A regulation to fight against falsified medicines

The production, distribution and sale of falsified medicines constitute illegal activities increasingly growing over the world.

More than 1 million people die every year from counterfeited healthcare products.

In some parts of Asia, Africa and South America, falsified medicines would account for more than 30% of drugs on the market.

It is estimated that one out of every ten drugs sold in the world is probably false.

About 50% of medicines sold on the internet are fake drugs (counterfeit drugs, ...)

A regulation to improve traceability of medicines

The new European Directive 2011/62 on traceability of medicines includes a unique identifier on the box in addition to the lot number and the expiry date. This helps ensure patient safety and facilitates drug recall procedures.

In case of incident or doubt on a lot, recall of the drug is required by the Health Authorities. This procedure is reinforced by the new regulation on safety features.

Recall can be done when non-compliance with the specifications described in the marketing authorization file has been detected or following the identification of a deviation from Good Manufacturing or Distribution Practices. These quality defects can be discovered by health professionals, pharmacists or patients, but also when controls are carried out for the market surveillance.