Position on Counterfeit Healthcare Products

Background
Counterfeit medicines, including substandard, falsified, untested, unregistered and unlicensed drugs, represent a public risk well known to health organizations worldwide. Trade in counterfeits has been estimated at US$75 – 200 billion annually, reaching up to 30% of the market in certain countries. More importantly, counterfeits are associated with hundreds of thousands of deaths per year; a recent report quotes 250,000 child deaths per year from fake medicines. Counterfeits cover the spectrum of medicines, both prescription and OTC, as well as different forms of medical devices and surgical instruments and a range of consumer products. In many cases, counterfeit or fake, products are indistinguishable to patients, consumers and healthcare professionals, so detection by specialists is needed. Counterfeit medicines and consumer health products are readily available today in many countries, especially online, and are typically offered at attractive price points, luring buyers with what appears to be “a good deal.”

Relevance
For a large, reputable pharmaceutical, medical devices 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 serious health problems and potentially even death. Fake medicines undermine confidence in product quality, safety and reliability, which, at Johnson & Johnson, is 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. For Johnson & Johnson, as we aim to protect those who use our products and maintain our product integrity, we believe the trade in counterfeit healthcare products must be stemmed for the benefit of all.

Guiding Principles
- Johnson & Johnson’s 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 brand. See our Position on Quality and Compliance.

1 https://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products
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 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 130 years, we have aimed to keep people well at every age and every stage of life. Today, as the world’s largest and most broadly based healthcare company, we are committed to using our 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.

- **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.

Our advanced capabilities in data analytics include leveraging innovative digital technologies to enhance supply chain integrity, safeguard our markets (through 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 robust process for alerting 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, we maintain traceability within the medical devices distribution chain through an enterprise-wide Unique Device Identification (UDI) program to comply with global regulations, and satisfy customer requests related to data submissions, barcodes, and direct marking. Our current efforts include achieving compliance for published UDI regulations in several countries.

- **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.

- **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. Key groups we engage with on a regular basis include:
o IACC (International Anti-Counterfeiting Coalition)
o A-CAPP MSU (Center for Anti-Counterfeiting and Product Protection at Michigan State University)
o Rx360 – An International Pharmaceutical Supply Chain Consortium
o PSI (Pharmaceutical Security Institute)
o ASOP (Alliance for Safe Online Pharmacies)
o QBPC (Quality Brands Protection Committee of China Association of Enterprises with Foreign Investment)
o EAASM (European Alliance for Access to Safe Medicines)
o Gulf Brand Protection Group

- **Training our employees in our Safe and Secure Supply Chain Best Practices** that provide guidance on employing brand protection controls and safeguards in our supply chain. We also extend brand protection training to our suppliers, distributors and customers.

- **Helping raise awareness of the dangers of counterfeit healthcare products** and educating people in the role they can play in assisting the elimination of illicit trade.

**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: February 2021*