

Position on Impact of Pharmaceuticals and Personal Care Products in the Environment

Background

Pharmaceuticals and personal care products (PCPE) enter the environment through several different pathways. The vast majority of active pharmaceutical ingredients (APIs) found in aquatic ecosystems are a result of normal patient and consumer use and excretion following the use of medicines that are taken to prevent, cure or alleviate a medical condition.¹ A second pathway is through improper disposal of unused or expired medicines by patients and consumers who flush them down toilets or pour them into drains.² The third pathway is through wastewater discharged from API manufacturing sites.³ A major source of PCPE is from washing off products from the body during cleansing activities.⁴

Relevance

As the world's largest and most broadly based healthcare company, Johnson & Johnson plays an important role in supporting initiatives to address pharmaceuticals in the environment (PIE) and PCPE.

Guiding Principles

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." Our Credo and our aspiration to change the trajectory of health for humanity are at the heart of our commitment to creating a healthier environment to support better human health.

Our Position

We are committed to the proactive risk assessment of our APIs and active personal care ingredients that may enter aquatic and terrestrial ecosystems. We do this by:

¹ *Pharmaceuticals in the Environment*, <https://doi.org/10.1039/9781782622345> (last accessed 5/2021)

² Ibid.

³ Ibid.

⁴ "Environmental Safety Aspects of Personal Care Products," <https://doi.org/10.1897/09-104.1> (last accessed 5/2021)

Identifying the full portfolio of our APIs entering the environment and conducting environmental risk assessments to understand their impacts in the environment

Since 2006, we have conducted environmental risk assessments (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 products⁵ 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.

Advancing the science of conducting ERAs for APIs

While conducting ERAs for a single chemical has become routine, we have been working with leading academics to study how mixtures of chemicals interact in the environment with a goal of understanding whether and how this combination can change the scale and the scope of impacts to aquatic systems. For mixtures, we have focused our research efforts to date on endocrine-disrupting chemicals and non-steroidal anti-inflammatory drugs (NSAIDs) to understand whether they have synergistic or antagonistic effects. We are also currently studying how environmental exposures impact the development of antibiotic resistance in aquatic and soil-based microbes and are working to advance science-based discharge limits specifically for antibiotics that are protective against formation of antibiotic resistance. See our [Position on Antimicrobial Resistance](#) for more information.

Advancing the science of assessing the environmental impacts of personal care products

For our personal care products that are susceptible to entering the environment (e.g., rinse-off and leave-on formulations), there is no regulatory-mandated or widely adopted industry ERA system. Therefore, we have developed our own patented science-based system to assess the potential aquatic impacts of formulations under development. This system, referred to as GLOBAL AQUATIC INGREDIENT ASSESSMENT TOOL (dubbed GAIA), helps ensure that our products meet our product stewardship standards designed to minimize environmental impacts. Using GAIA, ingredients are scored on a 100-point scale using available data on inherent PBT properties. A higher score indicates more favorable environmental safety characteristics. When published data are not available, we use modeled data, and GAIA scores are reduced for uncertainty. More information regarding our GAIA approach can be found on the [Johnson & Johnson Consumer Health website](#). Our GAIA approach to evaluating ingredients has also been published in a peer-reviewed journal.⁶

We are committed to controlling the concentrations of active pharmaceutical ingredients that may enter the environment from our manufacturing plants.

At our manufacturing plants handling active pharmaceutical ingredients, we monitor our wastewater for potential toxicity to aquatic species using a variety of methods (e.g., analytical testing, mass balance calculations and whole effluent testing). We provide secondary wastewater treatment at a minimum for our manufacturing plants, and treatment may also include advanced technologies that target removal of APIs from wastewater.

We are committed to collaborating with suppliers and educating patients and consumers to help mitigate concentrations of active pharmaceutical ingredients in the environment.

As outlined in our [Responsibility Standards for Suppliers](#), suppliers to the Johnson & Johnson Family of Companies 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

⁵ Products that result in a predicted surface water concentration of less than 0.01 ug/L

⁶ <https://www.sciencedirect.com/science/article/pii/S0959652618301628> (last accessed 5/2021)

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

We educate 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. We 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.

We believe in the power of partnerships to accelerate the advancement of science related to PIE and PCPE. We demonstrate this belief by:

Proactively collaborating with other commercial partners

We often partner with our peers in the pharmaceutical and personal care products industries to drive progress on these issues. For example, we are an active partner in the European-based Inter-Association Initiative on Pharmaceuticals in the Environment, which consists of the Association of the European Self-Medication Industry, the European Federation of Pharmaceutical Industries and Associations (EFPIA), and Medicines for Europe. Together this collaborative group created the Eco-Pharmaco-Stewardship framework to address PIE, which includes an approach to extended environmental risk assessments for pharmaceuticals. For more information on this effort, visit the [EFPIA website](#).

We also partnered with our peers to advance the science around microbial resistance to antibiotics in the environment through our collaboration in the Antimicrobial Resistance Industry Alliance (AMRIA). In this collaboration, we contributed to the research, which developed a methodology to determine the PNEC specifically for antibiotics.

Partnering with regulators and governmental agencies

We participated in public-private partnerships that advanced the science around PIE. For example, we contributed to the development of advanced computer-based tools to rapidly assess aquatic toxicity impacts of APIs through the Innovative Medicines Initiative (IMI) iPiE Project. We aim to continue our contribution in this area with the successor project, the IMI PREMIER project, in which we have applied for membership.

Developing new science with leading academics

We partner with academics to advance the science of PIE and PCPE both through Company-directed research and through public-private research consortiums. An example is our involvement in the Water, Energy and Technology (WET) Center, which 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 new technologies to address both traditional and emerging water contaminants and to treat water and wastewater in a sustainable manner. With the WET Center, we have supported research to better understand the environmental impacts of mixtures and the impacts of wastewater treatment on formation of resistance in bacteria. Additionally, we have collaborated to develop highly selective and effective treatment technologies to remove specific APIs from wastewater.

We believe in the value of transparency and are committed to actively sharing our knowledge of PIE and PCPE issues. For example:

- We regularly contribute to scientific journal publications and presentations related to PIE and PCPE, including important peer-reviewed publications such as the “Science-based Targets for Antibiotics”⁷ and “A Risk-based Approach to Managing APIs.”⁸
- To facilitate access to data on the fate and effects of APIs, we have developed a database, curated by Temple University, which includes some physical data as well as the predicted no-effect concentration (PNEC) (acute and chronic) for approximately 100 non-antibiotic APIs. Additionally, we have published PNECs for aquatic life PNEC-Environment (PNEC-ENV) and to prevent selection for resistance Minimum Inhibitory Concentration (PNEC-MIC) for our antibiotics in the [AMRIA PNEC list](#).
- To assist physicians in prescribing drugs with preferable environmental profiles, we publish the PBT profiles of our compounds in the [Swedish Kloka Listan](#) (“Wise Formulary”) website.

Application

This Position is relevant for the Johnson & Johnson Family of Companies, as detailed in our [governance](#) materials. We provide relevant progress updates in our annual [Health for Humanity Report](#).

Last Updated: May 2021

⁷ “Science-based Targets for Antibiotics in Receiving Waters from Pharmaceutical Manufacturing Operations”

⁸ “A risk-based approach to managing active pharmaceutical ingredients in manufacturing effluent,” <https://doi.org/10.1002/etc.3163> (last accessed 5/2021)