Position on Pharmaceuticals in the Environment

Our position

As stated in Our Credo: “We are responsible to the communities in which we live and work and to the world community as well… We must maintain in good order the property we are privileged to use, protecting the environment and natural resources.” These values guide our efforts to proactively assess and mitigate potential risks associated with our active pharmaceutical ingredients (APIs) that may enter aquatic and terrestrial ecosystems.

Our approach

Since 2006, we have conducted environmental risk assessments (ERAs) of all small molecule APIs used in our commercially marketed products. ERAs range from exposure assessments and screening for characteristics of persistence, bioaccumulation and toxicity (PBT) for low-volume products to more extensive risk assessments involving environmental toxicology tests that are used to determine predicted no-effect concentrations (PNECs). We have also completed ERAs for the majority of our legacy APIs that received marketing authorization before ERA test methodologies were standardized and adopted by regulatory authorities.

We apply good management practices, such as closed material transfers, dry equipment cleaning, and advanced dust capture, at our manufacturing sites that handle APIs to minimize releases to the environment. We monitor wastewater for potential aquatic toxicity (e.g., mass balance, analytical testing and whole-effluent testing). All our facilities have wastewater treatment installations or use approved third-party operations for treatment. For plants that handle active pharmaceutical ingredients (APIs), treatment may include advanced technologies to enhance API removal.

We expect suppliers to meet the Johnson & Johnson Responsibility Standards for Suppliers and to manage environmental impacts, including maintaining compliant wastewater programs that mitigate risk. We verify supplier performance through EcoVadis, participation in the Pharmaceutical Supply Chain Initiative, and risk-based remote and on-site assessments.

We help to advance the science on pharmaceuticals in the environment (PIE) to better assess and reduce potential risks. We collaborate with peers, regulators and academics to develop advanced screening tools for aquatic toxicity of APIs (e.g., as a member of the Prioritization and Risk Evaluation of Medicines in the Environment (PREMIER) project). With our peers, we supported development of the Eco-Pharmaco-Stewardship framework, including extended environmental risk assessment approaches, and contributed to the creation of the Antibiotic Manufacturing Standard. Finally, we support research to develop new targeted wastewater treatment technologies (e.g., as a founding member of the Water and Environmental Technology (WET) Center[1]).

We promote responsible medication disposal and discourage flushing through outreach such as the MyOldMeds initiative (U.S.) and MEDSDISPOSAL (EU). We also helped found the Pharmaceutical Product Stewardship Working Group, an extended producer responsibility organization supporting collection and safe disposal of unused/expired medicines and used sharps.

Application

This Position is relevant for all Johnson & Johnson businesses, as detailed in governance materials. We provide updates, where relevant, relating to responsible chemical management in our annual Health for Humanity Report. Johnson & Johnson's Policies and Positions on these and other issues are available in full here.

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[1] WET Center is a National Science Foundation Industry/University Cooperative Research Center led by Temple University with partner sites at the University of Arizona and Arizona State University. With over 30 industrial and government members, the WET Center conducts research and development that leads to the development of new water and wastewater treatment technologies and insights.