidence which are then corroborated with information gathered from the field and shared with other pharmaceutical groups. This collaboration is the work of members of the PSI (Pharmaceutical Security Institute), an institution composed of representatives from 30 pharmaceutical groups.

What is your approach to the fast-growing use of the Internet?

We have a team in charge of researching counterfeit products on the Internet, liaising with the drug security managers of our subsidiaries. The goal is to identify unlawful platforms that sell the group's molecules then to implement the appropriate actions. For instance, information may be passed on to Interpol, which each year carries out wide-scale operations to take down illegal networks selling medicines online.



CREDIT DR. SANOFI

Karen Herrera
Safety partner and HSE coordinator, Mexico

“Counterfeit medicine is an endemic menace in Mexico. It affects all categories of drugs and seriously threatens the health of patients throughout our country. Within Sanofi, my team and I are doing everything on a day-to-day basis in order to be able to effectively combat this organized criminal phenomenon.”

» What about international cooperation?

Sanofi has made a commitment to engage the public authorities and prompt the powers that be to take the strongest possible legal provisions in order to combat fake medicines. In December 2010, the **Council of Europe** adopted the MEDICRIME Convention, signed by **27 countries** and ratified by 9 others (Burkina Faso being the latest on February 16, 2017).

Sanofi has mobilized the **United Nations Office on Drugs and Crime** (UNODC). The United Nations, through their global political dimension, can effectively play a decisive role under the United Nations Convention of 2000 against transnational organized crime by making the counterfeiting of medicine a criminal activity.



Interpol is a collaborative facility that mobilizes police forces worldwide urging law enforcement authorities international unlawful activities a key issue in their activities. In 2016, and for the ninth consecutive year, 103 countries collaborated in Operation Pangea IX to combat illegal online drug sales. It led to the closure of 4,932 websites and the seizure of over 12.2 million life-threatening drugs, valued at approximately \$ 53 million².

On its side, the **World Customs Organization** has organized spot-check operations with the opening of containers in different regions of the world. The WCO has developed a customs information and cooperation tool, to which Sanofi has subscribed. Customs authorities log into the data base and visualize images of different products, thereby making it easier to identify counterfeit medicines.

The **World Health Organization** (WHO) plays a leading role to promote cooperation between and with Member States, UN Organizations and other stakeholders. It also helps in the sharing of information and has published a «manual for measures aimed at eliminating counterfeit medicines», which guides Member States in the drawing up of national measures and strategies for the fight against counterfeiting. This very comprehensive document also addresses field studies, the inspection and the vetting of potentially counterfeit drugs, and training in human resources.

\$US 1000 invested in the trafficking of fake medicines can earn ***criminal organizations up to \$US 500 000 dollars.***

Source IRACM 2015

1 <http://apps.who.int/medicinedocs/fr/d/Jwhozip41/>
2 Interpol, 2016

» How do we protect our medications against counterfeiting?

The three levels of protection

The Group has introduced three levels of protection. Only levels 1 and 3 are required by the European Directive of July 2011 governing fake medicines.

LEVEL 1 Protecting the integrity and inviolability of the box

For Aziz Benrebbah, Quality Manager - Global Supply Chain and Purchasing GMQO, Global Quality, "this level 1 is very important. If you protect your box without ensuring tamper-proof inviolability, counterfeiters can open the box and insert fake products instead." Tamper indicators built into our inviolability systems come in different forms: pre-perforation; glue points that tear the whole system; labels placed on the box's tab...

LEVEL 2 Authenticating the product

To verify the authenticity of products, Sanofi has developed special high-security labels that contain items of identification, some of which are visible (for retailers and patients), others invisible (known only to Sanofi). This level of protection is used for the medicines where the risk of counterfeiting is the highest, and for all the group's new drugs. Others may also be concerned when specifically targeted by counterfeiters in certain countries. Aziz Benrebbah explains: "faced with a regional or historical rise in fake medicines, we may decide to protect certain products using specific high-security labels, because for Sanofi the health of patients is key."



LEVEL 3 Identification of each box with a Data Matrix

Since January 1, 2011, in compliance with applicable legislation, all Sanofi products marketed in France are identified with a 2-D bar-code printed on each box containing traceability data: product code, lot number and sell-by date. The systematic scanning of the Data Matrix in pharmacies helps improve the traceability of products delivered to the pharmacy or hospital and affords the automatic detection of products beyond their sell-by date.



Taking traceability a step further

Sanofi has supported the **serialization project put forward by the EFPIA** that provides for on-box identification. The idea is to combine a random series number – specific to each box – with the data matrix. Written in code form, the number will be added when packing the product and sent to a central data base. When the pharmacist queries the system, s/he will know whether the number really exists and if the product already has been sold. Aziz Benrebbah adds that "this is the most complex component to introduce. The data base effectively has to be confidential and reliable, with a short response time for pharmacists. This control will also help to combat social security fraud." The European Commission has adopted the delegated acts relative to the directive for fake medicines, which will apply to medicines supplied with or without prescription. The secondary packaging for these medicines destined for the European market should be fitted with these security devices (the use of a tamper-evidence seal and serialization with the help of a Data Matrix code containing a unique identifier). These measures should be implemented in Europe by the end of 2018-early 2019. The goal is to harmonize identification technologies for optimal effectiveness.

» Building awareness for all the players involved

The general public: “The general public has no real information about the existence of fake medicines or of the risks they are taking,” emphasized Geoffroy Bessaud. In December 2012 and January 2013, Sanofi launched an awareness campaign aimed at over four million Air France travellers headed for North America, Latin America, Africa, the Mid-East, Asia and the Pacific by way of a film screened aboard planes, plus a page of practical advice published in the Air France inflight magazine. Sanofi has also published a brochure for Internet users.

In the same way, Sanofi has created a website for information and advice to offer protection against fake medicines – fakemedicinesrealdanger.com - plus a “travel tips” application for travelers.

The scientific and medical communities. The objective is to get all healthcare professionals fully on board with the messages we deliver. In France, pharmacists have been fully alerted and are in a position to explain the risks involved when buying medicines through unlawful channels.

Police and customs authorities. Sanofi has signed a partnership agreement with Interpol implicating 29 major pharmaceutical groups.* This 3-year agreement, worth a total amount of €4.5 million, concerns the creation of the Interpol Program for Pharmaceutical Criminal Activity, focused in particular on the fight against counterfeit medicines. It will combine training and the reinforcement of targeted crack-down operations.

Governments and institutions. Sanofi participates in a number of task forces and conferences, for instance the UNODC convention held in February 2013 attended by Interpol, MDG, the WHO, Member States and pharmaceutical groups. The goal is to mobilize countries and prompt them to amend legislation whenever penalties are seen to be too light. The topic was also raised at the G8 summit meeting.



* Source: <http://www.interpol.int/Crime-areas/Pharmaceutical-crime/Pharmaceutical-Industry-Initiative-to-Combat-Crime>.

THE CENTRAL ANTI-COUNTERFEITING LABORATORY: A HIGH-TECH UNIT TO COMBAT FAKE MEDICATION

In 2008, Sanofi created the Central Anti-Counterfeiting Laboratory (LCAC) in Tours to handle all Sanofi products calling for verification in the face of potential counterfeiting. Its objective is to detect fake medicines with a dedicated team of experts using the most advanced technologies.

» Who forwards products to the laboratory?

Most of the products received by the laboratory are sent in by market watchdog units run by Sanofi and stem from test shopping in high-risk countries and sensitive products from both the Internet and pharmacies. The rest come from customs, police and health authorities, and from healthcare professionals. Patients may also notify branches in the event of a suspect product.



CREDIT: DR. SANOFI

» What are the laboratory's assignments?

» **To conduct technical examinations of packaging and leaflets**, along with in-depth chemical analyses of suspect samples taken from the most frequently counterfeited products.

» **To devise analysis methods** and circulate them worldwide if needed to enable each of the group's industrial sites, wherever in the world they may be, to examine and analyze, along the same criteria, all suspect products akin to those manufactured by the Group.

» **To centralize "identity cards"** related to listed counterfeit products in a single central data base, which alone is able to make the connections between various counterfeit products.

The LCAC represents one of the most highly accomplished facilities of all pharmaceutical groups. The process set up is highly advanced and includes more specifically the creation of identity cards.

» How to detect a fake in four stages?

STAGE 1 Traceability

The first level of assessment is to research information in the data base to ascertain whether or not the product was manufactured at a Sanofi site. All data is analyzed, including the lot number, date of manufacture, packaging, etc.

STAGE 2 Meticulous visual examination

The product is "put under the microscope": print fonts, printing techniques used for packaging, engraving prints, glue tabs on boxes. Comparisons are made using high-tech imagery.

STAGE 3 General chemical analysis

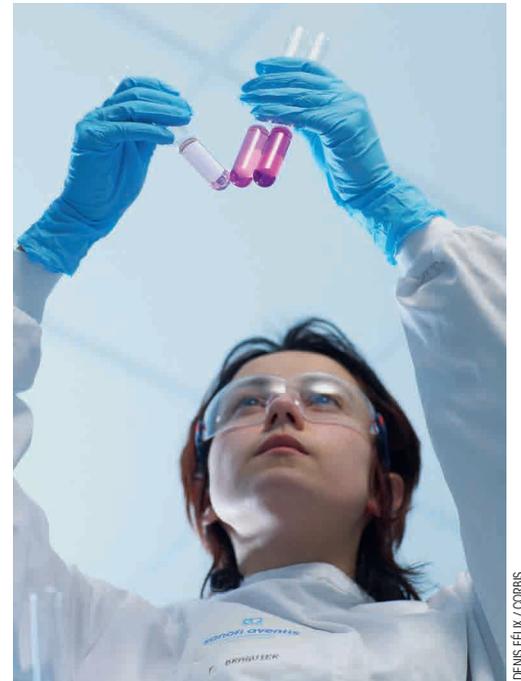
The product's chemical fingerprint is observed using spectroscopic techniques from which we obtain a first level of reading of the product's composition; this is then compared with the characteristics of reference products stored in data bases.

In the vast majority of cases, these three stages will tell us very quickly whether or not we are dealing with a counterfeit product.

STAGE 4 High-precision chemical analysis

If the product is proven to be counterfeit, the final stage is set in motion. This consists in pursuing the chemical analysis to ascertain whether or not the product contains the active ingredient, or toxic compounds...

This finer composition is researched using gas or liquid chromatography techniques that help to identify unknown compounds, either in traces or in larger quantities.



DENIS FELIX / COORBIS



J.L. AUBERT / IMAGEN

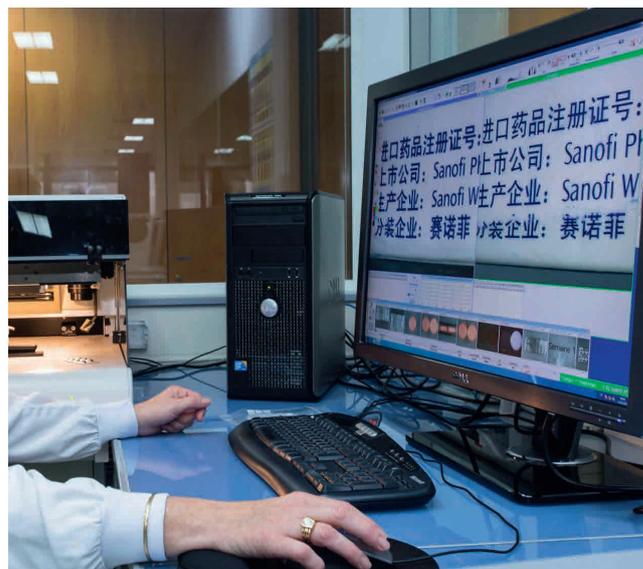


J.L. AUBERT / IMAGEN

» What do you do with the data you collect?

A report wraps up all the results collected from the product. This is then sent to the coordination unit, which conducts the appropriate actions with the authorities concerned.

Since 2008, the Laboratory has analyzed over 30,000 suspect products. The results of our analyses provide us with solid bases with which to engage local authorities, to carry out legal actions and to develop proactive programs in the fight against counterfeit medicines in the countries where fake products have been identified.



CREDIT DR SANOFI

» How to anticipate and adapt to new tactics of counterfeiters?

Nathalie Tallet
Head of
the LCAC



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In the space of nine years, the laboratory's staff has more than tripled, rising from five to nineteen colleagues. "Over and above the

volume of work, it is the way the function has evolved and the development of new areas of expertise that are really important," feels Nathalie Tallet. "In 2008, when our activity started up, we were more into standardized quality control techniques. Since then, we have developed more specific areas of expertise." For example, expertise with which to work faster and to develop techniques for large volumes of work. It is not

so much the volume, more the expertise that requires a greater variety of skills and more tightly organized teams. While there has been no huge change in the number of medicines received, the same cannot be said for the nature of products that are analyzed. Nathalie Tallet dwells on the need for the laboratory technically to stay at the leading edge so as to be able to meet the challenges set by the growing diversity of products: "all therapeutic classes are concerned by faking. The portfolio of analyzed products has become very broad."

New pharmaceutical forms are also being concerned by counterfeiting. While in 2008 the menace was largely focused on dry medicines, today it is affecting more and more injectable products (used to treat cancers and heavy pathologies), vaccines and rare diseases.

**Since 2008,
the Laboratory has analyzed over 35,000 suspect products.**

ADVICE FOR PATIENTS: ON THE INTERNET AND WHEN TRAVELING



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» What are the risks online?

Some online pharmacies exist within the law and have been created to facilitate access to medicines (examples are Germany, the United States, France, the Netherlands, Portugal and the UK). Some fifteen European countries have legalized the sale of medicines on the Internet. However, a large number of websites are totally unlawful and freely propose drugs that normally require a prescription, together with other unapproved or fake medicines. In the hands of illegal organizations, these structures operate as networks, masking their true identity or cheating as to their whereabouts.

The European Directive on fake medicines includes a special chapter about the Internet, particularly the introduction of a system of lists of online pharmacies that have been approved by the competent authorities, the inclusion of a common "European Union" logo, and an information campaign aimed at patients explaining the risks of medicines sold illegally online.

In France, Sanofi is one of the signatories of the Charter against Online Counterfeiting introduced in 2009. With this document, the holders of intellectual property rights and e-commerce platforms have committed to setting up concrete ways and means to fight the sale of counterfeit products on the Internet.

Sanofi works closely with the competent authorities, technical operators, financiers and e-commerce platforms to carry out effective operations against unlawful pharmacies and fake medicines on the Internet.

According to the WHO, over 50% of medicines purchased from websites that conceal their true address are probably counterfeit. **Furthermore, 96% of online pharmacy sites are said to be unlawful.***



» What can I do, practically speaking?

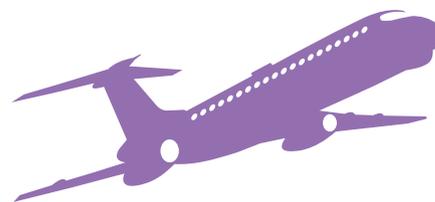
- » Never reply to spam e-mails offering to sell medicines. Very often the products in question are bogus.
- » Do not give any information about your state of health online.

In France, since the Statute published in the Official Journal on January 1, 2013, the sale of medicines online is legal, under certain conditions. This does not concern prescription drugs: the list of medicines that

can be sold online is published on the site of the ANSM (National Agency for the Safety of Medicines and Healthcare Products). Only dispensing pharmacists are authorized to open an online pharmacy, subject to their respecting very strict specifications, run by the Regional Healthcare Agency. **The list of authorized French pharmacies online is available on the website of the National Council for the Order of Pharmacists and the Ministry of Health.**

* Source: According NABP (Internet Drug Outlet Identification Program, Progress Report for State and Federal Regulators, April 2013), the unlawful sale of medicines accounts for 97% of the activity of online pharmacies: "NABP continues to find the vast majority of drug sites (97% of those reviewed) to be operating in contravention with US federal and state pharmacy laws".

» Travelers: be on your guard!



Before setting out

Prepare a travel case suited to your destination and take the quantity of medicines you will need for the period of time you will spend traveling. In cases of chronic conditions, you are recommended to take with you a higher than necessary quantity of medicines, in case your return journey is delayed. Medical prescriptions (with the names of the molecules and manufacturers) should be easy to reach in your hand baggage, the same goes for essential medicines or your first-aid kit. For other medicines, place one half in your suitcase, the other in hand baggage so as not to be left wanting in the event of your luggage being lost or stolen.

During your stay

In the event of health problems, patients should consult a physician (a list is available at embassies) before buying any medicines, something you should do only through official retail channels (mainly pharmacies). When purchasing medicines, check the integrity of the packaging and the absence of any visible anomaly on the box, in the leaflet, on the blister pack or on the

actual medicine. Alert the pharmacist and manufacturer of any anomaly (a toll-free number is given on the pack). Be careful! A very low-priced medicine may be a telltale sign of a counterfeit product. For any undesirable side-effect, consult a physician, it could be the result of a counterfeit drug. Finally, only buy the quantities you need for your personal use: the importation and exportation of medicines are subject to border controls.

After your stay

When carrying medicines, the conditions for importing them into France are as follows:

» when coming from non-EU or non-Schengen space countries, the quantity must match the length of treatment. A doctor's prescription must be presented to customs .

» from EU countries, the quantity must bear relation to personal usage. An administrative medical certificate must be presented to customs.



APPLI TRAVEL TIPS



THE FACILITY IN TOURS

Staff numbers: 330 persons

Created in 1967, the Sanofi facility in the city of Tours has successfully adjusted to the new challenges facing the pharmaceutical industry. In recent years it has been transformed with the arrival of new products calling for capital investment in buildings and facilities, including a high-volume factory and a new micro-grain workshop.

The site produces tablets (multi-layer or phased-release) and capsules (powder and phased-release micro-granules). Packaging covers blister-packs, jars and tubes. Tours is recognized for its high level of quality, illustrated by the excellent results from inspections conducted by the FDA in 2010, 2012 and 2014 over expertise in the harnessing of complex processes for demanding markets and the site's very high standard of customer service.

The site's highly qualified teams feel passionately about their profession and are totally focused on the facility's global performance. As early as 2011, production sectors were mobilized to implement the LEAN process designed to optimize performance, which today is entrenched in the plant's culture.

The site exports 90% of its production to Europe, Asia, Africa, the Mid-East, Latin America, the United States, Australia and Japan. Tours is part of the Solid Pharma Division and also houses an Industrial Support Center and the Central Anti-Counterfeiting Laboratory.



CREDIT PHOTO : SANOFI

Production

Amaryl®, Allegra®, Allegra D24®, Aprovel/Co-Aprovel®, Cardizem®, Mizollen®, Tildiem®, Telfast/Allegra®, Stilnox/Ambien®, Xatral®

Regulatory status

Approved by: ANSM, EMA, FDA, PMDA (FRANCE, EUROPE, USA and JAPAN)

Key Figures

2.9 billion tablets and capsules p.a.
59 million packed boxes p.a.

Sanofi Tours: from the production of medicines to the fight against counterfeit medicines
<https://www.youtube.com/watch?v=Uw1DwfUzqdM>

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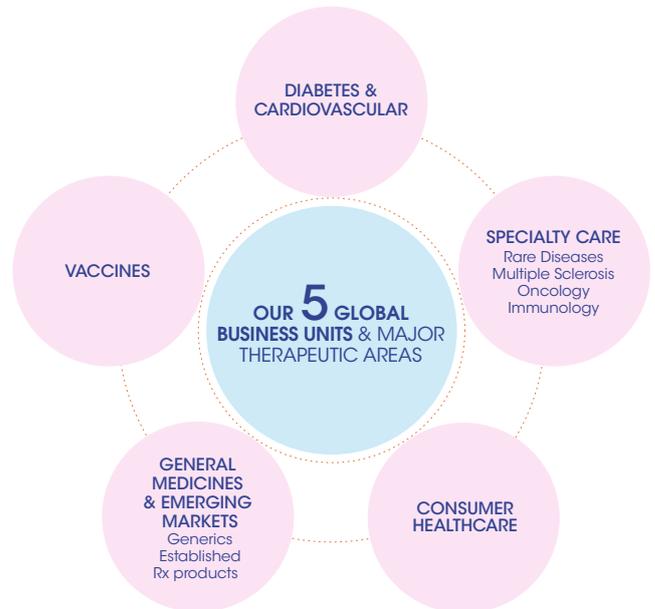


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38 COUNTRIES⁽²⁾

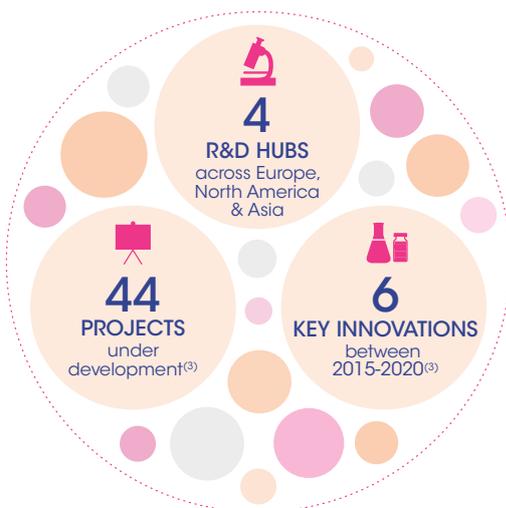
TO PRODUCE

GLOBAL BUSINESS UNITS & THERAPEUTIC AREAS



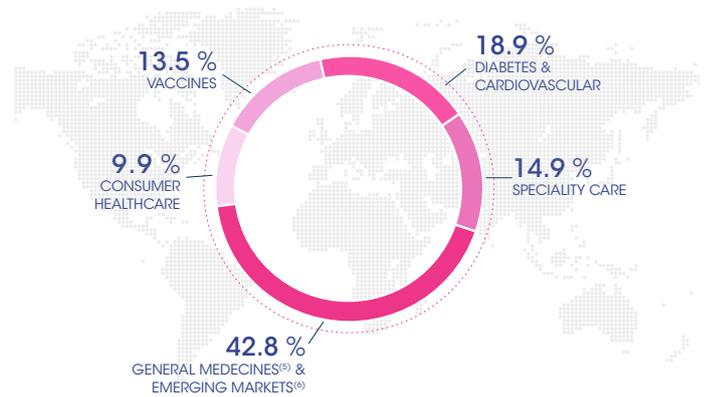
PUSHING FOR INNOVATION

€5.2 billion
invested in R&D in 2016⁽¹⁾
➔ up to **€6 billion** annual investments by 2020



KEY FIGURES

33.8 billion
in 2016⁽⁴⁾



(1) Annual Report on Form 20-F 2016

(2) As of January 1st, 2017

(3) As of February 2017

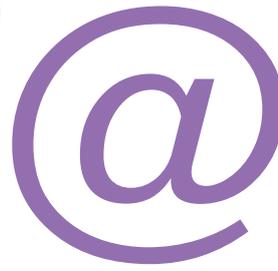
(4) Excluding Animal Health, Source Form 20-F 2016, p.91.

(5) Including Established Rx products & Generics

(6) Emerging Markets: world excluding U.S., Canada, Western Europe (France, Germany, UK, Italy, Spain, Greece, Cyprus, Malta, Belgium, Luxembourg, Portugal, the Netherlands, Austria, Switzerland, Sweden, Ireland, Finland, Norway, Iceland, Denmark), Japan, South Korea, Australia, and New Zealand

(7) Rest of the World: Japan, South Korea, Canada, Australia and New Zealand

USEFUL LINKS



World Health Organization (WHO)

http://www.who.int/topics/pharmaceutical_products/en
<http://www.who.int/mediacentre/factsheets/fs275/en/>



International Medical Products Anti-Counterfeiting Taskforce (IMPACT)

<http://www.who.int/impact/en/>



European Federation of Pharmaceutical Industries and Association (EFPIA)

<http://www.efpia.org/>



International Pharmaceutical Federation (FIP)

<http://www.fip.nl/www/index.php>



International Federation of Pharmaceutical Manufacturers and Association (IFPMA)

<http://www.ifpma.org/en/news/news-releases/news-details/article/pour-une-approche-integree-contre-les-faux-medi.html>



U.S. Food and Drug Administration (FDA)

<http://www.fda.gov/oc/initiatives/counterfeit/default.htm>
<http://www.fda.gov/opacom/7alerts.html>



Reporting Unlawful Sales of Medical Products on the Internet

<http://www.fda.gov/oc/buyonline/buyonlineform.htm>



Medicines and Healthcare products Regulatory Agency (MHRA)

<https://www.gov.uk/search?q=counterfeit>



Pharmaceutical Research and Manufacturers of America (PhRMA)

<http://www.phrma.org/>



National Association Boards of Pharmacy (NABP)

<http://www.vipps.info/>



World Health Professions Alliance

<http://www.whpa.org/>



INTERPOL

<http://www.interpol.int/>



Institut International de Recherche Anti-Contrefaçon de Médicaments (IRACM)

<http://www.iracm.com/>

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