

Roche Position on Product Stewardship – We minimize the negative health and environmental impact of our products

Roche's Position

Recognizing that all our business activities and our products may lead to negative impacts, in particular on the environment, Roche has developed and implemented an effective Safety, Security, Health and Environmental protection (SHE) management system. We have established internal guidelines and directives to continuously reduce the negative impact of our business operations and we work to implement corresponding measures in all our activities. We verify the implementation of these measures through regular SHE audits at our sites and keep our management informed about the status of the programs in place.

Product Stewardship (PS), also known as Extended Product Responsibility (EPR), is a SHE management strategy guided by the principle that in all stages of the life-cycle of a product (“from-cradle-to-cradle”) all involved stakeholders take responsibility for minimizing the negative impact on people and the environment.

A comprehensive and continuously improving PS Program helps to reduce the SHE impact of all our business activities, including research and development, production, marketing and sales, – and also of our products.

Open communication with our employees, shareholders and our external stakeholders, e.g. patients, downstream users such as nurses and pharmacists, laboratories, lawmakers, authorities, non-governmental organizations, suppliers, clients, and disposal service providers, is a key pillar of our product stewardship program.

The global situation

In recent years, more and more countries have implemented policies and provisions to reduce pollution and the generation of end of product-life wastes. In our industry, increased scrutiny is being paid to the presence of pharmaceuticals and other chemicals in our drinking water and food (i.e. Pharmaceuticals in the Environment, PIE). As a result, the political pressure on countries, and increasingly also on companies, is growing continuously.

Faced with the significant increase of consumer waste, many countries have developed new strategies to address this issue. One strategy, Product Stewardship includes placing the responsibility for the post-consumer phase of certain goods on the producers. PS is an

approach where producers accept responsibility (financial and/or physical) also for the treatment or disposal of products at the end of their useful life. By assigning this responsibility to the producer, an incentive to prevent wastes at the source, promote environmentally compatible product design and support recycling and materials management goals is anticipated.¹ To encourage advancements in this area, several countries have established mandatory recycling rate targets and have mandated take-back programs for a number of key products, including pharmaceuticals, packaging materials, electronic and electrical equipment and batteries.

Pharmaceuticals are biologically active molecules. If not handled properly, their negative side effects can also become manifest in medical professionals who prepare and administer them (nurses, pharmacists etc.). The prevention of effects in these target groups has increasingly become an objective of authorities in charge of occupational health.

The situation at Roche

Roche's product stewardship program is designed to help reduce the SHE impact of our products. To reach this goal, we have, for some time, developed internal directives, standards and guidelines which incorporate the following key policies and practices:

- **Responsibility:** Roche cares about people and the environment and wants to be viewed as a responsible producer of medicines and diagnostic devices and kits. We take the responsibility for our products over their whole life-cycle.
- **Goals to improve Product Stewardship:** We have established ambitious and challenging SHE goals to ensure a continuous improvement in our product stewardship program (e.g. provisions on energy efficiency, eco-balance, emissions, and waste reduction).
- **Development of “greener” products:** Our primary goal is to develop innovative medicines and diagnostic devices and kits to improve patients' lives. From the point of conception of a new product, we strive to optimize our processes with regard to minimizing the use of resources (e.g. energy and water) as well as hazardous substances and materials.
- **Take-back programs:** For the disposal of unused medicines we support international, national and local take-back programs. We are convinced that take-back programs are an important step to reduce the presence of Pharmaceuticals in the Environment

¹ Expectations of the OECD on Product Stewardship (see “OECD Guidance Manual for Governments”)

(PIE), one of the most challenging SHE issues facing the pharmaceutical industry in the future.

- **Recycling:** Wherever technically feasible and financially justifiable we recycle chemicals, e.g. waste solvents from production processes as well as, parts of diagnostic devices.
- **Waste disposal:** We strive to reduce waste and recycle what remains wherever feasible. We have established a clear policy that the landfilling of chemical and problematic medicinal waste is prohibited, and that all such wastes must be incinerated.
- **Legal SHE requirements:** We strive to ensure that Roche is compliant with all legal requirements wherever we do business. Compliance with the relevant SHE laws is a minimum requirement, and most of our programs and processes go beyond these basic expectations.
- **Development and communication of product safety, security, health and environmental protection data:** All of the active pharmaceutical ingredients (API) and excipients used in our medicines, as well as the chemicals used in our diagnostic devices and kits, are evaluated from a SHE perspective. Our Safety Data Sheets (Material Safety Data Sheets in the US), which include SHE-related information such as hazard data and waste disposal guidance, are accessible both internally to our employees, and externally via the internet² to the public to ensure transparency.
- **Contacts, communication and cooperation with our stakeholders:** We seek opportunities for dialogue with patients, downstream users, clients, law makers, regulators, the public, academia, competitors, suppliers, and non-governmental organizations to better understand their needs, and to assist them as we strive to continuously reduce our environmental footprint.
- **Audits to ensure Product Stewardship:** As part of our governance system, we regularly perform SHE audits of our own business activities, of our suppliers and other service providers (e.g. waste vendors) throughout the world. We expect that our suppliers will meet the same high SHE standards and we check their performance through audits at their plants. We do not accept lower quality and SHE standards for our suppliers than for ourselves and if suppliers do not deliver to our expectations or are not willing to improve, we will not continue to do business with them.
- **Participation in state-controlled or private Product Stewardship programs:** Several countries and local states are running non-mandatory product stewardship programs

² http://www.roche.com/corporate_responsibility/environment/safety_data_sheets.htm

which we fully support. In addition, we participate in several industry-based programs aimed at promoting improved product stewardship performance in industry. As an example, we participate in Responsible Care, which aims to promote continuous improvement in the SHE performance of “processes and products over their life-cycles so as to avoid harm to people and the environment.”

Further information

Roche position papers on several health and environmental topics:

http://www.roche.com/corporate_responsibility/environment/she_management/policy_guidelines_and_audits.htm

International organizations on Product Stewardship:

OECD Guidance Manual for Governments

(<http://www.calpsc.org/assets/solution/OECD%20EPR%20Guidance%20for%20Governments.pdf>)

Global Product Stewardship Council (<http://www.productstewardshipcouncil.net>)

The Product Stewardship Institute (<http://www.productstewardship.us>)

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