Antibiotice

Policy on the management of hazardous substances and chemicals

2024

This policy is part of the Antibiotice ‘s Environmental Policy.

Antibiotice is aware of the significant impact of hazardous substances and chemicals on human health, environment, employee safety and the community in which it operates.

The company aims to adopt a responsible approach to their management, ensuring that international regulations are met and promoting sustainable solutions. The goal is to reduce and eliminate the negative impact of chemicals, minimizing financial damage and health impacts.

In addition, Antibiotice is committed to mitigating short and long-term effects on the environment by implementing practices that comply with regulations and standards in force.

To achieve these objectives, Antibiotice establishes the following guidelines:

- Continuously identifying and assessing the risks associated with the use of hazardous chemicals and replacing them with safer alternatives when possible.
- Implementing rigorous internal programs for chemical management, including monitoring, inventorying, and complying with safety standards.
- Promoting research and development of innovative solutions for reducing the impact of chemicals.
- Working closely with suppliers and business partners to ensure transparency and compliance with hazardous substance regulations.
- Collaborating with government authorities, non-governmental organizations, educational institutions, communities and other stakeholders for developing sustainable solutions for chemicals management.
- Continuous promoting and awareness-raising of employees, suppliers, business partners and other stakeholders on the importance of applying sustainable principles regarding the management of hazardous substances.
- Periodically reporting and communicating to stakeholders the progress in achieving objectives on the management of hazardous substances and chemicals through the Annual Sustainability Statement.

Top management, employees, suppliers and business partners of Antibiotice are required to comply with legislation, norms, regulations and this policy in all the company operations, including production, research and distribution.

Position on the environmental impact of pharmaceuticals

This position was adopted to support the implementation of the Antibiotice's Environmental Policy. The impact of medicines on the environment (*Pharmaceuticals in the Environment - PIE*) represents a global environmental and public health challenge. Although medicines can enter the environment through several pathways: natural excretion during patient use, improper disposal of unused medicines, or discharges from the manufacturing process, the largest overall contributor to PIE is patient use.

Commitments and Objectives

Antibiotice recognizes the critical importance of protecting the environment and the impact that pharmaceuticals can have on global ecosystems. In this context, the company reaffirms its commitment to proactively and responsibly address this challenge by integrating sustainable practices into all aspects of its operations.

Medicine Impact Assessment

In Antibiotice, medicines are subject to risk assessments from the development stage, according to global standards and applicable regulations, such as those of the *European Medicines Agency* (EMA). These assessments establish safe concentrations for the environment, using tools such as P*redicted No-Effect Concentrations* (PNEC) and *Environmental Risk Assessments* (ERA).

Production waste

Antibiotice supports science and research-based programs as well as the implementation of programs to minimize the environmental risk generated by production discharges, such as reducing antibiotic residue discharges to minimize selection pressure on resistant microorganisms.

Through its own treatment plant, all wastewater on the company's site is pretreated before being discharged into the public sewer network. This way, we ensure strict monitoring and control of wastewater discharges from the company, in compliance with environmental standards and the adoption of internal programs that establish clear quality criteria for wastewater.

Green chemistry principles are applied in the company to reduce consumption of resources, such as energy and water, and to reduce production-generated waste.

Responsible Disposal of Medicines

Since 2023, Antibiotice initiated a campaign to collect unused and expired medicines, targeting its own employees, this project targeting also the communities in the future.

Furthermore, the company supports and develops awareness and information campaigns for employees and the general public, through mass media or social networks, in order to properly use, store and dispose of unused or expired medicines.

Education and Awareness
Antibiotice supports global education efforts by organizing actions and conferences to inform the public and professionals in the field about the responsible use of medicines (e.g. the social responsibility program *Antibiotics of the Third Millennium*). Antibiotice promotes the dialogue with stakeholders to reduce the unjustified use of medicines, thus contributing to reducing the excretion of pharmaceutical substances into the environment.

Stakeholder collaboration
A small portion of the company's production is carried out by external suppliers who share our commitment to ethics and integrity. The company has adopted the *Pharmaceutical Supply Chain Initiative* (PSCI) and applies the AMR Industry Alliance principles, promoting common standards of responsible manufacturing, and encourages its external partners to do the same.

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