

Position on Patient Safety

Background

Our work across Pharmaceuticals, Medical Devices and Consumer Health plays an essential role in bringing lifesaving and health-improving medical solutions that address the health needs of populations around the world. In all development and commercialization of medicines, healthcare products or medical devices, manufacturers must demonstrate that the benefits of each product outweigh the risk to patients, consumers or users, starting at the product development stage and continuing once the product is available to the public.

Relevance

As the world's largest and most broadly based healthcare company, reaching patients and consumers each day with our medicines, consumer products and medical devices, Johnson & Johnson makes patient safety an essential part of its promise to those we serve. Uncompromising insistence on patient safety at every stage of product development, manufacturing, supply chain and commercialization is critical to ensure our products are as effective and safe as possible.

Guiding Principles

As stated in [Our Credo](#): "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. In meeting their needs everything we do must be of high quality." This serves as a constant guide to our decision-making and reinforces that patient safety should always be a priority.

We adhere to a set of Medical Safety Guiding Principles that we developed in 2013 and that remain wholly relevant today:



Our Position

At Johnson & Johnson, we recognize our fundamental responsibility is to provide patients, consumers and healthcare providers with products that are as effective and safe as possible. We take an evidence- and science-based, ethics- and values-driven approach to medical safety, putting patient and consumer wellbeing first and foremost in our decision-making and actions, with an emphasis on transparency.

We maintain a robust organizational structure for patient safety. The Office of the Chief Medical Officer (OCMO) is our independent, objective and accountable Medical Safety Organization that drives objective, independent, science-based decision-making across the total product lifecycle. It comprises a global internal team of medical and scientific professionals, including safety experts, from all three segments of Johnson & Johnson: Consumer Health, Medical Devices and Pharmaceutical. Functionally independent from commercial and development portfolio interests, Johnson & Johnson's OCMO focuses on the safety of our products through people-driven processes, initiatives and policies that are reinforced by a single medical safety standard to which all our products are held.

The responsibilities of OCMO include:

- Medical safety
- Epidemiology and health informatics
- Bioethics and science policy
- Cross-sector clinical, regulatory and planning operations transformation
- Preclinical science and safety
- Objective and expert pipeline and product review

Our Position on Patient Safety is based on multiple policies, standards, processes and internal and external collaboration. Key elements include:

- **Rigorous quality testing:** At the manufacturing phase before our products leave our manufacturing facilities, we conduct rigorous quality testing to ensure that products are manufactured according to specifications. See our [Position on Quality and Compliance](#) and [Johnson & Johnson Quality Management Framework](#).
- **Proactive safety risk management:** We develop risk management plans that are regularly reviewed and updated when additional safety information becomes available with more people using our products over a longer period of time. Where appropriate, we liaise closely with regulatory authorities to update product labels for patients and healthcare practitioners.
- **Assuring the safety of patients participating in clinical trials:** We maintain policies and standards that govern the ethical treatment of trial participants and the protection of their health and safety. See our [Position on the Conduct of Clinical Trials](#) and our [Ethical Code for the Conduct of Research and Development](#).
- **Partnering for patient safety:** Partnerships are an integral element of our approach to medical safety surveillance. We work closely with regulatory authorities, healthcare professionals, patient advocacy groups and leading research institutions to improve safety research, science and education.
- **Supporting healthcare providers:** We recognize we have an important role to play in ensuring healthcare providers using our products have the knowledge to use them safely, and we provide information, education and practical tools to help physicians and caregivers prescribe and administer products for maximum safety to patients.

- **Engaging patients:** Patients are at the center of our safety surveillance activities. As increasingly active owners of their own healthcare journeys, patients and their caregivers are well positioned to provide unique insights into our product research and development (R&D) processes. We engage patients and seek to integrate their input throughout all stages of a product's lifecycle—from development, including clinical trial design, to commercialization.
- **Combatting counterfeiting:** In addition to proactively managing the safety and safety risks related to our own production and marketing of our products, we carefully monitor and work to eliminate the illicit trade in counterfeit products in order to protect consumers from the considerable risks associated with such products. See our [Position on Counterfeit Healthcare Products](#).

Application

This position is relevant for all pharmaceutical and medical R&D activities of the Johnson & Johnson Family of Companies, as detailed in our [governance materials](#).

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