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

Background

The pharmaceutical and consumer healthcare industries recognize the concerns raised by stakeholders regarding the presence of pharmaceuticals in the environment (PIE) and personal care products in the environment (PCPE). The major source of pharmaceuticals entering the environment is via patient excretion following use of medicine that is taken to prevent, cure or alleviate a medical condition. A comparatively smaller contribution to PIE stems from emissions resulting from the manufacturing process and from improper disposal of medications. The major source of personal care products entering the environment is via use of products and removal from the body during bathing activities.

Relevance

As the world's largest and most broadly based healthcare company, Johnson & Johnson plays an important role in supporting initiatives to reduce the impact of 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 create a healthier environment to support better human health.

Our Position

As a science-based healthcare company, Johnson & Johnson is committed to advancing society's understanding of how pharmaceuticals and personal care products impact the environment so that we can protect environmental and human health. We take a strategic approach to controlling and reducing the impact of PIE and PCPE, in line with the following strategies:

Understanding our impacts: Since 2006, we have conducted environmental risk assessments (ERAs) of all active pharmaceutical ingredients (APIs) used in our products prior to market approval to determine sensitive aquatic and benthic species, the predicted no-effect concentration, and the predicted environmental concentration to determine whether there is potential for environmental impacts. 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. In these ERAs, we used risk-based prioritization and focused on APIs for which the environmental impact is not already well characterized.

For our personal care products that are susceptible to entering the environment (e.g., rinse off formulations), there is no regulatory-mandated or widely adopted industry ERA system. Therefore, we have developed our own science-based system to assess the potential aquatic impacts of formulations under development. This system, referred to as Global Aquatic Ingredient Assessment (GAIA), helps ensure that our products meet our product stewardship standards designed to minimize environmental impacts.

While conducting ERAs for a single chemical compound has become a routine standard operating procedure, we have also been working with leading academics to study how mixtures of compounds 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 specifically focused on endocrine-disrupting compounds to understand whether they have synergistic or antagonistic effects. We are also currently studying how environmental exposures impact the development of antibiotic resistance in microbes, and are working to establish science-based discharge limits specifically for antibiotics that are protective against formation of antibiotic resistance.

Controlling our impacts: We are committed to reducing or eliminating the small amounts of APIs discharged in the wastewater from our manufacturing sites. We monitor our pharmaceutical manufacturing wastewaters for potential toxicity to aquatic species using a variety of methods (e.g., analytical testing, mass balance calculations, whole effluent testing). Where no specific regulatory limits exist, we establish discharge limits for wastewater based on World Health Organization Guidelines for Drinking-Water Quality Standards. Discharges from our manufacturing plants must receive at least secondary wastewater treatment, and many include advanced treatment technologies that are highly effective at removing APIs from wastewater.

We are also committed to sourcing practices that help ensure that our chemical and API suppliers employ appropriate practices to protect human and environmental health. We verify supplier environmental performance through a number of channels including: on-site audits conducted by Johnson & Johnson environmental professionals; supplier scans through EcoVadis, a technology 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 also work to help control impacts from patients by helping them prevent improper disposal. We do this through several patient-education efforts including the U.S. MyOldMeds initiative, which helps patients locate disposal options and instructs them on proper disposal methods to avoid flushing.

Engaging and partnering with others: The issue of PIE and PCPE is complex and involves many sectors of society. We proactively collaborate with other industrial partners, leading academics, government and non-governmental organizations to ensure that all stakeholders' inputs are known, understood and considered. The pharmaceutical and personal care products industries have created work groups to facilitate collaboration among members on these issues.

An example is the Europe-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. This framework is designed to:

- develop new science and models that will enable focused environmental testing of pharmaceuticals and early identification of pharmaceutical substance properties and the associated environmental risk potential;
- evaluate and control manufacturing facility wastewater discharges, including those in the external supply chain; and
- develop an extended environmental risk assessment process for pharmaceuticals.

For more information on this effort, visit the EFPIA website.

We partner with academics to advance the science of PIE and PCPE both through Company-directed research as well as through public-private research consortiums. An example is our involvement in the 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 will lead to new technologies to address both traditional and emerging water contaminants and enable effective treatment of water and wastewater in a sustainable manner.

Advocating for sound, science-based policy: We actively monitor scientific and policy developments in the areas of PIE and PCPE and engage with policy makers—both through our trade representatives and as an individual company—to share our knowledge and beliefs on these issues.

First and foremost, we believe that science should guide the regulation of PIE and PCPE. Considering the significant, life-altering benefits to humans that come from pharmaceutical products, and considering that pharmaceuticals are the most widely studied compounds known to society and the only category of compounds that are tested in humans prior to marketing, any regulation of pharmaceuticals should be based on a risk-benefit analysis, should not be hazard-based, and should not restrict access to potentially lifesaving medicines.

We believe that pharmaceuticals should not be regulated in the same manner as industrial chemicals and that human health agencies are best positioned to evaluate medicinal products based on a risk-benefit analysis as they have the most in-depth understanding of, and greatest visibility to, human health data.

We recognize that people are concerned that pharmaceuticals can be detected in the environment. However, few members of the public outside the scientific community understand what it means for something to be detected at parts per billion (ppb) or even parts per trillion (ppt)—the levels at which most pharmaceuticals are detected in the environment. As acknowledged by the World Health Organization[1], "concentrations of pharmaceuticals in drinking water are generally more than 1000-fold below the minimum therapeutic dose (MTD), which is the lowest clinically active dosage…which suggests that appreciable risks to health arising from exposure to trace levels of pharmaceuticals in drinking water are extremely unlikely." Presence of a chemical in the environment does not automatically equate to a human or environmental health risk. Through our efforts under the strategic framework described above, we hope to increase stakeholder understanding of risks versus hazards.

Sharing best practices and our knowledge: At Johnson & Johnson, we continue to be transparent about our products and businesses, including in our work with PIE and PCPE.

[1] World Health Organization, Pharmaceuticals in Drinking Water, 2012

We have been working on these issues more than a decade and have actively shared what we have learned through several different channels, including academic journals, conferences, trade group working committees on PIE and PCPE, and portals that contain information about the environmental fate and effects (F&E) of PIE and PCPE. For example:

- We share information with our customers about the F&E of our products through our Product Safety Data Sheets.
- To assist physicians in prescribing the most environmentally friendly drugs, we publish the persistence, bioaccumulation and toxicity profiles of our compounds in the Swedish Kloka Listan ("Wise Formulary") website.
- To facilitate access to data on the F&E of APIs, we have developed a database, curated by Temple University, which includes some physical data as well as the predicted no-effect concentration (acute and chronic) for approximately 100 APIs.

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.

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