

Position on Counterfeit Healthcare Products

Background

It is estimated that international trade in counterfeit and pirated products exceeds \$500 billion or 3% of world trade.¹ In some countries, counterfeits are believed to encompass up to 30% of the market.² Unfortunately, healthcare products are not immune from bad actors.

Counterfeit healthcare products are designed, dressed, branded, and/or packaged in a manner intended to be indistinguishable from that of the genuine original and not manufactured and/or distributed with the authorization of the legal brand owner. These counterfeit products pose serious patient and consumer safety risks and are a global health issue known to health organizations worldwide.

More importantly, counterfeit and substandard drugs are believed to be responsible for over 1 million deaths each year, including hundreds of thousands of children.³ Counterfeits cover the spectrum of medicines, both prescription and over-the-counter (OTC), as well as medical technologies, surgical instruments and a range of consumer products. In many cases, counterfeit or fake products are so sophisticated that they are virtually indistinguishable to patients, consumers and healthcare professionals. The COVID-19 pandemic altered consumer purchasing and significantly increased online shopping. New opportunities have arisen for criminals to capitalize on supply chain shortages, resulting in the availability of low-priced counterfeit medicines and consumer health products in many countries, especially online.

Relevance

For a large, reputable pharmaceutical, medical technologies and consumer healthcare company such as Johnson & Johnson, trade in counterfeit products is enormously concerning. Counterfeit healthcare products place people—the very people we aim to help—at risk of adverse events, serious health problems and potentially even death. Fake medicines, medical devices and consumer healthcare products undermine confidence in product quality, safety and reliability, which, at Johnson & Johnson, are at the center of everything we do. Additionally, counterfeit healthcare products destroy the economy of healthcare, diverting income and tax revenues from those who work to improve healthcare while adding a cost burden of monitoring and control, and impacting health outcomes. Counterfeiting and illicit trade also fund a variety of criminal activities including organized crime, child labor and even terrorist activity.⁴ At Johnson & Johnson, we aim to protect those who use our products; we maintain our product integrity and believe the trade in counterfeit healthcare products should be eliminated for the benefit of all.

¹ <https://www.worldtrademarkreview.com/global-guide/anti-counterfeiting-and-online-brand-enforcement/2021/article/counterfeiting-and-piracy-in-2021-the-global-impact>

² <https://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products>

³ <https://www.ajtmh.org/view/journals/tpmd/100/5/article-p1058.xml>

⁴ <https://www.iacc.org/resources/about/what-is-counterfeiting>

Guiding Principles

All our values and principles guide us to actively engage in improving health and to operate with integrity. This means we must be proactive in addressing issues that harm people's health or undermine the credibility of healthcare systems or our business. Our guiding principles include the following:

- At Johnson & Johnson, [Our Credo](#) states: "We believe our first responsibility is to the patients, doctors and nurses, to mothers and fathers and all others who use our products and services."
- Our [Code of Business Conduct](#) states that "we aspire to bring the highest standards and level of integrity" to all our business activities.
- Our commitment to product quality, safety and reliability is always a priority for Johnson & Johnson, and this includes active measures to combat counterfeiting and to protect our brands. See our [Position on Quality and Compliance](#).

Our Position

At Johnson & Johnson, we believe good health is the foundation of vibrant lives, thriving communities and forward progress. That's why for more than 135 years we have aimed to keep people well at every age and every stage of life. Today, as the largest, most diversified healthcare products company, Johnson & Johnson is committed to using its reach and size for good. In today's global economy, where patients and consumers may potentially be exposed to counterfeit products in stores, online, or even in healthcare settings, we must take tangible steps to help ensure that they receive only genuine products of the Johnson & Johnson Family of Companies.

Johnson & Johnson is committed to identifying and mitigating the risks of counterfeit healthcare products in several ways. These include:

- **Implementing product and packaging security measures** that help distinguish the authentic product from a counterfeit, and aid in minimizing the potential for tampering.
- **Improving controls in our supply chain**—from sourcing of ingredients and manufacturing through distribution—to help minimize the risk of counterfeit products entering the system.
- **Monitoring markets and investigating counterfeiting** activities in full collaboration with regulatory and law enforcement authorities to locate and remove counterfeits from the market, seize and destroy the manufacturing equipment, and prosecute or take civil action against the perpetrators.
- **Working with governments and regulators** to identify opportunities to strengthen laws and enforcement efforts to ensure the integrity of distribution channels.
- **Training our employees** on suspicious product reporting. We also extend brand protection training to law enforcement agencies, including the U.S. Customs and Border Protection, to help ensure a safe and secure supply chain.
- **Helping raise awareness of the dangers of counterfeit healthcare products** and educating people in the role they can play in advancing the elimination of illicit trade.
- **Leveraging innovative digital technologies** to enhance supply chain integrity, enable early detection of the presence of illicit trade, and more effectively expose the sources, networks and patterns of illicit trade throughout our global markets and channels. Our illicit trade analytics platform

enables us to generate actionable intelligence and insights from numerous disparate data sources, both internal and external.

- **Engaging with external trade groups, alliances, organizations and agencies**—either in leadership positions or as a member of industry working groups—to help collaboratively combat trade in counterfeit healthcare products. In any given year, our engagement and collaboration span multiple countries and groups, and activities differ depending on issues that arise. Some key groups we engage with on a regular basis include:
 - Alliance for Safe Online Pharmacies (ASOP)
 - Alibaba Anti-Counterfeiting Alliance
 - Center for Anti-Counterfeiting and Product Protection at Michigan State University (A-CAPP MSU)
 - International Anti-Counterfeiting Coalition (IACC)
 - International Trademark Association (INTA)
 - Pharmaceutical Security Institute (PSI)
 - Quality Brands Protection Committee of China (QBPC)
 - Rx-360 – The International Pharmaceutical Supply Chain Consortium

We are also members of—and/or hold board positions on—several additional region-specific industry groups.

Our robust process for alerting health agencies, customers and business partners of confirmed instances of counterfeiting, illegal product diversion or product tampering activities is governed by standard operating procedures and regulatory requirements. For example, one of our Enterprise supply chain programs, Serialization and Traceability, helps to secure the healthcare supply chain and provides the ability to track and trace most pharmaceutical products from manufacturing to point of dispense. Through our work on serialization and traceability, we're creating unique identifying information at all levels of production. Each saleable item, case and pallet has a unique identifier, and the unique numbers are uploaded onto a database, providing actionable product intelligence.

As an output to these comprehensive strategies and actions, we strive to ensure that all who use our products have unequivocal confidence in their quality, safety and authenticity. We continue to aggressively manage risks related to illicit trade to protect patients and consumers from potential harm.

Application

This Position is relevant for the Johnson & Johnson Family of Companies, as detailed in our [governance materials](#). We report relevant progress in anti-counterfeiting in our annual [Health for Humanity Report](#).

Last Updated: March 2023