

Public Policy Position

Pharmaceuticals in the Environment

- Merck understands that the presence of trace amounts of pharmaceuticals in the environment (PIE) is a concern to regulators, policy makers, community groups and patients. We are working closely with government agencies, the scientific community and other stakeholder organizations to address this issue.
- Merck carefully monitors scientific research on the PIE issue. The studies conducted to date have found no evidence of adverse human health effects from the trace quantities of pharmaceuticals detected in the environment. However, we agree it is appropriate that additional studies be conducted to evaluate potential effects that pharmaceutical products may have on the aquatic environment.
- Merck is committed to understanding and managing the environmental impacts of our products from discovery, through manufacturing, patient use and disposal. Environmental risk assessments are conducted on products in our pipeline long before they reach the marketplace. As required, we submit environmental fate and effects data to appropriate drug review agencies during the drug registration process, and we develop and implement strategies to minimize any environmental impact from the production of our products. In addition, Merck continues to drive toward the application of “green chemistry” in producing new products. These principles allow us to reduce or eliminate the use of hazardous substances in our manufacturing by building in environmentally sound processes up front in process design.
- Merck supports the use of science-based environmental risk assessments to evaluate the PIE issue and comply with drug registration requirements globally. 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 pharmaceuticals in the environment. This effort will include working with organizations such as the Water Environment Research Foundation (WERF) to support research on new wastewater treatment technologies to improve the removal of pharmaceuticals in trace amounts from water.
- Although evidence indicates that over 90 percent of the pharmaceuticals present in the environment result from patient excretion, Merck recognizes that some pharmaceuticals in water can also be traced to the improper disposal of unused medicines in sewer systems. To address this concern, Merck works through trade associations and other partners to support the education of the public about proper drug disposal methods, including the guidelines issued by [the SMARxT DISPOSAL™ program](#) and the White House Office of National Drug Control Policy. Working with these groups, Merck will also participate in pilot drug take-back programs designed to develop data needed to assess the value of these programs and other viable alternatives.

Recognizing that the improper disposal of unused pharmaceuticals can also be addressed by increasing patient compliance with treatment regimens, Merck will collaborate with stakeholders (governments, pharmacy organizations, etc.) to increase the understanding of the causes of patient non-compliance and the reasons for the generation of unused medicines and, with other stakeholders, will support efforts to promote patient compliance.

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