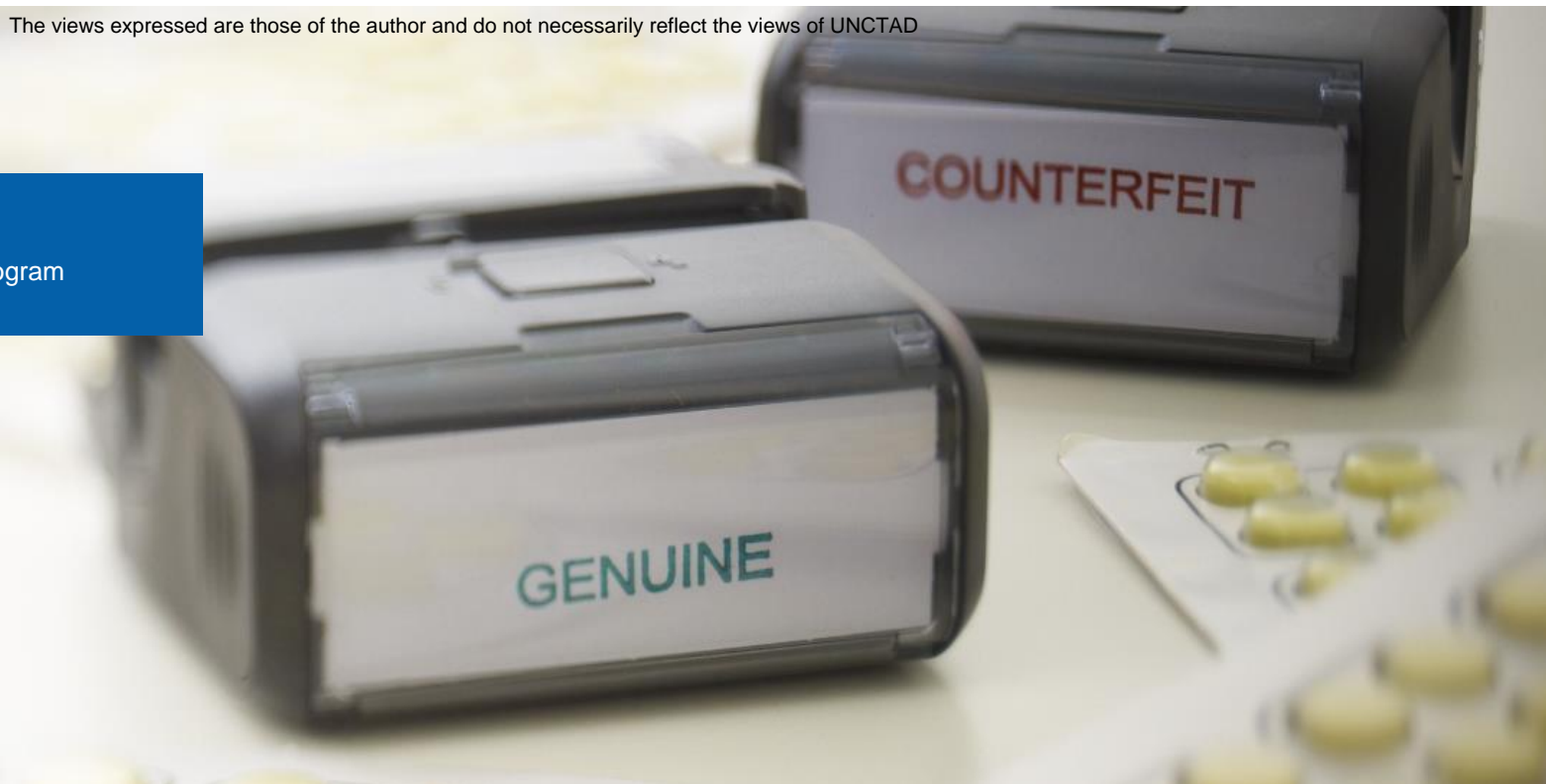


Novartis
Anti-Counterfeiting Program



UNCTAD Illicit Trade Forum

The role of the private sector

Geneva
04 Feb 2020

Stanislas Barro
Global Head of Anti-counterfeiting



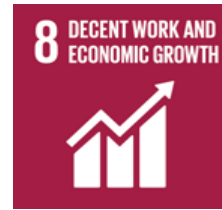
Pharmaceutical crime at a glance

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 medicines¹.

Urgent health challenges for the next decade



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 revenue².

€10.2 billion lost every year across the EU due to fake medicines PRESS RELEASE
September, 29, 2016



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**³.



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

² https://euiipo.europa.eu/tunnel-web/secure/webdav/guest/document_library/observatory/resources/research-and-studies/ip_infringement/study9/Press_release-pharmaceutical_sector_en.pdf

³ <https://anticorruption-integrity.oecd.org/reports/illegal-trade-converging-criminal-networks-aci.html>

Pharmaceutical crime at a glance

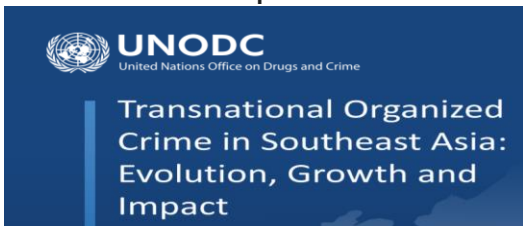
Impact on the United Nations Sustainable Development Goals



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 yr**¹.

Fake drugs: How bad is Africa's counterfeit medicine problem? **BBC NEWS**



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.

BENIN DESTROYS 118 TONS OF COUNTERFEIT PHARMACEUTICALS



Crews prepare chemicals
USAID

Thursday, January 25, 2018



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



¹https://www.unodc.org/documents/southeastasiaandpacific/Publications/2019/SEA_TOCTA_2019_web.pdf; <https://www.bbc.com/news/world-africa-51122898>

²<https://www.usaid.gov/benin/news/benin-destroys-118-tons-counterfeit-pharmaceuticals>

³<https://www.europol.europa.eu/newsroom/news/keeping-sport-safe-and-fair-38-million-doping-substances-and-fake-medicines-seized-worldwide>; <https://www.securindustry.com/pharmaceuticals/study-backs-organised-crime-links-to-counterfeit-medicines-/s40/a2243/#.XirLPIK82w>

⁴https://unctad.org/meetings/en/Contribution/DITC2019_TRACT_ILlicitTradeandSDGs_fullreport_en.pdf

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: Opioids 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.

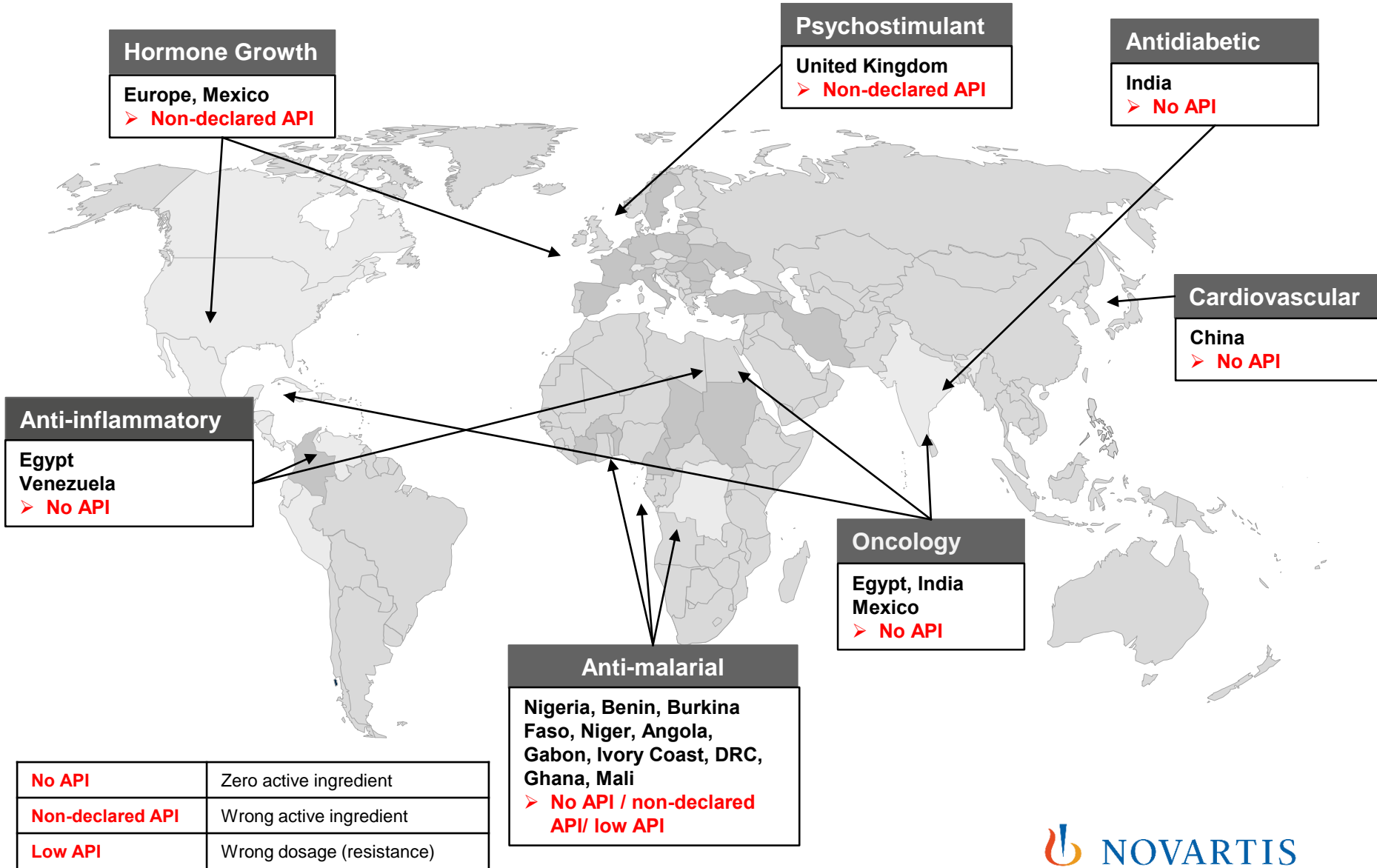


➤ Breached LSC

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



Patient Safety

Measuring the patient safety impact



≥90%

**Incidents reaching Level 3 ▲
Highest risk – life threatening
causing serious harm and/or
leading to death**

Harmful ingredients found during tests on falsified Novartis medicines

<p>HEAVY METALS</p>	<p>POISONS</p>	<p>CHEMICALS</p>	<p>NON DECLARED APIs</p>	<p>NON DECLARED EXCIPIENTS</p>
<ul style="list-style-type: none"> Mercury Aluminium Uranium Arsenic Lead Chrome 	<ul style="list-style-type: none"> Rat poison Benzopyrenes Boric acid Antifreeze BCPs 	<ul style="list-style-type: none"> Road paint Wall paint Brick dust Floor wax Sheet rock Paint thinner 	<ul style="list-style-type: none"> Aminotadalafil Homosildenafil Sildenafil Sibutramine Haloperidol Ciprofloxacin 	<ul style="list-style-type: none"> Dextrose Dextrin Lactose Starch Salt Saline

≈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



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 Report 2019

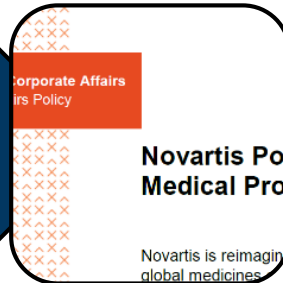
NOVARTIS

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



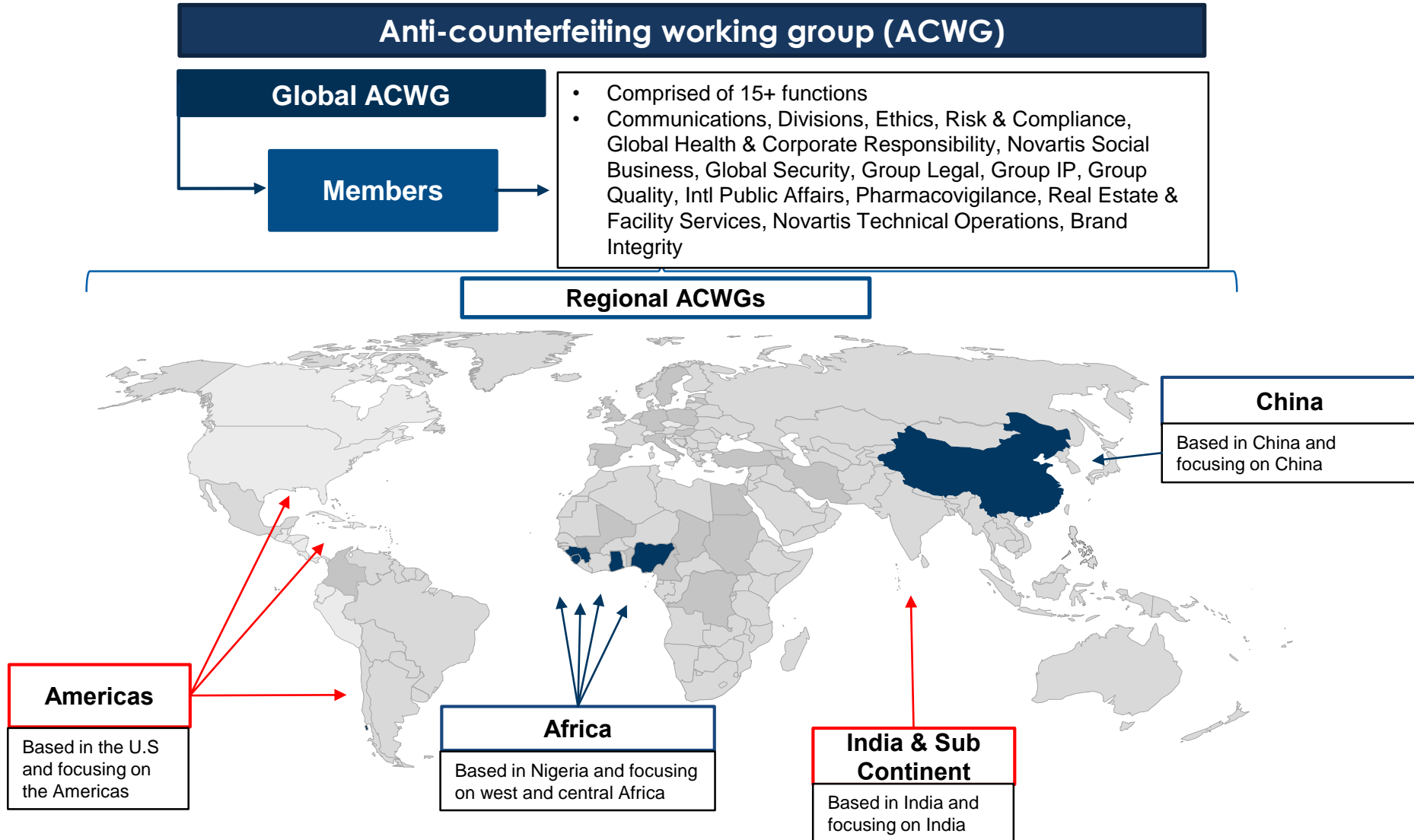
Trust & Reputation Committee

EXECUTIVE COMMITTEE

Briefed the company's ECN Trust & Reputation committee on the risks of counterfeiting

Governance & Reporting

Anti-counterfeiting working groups accelerating delivery



To be launched 2020 Ongoing

Intelligence

Continuous market monitoring of Novartis products

ONLINE

- Monthly online monitoring of top 25 Novartis Pharmaceutical, Oncology and Sandoz products on:
 - ✓ Rogue online pharmacies (ROLPs)
 - ✓ Marketplaces
 - ✓ Social media platforms
- PSI Disruption program: working jointly on disrupting rogue online pharmacies (incl. social media and commercial platforms)



OFFLINE

- Continuous monitoring of suspected counterfeit/falsified products in key markets
- Example of country market surveys conducted in 2019 to detect falsified medicines



Enforcement

Protecting Novartis patients and reputation worldwide

SOCIAL SECURITY FRAUD SCHEME

Colombia, 4 cities

13 arrests
Media coverage
Mix of falsified medicines
Ongoing prosecution

ORGANIZED CRIMINAL GROUP

Italy, multiple cities

Hospital theft
34 raids & 14 arrests
834 units seized
Ongoing prosecution

MARKET SURVEY ANTI-MALARIAL

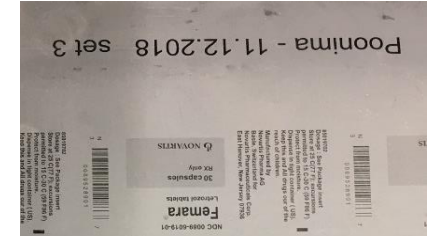
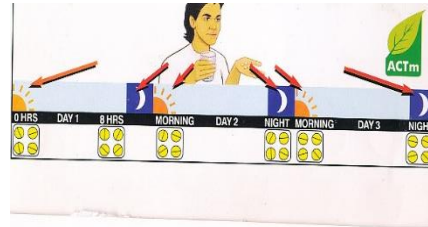
Cameroon, 3 cities

Proactive market survey
58 samples, 17 falsified
Escalated to HA & WHO
No API

ILLEGAL MANUFACTURING

India, Mumbai

Raid on a printing shop
Over 27,449 labels seized
9 printing plaques seized
No API



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



3

SPECTROMETRIC
TOOLKITS



3

INTERNAL
LABS



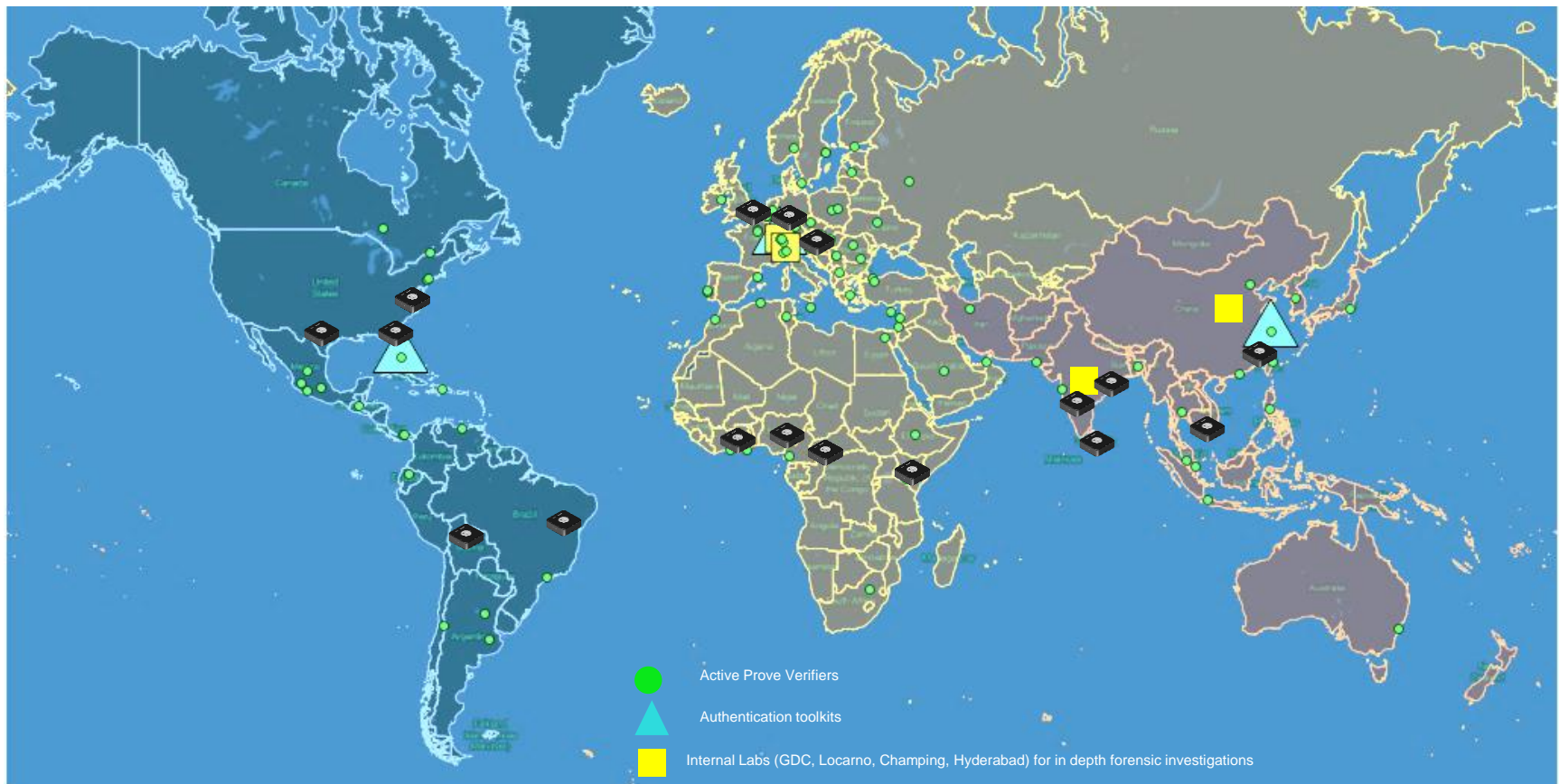
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PROVE
VERIFIERS



50

AUTHENTIFIED BY
NOVARTIS DEVICES
DEPLOYED*



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**)



OECD Task Force on Countering Illicit Trade

« The **OECD** High Level Risk Forum approved the creation of the Task Force on Countering Illicit Trade as a sub-body to advance the policy agenda for enhancing national resilience and responsiveness to illicit trade and all forms of trafficking with linkages to transnational organised crime. »

OECD Public Governance Directorate
High Level Risk Forum