



## **COMMISSION UNIFAB - APRAM**

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**Meriem BOURAHLA-LOUDIYI**

**Directrice**

**Marques & Lutte contre la Falsification**

- I. SERVIER IN A SLIDE**
- II. CHALLENGES OF PHARMA INDUSTRY  
& OUR EXPERIENCE**
- III. OUR ACTIONS AT SERVIER**



## I. SERVIER IN A SLIDE

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**€ 4,7 billion in revenue**

Servier's products 3,3bn €

Generics 1,4bn €



**N°2 largest pharmaceutical Group in France**

**31<sup>st</sup> largest pharmaceutical company worldwide**

16 chemical and pharmaceutical production sites

15 International Centers for Therapeutic Research



**22,500 employees in 66 countries**

(5,000 in France)



**4 therapeutic areas**

**100 million patients in 150 countries**

treated daily with Servier's products and generics



**23% of Servier's turnover invested in R&D**



**A leader in cardiology**

2<sup>nd</sup> pharmaceutical company in Europe

3<sup>rd</sup> pharmaceutical company Worldwide



**SERVIER**

## II. CHALLENGES OF PHARMA INDUSTRY & OUR EXPERIENCE

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### 1. Overview

WHO - Falsified medicines: Medical products that deliberately / fraudulently misrepresent their identity, composition or source

Pharmaceutical crime is a global problem with global networks. No region in the world is spared, even in Europe!

Pharmaceutical crime: a crime with low risks (penalties) & high financial returns (worth \$200 billion a year – 10 to 25 times more profitable than drug trafficking)

Falsified medicines = Public Health issue

## II. CHALLENGES OF PHARMA INDUSTRY & OUR EXPERIENCE

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### 2. Why is it Harmful for Patients?

No active ingredient

Wrong amount of the  
correct active ingredient



Wrong active ingredient

Toxic chemicals (unknown  
impurities, contaminated  
with bacteria, poison such  
as mercury, arsenic, rat  
poison or cement)



## II. CHALLENGES OF PHARMA INDUSTRY & OUR EXPERIENCE

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### 2. Why is it Harmful for Patients?

#### ILLCIT MANUFACTURING



#### SERVIER FACTORY



## II. CHALLENGES OF PHARMA INDUSTRY & OUR EXPERIENCE

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### 3. Challenge: Impossible to Differentiate Counterfeit from Genuine Products

**FAKE**



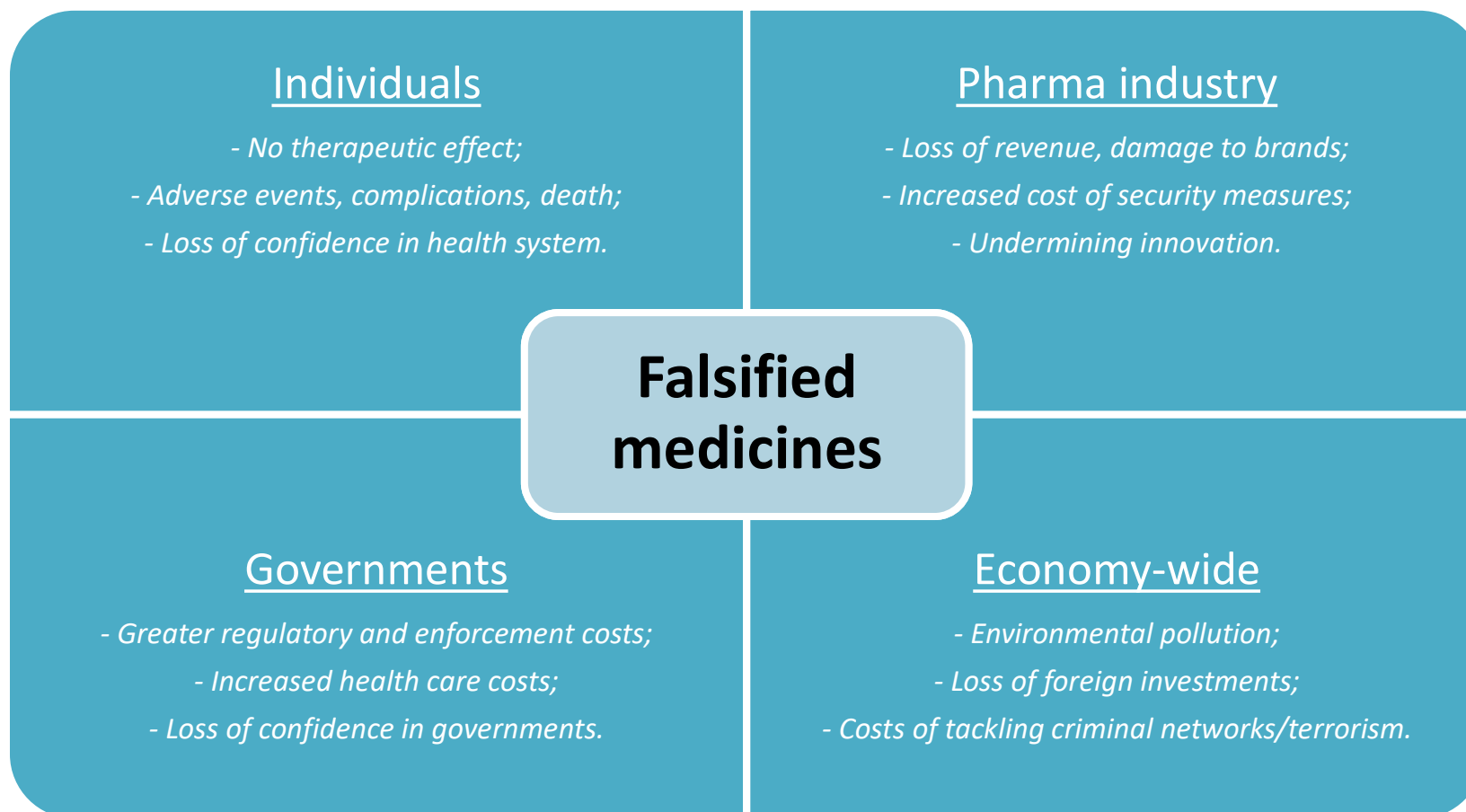
**GENUINE**



## II. CHALLENGES OF PHARMA INDUSTRY & OUR EXPERIENCE

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### 4. Dangers of Falsified Medicines





## II. CHALLENGES OF PHARMA INDUSTRY & OUR EXPERIENCE

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### 5. New Trend – Illicit Sales on the Internet



- The **Internet** has become one of the **preferred vehicles for the circulation of fake medicines**, which has been highlighted during the Covid-19 pandemic.
- Up to **35,000** illegal websites target consumers and patients.
- **96%** of online pharmacies are illicit.



(Study published by LegitScript in January 2016: <https://buysaferx.pharmacy/wp-content/uploads/2018/12/Fake-Medicines-patient-leaflet.pdf>)

## II. CHALLENGES OF PHARMA INDUSTRY & OUR EXPERIENCE

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### 5. New Trend – Illicit Sales on the Internet



**Illicit Online Pharmacies**



**Social Media Platforms  
& Marketplaces**

**Major issue: almost impossible to identify which websites are selling falsified/counterfeit products**

**Safety issue**

**Lists of authorized websites + EU common logo in the EU should facilitate the identification of illicit online pharmacies within the EU**

## II. CHALLENGES OF PHARMA INDUSTRY & OUR EXPERIENCE

- A **common European legal framework** for the common logo is set out in European Commission [Directive 2001/83/EC](#) as amended by [Directive 2011/62/EU](#) on falsified medicines for human use and by the [Implementing Regulation 699/2014](#) on 24 June 2014.
- Since the 1<sup>st</sup> of July 2015:
  - **National regulatory authorities in the EU are obliged to list all registered online medicine retailers in their country on their websites;**
  - Member States have to ensure that the **legal provisions on the common logo** are applied in their country;
  - **All online medicines retailers** registered in the EU should **display the common logo**.
- The Directive also obliges Member States to conduct and promote **information campaigns** on:
  - The dangers of falsified medicines,
  - The risk of medicinal products supplied illegally online,
  - The functioning of the common logo for online sales of medicinal products.



## II. CHALLENGES OF PHARMA INDUSTRY & OUR EXPERIENCE

- Patients should **only buy medicines from online retailers registered** with the national competent authorities in the EU Member States.

➡ See: List of registers of online medicine retailers on EMA website  
(<https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/falsified-medicines/buying-medicines-online>).



List of registers of online medicine retailers

EU Member State	Register of online retailers
 Austria	<a href="https://versandapotheeken.basg.gv.at">https://versandapotheeken.basg.gv.at</a> (DE)
 Belgium	<a href="http://www.fagg-afmps.be">http://www.fagg-afmps.be</a> (NL) <a href="http://www.fagg-afmps.be">http://www.fagg-afmps.be</a> (FR)
 Bulgaria	<a href="http://www.bda.bg">http://www.bda.bg</a> (BG)
 Croatia	<a href="http://www.halmed.hr">http://www.halmed.hr</a> (HR)
 Cyprus	<a href="http://www.moh.gov.cy">http://www.moh.gov.cy</a> (EL) <a href="http://www.moh.gov.cy">http://www.moh.gov.cy</a> (EN)
 Czech Republic	<a href="http://www.sukl.eu">http://www.sukl.eu</a> (EN)
 Denmark	<a href="http://laegemiddelstyrelsen.dk">http://laegemiddelstyrelsen.dk</a> (DK) <a href="http://laegemiddelstyrelsen.dk">http://laegemiddelstyrelsen.dk</a> (EN)
 Estonia	<a href="http://rkav.sm.ee">http://rkav.sm.ee</a> (ET/EN)
 Finland	<a href="http://www.fimea.fi">http://www.fimea.fi</a> (FI)
 France	<a href="http://www.ordre.pharmacien.fr">www.ordre.pharmacien.fr</a> (FR)
 Germany	<a href="http://www.dimdi.de">http://www.dimdi.de</a> (DE)

### Rechercher un site autorisé pour la vente en ligne de médicaments

Comment rechercher un site autorisé pour la vente en ligne de médicaments ?

- accès à toute la liste : cliquer sur « [Voir toute la liste](#) » pour accéder à la liste complète des sites autorisés pour la vente en ligne
- recherche simple : indiquer le nom du site (sans les « www. ») ou du pharmacien ou de la région
- recherche avancée : indiquer dans le champ correspondant le nom du site (sans « www. ») et/ou la région et/ou le nom du propriétaire de la pharmacie.

Vous pouvez également

- trier les résultats de recherche par région, département, commune ou ordre alphabétique de nom des sites
- filtrer les résultats par région, puis par département enfin par commune.

Par défaut les sites autorisés pour la vente en ligne de médicaments s'affichent par ordre alphabétique.

> [Télécharger la liste de l'ensemble des sites](#)

### III. OUR ACTIONS AT SERVIER

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#### SERVIER'S STRATEGY

##### DETECT

- **Internal process and program** to detect and manage cases of suspect falsified products
- **Applications for Action** (Customs)
- **Internet monitoring**
- **Market surveillance**
- **Intelligence-led database**

##### PREVENT

- **Serialization** (FMD) and additional authenticating features on packaging
- **Trainings** for law enforcement authorities (customs, police, regulatory agencies ...)
- **Awareness events**

##### RESPOND

- **Collaboration** between pharma companies through associations (EFPIA, PSI, ASOP EU, G5 Santé, ...)
- **Cooperation** with LEAs and health authorities,
- **Investigations**
- Participation to **joint operations** with Interpol, WCO, Europol, ...
- **Analyses** of the suspect samples
- **Legal proceedings**



### III. OUR ACTIONS AT SERVIER

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#### 1. Online Monitoring Programs



### III. OUR ACTIONS AT SERVIER

#### 1. Online Monitoring Programs

##### ❖ DISRUPTION PROGRAMS WITH PSI INITIATIVES

- ❑ Several disruption programs in previous years: D17, D18, D19
- ❑ Ongoing one: **D21 - 10 pharmaceutical companies**, including Servier, led by the PSI (Pharmaceutical Security Institute).
  - Deter the **illegal sale** of potentially unsafe medicines from online pharmacies (OLPs), social media platforms and marketplaces for disruption.

##### ❖ « G5 SANTÉ » INITIATIVES

- ❑ Signature of partnership agreement with OCLAESP on 9 January 2020;
- ❑ Two monitoring programs launched in 2020 and 2021:
  - Covid-19
  - Oncology products
- Identify **illicit networks** selling products of participating laboratories and share the results to **French authorities (OCLAESP)** and **EUROPOL** to potentially dismantle networks.

### III. OUR ACTIONS AT SERVIER

#### 2. Contribution to Associations

##### ❖ Contribution to EFPIA and G5 Santé position papers for the Digital Service Act:

- The illicit sale of medicines is *per se* **dangerous as illegal content**.
- **Aligned with general principle** that everything which is forbidden offline should also be forbidden online.
- Our proposals towards the particularities of the **pharmaceutical sector**:
  - Broaden « KYBC » principle to **all online intermediaries** (regardless of size and **including domain name registrars**) and especially for the sale of **medicines**;
  - Share information on **delisted contents**, at least for dangerous illegal content with patient/consumer, pharma companies, LEAs;
  - Pro-active measures: Online platforms to verify (i) if the medicine is under prescription or not, (ii) Marketing Authorization status in the targeted country (iii) authorized status of the seller and (iv) the display of common logo. The advertisement of prescription pharmaceutical products should also be delisted.

### III. OUR ACTIONS AT SERVIER

#### 2. Contribution to Associations

##### ❖ La proposition de loi visant à moderniser la lutte anti-contrefaçon en France avec l'UNIFAB et le G5 Santé :

- La mise en place d'une amende forfaitaire de 200€ pour tout délit de détention de marchandises contrefaisantes et la possibilité pour la Douane de réaliser des coûts d'achats pour les marchandises contrefaisantes **et les médicaments falsifiés**.
- Une collecte, par l'INPI, de l'ensemble des données utiles à la quantification de la contrefaçon afin de réaliser une analyse objective de ses diverses conséquences;
- La possibilité pour les agents assermentés de prouver la matérialité de toute infraction aux dispositions du Code de la Propriété Intellectuelle;
- La possibilité aux entreprises de demander la suppression de noms de domaines ou comptes de réseaux sociaux portant atteinte à leur marque, de permettre à la Douane de mettre en place une procédure graduée incitant les intermédiaires Internet à davantage de responsabilité et d'utiliser la blockchain comme garantie et indicateur de l'origine des produits et services;
- De permettre aux agents de Police municipale de constater les infractions de vente de biens à la sauvette.'

### III. OUR ACTIONS AT SERVIER

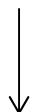
#### 3. Collaboration with ALL stakeholders

##### ❖ Cooperation with platforms :

- Signature of MoU with JD and member of Alibaba Alliance in China;

##### ❖ Participation to the platforms programs, for example:

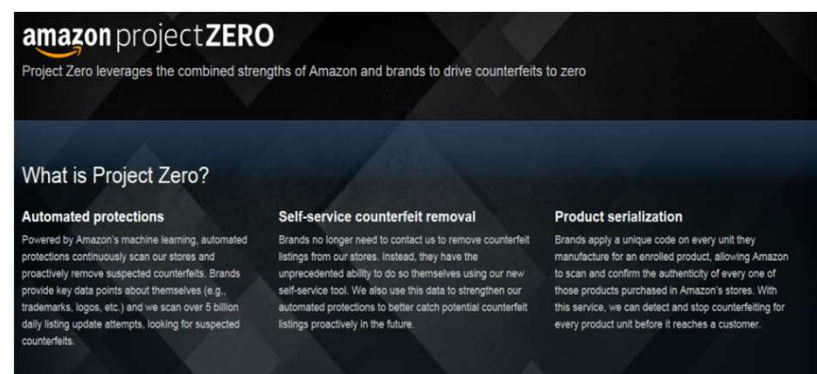
- **VeRO** program by 



#### VeRO – What is it?

- **Verified Rights Owner** programme
- Anti-counterfeiting
- Free
- Fast
- Ideal for stopping small scale infringement

- **Zero Project** by 



The screenshot shows the Amazon Project Zero website. At the top, it says "amazon projectZERO" and "Project Zero leverages the combined strengths of Amazon and brands to drive counterfeits to zero". Below this, there is a section titled "What is Project Zero?" which is divided into three columns: "Automated protections", "Self-service counterfeit removal", and "Product serialization". Each column contains a brief description of the service.

Automated protections	Self-service counterfeit removal	Product serialization
Powered by Amazon's machine learning, automated protections continuously scan our stores and proactively remove suspected counterfeits. Brands provide key data points about themselves (e.g., trademarks, logos, etc.) and we scan over 5 billion daily listing update attempts, looking for suspected counterfeits.	Brands no longer need to contact us to remove counterfeit listings from our stores. Instead, they have the unprecedented ability to do so themselves using our new self-service tool. We also use this data to strengthen our automated protections to better catch potential counterfeit listings proactively in the future.	Brands apply a unique code on every unit they manufacture for an enrolled product, allowing Amazon to scan and confirm the authenticity of every one of those products purchased in Amazon's stores. With this service, we can detect and stop counterfeiting for every product unit before it reaches a customer.





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**MERCI!**