Public Policy Statement: We Support Action on Pharmaceuticals in the Environment

Merck & Co., Inc., Kenilworth, NJ, USA supports science-based, environmentally sound international and national programs to address the challenges presented by pharmaceuticals in the environment (PIE), including: conducting environmental risk assessments of our products to support drug marketing authorizations, implementing programs to minimize environmental risk from manufacturing discharges, supporting industry efforts to offer medicine disposal programs and supporting research to fill data gaps and advance the science to mitigate the risks of PIE.

Managing Risk in Our Operations

Environmental Risk Assessments

Our company conducts environmental risk assessments on our products from the development phase through product launch to understand and manage product impacts from manufacturing and patient use. Our environmental risk assessments are conducted in accordance with applicable stringent global regulations, including the regulatory review processes of the U.S. Food and Drug Administration (FDA) and the European Medicines Agency. Product environmental safety profiles are reassessed during periodic renewals of product filings and risk mitigation actions are implemented when needed.

Manufacturing

Our Human and Animal Health manufacturing facilities must ensure their operations are compliant and protective of human health and the environment. Our sites are required to incinerate product-containing solid waste streams, unless restricted by local regulation. Our facilities are also required to comply with an internal Environmental Quality Criteria (EQC) program which evaluates potential human health and environmental impacts in waterbodies into which we discharge waste water. These standards are based on criteria established in accordance with stringent regulatory review processes. Each facility is required to assess the potential risk from their operations using industry accepted risk assessment methods, minimize impacts from wastewater discharges, and establish procedures for managing and controlling active pharmaceutical ingredients (APIs). In addition, production facilities have, or are being provided with, API-treatment technology to ensure that our wastewater meets these internal EQC standards.

Some of our production is performed by external suppliers. Our practice is to work with suppliers that share our commitment to ethics and integrity. Our Business Partner Code of Conduct, along with our company's Supplier Performance Expectations, are communicated to all existing and potential third-party suppliers. In addition, we participate in the Pharmaceutical Supply Chain Initiative's (PSCI) Pharmaceutical Industry Principles and are a signatory to the 10 Principles of the United Nations Global Compact. We also provide the relevant EQC criteria to each of its suppliers.

Using a risk-based approach, supplier assessments and audits are conducted based on multiple factors including engagement type, geography and the potential impact of any identified issues upon our finished products and our customers. The assessments and audits evaluate a supplier's ability to meet both industry and our company's specific standards for ethical business practices, including among other things environmental, health and safety issues.

Where assessments and audits identify deficiencies or opportunities for improvement, we collaborate closely with our suppliers or potential suppliers to ensure that any gaps are addressed in a responsible and compliant manner.

Supporting Research on PIE and Proper Disposal

Research

We carefully monitor scientific research on the issue of PIE, in particular, studies that evaluate the potential effects pharmaceutical products may have on the aquatic environment and human health. We support the use of science-based environmental risk assessments, and we will continue to collaborate with regulatory, academic, health care and research organizations to identify additional data needs on the transport, fate and effects of PIE. We are a partner with the Innovative Medicines Initiative on PIE (iPIE) and have committed to providing data for analysis and the conducting of new studies to fill identified data gaps.

In addition, we work to reduce the environmental impacts of our products in the process design stage, through our Green & Sustainable Science program. By using more efficient processing methods, we can reduce the amount of energy, water and raw materials we use to make our products, and also reduce the amount of waste we generate.

Disposal

Our company also supports the development of science-based, cost-effective, and environmentally sound programs that promote the proper disposal of unused medicines in accordance with regional requirements. For more information see our public position statement on Responsible Disposal of Medicines in the Household.

Stakeholder Engagement and Advocacy

We participate in efforts to address PIE with various organizations, including the European Federation of Pharmaceutical Industries (EFPIA).

The EFPIA, the Medicines for Europe, and the Association of the European Self-Medication Industry (AESGP) together developed the Eco-Pharmaco-Stewardship (EPS) initiative. The EPS considers the entire life-cycle of a medicine and addresses the roles and responsibilities of all parties including public services, the pharmaceuticals industry, environmental experts, doctors, pharmacists, and patients.

The EPS initiative is supported by the following three 'pillars', which have been identified as the initial key areas of focus for the pharmaceutical industry:

1. The identification of the potential environmental risks of existing and new active pharmaceutical ingredients (API) through intelligent and targeted assessment strategies (see above iPIE initiative);
2. The compilation of best industry practices enabling manufacturers to minimize losses to the environment (see Caldwell et al. 2015 publication "A Risk Based Approach To Manage Active Pharmaceutical Ingredients In Manufacturing Effluent"; and,
3. The refinement of the existing environmental risk assessment (ERA) process for medicinal products to ensure that they remain up-to-date and relevant.

Our company actively participates in developing and executing these initiatives by conducting detailed evaluations of our products (old and new), identifying and filling data gaps, and updating our assessments as needed.

October 2016