The role of the private sector

Novartis Anti-Counterfeiting Program

UNCTAD Illicit Trade Forum

Geneva 04 Feb 2020

Stanislas Barro
Global Head of Anti-counterfeiting
Pharmaceutical crime at a glance
Impact on the United Nations Sustainable Development Goals

Hinders access to affordable, quality-assured medicines for life-threatening diseases. E.g., The large majority of falsified medicines seized and tested were found to have no API—having severe patient safety impact. As such tackling falsified medicines is part of WHO’s top 10 urgent health challenges under the umbrella of access to medicines.

Undermines investment in R&D of new drugs and has a negative impact on innovation and access to affordable medicines. E.g., According to the OECD counterfeiting reduces incentive to invest and innovate and lowers funding for R&D—further it disproportionately impacts innovation in developing countries.

Hinders economic growth and development, impacts government revenue (Healthcare). E.g., EUIPO estimates that counterfeiting costs the EU pharma sector 10.2 billion each year, 90,000 jobs, and 1.7 billion in lost government revenue.

Urgent health challenges for the next decade

€10.2 billion lost every year across the EU due to fake medicines

Press Release
September 29, 2016

1 https://www.who.int/news-room/photo-story/photo-story-detail/urgent-health-challenges-for-the-next-decade

Novartis Business Assurance & Advisory (NBAA) | Global Security
Pharmaceutical crime at a glance
Impact on the United Nations Sustainable Development Goals

Hinders the ability to reduce inequalities & maintains disparities regarding access to health/ social services
E.g. According to PwC, the proportion of fake pharmaceuticals in some developing regions such as in Africa can be as high as 70%. Further a WHO commissioned study found that fake antimalarials in SSA cost patients and health systems on average $38.5m per yr¹.

Fake drugs: How bad is Africa’s counterfeit medicine problem?  

Undermines sustainable consumption and production patterns and safe waste management
E.g. Benin Health Authorities with the support of USAID destroyed 118 tons of counterfeit pharmaceuticals during a single seizure².

Perpetuating violence, corruption, and undermining trust in institutions
E.g. UNODC reported a growing link between counterfeiting and organized criminal groups. In recent years a number of initiatives were aimed at dismantling these groups e.g. Operation Viribus dismantled 17 organized criminal groups³.

Study backs organised crime links to counterfeit medicines

Pharmaceutical crime trends

Continuously adapting to a volatile environment

➢ Mixed genuine/counterfeit

**Example:** Primary packaging genuine while the actual compound is counterfeit. Or primary packaging falsified while the actual compound is genuine (i.e. generally expired or stolen).

➢ Public sector theft (and/or non destruction)

**Example:** Large scale media exposed 2018 cases in Italy and Greece. The Greek case shows that cancer drugs were stolen by criminal gangs from public hospitals (e.g. Egypt) and smuggled them into the EU for resale at much higher prices. Involving 500 Pharmacists and 100 clinics. Recent incident in India with PAP’s.

➢ «Full salt, half salt, chalk-mitty?»

**Example:** options offered by counterfeit manufacturers to include the «right» dosage of API, a portion of it or none according to business model and destination countries targeted

➢ Off label use

**Example:** Opiods analgesics, Human Growth Hormone, ADHD treatments and ovarian stimulation treatments are among the few therapeutic areas highly targeted by criminal network, notably on the internet.

➢ Breached LSC

**Example:** Succession of cases reaching hospital, clinic and pharmacy level occurring on all continents. Particular situation of the EU with a series of incidents of falsified medicines found in the supply chain of parallel traders.
Most impacted therapeutic areas
Counterfeit cases with critical patient safety impact

- **Hormone Growth**: Europe, Mexico
  - Non-declared API

- **Psychostimulant**: United Kingdom
  - Non-declared API

- **Antidiabetic**: India
  - No API

- **Cardiovascular**: China
  - No API

- **Anti-infective**: Egypt, Venezuela
  - No API

- **Anti-malarial**: Nigeria, Benin, Burkina Faso, Niger, Angola, Gabon, Ivory Coast, DRC, Ghana, Mali
  - No API / non-declared API / low API

- **Oncology**: Egypt, India, Mexico
  - No API

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<table>
<thead>
<tr>
<th>Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>No API</td>
<td>Zero active ingredient</td>
</tr>
<tr>
<td>Non-declared API</td>
<td>Wrong active ingredient</td>
</tr>
<tr>
<td>Low API</td>
<td>Wrong dosage (resistance)</td>
</tr>
</tbody>
</table>
**Patient Safety**

Measuring the patient safety impact

≥90%

Incidents reaching Level 3 ▲

Highest risk – life threatening causing serious harm and/or leading to death

≈1,200,000**

Patients projection (i.e. in treatment equivalent terms) for which safety risks have been mitigated due to seized falsified medicines

** Very conservative number exclusively focused on falsified Novartis medicines seized since 2017

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Harmful ingredients found during tests on falsified Novartis medicines

**HEAVY METALS**
- Mercury
- Aluminium
- Uranium
- Arsenic
- Lead
- Chrome

**POISONS**
- Rat poison
- Benzopyrenes
- Boric acid
- Antifreeze
- BCPs

**CHEMICALS**
- Road paint
- Wall paint
- Brick dust
- Floor wax
- Sheet rock
- Paint thinner

**NON DECLARED APIs**
- Aminotadalafil
- Homosildenafil
- Sildenafil
- Sibutramine
- Haloperidol
- Ciprofloxacin

**NON DECLARED EXCIPIENTS**
- Dextrose
- Dextrin
- Lactose
- Starch
- Salt
- Saline

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Novartis Business Assurance & Advisory (NBAA) | Global Security
Governance & Reporting
Ensuring accountability and delivery on strategic priorities

**NOVARTIS IN SOCIETY**
Program featured in the company’s annual corporate responsibility report outlining projects, key achievements, and challenges

**NOVARTIS ANNUAL RISK**
Counterfeiting featured as an emerging risk in the 2019 report together with a mitigation plan

**NOVARTIS POSITION**
Publicly states the company’s position and approach on tackling counterfeit/falsified medicines

**ANTI-COUNTERFEITING STEERING COMMITTEE**
3 executive committee members and 7 function heads governing the program strategy and operations

**ACCESS TO MEDICINES**
Transparent disclosure of our incident escalation system as part of this biennial industry access benchmark

**EXECUTIVE COMMITTEE**
Briefed the company’s ECN Trust & Reputation committee on the risks of counterfeiting

**Trust & Reputation Committee**
Governance & Reporting
Anti-counterfeiting working groups accelerating delivery

Anti-counterfeiting working group (ACWG)

Global ACWG
- Comprised of 15+ functions

Members

Regional ACWGs

China
Based in China and focusing on China

Americas
Based in the U.S and focusing on the Americas

Africa
Based in Nigeria and focusing on west and central Africa

India & Sub Continent
Based in India and focusing on India

To be launched 2020
Ongoing
**Intelligence**

**Continuous market monitoring of Novartis products**

<table>
<thead>
<tr>
<th>ONLINE</th>
<th>OFFLINE</th>
</tr>
</thead>
</table>
| ▪ Monthly online monitoring of top 25 Novartis Pharmaceutical, Oncology and Sandoz products on:  
  ✓ Rogue online pharmacies (ROLPs)  
  ✓ Marketplaces  
  ✓ Social media platforms  
| ▪ Continuous monitoring of suspected counterfeit/falsified products in key markets  
| ▪ Example of country market surveys conducted in 2019 to detect falsified medicines |

- **Cambodia**  
- **Egypt**  
- **India**  
- **Nigeria collaboration with NAFDAC**  
- **Brazil**  
- **Mexico**
## Enforcement

Protecting Novartis patients and reputation worldwide

<table>
<thead>
<tr>
<th>SOCIAL SECURITY FRAUD SCHEME</th>
<th>ORGANIZED CRIMINAL GROUP</th>
<th>MARKET SURVEY ANTI-MALARIAL</th>
<th>ILLEGAL MANUFACTURING</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Colombia, 4 cities</strong></td>
<td><strong>Italy, multiple cities</strong></td>
<td><strong>Cameroon, 3 cities</strong></td>
<td><strong>India, Mumbai</strong></td>
</tr>
<tr>
<td>13 arrests</td>
<td>Hospital theft</td>
<td>Proactive market survey</td>
<td>Raid on a printing shop</td>
</tr>
<tr>
<td>Media coverage</td>
<td>34 raids &amp; 14 arrests</td>
<td>58 samples, 17 falsified</td>
<td>Over 27,449 labels seized</td>
</tr>
<tr>
<td>Mix of falsified medicines</td>
<td>834 units seized</td>
<td>Escalated to HA &amp; WHO</td>
<td>9 printing plaques seized</td>
</tr>
<tr>
<td>Ongoing prosecution</td>
<td>Ongoing prosecution</td>
<td>No API</td>
<td>No API</td>
</tr>
<tr>
<td></td>
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</tbody>
</table>
Prevention
Forensic tools used for product authentication

PROVE & MOVE
Authentication of secondary packaging security features via scanner and soon mobile device

SPECTROMETRIC TOOLKITS
Mobile laboratories containing vibrational spectroscopy enabling fast time authentication of suspected products

AUTHENTIFIELD BY NOVARTIS
Mobile cloud based cost-effective spectrometric sensor empowering LMICs with fast time product authentication
Prevention
Global footprint of our forensic capabilities

- SPECTROMETRIC TOOLKITS: 3
- INTERNAL LABS: 3
- PROVE VERIFIERS: 248
- AUTHENTIFIELD BY NOVARTIS DEVICES DEPLOYED*: 50

*Internal Labs (GDC, Locarno, Champing, Hyderabad) for in depth forensic investigations
Stakeholder Engagement
Engaging on multiple fronts

**Public Awareness**
- Sponsor of the **INTA Unreal Campaign** focusing on raising awareness about the **dangers of counterfeit products** amongst teenagers and young adults
- Supporting the IFPMAs **Fight the Fakes campaign** raising awareness about the **dangers of falsified medicines**

**Capacity Building**
- Implemented a train the trainer format to train **Novartis Quality and Regulatory associates** on counterfeit detection, who will **train law enforcement**
- Sharing **Best Practices with International law Enforcement** (E.g. panel with FBI, Interpol and Spanish Police during INTA 2019)

**Policy & Advocacy**
- Advance policy and advocacy with effective collaboration with **OECD, WHO, UNCTAD, and PhRMA**
- Working with Transnational Alliance to **Combat Illicit Trade** (TRACIT) to advance our messaging on the impacts of illicit trade (i.e. falsified medicines) on the United Nations Sustainable Development Goals (UN SDGs)