Public Policy Statement | March 2026

Pharmaceuticals in the Environment

Merck 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.

Our Position

1. Managing Risk in Our Operations

Environmental Risk Assessments

Our Company conducts environmental risk assessments of our products from the development phase through product launch to understand and manage potential product impacts from both manufacturing and patient use. We conduct these assessments in accordance with applicable stringent global regulations, including the regulatory review processes of the U.S. Food and Drug Administration 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 strive to ensure their operations are both compliant and protective of human health and the environment. Our sites incinerate products containing solid waste streams, unless restricted by local regulation. Our facilities comply with an internal Environmental Quality Criteria (EQC) program that evaluates potential human health and environmental impacts in waterbodies where we discharge wastewater. These standards are based on criteria established in accordance with stringent regulatory review processes. Each facility assesses the potential risk from operations using industry accepted risk assessment methods, minimizes impacts from process wastewater discharges, and establishes procedures for managing and controlling the discharge of active

pharmaceutical ingredients (APIs). Risk minimization measures at Company production facilities may include API treatment technologies when deemed necessary.

Some of our production is performed by external suppliers who share our commitment to ethics and integrity. We communicate our Business Partner Code of Conduct, which includes our supplier performance expectations, to all contracted external suppliers and provide them with available wastewater discharge criteria. In addition, we have adopted the Pharmaceutical Supply Chain Initiative's (PSCI) Pharmaceutical Industry Principles and encourage our external partners to do the same. In addition, our Company is a signatory to the 10 Principles of the United Nations Global Compact.

We conduct assessments of external suppliers using a risk-based approach based on multiple factors including engagement type, geography, and the potential impact of any identified issues upon our finished products and our customers. These assessments evaluate an external supplier's ability to meet environmental, health and safety regulatory requirements and industry standards, the PSCI Principles, and our Company's specific standards for ethical business practices. When we identify deficiencies or opportunities for improvement, we collaborate closely with our external suppliers, or potential external suppliers, to close any gaps.

2. Supporting Research on PIE and Proper Disposal

Research

We carefully monitor scientific research on the issue of PIE, particularly 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 (PREMIER) and have provided data for analysis and conducting new studies to fill any identified data gaps. We also contributed data to help establish the PREMIER database, a free, publicly available and transparent web platform that centralizes reliable, up-to-date information on pharmaceutical impacts in aquatic environments to support evidence-based research and decision-making.

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, while reducing the amount of waste we generate.

Disposal

Our Company 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, refer to 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 and Associations (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.

Our Company actively participates in developing and executing these initiatives by conducting detailed evaluations of our products, identifying and filling any data gaps, and updating our assessments as needed.

As a member of the Antimicrobial Resistance (AMR) Industry Alliance (AMR IA) and signatory to the Industry Roadmap for Progress on Combating Antimicrobial Resistance, we support a common standard for safely manufacturing antibiotics. The standard includes best practices for minimizing discharges as well as development of Predicted No-Effect Concentrations (PNECs) to support environmental risk assessments, which are designed to reduce the selection pressure from antibiotic residues in water and protect ecological species.

For more information related to antibiotics, see our Global Antimicrobial Resistance Action Plan.

References

Responsible Disposal of Medicines in the Household

Global Antimicrobial Resistance Action Plan