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
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Assuring patient safety throughout the entire life cycle of our medicines

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.

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/exipients, 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
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** | Deploy 550 pocket sized mobile and application enabled sensors

2. **Global reach** | Equip 96 countries where Novartis has offices

3. **Training** | Train and onboard 1000 Novartis end-users

4. **Portfolio coverage** | Onboard 100 Novartis products in the library (risk-based methodology)
**Timely authentication | Secondary packaging testing**

Leverage technology to accelerate the detection of falsified medicines locally

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**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.

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**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

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MoVe Packaging testing
Timely reporting | World Health Organization
Systematic reporting of confirmed incidents of falsified medicines to WHO within ten days

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<td>In 2019, <strong>Novartis pledged to report all incidents</strong> of confirmed <strong>falsified medicines</strong> to the <strong>World Health Organization</strong> within 10 working days*. <strong>Novartis</strong> was also <strong>among the first pharmaceutical companies</strong> to <strong>join</strong> the WHO’s <strong>new online reporting platform</strong> for falsified medicines incidents. Our <strong>reporting efforts</strong> have been <strong>recognized in 2021 as a best practice</strong> by the <strong>Access to Medicine Foundation</strong>.</td>
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<th>Ensuring timely reporting</th>
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<td>To date, +300 associates trained across the organization</td>
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<td>Timely reporting embedded in standard operating procedures reviewed periodically</td>
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<td>Ongoing engagement with key stakeholders (e.g. WHO, ATMI) to report on compliance rate</td>
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<td>Timely reporting is part of the company-wide ESG commitment and effort as featured in the Integrated Annual Report</td>
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*10 working days requirement is outlined by the ATMI. Internally, Novartis committed to report all confirmed cases in 7 working days.
Collective action | Public awareness
Educating consumers and patients about the dangers of falsified medicines and the legitimate supply chain

FIGHT THE FAKES CAMPAIGN

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.

INTA UNREAL CAMPAIGN

The INTA Unreal Campaign is a consumer awareness initiative which aims to educate those aged 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).

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

India | Symbiosis law college workshop | +180 students reached
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

- **1,553** Drug product authentication since 2020
- **1,502** Packaging authentication since 2020
- **24** Countries
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

Collective action | Capacity building
Efforts resulting in successful transnational enforcement operations
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*
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.
Thank You