Impact of Pharmaceuticals and Personal Care Products in the Environment

Background

The pharmaceutical and personal care 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.

As a science-based health care 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. To guide our efforts in this area, we are implementing strategies that are based upon the following strategic pillars: understanding our impacts; controlling our impacts; engaging and partnering with others; advocating for sound, science-based policy; and sharing best practices and our knowledge on these issues.

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 which received marketing authorization before ERA test methodologies were standardized and adopted by regulatory authorities, using risk-based prioritization and focusing 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 marketed PCPE formulations meet our product stewardship standards designed to ensure minimal 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 WHO 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: onsite audits conducted by Johnson & Johnson environmental professionals; supplier scans through Ecovadis, an innovative technology firm that evaluates companies' environmental responsibility, ethical treatment of workers and other practices; and, through membership in the Pharmaceutical Supply Chain Initiative (PSCI), which sets common standards for ethics, labor, health and safety, environment and related management systems, and shares assessment results among members to help them make informed sourcing decisions. 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 European-based Inter-Association Initiative on Pharmaceuticals in the Environment (IAI PIE), which consists of the Association of the European Self-Medication Industry (AESGP), the European Federation of Pharmaceutical Industries and Associations (EFPIA), and Medicines for Europe. Together this collaborative group created the EcoPharmacoStewardship (EPS) framework to address PIE. This framework is designed to:

1. 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 through a four-year, 10-million Euro research project;

2. evaluate and control manufacturing facility wastewater discharges, including those in the external supply chain; and,

3. develop an extended environmental risk assessment process for pharmaceuticals introduced prior to 2006, when the existing risk assessment process for PIE went into effect.

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 (I/UCRC) led by Temple University with partner sites at the University of Arizona and Arizona State University. With over 30industrial and government members, the WET Center works to conduct 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 life-saving 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; yet few members of the public outside of 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. By comparison, some vegetables, drinks, meat and most fruits contain formaldehyde, a known human carcinogen, at concentration up to 60 parts per million (ppm). As acknowledged by the World Health Organization, "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 on these Issues

At Johnson & Johnson, we have long held a commitment to being transparent about our products and businesses. This commitment applies to our work with PIE and PCPE issues as well. We have been working on these issues for well over a decade now 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. With our customers, we share information 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.

Moving Forward

The strategic framework above represents what we are doing currently to address the issues of PIE and PCPE. However, in the long run, we believe that the investments that Johnson & Johnson is making in prevention-focused research units (such as the Disease Interception Accelerator, the Prevention Institute, and the Human Microbiome Institute) to help achieve the vision of a world without disease will deliver new care and treatment paradigms that will not only improve outcomes and reduce the cost of health care, but will also make treatments less reliant on chronic use of pharmaceuticals. In moving the focus of health care from chronic and acute disease management to a paradigm based on prevention and maintaining health and wellness, we all have the opportunity to significantly reduce the amount of pharmaceuticals in the environment in the future and improve health for humanity.

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