

Novartis Position on Falsified and Counterfeit Medical Products

Novartis is reimagining medicine to improve and extend people's lives. As a leading global medicines company, we use innovative science and digital technologies to create transformative treatments in areas of great medical need. Falsified and counterfeit medical products¹ represent a serious and growing problem for patients, public health and other authorities and pharmaceutical manufacturers alike. For patients who are generally unable to distinguish between authentic, falsified and counterfeit products, the health risks are enormous.

Novartis Position

We believe falsification of medical products poses a significant threat to public health, and that solving the issue requires sustained commitment not only from national governments and international health organizations, but also from the pharmaceutical industry and other healthcare stakeholders, such as pharmaceutical distributors.

Such integrated multi-stakeholder approach should:

- Secure the supply chain for medical products using technologies that are proven cost-effective, are harmonized across countries and regions, and are coupled with respective enforcement measures to ensure implementation of the safeguards by stakeholders, especially in middle and low-income countries.
- Seek adoption and enforcement of strong legislative frameworks that criminalize falsification and respond with adequate penalties.
- Strengthen 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).
- Provide regulatory and enforcement authorities with adequate technical, financial, and human resources to enable effective actions against counterfeit and falsified products and the responsible perpetrators.
- Prioritize data collection and policy research through a recognized organization (such as the Pharmaceutical Security Institute).
- Raise awareness and educate patients to help avoid this threat and safeguard their own health.

¹ Novartis endorses the definition of falsified medical products adopted by the WHO, as *medical products that deliberately/fraudulently misrepresent their identity, composition or source*. Novartis supports efforts to harmonize definitions of falsified medicines as a mechanism to facilitate coordination amongst different countries and international organizations. Reference to counterfeiting will continue being used in the context of products *deliberately and fraudulently mislabeled with respect to identity, source or history, with Trademark infringement implications*.

Novartis is committed to working with all stakeholders to pursue a long-term, sustainable strategy to fight this global threat to public health, and is actively participating in cooperative efforts with many industry and public health groups.

With regards to Novartis' portfolio, it is paramount that we can assure patients that products that bear our name are, in fact, our products, backed by superior, unwavering standards of quality, safety, and efficacy. Consistent with our longstanding commitment to the health and safety of patients who use our products and public health in general, we take a diverse and multi-pronged approach:

- We continuously monitor and improve the security of our distribution chain, as well as the security of the packaging of our products.
- We investigate all reported cases of falsified and counterfeited Novartis products, regardless of where they are made available – via internet or on local markets.
- We maintain a global intelligence effort and investigate illegal supply chains to identify the manufacturers, distributors, importers, and exporters of falsified and counterfeit medical products.
- We report confirmed cases to local law enforcement and health authorities so that falsified and counterfeit products are seized and destroyed and the individuals operating these criminal networks are brought to justice.
- We report all incidents of confirmed counterfeit and falsified medicines to WHO within the prescribed timeframe, in alignment with our escalation procedure.
- We actively contribute to and are compliant with the WHO guideline on authentication of “suspected” falsified medicines.

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