



Pharmaceuticals in the Environment (PIE)

Policy Statement

Pfizer Inc is committed to understanding the potential impacts associated with Pharmaceuticals in the Environment (PIE). Pfizer is contributing to scientific and policy developments through internal initiatives and by partnering with government agencies, academia, and other stakeholders. Pfizer supports the transparency of environmental safety data for human and veterinary medicines.

Pharmaceutical Pathways to the Environment

Patient use of prescription and over-the-counter (OTC) medications is the most significant pathway by which trace amounts of pharmaceuticals enter the environment. A small quantity of pharmaceuticals may be introduced into the environment when patients dispose of unused medications in landfills or sewage systems, but disposal is not believed to be a major pathway by which pharmaceuticals enter the environment.

Pharmaceuticals used by patients generally are not fully metabolized or absorbed by the body. Consequently, pharmaceuticals are excreted by patients into domestic wastewater (sewage). Excreted pharmaceuticals can be released to rivers and other surface waters in the effluent from sewage treatment plants since these plants generally are not able to remove all trace constituents.

Patient use has resulted in the release of pharmaceuticals to the environment for as long as pharmaceuticals have been used to treat disease. With the development of new analytical technologies that result in the detection of minute traces of pharmaceuticals and other organic chemicals in the environment, awareness of this situation has increased. This emerging area is now the subject of study by academia, industry and regulators in the U.S. and abroad.

PIE and Human Health

Several studies to date indicate that the presence of trace concentrations of pharmaceuticals in surface water and drinking water present no appreciable risk to human health.¹

Scientific knowledge on the cumulative or long-term effects of trace levels of pharmaceuticals in the environment with regard to human health is in the early stages of development. Pfizer is an active participant in efforts to advance the understanding of any potential impacts in cooperation with academic researchers and government partners.

PIE and Ecosystems

Based on the trace concentrations of pharmaceuticals in surface water and drinking water detected today, scientists have concluded that there is a low potential for an acute impact to the environment. The potential for pharmaceuticals to have chronic environmental effects, though, is still being evaluated through data collection and evaluation, some of which is driven by regulatory requirements.

¹ For example, *Human pharmaceuticals in US surface waters: A human health risk assessment*, Schwab, et al. Regulatory Toxicology and Pharmacology, Volume 42, Issue 3, Pages 296-312 (August, 2005)



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Because Pfizer is committed to adhering to principles of responsible environmental stewardship, we are working in close cooperation with the scientific community to develop and advance the body of knowledge related to PIE and potential ecosystem impacts.

Patient and Environmental Safety: Leading Pfizer Priorities

As part of the process of bringing a new medicine to market, Pfizer and all pharmaceutical companies are required to complete extensive testing to assure that each product is safe for use by patients. We are using this information to verify that the trace levels of those pharmaceuticals that do make their way into the rivers, streams and other surface waters will not have a significant human health or environmental effect.

Pfizer is committed to using best available pollution controls to limit emissions and discharges from our manufacturing facilities. Pfizer adheres rigorously to all regulatory standards aimed at controlling industrial emissions and discharges from our facilities. In addition, Pfizer already has significantly reduced solvents used in and waste generated from our manufacturing processes as a result of implementing many process improvements and our aggressive 'green chemistry' program.

Pfizer's Approach to PIE

Pfizer is already working with regulatory agencies in the industry and in the academic community to better understand the potential impacts of pharmaceuticals in the environment. We also welcome cooperation and collaboration with non-governmental organizations, environmental groups, physicians, patient advocacy groups, and hospital and health care provider groups in the development of a science-based approach to the PIE issue.

For instance, Pfizer was an active participant in the pharmaceutical industry's development of the PhATE model, a scientific tool that can be used to realistically estimate the concentration and distribution of human pharmaceutical actives discharged into U.S. surface waters.

Pfizer, together with other pharmaceutical companies, is evaluating unused medicine disposal practices, including take-back options. Pfizer believes that the disposal of unused medicines in household trash is protective of the environment where the disposal of household trash occurs in well designed, controlled landfills (e.g., municipal solid waste landfills in the U.S.) or by incineration. In addition, Pfizer believes that the best option for minimizing the amount of unused medicines that will require disposal is through thorough patient compliance with prescribed medicine regimens. Pfizer currently participates in pharmaceutical take-back programs in countries (including the member states of the European Union) that have initiated them.