Novartis Public Affairs

Novartis Position on Falsified Medical Products

The World Health Organization (WHO) defines 'falsified' medical products as those that deliberately and fraudulently misrepresent their identity, composition or source. Four specific types of falsification of medical products can be distinguished: counterfeiting, tampering, theft and illegal diversion. The Pharmaceutical Security Institute reported a 10% increase in pharmaceutical crime incidents worldwide in 2022 – the highest number of incidents recorded in a single year.

Falsified medical products may contain harmful chemicals, no active ingredient, or undeclared active ingredients and excipients or the wrong dosage of the correct active ingredient. They impact all geographies and all therapeutic areas.

For patients who are usually unable to distinguish between authentic and falsified medical products, the health risks are enormous, as a falsified medicine may not only cause an obvious adverse reaction. It will often fail to properly treat the disease or condition for which it was intended and can lead to therapeutic failure or even death. Between 2017 and 2023, over 89% of confirmed falsified medical products forensically tested by Novartis were classified as Level III of safety impact[2] on patients, the highest.

In addition to threatening patients' safety, falsified medical products represent a serious and growing problem for public health (e.g. anti-microbial resistance), healthcare systems (e.g. access, social security fraud and overall trust in the system), governments (e.g. tax) and healthcare companies (e.g. patients' trust and intellectual property).

With the increasing online sales of medical products[3] comes increased patient exposure to falsified medical products through unregulated websites, social media platforms and smartphone applications.[4] A 2020 study by the Pennsylvania State University found that illicit online pharmacies, which provide access to prescription drugs, controlled substances, and substandard or counterfeit drugs, represent between 67% and 75% of web-based drug merchants.[5]

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[1] Incident Trends PSI; psi-inc.org
[2] Novartis methodology co-developed by Global Security and Pharmacovigilance. The 3 levels of safety are: I. May not pose a significant hazard to health but induce recall with financial consequences, II. Potentially cause illness or mistreatment, and III. Potentially life-threatening or could cause serious risk to health
[3] Alliance for Safe Online Pharmacies (ASOP Global) / Abacus Data, 2020 National Survey on American Perceptions of Online Pharmacies (Oct. 2020),
[4] At any given time, there are 35,000 active online pharmacies operating worldwide, 96% of which are operating illegally in violation of state and/or federal law and relevant pharmacy practice standards; FDA, Internet Pharmacy Warning Letters (Mar. 2021)
[5] Managing Illicit Online Pharmacies: Web Analytics and Predictive Models Study; Journal of Medical Internet Research (Aug. 2020)

Novartis supports the World Health Organization's position that fighting falsified medical products should be a priority focus area to tackle the global health challenge of expanding access to medicines.

Novartis Position

Key messages

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.

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.

Having a tangible and long-lasting impact in combatting falsified medical products requires a multi-pronged and coordinated approach with public and private partners to:

- Digitalize, localize, standardize, and ultimately accelerate the detection of falsified medicines.
- Harmonize regulatory and legislative best practices including systematic reporting of confirmed incidents within a defined period, especially in countries most afflicted by falsified medical products.
- Leverage the Medicrime Convention and the UNODC Guide to Good Legislative Practices, both aiming to combat pharmaceutical crime and to safeguard public health.

A general concern is the fragmentation of initiatives across many key stakeholders particularly in the fields of awareness and capacity building which eventually dilute the intended impact. Novartis is calling for a much more coordinated approach to leverage the full potential and impact of our efforts on combating falsified medical products.

Novartis commitment to combat falsified medical products

The Novartis program on Combating Falsified Medicines aims at protecting patients' safety and patients' trust as well as expanding access to quality medicines worldwide. The main objectives of the program are to advocate for the use of sophisticated technologies to achieve faster and more standardized detection of falsified medicines, and to support stronger protection and controls of the legitimate supply chain operations. It is strongly rooted in Novartis corporate governance and reporting.

We commit to contribute to the global fight against falsified medicinal products through four operational pillars, (1) Intelligence, (2) Prevention, (3) Enforcement, and (4) Stakeholder Engagement:

1. *Intelligence*: Empower countries with field-based, mobile, fast and reliable digital solutions to accelerate local detection. Novartis has several ongoing projects, one of which is a public-private partnership, leveraging digital technologies focusing on packaging verification and product authentication at a local level.
2. *Prevention:* Timely report all confirmed incidents of falsified medicines to local health authorities, as per local laws and regulations, and to the WHO within 7 working days.

Cooperate with major internet service providers, portal sites and search engines for earlier identification and tracking of unauthorized suppliers of active pharmaceutical ingredients through business-to-business websites.

3. *Enforcement:* Promote international frameworks and guidelines as best practice standards, such as the Medicrime Convention[6] and the UNODC Guide to Good Legislative Practices on Combating Falsified Medical Products-Related Crime[7] of 2019.

   Actively collaborate with supra-national organizations, such as the OECD and relevant bodies of the United Nations such as the WHO, UNODC and UNCTAD on the strengthening of regulatory frameworks to prevent falsified products entering the supply chain, to have effective detection mechanisms in place and to enable a timely and proportionate response, including seizing, testing and if needed immediately recall from the market to protect patient safety.

4. *Stakeholder Engagement:* Capacity building activities with law enforcement and health authorities, intelligence sharing, and authentication support. Support inter-governmental organization such as Interpol, Europol, Afripol and the World Customs Organization during their transnational enforcement operations. Engage in public-private partnerships with key public administrations, academia and industry to raise awareness.

For successful operation in these four operational pillars, Novartis believes that a multi-pronged approach and public-private partnerships are paramount. Collaboration between different stakeholders will help to achieve tangible impact and pursue a long-term sustainable strategy in the fight against this global threat to public health.

Novartis governance structure and program

Governance - Empowered by the Novartis Environmental, Social and Governance (ESG) Committee, the cross-functional Anti-Falsified Medicines Working Group, established since 2017, is responsible for implementing and operationalizing the Novartis strategy to combat falsified medical products while ensuring a coordinated, systematic, efficient and effective approach.

Reporting – We report our activities in the Novartis Integrated Annual Report, the Risk Report, and the Human Right Statement[8] and they are part of the internal Environment Social Governance (ESG) Roadmap.

Our efforts, notably on timely reporting to the WHO, have also been recognized in the Access to Medicines Index.

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[6] https://www.coe.int/en/web/medicrime/the-medicrime-convention
[7] https://www.unodc.org/documents/treaties/publications/19-00741_Guide_Falsified_Medical_Products_ebook.pdf
[8] Novartis reporting hub: https://www.reporting.novartis.com/2021/