Pharmaceuticals in the Environment

GRI Standards:

304-2: Significant impacts of activities, products, and services on biodiversity

306-5: Effluents and Waste

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1. Our commitments to PIE

Among the large number of organic compounds that may enter the environment, pharmaceuticals have been a focus of attention for many years due to their biological activity and evidence of their presence in the environment, although generally at low concentrations.
Pharmaceutical substances may end up in the environment in various ways (Figure 1), and the use & excretion of pharmaceuticals by patients is considered the main source. After pharmaceuticals are administered or absorbed, a fraction may be excreted by patients unchanged, and another transformed by the body into metabolites. Excreted pharmaceuticals & metabolites are then released into the environment through sewers and sewage treatment plants. Other, less prominent sources of pharmaceuticals in the environment include emissions from manufacturing plants and the inappropriate disposal of unused or expired medicines.

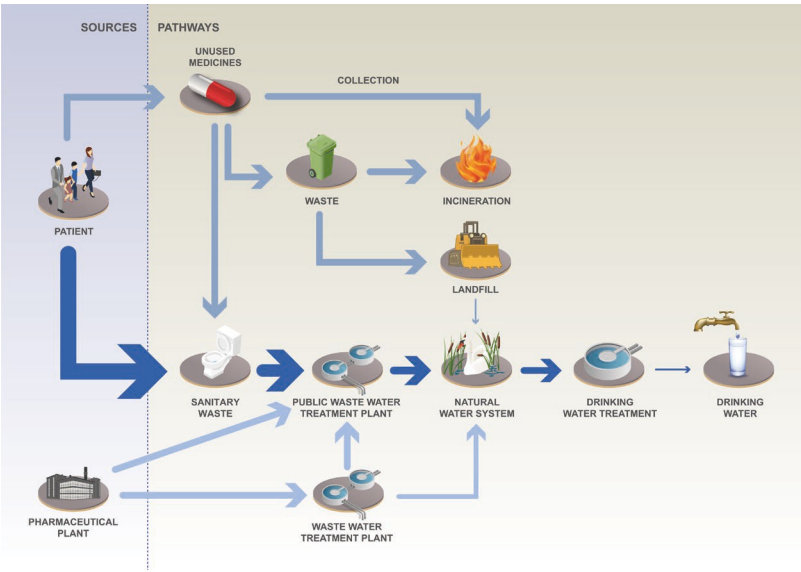

Figure 1. Main sources and pathways of pharmaceutical residues in the environment

With the improvement in analytical methods, it is now possible to detect the presence of an increasing number of pharmaceuticals in the environment. Depending on the substances and the locations, they may be present in very low concentrations in various environmental compartments.
Considering the observed exposure levels, available data suggest a low risk to human health. A major study by the World Health Organization (WHO) concluded that at current levels of exposure in drinking water, adverse impacts on human health are very unlikely[1]. However, concerns have been raised on the potential long-term environmental effects of certain classes of pharmaceutical products. Nevertheless, further research about the potential impact of combinations of pharmaceuticals, metabolites and other chemicals that may be present in low concentrations in the environment is necessary to improve our understanding of the potential long-term effects on the environment and human health.

Sanofi is committed to minimize the potential environmental impacts of its medicines throughout their lifecycle. This commitment is reflected in our environmental sustainability strategy, Planet Care, by specific goals:
Limit our environmental footprint:

- In 2025, Sanofi implemented a risk-based approach to managing pharmaceutical emissions to wastewater across selected manufacturing sites, with monitoring and reduction plans in place wherever risks were identified. Sanofi is reinforcing this through the deployment of best available wastewater

[1] "Targeted investigations conducted in the UK, the US and Australia found that pharmaceuticals are largely present in drinking water at concentrations several orders of magnitude (more than 1,000-fold) below the lowest therapeutic dose and largely below the calculated acceptable daily intakes. The substantial margins of safety for individual compounds suggest that appreciable adverse impacts on human health are very unlikely at current levels of exposure in drinking water." Conclusions of WHO Pharmaceuticals in Drinking Water Report, 2012.

treatment technologies at targeted sites.

Improve the environmental profile of products:

- Sanofi's commitment to prevent and mitigate environmental risks is central to our Sustainability and HSE policies. We have established a sound governance system for assessing the potential impacts of our products on the environment throughout their lifecycle from development to post-market.
- A voluntary program was implemented to evaluate our legacy products that were brought to market prior to enactment of regulatory requirement. This program aims to increase knowledge about the environmental fate and effects of our marketed products, and to evaluate the related environmental risks. These assessments consider all available data and may lead to additional testing where needed.

2. Performance

Evaluating and minimizing emissions to the environment from manufacturing:

- we continue to proceed with the implementation of our risk-based program for managing emissions of active ingredients in wastewaters from pharmaceutical manufacturing plants; and
- we continued to define science-based environmental thresholds for APIs.

Assessing the environmental impacts related to the use of our products:
we continue to expand our knowledge on the environmental fate and effects of our new and legacy active pharmaceutical ingredients, irrespective of regulatory requirements.

3. Actions

Our strategic approach covers the entire life cycle of our medicines, from production to their use by patients. It encompasses several initiatives or programs organized around three main pillars:

- evaluating and minimizing the environmental impacts of manufacturing activities;
- increasing knowledge of the environmental fate and potential impact of our products before and after their launch to market; and
- promoting the responsible use and the proper disposal of unused medicines.

3.1. EVALUATING AND MINIMIZING EMISSIONS TO THE ENVIRONMENT FROM MANUFACTURING

At Sanofi, we are committed to continuously striving to make our processes safer in order to minimize environmental impacts. Industrial effluents (wastewater) are treated either at the sites' wastewater treatment plants (WWTPs) and/or at external treatment plants in accordance with operating permits. The choice and performance of technologies for on-site effluent treatment are adapted to site-specific conditions. Effluents may undergo further treatment at the factory level or upon exit from the site, when required and appropriate. The Company's manufacturing sites seek to adopt best practices.

Sanofi invests in advanced wastewater treatment — including quaternary technologies such as ozonation and activated carbon — to minimize pharmaceutical emissions in effluents. Alongside end-of-pipe treatment, we prioritize source reduction to limit discharges before they reach treatment systems. At targeted sites, these technologies achieve micropollutant removal well beyond regulatory permit thresholds. Further to its commitment to minimize the impact on the environment of industrial sites, in particular the aquatic environment, Sanofi has implemented an environmental risk management program targeting pharmaceuticals in wastewaters. This program includes the following elements: estimation or measurement of pharmaceuticals in wastewaters and receiving water bodies; setting of substance-specific safe discharge targets based on available data and standard methods; characterization of risks for aquatic ecosystems and other environmental compartments where relevant; implementation of case-by-case risk mitigation measures from source reduction measures to end-of-pipe treatment solutions.

This program has been implemented in all our manufacturing sites based on prioritization framework. It

is supported by:

- a mass balance approach & tool to estimate emissions from production processes and characterize the related environmental risks;
- specific analytical methods allowing to quantify pharmaceuticals in wastewaters or receiving water bodies;
- substance-specific safe discharge targets used to characterize risks for aquatic ecosystems. Environmental fate & effects studies are conducted if necessary to address potential knowledge gaps; and
- effect-based monitoring tools tested and applied in wastewaters and receiving water bodies.

For more information, see in our ESG Index: Water

3.2. ASSESSING THE ENVIRONMENTAL IMPACTS RELATED TO THE USE OF OUR PRODUCTS

An Environmental Risk Assessment (ERA) is required for all pharmaceutical product marketing authorization applications in the European Union (since 2006), in the United States (since 1998) and in some other countries. As a result, all new Sanofi medicines are systematically assessed under these requirements. This assessment considers environmental fate and effects information as well as all other relevant information generated during drug development.

While new drugs today are fully assessed for environmental risks, older drugs that are already on the market may have been studied less thoroughly, since regulatory requirements were not as stringent at the time they were launched, and new studies are often not required unless marketed quantities are expected to increase significantly.

To complement this regulatory baseline, Sanofi has launched a voluntary Eco-Pharmaco-Vigilance (EPV) program to assess the environmental profile of legacy products. The program aims to strengthen our understanding of the environmental fate and effects of our marketed products and to evaluate their associated environmental risks. Assessments draw on all available data and may be complemented by additional testing where needed. Following a pilot phase on 5 APIs in 2024, we started extending the EPV program to cover more APIs and countries. We also developed a digital mapping tool for supporting our EPV risk monitoring. In 2025, a total of 25 APIs were managed under an EPV approach. By 2027, our top 100 selling products & any new medicine will be managed by an EPV approach. Where APIs are identified as potentially higher risk, we monitor environmental exposure (e.g. through comparison with measured environmental concentrations) and, where appropriate, develop targeted risk mitigation plans.

A growing proportion of Sanofi's portfolio (e.g. therapeutic proteins, monoclonal antibodies) is manufactured using biotechnology. Consistent with EMA guidelines, biologics are generally considered biodegradable — unless substantially modified — and are expected to present a significantly lower ecosystem risk than conventional (synthetic) molecules. We reinforce this through our EPV program by voluntarily testing biodegradability of our biologics and validating their low environmental risk profile.

3.3. ENCOURAGING THE PROPER USE AND PROPER DISPOSALOF MEDICINES

Medicines are not ordinary consumer goods. At each link in the healthcare chain, professionals, public authorities, patients and the public must be informed about the proper use of medicines, which is essential to ensuring their safety and efficacy. While proper use of medicines benefits patient health primarily, it also includes an environmental dimension. Inappropriate use leads to unnecessary and avoidable emissions of pharmaceuticals in the environment. Fostering the proper use of drugs can in fact benefit the environment as well. Flushing unused drugs into sewer systems or throwing them in

the trash when household waste is not treated in an environmentally responsible way constitutes a gateway into the environment. Sanofi is committed to encouraging the proper disposal of unused medicines. Simple steps, taken by the patient, can significantly reduce emissions contributing to environmental pollution.

OUR RECOMMENDATIONS FOR USERS: HOW TO PROPERLY DISPOSE OF YOUR MEDICINES?

Most importantly, do not dispose of unused medicines down the drain. That is, medicines should be neither flushed down the toilet nor poured down the drain.

Follow local disposal practices and use community pharmaceutical take-back programs where available. Disposal practices vary depending on the area.

In most European nations, unused medicines can be returned to the pharmacy for safe collection and disposal by incineration (e.g. France) or by household waste for incineration (e.g. Germany). In the United States and in many other countries, local take-back programs are often in place through pharmacies, government or community waste treatment programs. Contact https://myoldmeds.com (US), https://healthsteward.ca (Canada), your pharmacy or local waste disposal agencies, for more information if needed.

If no local take-back programs are available in your area, you can dispose of unused medicines in the household trash, taking measures to avoid accidental misuse or possible diversion for drug abuse. Render unused medicines undesirable and unrecognizable (e.g., mix them with household waste in unreadable packaging). Scratch out or remove any labeling identifying personal prescription information.

Do not forget a simple waste-reduction measure: whenever possible, try to obtain only the quantity of medicine you need. This will minimize the disposal of expired unused medicines later.

3.4. ADVANCING SCIENTIFIC RESEARCH BY COLLABORATING WITH OTHER STAKEHOLDERS

As part of our commitment to advancing knowledge about pharmaceuticals in the environment, we have formed research collaborations with academia, regulators, and we work closely with pharmaceutical trade and research associations. We also share this knowledge with other stakeholders as appropriate.

We continue to participate in collaborative programs and initiatives by pharmaceutical trade groups, academia, organizations and other stakeholders to expand scientific knowledge in this area and to better assess and limit emissions of pharmaceuticals in the environment. These include for instance research programs organized by the Innovative Medicines Initiative (IMI) on prioritization and risk evaluation of medicines in the environment (PREMIER).