Global Security
Combating Falsified Medicines

UNCTAD 2nd Illicit Trade Forum

Session 3 | Trade in falsified medicines: a danger to health and development

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The views expressed are those of the author and do not necessarily reflect the views of UNCTAD

Agenda

Our vision on where we can have impact

Assuring patient safety throughout the entire life cycle of our medicines

OUR MISSION

> Delivering safe, high-quality medicines is at the heart of Novartis commitment to improve and extend people's lives. Patient safety is fundamental to our purpose and is assured throughout the entire life cycle of our medicines by product quality, pharmacovigilance and combating falsified medicines

THE CHALLENGE

- **Falsified medicines** are a **growing global health** problem which **impacts all geographies** and **therapeutic areas**. They represent a **serious** and **growing** problem for **public health**, **healthcare system**, **governments**, and **pharmaceutical manufacturers** (e.g. anti-microbial resistance, access fraud, reputation)
- **Falsified medicines** poses an enormous **risk** to **patient** health and **safety** (e.g. therapeutic failure and/or death)
- **Falsified medicines** can often **contain harmful chemicals**, **no active ingredient**, **undeclared** active **ingredients** /excipients, or the **wrong dosage** of the **correct** active **ingredient**
- **At Novartis**, between 2017 and 2021, **over 90%** of **confirmed falsified** medical products **forensically tested** were **classified** as **Level III-** the **highest** patient **safety risk leading to therapeutic failure, serious harm or death**.

OUR POSITIONING

Novartis commits to **monitor**, to **timely authenticate** and **report** incidents of **falsified medicines** and to **work** with **national authorities** and **inter-governmental agencies**, such as **WHO**, to **protect patients**' safety **as reflected** in Novartis **corporate governance** and **reporting**.

INTEGRATED ANNUAL REPORT
Progresses and KPI's featured in the company Integrated Annual Report

POSITION PAPER
Publicly available position paper on falsified medicine

RISK REPORT
Falsified Medicines featured as a top Awareness risk

ACCESS TO MEDICINES INDEX
Timely reporting efforts recognized in the Access to Medicines Index

HUMAN RIGHTS
Falsified Medicines featured in the Novartis Human Rights Statement

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Timely authentication | Drug product testing

Leverage technology to accelerate the detection of falsified medicines in the field

AUTHENTIFIELD BY NOVARTIS™

Pocket size, mobile and application enabled spectrometric sensors which aim to accelerate the authentication of falsified medicines locally

KEY MILESTONES BY MAY 2023

1. **Sensors** I Deploy 550 pocket sized mobile and application enabled sensors
2. **Global reach** I Equip 96 countries where Novartis has offices
3. **Training** I Train and onboard 1000 Novartis end-users
4. **Portfolio coverage** I onboard 100 Novartis products in the library (risk-based methodology)

Ghana | Deployment and Training of Authentifield end-users

Lab | Authentifield by Novartis testing

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1

Timely authentication | Secondary packaging testing

Leverage technology to accelerate the detection of falsified medicines locally

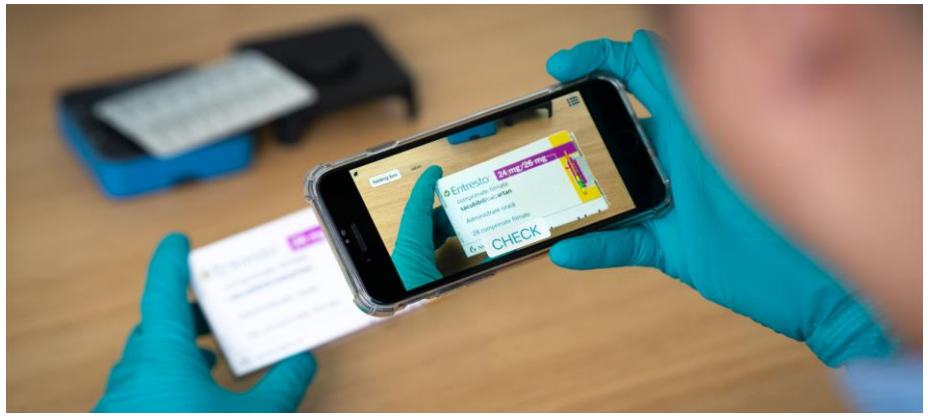
PACKAGING TESTING

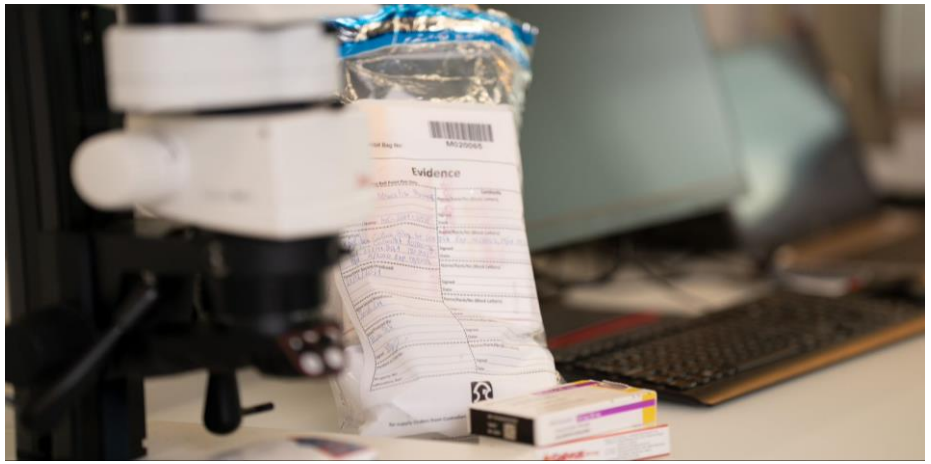
MoVe

Novartis proprietary technology which enables associates to quickly verify the Novartis security features (NSS) printed on the secondary packaging of the product via a mobile application

KEY MILESTONES

1. **Application** I Since 2020, the tool has been fully deployed
2. **Global reach** I tool deployed and active in 29 countries
3. **Training** I +190 Novartis associates have been trained and are operating the tool
4. **Portfolio coverage** I 80% coverage of the Novartis & Sandoz portfolio





MoVe Packaging testing

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Timely reporting | World Health Organization

Systematic reporting of confirmed incidents of falsified medicines to WHO within ten days

Background

In 2019, **Novartis pledged** to **report** all **incidents** of confirmed **falsified medicines** to the **World Health Organization** within **10** working **days***. **Novartis** was also **among** the **first** pharmaceutical **companies** to **join** the WHO's **new online reporting platform** for falsified medicines incidents

Our **reporting efforts** have been **recognized** in 2021 as a **best practice** by the **Access to Medicine Foundation**

Ensuring timely reporting

1 **Continuous training**
To date, +300 associates trained across the organization

2 **Periodic review of processes**
Timely reporting embedded in standard operating procedures reviewed periodically

3 **Public accountability**
Ongoing engagement with key stakeholders (e.g. WHO, ATMI) to report on compliance rate

4 **Embedded in ESG strategy**
Timely reporting is part of the company-wide ESG commitment and effort as featured in the Integrated Annual Report

*10 working days requirement is outlined by the ATMI. Internally, Novartis committed to report all confirmed cases in 7 working days

2 Collective action | Public awareness

Educating consumers and patients about the dangers of falsified medicines and the legitimate supply chain

FIGHT THE FAKES CAMPAIGN

FOCUS: SOCIAL MEDIA

The Fight the Fakes campaign and its **members** aim to **raise awareness** and **influence change** about the **proliferation** of **substandard** and **falsified medicines**

Novartis has been **supporting** the **campaign** and its **activities** for **several years**, playing an **active role** in the **fight** the **fakes awareness week**, **delivering** student-centered **interactive workshops**, and **working alongside** industry **peers** and the **IFPMA** to **upgrade** the **campaign** to an **Alliance**

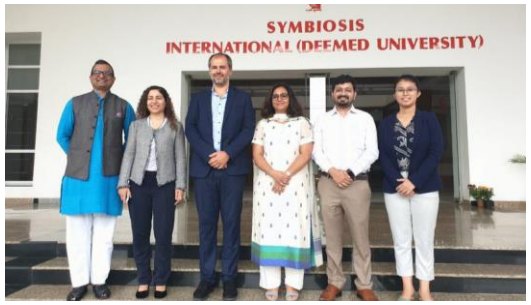
Geneva, Switzerland | Global Health Alliance Workshop | +30 students reached

INTA UNREAL CAMPAIGN

FOCUS: YOUNG ONLINE CONSUMERS

The **INTA Unreal Campaign** is a **consumer awareness initiative** which aims to **educate** those a**ged 14 to 23** about the **importance** of **brands** and the **dangers** of **purchasing counterfeit products**. Young people are largely **reached** at **schools**, youth-oriented **events**, or **virtual platforms**/social media

Novartis has been a **Platinum sponsor** of the INTA **Unreal Campaign** for **several years** and has **played** an **active role** in **delivering workshops** across **different countries** (e.g. India, US)



India | Symbiosis law college workshop | +180 students reached

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Collective action | Capacity building

Training and supporting local authorities to have a deterrent impact against pharma crime

Training and intelligence sharing

Providing targeted training and sharing intelligence with health authorities, law enforcement (e.g. customs, police) and inter-governmental organization (e.g. interpol) across the globe

166 Training conducted since 2019

11 800 Stakeholders reached since 2019

27 Countries

Testing and authentication support

Providing timely and quality testing and authentication support to law enforcement and health authorities to support investigations and legal proceedings

1553 Drug product authentication since 2020

1502 Packaging authentication since 2020

24 Countries

2

Collective action | Capacity building

Efforts resulting in successful transnational enforcement operations

Novartis has worked closely with key intergovernmental organizations (i.e. Interpol, Europol, WCO) on several transnational enforcement operations by (1) sharing intelligence, (2) providing information on products/indicators, (3) providing authentication support and (4) conducting trainings

Europol Shield 2

- 01 Apr-15 Oct 2021
- 42 countries involved in operation
- Target: hormone growth, opioids, oncology treatments, and Covid-19 vaccines
- 25 M units of falsified medicines seized

WCO STOP

- 30 Apr- 4 May 2022
- 160 member countries of the WCO
- +50 M units of falsified medicines seized
- The role of Novartis & pharma companies underlined by the secretary general

Interpol- Pangea XIV

- 18 May-25 May 2021
- Involved authorities from 92 countries
- 113 020 web links removed and 23 M worth of illicit products seized

European Anti-Fraud Office

- 01 Apr-30 Oct 2021
- 17 customs and police authorities focused on fighting against stolen Oncology medicines
- 254,731 tablets & 131,027 vials of medicines intercepted

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Collective action | Policy & Advocacy

Continued close collaboration with the United Nations on building a stronger, harmonized legislative environment to effectively combat falsified medicines and better protect patients safety

UNCTAD

- Educated Member States on FM* during 1st Illicit Trade Forum
- Support UNCTAD's future illicit trade work program

UNODC

- Promoting legal and regulatory best practices on FM* via TRACIT-UNODC MoU
- Establishing activities in the area of policy, capacity building and awareness raising

OECD

- Contributed (i.e. expert panel) to the "*Trade in Counterfeit Pharmaceutical Products*" publication
- Engaged with the OECD taskforce on illicit trade

WTO

- Supporting TRACIT consultations with WTO to shape FM* position
- Contributing private sector views on emerging plan for inter-UN agency cooperation to fight FM*

*Falsified Medicines

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Call for action

Drive impact by supporting further harmonization and consolidation of ongoing initiatives in the fields of product authentication, reporting and collective action

Key takeaway messages:

1

Build engagement impact
Call for harmonization of efforts and the establishment of a coordinated approach across awareness raising, capacity building and policy making activities with a common message

2

Harmonize detection & reporting efforts
Harmonize policy framework on authentication/reporting (criteria, timeliness, format) across all stakeholders and geographies

3

Leverage and consolidate technology use
Collective effort is required to identify suitable digital technologies and standards enabling fast detection of falsified medicines and strengthen the legitimate supply chain

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Thank You

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