# Position on Pharmaceuticals in the Environment

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. We do this by:

**Conducting environmental risk assessments (ERAs) of our APIs to understand their impacts in the environment** - Since 2006, we have conducted ERAs of all small molecule APIs used in our products prior to market approval. ERAs can range from exposure assessments and screening for characteristics of persistence, bioaccumulation and toxicity (PBT) for low-volume products to more extensive risk assessments that determine predicted no-effect concentrations (PNECs) based on environmental toxicology tests. 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.

**Controlling the concentrations of APIs that may enter the environment from our manufacturing plants** - At our manufacturing plants handling APIs, we employ good management practices to limit the amount of APIs that may enter the environment. This includes closed transfers of process materials, dry cleaning of manufacturing processing equipment, collection of any spilled dry powder materials and advanced dust collection techniques. We monitor our wastewater for potential toxicity to aquatic species using a variety of methods (e.g., mass balance calculations, analytical testing and whole effluent testing). We ensure secondary wastewater treatment at a minimum for our manufacturing plants, and treatment may also include advanced technologies that target removal of APIs from wastewater.

**Collaborating with suppliers to help mitigate concentrations of APIs in the environment** - As outlined in our Responsibility Standards for Suppliers, suppliers to Johnson & Johnson are expected to operate in a sustainable and environmentally responsible manner, including continually working to reduce the environmental impacts of their operations and implementing programs to manage wastewater that ensure compliance and mitigate impacts to the environment. We verify supplier environmental

performance through several channels, including: supplier scans through EcoVadis, a sustainability ratings firm that evaluates companies' environmental and social responsibility; active participation in the Pharmaceutical Supply Chain Initiative, which sets common standards for responsible supply chain practices; and remote and on-site assessments conducted by Johnson & Johnson employees on a risk-based frequency.

**Advancing the science related to PIE** - We are committed to advancing the science related to PIE to help assess and address potential risks related to PIE. Our commitment is demonstrated by:

- Partnering with regulators, governmental agencies and peers to develop advanced computer-based tools to rapidly assess aquatic toxicity impacts of APIs through the Innovative Medicines Initiative (IMI) iPiE Project and through the successor project, the IMI Prioritization and Risk Evaluation of Medicines in the Environment (PREMIER) project.
- Helping to launch the Water and Environmental Technology (WET) Center[1] as a founding industrial member. Through the WET Center we have supported research to develop targeted wastewater treatment technologies that address both traditional and emerging water contaminants in a sustainable manner.
- Contributing to scientific journal publications and presentations related to PIE, including important peer-reviewed publications such as the "Science-based Targets for Antibiotics", and "A Risk-based Approach to Managing APIs in Manufacturing Effluent", which serves as the basis for the industry's "Responsible Manufacturing Effluent management Technical Guidance Document".

**Educating patients and consumers on how to locate disposal options and instruct them on proper disposal methods to avoid flushing** - We do this through several outreach efforts including the MyOldMeds initiative in the United States and MEDSDISPOSAL in the EU. WWe were also a founding member of the Pharmaceutical Product Stewardship Working Group, which is the largest extended producer responsibility (EPR) organization in the United States dedicated to ensuring the proper collection and disposal of unused and/or expired medicines as well as used sharps.

[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.

**Advocating for good PIE management practices** - Through our membership in the European-based Inter-Association Initiative on Pharmaceuticals in the Environment (IAI PIE Taskforce), we supported development of the Eco-Pharmaco-Stewardship framework to address PIE, which includes an approach to extended environmental risk assessments for pharmaceuticals. Also, we contributed to the development of the Antibiotic Manufacturing Standard.

## Governance

Johnson & Johnson's work to assess and mitigate potential risks associated with Pharmaceuticals in the Environment is overseen by the Company's Chief Sustainability Officer (CSO). At the management-level, the CSO is a standing member of the Enterprise Compliance & Risk Committee (ECRC). The ECRC, chaired by our Chief Technical Operations & Risk Officer, is a centralized Committee that provides governance and oversight of risk management activities, including on environmental-related issues across Johnson & Johnson. The ECRC has representation across sectors and functions and meets regularly to proactively review risk areas, integrate external risks and opportunities and monitor risk mitigation plans and actions. A third-party independent review of our environmental performance is conducted annually as part of our ISO 14001 Certification process.

## Application

This Position is relevant for all Johnson & Johnson businesses, as detailed in governance materials. We provide updates, where relevant, relating to pharmaceuticals in the environment 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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