

## Counterfeit drugs – a global public health scourge

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**Along with Asia and Latin America, Africa is currently one of the regions most affected by the trade in counterfeit drugs which account for almost one-third of pharmaceutical products on sale in these regions. The stakes are huge for the governments concerned but existing legislation is still too deficient - or even non-existent - to banish this scourge.**

The World Health Organisation (WHO) estimates that one out of every ten drugs is a fake (i.e., deliberately or fraudulently usurping the identity, composition or source of a drug). Asia, Latin America and Africa are worst affected. Exercising control over distribution channels is more difficult in these regions and up to 30% of medicines on the market may be counterfeits - rising to 50% or even 70% for certain classes of drug.

These days, all therapeutic classes and new forms of drugs are concerned - an increasing number of injectable products for treating serious illnesses like cancer as well as vaccines - and counterfeit medicines can have a whole host of undesirable effects. They can render the treatment ineffective, cause serious side effects and, in the worst cases, result in death. Every year, fake drugs are estimated to kill several hundred thousand people throughout the world.

It is an especially lucrative trade: it is estimated that an investment of 1,000 dollars can generate returns of between 200,000 and 500,000 dollars and the related sanctions are relatively innocuous. Internet has become the favoured means of distributing falsified medicines. A very large number of the 50,000 websites identified throughout the world are operating completely illegally, selling medicines that normally require a prescription as well as unapproved or fake drugs. The National Association of Boards of Pharmacy (NABP) believes that 95.7% of websites selling drugs online are illegal.

### **The African trade in falsified drugs**

Fake drugs account for around 10% of the global pharmaceutical market and at least 30% of drugs consumed in Africa, the Continent worst affected by this affliction. The impacts in public health terms are huge with thousands of deaths every year and increased resistance to antibiotics. Some of the most common diseases like malaria and tuberculosis are concerned but they are not the only ones and paediatric vaccines are also a target of predilection.

Economic and cultural factors help explain both the extent and the deleterious effects of street drug markets in this domain. Transnational organised crime is increasingly focusing on this activity for two main reasons: the enormous potential gains (estimated global sales of almost US\$ 200 billion ) and the virtually non-existent criminal sanctions. One-off initiatives conducted by the World Customs Organization (WCO) over the past three years with the French backing of the Institute of Research Against Counterfeit Medicines (IRACM) have highlighted the seriousness of the problem as they have resulted in 900 million of fake drugs being seized in African ports .

When it comes to dealing with counterfeit medicine, national legislation remains grossly deficient or completely non-existent: the sanctions available for punishing smugglers are often derisory, non-dissuasive or not even applied; regional customs frequently have neither the resources nor the experience for targeting and searching incoming containers; law enforcement agencies cannot handle the international dimension of traffic; and the courts generally have no training in this area and are in no position to support the international effort needed to investigate and locate the distribution channels and freeze smugglers' assets.

## **Deploying concrete measures**

As a stakeholder in the battle against counterfeit drugs, Sanofi set up a dedicated internal coordination unit in 2007 that brings together experts from the divisions concerned, i.e., medical, pharmacovigilance, security, industrial affairs, regulatory, legal and public affairs, etc. In 2008, Sanofi also set up its own Central Anti-Counterfeiting Laboratory in Tours, France, to analyse suspected fake drugs and enhance global knowledge in this domain.

Suspicious samples forwarded to the lab for analysis can originate from various different sources: an external request (from health authorities for example) or drugs seized by the police or customs; internal surveillance conducted in partnership with pharmacovigilance and quality services to track any drugs suspected of being counterfeit; or market surveillance conducted by Sanofi itself (sample purchases made both online and in pharmacies, targeting risky countries and products).

The Group has also deployed three levels of industrial protection. The first guarantees the integrity and inviolability of packaging. Various forms of tampering are tackled by the inviolability initiatives - security cuts and perforation labels, stick pack pouches and delaminating labels, etc. The second level concerns product authentication: Sanofi has developed high-security labels with visible (both for distributors and patients) and invisible identification features (known only to the company). The third level involves identifying each pack using a Data Matrix. Since 1 January 2011, pursuant to current legislation, all Sanofi products marketed in France have a 2D barcode printed on each pack containing all traceability data: product code, batch code and expiry date. Scanning with the Data Matrix in the pharmacy enhances the traceability of drugs delivered to dispensing pharmacies or hospitals and automatically detects all batches that have expired.

Sanofi has supported the pharma-serialisation initiative being sponsored by the European Federation of Pharmaceutical Industries and Associations (EFPIA) that facilitates package identification. It is based on the principle of assigning each package a unique random serial number within the Data Matrix in the form of a code that will be attached during product packaging and transmitted to a central database. Serialisation will be rolled out to all countries in which it has been made mandatory by regulatory authorities (i.e., from February 2019 in Europe).

Sanofi has also deployed "End-to-end" processes all over the world designed to safeguard our supply chain across the entire drug distribution channel - from raw material procurement through product destruction and including all of the production, packaging and distribution stages in between.

On 14 January 2017, during the 27th Africa-France Summit held in Bamako, Mali, the African heads of state vowed to "step up their efforts to combat terrorism and illegal trade" stressing "the serious dangers, in particular for the health of their people, posed by the growing trade in counterfeit drugs organised by transnational crime gangs across Africa. The heads of government committed to combating this scourge by deploying a coherent global strategy." This decision could be seen as an echo of the call by former French president Jacques Chirac, in Cotonou on 12 October 2009, to combat the trade in counterfeit drugs. More recently in a speech in Ouagadougou, President Emmanuel Macron reminded his audience that this same battle was a major public health concern for all of Africa.

