

Position on Patient Safety

Background

Our work across Pharmaceuticals, MedTech 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 technologies, 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

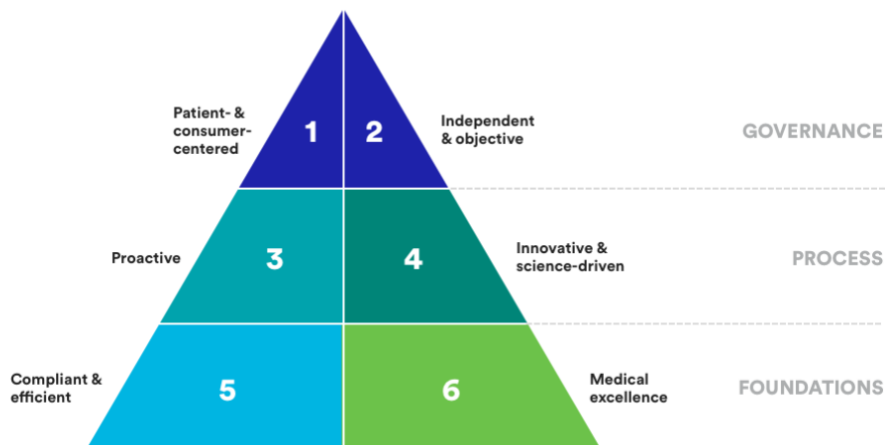
As the world’s largest and most broadly based healthcare company—reaching patients and consumers each day with our medicines, consumer products and medical technologies—Johnson & Johnson makes patient safety an essential part of its promise to those we serve. Uncompromising insistence on patient safety 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:

Medical Safety: Our Guiding Principles



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 well-being 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, MedTech 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
- Pharmacovigilance
- 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

About our Medical Safety Standard:

- Covers all products that are marketed or bear a company name, trade name or trademark symbol belonging to any of the Johnson & Johnson Family of Companies, irrespective of whether the product is produced solely under our control or is partially or completely produced by another entity (except in certain cases defined in the Standard).
- Encompasses the safety of patients, consumers and users of products. Medical safety includes any assessment or decision based on the identified or potential risk of an adverse health effect or medical device malfunction on patients/consumers/users in the context of the benefit-risk profile of the Johnson & Johnson product.
- Is supported by defined medical safety governance at the corporate, regional and local levels. This includes Safety Management Teams established in each sector or operating company that play a role in assessing safety signals and appropriate actions for escalation if required.

Our Position on Patient Safety is based on our Medical Safety Standard and references additional 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 our [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.

- **Maintaining robust and comprehensive pharmacovigilance processes and practices:** As part of OCMO's overall responsibility for medical safety, we maintain a comprehensive set of protocols and standards governing pharmacovigilance (which is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse events or any other drug-related problems). Pharmacovigilance is led globally through OCMO and implemented locally, market by market (with the support of Safety Management Teams), under the oversight of trained professionals and supported by advanced digital reporting tools and tracking mechanisms. All relevant staff have a duty to report safety signals/adverse events both within the Company and to relevant drug authorities as required by law. We aim to learn all we can from adverse events in order to help improve the safe use of our products for patients and consumers everywhere.
- **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](#), our [Ethical Code for the Conduct of Research and Development](#) and our [Ethical Framework for Decision-Making During the COVID-19 Pandemic](#).
- **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, medical devices and consumer R&D activities of the Johnson & Johnson Family of Companies, as detailed in our [governance materials](#). We provide updates relating to patient and consumer safety in our annual [Health for Humanity Report](#).

Last Updated: November 2021