



Protect medicines against product crime and in parallel promote digitization



Dr. Pius Waldmeier, Head of Global Roche Anti-Counterfeit Commission (GRACC) and Patient Safety



Hoffmann - La Roche at a glance

Maintaining a long-term orientation



1896

Founded in Basel
Family still holds
majority stake



Reliable partner during
COVID-19 pandemic



Leader in
Diagnostics and
Pharma



#1

R&D investor in
healthcare

100,920
Employees worldwide

16.4 million
People treated with
our medicines in 2021



32 medicines
on the WHO List of
Essential Medicines



Sustainable
one of the most sustainable healthcare company
in the Dow Jones Sustainability Indices

27 billion
tests conducted with
our Diagnostics
products in 2021

We are committed to **protect our patients** and Roche against counterfeit and product crime.



Generate awareness of the serious counterfeit topic



Define strategies for **preventive and responsive actions**



Coordinate **counterfeit investigations** and define **follow-up** and **communication activities**



Be proactive

What is GRACC doing?

Activities across multiple disciplines



Counterfeit is a big global, serious issue

...and was even more observed during Covid-19



➤ **Up to 1 million people die each year due to counterfeit drugs!!**

Pharmaceutical Counterfeit is a **\$200 billion** business. It is the biggest counterfeit sector in the world

9 mio illicit medicine units seized in 92 countries during PANGEA XIV 2021 (18-25 May) worth ca. 23 mio \$, 113'020 websites closed, 277 arrests.

30% of medicines in developing countries are counterfeit

50% of medicines purchased online are counterfeit

90% of drugs purchased online come from different country the website claims

Up to **50'000** online pharmacies, **95%** are not compliant with law or industry standard

The impact of counterfeited/falsified medicine is severe

Please be aware of the risks



- **Patient safety** is at risk, with a possibility of
 - Adverse events
 - Therapeutic failure
 - Drug resistance
 - **Death**
- **Loss of confidence** in public healthcare systems
- Impact on **brand/company reputation**



It might happen anywhere

The Lunapharm Case



- **“Trade with stolen drugs:** The Brandenburg pharmaceutical company Lunapharm is suspected of having traded for years with stolen and possibly ineffective cancer drugs.”
- **“Stolen in Greece, sold in Germany”**
- **“The scandal surrounding the Brandenburg pharmaceutical company Lunapharm is expanding: in Germany and Switzerland, there were several raids, it is about the charge of commercial stolen goods.”**
- ...



REF: <http://www.spiegel.de/gesundheit/diagnose/lunapharm-ermittler-ruecken-zu-razzien-im-fall-lunapharm-aus-a-1224577.html>

REF: http://www.xing-news.com/reader/news/articles/1985555?cce=em5e0cbb4d.%3AzuegbR05ainHg-8m3TcsAJ&link_position=digest&newsletter_id=40835&toolbar=true&xng_share_origin=email

Online Roche Brand Protection

Monitoring Market Places, Social Media & Websites



2021 Actions & Activity

	Reported	Removed	Success
Website	1753	1523	87%
Marketplaces	3174	2990	94%
Social Media	3238	1857	57%

Infringement Reports on Continents

❖ Asia:	49%
❖ North America:	38%
❖ Europe:	11%
❖ South America:	3%
❖ Africa:	0.05%

- **Top Countries:** Indonesia, India, Philippines
- **Top Marketplaces:** Tokopedia, IndiaMart, Lazada
- **Top Social Media Platforms:** Facebook, Instagram, Twitter

Can you tell which one is a counterfeit?



Can you tell which one is a counterfeit?

- It is difficult to find out if you do not have the original sample to compare
- Therefore additional features and technologies are needed to identify fake drugs



Global Prevention Strategy

Implementation for all New Product Launches



Serialization

GTIN 12345678901234

S/N 9999999999999999
EXP 99 9999
LOT 99999999



Single Unit Code



Tamper Evidence

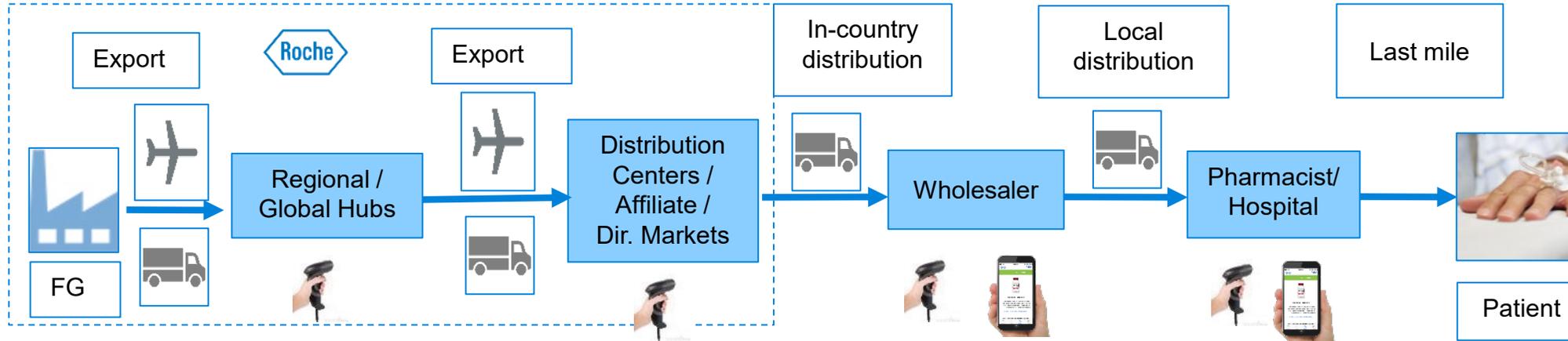
Covert Authentication Feature

Benefits & Impact of digitized products

For full Track & Trace and inventory visibility



GS1 "one barcode" strategy



Verification and Decommissioning App

❖ Serialization/Single Unit Coding/Single Unit Serialization

- for authentication, re-imbursments and re-selling
- for full visibility of E2E Supply Chain inventory
- to detect counterfeit, illegal parallel imports, enables recalls
- to avoid medication errors e.g. via bed-side scanning
- reduces cost for hospitals (re-labelling step eliminated)
- fulfil customers needs and meet tender requirements
- significantly increase hurdles for counterfeiters, detect re-used or re-filled vials and increase **patient safety**

Track & Trace in many Countries planned e.g. Ecuador, Kazakhstan, Bahrain ...

❖ ePI

- exchange product information paperless via mobile phone App (with many features serving data hungry patient/HCP/HA).

Summary and Lesson Learned

Help us to spread the message



- **Patient Safety** is the primary concern
- Counterfeit/product crime is a **global issue**
- **Be cautious** when buying through the internet. Avoid buying medicine outside of authorized distribution channels
- **Be suspicious** of extraordinarily low prices
- When buying the same medicine repeatedly, **compare** the new and old packaging and, if they differ (e.g. size, shape, color, lack of tamper evidence), ask your pharmacist
- **Check** if the packaging indicates the batch number, manufacturing date, expiry date, and the manufacturer's name
- **Inform** the manufacturer in case of suspicion



BEWARE OF FAKE MEDICINES

TRAVEL TIPS

BEFORE SETTING OUT

Prepare the quantity of medicines in advance that you will need during the period of time that you will spend traveling. (In cases of chronic conditions, you are recommended to take with you a higher than necessary quantity of medicines). If you need to renew your prescription, plan well ahead to have sufficient time to get the prescription issued. Consider that some medicines may be out of stock in the pharmacy and need to be ordered first. Pack your medical prescriptions (with the trade marks, generic names, distributors and manufacturers), and keep them with you in your carry-on luggage (you may be asked for them at borders and security control).

PROTECT YOURSELF YOUR FAMILY AND FRIENDS

Remember that you always carry a lot of all the medicines you take in your purse or wallet. If you lose your medication, you may need a new prescription. In case you have to go to the emergency room it is crucial to be helpful.

FIGHT THE FAKES!

INTERNET RISKS

BE AWARE WHEN BUYING MEDICINES ON THE INTERNET

Buying from online pharmacies can be dangerous. Before you order medicine online, it is important to know the risks of buying from online pharmacies. They may look professional and legitimate – but they could actually be an illegal operation that offer dangerous drugs that have not been checked for safety or effectiveness. These websites often sell counterfeit products. Many online pharmaceutical sales sites look professional and legitimate. These sites could actually be a front for an illegal operation that offers dangerous drugs that have not been checked for safety or effectiveness. These websites frequently sell counterfeit products and the source of the products is often unknown.

PROTECT YOURSELF YOUR FAMILY AND YOUR FRIENDS

Tips on Proper Waste Management

Roche is committed to protecting patients from counterfeit and illegally traded medicines. Criminals commonly recycle used packaging when they are producing counterfeit medicines (e.g. folding box, syringes, vials, leaflets). For this reason, Roche wishes to share recommendations for handling waste products.



Labelled Syringes, Vials, Pens, etc

Do not dispose of intact primary packaging material in regular waste. Instead:

Destroy vials or syringes by using crushers

Deface labels on vials or syringes by using permanent markers

Dispose of these products in designated sharp boxes



Folding boxes, leaflets, plastic bottles, etc

Do not dispose of intact folding boxes or patient information leaflets in regular waste. Instead:

Destroy them by tearing or cutting the folding boxes and leaflets

Deface folding boxes, leaflets or labels on bottles by using permanent markers

Dispose of these products in designated containers

Roche Contact information

Patient Safety is our primary concern



Dr. Pius Waldmeier

Head of Global Roche Anti-Counterfeit Commission (GRACC) & Patient Safety
GS1 Healthcare Leadership Team Member

F. Hoffmann - La Roche Ltd.
CH-4070 Basel
Switzerland

pius.waldmeier@roche.com



Doing now what patients need next

Europol Shield Operation 1. April to 15. October 2021



...544 arrests and €63 million of fake pharmaceuticals and illegal doping substances seized

The abuse represents a significant threat to users' health. Even greater is that posed by the use of counterfeit medications. Contrived in underground labs with no hygiene or security procedures in place, these products often contain harmful ingredients. Since the beginning of the COVID-19 pandemic, criminals have further invested efforts into counterfeiting medications that are in the highest demand. To increase their profits, criminal networks have focused on distributing fake "corona-cures" and counterfeiting medical devices and sanitisers, which are then sold online.

During Operation Shield II, law enforcement officers targeted criminal groups trafficking doping substances (hormone and metabolic regulators) and various medications such as anti-cancer drugs, erectile dysfunction medicines, pseudoephedrine, painkillers, antioestrogens, antivirals, hypnotics, antihistamines and anxiolytics.



<https://www.europol.europa.eu/media-press/newsroom/news/544-arrests-and-%E2%82%AC63-million-of-fake-pharmaceuticals-and-illegal-doping-substances-seized>

GRACC

Global Roche Anti-Counterfeit Commission

Principal Findings 2021

- Overall 15% decline in new pharmaceutical crime incidents due to disruptions in the supply and delivery services faced by criminal organizations.
- Injectables reached 24% of all counterfeit medicines detected.
- COVID-19 related medicines experienced a 273% increase in pharmaceutical crime incidents.
- Despite a decline in illegal medicine seizures, arrests reached 2,574 globally, which is the largest number ever recorded by the PSI.